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REVIEW ARTICLE

Crouch Gait in Cerebral Palsy: Current Concepts Review

Ritesh Arvind Pandey[1] · Ashok N. Johari[2] · Triveni Shetty[3]

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Abstract

Background and Objective Crouch gait is the most common pathological gait pattern in cerebral palsy and is commonly seen in patients with spastic diplegia. It is characterized by excessive knee flexion throughout the stance phase of gait cycle. The aim of this review is to discuss the current literature about CG for a more comprehensive understanding.

Methods A literature review about various aspects of crouch gait in cerebral palsy was undertaken. This included its etiology and pathophysiology, biomechanics in crouch gait, natural history of untreated crouch gait, clinical and radiological evaluation and different modalities of available treatment.

Results The etiology is multifactorial and the pathophysiology is poorly understood. This makes its management challenging, thereby leading to a variety of available treatment modalities. Inadvertent lengthening of muscle–tendon units is an important cause and can be avoided. A meticulous clinical and radiological evaluation of patients, supplemented by observational and instrumented gait analysis is mandatory in choosing correct treatment modality and improving the treatment outcome. Younger children can be managed satisfactorily by various non-operative methods and spasticity reduction measures. However, crouch gait in cerebral palsy has a progressive natural history and surgical interventions are needed frequently. The current literature supports combination of various soft tissue and bony procedures as a part of single event multilevel surgery. Growth modulation in the form of anterior distal femur hemiepiphysiodesis for correction of fixed flexion deformity of knee has shown encouraging results and can be an alternative in younger children with sufficient growth remaining.

Conclusions In spite of extensive research in this field, the current understanding about crouch gait has many knowledge gaps. Further studies about the etiopathogenesis and biomechanics of crouch using instrumented gait analysis are suggested. Similarly, future research should focus on the long term outcomes of different treatment modalities through comparative trials.

Keywords Child · Cerebral palsy · Crouch gait · Knee · Spastic diplegia

✉ Ritesh Arvind Pandey
riteshpandey8262@yahoo.com

Ashok N. Johari
drashokjohari@hotmail.com

Triveni Shetty
tshetty@mgmsopnm.edu.in

1 Department of Orthopaedics, All India Institute of Medical Sciences (AIIMS), Phulwari Sharif, Aurangabad Road, Patna, Bihar 801507, India

2 Children's Orthopaedic Centre, 2nd Floor, Bobby Apartments, 143 L.J. Road, Mahim (West), Mumbai 400016, India

3 MGM School of Physiotherapy, MGM Institute of Health Sciences, Navi Mumbai 410209, India

Introduction

Crouch gait (CG) or flexed knee gait is the most common pathological gait pattern in cerebral palsy (CP) with prevalence as high as 76% [1]. It is characterized by excessive knee flexion throughout the stance phase of gait cycle. There is no consensus so far about the exact definition of CG. While majority see it as excessive hip and knee flexion and ankle dorsiflexion, others consider it as a flexed knee gait regardless of the ankle position [2, 3]. Severity of knee flexion and duration of flexed position during stance phase was considered as criteria in few studies [1]. Rotational deformities of femur, tibia and planovalgus foot deformity, referred to as lever arm disorders are also frequently seen [Fig. 1]. Five CG patterns have been identified in the order of increasing pathology [3]. These are

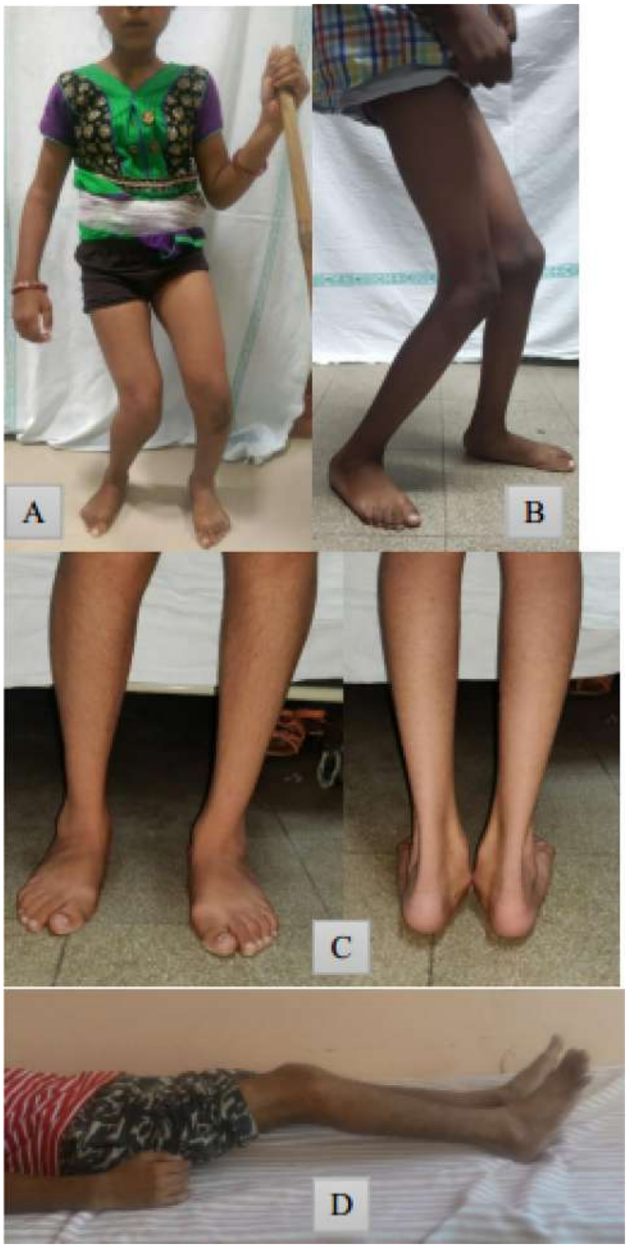

Fig. 1 Characteristics of crouch gait. **A & B**—Flexion at hip and knee, dorsiflexion at ankle, rotational deformities in femur and tibia. **C**—Planovalgus foot deformity. **D**—Fixed flexion deformity at knee

mild crouch with mild equinus, moderate crouch, moderate crouch with anterior pelvic tilt, moderate crouch with equinus and severe crouch. The etiopathogenesis and biomechanics of CG in CP are still not very clearly understood. This makes its management challenging, thereby leading to a variety of available treatment modalities. The aim of this review is to discuss the current literature about CG for a more comprehensive understanding.

Etiology

The etiology of CG is multifactorial [Fig. 2]. It is frequently seen in children with severe diplegia or quadriplegia and is less common in hemiplegic CP [2]. It is known that the sagittal gait pattern in diplegic CP is unstable and changes with the age of patient [4]. CG usually develops during the pubertal growth spurt and is related to increased body mass with an unfavorable mass to strength ratio [3]. In a retrospective observational study, the sagittal gait pattern in most of the children with diplegic CP changed from equinus or jump gait to a moderate or severe CG as they reached puberty [4]. There was no statistically significant increase in mean knee flexion in stance and passive knee flexion contracture but the ankle dorsiflexion in stance increased from $-0.3°$ to $9.0°$ ($p<0.001$).

Hamstring contracture was considered to be the primary culprit for CG. However, this concept was challenged by the studies reporting normal length of hamstrings in patients with CG [5]. Instead, fixed flexion deformity at the knee of more than 10° has been observed to be a more significant contributor. Weakness of quadriceps is another important factor as it prevents adequate knee extension during stance. Similarly, presence of overactive hip flexors and weak hip extensors results into a flexed position at hip. This is compensated by development of flexion at knee through mechanism of dynamic coupling [6].

The role of weak plantar flexors at ankle is well established [1, 7]. It could be a result of primary brain insult or as a result of iatrogenic isolated heel cord over lengthening. Besides this, the increased activity of bi-articular gastrocnemius muscle may inhibit the knee extension during stance. However, Kanashvili et al. did not observe any statistically significant effect of gastrocsoleus complex lengthening at younger age on final knee position at maturity [4]. Similarly, Huh et al. reported development of calcaneus gait in 21% of children with diplegic CP without any history of earlier calf muscle–tendon lengthening [8].

Lever arm disorders may contribute in development of CG. External tibial torsion greater than 30° is known to inhibit the function of soleus and hip extensors [9]. Similarly, abnormal femoral anteversion may inhibit the extension of knee [10]. Planovalgus foot deformity with midfoot break leaves the midfoot in a loose unlocked position during stance and reduces the effect of lever arm. Additionally, the foot is externally rotated and is associated with external tibial torsion.

Pathophysiology and Biomechanics

In the second half of stance phase, knee extension is primarily maintained by plantar flexion–knee extension couple. Contraction of soleus inhibits progression of tibia and

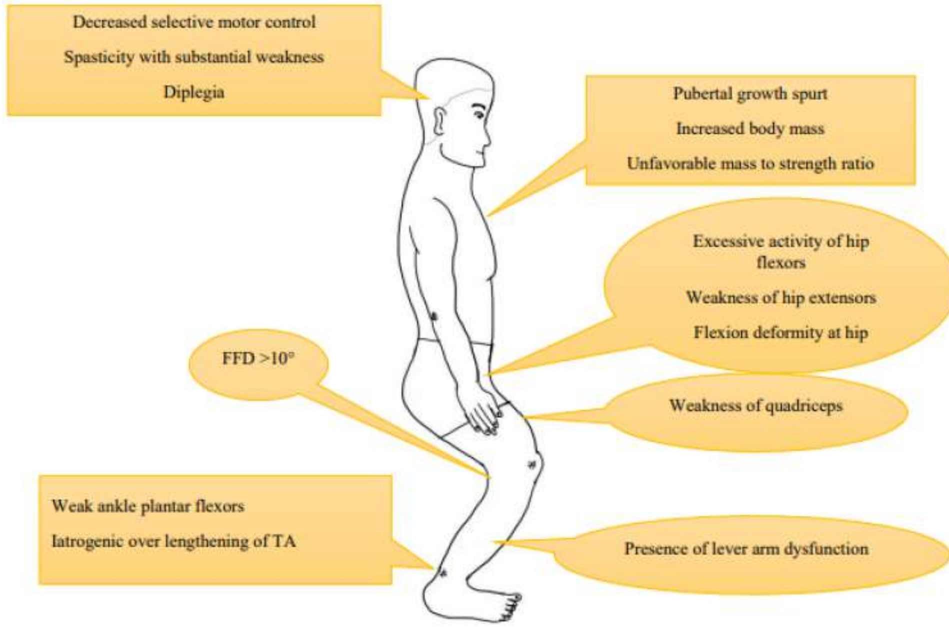

Fig. 2 Etiopathology of crouch gait

maintains the ground reaction force anterior to the knee joint, thereby keeping knee in extension without the activity of quadriceps. Due to weakness of soleus, this plantar flexion–knee extension couple is inefficient and the progression of tibia during stance phase is not inhibited. This brings the ground reaction force posterior to knee joint and produces knee flexion. The force is also anterior to hip, thereby producing hip flexion.

In majority of cases, excessive knee flexion is believed to be a result of short hamstring causing static knee contracture. When stretched, short hamstrings may generate excessive passive forces that limit the knee extension. In other words, hamstrings are working at abnormally short muscle tendon lengths and their surgical lengthening may improve knee extension by reducing the passive forces, thereby enabling them to work at longer muscle tendon lengths [5]. Contrary to this, hamstring lengthening procedure will be ineffective if muscle is not operating at shorter muscle tendon length. A short hamstring is not observed in every case of CG [11]. This could be due to the fact that shortening of hamstring produced by knee flexion contracture gets compensated by its stretching due to hip flexion contracture. Moreover, abnormally long hamstrings have been observed in some patients by Delp et al. [6]. Spastic hamstrings with normal muscle tendon length may be the reason for excessive knee flexion [11]. Besides this, increased and extended hamstring activation in stance phase has been observed [12]. In such cases, CG is due to exaggerated, velocity dependent resistance of hamstring to stretch and the muscle spasticity can be overcome at slower stretch velocities. Surgical lengthening of hamstrings in these cases may improve knee extension by reducing the response to stretch and enabling them to operate at greater stretch velocities [13]. Opposite to this, if hamstrings are not operating at short lengths or do not overcome spasticity at slow stretch velocities, patients may not benefit from a hamstring lengthening surgery [5]. Inadvertent lengthening of a normal length hamstring should be avoided as it may cause increased pelvic tilt, knee hyperextension and stiff knee gait [14].

Abbasi et al. further reported the influence of abnormal knee and ankle kinematics on characteristics of trunk movements. [15]. When compared to normal population, the trunk tilt range of motion in patients with CG did not show any significant difference. However, trunk bending and rotation were significantly reduced and this had a positive correlation with the severity of abnormal knee and ankle kinematics. Range of movements of the trunk decreased further with increase in knee flexion. Excessive dorsiflexion and plantar flexion at ankle were observed to produce a flexed and extended posture in trunk, respectively. Thus, correcting the abnormal knee and ankle kinematics in CG may improve the trunk kinematics and improve ambulation.

Natural history

The natural history of untreated CG is not clear. Two different patterns of worsening have been reported [16]. The one with slow progression seen in mild crouch (10–20° mid stance knee flexion) is well tolerated without any surgical intervention. Another pattern with rapid worsening observed in moderate (25–45° mid stance knee flexion) and severe (> 45° mid stance knee flexion) crouch needs timely surgical intervention. Irrespective of the etiology, an unlocked knee is pulled into flexion by the hamstrings, thereby causing compensatory increase in the activity of quadriceps. Increased activity of the quadriceps puts greater demand on hip extensors including the hamstrings. Thus a vicious cycle is initiated, causing increased flexion at hip and knee over time. The patellar tendon is stretched and elongated, causing further weakening of the quadriceps mechanism. The presence of patella alta increases force and pressure across the patello-femoral joint and causes anterior knee pain in untreated cases. Incidence of patellar or tibial tubercle stress fractures and apophysitis have also been reported [17]. Ambulation in severe cases has very high energy expenditure resulting in early fatigue of muscles across the knee, hip and back. The foot clearance during walking becomes difficult with time and orthosis are often not able to support the collapsing foot. Gradually, patients start losing motivation to walk and become wheelchair dependent [16].

Clinical evaluation

Clinical presentation of CG may vary from only mild disability to severe difficulty in ambulation. Evaluation of patients includes a comprehensive assessment of medical history, functional status, clinical examination and relevant investigations. A good evaluation is prerequisite for identifying the patients at the risk of further progression and helps in deciding the appropriate treatment, thereby giving best possible outcome.

Medical history should include the details of perinatal complications and the major milestones. History about existing medical comorbidities and ongoing medications should be taken. Information about the treatment taken so far for crouch, their outcomes and compliance of family towards the treatment measures helps in choosing further interventions and preparing the family in a better way. Similarly, an insight of current functional status in the terms of Gross Motor Function Classification System (GMFCS) and Functional Mobility Scale (FMS) helps in setting realistic goals and counselling the parents about best possible treatment outcome.

Clinical examination aims at identifying both static and dynamic components of deformity by examining the patient on a couch and by doing gait analysis, respectively. Any trunk imbalance and spine deformity should be noted and evaluated further. Static measures include assessment of muscle tone, muscle power, motor and sensory reflexes and deformities across the joints. Spasticity is usually evaluated by modified Ashworth scale and Tardieu scale which is based on passively stretching the muscle at different velocities and assessing the encountered resistance.

The fixed flexion deformity at knee is evaluated by popliteal angle test. Subsequently, hamstring shift test is used to exclude the contribution of concomitant hip flexion contracture and anterior pelvic tilt [Fig. 3]. The different muscle lengths and contractures across hip joint can be evaluated by specific clinical tests. Both Thomas' hip flexion test and Staheli prone extension test can be used effectively but the later has been reported to be more accurate for CP [18]. The Duncan-Ely's prone rectus test is used to assess rectus femoris contracture. Adductor contracture is tested with Phelp's test to differentiate hip adductor contracture from medial hamstring contracture.

It is of utmost importance to look for a concomitant lever arm dysfunction in the form of planovalgus foot and torsional deformities in femur and tibia. Excessive femoral anteversion causes intoeing gait and is clinically assessed by Craig's test or trochanteric prominence test. Similarly, tibial torsion can be identified and measured by thigh foot angle test, bimalleolar axis test and second toe test.

Muscle strength is commonly assessed by using Medical Research Council (MRC) grading for muscle strength assessment. However, for children with CP, the use of manual testing with Kendall scale or with a dynamometer is preferred [19]. The reduced selective motor control is documented and graded from 0 to 2 where grade 0 is no ability, while grade 2 is the complete ability for doing isolated movements.

The upper extremities should be evaluated in a similar way for tone, muscle strength, deformities and function. This

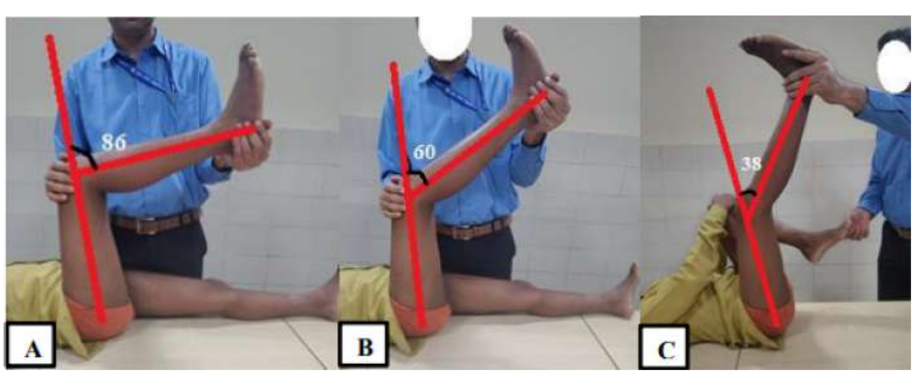

Fig. 3 Popliteal angle test and hamstring shift test. The patient lies supine on a couch with both hip and knee extended. [**A**] – R1 position showing a value of 86°. [**B**] – R2 position showing improvement in popliteal angle with a value of 60°. [**C**] – Hamstring shift test showing further correction of the knee flexion deformity and popliteal angle of 38º

is especially important for children ambulating with support who need good hand function for daily activities. The routinely used functional scales for upper extremity are the manual ability classification system (MACS) and quality of upper extremity skill test (QUEST).

Observational gait analysis and video recordings

Analysis of gait pattern provides information about the dynamic component of deformity and reveals relative functional deviations. Observational gait analysis refers to watching the children while they are walking. Child is exposed from foot to umbilicus and is made to walk several times with examiner seated with his eyes at the level of patient's knee. Child is observed meticulously while walking from front, side and back and the joint angles at hip, knee and ankle are noted at different stages of gait cycle. Simultaneous video recording of gait (videographic gait analysis) enables the examiner to analyze the gait pattern several times at his own convenience and in slow motion. Observational gait analysis though subjective and not very precise, provides sufficient information in experienced hands. It is an important tool especially in developing nations where the majority of health centers lack proper infrastructure and do not have access to instrumented 3D gait analysis.

Instrumented 3D Gait analysis (I3DGA)

In conjunction with physical examination and observational gait analysis, I3DGA offers quantifiable data to direct treatment for gait problems and evaluate its effectiveness in children with CG. It provides a more detailed and precise assessment of the gait pattern, which can aid in the development of targeted interventions to improve gait function. Furthermore, the assessment of dynamic muscle tendon length using I3DGA can provide additional insight into the underlying causes of the crouch gait pattern, which can inform treatment decisions. Yet, decision making is challenging due to lack of defined standards to interpret the data and select the surgery [20].

According to a recent review, I3DGA adds objective and evidence-based value to clinical examination by providing correct number and selection of treatment procedures. It allowed greater insight to the causes of gait problems, particularly for internal hip rotation and flexed knee gait. Earlier, these issues were attributed to muscular spasticity; however, with I3DGA, they were attributed to structural abnormalities like patellar tendon laxity, femoral anteversion, and knee flexion contractures [21]. I3DGA altered surgical recommendations in 52% of cases of spastic CP [7]. Incidence of severe CG decreased from 25 to 4% as a result of practice adjustments after inclusion of I3DGA [22]. Surgical decision post I3DGA demonstrated agreement with clinical assessment in 86% patients, whereas there was agreement with clinical assessment in 97% cases for non-operative treatment [22]. Overall, the results led to a reduction in the number of patients recommended for surgery. Also, recommendations for the degree or type of surgery to be performed changed in 40% of cases.

Most studies reported a good agreement between I3DGA and clinical assessment for bone surgery, suggesting that clinical evaluation of torsional problems was fairly reliable. However, there was poor agreement for soft tissue procedures, probably reflecting the added difficulties in clinical assessment of tone-related problems. Agreement between the two measures was greater for hamstrings and gastrocnemius muscle than for other muscle groups, probably as their length facilitates clinical assessment better than shorter muscle groups [23]. Few studies have reported better effects of using I3DGA on surgical outcomes. Previous studies have reported insufficiency of physical evaluation in decision-making for femoral derotation osteotomy (FDRO) [24]. I3DGA helped in deciding the need as well as degree of derotation in such patients and they showed considerable improvement in their CG when the recommended FDRO was performed [20, 24]. Similarly, passive and dynamic hip rotation demonstrated minimal improvement, when treatment was given without I3DGA data [23]. Improvement in knee flexion angle was positively associated with three biomechanical variables that were drawn from findings of I3DGA: *(i)* adequate hamstrings lengths and velocities, *(ii)* normal tibial torsion, possibly achieved via tibial derotation osteotomy, and *(iii)* sufficient muscle strength [20].

Example [Fig. 4]:

The comparison of 3-dimensional gait analysis and bedside clinical evaluation of a 17-year-old child and a 14-year-old child with spastic diplegia revealed a similar crouch gait pattern. This was demonstrated by both children exhibiting a similar shortening of hamstrings length using modified popliteal angle test during bedside clinical evaluation. However, the 3D gait analysis of the 14-year-old child revealed a crouch angle of 90°, whereas the 17-year-old child demonstrated a crouch angle of 40°. Additionally, instrumented 3D gait analysis demonstrated that both the children with crouch gait had dynamic hamstring muscle tendon length well within the reference range.

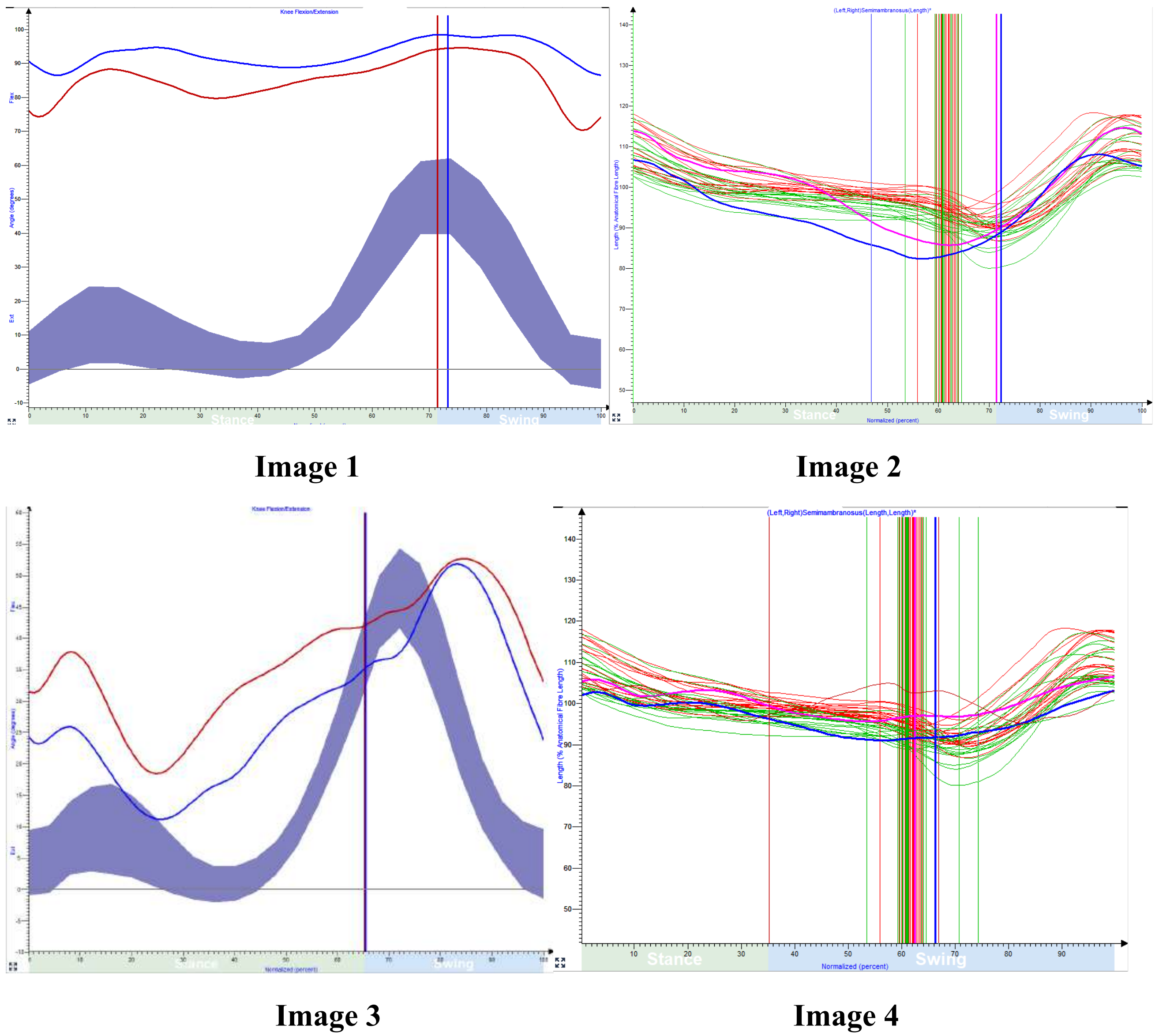

Fig. 4 **Image 1 & 2** represent the knee kinematic and dynamic muscle tendon length–semimembranosus muscle of 14-year-old with spastic cerebral palsy. **Image 3 & 4** represent knee kinematics and dynamic muscle tendon length (DMTL) of 17 year old with spastic CP

Thus, the combination of bedside clinical evaluation and I3DGA can provide a more comprehensive assessment of CG in children with spastic diplegia.

Radiological evaluation

Radiological evaluation consists of anteroposterior (AP) and lateral view radiographs of pelvis with both hips and of both knees. Hip radiographs are looked for any dysplastic changes, deformity and uncovering of femoral head. Radiographs of the knees are taken with the knee in maximum possible extension to document and quantify any coronal plane deformity and fixed flexion deformity around knee. Another lateral radiograph with knee flexed in 30–90° evaluates the position of patella by calculating Insall Salvati Index and Koshino index [Fig. 5]. Weight bearing radiographs of the feet are useful for evaluating and planning treatment of foot deformity. An anteroposterior and lateral X-ray scanogram of both lower limbs helps in better analysis of deformities and to rule out any limb length discrepancy.

Computerized tomogram (CT) scan of femur and tibia are used to analyze rotational deformities. It also identifies early stress fracture of patella and avulsion injury of tibial tuberosity in severe crouch which may not be apparent on radiographs. Finally, magnetic resonance imaging (MRI)

Fig. 5 Radiological evaluation of crouch gait. [**A**] AP radiograph of pelvis and both hips showing dysplastic changes and increased uncovering of femoral head (migration index = 60%) on right side. Coxa valga (neck shaft angle = 152.4°) is present on left side. [**B**] Frog leg lateral radiograph of same patient showing dysplastic changes on right side. [**C**] Lateral radiograph of knee showing patella alta (Insall Salvati Index = 1.57, Koshino Index = 1.35) [**D**] Plano valgus deformity in foot

of knee can be helpful in evaluating a painful knee and in revealing subtle findings like bone marrow oedema, meniscal tears and issues in ligaments around the knee.

Treatment

The treatment of CG should be directed towards its cause and should take care of patient's specific musculoskeletal issues. A variety of nonsurgical and surgical treatment modalities have been suggested. Some factors deciding the type of intervention include the age of patient, severity of spasticity, presence of dystonia, severity of deformity and patient's GMFCS level. Nonsurgical methods alone like physiotherapy, orthosis and spasticity management can be effective in treatment of younger children and those with mild crouch. Besides, they have a role in further rehabilitation of surgically treated patients. Surgical intervention is indicated when conservative treatment fails. It aims to correct the flexion deformity at knee, reduce hamstring spasticity and restore length, thereby facilitating hip and knee extension [Fig. 6].

Non-operative

Exercises

Even though, there is lack of convincing evidence about effectiveness of physiotherapy measures in treatment of CG, they are frequently advised. Some functional improvement has been reported with strength training [25]. However, it was refuted by Scianni et al. after a meta-analysis of randomized trials [26]. Steele et al. reviewed the effect of progressive resistance strengthening program and identified the presence of hamstring spasticity and slower walkers as poor prognostic factors for improvement in knee extension [27]. Early encouraging results of robot assistance to soleus and functional electrical stimulation of quadriceps has been published [28, 29]. But effectiveness of these methods needs further validation by doing longer follow up studies.

Bracing

The role of bracing and type of orthosis in management of CG remains controversial. Due to excessive ankle dorsiflexion the standard ankle foot orthosis is poorly tolerated.

Fig. 6 Case example of a patient with crouch gait treated surgically. [**A & B**] Preoperative clinical images [**C & D**] Post-operative clinical images [**E & F**] Post-operative radiographs showing correction of knee deformities and lever arm dysfunction

The Ground Reaction Ankle Foot Orthosis (GRAFO) avoids excessive dorsiflexion at ankle and maintains plantar flexion–knee extension couple by imparting extension force over anterior aspect of leg, thereby maintaining the knee extension during stance phase [30]. However, Ries et al. did not observe any difference in outcome between solid ankle foot orthosis (SAFO) and GRAFO [31]. Furthermore, the role of GRAFO has been questioned in presence of fixed deformities, excessive tibial torsion and weak quadriceps [30].

Spasticity reduction

The methods of spasticity reduction could be global or local and may have either temporary or permanent effect. A variety of treatment modalities ranging from the use of oral muscle relaxants to invasive procedures like selective dorsal rhizotomy have been described. Currently, the method of injecting botulinum toxin in the target muscles is preferred [32]. It is also used as a diagnostic test before muscle–tendon complex lengthening to anticipate the outcome after surgery. However, the overall functional improvement after botulinum toxin injection is reportedly small and short lasting [33].

When initiated at an early age, non-operative measures can delay the need for surgical intervention later. However, due to typical natural history of CG being progressive over time, these measures are poorly tolerated. Surgical interventions are commonly needed and the rate of bony procedures remains unchanged.

Operative

SEMLS

Single event multilevel surgery (SEMLS) refers to dealing with all deformities simultaneously and has become the standard practice for ambulatory patients with CP [34]. It prepares the child instantly for rehabilitation and is more convenient to the family by reducing the cost of treatment and incidences of missing school.

Hamstring lengthening (HL) and Hamstring transfer (HT)

Selective medial HL has been reported to improve the knee flexion contracture and overall functional outcome [35]. Traditional open approach through a posterior midline incision is commonly used. Recently, percutaneous technique has been reported to be equally effective [36]. Combined medial and lateral HL offers greater improvement and is reserved for severe flexion contracture. However, it increases the risk of knee hyperextension, neurological stretch injury and post-operative calf spasticity. The HL procedure should be used judiciously as it reduce the power of muscle and can have a contrary effect on the relevant joint kinematics. Moreover, a large proportion of patients with CG have normal length of hamstrings [5]. As hamstrings also act as hip extensor, its inadvertent lengthening specially in GMFCS III, may increase the hip flexion deformity, anterior pelvic tilt and lumbar lordosis, therewith worsening the knee deformity further [37]. Increased tone in rectus and a weak hip extensor before surgery could predict for increased pelvic tilt after HL [38]. Recurrence of crouch after HL is usually due to factors like quadriceps insufficiency and weak soleus muscle [39]. Repeating HL in such cases is less effective and hence interventions other than repeat hamstring lengthening should be considered [39, 40].

Transfer of semitendinosus to the adductor magnus or adductor tubercle of femur inhibits its activity as knee flexor, while allowing it to act as a hip extensor [41]. Both HL and HT have been reported to produce identical improvement in knee range of movement and the long term outcome [35, 42]. Combining semitendinosus transfer with lengthening of other hamstrings may have added benefits [41]. It may improve knee kinematics and is indicated for knee flexion contractures with concomitant anterior pelvic tilt [43].

Posterior knee capsulotomy

Posterior capsulotomy of knee can effectively correct mild to moderate knee flexion deformity. When combined with medial hamstring lengthening it improves both static and dynamic knee flexion and walking velocity and avoids bony procedure in younger children [44]. However, forceful extension of knee after the procedure is discouraged to avoid sciatic nerve stretch injury. Instead, serial casting on weekly basis is recommended to correct the residual deformity.

Concomitant soft tissue surgeries around hip and ankle

Concomitant soft tissue surgeries around hip and ankle should be performed if indicated, as a part of SEMLS. The most common interventions around hip are psoas and rectus femoris lengthening. As Iliacus muscle is usually spared, aponeurotic lengthening of psoas at pelvic brim is encouraged instead of iliopsoas tendon lengthening [45]. Similarly, resection of the direct head of rectus femoris is preferred, keeping the reflected head intact to avoid unwanted weakness in knee extension. Around the ankle, decision for lengthening of gastrocnemius or tendo-Achilles is made (based on the findings of Silfverskiold test) after correction of knee and foot deformity. Achilles tendon shortening may be needed in presence of plantar flexion lag [46].

Anterior distal femoral hemiepiphysiodesis (ADFH)

ADFH has been reported to correct knee flexion deformity effectively without causing physeal arrest [47–49]. It offers gradual correction of deformity is less invasive and allows early weight bearing. The use of two 4.5 mm cannulated screws across the anterior 1/3rd of physis is preferred over 8 plate due to less incidence of post-operative anterior knee pain [50]. Correction rate of 0.5–1° per month has been reported. ADFH, when combined with hamstring lengthening, produces greater improvement in popliteal angle, knee flexion contracture and peak knee extension during stance [47]. A similar benefit is not observed in combination with patellar tendon shortening (PTS) and a simultaneous PTS has been suggested only for severe contractures more than 30° [48]. There is consensus for ADFH in ambulating children with less than 30° of flexion contracture and more than two years of growth remaining [51].

Distal Femur Extension Osteotomy (DFEO) and Patellar Tendon Advancement (PTA)

Stout et al. advocated the combined use of DFEO and PTA to correct flexion deformity of knee in CP and reported better clinical, radiological and functional outcome when compared to isolated DFEO or PTA [52]. Subsequently, this method has evolved as the standard practice for correction of CG in CP with many studies reporting satisfactory results [Table 1] [46, 52–72].

The technique consists of removing an anterior-based wedge from distal femur and closing the osteotomy by extending and posteriorly translating the distal fragment. A trapezoid shape wedge is advised for flexion contractures greater than 30° to add shortening and avoiding stretch injury to the posterior neurovascular structures. A higher location of osteotomy should be avoided as it necessitates greater translation of distal fragment. Any rotational deformity in the femur is corrected simultaneously. PTA is accomplished by shortening the patellar tendon in skeletally immature children and by advancing the tibial tuberosity to a more distal position when physis is closed. Concomitant hamstring lengthening has been suggested for deformities greater than 30°, however, Healy et al. did not find it necessary [57].

The incidence of neurological complications after surgery varies between 3 and 12% and is an important concern [52, 60]. However, it does not correlate with the severity of flexion deformity before surgery, the amount of correction done or the scarring from previous surgeries [59, 73]. Leaving the posterior cortex intact as suggested by Stout et al. may lead to the stretching of posterior neurovascular structures [52]. Adequate femoral shortening, avoiding forceful correction and a stable internal fixation are the key factors in reducing the incidence of stretch injuries. [59, 73].

Filho et al. reported increase in anterior pelvic tilt after DFEO with PTA but it was lesser when compared to DFEO or PTA alone [63]. The tilt was higher when hamstring lengthening was added to the procedure. Opposite to this, Klotz et al. reported comparatively greater increase in anterior pelvic tilt in patients undergoing DFEO with PTA when compared to DFEO alone [60]. Boyer et al. reported greater knee extension dysfunction during sit to stand after DFEO with PTA when compared to those receiving other conventional methods of treatment [61]. Subsequently, they compared the long term outcomes between the two groups and reported better improvement of knee flexion contracture and stance phase knee extension in earlier group [62]. However, slight subsequent decline of the short term improvement was noted. Moreover, these benefits did not improve the overall functional outcome, mobility and participation of patients in various activities. The knee pain and osteoarthritis scores in early adulthood were also similar in both groups. Thus, even though DFEO with PTA improves the knee kinematics, these benefits are not converted into a better quality of life in long term.

Correction of lever arm dysfunction

Derotation osteotomies should be added to correct the rotational deformities in femur and tibia. For femur, it can be performed simultaneously with DFEO. Tibial derotation is commonly performed through a supramalleolar osteotomy. For planovalgus foot deformity, MOSCA procedure, consisting of lateral column lengthening and medial soft tissue plication is recommended if deformity it flexible and not very severe. More severe and stiff foot deformities will need complex mid foot osteotomies or a triple arthrodesis.

Conclusion

CG is fairly common in patients of diplegic CP. The etiology is multifactorial and in majority, it is beyond the control of treating physician. However, one should be aware of the effect of unnecessary over lengthening of muscle–tendon units, particularly, the soleus and hamstrings in causing CG. Meticulous clinical and radiological evaluation in combination with I3DGA helps in planning appropriate treatment. Younger children are managed effectively with methods of temporary spasticity management and physiotherapy measures, while soft tissue lengthening is reserved for joint contractures. ADFH is a viable option for fixed flexion deformity of knee before maturity. For those around maturity, bony procedures with concomitant soft tissue surgeries are known to give satisfactory results. In spite of extensive research in this field, the current understanding about crouch gait remains deficient. Further studies focusing on etiopathogenesis, biomechanics and long term outcome of different treatment modalities are suggested.

Table 1 Literature review of studies on DFEO and PTA

Study	Sample size (*n*)	Mean age (years)	Mean follow up (months)	Level of evidence	Important conclusions
Stout et al. 2008 [52]	73	13.8	15	III	PTA combined with DFEO has better results when compared to both procedures in isolation
Filho et al. 2008 [54]	12	13.1	28	IV	DFEO + medial hamstring lengthening without PTA is effective in improving knee extension but recurrence and anterior pelvic tilt is common
Novacheck et al. 2009 [55]	73	NA	NA	III	Inclusion of PTA with DFEO is necessary to achieve optimal results
Joseph et al. 2010 [56]	17	12.4	24	IV	Two staged surgery is recommended 6 weeks apart Stage 1—DFEO + PTA) Stage 2—Hamstring lengthening
Ganjwala 2011 [46]	18	14.6	24	IV	Multilevel surgery including DFEO + PTA improves mobility and function and the results are maintained till 2 years after surgery
Healy et al. 2011 [57]	32	NA	NA	IV	Concomitant hamstring lengthening is rarely needed with DFEO + PTA
Das et al. 2012 [58]	14	13.6	36	IV	DFEO + PTA improve function and knee extension and reduce knee pain
Inan et al. 2015 [59]	28	13	NA	IV	Reported 10% incidence of neurological complications. However it was not correlated with amount of deformity and correction
Lenhart et al. 2017 [53]	Experimental study				DFEO alone stretches the hamstrings and shortens the femur and quadriceps. A cuneiform wedge resection reduces the stretch on hamstring while PTA takes care of quadriceps shortening
Klotz et al. 2017 [60]	22	12.1	15.6	IV	PTA increases the anterior pelvic tilt
Boyer et al. 2017 [61]	51	20	96	III	DFEO + PTA causes knee extensor dysfunction during sit to stand activity
Boyer et al. 2018 [62]	51	26.1	156	III	DFEO + PTA improves knee extension in short term but does not impart any significant benefit in long term
Filho et al. 2018 [63]	95	14.3	32.1	III	Addition of PTA and hamstring lengthening increases the anterior pelvic tilt
Salami et al. 2018 [64]	19	13	13–60	III	DFEO + PTA improve knee kinematics at mid-term but does not increase the length or velocity of hamstring muscle
Pelrine et al. 2020 [65]	51	12.8	12	III	Surgery does not decrease the prevalence of knee pain
Aroojis et al. 2019 [66]	26	14.3	22	IV	DFEO + PTA are effective in treatment of crouch gait. Pediatric condylar locking compression plate provides stable fixation and allows for early mobilization
Park et al. 2019 [67]	33	12.2	26.9	IV	DFEO + PTA improve knee kinematics but increases anterior pelvic tilt and incidence of stiff knee gait
Hefny et al. 2020 [68]	20	12.5	24	IV	DFEO + PTA improve knee kinematics. Simultaneous hamstring lengthening increases anterior pelvic tilt
Hyer et al. 2021 [69]	28	13.2	12	IV	DFEO + PTA improves clinical, radiological and gait analysis parameters around knee
Emara et al. 2021 [70]	20	11.1	16.2	IV	DFEO + PTA improve the range and strength of knee extension and reduces knee pain
Liou et al. 2022 [71]	25	11	12	III	DFEO at a lower level with a distally placed plate near physis can produce genu valgum deformity. Fixation of osteotomy in slight varus is recommended
Erdal et al. 2022 [72]	12	NA	37	IV	The use of intraoperative neuromonitoring decreases the incidence of neurological complications

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Declarations

Conflict of interest The authors state that they have no conflict of interest, financial or otherwise, concerning the material or methods used in this study or the findings specified in this paper.

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REVIEW ARTICLE

Global Research Trends in Limb Salvage Surgery for Osteosarcoma: Findings from a Bibliometric and Visualized Analysis over 15 Years

Manish Raj[1] · Amiy Arnav[2] · Arup Kumar Pal[3] · Shukla Mondal[3]

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Abstract

Background Limb salvage surgery in osteosarcoma requires a multidisciplinary team of experts, due to which research interest has remained limited globally. This article analyzes research trends over 15 years from 2007 to 2022.

Materials and Methods Publications on limb salvage surgery in osteosarcoma were retrieved using the Web of Science. Bibliometric analysis of the publication metadata was done using R software. VOS viewer software was used to analyze the bibliographic coupling, co-citation, co-authorship, and co-occurrence to report the current trends in global research on limb salvage surgery in osteosarcoma.

Results A total of 693 articles were retrieved. On applying the inclusion and exclusion criteria, a publication metadata of 276 articles was analyzed using the methodology mentioned. Annual scientific production on the subject has shown a steady rising trend globally. China has the highest number of publications on the topic; however, the USA has the highest citations globally. The Journal "Clinical Orthopedics and Related Research" remains the pioneer in the topic with the highest number of publications and H index among all journals. Most of the research interest is generated in the developed countries of the USA, Europe, and China. Keyword analysis suggested 4 clusters of surgical reconstruction, Survival, Chemotherapy, and general management related. Newer keywords such as biological reconstructions, allograft, metastases, cell, and chemotherapy suggest future research topics in the field.

Conclusion Research interest in limb salvage surgery in osteosarcoma continues to grow with the introduction of concepts such as biological reconstructions and allografts. However, for more inclusive research on the topic, research interest must also be encouraged in underdeveloped and developing countries.

Keywords Limb salvage · Osteosarcoma · Global research · Trends · Bibliometric · Visualized analysis

✉ Amiy Arnav
manish.orthopaedics@aiimsdeoghar.edu.in

Manish Raj
drmanishraj4u@gmail.com

Arup Kumar Pal
arupkrpal@iitism.ac.in

Shukla Mondal
shuklamondal.cse@gmail.com

1 Department of Orthopaedics, All India Institute of Medical Sciences, Deoghar, India

2 Department of Surgical Oncology, All India Institute of Medical Sciences, Deoghar, India

3 Department of Computer Science and Engineering, Indian Institute of Technology (ISM), Dhanbad, India

Introduction

As a disease predominantly occurring in young children, adolescents, and young adults, osteosarcoma is notorious for involving periarticular areas of long bones. Amputation was considered the gold standard for tumor ablation until the 1970s; however, highly effective perioperative chemotherapy and the wide availability of endoprosthesis ushered in the era of limb salvage surgery in the 1980s [1]. Initially, limb salvage techniques were restricted to European and developed countries. However, in the early twenty-first century, limb salvage surgery became the standard of care for osteosarcoma patients and, along with perioperative chemotherapy, has demonstrated a consistent level of long-term outcomes of 60–80% [2]. Current techniques for limb salvage in osteosarcoma include expandable and non-expandable tumor prostheses, resection arthroplasties, distraction osteogenesis, segment transport, or total joint replacements [3]. Unfortunately, these limb salvage techniques are not popular worldwide due to constraints such as a lack of infrastructure, appropriately trained teams, costly prostheses, and bone banks for storing allografts [4]. Bibliometric analysis from published articles provides a systemic and informative way of analyzing the current research trends in a particular topic. Using this analytical tool, one can evaluate a research topic's past, current, and future evolution and investigate the variations in research interest at a global level, thus pinpointing areas needing development in that research field [5]. In our study, we have performed a bibliometric and visualized analysis of research trends in limb salvage surgery for osteosarcoma patients over the past 15 years to gain perspective toward the status of research distribution in the field globally.

Methodology

Data Search and Search Strategy

The database of the Web of Science was used to collect the published articles. On using the keywords "Limb salvage surgery" and "Osteosarcoma", the search showed a total of 693 articles over a search period from 01/01/2007 to 21/11/2022. To analyze the use of limb salvage surgery exclusively in osteosarcoma, all articles which dealt with tumors other than osteosarcoma or performed on animals were excluded. On applying the screening criteria, we obtained 276 eligible published articles (Fig. 1).

Data Collection

The data from the eligible studies were downloaded from the Web of Science and PubMed as a TXT file. The data included article title, year of publication, author names, author nationalities, author affiliations, journal names, keywords, and abstract. These data was eventually imported into Microsoft Excel (Microsoft 365). The data collection, screening, and extraction were performed independently by two authors and any disagreements were resolved using discussions until a consensus was reached.

Bibliometric and Statistical Analysis

Using the built-in features of the Web of Science (WoS), essential bibliographic characteristics and country-wise data for publications could be analyzed. The rest of the analysis was done using R Software (Version 4.2.2), including the ggplot2 and bibliometrix packages.

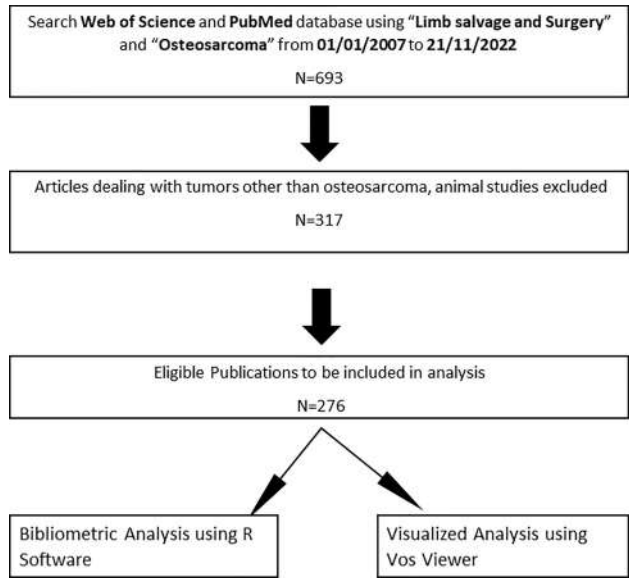


Fig. 1 Article search and inclusion strategy

Visualized Analysis

Visualized analysis was done using VOS viewer (Version 1.6.18), Leiden University, Leiden, Netherlands). The analysis included bibliographic coupling, co-authorship, co-citation, and co-occurrence. In the depicted maps, the larger the dots were, larger the number of studies, and the thicker the line, the stronger the association in bibliographic coupling.

Results

Annual Scientific Production

As shown in Fig. 2a, the annual publication in the research field has an ebb-and-flow growth pattern, with a peak in 2014 when 25 publications were published. Another peak occurred in 2020, with 23 articles after a consistent annual increase over 2 years. The number of annual publications on the topic has declined since then. The annual growth rate of scientific production on the topic was 3.71%.

Mean Total Citation per Year and per Article

As shown in Table 1, the mean total citation per article was highest in 2007 with a score of 60.64, followed by the year 2010 with a score of 56.36 and year 2016 with a score of

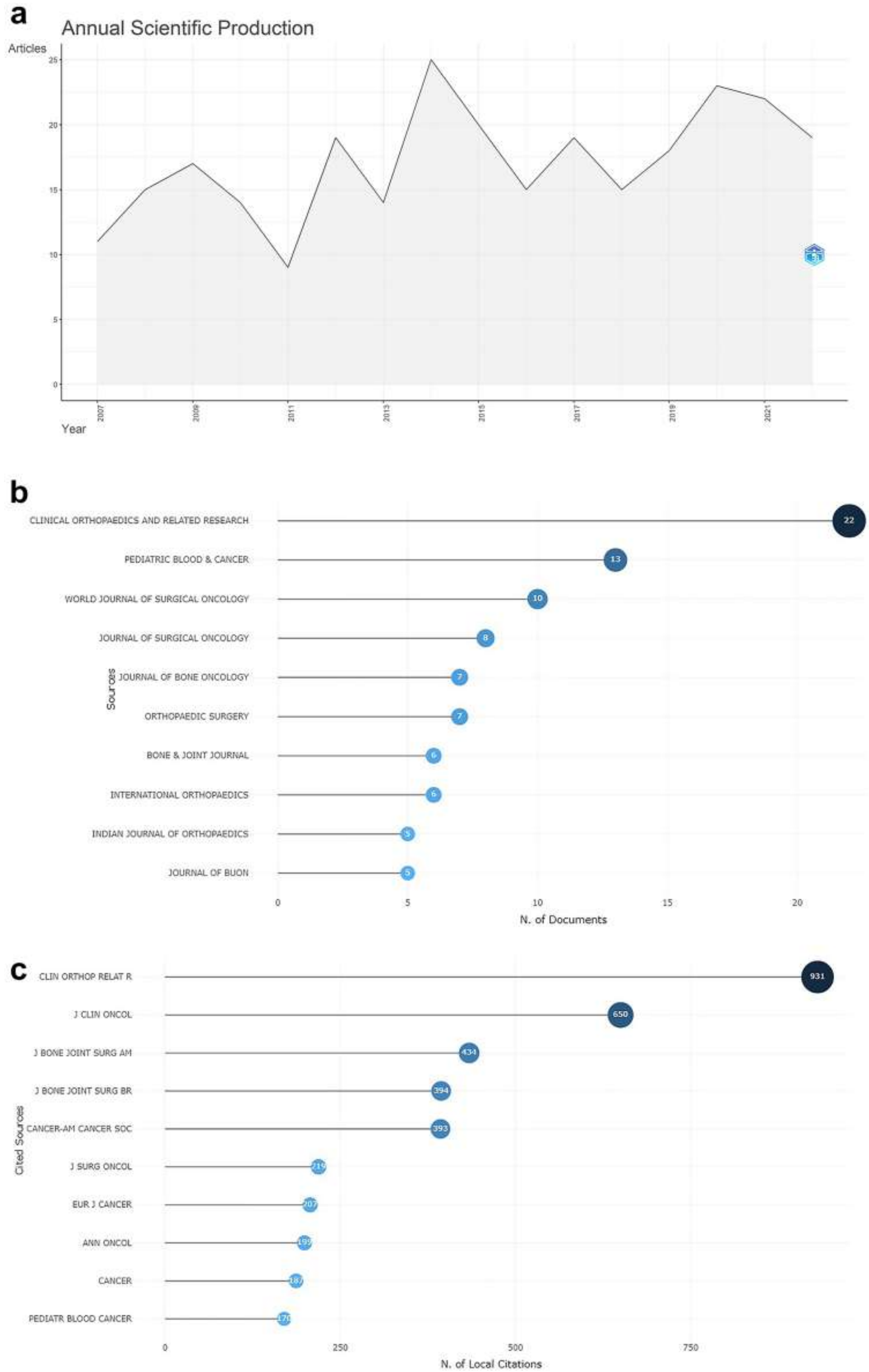


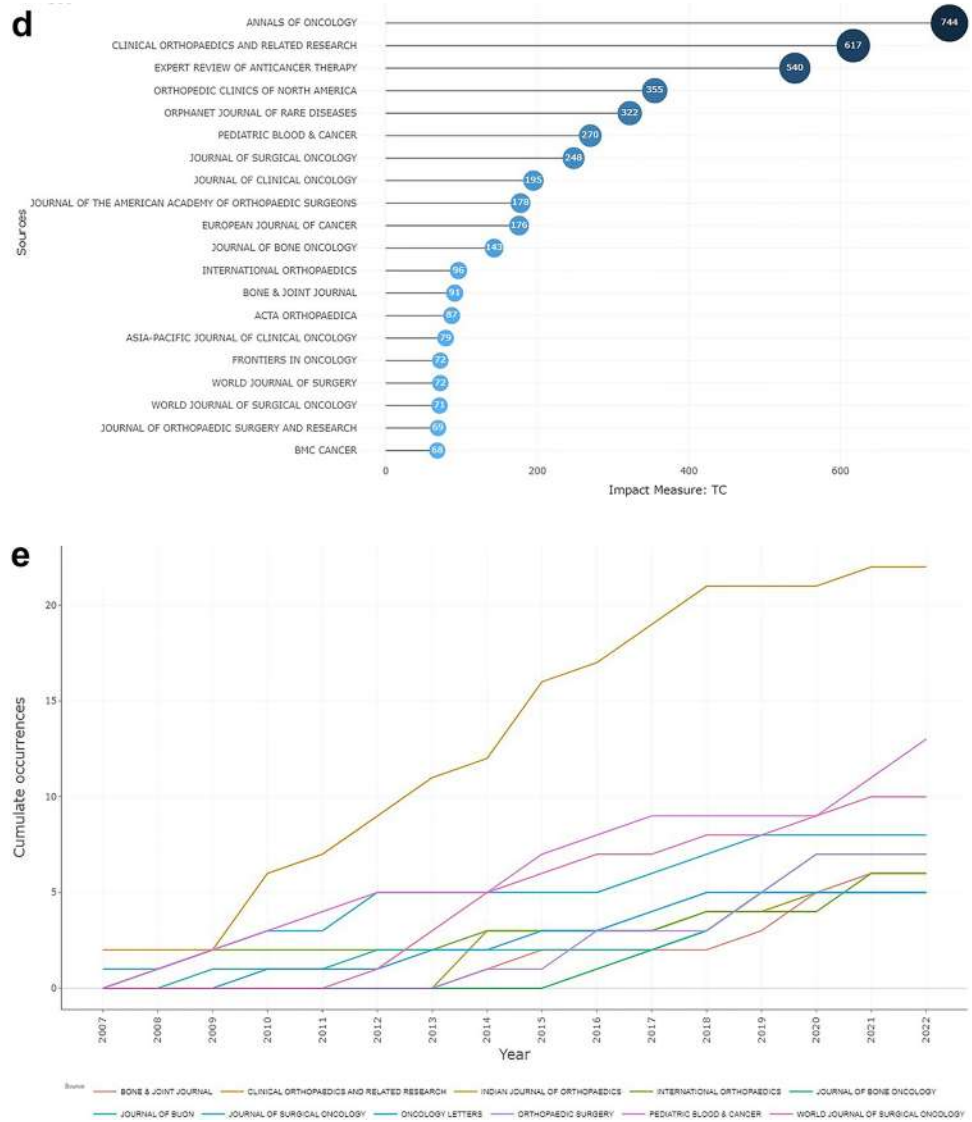
Fig. 2 **a** The ebb-and-flow pattern of article publication through the years. The last peak of publications was in 2020. **b** Top ten journals according to publications on the research topic. **c** Top ten journals according to local citations. **d** Top ten journals according to global citations. **e** Graph depicting the journal wise publications through the years

46.53. However, when we analyzed the mean total citation per year, it was highest in the year 2018 with a score of 11.17 followed by the year 2016 with a score of 7.76, and in the year 2021 with a score of 6.86.

Journal Metrics

The maximum number of publications on the current topic was published in the journal "Clinical Orthopaedics and Related Research" with a total of 22 publications, followed

Fig. 2 (continued)



by 13 publications in the journal "Pediatric Blood and Cancer" and 10 publications in the journal "World Journal of Surgical Oncology" (Fig. 2b). In terms of local citation, i.e., how many times an author (or a document) included in this collection had been cited by the documents also included in the collection, again, "Clinical Orthopaedics and Related Research" was way ahead of its peers with 931 local citations (Fig. 2c). However, when total citation was considered, "Annals of Oncology" topped the charts with 744 total citations, and "Clinical Orthopaedics and Related Research" came second with 617 total citations followed by the journal "Expert Review of Anticancer therapy" with 540 citations (Fig. 2d). On further analysis, among the top three cited journals, the earliest publication on the topic for the journal "Annals of Oncology" was 03 years later; the number of citations was higher because of one article by Ritter J et al. in 2010, which has the highest global citations on the topic till date (Table 2). Figure 2e suggests the steady and persistent increase in the publications by the journal "Clinical Orthopaedics and Related Research" followed by "Pediatric Blood and Cancer" and "World Journal of Surgical Oncology."

On using the H index for the journal, which was calculated as the number of publication outputs by the journal that has each been cited at least H times by other publications, "Clinical Orthopaedics and Related Research" again topped the charts with an H Index of 16 which was double the 2nd placed journal "Journal of Surgical Oncology" [6]. G index for the journal was calculated as the distribution of citations received by a given journal's publications, such that given a set of articles ranked in decreasing order of the number of citations that they received, the G index is the unique largest number such that the top g articles received together at least g2 citations [7]. "Clinical Orthopaedics and Related Research" had the highest G index of 22 among all

Table 1 Mean total citation per year and per article

Year	N	Mean total citations per article	Mean total citations per year	Citable years
2007	11	60.64	4.04	15
2008	15	19.07	1.36	14
2009	17	31.59	2.43	13
2010	14	56.36	4.7	12
2011	9	35.67	3.24	11
2012	19	28.68	2.87	10
2013	14	10.79	1.2	9
2014	25	12.32	1.54	8
2015	20	16.95	2.42	7
2016	15	46.53	7.76	6
2017	19	15.58	3.12	5
2018	15	44.67	11.17	4
2019	18	13.89	4.63	3
2020	23	8.35	4.17	2
2021	22	6.86	6.86	1
2022	19	0.74		0

other journals, followed by the journal "Pediatric Blood and Cancer." M index is another variant of the H index that displays the H index per year since the journal's first publication [8]. To no surprise, "Clinical Orthopaedics and Related Research" again had the highest M index of 1.0 among all other journals, followed by the journal "Cancers" with an M Index of 0.75 (Table 2).

Author Metrics

The author Dr. Xu Meng, from the Department of Orthopaedics, General Hospital of PLA, Beijing, China, had the highest number of publications, i.e., 12 in total, with Wang Zhen from the Department of Orthopedics, Xi-jing Hospital, Air Force Military Medical University, Xi'an, China coming a close second with 10 publications on the topic followed by Dr. Xiu Chun Yu from the 960th Hospital of PLA, China with 9 publications (Fig. 3a). On further analysis, Dr. Xu Meng and Dr. Yu XC began publishing around 2014 compared to Dr. Wang Zhen, who started in 2012. However, both were consistently involved in the research topic and have regularly been published even as recently as 2022 (Fig. 3b). In terms of author productivity, on applying Lotka's law, the graph demonstrated a sharp decrease as the number of publications done by an individual researcher increased to two and beyond (Fig. 3c).

Stefan S. Bielack from the Department of Paediatric Haematology and Oncology, University of Muenster, Germany, came in second place with 607 citations when the total number of citations was used as a metric (Fig. 3d). Dr. Piero Picci, the founder and past president of the Italian Sarcoma Group, received the most citations with 676 citations (Fig. 3d).

Among the authors, Dr. Xu Meng has the highest H Index of 8 followed by Dr. Piero Picci and Dr. Yu XC with an H Index of 7. Dr. Xu Meng has the highest G Index of 12, followed by Dr. Wang Z and Dr. Yu XC with a G Index of 10 and 9, respectively. Dr. Xu Meng also has the highest M index of 0.889, followed by Yu XC with a score of 0.778 (Table 3).

Institution Metrics

With 16 publications on the research topic, St. Jude Children's Research Hospital, Memphis, Tennessee, USA had the highest number of publications globally. Peking University, Beijing China, and Universiti Sains Malaysia (USM), Penang, Malaysia each had 12 publications. Only one institution in India, the All India Institute of Medical Sciences in Delhi, had significant publications (Fig. 4a). As shown in Fig. 4b, almost all universities—primarily those in China and the United States—have seen a steady rise in the number

Table 2 Top ten journals based on H index

Journal name	H index	G index	M index	Total citation	Net publications	Publication year start
Clinical Orthopaedics and Related Research	16	22	1	617	22	2007
Journal of Surgical Oncology	8	8	0.5	248	8	2007
Pediatric Blood and Cancer	7	13	0.467	270	13	2008
Orthopaedic Surgery	6	7	0.667	62	7	2014
Journal of BUON	5	5	0.357	53	5	2009
World Journal of Surgical Oncology	5	8	0.455	71	10	2012
Acta Orthopaedica	4	4	0.25	87	4	2007
BMC Cancer	4	4	0.333	68	4	2011
Bone and Joint Journal	4	6	0.444	91	6	2014
European Review for Medical and Pharmacological Sciences	4	4	0.286	38	4	2009

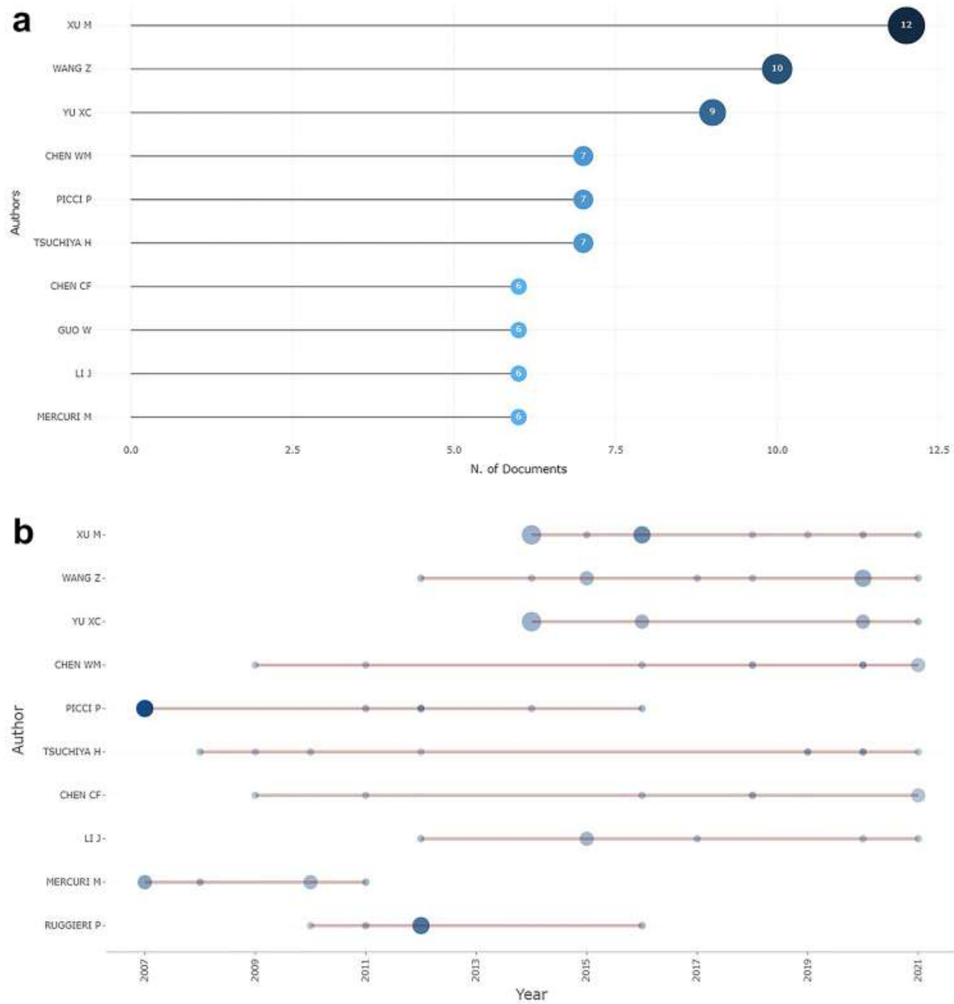


Fig. 3 Author-wise metrics: **a** top ten authors according to publications on the research topic. **b** Author production over time. **c** Graph attained after applying Lotka's Law: a sharp decline as number of articles increase to 2. **d** Top 20 authors according to total global citations

of publications; however, at the Korea Cancer Central Hospital, the number of publications has plateaued since roughly 2010.

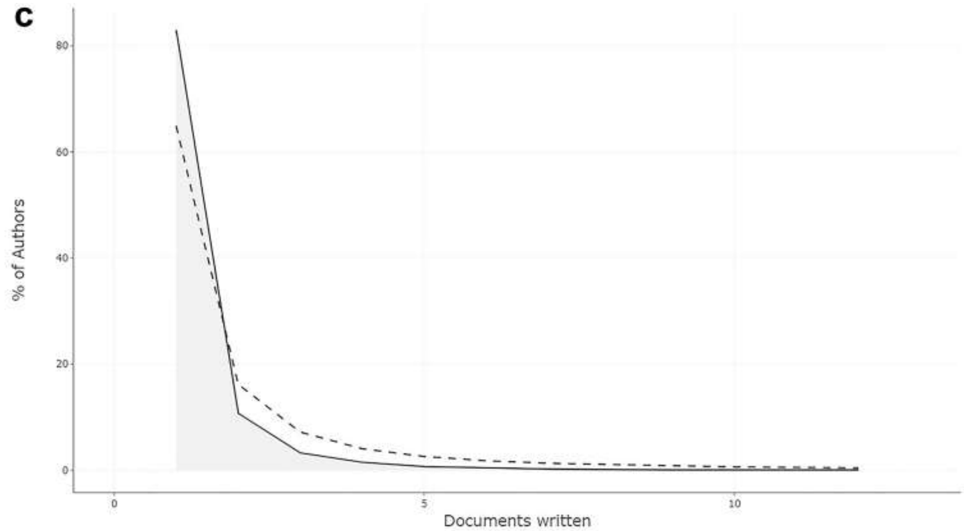
Country Metrics

Regarding the number of publications on the research topic globally, China leads the way with 244 publications to its credit, with the USA coming 2nd with 164 publications and India in fifth place with 38 publications (Fig. 4c). However, as depicted in Fig. 4d, e, the USA had more multi-country collaborations than China, which had single-country collaborations predominantly. Figure 4f shows the steady increase in publications by USA and China, with China surpassing the USA at around 2017–2018. However, if we take the total number of citations as a metric, the USA is far ahead of any other country with total citations of 1802, China is a distant 2nd with 1273, and Italy with 887 (Fig. 4g). On average article citations, Germany had the highest average of 109.17, followed by Italy (68.23) and the USA (43.95). India has a total global citation of 125 and an average article citation of 3.28 (Fig. 4h).

Article Metrics

Globally, the article titled "Osteosarcoma" by Ritter J et al. published in Oct 2010 in Annals of Oncology was the most commonly cited article on the research topic with 513 citations [9]. This article described the current practices for the management of osteosarcoma. A relatively recent article, "Current and future therapeutic approaches for osteosarcoma." by Harrison DJ et al. which got published in January 2018 in the journal "Expert review of anticancer therapy," was the second most commonly cited article with 413 citations [10]. Anderson et al. published the third most commonly cited article titled "Update on Survival in Osteosarcoma" in the journal "Orthopedic Clinics" published in 2016 [11] (Fig. 5a). After applying the screening criteria, the article titled "Local recurrence and local control of non-metastatic osteosarcoma of the extremities: a 27-year experience in a single institution" by Bacci G et al. published in

Fig. 3 (continued)



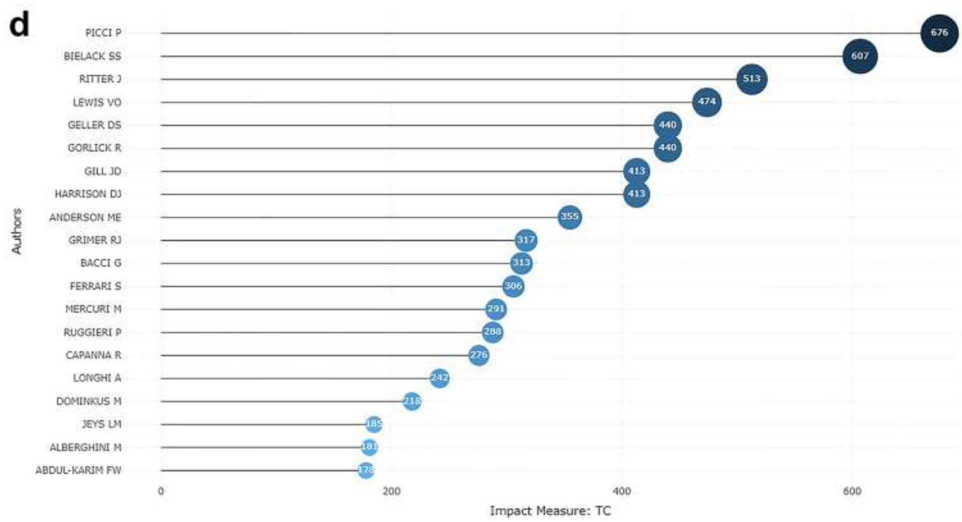


Table 3 Author metrics: various indices of top authors on the topic

Author name	h_index	g_index	m_index	TC	NP	PY_start
Xu Meng	8	12	0.889	177	12	2014
Picci Piero	7	7	0.438	676	7	2007
Yu XianChu	7	9	0.778	96	9	2014
Mercuri M	6	6	0.375	291	6	2007
Ruggieri P	6	6	0.462	288	6	2010
Wang Z	6	10	0.545	103	10	2012
Xu SF	6	6	0.667	67	6	2014
Ferrari S	5	5	0.313	306	5	2007
Li J	5	6	0.455	74	6	2012
Tsuchiya H	5	7	0.333	114	7	2008

the Journal of surgical oncology in Aug 2007 was most cited in the dataset. It dealt with the incidence of local recurrence and margins in osteosarcoma cases and suggested using limb salvage only when adequate margins can be obtained [12]. Ironically, the article by Ritter J et al. was cited only 11 times in our dataset (Fig. 5b). On further analysis, when we compare the local to global citation ratio, the highest score of 45.71 was achieved by an article titled "Clinical and functional outcomes of patients with a pathologic fracture

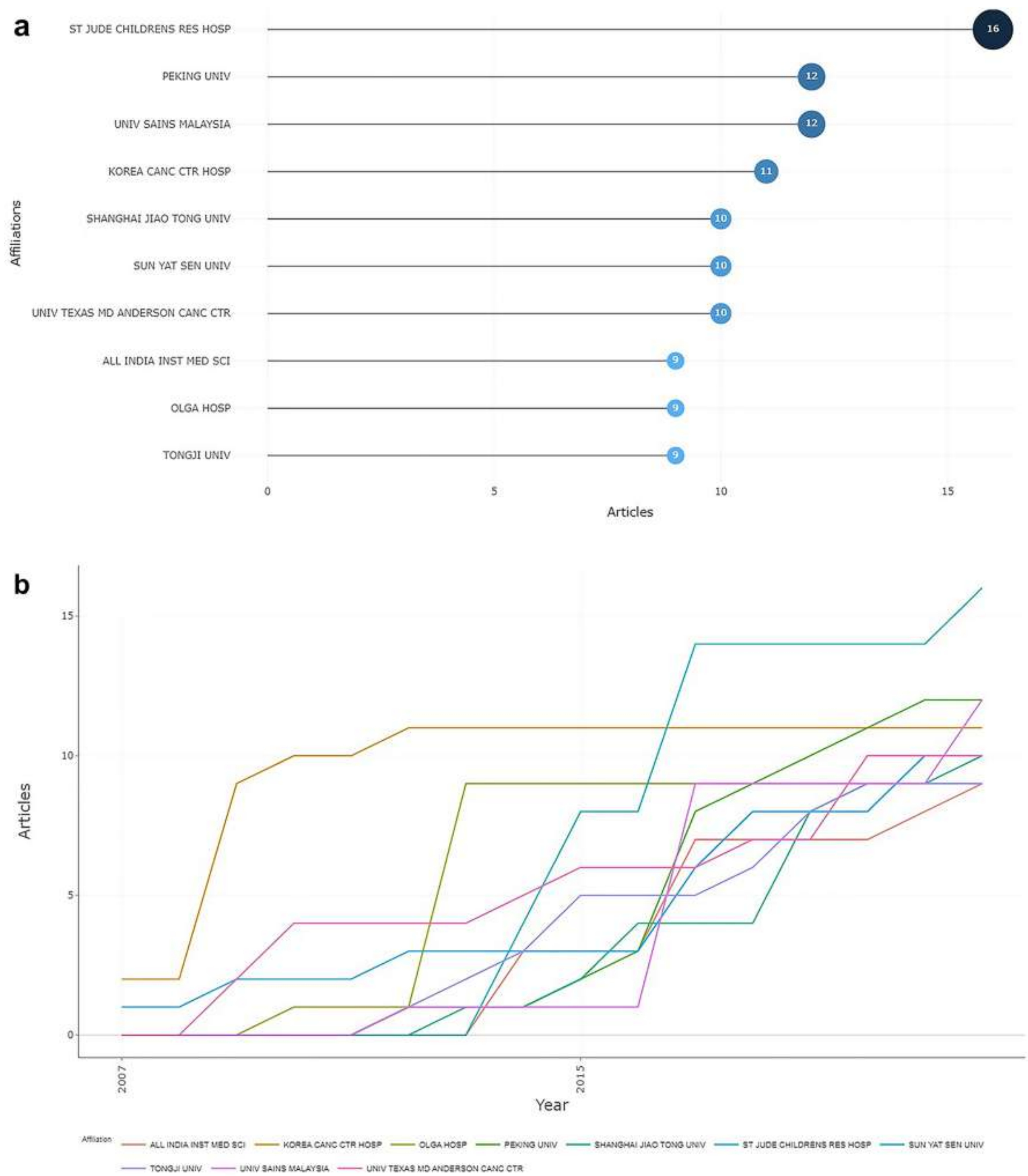


Fig. 4 Institution and country-wise metrics: **a** top ten institutions according to publications on the research topic. **b** Publication trends of top institutions over time. **c** Graph depicting countries according to publications on the research topic. **d** Countries according to multicenter collaborative projects (MCP) or single center projects (SCP). **e** Network map showing collaboration between different countries. Each line represents collaboration between the two countries. The thicker the line is, greater the collaboration. **f** Publication trends of top countries over time. **g** Top ten countries ranked according to total global citations. **h** World map showing distribution of publications on limb salvage in osteosarcoma

in high-grade osteosarcoma" by Ferguson et al. published in the "Journal of Surgical Oncology" in August 2010.

Keyword Analysis

As depicted by the word cloud (Fig. 5c), the keyword "osteosarcoma" appeared most in our dataset (166), followed by limb salvage (42), chemotherapy (33), amputation

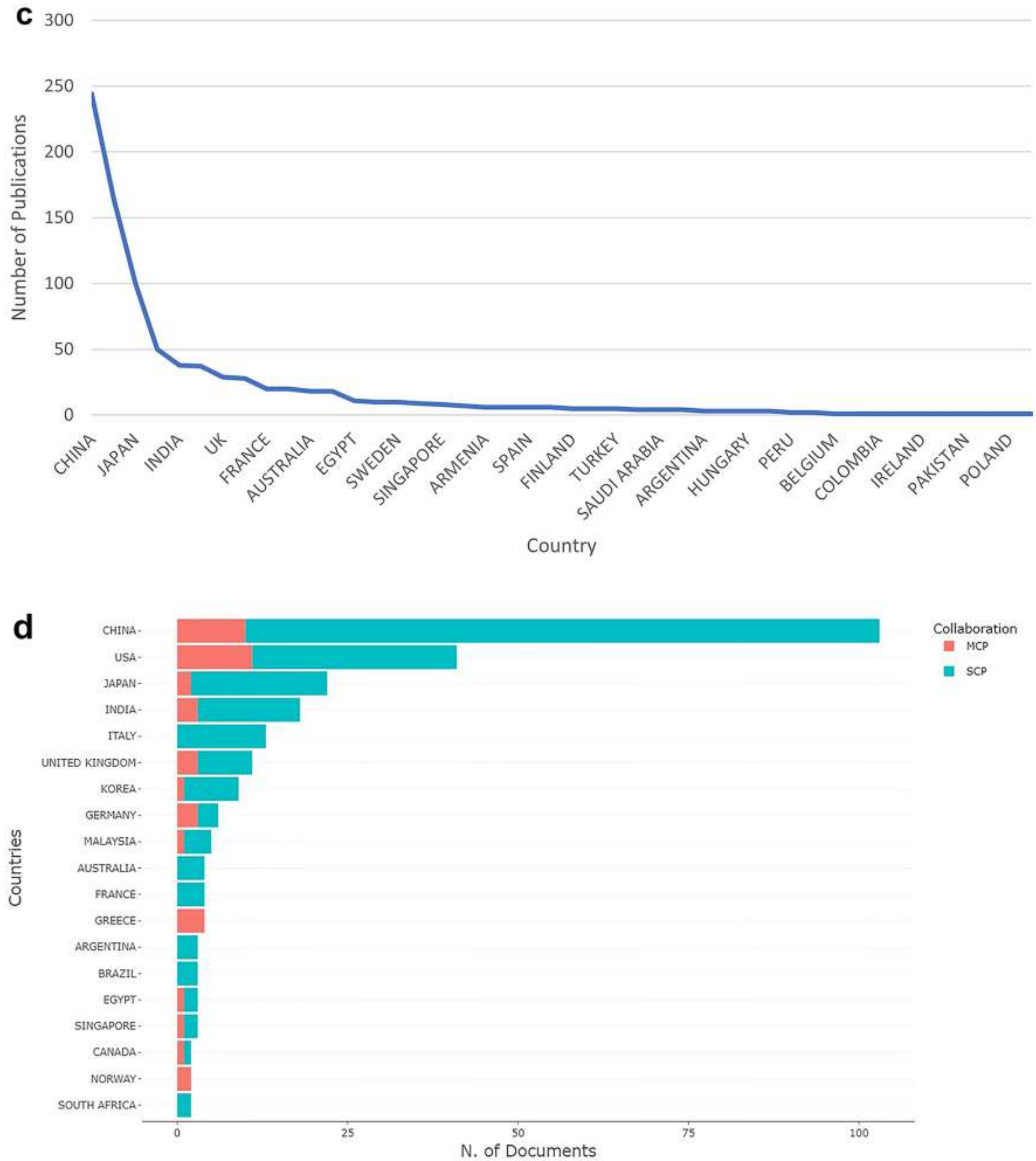


Fig. 4 (continued)

(20), survival (18), limb salvage surgery (16), neoadjuvant chemotherapy (15), prognosis (12), local recurrence (10) and pathologic fracture (9). All other keywords were cited less than nine times throughout the dataset (Fig. 5d).

The most commonly cited article by the top authors Xu M, Wang Z, and Picci P was an article published by Willian Enneking et al. in 1993 titled “A System for the Functional Evaluation of Reconstructive Procedures After Surgical Treatment of Tumors of the Musculoskeletal System” followed by an article titled “Prognostic Factors in High-Grade Osteosarcoma of the Extremities or Trunk: An Analysis of 1702 Patients Treated on Neoadjuvant Cooperative Osteosarcoma Study Group Protocols” by Bielack SS et al. [13, 14] (Fig. 5e).

Bibliographic Coupling Analysis

Citation analysis helps establish a linking measure between various publications. If two publications cite a third common article, then the publications are considered “coupled” because of the possibility of sharing a common topic.

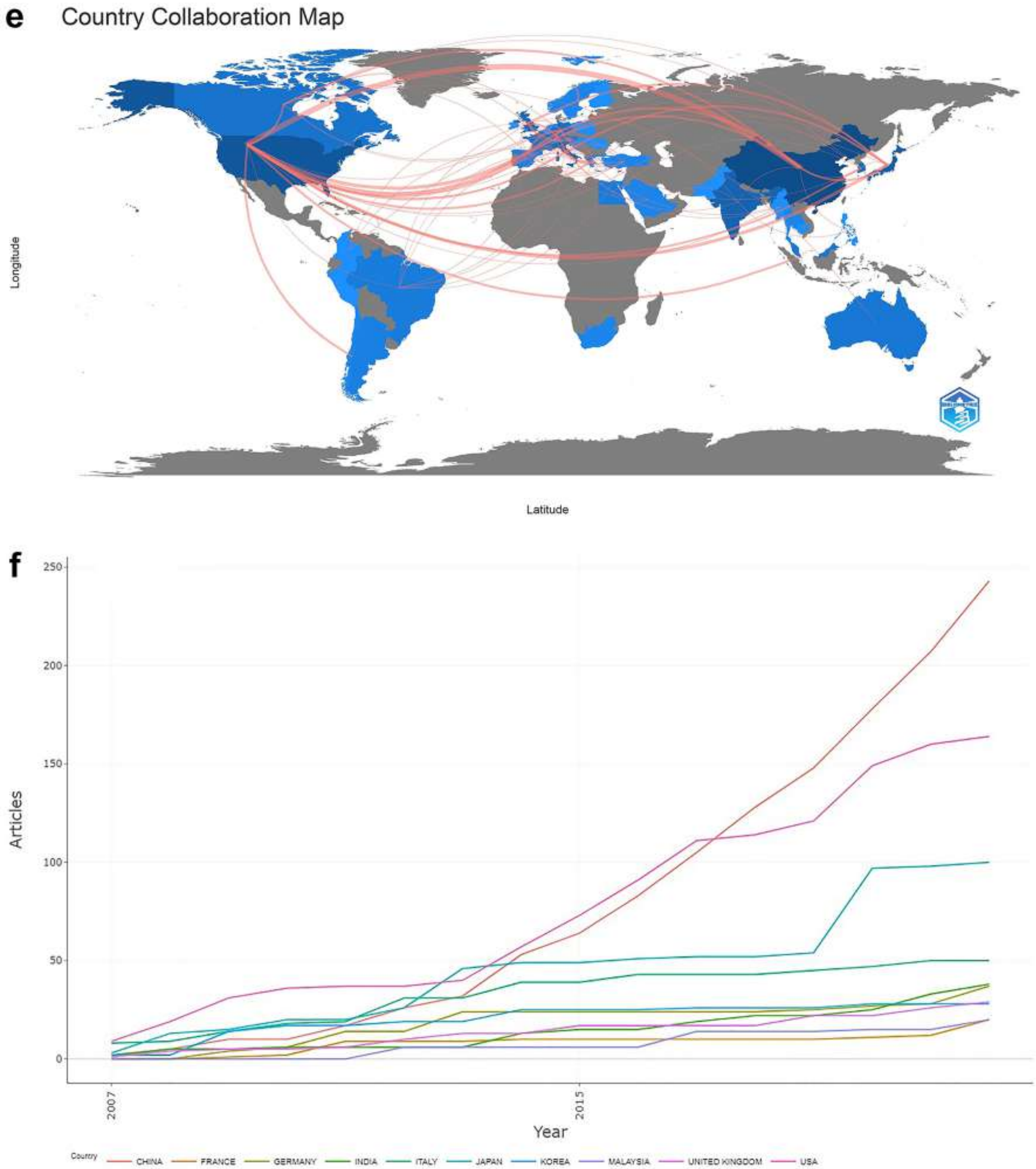


Fig. 4 (continued)

Therefore, a higher coupling or link strength would denote a higher association with the concerned topic/field.

Article Coupling

For the publications included in the study, articles that had been cited for a minimum citation of 20 times or more were analyzed using VOS Viewer, and it identified 80 articles out of 276. The top 4 article coupling in terms of link strength were Bielack SS et al. titled "MAP plus maintenance pegylated interferon alpha-2b (MAP-IFN) versus MAP alone in patients with resectable high-grade osteosarcoma and good histologic response to preoperative MAP: First results of the EURAMOS-1 good response randomization" published in 2013 {Total Link Strength = 268 times} [15] closely followed by Matterschimitt et al. in 2009 {Total link strength = 266 times} [16], Harrison, et al. in 2018 {Total Link Strength = 226 times} [10] and Angelini et al. in 2016 {Total Link strength = 226 times} [17]. Interestingly, other than the article by Harrison et al., none of the articles has more than 50 citations (Fig. 6a). This implies that these

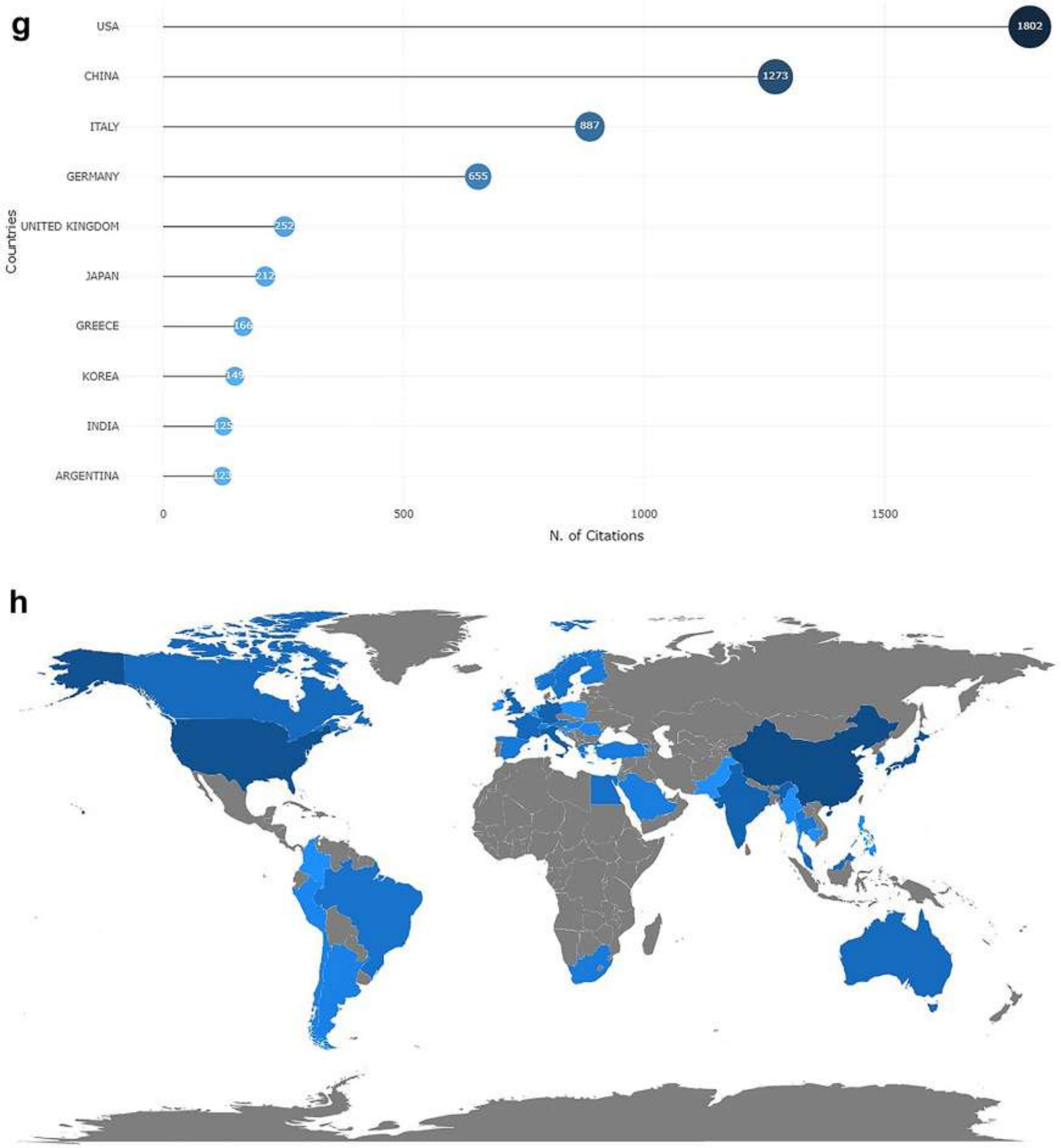


Fig. 4 (continued)

articles were more specific to our research topic than other articles with extremely high citations, which were broader.

Journal Coupling

Out of all the 122 journals which were analyzed in the study using VOS Viewers, only 46 journals had a minimum of 2 publications on the topic and ≥ 10 citations. The top five Journals based on link strengths were Clinical Orthopedics and Related Research (Total Link Strength = 2263 times), Journal of Surgical Oncology (Total Link strength = 1425 times), Pediatric blood and cancer (Total Link Strength = 1392 times), Bone and Joint Journal (Total Link Strength = 1281 times) and Expert Review of Anti-Cancer Therapy (Total Link Strength = 931). However, the journal with the highest citations, i.e., "Annals of Oncology" was not in the top five journals due to the fewer articles on the topic published in the journal (Fig. 6b).

Author Coupling

Among the publications included in the study, out of the 1468 authors, only 23 had produced a minimum of 4 publications and had more than 10 citations which were

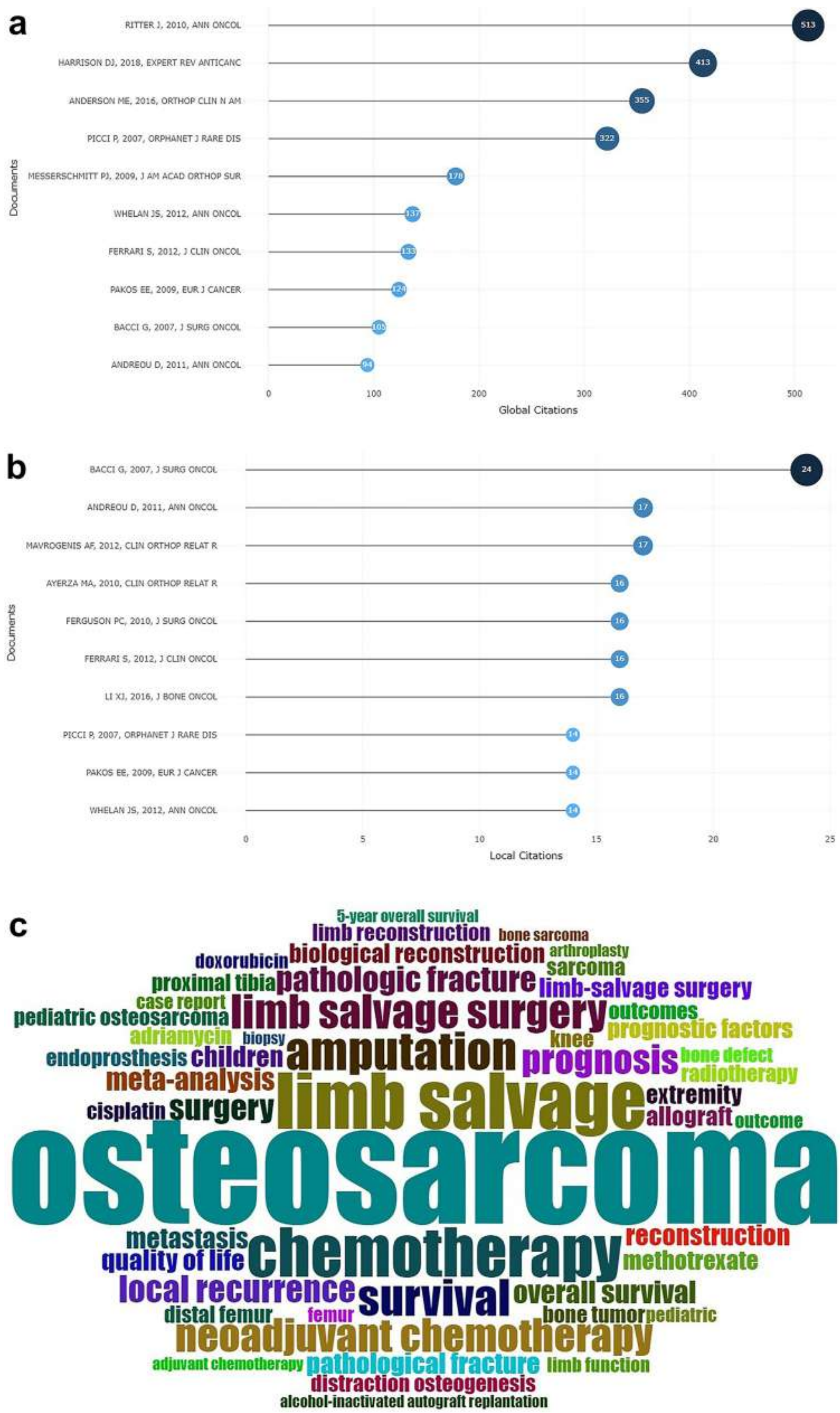
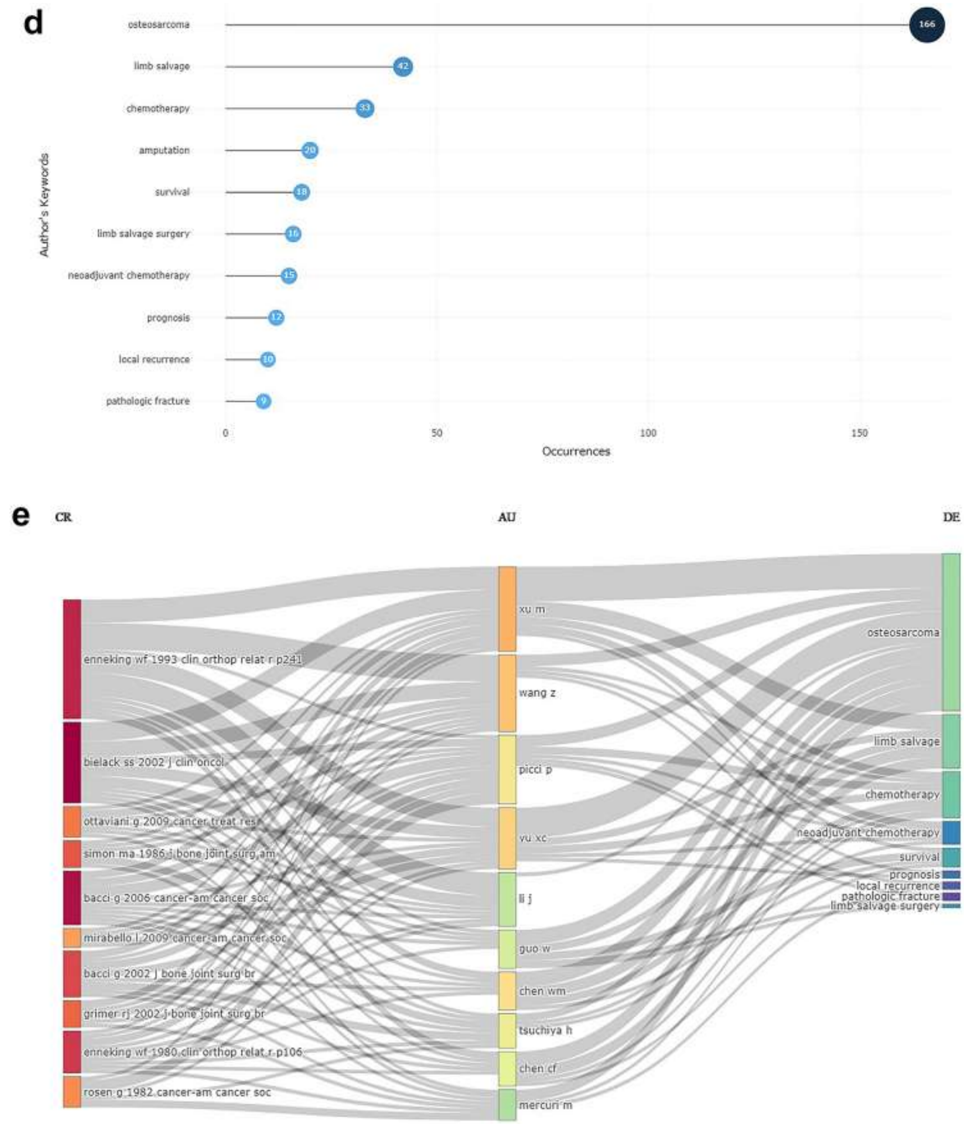


Fig. 5 **a** Globally top ten most cited articles. **b** Top ten most cited documents in our dataset. **c** Word cloud—larger the font, greater the occurrence of the keyword in publications. **d** Top ten most common author keywords. **e** Three field plot linking top authors, keywords, and top cited articles by the authors. CR depicts the cited reference, AU depicts authors, and DE depicts the author keywords. Every line links a cited article or keyword to the author

Fig. 5 (continued)



analyzed using VOS Viewer. The top five authors with the highest total link strength were Dr. Piero Picci {Total Link strength = 1417 times} followed by Dr. Wang Zhen {Total Link strength = 1128 times}, Dr. Wei Ming Chen {Total Link strength = 1121 times}, Dr. Xu Meng {Total Link strength = 1061 times} and Dr. Po-Kuei Wu {Total Link strength = 1034 times}. Dr. Ashish Gulia and Dr. Ajay Puri, both from Tata Memorial Hospital, Mumbai were the only authors to feature in the list from India (Fig. 6c).

Institution Coupling

Out of the 428 institutions, only 30 had a minimum of 3 publications and at least 10 citations. They were analyzed using VOS Viewer and the top 5 institutions having the greatest link strength were Royal orthopedics hospital, Birmingham, UK {Total Link strength = 1157 times} followed by Istituto Ortopedico Rizzoli, Italy (1133), Tongji University (1126), Shanghai Jiao Tong University (1091), both from Shanghai, China and University of Padua, Italy (1013). All India Institute of Medical Sciences, Delhi and Tata Memorial Hospital, Mumbai, are the only two Indian institutes that appear in this list (Fig. 6d).

Country Coupling

Among the publications included in our study, out of the 47 countries, only 27 had a minimum of 2 publications and 10 citations, which were analyzed using VOS viewer. The top 5 countries with the greatest link strength are the People's Republic of China (total link strength = 14,030) followed by the USA (11,690), Italy (5962), Japan (5449), and England (5358). It can be observed that as the number of publications decreased, the total link strength also decreased. India

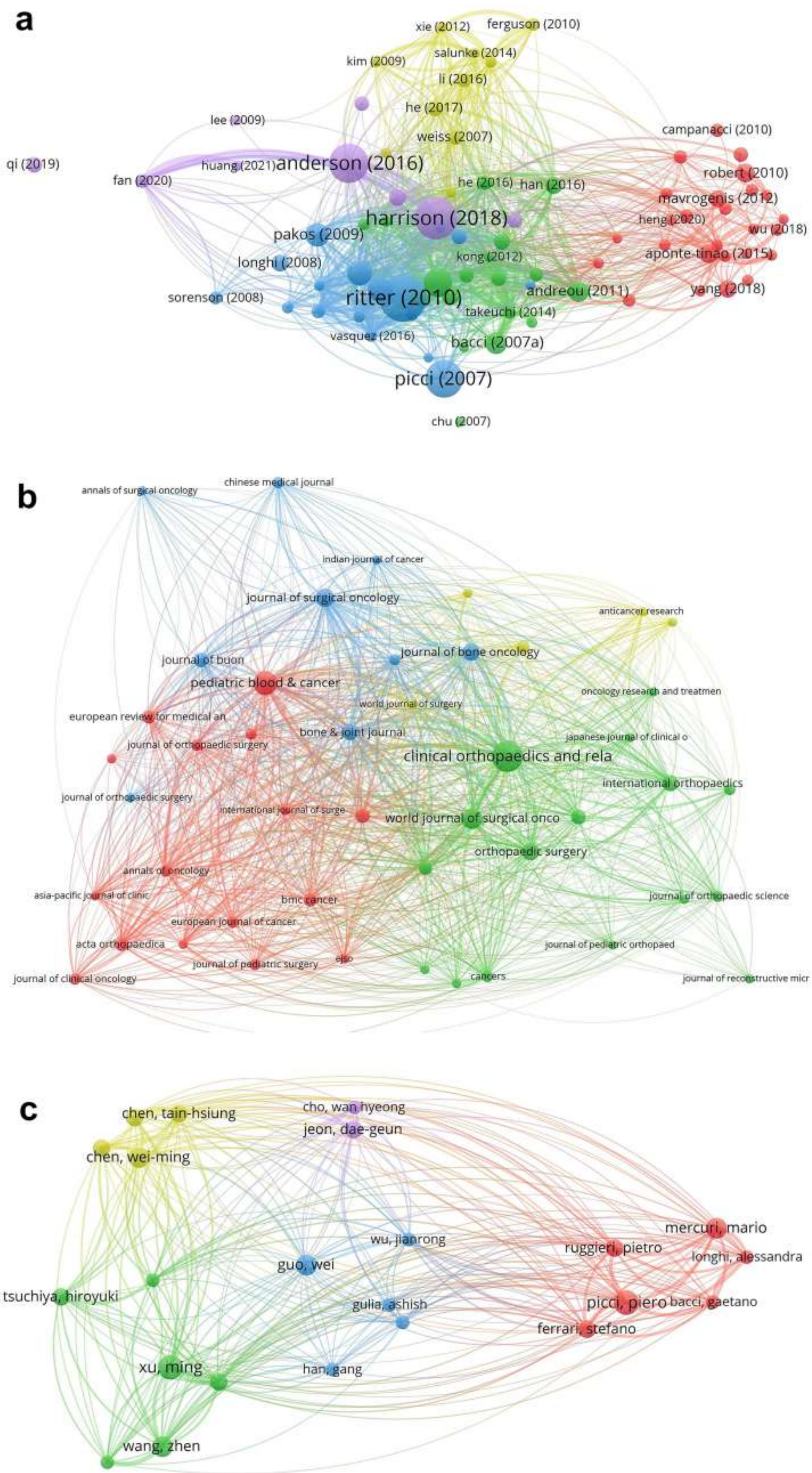
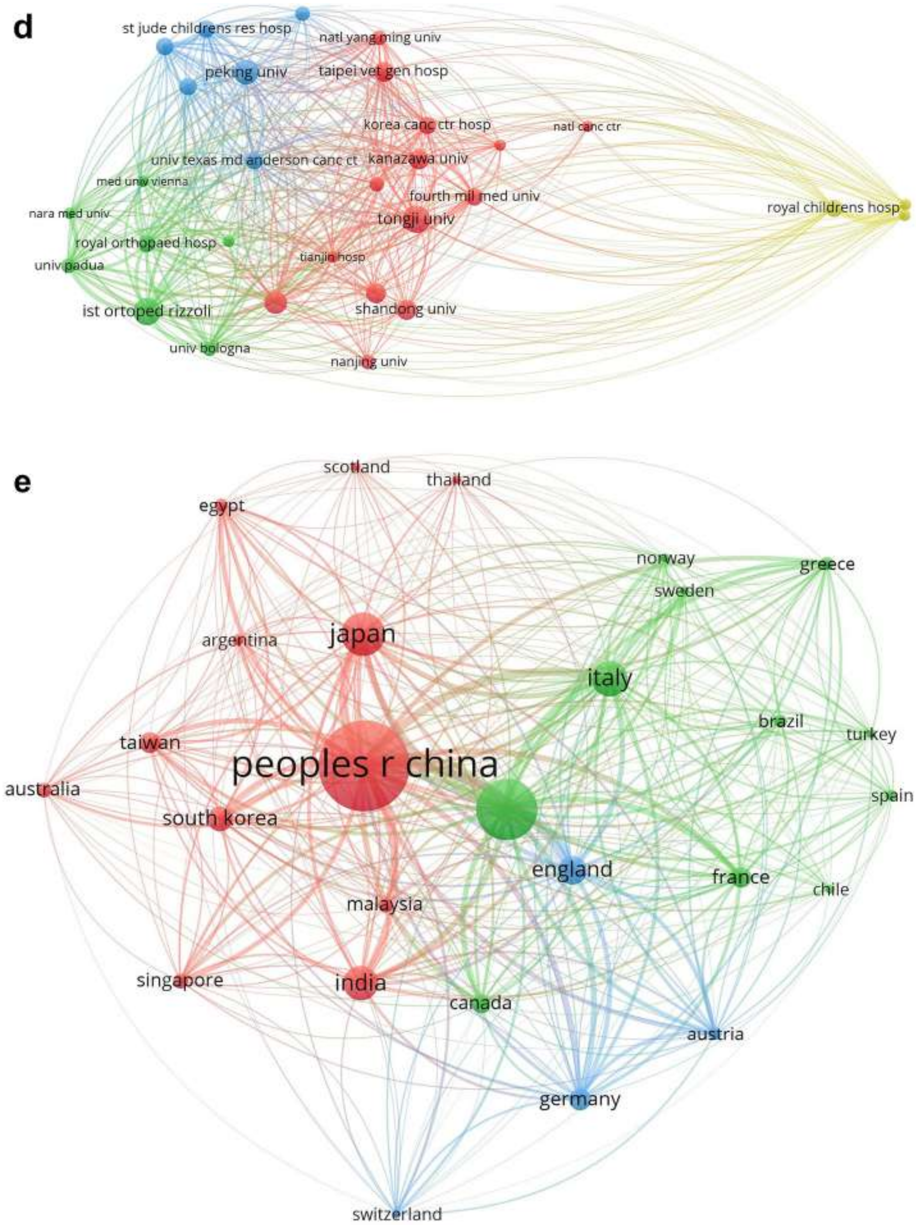


Fig. 6 Bibliographic coupling analysis of global research on limb salvage surgery in osteosarcoma: **a** network map of 80 articles having ≥ 20 citations out of 276. **b** Network map of 46 journals having ≥ 2 publications and ≥ 10 citations out of 122. **c** Network map of 23 authors having ≥ 4 publications and ≥ 10 citations out of 1468. **d** Network map of 30 institutions having ≥ 3 publications and ≥ 10 citations out of 428. **e** Network map of 27 countries having ≥ 2 publications and ≥ 10 citations out of 47. The line between two points in the figure represents those two authors/institutions/countries had established collaboration. The thicker the line, the closer the collaboration between the two authors/institutions/countries

Fig. 6 (continued)



stood at number seven on this list with a link strength of 3438 (Fig. 6e).

Co-citation Analysis

Co-citation analysis is a technique for science mapping that assumes publications cited together frequently are similar thematically so that in a co-citation network, two publications are connected when they co-occur in the reference list of another publication [5]. Co-citation for the cited references, authors, and journals was performed using VOS viewer.

Reference Analysis

Of the 5340 cited references in our study publications, only 114 had more than 10 citations. The article with the highest total link strength was "Prognostic Factors in High-Grade Osteosarcoma of the Extremities or Trunk: An Analysis of 1702 Patients Treated on Neoadjuvant Cooperative Osteosarcoma Study Group Protocols" by Bielack SS et al. published in 2002 {Total link strength = 764} [13]. This was followed by the articles by Bacci G et al. in 2006 {Total link strength = 483} [18], Enneking WS et al. in 1980 {total link strength = 427} [19], and Bacci G et al. in 2002 {Total link strength = 384} [20]. As expected, these articles are the

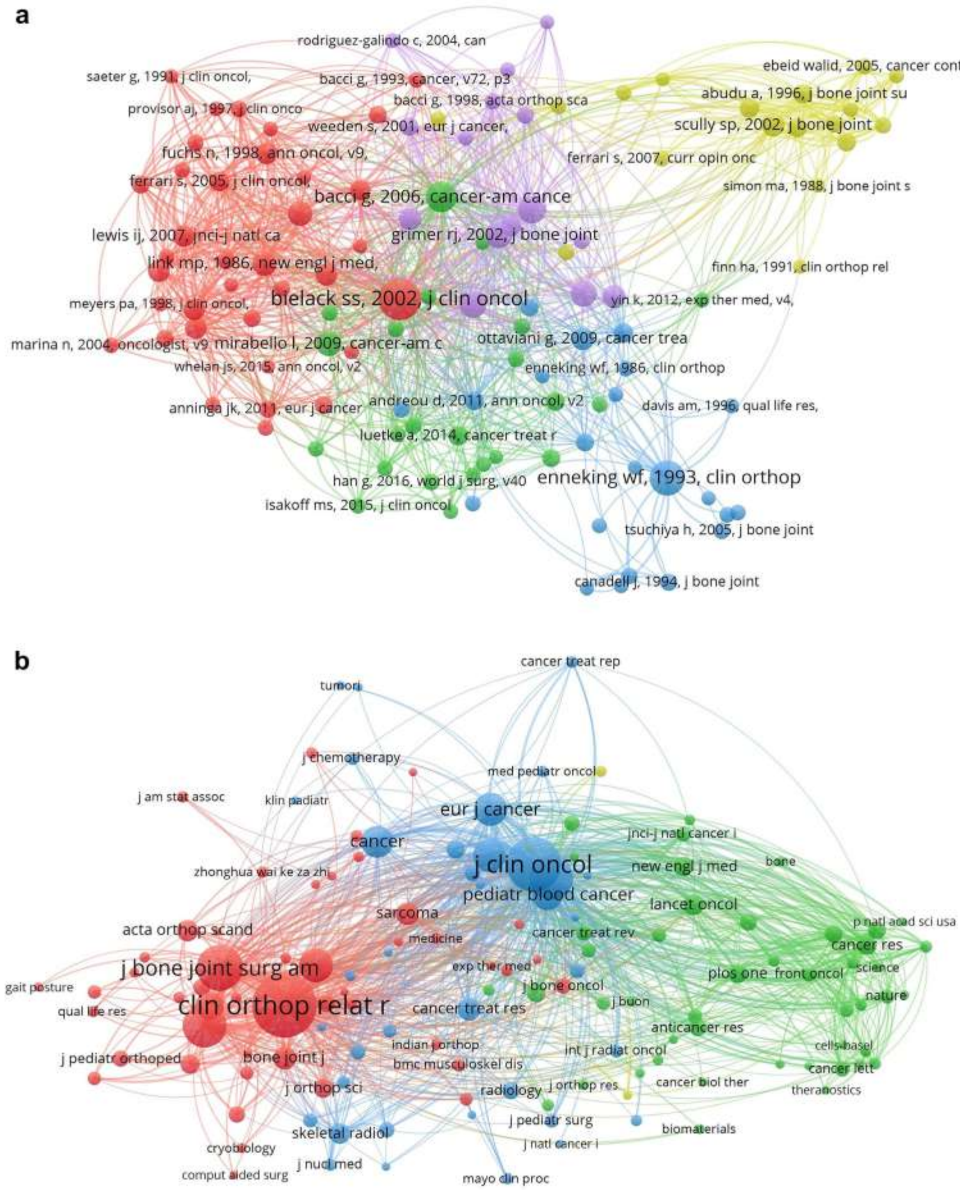


Fig. 7 Co-citation analysis of global research on limb salvage surgery in osteosarcoma: **a** Co-citation analysis of 114 references having ≥ 10 citations out of 5340 references. **b** Co-citation analysis of 134 journals having ≥ 10 citations out of 1440 journals. **c** Co-citation analysis of 142 authors having ≥ 10 citations out of 3994 authors. The line between two points in the figure represents those two authors/institutions/countries had established collaboration. The thicker the line is, the closer the collaboration between the two authors/institutions/countries

foundations for the current management of osteosarcoma and thus are cited by various authors commonly (Fig. 7a).

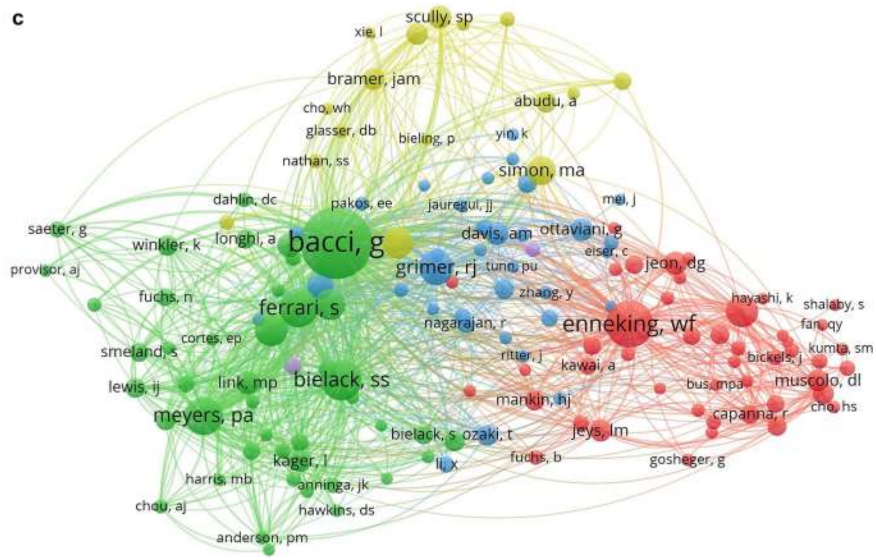
Journal Analysis

Out of the 1440 journals cited by the authors in our study publications, only 134 journals had more than 10 citations. The top five journals based on total link strength were Clinical Orthopedics and Related Research (24,795), Journal of Clinical Oncology (24,681), Cancer (16,550), Journal of bone and joint surgery {American Volume} (11,817} and Journal of bone and joint surgery {British Volume} (11,072). Interestingly, these are the journals in which the previously mentioned articles were published (Fig. 7b).

Author Analysis

Out of the 3994 authors of the publications cited by the authors in our study publications, only 142 authors had more than 10 citations. The top five authors based on total link strengths were Dr. G. Bacci (5950 times), followed by Dr. PA Meyers (2170), Dr. Bielack SS (2158), Dr. William Enneking (2098), and Dr. S Ferrari (1996). As expected, Dr. G. Bacci, Dr. William Enneking, Dr. Stephan Bielack, and Dr. Steffano Ferrari are the pioneers of the current management in osteosarcoma and hence are the authors of the most cited articles. Both DR PA Meyers and Dr. S Ferrari have contributed to compiling the updates for the overall management of osteosarcoma and chemotherapy, respectively (Fig. 7c).

Fig. 7 (continued)



Co-authorship Analysis

Co-authorship analysis measures the relations between the various scholars in the field of interest. It explains how the scholars (including affiliations and countries) interact and collaborate on a particular topic.

Author Analysis

Out of the studies included in our publications, only 202 out of 1468 authors had a minimum of 2 publications and a minimum of 5 citations. The top five authors with the highest total link strength are Dr. Piero Picci (43) followed by Dr. Steffano Ferrari (37), Dr. Gaetano Bacci (31), Dr. Mario Mercuri (25), and Dr. Alessandra Longhi (23) (Fig. 8a).

Institution Analysis

Out of the studies included in our publications, only 80 institutes (affiliations of authors) out of 428 institutions had more than 02 publications and 10 citations. The highest total link strength was 12, and seven institutes achieving this were Astrid Lindgren Children's Hospital, Haukeland Hospital, Karolinska Hospital, Oslo University Hospital, Sahlgren's Hospital, University Lund Hospital, and University Oslo (Fig. 8b).

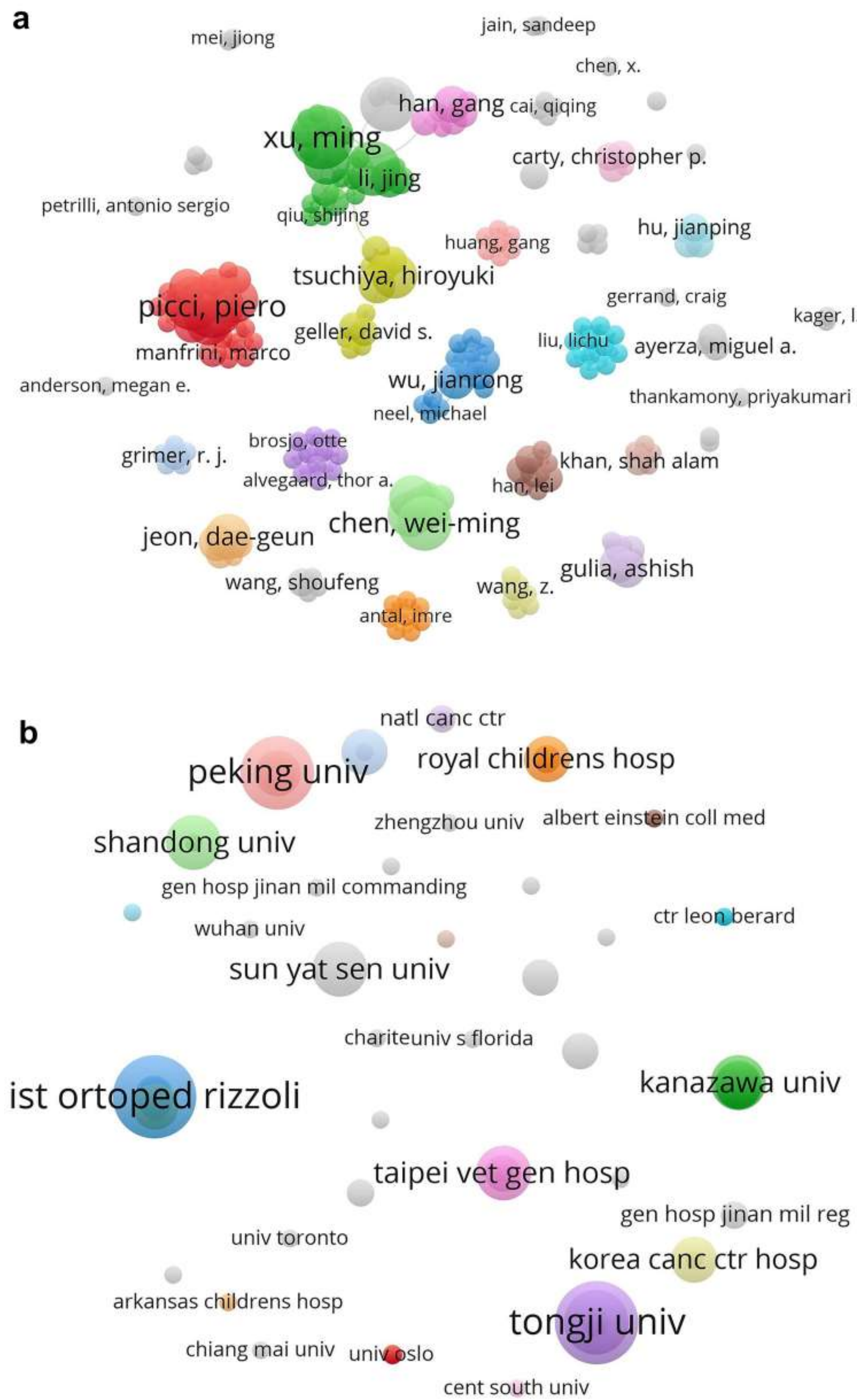
Country Analysis

Out of the studies included in our publications, only 27 out of 47 countries had more than 02 publications and 10 citations. The top five countries based on total link strength were the USA (37), followed by the People's Republic of China (19), France (18), Germany (16), and England (15). As depicted in Fig. 8c, the USA had several multi-country collaborations on the topic as compared to other European or Asian countries.

Co-occurrence Analysis

Co-occurrence analysis is performed to identify the frequency of terms or keywords occurring together within the publication, providing research directions in a particular field [5]. On performing the analysis using "All Keywords," out of the 990 keywords, only 105 had more than 5 occurrences across the publications included in the study. The top five keywords based on total link strength were osteosarcoma (1141) followed by neoadjuvant chemotherapy (634), limb salvage (545), chemotherapy (537), and survival (532). As demonstrated in Fig. 8d, four clusters could be approximately identified, which are encircled and color-coded. The red cluster demonstrates the keywords related to surgical reconstructions, accuracy, and various surgical procedures such as limb salvage and amputations. The blue cluster identifies with survival, prognosis, and follow-up of the treated patients. The green color is related to the current management protocol of neoadjuvant or preoperative chemotherapy, whereas the yellow cluster is mainly related to the general management of osteosarcoma. These clusters identify the most pertaining research terms and directions related to osteosarcoma. When we shifted to focus on the "Author Keywords" or the keywords assigned by the authors to identify their publication, 507 keywords appeared, out of which, 24 keywords occurred 5 or more times in the publications included in this study. As shown in Fig. 8e, the clusters in author keywords were markedly different. These clusters added several newer keywords such

Fig. 8 Co-authorship analysis and co-occurrence analysis of keywords of global research on limb salvage surgery in osteosarcoma: **a**: co-authorship analysis of 202 authors having ≥ 2 publications and ≥ 5 citations out of 1468. **b** Co-authorship analysis of 80 institutions having ≥ 2 publications and ≥ 10 citations out of 428. **c** Co-authorship analysis of 27 countries having ≥ 2 publications and ≥ 10 citations out of 47. The line between two points in the figure represents those two authors/institutions/countries had established collaboration. The thicker the line is, the closer the collaboration between the two authors/institutions/countries. **d** Co-occurrence analysis of all keywords (105 having ≥ 5 occurrences out of 990) depicting 4 clusters of red (reconstruction), blue (survival), green (chemotherapy) and yellow (general management). **e** Co-occurrence analysis of author keywords (24 having ≥ 5 occurrences out of 507). **f** Trends of occurrence of keywords in a time-based manner



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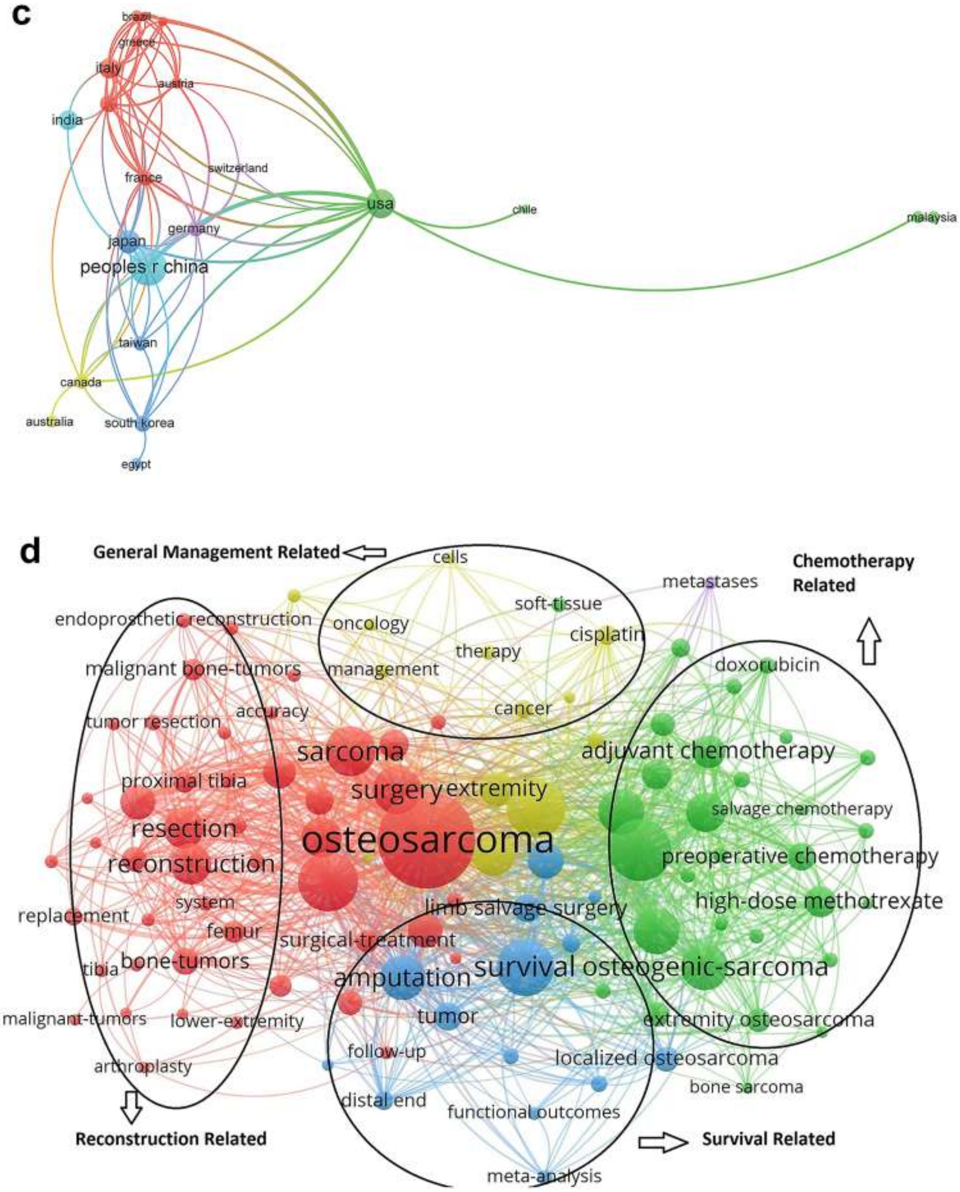


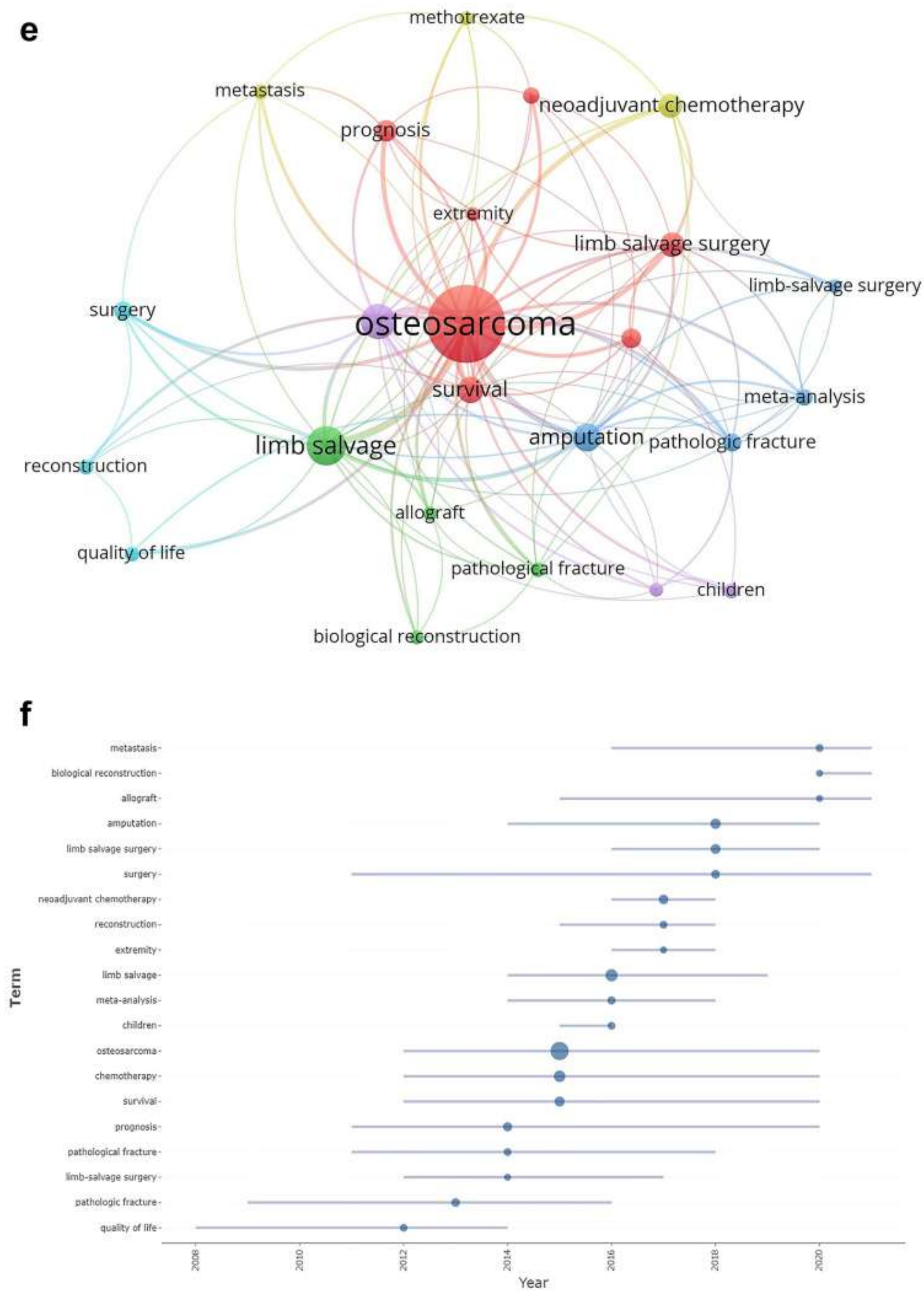
as Biological reconstruction, allograft, metastases, Cell, and Meta-analysis.

Discussion

Global Trends over Time

Being the most common cause of bone cancer, the optimal management of osteosarcoma has been a topic of research for over a century with the initial publications dating back to the late nineteenth century [1]. With landmark publications establishing the safety and efficacy of limb salvage surgery and perioperative chemotherapy during the 1980s, there was a surge of research interest in the topic since the early 2000s. This research trend is in tune with the increasing acceptance of perioperative chemotherapy and the widespread use of mega prostheses to achieve limb salvage in osteosarcoma patients. With 23 publications in 2020, the research topic remained an area of interest for physicians till the COVID-19 pandemic appeared. There was a sudden decline in the number of publications during and after 2020, which can be explained by the fact that many surgeries and perioperative chemotherapies were interrupted during the pandemic. As we get past the pandemic, the research topic will again generate the interest it used to garner earlier.

Fig. 8 (continued)



Global Trends in Quality of Publications

In terms of the sheer number of publications, China has dominated this field since 2014 and currently has the highest number of publications. However, on assessing the quality metrics such as the total number of citations and average citations, the USA and European countries fared much better than China or Asian countries. Unfortunately, the only developing country to feature in the list was India. This suggests that limb salvage is yet to be accepted as a global standard by developing or underdeveloped countries. There may be several reasons for this, such as the late stage of presentations, low publication or research motivation, or costs associated with prostheses and chemotherapy. In analyzing journals, the journal "Clinical Orthopaedics and Related Research" has been at the forefront of research on this topic and has been a pioneer in terms of the number of publications, citations, H index, G index, and M index. This shows the persistent commitment of the journal to the research topic considering the fact that it is a non-oncology-specific journal. Most of the other top five journals were Oncology specific journals. The only journal featured in the top ten relevant sources on the topic from Asia was the Indian Journal of Orthopedics. Using Co-Citation analysis, we realized that the most commonly co-cited articles were written by the most co-cited authors and were also published in the "Clinical Orthopaedics and Related Research" followed by the "Journal of Clinical Oncology" and "Cancer" journals. This signifies the landmark nature of these articles, which authors often cite all over the globe for this research topic. Among the Institutions, we had strikingly different results when we compared general metrics, bibliographic coupling, and co-authorship analysis. Although the highest overall publications were from St. Jude Children's Research Hospital, USA, this hospital did not feature in the Bibliographic coupling or co-authorship analysis. On Bibliographic coupling, the institutes with the highest link were Royal Orthopedic Hospital, UK, followed by Istituto Ortopedico Rizzoli, Italy, and Tongji University, China. The authors with the most publications also belonged to the above universities. Interestingly, on Co-authorship analysis, the top 5 authors with the highest total link strength were from Italian institutions. This implies a strong collaboration between the European countries on the research topic.

Future Directions of Research

The co-occurrence network mapping in figure identified four clusters of surgical techniques of reconstruction, Survival, neoadjuvant chemotherapy, and overall management. On analyzing the trends of keywords in a time-based manner (Fig. 8f), we can observe that the keywords limb salvage, quality of life, and pathological fracture appeared more often before 2012. However, the current, more commonly used keywords are osteosarcoma, neoadjuvant chemotherapy, and surgery. Newer keywords such as allograft, neoadjuvant chemotherapy, and metastases started to appear after 2012, whereas "biological reconstruction" started to appear after 2018. This suggests a growing interest in the latest upcoming techniques of limb salvage surgery using allograft and biological reconstructions and its effect on prognosis and survival.

In recent times, the focus has changed from limb salvage alone in osteosarcoma towards newer techniques of reconstructions such as biological reconstructions and allografts to provide better functional long-term outcomes to the surviving population. Recently, "Meta-analysis" has also appeared as a dominant keyword, suggesting a growing realization of providing level I evidence for limb salvage in osteosarcoma. Another recent keyword is "Metastases," suggesting the exploration of limb salvage in advanced-stage diseases. The biological reconstruction technique implies that the diseased bone is replaced by an expendable bone, which completely replaces the role of the removed portion and can be classified as either viable or nonviable [21]. The use of biological reconstructions has the advantage of avoiding some of the shortcomings of artificial mega prostheses such as loosening, wear, breakage, and inability to use in small children and thus has garnered much interest lately. Similar to biological reconstruction, Allografts rely on bone banks and help in a like-for-like reconstruction for limb salvage and have been a topic of much discussion among oncologists and orthopaedicians [22]. With newer targeted agents and genome-based therapy being discovered for bone sarcomas, the field of oncology has been witnessing an ever-changing scenario of newer armamentariums against this deadly disease, and this is one of the recent research interests for the authors [23].

Limitations

Although multiple databases exist for conducting such an analysis, we chose the Web of Science for its global recognition and representation for the global publication scenario. This also meant that we might need to include articles being published in other databases such as Pubmed or local country-based databases. Since limb salvage surgery requires a highly well-trained multidisciplinary team and costly custom prostheses, these procedures are more commonly performed at universities or multispecialty hospitals of developed nations than in developing nations, which may explain the dearth of publications from developing/underdeveloped nations. To overcome this lack of data, we suggest increasing collaborations among the institutes in each country and with the other developing countries. The inherent bias in bibliographic coupling and co-citation analysis is due to which these articles favor older publications as they get more time to garner interest and citations compared to the recent articles. This may impact our understanding of the significance of more recent articles that may be highly relevant. Another relevant limitation may be the non-inclusion of articles in languages other than English.

Conclusion

Through this bibliometric and visualized analysis, we have tried to identify research trends over 15 years and future trends for limb salvage in patients with osteosarcoma. Although China dominated the field with almost double the number of publications than the USA, quality-wise, the USA and European countries still had the highest citations and link strengths of their publications. There need to be more publications on the research topic from developing or underdeveloped nations. The journal “Clinical Orthopedics and Related Research” remained the pioneer for the research field in quantity and quality throughout this period. With the appearance of keywords such as biological reconstructions, allografts, and chemotherapy in recent articles, these are likely going to be the focus in the future as we try to achieve the best quality of life for patients of osteosarcoma.

Declarations

Conflict of Interest The authors declare no conflict of interest.

Ethical Approval This article does not contain any studies with human or animal subjects performed by the any of the authors.

Informed Consent For this type of study, informed consent is not required.

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REVIEW ARTICLE

3D Bioprinting: A Systematic Review for Future Research Direction

Kavita Kumari Thakur[1] · Ramesh Lekurwale[1] · Sangita Bansode[1] · Rajesh Pansare[1]

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Abstract

Purpose 3D bioprinting is capable of rapidly producing small-scale human-based tissue models, or organoids, for pathology modeling, diagnostics, and drug development. With the use of 3D bioprinting technology, 3D functional complex tissue can be created by combining biocompatible materials, cells, and growth factor. In today's world, 3D bioprinting may be the best solution for meeting the demand for organ transplantation. It is essential to examine the existing literature with the objective to identify the future trend in terms of applicationof 3D bioprinting, different bioprinting techniques, and selected tissues by the researchers, it is very important to examine the existing literature. To find trends in 3D bioprinting research, this work conducted an systematic literature review of 3D bioprinting.

Methodology This literature provides a thorough study and analysis of research articles on bioprinting from 2000 to 2022 that were extracted from the Scopus database. The articles selected for analysis were classified according to the year of publication, articles and publishers, nation, authors who are working in bioprinting area, universities, biomaterial used, and targeted applications.

Findings The top nations, universities, journals, publishers, and writers in this field were picked out after analyzing research publications on bioprinting. During this study, the research themes and research trends were also identified. Furthermore, it has been observed that there is a need for additional research in this domain for the development of bioink and their properties that can guide practitioners and researchers while selecting appropriate combinations of biomaterials to obtain bioink suitable for mimicking human tissue.

Significance of the Research This research includes research findings, recommendations, and observations for bioprinting researchers and practitioners. This article lists significant research gaps, future research directions, and potential application areas for bioprinting.

Novelty The review conducted here is mainly focused on the process of collecting, organizing, capturing, evaluating, and analyzing data to give a deeper understanding of bioprinting and to identify potential future research trends.

Keywords 3D bioprinting · Biomaterials · Bioink · Meta-analysis · Systematic literature review

Introduction

To build 3D structures for bio-applications, layer-by-layer precise positioning of biological materials, biochemicals, and living cells is used in 3D bioprinting, along with spatial control of the positioning of functional components [1]. The technology has emerged as a key driver by precise deposition and assembly of biomaterials with patient's/donor cells. It is described as a collection of methods that use computer-aided printing technology to deposit living cells, biomaterials, extracellular matrix (ECM) elements, biochemical factors, proteins, or medications on a receptive solid or surface [2]. There are a few things that all three-dimensional printing methods have in common: (a) creating blueprints or

✉ Kavita Kumari Thakur
kavitakumari.t@somaiya.edu

Ramesh Lekurwale
rameshlekurwale@somaiya.edu

Sangita Bansode
sangeetabansode@somaiya.edu

Rajesh Pansare
rajeshpansare@somaiya.edu

[1] Department of Mechanical Engineering, K.J.Somaiya College of Engineering, Somaiya Vidyavihar University, Mumbai, Maharashtra 4000 77, India

computer-aided designs through pre-processing using surface laser scan, computed tomography, magnetic resonance, or other imaging modalities; (b) processing to create a real-world 3D duplicate of a created model; and (c) post-processing to accelerate organ development and transplantation [3]. Inkjet, micro extrusion, and laser-assisted bioprinting are the three basic types of 3D bioprinting technology [4]. Bioink or cells are delivered thermally or acoustically in inkjet bioprinting. In extrusion bioprinting process by applying a precise amount of bioink through a needle with the help of pneumatic pressure or mechanical pistons, bioprinting constructs are created, producing a three-dimensional structure. A high-energy laser is used to create a high-pressure system that ejects the biomaterial onto the collecting plate in laser-assisted bioprinters [5]. To create delicate structures, 3D bioprinting relies on the micrometer-scale deposition of biomaterials that either enclose cells or are afterward loaded with cells. Extruders that print bioink are often managed by a three-axis mechanical platform. The coordinates set by the designer and saved in a file format like G-code, which the printer can easily follow, regulate the algorithm and form that are necessary for this platform's movement.

Due to benefits including precise deposition, cost-effectiveness, simplicity, and controllable cell dispersion, 3D bioprinting has grown rapidly in popularity in recent years. As a result, there is a greater need for novel bioinks with the attributes necessary for appropriate printing, such as printability, printing fidelity, and mechanical qualities. This has resulted in a need for extensive research and development. The contributions of the researchers working in this field have created awareness about the 3D bioprinting and development of new bioink which can be suitable for human transplantation. The new bioink should be biocompatible when implants are to be used in a patient's body for a longer duration of time [6]. An investigation of the current bioprinting literatures is needed for this aim, as it has been done by many researchers in their field [7]. A literature review is also necessary to examine current biomaterials, identify new biomaterials, printing methods, and medicinal applications for bioprinting, all of which are crucial for successful bioprinting development. Important research topics pursued by this domain's researchers must also be visible at a glance. This type of research can suggest future research directions in this sector, which will be useful to a wide range of academics and practitioners.

As a result, to address the aforementioned issues, it is required to review the bioprinting literature. The first question for research is.

Que 1: What is the state of the bioprinting literature right now, where are the research gaps, and what are the expected trends?

It is simple to understand the extent to which the various bioprinting-related disciplines have been studied by earlier researchers, as well as the gaps and potential future developments. Because researchers had studied bioprinting using a variety of biomaterials and bioprinting methodologies, it was required to review the articles to acquire relevant information. As a result, the second research question was:

Que 2: What biomaterials and bioprinting processes have been studied or applied in previous bioprinting research?

This leads to the review of development of biomaterials and bioprinting processes for future usage.

Finding innovative biomaterials combinations for bioink development is a critical aspect in tissue growth and development. Although researchers have attempted to improve the bioprinting performance, more advancement in 3D printing technology are needed to boost the resolution without sacrificing scaffold design, strength, or flexibility. While emerging difficulties originating from an innovative approach to bioprinting were discussed, less emphasis was given on producing a new bioink for performance enhancement. The author's attempts to raise awareness of bioprinting research by identifying key participants, interventions, and outcomes during the last two decades of research. The objective of present research is to identify the top universities, regions, journals, publishers, and authors of bioprinting research publications. The third important question is therefore,

Que 3: What are the trends in publications year over year, country over country, and publisher and university involvement in bioprinting research?

Six sections comprise this paper, the current one being one of them. Section 2 discusses the literature review on bioprinting, while Sect. 3 discusses the classification of the analysis and the study technique. Section 4 describes how articles were analyzed using several criteria that were included in the classification. Section 5 consists of a summary and discussion. The study's conclusion is detailed in Sect. 6, along with the study's key results, gaps, ramifications, and future trends.

Literature Review

The current section is divided into subsections and discusses existing literature review research publications. The background of bioprinting was studied and summarized based on existing research articles.

General Trends and Issues in the Bioprinting

The 3D bioprinting utilizes 3D printing techniques using biomaterials to manufacture biomedical parts. Table 1

Table 1 Comparison of extrusion, inkjet, stereolithography, and laser-assisted bioprinting methods

Method of bioprinting	Advantage	Disadvantage	Parameters	References
Extrusion	Printing diverse biomaterials is simple, capable of printing high cell densities	Works very well with sticky liquids only	Speed is slow **Cell viability is** 89.46 ± 2.51% Cell density is High Resolution is 100 µm Viscosity is 30–6 × 10^7 mPa s	[8, 9]
Inkjet	Simple biomaterial printing capability, low cost, high resolution and rapid production speed	Low cell densities, unable to give continuous flow, and not able to give vertical structural functionality	Speed is fast **Cell viability is** 80–95% Cell density is Low Resolution is 50 µm Viscosity is < 10 mPa s	[10], [9]
Stereolithograpy	This method has the advantages of being nozzle-free, excellent accuracy, complex structure	The inability to print multi-cells, the toxicity of UV light to cells, and cell damage during photocuring	Speed is fast **Cell viability is** > 90% Cell density is Medium Resolution is 100 µm No limitation on Viscosity	[9, 11]
Laser-assisted	Resolution is very high for deposition of biomaterial in the solid or liquid phase	High price and thermal damage brought on by nanosecond/femtosecond lasers	Speed is medium **Cell viability is** < 85% Cell density is Medium Resolution is 10 µm Viscosity is 1–300 mPa s	[4, 9]

compares extrusion, inkjet, stereo lithography, and laser-assisted bioprinting methods, with extrusion-based bioprinting being the mostly used.

The bioink's rheological properties and surface tension, process-induced mechanical forces, printing flow rate control, and crosslinking mechanisms are all important qualities for bioprinting [12]. The important design elements in bioprinting include shape and resolution, cellular-material remodeling dynamism, and material heterogeneity [13]. 3D bioprinted components have been used for applications such as drug delivery and discovery, research models, and toxicology.

Reviews of the Available Literature on Bioprinting

Before starting the literature review, it is necessary to research prior literature review papers from the relevant subject. A thorough awareness of current advances and research fields can be acquired by carefully examining the available literature review publications. Table 2 presents the findings of a comprehensive examination of recent papers in the bioprinting domain.

Researchers Lapomarda et al. [14] identified that pectin can be used for enhancing the rheological properties of gelatin. Pectin improves viscosity as well as yield stress of solution made from gelatin. According to Boyd-Moss et al. [15] protein- and peptide-based biomaterials can easily imitate the native ECM by forming highly printable hydrogels. Further, Müller et al. [16] investigated that the combination of alginate sulfate and nano-cellulose had good printability; whereas, Fan et al. [17] developed a hybrid matrigel-agarose hydrogel system, which had provided essential microenvironment for cell growth. Miao et al. [18] discussed about 4D printing of novel biometric gradient tissues. Stevens et al. [19] discussed about purification and modification methods of gellan gum; however, Ersumo et al. [20] highlighted the mechanical and swelling properties of gelatin-based hydrogel and also discussed the ways of enhancing the mechanical properties. Additionally, Kim et al. [21] discussed about the use of synthetic polymer for cell-printed constructs and Mouser et al. [22] investigated the suitability of GelMA supplemented with gellan gum, and found that this combination can be suitable to use as a bioink. Leite et al. [23] investigated the bio-plotting characteristics of bioactive alginate and by EDS (energy-dispersive X-ray spectroscopy) analysis, it was observed that growth of bone-like apatite layer happened. However, Gu et al. [24] discussed printing neural tissue from human neural stem cells that have in situ grown into active neurons and supporting neuroglia. Further, Hartwell et al. [25] discussed about the stabilization of collagen solution by the addition of polyvinyl alcohol hydrogel and Madl et al. [26] developed the engineered elastin-like protein, which can be a appealing material for therapeutic cell injection by SPAAC(strain-promoted azide-alkyne cycloaddition) crosslink; whereas, Lee et al. [27] investigated the PLGA (poly D,L-lactic-co-glycolic acid) scaffold

Table 2 Analysis of available literature review articles on bioprinting

Title	Year	Biomaterial studied	Study focus	Study finding	Total citations
Synthesis and application of fish gelatin for hydrogels/ composite hydrogels: A review	2022	Gelatin	Fabrication of fish gelatin	Gelatin's tripeptide pattern promotes cell adhesion	3
Conductive and injectable hyaluronic acid/gelatin/gold Nano rod hydrogels for enhanced surgical translation and bioprinting	2022	Hyaluronic acid, gelatin hydrogel	High aspect ratio citrate-gold nanorods (GNRs) were added to a hyaluronic acid and gelatin hydrogel to generate a conductive hydrogel	There are three main obstacles to be addressed in the development of conductive biomaterials: (3) Many conductive biomaterials are pre-formed scaffolds that cannot be injected. (1) Many conductive components are cytotoxic. (2) Many conductive biomaterials are pre-formed scaffolds that cannot be injected	0
Development of Silk Fibroin Scaffolds by Using Indirect 3D-Bioprinting Technology	2022	Silk fibroin	Using indirect 3D bioprinting technology, natural polymer silk fibroin can be used to create new scaffolds	The flexibility of the scaffolds could be regulated by changing the solvent for the silk fibroin solution used to make them	4
Printable gelatin, alginate and boron nitride nanotubes hydrogel-based ink for 3D bioprinting and tissue engineering applications	2022	Alginate, Gelatin, Boron nitride nanotubes (BNNTs)	A new printable hydrogel-based ink solution was created using gelatin-alginate (GA) and boron nitride nanotubes (BNNTs)	Increasing the concentration of BNNTs in GA resulted in a larger compressive stress load	3
Hybrid bio fabrication of 3D osteo conductive constructs comprising Mg-based nanocomposites and cell-laden bioinks for bone repair	2022	Magnesium hydroxide nanoparticles (Mg), polycaprolactone (PCL)	The creation of a strong and bioactive bone regeneration scaffold for 3D printing using magnesium hydroxide nanoparticles (Mg) and polycaprolactone (PCL) thermoplastic nanocomposite biomaterial ink (Mg-PCL)	In an accelerated-degradation assay, Mg-PCL degrades faster than standard PCL, which has implications for in vivo implant degradation and bone regeneration	4
Challenges and recent trends with the development of hydrogel fibre for biomedical applications	2022	Nano-cellulose-based hydrogel	Current hydrogel development trends and challenges for biological applications	Surface energy, intermolecular interactions, and hydrogel adhesion force interactions are all key issues in the production of hydrogels	2
Chitosan as an underrated polymer in modern tissue engineering	2021	Chitosan	Chitosan and its alterations in a unique application	The molecular structure of chitosan, as well as the presence of active chemical groups, allows for material customization to fit specific needs	2
Clay minerals as bioink ingredients for 3d printing and 3d bioprinting: Application in tissue engineering and regenerative medicine	2021	Clays, hydroxyapatite, graphene, carbon nanotubes, silicate nanoparticles	Use of clays (both natural and synthetic) for tissue engineering and regenerative medicine	Clay is a naturally occurring substance with well-known biocompatibility and bioactivity, making it ideal for this cutting-edge technology	1
The effect of silk–gelatin bioink and TGF-β3 on mesenchymal stromal cells in 3D bioprinted chondrogenic constructs: A proteomic study	2021	Silk fibroin–gelatin (SF–G) bioink	An SF-G-based 3D bioprinted construct can be used for articular cartilage	SF-G bioink enhanced various chondrogenic pathways, including Wnt, HIF-1, and Notch, when combined with hMSCs	1

Table 2 (continued)

Title	Year	Biomaterial studied	Study focus	Study finding	Total citations
Nano clay Reinforced Biomaterials for Mending Musculoskeletal Tissue Disorders	2021	Graphene, carbon nanotubes, MXenes, nanoclays	Application of nanomaterials for in vivo study	Properties of Nanomaterials including graphene, carbon nanotubes, MXenes, and nanoclays can be transferred to biomaterials by a simple inclusion technique	2
Pectin as rheology modifier of a gelatin-based biomaterial ink	2021	Gelatin, pectin, GPTMS(3-glycidyloxy-propyltrimethoxysilane)	Using pectin as a rheology modification of gelatin to improve gelatin bioprinting performance	Pectin improves the viscosity and yield stress of gelatin solutions with a low viscosity	6
Determination of the geometrical and viscoelastic properties of scaffolds made by additive manufacturing using bio plotter	2017	Polylactic acid (PLA) and, polyhydroxy-butyrate (PHB),	On the qualitative, mechanical, and geometrical features of printed items, printing parameters and technological pre-processing of the material have an impact	The material is more stable once it has been dried before it is printed	0
A dual crosslinking strategy to tailor rheological properties of gelatin methacryloyl	2017	Gelatin methacryloyl (GelMA)	An enzymatic crosslinking method powered by $Ca2+$-independent microbial transglutaminase (MTGase) was introduced to catalyze the development of isopeptide linkages between chains of GelMA, which may improve its rheological characteristics, mainly its viscosity	It is feasible to adjust the fluid viscosity and rapidly stabilize the gelatin macromolecules by combining enzymatic crosslinking and light crosslinking	35
Bioprinting and bio fabrication with peptide and protein biomaterials	2017	Protein, peptide-derived biomaterials	Application specific, peptide-based bioprinting approaches	Numerous regenerative applications, including both organ bioprinting and non-organ bioprinting, have made use of these materials' capacity to produce highly printable hydrogels that are similar to the natural ECM	15
Development of scaffolds for vascular tissue engineering: Biomaterial mediated neovascularization	2017	Synthetic polymers with polysaccharides	The biocompatibility and mechanisms underlying stem cells' proliferation, migration, adhesion, differentiation, and organization in vascular networks are highlighted in recent research on the polymers and scaffolds used to improve neovascularization	Conjugation of synthetic polymers with polysaccharides or proteins attempt to improve the biocompatibility of scaffolds	3
Alginate Sulfate–Nanocellulose Bioinks for Cartilage Bioprinting Applications	2017	Mitogenic hydrogel, alginate, sulfate	To convert alginate sulfate to a printable bioink by combining with nanocellulose	The non-printed bioink substance encouraged cell spreading, proliferation, and collagen II synthesis by the encapsulated cells while the alginate sulfate/nano-cellulose ink demonstrated good printing capabilities	261

Table 2 (continued)

Title	Year	Biomaterial studied	Study focus	Study finding	Total citations
Bio-printing cell-laden Matrigel-agarose constructs	2016	Matrigel, agarose	Development of a hybrid Matrigel-agarose hydrogel system	Agarose helps in maintenance of 3D-printed structures, Matrigels provides essential microenvironment for cell growth	83
Four-Dimensional Printing Hierarchy Scaffolds with Highly Biocompatible Smart Polymers for Tissue Engineering Applications	2016	Poly-caprolactone	4D printing of novel biomimetic gradient tissue	Glass transition temperature range is in 8 °C to 35 °C	98
Tissue engineering with gellan gum	2016	Gellan gum	Purification and modification of gellan gum	Gellan gum is an anionic polysaccharide	90
Differences in time-dependent mechanical properties between extruded and molded hydrogels	2016	Gelatin	Mechanical and swelling properties of conventional molded gelatin-based hydrogel	Young's modulus and the ideal extruding pressure increased with the amount of polymer used while printing resolution increased with both printing speed and nozzle gauge	23
Three-dimensional bioprinting of cell-laden constructs with polycaprolactone protective layers for using various thermoplastic polymers	2016	Poly-caprolactone (PCL)	Use of synthetic polymer in in fabrication of cell-printed constructs	PCL layer prevent the thermal damage	50
Yield stress determines bioprintability of hydrogels based on gelatin-methacryloyl and gellan gum for cartilage bioprinting	2016	Gelatin-methacryloyl (gelMA), gellan gum	Investigating whether gelMA/gellan is appropriate for cartilage bioprinting	A promising bioink is gelatin-methacryloyl (gelMA) combined with gellan gum	2
Bio plotting of a bioactive alginate dialdehyde-gelatin composite hydrogel containing bioactive glass nanoparticles	2016	Alginate dialdehyde-gelatin (ADA-GEL), BGNPs	Bio-plotting of bioactive alginate	EDS analysis suggested that the BGNPs loading promoted the growth of bone-like apatite laye	69
Functional 3D Neural Mini-Tissues from Printed Gel-Based Bioink and Human Neural Stem Cells	2016	Alginate, carboxymethyl-chitosan, agarose	Human neural stem cells have been used to print neural tissue	Bicuculline-induced enhanced calcium response in differentiated neurons	256
Polyvinyl alcohol-graft-polyethylene glycol hydrogels improve utility and bio functionality of injectable collagen biomaterials	2016	Collagen	Interactions of polyvinyl alcohol blend variants, as non-polymer surfactants	Stabilization of collagen solution by addition of Polyvinyl alcohol hydrogel	8
Bio-Orthogonally Crosslinked, Engineered Protein Hydrogels with Tunable Mechanics and Biochemistry for Cell Encapsulation	2016	Arginine–glycine–aspartic acid (RGD)	Development of engineered elastin-like proteins (ELPs)	ELP hydrogels with SPAAC crosslinks are appealing materials for therapeutic cell injection and bioprinting	114

Table 2 (continued)

Title	Year	Biomaterial studied	Study focus	Study finding	Total citations
Gelatin-Methacryloyl Hydrogels: Towards Biofabrication-Based Tissue Repair	2016	Gelatin-methacryloyl (gelMA)	Development of GelMA hydrogel by changing combination of gelatin's inherent bioactivity and photo-cross linkable hydrogels' physicochemical tailor ability	GelMA will enhance the development of bio fabricated constructions containing cells	484
Investigation of thermal degradation with extrusion-based dispensing modules for 3D bioprinting technology	2016	Poly-lactic-co-glycolic acid (PLGA)	Polylactic-co-glycolic acid(PLGA) prepared by syringe type and filament type	The Filament dispensing module retained the characteristics of the PLGA scaffold, but the syringe dispensing module caused thermal deterioration	21
Recent progress in stem cell differentiation directed by material and mechanical cues	2016	Polyacrylamide (PAM),polydimethylsiloxane (PDMS)	The use of biophysical signals to drive stem cell differentiation could be beneficial	The main materials are polyacrylamide (PAM) and polydimethylsiloxane (PDMS) hydrogels	68
Silk fibroin as biomaterial for bone tissue engineering	2016	Silk fibroin (SF)	different fabrication and functionalization methods of silk fibroin	Silk fibroin and HA were combined to generate a composite scaffold that closely resembles the natural bone environment	542
Polyelectrolyte gelatin-chitosan hydrogel optimized for 3D bioprinting in skin tissue engineering	2016	Chitosan	chitosan-based biomaterials modified for functional 3D bioprinting	Chitosan-based hydrogels have outstanding room-temperature printability, high shape accuracy in printed 3D constructions, and strong biocompatibility with fibroblast skin cells	206
Methacrylate gelatin and mature adipocytes are promising components for adipose tissue engineering	2016	Methacrylate gelatin (GM)	For the composition of fatty tissue equivalents in vitro, mature adipocytes are a hugely relevant cell source	Methacrylate gelatin that can be photo crosslinked is an effective tissue scaffold	90

preparation method by syringe type and filament type based on extrusion-based dispensing. Researchers observed that filament-based module was more suitable. Melke et al. [28] discussed regarding different fabrication, functionalization method of silk fibroin and observed that silk fibroin combined with HA(hydroxyapatite) can provide scaffold that closely resembles the natural bone. The two tissue research investigations below indicate how the use of scaffolds composed of various biomaterials might improve bone growth naturally. The presence of mesenchymal stem cells, chondroprogenitor cells, and pluripotent cells can be enhanced in an in vitro examination applying thermos-reversible gelatin, which may be useful for treating osteoarthritic chondrocytes in elderly patients [29]. SCID mice with severe combined immunodeficiency (SCID) were used to study bone formation using β-tricalciumphosphate (β-TCP) scaffolds coated with hBMSC and hRIA-MSC [30].

The Research Strategy Implemented in the Study

Every research project should include literature analysis because it enables you to examine current trends and active areas in a certain field. The selection and categorization of the articles will be covered in this part.

Criteria for Selection of Articles

The main objective of this analysis is to use the Scopus database to discuss developments and research areas in the field of bioprinting. All academic papers having the phrase "Bioprinting and Biomaterial" in their titles or keywords that had been published in peer-reviewed journals were indexed for this study. Book chapters, brief notes, conference papers, and editorial remarks were among the items that were initially filtered out. This study includes articles authored between 2004 and 2022. It would be difficult to include bioprinting in a single discipline due to its wide range of applications; as a result, peer-reviewed publications from respected publishers including Taylor & Francis, Elsevier, MDPI AG, Emerald, and SAGE Publications Ltd. have been chosen for research purposes. These publications are recommended since they provide high-quality papers on bioprinting and have numerous applications in several sectors. The exploring method used to choose this analysis produced 1002 articles encompassing a variety of contexts, including biomaterial, bioink, bioprinting methods, etc. These articles were then reviewed utilizing a system of groupings between different points of view. The selection and classification of articles are shown in Fig. 1.

In summary, 1002 research articles on the topic of bioprinting and biomaterials were chosen for the study. It i probable that some crucial publications were missed, though, because the authors worked through a procedure before selecting the papers for the study. In an effort to identify biomaterials, bioprinting techniques, and applications, the papers now are further categorized based on the many parameters as shown. The study's conclusions also analyzed its findings, research gaps, implications, and future research direction. The classification strategy developed themes, and research findings are expected to be useful to both researchers and clinicians.

Classification Scheme for Analysis

For the examination of research publications on bioprinting, a classification technique was suggested. The following nine essential criteria are used to evaluate and categorize papers:

(1) Classification based on year of publication.
(2) Classification based on articles and publishers.
(3) Classification based on nation.
(4) Classification based on affiliation of author.
(5) Authors who are currently working in bioprinting.
(6) Top bioprinting publications in terms of citations.
(7) Natural and synthetic polymer-based biomaterial classification. Classification on the basis of Polymer based biomaterials
(8) Bioprinting method-based classification.
(9) Application area of bioprinting.

The classification described above will provide a roadmap for additional research by highlighting the domain's progressive development, research types, applications, and obstacles.

Evaluation of Articles Based on Bioprinting

The short-listed research article of bioprinting, along with their detailed analysis, is discussed in the current section to provide some insight into the research topic.

Classification Based on Year of Publication

In this study, articles published between 2004 and 2022 were selected, for the year 2022 articles were selected up to January. Figure 2 represents the regression line and trends for the number of articles published per year. Linear trend represents the most appropriate points for the selection and that is why it was selected.

Because of the trend line's positive linear shape, there has been an increase in publications since 2011. Since the number of publications has also significantly increased since 2014 and will continue to do so until 2021. The regression

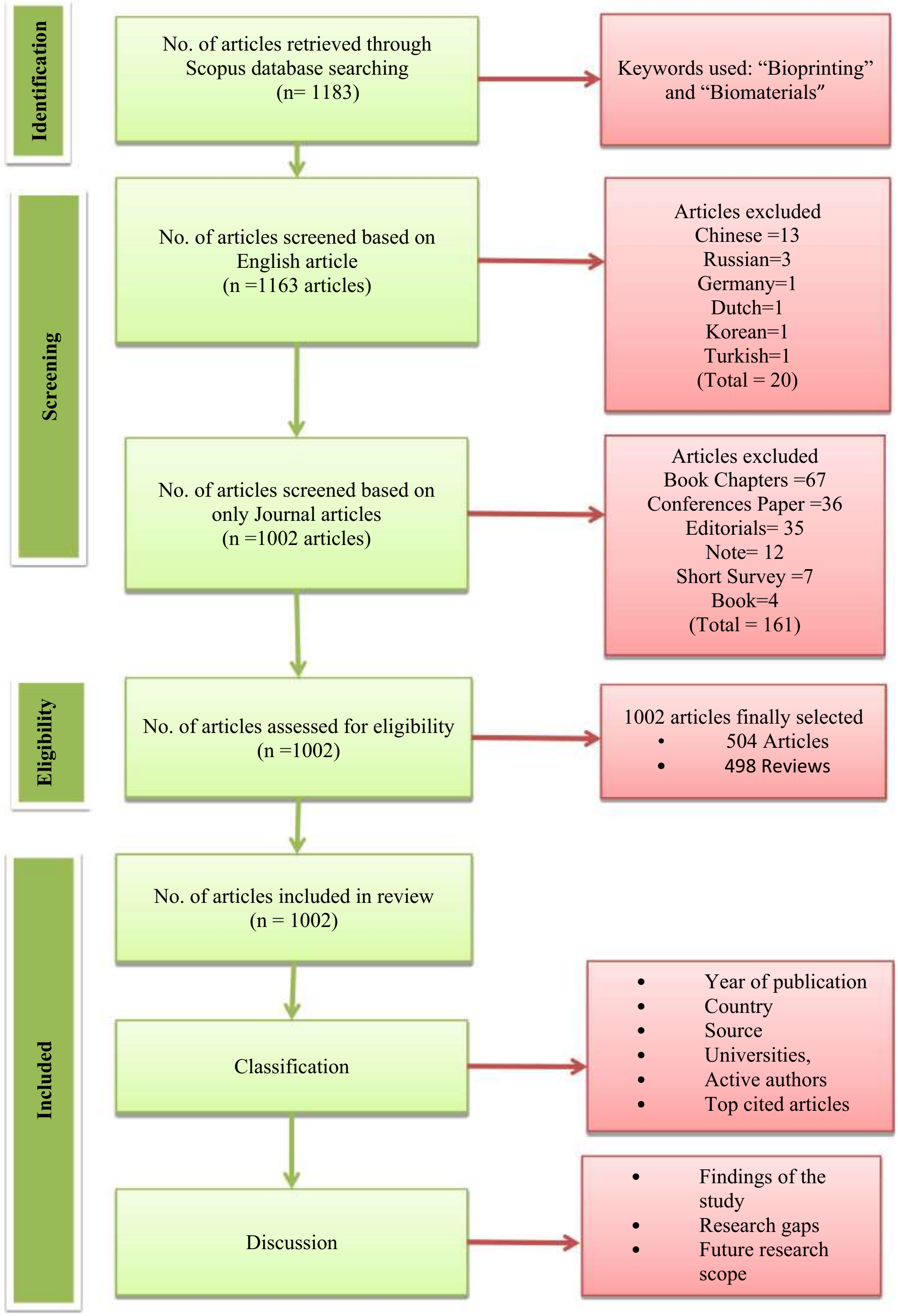

Fig. 1 Flow chart for the research methodology

equation for the obtained curve shows that there has been and will continue to be an increase in the number of research publications. Additionally, the number of articles published over the past ten years has increased by more than 60%, demonstrating the growing significance of bioprinting in view of the growing demands for organ transplants, drug testing, and biological research models purpose. Various traditional methods available like autograft, allograft, and xenograft are having their own advantages and disadvantages and these methods cannot fulfill the demand needs of patients waiting for transplantation. On the other hand, there is scarcity of biological models for research and drug testing. So, for overcoming the above-mentioned challenges, bioprinting is the best way in which cells, proteins, and biomaterials are used as building blocks for 3D-printed biological models, biological systems, and pharmaceutical products [31]. This

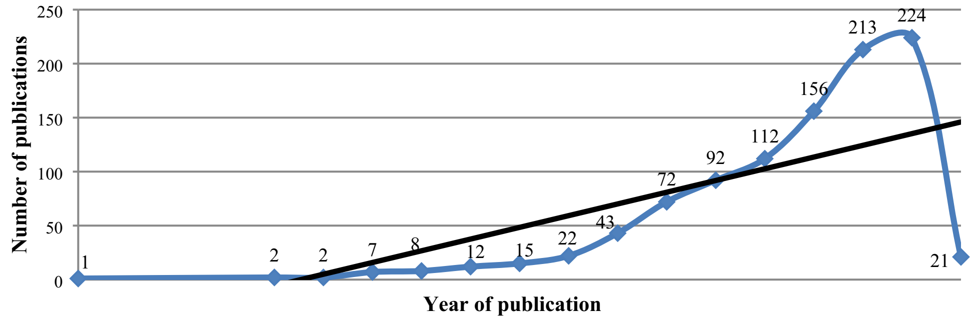

Fig. 2 No. of articles published per year

analysis helps in answering research question number one and three.

Classification Based on Articles and Publishers

The electronic database in which the chosen research publications were published was used to further categorize them. The Institute of Physics Publishing, John Wiley and Sons Inc., Elsevier Ltd., Elsevier B.V., and MDPI (Multidisciplinary Digital Publishing Institute) are the primary electronic databases mentioned in this research (Multidisciplinary Digital Publishing Institute). Table 3 provides a summary of the distribution of articles based on journals and publishers for the top 10 journals. The answers to research questions one and three may be found with the help of this analysis.

Classification Based on Nation

A close examination of the chosen papers demonstrates that bioprinting is a global phenomenon, with publications in 67 nations. Because of the growing demand for organ transplantation, 3D bioprinting is gaining popularity due to its capacity to print a variety of cell types in specific spatial areas, making it suited to regenerative medicine to address the demand for transplantable organs and tissue[32]. Several governments are encouraging scientists to conduct bioprinting research and develop cutting-edge technology. Table 4 summarizes the top ten countries that contribute to the bioprinting domain. This analysis can assist to find answer for research questions one and three.

According to Table 4, the US has contributed a total of 374 articles. Researchers from nations like China, Germany,

Table 3 Journal-based classification

Sr. no	Source title	Publisher	Total articles	Citation*	H-index#	Main theme of research
1	Bio fabrication	Institute of Physics Publishing	63	5264	80	Crosslinking, hydrogel scaffold, bioink development
2	Advanced Healthcare Materials	John Wiley and Sons Inc	43	2013	90	Bioink, silk fibroin, bone tissue engineering
3	Acta Biomaterialia	Elsevier Ltd	42	3383	190	Bone regeneration, cartilage tissue engineering, hyaluronic acid
4	Bioprinting	Elsevier B.V	36	132	16	Extrusion-based bioprinting, gelatin, biocompatibility
5	International Journal Of Molecular Sciences	MDPI Multidisciplinary Digital Publishing Institute	28	449	162	Scaffold, antibacterial polymer, bioink development
6	Biomaterials	Elsevier BV	27	4280	381	Bioink, GelMa, hydrogel
7	Biomedical Materials Bristol	IOP Publishing Ltd	16	367	72	Hydrogel, biomaterial, microfabrication
8	Tissue Engineering Part B Reviews	Mary Ann Liebert Inc	16	673	91	Bioink, skin bioprinting, bone substitutes
9	ACS Biomaterials Science And Engineering	American Chemical Society	15	513	50	Hydrogel, GelMA, bone tissue engineering
10	ACS Applied Materials And Interfaces	American Chemical Society	14	348	50	Mechanical properties, GelMA, biomaterials

*Citations are for specific publications that have been evaluated in that particular journal and can be found at https://www.scimagojr.com

Table 4 Nation-based bioprinting articles

Sr. no	Nation	No. of articles	No. of citation	Topics of research
1	United States	374	22,765	Bioink development, hydrogel
2	China	176	3802	Biomaterial selection, cartilage regeneration
3	Germany	84	2175	Alginate-based bioink, bioink development
4	South Korea	84	2153	Crosslinking mechanism
5	United Kingdom	70	1380	Skin regeneration, medical device development
6	India	67	1653	Biomaterials development, printing process parameters
7	Australia	62	1750	Printability, bioethics
8	Canada	54	1848	Hybrid Scaffold, bone tissues engineering
9	Netherlands	52	3837	Drug delivery, scaffold
10	Italy	42	505	Standardization, scaffold, tissue regeneration

South Korea, the United Kingdom, and India have contributed to the study's foundation and strength.

Classification Based on Affiliation of Author

Researchers who have written about bioprinting are associated with a university. Researchers claim that the increased demand for organ transplants and the scarcity of donors are compelling scientists and medical professionals to adopt the bioprinting idea, which makes complex tissue architectures simple to print. Researchers working with various universities are motivated by the current situation to conduct bioprinting research. Examining the contributions made by various nations in this sector was necessary to comprehend the future trend in this domain. 160 universities from around the world have submitted 1002 articles on bioprinting. Research questions one and three of this study are addressed in Table 5, which provides information about the top 10 universities.

44 scientific articles from Harvard Medical School addressed important issues such as bone deformity and bioink creation. Silk-based bioink is being developed by scientists at Pohang University of Science and Technology.

Authors Who are Currently Working in Bioprinting

Researchers and practitioners had contributed to bioprinting research and tried to develop bioink and select suitable combination of biomaterial and cells as per the requirement of tissue application. The contributions of numerous researchers are listed in this article, and Table 6 lists the top ten authors.

Khademhosseini A. addressed many applications of bioprinting with his maximum contribution of twenty-five articles, including bioengineering, drug delivery, biomaterials, tissue engineering, and regenerative medicine. During his work, he explained about cell responsive behavior of gelatin methacrylate (GelMA). Furthermore, the researcher Malda, J. contributed sixteen articles on

Table 5 University-based classification of bioprinting articles

Sr. no	Affiliation	No. of documents	No. of citation*	Main theme
1	Harvard Medical School	44	5269	Bone defect, GelMa, bioink development
2	Brigham and Women's Hospital	37	4724	Bone regeneration, hydrogels, cell-laden fibers
3	Massachusetts Institute of Technology	31	5338	Regenerative engineering, hydrogels, bone regeneration
4	Wake Forest School of Medicine	26	3096	Bioink, collagen, biocompatibility
5	Harvard-MIT Health Sciences and Technology	26	3835	Vascularization, hydrogels, Tissue Engineering
6	University of California, Los Angeles	24	1179	Multi-material 3D bioprinting, personalized medicine, tissue engineering
7	Chinese Academy of Sciences	21	1125	Skin tissue engineering, scaffold, bone tissue engineering
8	Pohang University of Science and Technology	20	1296	Natural polymer, stem cell engineering, silk-based bioink
9	Harvard University	18	3025	Bioink development, bioprinting, hydrogels
10	Tsinghua University	18	1429	Biomaterials, hydrogels, tissue engineering

*Determines the references for each document from a certain university that has been reviewed

Table 6 Active author-based classification of bioprinting articles

Sr. No	Author name	Total article	Total citations*	Overall h-index #	Theme
1	Khademhosseini, A	25	93,369	153	Bioengineering, drug delivery, biomaterials, tissue engineering, regenerative medicine
2	Malda, J	16	19,007	69	Bio fabrication in translation
3	Cho, D.W	15	19,860	76	3D printing, cell printing, tissue engineering
4	Zhang, Y.S	14	21,113	73	3D bioprinting, biomaterials, regenerative engineering, organ-on-a-chip, bioanalysis
5	Moroni, L	13	11,490	55	Biofabrication 3D cell culture, scaffolds, regenerative medicine, biomaterials
6	Ashammakhi, N	9	9312	49	Tissue engineering, biomaterials, 3D printing, organ-on-a-chip
7	Gelinsky, M	9	11,017	57	Biomaterials, tissue engineering, 3D printing, bioprinting, bio fabrication
8	Burdick, J.A	8	41,355	113	Biomaterials, tissue engineering, bioengineering, hydrogels
9	De Maria, C	8	1656	19	Biofabrication, additive manufacturing, open source medical devices
10	Dokmeci, M.R	8	22,047	77	Bioengineering, biosensors, organs on a chip, biomaterials

*Citations are for specific documents that the author has studied; data were obtained from Google Scholar

bio fabrication in translation. Researchers worked on designing of porous scaffold in which by varying PEGT (poly-ethylene glycol-terephthalate)/PBT (poly-butylene terephthalate) composition, porosity and pore geometry 3D-deposited scaffolds were produced with a range of mechanical properties [33]. This analysis can assist to find answer for research questions one and three.

Top Bioprinting Publications in Terms of Citations

Numerous experts in the field of bioprinting contributed to the investigations and wrote papers that were included in prestigious journals. It was important to find major publications in this topic to learn more about bioprinting. As indicated in Table 7, the authors of this research attempted to identify the top ten most cited articles in the field of bioprinting.

With 1342 citations, the research publications authored by Kang et al. [34] was the most cited of the 1002 articles. The integrated tissue–organ printer (ITOP) described in this paper can build any shape of stable, human-scale tissue constructs. Madl et al. [26] aimed to develop new ideas and improvements in hydrogel design and tailoring. Yue et al. [35] aimed to identify GelMa-based hydrogels application to engineer cardiac, vascular, bone, and cartilage tissues. These articles may assist researchers, particularly beginners, in better understanding of the bioprinting concept. As previously stated, this knowledge solves research question number one and three.

Classification on the Basis of Polymer-Based Biomaterial

Biomaterials serve a variety of uses in prosthetics and medical devices. Polymers are the broadest category of biomaterials [36]. Natural and synthetic polymer biomaterial are mostly used for bioprinting. It is important for future researchers to understand what the various polymer-based biomaterial used in bioprinting are. As shown in Table 8, natural biomaterial, Alginate with 101 articles represents its application in tissue engineering for bone, cartilage, and regenerative medicine. Collagen with 68 articles shows application in skin tissue engineering, vascularized bone model.

Synthetic polymer biomaterial, poly-lactic acid (PLA) with 212 articles represents its application in bone tissue engineering, skin regeneration, and cartilage tissue engineering. Poly-caprolactone (PCL) with 25 articles has various applications for regenerative medicine, skin tissue engineering, and bone tissue engineering. This analysis can assist to find answer for research questions one, two, and three.

Bioprinting Method-Based Classification

The medical sector and the manufacturing of medical materials have been radically impacted as a result of the rapid rise of 3D bioprinting in the medical profession. Complex tissues and organ constructs have been created using this technology. 3D bioprinting is divided into several categories based on how it works. Extrusion-based

Table 7 Top citation-based classification of bioprinting articles

Sr. no	Authors	Title	Year	Source title	Citation	Theme
1	Kang H.-W., Lee S.J., Ko I.K., Kengla C., Yoo J.J., Atala A	A 3D bioprinting system to produce human-scale tissue constructs with structural integrity	2016	Nature biotechnology	1342	Tissue construct
2	Malda J., Visser J., Melchels F.P., Jüngst T., Hennink W.E., Dhert W.J.A., Groll J., Hutmacher D.W	25th anniversary article: Engineering hydrogels for bio fabrication	2013	Advanced materials	1028	Design and tailoring of hydrogels
3	Yue K., Trujillo-de Santiago G., Alvarez M.M., Tamayol A., Annabi N., Khademhosseini A	Synthesis, properties, and biomedical applications of gelatin methacryloyl (GelMA) hydrogels	2015	Biomaterials	962	GelMA-based hydrogels
4	Chia H.N., Wu B.M	Recent advances in 3D printing of biomaterials	2015	Journal of biological engineering	897	Biomaterials review
5	Mandrycky C., Wang Z., Kim K., Kim D.-H	3D bioprinting for engineering complex tissues	2016	Biotechnology Advances	680	Review on complex bioprinting
6	Kim Y., Yuk H., Zhao R., Chester S.A., Zhao X	Printing ferromagnetic domains for untethered fast-transforming soft materials	2018	Nature	654	ferromagnetic domains program for soft material
7	Guillotin B., Souquet A., Catros S., Duocastella M., Pippenger B., Bellance S., Bareille R., Rémy M., Bordenave L., Amédée j J., Guillemot F	Laser assisted bioprinting of engineered tissue with high cell density and microscale organization	2010	Biomaterials	471	Precision for printing miniaturized tissue
8	Jia W., Gungor-Ozkerim P.S., Zhang Y.S., Yue K., Zhu K., Liu W., Pi Q., Byambaa B., Dokmeci M.R., Shin S.R., Khademhosseini A	Direct 3D bioprinting of perfusable vascular constructs using a blend bioink	2016	Biomaterials	457	Bioink formulation
9	Hölzl K., Lin S., Tytgat L., Van Vlierberghe S., Gu L., Ovsianikov A	Bioink properties before, during and after 3D bioprinting	2016	Bio fabrication	453	Review on effect of cells on hydrogel processing
10	Schuurman W., Levett P.A., Pot M.W., van Weeren P.R., Dhert W.J.A., Hutmacher D.W., Melchels F.P.W., Klein T.J., Malda J	Gelatin-methacrylamide hydrogels as potential biomaterials for fabrication of tissue-engineered cartilage constructs	2013	Macromolecular bioscience	441	Study of GelMA hydrogel

bioprinting, the most popular method, uses bioinks that are continually dispensed or extruded as filaments to create three-dimensional objects[1]. Extrusion-based bioprinting has 31 articles which show its importance in bioprinting techniques. It is mainly used for scaffold development of smart bioink and skin tissue engineering. Thermal inkjet printing with 20 articles was mainly used for its fast fabrication speed and resolution. It is mostly applied in the field of bone tissue engineering, cartilage tissue engineering, and skin tissue engineering as shown in Table 9. This analysis can assist to find answer for research questions one, two, and three.

Application Area of Bioprinting

Bioprinting is gaining more attention because of its unique feature of recreating the complicated human tissue with accuracy. As there is a lack of donor available for fulfilling the requirement of transplantation, bioprinting is a playing a major role for fulfilling that gap. Table 10 represents various application of bioprinting addressed by several researchers of the selected articles. Cartilage tissue with 46 articles represents highest application of bioprinting. It is used in a variety of applications besides cartilage tissue, including bone tissue engineering, skin tissue, cardiac tissue, heart

Table 8 Classification on the basis of polymer-based biomaterial used

Sr. no	Biomaterial	Total articles	Application of research
Natural biomaterial			
1	Collagen	68	Skin tissue engineering, vascularized bone model, skeletal muscle cell
2	Fibrin	17	Vessel substitute, skin tissue engineering, regenerative medicine
3	Silk	8	Bone tissue engineering, biomedicine, therapeutic application
4	Agarose	10	Skeletal muscle, bio-artificial bone, cartilage tissue engineering
5	Alginate	101	Bone tissue engineering, cartilage tissue engineering, regenerative medicine
6	Hyaluronic	2	Wound healing, hydrogel formation
7	Chitosan	29	Bone tissue engineering, regenerative medicine, skin tissue engineering
Synthetic biomaterial			
1	Poly-lactic acid (PLA)	212	Bone tissue engineering, skin regeneration, cartilage tissue engineering
2	Poly-caprolactone (PCL)	25	Bone tissue engineering, skin tissue engineering, regenerative medicine
3	Polyethylene glycol (PEG)	4	Bio-artificial vascular graft, cartilage tissue engineering, shape morphing hydrogel
4	Polyacrylamide (PAAm)	3	Skin tissue engineering, vascularization
5	Poly-vinyl alcohol (PVA)	2	Skin tissue engineering, regenerative medicine, bone tissue engineering

Table 9 Classification on the basis of bioprinting method

Sr. no	Bioprinting method	No. of article	Main theme
1	Thermal inkjet printing	20	Skin tissue engineering, cartilage tissue engineering, bone tissue engineering
2	Mechanical/Pneumatic extrusion	31	Scaffold development of smart bioink, skin tissue engineering
3	Laser-guided direct writing	14	Skin tissue engineering, vascularized tissue bio fabrication
4	Stereolithography (SLA)	2	Cartilage tissue engineering, scaffold
5	Digital light processing (DLP)	4	Vascularized tissue engineering, cardiac tissue engineering

Table 10 Classification on the basis of application area

Sr. no	Application area	No. of articles	Main research theme
1	Bone tissue	24	Development of bioink, cell-laden scaffolding
2	Cardiac tissue	21	Cardiac construct, reconstruction of the heart
3	Cartilage tissue	46	In vivo human cartilage formation, scaffolding for nasal cartilage defect
4	Heart valve	4	Cardiac valve, tissue engineering of human heart valve
5	Neural tissue	4	Scaffold to repair the damaged spinal cord, functional 3D neural mini-tissue
6	Skin tissue	26	Scaffold for skin wound healing, skin disease modeling

valve, neural tissue, etc. In various tissue applications, scaffolding is main aim. This analysis can assist to find answer for research questions one, two and three.

Summary and Analysis

The presented literature research examined 1002 bioprinting articles to identify significant problems and potential developments. Researchers in this domain have conducted study and presented their findings on the several key aspects of bioprinting. Despite numerous studies in the field of bioprinting, issues with the bioprinted component's mechanical strength must be resolved. However, over the past 18 years, 1002 articles in peer-reviewed journals have been found that contain the phrase "Bioprinting and Biomaterial" either in their title or in the keywords. Research in this area is still in its infancy, and many lines of inquiry remain open, according to a study of the bioprinting studies that made the shortlist. Although many studies have contributed to the backdrop for bioprinting, bioink development is still necessary to increase the adoption and performance of bioprinted tissues and models. Many academics have pinpointed beneficial findings and future prospects, but very few authors have attempted to identify gaps in this field's domain of research.

The Study's Utmost Important Findings

The following is a summary of study conclusions based on a comprehensive review of the documents:

- It was noticed while reading the numerous literature reviews available on bioprinting that literature review papers focus on specific tissue application. The purpose of the research described in this article is to provide a multi-dimensional view of bioprinting.
- The United States, China, Germany, South Korea, the United Kingdom, and India were among the source nations where 1002 research articles on bioprinting were examined. To meet their need for organ supply for the patients waiting for their transplants, countries have been seen conducting substantial study in this area. Prominent researchers, Khademhosseini, A., Malda, J., Cho, D.W., Zhang, Y.S., Moroni, L., Ashammakhi, N., etc. have made a considerable impact on bioprinting-related research.
- The biomaterials, bioprinting procedures, and bioink development techniques that have been discovered by numerous bioprinters researchers have been compiled in this publication and can be used as a ready-to-use resource by present and future researchers and practitioners. Bioprinting researchers work on a variety of topics, but the most frequent ones are bone tissue engineering, skin bioprinting, and cartilage regeneration. The themes addressed throughout this study can serve as a guide for future scholars in this field.
- Many studies have concentrated on the development of bioink, but only a few have focused on improving the qualities of bioprinted components such as biocompatibility, biodegradability, mechanical strength, and structural stability.

Research Gaps

The literature review given identifies the following research gaps:

- In the medical field, there has been a considerable paradigm shift in bioprinting compared to standard graft implantation, as documented by literature. There is, however, a paucity of material for the development of a new bioink and improving the properties like mechanical/electrical, biocompatibility, and biodegradability of bioprinted components for direct use in transplantation.
- While collecting the polymer-based biomaterials for bioprinting, it was discovered that just a few biomaterial combinations had been investigated for the development of bioink.
- Only a few studies have shown the use of bioprinting in a variety of medical sectors.
- Several bioprinting studies have found that the bioprinting aspect of bioink requires a lot of parameter control, such as composition and structure, biocompatibility, surface functionalization and characterization, etc., as well as the proper composition of biomaterial that can match the exact composition of the human body matrix. Bioprinted components are still in the testing phase before being implanted due to the lack of appropriateness of the above features.
- Several articles discussed the benefits of bioprinting; however, there is still a lot of work to be done in terms of bioink development and improving the stability of bioprinted components for replacing missing tissues and replacing damaged tissues with a bioprinted component.

Implications of Research

A thorough literature assessment and analysis of a few key articles on bioprinting and biomaterials was conducted to review the current status of research in the chosen topic and to determine potential future research directions. The anticipated research implications of the study for researchers, clinicians, and doctors are listed below.

- The review's findings may be helpful to practitioners and researchers in assessing the state of research in the fields of biomaterials and bioprinting. Additionally, this will help learners understand how bioprinting research has developed since 2004 and where it stands today globally.

- Researchers and practitioners may find it useful to use the current study's analysis of contributions by publisher and source to find information sources for upcoming research and application. They can use this as a database for future research and to increase their understanding.
- The discovered bioprinting technologies and polymer-based biomaterials may help practitioners and doctors choose the appropriate bioprinting technology and biomaterial for the application. Furthermore, the study's findings may assist doctors and researchers in determining the benefits and drawbacks of adopting a specific type of biomaterial. This will help in the implementation of bioprinted component preventative measures before a problem emerges, making bioprinted component adoption for tissue engineering applications easier. Furthermore, researchers may get motivated to examine and discover new biomaterials combinations for the development of bioink for use in bioprinting.
- This could also serve as a platform for future bioprinted component enhancements. This could help surgeons choose biomaterials and bioprinting procedures for ready-to-use tissue transplantation in damaged or missing areas.
- By helping new researchers learn significant information and develop their skills, the top authors and resources featured here could boost their contributions to bioprinting research. Researchers and practitioners may also be able to find important documents and authors who have contributed significantly by doing this..

Finally, after careful review of the selected research articles, the framework was proposed for future research directions as shown in Fig. 3.

Conclusion and Future Scope

The goal of the study is to conduct a thorough assessment of the literature pertaining to the chosen bioprinting articles and to highlight recent advancements in the field. A total of 1002 research articles with the phrase "Bioprinting and Biomaterial" in the title or keywords were gathered for this study from the Scopus database between 2004 and 2022. The selected research articles were further analyzed for the assessment of neoteric developments in bioprinting research. According to this study, early trends focused primarily on bioprinting techniques, while later trends turned to the creation of bioink. Recently, several articles on the development of bioink employing biomaterial based on natural polymers were published. Among these, most of the literature highlights the use of natural biomaterial like Collagen, Silk, Alginate, Chitosan etc. for removing the issues of toxicity and non-biodegradability. Leading journals, publishers, academic institutions, writers, and other participants who have actively contributed to the

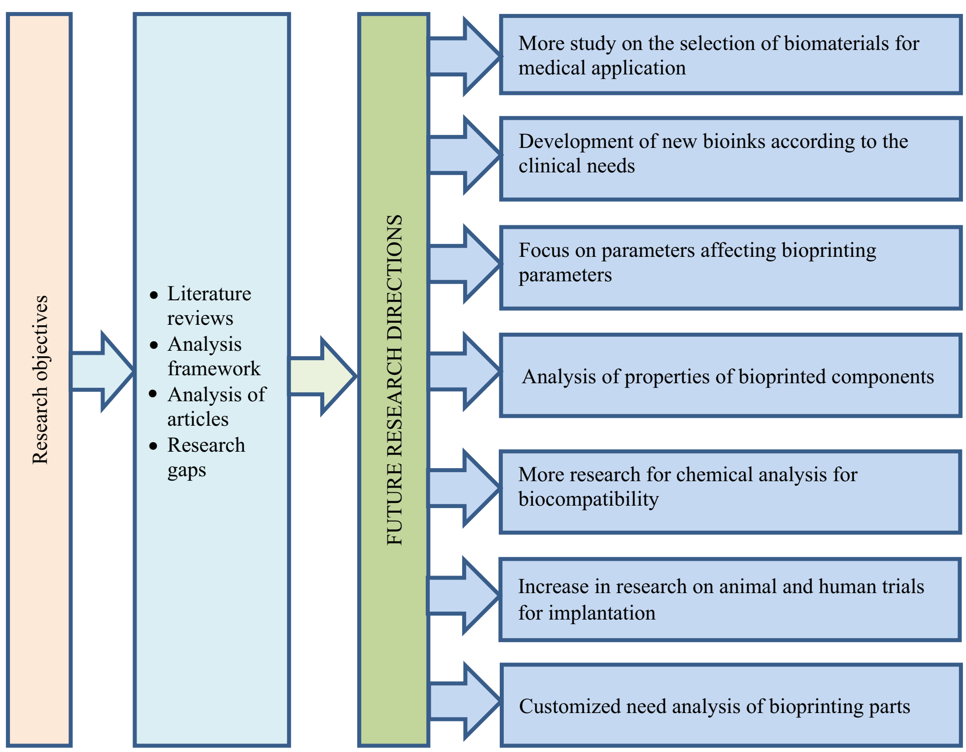

Fig. 3 Proposed framework for the future research directions

field of bioprinting research have been highlighted. This study also includes bioprinting techniques, polymer-based biomaterials, and bioprinting applications that have been reported by different authors. Implementing bioprinting in actual practice will require knowledge of the biomaterials utilized in the process, the bioprinting techniques, and the application area indicated in this research. Researchers and practitioners can both benefit from a deeper understanding of the topic thanks to the classification of bioprinting documents that is presented here based on many criteria. Even though the Scopus database contains a large number of research publications, the subject is still evolving, and the proposed framework lists a number of further prospects. It was also mentioned that numerous studies based on the development of bioink have successfully documented their research's findings. A limited amount of literature has been found to address the optimization of various parameters and to enhance the functionality of bioprinting. Research on bioprinting has been heavily influenced by nations including the United States, China, Germany, South Korea, United Kingdom, and India. Despite these efforts, bioprinted models are still in the research stage and are unable to be successfully used as transplants for various tissues because they lack the desired mechanical and morphological qualities. Future research on bioprinted components is also anticipated, and gaps must be filled. Future study is predicted to follow existing Graft implantation methods such as autograft, allograft, and xenograft by various researchers. Patients who are waiting for a donor for their damaged or missing tissues can easily meet their demand using bioprinted components. Future researchers on bioprinting will need to think about how to increase acceptability of the technology. To provide practitioners with guidance, it is important to identify and enhance the numerous factors that affect the adoption of bioprinting. To highlight the recent advancements in the field of bioprinting, this study adopts a classification of earlier work based on a number of different criteria. This will help in understanding bioprinting and be a useful resource for practitioners. However, the generalized technologies and applications of bioprinting in the area of bone tissue engineering, for bioprinting customized bone tissue can be included in the future studies for the benefits of academicians as well as for the orthopedic doctors. However, the authors of this research believe that the study has a few drawbacks, which are noted below:

- Our research is limited to looking at specific publications that include the term "Bioprinting and Biomaterials" in the title or keywords of the article, even though we acknowledge that there are several research articles that could not have used the term "Bioprinting and Biomaterials" in the keyword, the description could have focused on bioprinting.
- Journals published by the Institute of Physics Publishing, John Wiley and Sons Inc., and MDPI (Multidisciplinary Digital Publishing Institute) were excluded from this research. There are, however, research publications published by other publishers that can be utilized in the bioprinting and biomaterials-based studies. The collection is not exhaustive, but it is considered comprehensive because it includes a wide range of scholarly publications from a number of well-regarded journals.
- The authors of this study attempted to incorporate a wide range of parameters as well as all of the necessary bases for comparing the articles. However, the authors believe that a more complete study is needed to have a better knowledge of bioprinting and its application in the medical field.

Declarations

Conflict of Interest On behalf of all authors, the corresponding author states that there is no conflict of interest.

Ethical standard statement This article does not contain any studies with human or animal subjects performed by the any of the authors.

Informed consent For this type of study informed consent is not required.

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REVIEW ARTICLE

Evolving Role of Negative Pressure Wound Therapy with Instillation and Dwell Time (NPWTi-d-) in Management of Trauma and Orthopaedic Wounds: Mechanism, Applications and Future Perspectives

Ravi Saini[1] · Madhan Jeyaraman[2] · Tarun Jayakumar[3] · Karthikeyan P. Iyengar[4] · Naveen Jeyaraman[2] · Vijay Kumar Jain[1]

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Abstract

Introduction Negative Pressure Wound Therapy (NPWT) is a well-established method to promote wound healing by delivering negative pressure (a vacuum) at the wound site. Enhancement of NPWT techniques may allow an innovative way of treating trauma and orthopaedic wounds which provide unique challenges. We explore the role of negative pressure wound therapy with instillation and dwell time (NPWTi-d-) in the management of trauma and orthopaedic wounds.

Materials and Methods A comprehensive search strategy was conducted using databases of PubMed, Web of Science, Google Scholar, and Cochrane Library with the search words of 'NPWTid' or 'NPWTi-d-' or 'NPWT with instillation' or 'Negative pressure wound treatment with instillation' to generate this narrative review. The mechanism of action of NPWTi-d-, installation solutions and current applications in the trauma and orthopaedic wounds is evaluated.

Results NPWTi-d- provides additional mechanism to promote wound healing in a spectrum of acute and chronic orthopaedic wounds. The technique allows local delivery of hydration and elution of antibiotics to support growth of healthy granulation tissue. Various mechanism of actions contribute in drawing the wound edges together, reduce oedema, help decontamination, deliver local antibiotic and promote healing.

Conclusion NPWTi-d- permits an enhanced, supplementary technique to encourage wound healing in challenging traumatic and orthopaedic wounds. Future applications of NPWTi-d- will depend on cost-effectiveness analysis and development of its application guidelines based on longitudinal, randomized controlled research trials.

Keywords Negative pressure wound therapy · Granulation tissue · Wound healing · NPWT · NPWTi-d- · Instillation

Introduction

Trauma and orthopaedic wounds pose unique challenges in terms of their complex nature and potential complications, often requiring innovative and advanced treatment modalities for optimal healing. Among the emerging techniques, negative pressure wound therapy with instillation and dwell time (NPWTi-d-) has gained significant attention as a promising approach to address the complex wound management needs in orthopaedic practice [1–3]. NPWTi-d- combines the proven benefits of negative pressure wound therapy (NPWT) with the targeted delivery of topical solutions, offering a multifaceted approach to wound healing [4, 5].

The treatment of orthopaedic wounds necessitates a holistic approach that addresses not only the wound bed but also

✉ Madhan Jeyaraman
madhanjeyaraman@gmail.com

1 Department of Orthopaedics, Atal Bihari Vajpayee Institute of Medical Sciences, Dr Ram Manohar Lohia Hospital, New Delhi, India

2 Department of Orthopaedics, ACS Medical College and Hospital, Dr MGR Educational and Research Institute, Chennai, Tamil Nadu, India

3 Department of Orthopaedics, KIMS-Sunshine Hospital, Hyderabad, Telangana, India

4 Trauma and Orthopaedic Surgeon, Southport and Ormskirk NHS Trust, Southport PR8 6PN, UK

factors such as bone and soft tissue health, infection control, and overall patient well-being. NPWTi-d- encompasses the use of a specialized wound dressing coupled with negative pressure to create an environment conducive to wound healing [6–8]. Additionally, it introduces the instillation of topical solutions into the wound bed, allowing for targeted wound cleansing, removal of debris, and delivery of therapeutics, such as antimicrobial agents and wound healing-promoting substances [9, 10].

This review article aims to provide a comprehensive overview of the application of NPWTi-d- in the treatment of orthopaedic wounds. The underlying principles of NPWTi-d-, its mechanisms of action, and the scientific evidence supporting its efficacy and safety in the orthopaedic setting will be discussed. Furthermore, we will examine the various clinical scenarios in which NPWTi-d- has demonstrated beneficial outcomes, including open fractures, surgical site infections, complex soft tissue injuries, and non-healing wounds related to orthopaedic procedures. By delving into the current literature and clinical studies, this review seeks to elucidate the specific advantages and limitations of NPWTi-d- compared to traditional orthopaedic wound management approaches. Additionally, we will discuss practical considerations for the successful implementation of NPWTi-d-, including appropriate patient selection, wound preparation, instillation solutions, and monitoring parameters.

Ultimately, this comprehensive review aims to provide orthopaedic surgeons, wound care specialists, and healthcare professionals involved in managing orthopaedic wounds with an up-to-date understanding of the role of NPWTi-d- in optimizing wound healing outcomes. Through a critical evaluation of the available evidence, we aim to shed light on the potential benefits, challenges, and future directions of NPWTi-d- in the orthopaedic field, ultimately guiding clinical decision-making in the field of orthopaedic surgery.

Materials and Methods

Search strategy and design: This narrative review was conducted after a comprehensive search of PubMed, ScienceDirect, Web of Science, and Embase on 01.06.2023. The following search terms were used: 'NPWTid' or 'NPWTi-d-' or 'NPWT with instillation' or 'Negative pressure wound treatment with instillation'. Figure 1 depicts the articles included in this survey.

RCTs, case–control studies, prospective and retrospective cohort studies, and case series with at least five patients were all included. There were no restrictions on the follow-up period. Exclusion criteria included pre-clinical investigations, ex vivo studies, and studies conducted in languages other than English. All titles and abstracts were evaluated by two independent reviewers. Following this first screening, the papers that matched the selection criteria were examined for full-text eligibility. In the event of a dispute between the two reviewers, a third reviewer was consulted to achieve a consensus.

Research Objectives are as follows.

(a) RO 1: Elaborate mechanism of action of NPWTi-d-
(b) RO 2: Current applications in the management of trauma and orthopaedic wounds
(c) RO 3: To study significant benefits and challenges of NPWTi-d- in treatment of orthopaedic wounds
(d) RO 4: To analyse future perspectives of NPWTi-d-

Results

A comprehensive search strategy was conducted using databases of PubMed, Web of Science, Google Scholar, and Cochrane Library with the search words of 'NPWTid' or 'NPWTi-d-' or 'NPWT with instillation' or 'Negative pressure wound treatment with instillation' to generate this narrative review. Initially, a total of 251 studies met our selection criteria and after screening of abstracts and removing duplicates, 17 articles were eligible for final evaluation. The working model of NPWTi-d- is depicted in Fig. 2. The summary of 17 studies of NPWTi-d- is tabulated in Table 1.

Mechanism of Action of NPWTi-d-

1. **Negative pressure setting:** The innermost dressing layer is accessible to the irrigation solution and the wound bed when the proper negative pressure setting is used during the NPWTi phase. The majority of investigations have demonstrated that 125psi of negative pressure has beneficial and encouraging effects. Therefore, according to international consensus and following the findings of the majority of experimental research, the proper negative pressure setting for NPWTi should be between 125 and 150 mmHg [11, 12].
2. **Installation mode:** Persistent and intermittent instillation modes are typically included in the instillation mode. The NPWTi-d- intermittent instillation mode, which allows the solution to freely infiltrate the whole wound, has cycles made up of two phases: the negative pressure phase and the instillation and dwell phase. As a result, the intermittent instillation mode of NPWTi-d- is the advised therapeutic mode, and a 2- to 3-h negative pressure phase is advised [6, 13, 14]. The negative pressure is halted or lessened when the solution is infused into the dressing and wound bed, allowing it to thoroughly penetrate the wound tissue and exudate. The solution's capacity and dwell time, however, continue to be debatable. The amount of solution needed when

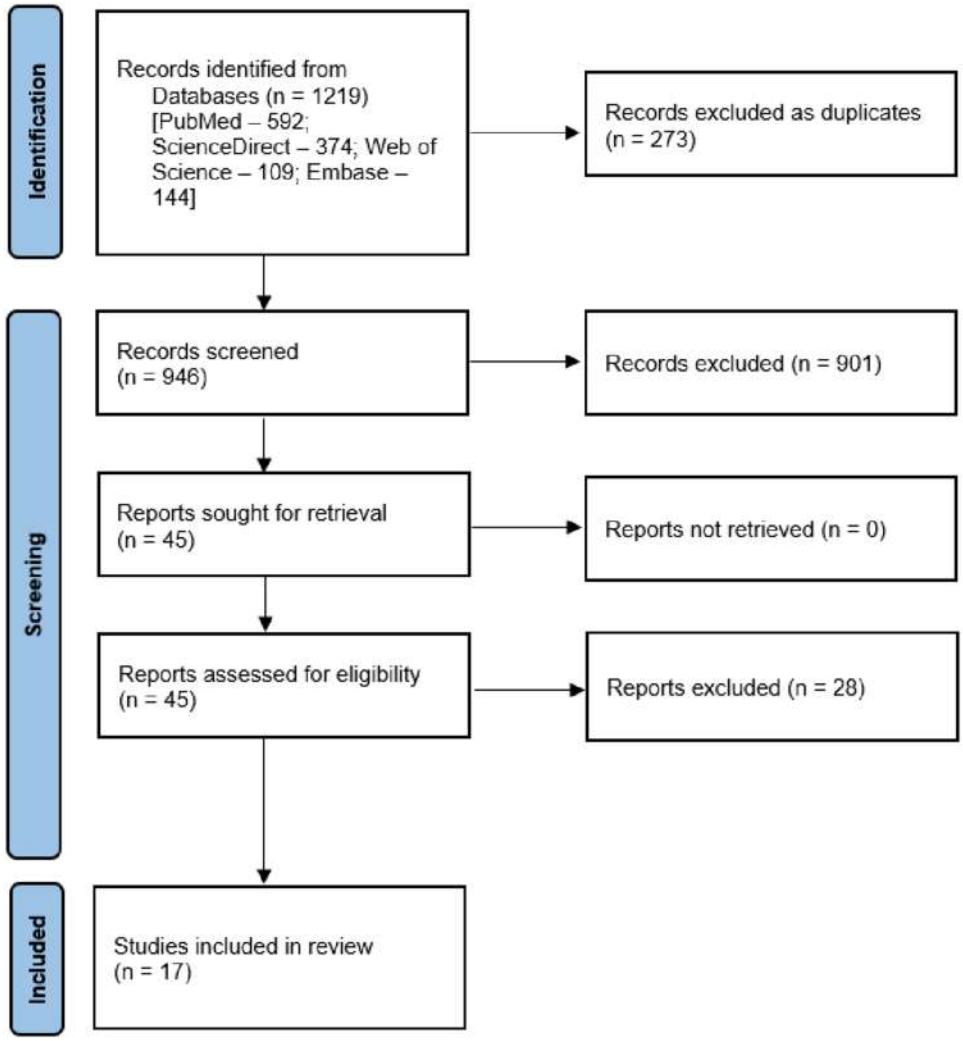

Fig. 1 Flowchart of included literature in the study

the dressing foam is completely absorbed and saturated is referred to as the "suitable volume". A volume that is too high will result in skin tissue infiltration at the margin of the incision, whereas a volume that is too low would compromise the irrigation effect. Longer dwell durations could have a harmful effect, so they are also crucial. It is currently uncertain how the installation solution will affect the dressing foam's ability to last. The ideal dwell period is typically 10 min, and the best volume is thought to guarantee that the solution can completely penetrate the dressing foam up until the sealing film starts to bulge [15]. However, in clinical practice, these conditions are typically challenging to implement, and the sealing film is readily harmed due to the high likelihood of an excessive solution level or prolonged dwell time.

3. **NPWTi duration time:** The type of wound and the goal of treatment will determine how long NPWTi-d- will be administered. Acute non-infectious wounds require NPWTi-d- treatment for 3–14 days, and chronically infected wounds require treatment for 7–60 days, according to studies [7]. It is generally accepted that NPWTi-d- termination should be taken into consideration once clinical objectives have been met, which include satisfactory wound bed cleaning, stimulation of granulation tissue, preparation for skin grafting or skin flap surgery, and dressing replacement.

Installation Solutions

1. **Normal saline:** Commonly used, safe, and non-toxic, normal saline is well tolerated. It works well to improve the formation of granulation tissue and to remove necrotic tissue from all kinds of wounds. Leung et al. discovered that NPWTi with regular saline may effectively stimulate the production of granulation tissue in a pig acute trauma model [16]. Kim et al. discovered that the effects of NPWTi when coupled with ordinary saline were similar to those of NPWTi with an antimicrobial solution (0.1% PHMB) following surgical debridement

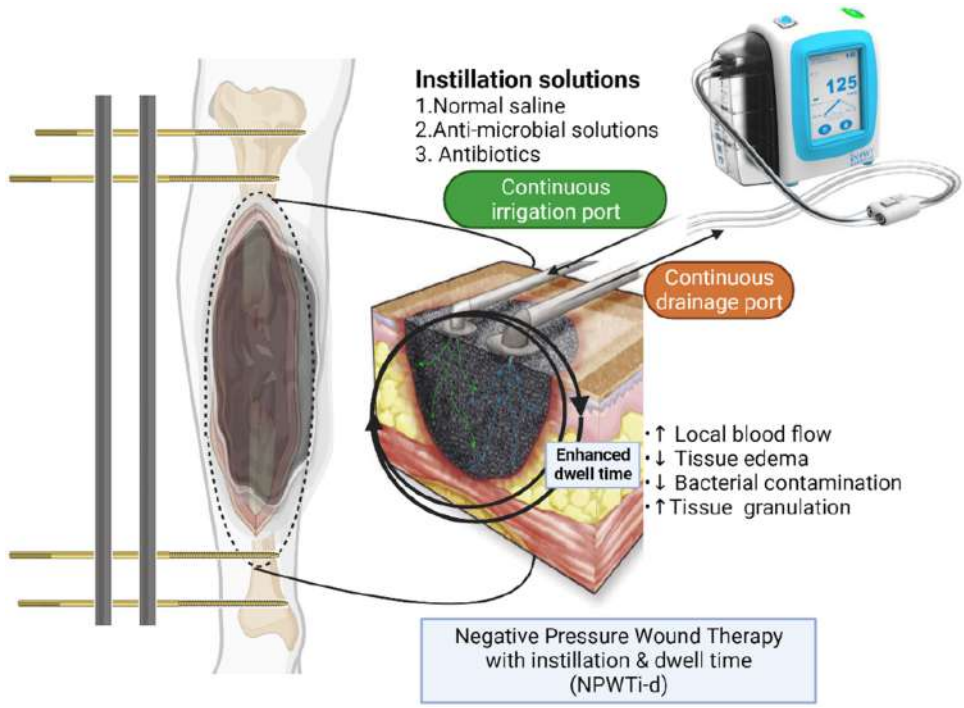

Fig. 2 Working model of negative pressure wound therapy with instillation and dwell time (NPWTi-d-)

[17]. Therefore, the first implanted fluid for NPWTi is advised to be normal saline, according to the global community.

2. **Antimicrobial solutions:** A range of chemical antiseptics, such as hypochlorous acid solution, sodium hypochlorite solution, silver ion solution, and polyhexamethylene biguanide (PHMB) solution, have been chosen as instillation solutions with NPWTi in the clinical setting. As compatible NPWTi instillation solutions, the international community often suggests antimicrobial solutions such as hypochlorous acid solution, sodium hypochlorite solution, acetic acid solution (0.25–1.0%), and polyhexamethylene biguanide (0.1%) + betaine (0.1%). PHMB (0.1%) and betaine (0.1%), which exhibit wide-ranging antibacterial activity, are the two main ingredients in the Prontosan solution [18]. Both bacterial growth and biofilm activity can be considerably inhibited by it. It is frequently used in chronic wound infections where bacterial biofilm development is strongly expected. Strong oxidizer solutions like Microcyn and Dermacyn are primarily made of sodium hypochlorite and hypochlorous acid. According to Landsman et al., irrigating diabetic foot sores with Microcyn solution effectively treats infections. Microcyn/Dermacyn instillation treatments for NPWTi are secure and efficient [19]. Sodium hypochlorite is the substance that makes Dakin's solution effective. It has already been proven that Dakin's solution has an antibacterial impact on *Enterococcus*, *Pseudomonas aeruginosa*, and MRSA. Additionally, publications have recognized the therapeutic benefits of additional antimicrobial solutions, such as iodine solution, oxygen-loaded solution, peroxy acid solution, and chlorhexidine solution, which are utilized for NPWTi.
3. **Antibiotics:** Although vancomycin, polymyxomycin B, and gentamicin have been documented, the use of antibiotics as a solution for instillation remains controversial.

Discussion

Negative pressure wound therapy, also known as vacuum-aided wound therapy, is a form of wound dressing that constantly or intermittently applies sub-atmospheric pressure to the surface of a wound to help in healing [20]. It was created in the 1990s and includes semipermeable foils, wound dressings, drainage tubes, and vacuum sources [7]. Despite the existence of numerous studies comparing the outcomes of NPWTi-d- with NPWT alone, there is a lack of evidence to support its benefits in the context of orthopaedic and plastic surgery, particularly in several complex wound types where advanced wound dressings or wet-to-moist dressing changes are used [20].

How NPWTi-d- Differs from Conventional NPWT

In 1998, Fleischmann proposed the extension of the NPWT technology by introducing the concept of instillation and dwell time (NPWTi-d-). The procedure was divided into three stages: irrigation, dwell, and drainage [7]. In addition

Table 1 Summary of clinical studies of NPWTi-d-

Author (year)	Type of study	Diagnosis/type of injury	No. of patients	NPWTi-d- protocol	Solutions used	Final wound closure (duration)	Complications	Follow up
Leffler et al. [20] (2009)	Case series	Subacute/chronic osteomyelitis	6	Application of NPWTi-d- in chronic wounds and their outcomes	Polyhexanide	Six months post-surgery	No	After NPWTi-d-, bacterial swabs and tissue biopsies were sterile; after 3 to 10 months, there was no recurrence of osteomyelitis
Timmers et al. [21] (2009)	Prospective cohort study	Osteomyelitis of pelvis or lower limb	Case control cohort studies	2 cohorts; I: NPWTi + debridement/antibiotics, C: standard of care (surgical debridement, gentamycin polymethylmethacrylate beads implantation, long-term IV antibiotics) I stands for V.A.C. Instill Polyhexanide Solution; Dwell time: 10–15 min; NP: 300–600 mmHg; Mean days of treatment: 6 to 60	Polyhexanide Gentamicin PMMA beads	Not available		The NPWTi-d- group underwent fewer operations and required a shorter stay in the hospital
Lehner et al. [22] (2011)		Infected orthopedic implants (THA 62.5%, TKA 31.3%, 6.2% osteosynthetic material)	32		Polyhexanide	Not available		86% (acutely infected) and 80% (chronically infected) of implants were retained

Table 1 (continued)

Author (year)	Type of study	Diagnosis/type of injury	No. of patients	NPWTi-d- protocol	Solutions used	Final wound closure (duration)	Complications	Follow up
Brinkert et al. [23] (2013)		Various wound types that are infected or at high risk of infection (such as open fractures, infected hematomas, PUs, and non-healing postoperative dehiscence wounds)	Prospective case series to evaluate the outcomes of 131 patients with complex wounds treated with NPWTi-d-	NPWTi-d- case series; V.A.C. VeraFlo; Solution: Normal saline; Dwell time: 10 min; NP: 4–12 h; Pressure: 125 mmHg; Mean days of treatment: 12.2	Saline	12–19 days	No incidence of wound recurrence or dehiscence was observed at operated site	Wound closure was achieved in 128 of 131 (98%) wounds • With respect to filling dead space more rapidly and completely, NPWTi-d- using saline showed improved granulation tissue production compared with NPWT
Fluieraru et al. [24] (2013)		Complex wounds (such as vast undermining tracts or deep wounds) or infected wounds that did not respond to NPWT	Retrospective case series of 24 patients - 12 patients who had been unsuccessfully treated with NPWT - 12 patients with complex wounds	Case series for NPWTi-d-; V.A.C. Instillation; Solution: Sterile saline; Dwell time: 10 min; NP: 4 h; Pressure: 125 mmHg; Days of treatment: 6–15	Isotonic saline	After one month		The lower extremities of the patient who did not recover was too devascularized to granulate effectively. The main outcomes of instillation therapy in these patients included encouraging the growth of granulation tissue and filling weakened holes

Table 1 (continued)

Author (year)	Type of study	Diagnosis/type of injury	No. of patients	NPWTi-d- protocol	Solutions used	Final wound closure (duration)	Complications	Follow up
Gabriel et al. [25] (2014)			Retrospective analysis comparing patients with NPWT ($n=34$) with NPWTi-d- ($n=48$) • A hypothetical economic model that compares patients with NPWT and NPWTi-d- utilising cost assumptions for debridement		Saline or polyhexanide	The NPWT-instillation-treated wounds were closed in 29.6 ± 6.5 days		Between NPWTi-d- and NPWT patients, there were significant differences (P 0.001) for the following: mean OR debridement (2.0 versus 4.4) - average length of hospital stay (8–1 vs. 27–4) - average LOT (4–1 versus 20–9) - Mean time to wound closure (4–1 days as opposed to 20–9) • The fictitious economic model suggested that there could be an average $8143 savings for OR debridement between NPWTi-d-($6786) and NPWT ($14 929) patients • The average cost of therapy varied between the two groups by $1418 ($799 for NPWTi-d- against $2,217 for NPWT)

Table 1 (continued)

Author (year)	Type of study	Diagnosis/type of injury	No. of patients	NPWTi-d- protocol	Solutions used	Final wound closure (duration)	Complications	Follow up
Goss et al. [26] (2014)		A substantial bacterial bioburden (> 10^5 CFU/g tissue) is present in DFUs, VSUs, and other wound aetiologies	Prospective pilot research in 13 patients	Prospective contemporaneous cohort design; NPWT (C) vs. NPWTi-d- I: V.A.C. Vera-Flo; C: Dakin's solution; Dwell time: 10 min; NP: 60 min; Pressure: 125 mmHg; Days of Treatment: 7	Dakin	Not available		NPWTi-d- wound treatment resulted in a decrease in the mean CFU/gram of tissue culture
Kim et al. [17] (2015)		Chronic wounds (neuropathic, ischaemic, traumatic)	142 NPWT group: 74 patients • NPWTi-d- 6-min dwell group: 34 patients • NPWTi-d- 20-min dwell: 34 patients	NPWT (C) vs. NPWTi-d- (I) (2 Subgroups I1 and I2); retrospective cohort-historical control design C: InfoV.A.C.; NP: -125 mm Hg, 7 days of treatment I1: V.A.C. VeraFlo; solution: polyhexanide + betaine; Dwell time: 6 min; NP: I1: 3.5 h; Pressure: − 125 mmHg; Days of treatment: 7 I2: V.A.C. VeraFlo; solution: polyhexanide + betaine; Dwell time: 20 min; NP: 2 h; Pressure: 125 mmHg; Days of treatment: 7	Prontosan	Not available		Patients treated with NPWTi-d- in the 6-min dwell group showed significantly lower rates of Higher percentages of wounds were closed before discharge (94% versus 62%) and had improved cultures for Gram-positive bacteria (90% versus 63%) (P 0001)

Table 1 (continued)

Author (year)	Type of study	Diagnosis/type of injury	No. of patients	NPWTi-d- protocol	Solutions used	Final wound closure (duration)	Complications	Follow up
Wolvos [27] (2015)		Variety of infected or complex wounds	Pilot study of consecutive case series with seven patients	NPWTi-d- case series V.A.C. VeraFlo; solution: Microcyn, Dakin's; Dwell time: 5–10 min; NP: 2–4 h; Pressure: 100–125 mmHg; Days of treatment: 7–54	Microcyn®, Dakin's Solution® (quarter strength)	Six months after surgery	No complications noted	The overall length of therapy ranged from 7 to 54 days. Wounds were closed by primary, secondary, delayed primary intention, or an STSG. Six of seven patients got NPWTi-d-, and one patient had NPWT alone
Davis et al. [28] (2020)		Complex foot infections (Charcot arthropathy, collagen vascular disease, hypercoagulable state)	Randomized clinical study in 90 patients		Saline	12 weeks	No	Between patients treated with various NPWT devices or NPWT with and without irrigation, we were unable to detect any appreciable differences in clinical outcomes or adverse events
Sung et al. [29] (2020)		Complex and infected wounds (necrotizing fasciitis, Fournier's gangrene, and gas gangrene)	Prospective study in 51 patients		0.9% Normal saline + 1% povidine iodine solution	Two individuals had partial graft failure, but after two weeks of secondary healing		All wounds were closed Though graft failure was noted in 2 cases, they healed by secondary healing by 2 weeks
Delapena et al. [30] (2020)		Necrotizing fasciitis	10	Wounds were intermittently managed with NPWTi-d- using HOCL	HOCL	Not available	No	Shorter hospital stays and improved wound care
Schreiner et al. [31] (2020)		Sternoclavicular joint infection	27 (21 men, 6 women)	Comparison of NPWT alone versus NPWTi-d- for the management of this condition	Polyhexanide	Not available	No	In patients with SCJI, the NPWTi-d-appears to be an effective therapy, resulting in a higher frequency of bacterial eradication and a shorter duration of wound care

Table 1 (continued)

Author (year)	Type of study	Diagnosis/type of injury	No. of patients	NPWTi-d- protocol	Solutions used	Final wound closure (duration)	Complications	Follow up
Elhessey et al. [32] (2021)		Complex infected orthopaedic wounds	Prospective study in 20 patients	The VeraLink Cassette (KCI, San Antonio, Texas) spike allowed to connect to the system. Vacuum-assisted closure (VAC) therapy was selected for the pre-programmed therapy unit, and it was started to offer a 20-min soak/dwell time followed by 2 h of therapy at a pressure of 125 mm Hg and medium pressure intensity	Prontosan	Wound closure at 6 weeks		Wound closure was achieved in 65% of cases
Zhang et al. [33] (2021)		Necrotizing fasciitis	32	Following aggressive surgical debridement, NPWTi-d- was initiated by instilling solution with a set dwell time of 5–10 min, followed by continuous NPWT of 125 mm Hg for 3–5 h	Prontosan	After 9–16 days	No	All wounds were successfully closed and no recurrence of infection or adverse event was observed during NPWTi-d- treatment
Enodien et al. [34] (2021)		Diabetic foot syndrome		Following surgical debridement, Acti-Maris sensitiveTM NPWTi-d- with super oxidised solution was infused. NaCl 1.2% and NaOCl 0.04% make up the alkaline (pH 8.5–10) hypertonic sea salt solution	Super oxidized solution	Six weeks		After 14 days of therapy, the wound and granulation tissue recovered quickly

Table 1 (continued)

Author (year)	Type of study	Diagnosis/type of injury	No. of patients	NPWTi-d- protocol	Solutions used	Final wound closure (duration)	Complications	Follow up
Pellegrin et al. [35] (2023)		Chronic wounds in orthoplastic surgery	To compare outcome of NPWTi-d- vs standard of care in orthoplastic surgeries		Saline	Not available	No	The results demonstrated that infected wounds treated with NPWTi-d- had a successful outcome when compared to NPWT

to the effects of standard NPWT, which promote healing by increasing local blood flow, reducing tissue edema, reducing bacterial concentration in the area, and increasing tissue granulation, NPWTi-d- may provide additional benefits in terms of wound cleansing [20]. The treatment outcomes in animal studies have shown that NPWTi-d- generated more granulation tissue and lesser bacterial growth than conventional NPWT [8, 21–23]. Additionally, it can promote exudate and necrosis removal both before and following surgical debridement [7]. NPWTi-d- allows for the intermittent instillation of liquids into wounds while maintaining negative pressure in a sealed environment [15, 24]. The application of NPWTi-d- in orthopaedics is depicted in Fig. 3.

Advantages of NPWTi-d-

De Pellegrin et al. stated that NPWTi-d- offers superior wound closure rates and fewer problems than NPTW or traditional dressings for the management of orthoplastic wounds ($P < 0.05$) [20]. Several comparison studies have shown that using NPWTi-d- and saline injection results in increased granulation tissue formation as compared to standard NPWT [25]. NPWTi-d- with polyhexanide instillation compared to NPWT, according to Kim et al. [3] there were fewer surgical visits, hospital stay was reduced, a shorter duration to the final surgical operation, and an increased proportion of wounds that are healed before discharge. NPWTi-d- has also been associated with fewer difficult and unpleasant dressing changes than NPWT. According to Gupta et al., the demonstrated clinical improvements make NPWTi-d- a potentially cost-effective supplementary technique of treating big, complex, and infected wounds in inpatient settings [22].

Disadvantages of NPWTi-d-

NPWTi-d- does not complement surgery or debridement. If the predetermined treatment plan and timeframe are not feasible, alternative treatment options should be considered. NPWTi-d- is advised not to use over split-thickness skin grafts, dermal replacements, wounds with organs and veins that are vulnerable and exposed, lesions covered in untreated abscesses, and critically ischemic wounds. NPWTi-d- should not be used as a bolster dressing, in contrast to normal NPWT. When hemostatic agents have been utilized in the wound bed, NPWTi-d- should not be started [26]. A case of tension pneuomocephalous has been report after the use of NPWTi-d- in post-surgical spinal infection [27].

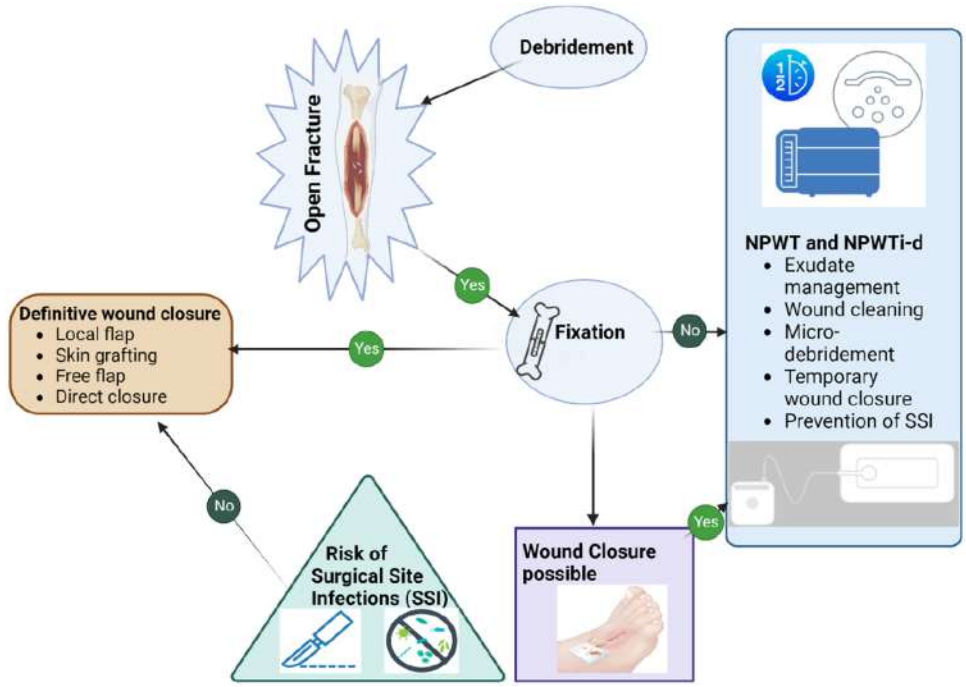

Fig. 3 Application of NPWTi-d- in orthopaedics

Applications of NPWTi-d- in Orthopaedics

(a) Acute Wounds

In Orthopaedics, open fractures, necrotizing fasciitis, and soft tissue injuries are typical acute wounds. The basics of treating open fractures are to prevent and limit wound infection and to cover the wound as quickly as feasible. Active wound drainage is provided by NPWTi-d- and continuous wound irrigation guarantees that the wound is continuously cleaned, preventing secondary infection and cutting treatment time. Ali et al. described a case of an open tibia fracture that was successfully treated with NPWTi-d- and skin grafts [28]. The case's primary goals preserving the leg's structural integrity, achieving bone union, and preventing infection were all met.

Numerous issues, including inadequate blood flow and wound infection, are frequently present in severe soft tissue injuries. Because of infection or oedema, primary closure cannot be established, and tissue with low vitality may continue to necrose and discharge. In addition to covering and protecting the wound, NPWTi-d- may efficiently drain wound exudate, necrotic tissue, and toxins [29, 30]. This promotes the formation of granulation tissue, which in turn produces the ideal environment for secondary wound repair [31].

When Ali et al. used NPWT and NPWTi-d- to treat a soft tissue injury to the lower extremity, even when there is fibrous and non-viable tissue, granulation tissue immediately developed over the exposed bone and a skin graft was used to successfully seal the wound [28]. In contrast to NPWT alone, Omar used NPWTi-d- with normal saline solution to treat acute lower extremity soft tissue injuries [32]. The findings demonstrated that NPWTi-d- could greatly shorten hospital stays and speed up wound healing, but there was no discernible difference between the two therapies in terms of the therapeutic result.

(b) Chronic Wounds

Chronic refractory and complex orthopaedic wounds [chronic infected wounds, chronic osteomyelitis, and wounds with bone, tendon, or internal fixation exposure] are extremely prevalent and untreatable. In addition to successfully removing damaging inflammatory cytokines, enhancing the wound microenvironment, reducing wound infection, encouraging the development of granulation tissue, and setting the stage for secondary repair, NPWTi-d- is an excellent approach for treating chronic wounds [33–35].

Gabriel found that when treating a variety of complex infected wounds, NPWTi-d- dramatically reduced the wound microbial load, length of stay in the hospital, and wound healing when compared to traditional wound care [26]. Hu discovered that using NPWTi-d- with a silver ion solution effectively controlled wound infection and greatly decreased hospital stay, complication occurrence, and blood inflammation [36]. Goss et al. emphasized that the use of NPWTi-d- after surgical debridement in chronically infected lower extremity wounds can significantly reduce the wound microbial burden when compared to NPWT alone. These advantages are favorable for future wound restoration [34].

Delapena et al. found that in patients with SCJI, the NPWT in conjunction with instillation and dwell time appears to be an effective therapy, resulting in a higher incidence of bacterial eradication and shorter wound care [37]. Sung et al. [38] and Rupert et al. [39] discovered that following wound debridement, the use of NPWTi-d- dramatically reduced the risk of infection returning, the length of stay in the hospital, and the number of operations when compared to conventional treatments (conventional surgical debridement, placement of gentamicin with sustained release, and long-term intravenous antibiotic infusion) [38, 39]. Jukema et al. demonstrated a decrease in the length of the infection's therapy, the quantity of surgeries performed, the length of hospitalization, and the recurrence rate in a group of patients with post-traumatic osteomyelitis [40].

Diabetes-related foot ulcers, which are brought on by a confluence of vascular conditions, neuropathy, and impeded wound healing, are among the leading causes of morbidity and mortality in diabetes patients. The application of NPWTi-d- in treating diabetic foot infections is promising, because it may provide additional benefits over NPWT alone, such as a reduction in bacterial count in wound bed, promotion of the growth of granulation tissue, and offering wound irrigation in a secure setting [30, 41]. Enodien et al. found that NPWTi-d- with the instillation of a superoxidized solution assisted in wound healing, the removal of infectious material, and the prevention of infection transmission [42]. Additionally to antibiotics, with diabetic foot syndrome comorbidities, and heavily infected wounds, this approach may still be beneficial for certain individuals.

Comparing NPWTi-d- to conventional NPWT alone in the treatment of ischial and sacral pressure sores, it has been demonstrated that NPWTi-d- aids in irrigating the wound, removing fibrinous exudates, and encouraging the growth of granulation tissue, all of which are associated with a decrease in surgical debridements and a reduction in hospital stays [43]. After operative debridement, wound closure using various local flaps, and treatment with NPWTi-d-, patients with pressure ulcers in various locations showed improvements in terms of aiding preparing the wound bed for subsequent healing [7, 31, 44]. Instillation and dwell time as an adjunct to NPWT was used in colonised wounds showed significant decontamination, reduction in bacterial count and improved granulation tissue to provide successful reconstruction [45].

(c) Salvage Orthopedic Fixation Hardware

NPWTi-d- has been tried in patients with post-fracture fixation surgical site infection with good success. The patients were manged with intramedullary and subcutaneous antibiotics and NPWT without removal of implants [46].

Newer Advances in NPWTi-d-

Newer modifications to NPWTi-d- include a Reticulated open cell foam dressing with through holes (ROCF-CC) which has been shown to be effective in accelerating wound healing. ROCF-CC is made of a highly porous foam with through holes that allow for increased drainage of wound exudate and better oxygenation of the wound bed. A recent study found that ROCF-CC was more effective than traditional NPWTi dressings in promoting wound healing in patients with diabetic foot ulcers. The study found that ROCF-CC dressings led to a significantly faster reduction in wound area and a higher percentage of wounds that healed completely. Another recent study found that ROCF-CC dressings were effective in reducing pain and improving quality of life in patients with chronic wounds. The study found that ROCF-CC dressings led to a significant reduction in pain scores and an improvement in quality of life measures, such as sleep quality and ability to perform daily activities [47].

Smart NPWTi-d-: Smart NPWTi-d- dressings are made with materials that can respond to changes in the wound environment. For example, some smart NPWTi-d- dressings can change color when they are exposed to bacteria, which can help clinicians to identify infected wounds. Other smart NPWTi-d- dressings can release drugs or other therapeutic agents in response to changes in the wound pH or temperature [45].

NPWTi-d- with nanomaterials: Nanomaterials have the potential to improve the performance of NPWTi-d- dressings in a number of ways. For example, nanomaterials can be used to create NPWTi-d- dressings that are more porous, have a higher surface area, and are more resistant to bacterial colonization [48].

3D-printed NPWTi-d-: 3D printing can be used to create custom-made NPWTi-d- dressings that are specifically tailored to the needs of each individual patient. This can be particularly beneficial for patients with complex wounds or wounds that are difficult to dress with traditional methods [49].

Future of NPWTi-d-

NPWTi-d- is a promising new treatment for difficult wounds. It combines the benefits of drainage and irrigation to successfully control local infection, improve wound healing, and eliminate exudate and necrotic tissue. Numerous studies and applications of NPWTi-d- have produced encouraging results. It is anticipated that NPWTi-d- will be used to treat a wide range of difficult wounds in the future.

Limitations must be understood, though, as the effectiveness of NPWTi-d- is influenced by a variety of variables, including the patient's overall health status, the wound characteristics and anatomical location and the treatment parameters. In addition, the majority of the current guidelines for the use of NPWTi-d- and its indications make reference to the conclusions of case review research and expert consensus. Therefore, additional randomized and controlled trial research are necessary to assure optimal treatment by choosing the right patient, treating the wound consistently, and creating an environment that addresses various wound types, as well as the customization, standardization, and improvement of therapy settings.

Another crucial topic of discussion is cost-effectiveness analysis, which enables comprehension of a medical or surgical procedure's viability. NPTWi-d-'s cost-effectiveness in comparison to other methods of wound management in various fields has not yet been demonstrated in the literature. This is also consistent with the current review, which only uses data from one trial to determine if NPWTi-d- is cost-effective. The enhanced efficiency in achieving complete wound closure may justify the costs associated with its consumables, and it may also assist alleviate the costs associated with delayed healing, therefore, future research should pay particular attention to this important feature.

This review is limited by the lack of large-scale randomized controlled trials, which precludes definitive conclusions about the efficacy and safety of NPWTi-d-. Additionally, there is no consensus on several important aspects of NPWTi-d-, including its impact on patient pain and comfort, ideal patient profile selection, efficacy against Gram-positive and Gram-negative bacteria, optimal instillation solution and volume, and cost-effectiveness compared to standard treatments. Further clinical trials are needed to establish definitive guidelines for the use of NPWTi-d- in clinical practice. Despite these limitations, NPWTi-d- remains a promising candidate for the management of complex wounds.

Conclusions

NPWTi-d- emerges as a groundbreaking approach for addressing a wide spectrum of wounds encountered in trauma and orthopaedic clinical settings. Its multifaceted mechanism of action introduces an additional dimension to the management protocol for acute, chronic, and stubborn wounds. NPWTi-d- offers the valuable advantages of promoting wound hydration and facilitating localized antibiotic delivery. The future utilization of this technique in clinical practice will be further refined through the establishment of application guidelines, rigorous cost–benefit assessments, and the outcomes derived from longitudinal, randomized trials.

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Declarations

Conflict of Interest The authors declare that they have no conflict of interest.

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REVIEW ARTICLE

Arthroscopy in India Through the Medicolegal Lens: A Comprehensive Review

Satvik N. Pai[1]

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Abstract

Introduction With the increasing number of Arthroscopic surgeries, comes with it, the undesirable problem of litigation associated with it. Arthroscopy does possess certain unique aspects which need to be understood from the legal point of view as well.

Materials and Methods We obtained information on specific medico-legal cases involving arthroscopy from books and websites containing collections of medico-legal judgments in Indian legal courts, consumer dispute redressal forums at the state and national levels, and state medical councils..

Results We assimilated and analysed all this information, combined it with our experience in the field of medical law, and have provided practical, enforceable ways to decrease the medicolegal risk for arthroscopy surgeons.

Conclusion This review provides a comprehensive overview of pressing issues in relation to the medicolegal aspects of arthroscopic surgery.

Keywords Arthroscopy · arthoscopic surgery · medicolegal · litigation · lawsuits

Introduction

Arthroscopy has gained widespread popularity and acceptance in the past two decades in India [1]. Today arthroscopy has already developed into a subspecialty of orthopaedics, with arthroscopy of the knee, hip, ankle, shoulder, elbow and wrist being done across the country [2, 3]. With the increasing number of these surgeries, comes with it, the undesirable problem of litigation associated with it. While litigation is not a problem restricted to arthroscopy surgeons, arthroscopy does possess certain unique aspects which need to be considered and understood from the legal point of view as well. This review is an attempt at exploring all of those aspects and provide a comprehensive overview of the pressing medicolegal issues in relation to arthroscopic surgery.

✉ Satvik N. Pai
satvik.pai@gmail.com

[1] Department of Orthopaedic Surgery, Aster RV Hospital, J P Nagar, Bangalore, India

Material and Methods

We conducted a thorough search of the literature to find studies on the medico-legal aspects of arthroscopy. We used PubMed and Cochrane Library databases, employing search terms and Boolean operators such as 'medico-legal' OR 'lawsuit' OR 'malpractice' OR 'litigation' AND ‘arthroscopy' OR 'arthroscopic surgery' OR. We did not limit the publication date and only included studies in English. Additionally, we searched the reference lists of identified articles to find more studies. We obtained information on specific medico-legal cases involving arthroscopy from books and websites containing collections of medico-legal judgments in Indian legal courts, consumer dispute redressal forums at the state and national levels, and state medical councils. We reviewed Indian legal databases for information on such cases, to identify the issue at hand, analysed the facts of the case, judgements delivered, and drew our learnings from such cases. We assimilated and analysed all this information, combined it with our experience in the field of medical law, and have provided practical, enforceable ways to decrease the medicolegal risk for arthroscopy surgeons.

Table 1 Most common reasons for litigation in arthroscopy cases

The 5 most common reasons for litigation in arthroscopy cases
Persistence of pain
Post-operative infection
Technical errors
Nerve damage
Vascular injury

Causes of Litigation

Any surgical procedure is associated with possible complications. But it is important to understand that not all complications lead to lawsuits. Furthermore, the mere occurrence of a complication, does not constitute medical negligence. Therefore data and reports of lawsuits following arthroscopy were analysed to identify the reasoning for malpractice claims (Table 1).

Rougereau et al. identified that the most common reason lawsuits following arthroscopy were persistence of pain (43%), postoperative infection (29%), technical errors (10%), nerve damage (5%), and vascular injury (2%) [4]. The two joints most commonly involved in litigation are, not surprisingly, the knee and shoulder [4–6], considering that they are most frequently operated joints. A failure to inform patients about possible complications was also a common reason for lawsuits [5]. A point of significance is that complications like vascular injury are much more likely to result in the surgeon being held guilty of negligence than claims like surgeon technical error. [7] Pulmonary embolism was noted to be most major complication that could lead to death of a patient [7]. Unfortunately there is no such organised data available for medicolegal cases in India. From our own experience dealing with medicolegal cases in India though, we found that disputed diagnosis, and change in surgical plan are common reasons for lawsuits in India. We explore some such cases in the later part of this paper.

Wrong sided Surgery

Wrong sided surgery is not uncommon with arthroscopy for obvious reasons that there may be no external markers of injury and similar appearance of anatomy on both sides. In fact arthroscopy is second most common type of surgical procedure to result in wrong sided surgery, second only to spine surgeries [8]. Wrong sided surgeries are one of those instances when even an excellent attorney may be unable to defend the surgeon successfully. Miller too remarks that wrong-site surgery results in a successful verdict for the plaintiff in all the court cases [9]. It is therefore paramount that wrong sided surgery be prevented from occurring in the first place. We recommend using the World Health Organisation surgical safety checklist in all surgical cases [10]. The extra minutes spent, if done in a timely manner, need not increase surgical time significantly, while possibly preventing a mishap and trouble for the patient and surgeon alike. It has proven to be successful in reducing the number of wrong sided surgeries [11]. It is our recommendation that the surgical site marking be done after confirming the site and side with the patient orally rather than only relying on the medical records. While the side marking of radiographs, computed tomography or Magnetic Resonance Imaging (MRI) films and reports should be used to reconfirm the side of surgery and procedure planned, they should be cross verified by other means as these imaging reports can occasionally be incorrectly marked.

Deep Vein Thrombosis (DVT) and its prophylaxis

Deep vein thrombosis is a serious complication that can occur following lower limb surgeries and can be a potential cause of litigation if it occurs. So use of prophylaxis for DVT becomes a very pertinent decision to consider for arthroscopy surgeons. The incidence of DVT following arthroscopic surgeries is low, with studies reporting it to be as low as 0.25%, [12] but some studies have also found the incidence to much higher when checked by venography, though most of those tend to remain asymptomatic [13]. DVT prophylaxis does come with its own drawbacks of increased risk of bleed and increased medical expense. So the question of whether DVT prophylaxis needs to be given in all patients undergoing arthroscopic surgeries becomes important from practical and legal perspectives [14]. While some studies concluded that it is beneficial in decreasing incidence of DVT and should be routinely used, [15, 16] some authors have cited the lack of clear benefit to warrant its use [17–21]. Overall, there appears to be a lack of consensus even among arthroscopy surgeons regarding its utility [22]. In this regard, a consensus study done in collaboration with several leading arthroscopy surgeons in India in 2022 is a pivotal point in this debate. The study concluded that the usage of DVT prophylaxis is justified only in a select group of patients undergoing arthroscopic surgery. The expert responses favoured usage of DVT prophylaxis based on patient factors like advanced age, past history of DVT, smoking, oral contraceptive use etc.[23] We believe this consensus report maybe the closest we have to act as a guideline for DVT prophylaxis, and would recommend following the same.

Infection

Infection is a difficult problem to manage for surgeons, and one that is aggravated by the fact that patients almost always attribute the cause to be a lapse by the surgeon or the surgical team. It is therefore not surprising that occurrence of a post-operative infection can pose not only a clinical problem, but a medicolegal one as well [24]. This is especially true for infection within a short period of time after surgery, which becomes arduous to defend. An analysis of the legal judgements by Indian courts in cases involving post-operative complications reveals that the courts acknowledge that the mere occurrence of a post-operative complication cannot be construed to be medical negligence [25]. However, it is imperative that infections be recognised early and treated accordingly [26]. We believe the failure to diagnose and appropriately treat the infection would be actual deficiency exposing oneself to legal retribution, rather than the occurrence of the infection itself. The legal defence we employ in cases involving post-operative infection would be to demonstrate that sufficient precautionary measures were employed throughout the surgery and follow up by the medical team.

A contentious point in relation to infection in arthroscopy cases would be the use of perioperative prophylactic antibiotics. The overall incidence of infection following arthroscopy is very low, and significantly lower than orthopaedic trauma surgeries and arthroplasties [27, 28]. This is attributed to the smaller incision size, shorter duration of surgeries and minimal soft tissue handling. But this does not mean infections do not occur. The risk of infection is increased considerably in patients with uncontrolled diabetes, immune disorders, etc. The increased use of implants, increased complexity of arthroscopic surgeries and corresponding increase in duration of arthroscopic surgeries can increase the risk of infection further [29]. This then gives rise to the question of prophylactic antibiotics. The use of perioperative prophylactic antibiotics has to be justified sufficiently as they increase costs, can cause adverse drug effects, and possibly contribute to the development of antibiotic resistance [30]. Studies have shown that use of perioperative antibiotics decreases the incidence of septic arthritis and defend its use [31, 32]. Other studies argue that their use may still not be warranted as the benefit in reduction of infection rate is insignificant. [33, 34]. Some authors therefore recommend a middle path of using prophylactic antibiotics only in selectively patients having risk factors for infection and in cases where implants are inserted [35]. While the cost–benefit analysis is still to be conclusively established, we recommend the use of prophylactic antibiotics in all arthroscopy surgeries, as it would be valuable in the legal defence if infection occurs, to demonstrate that all necessary and possible measures to prevent infection were employed by the surgeon.

Other Complications

Arthroscopy involving different joints can potentially cause distinct complications. While the complications are rare, we'd like to address two specific complications that are very often attributed to surgeon negligence. Nerve injury can occur during arthroscopy due to direct damage to nerves while making arthroscopic portals or during surgical manoeuvres, or indirect damage due to traction or pressure mechanisms. The use of a tourniquet can also lead to compression and ischemic nerve injury [36]. Nerve injuries are one of the complications that are difficult to defend in courts of law as it is difficult to attribute it to any reason other than iatrogenic, if it were to arise only after the surgery [37]. Hence it is imperative that arthroscopy surgeons be aware of possible neurological structures that can be damaged in the course of the surgery. If any degree of neurological injury is present before the surgery, it is imperative that the same be documented in the medical records. Prevention of such injuries not only entails a meticulous surgical technique but also simple, yet significant steps, like proper patient positioning and adequate padding of possible nerve compression sites.

Another potential complication which has been pinned on the surgeon is implant failure. There are several instances where, even though the surgical technique was impeccable, a failure of implant due to a manufacturing defect, has left the surgeon facing litigation [38]. Therefore it is vital that the surgeon be aware of various aspects of the implants being used, including verifying the presence of required licences for use of the implant. Discussing the implants with the patient pre-operatively is recommendable as it demonstrates transparency and fosters trust [39].

Operative Notes

One aspect of arthroscopic surgeries distinct from other orthopaedic procedures like trauma surgery, deformity correct, or arthroplasty, is that there it is seldom possible to visually demonstrate the correction of the problem to the patient. Radiographs are useful only if metallic anchors or interference screws are used and even then only depict a part of the procedure conducted and do not reveal the ligament or tendon repaired/reconstructed as such. Post-operative MRIs can depict the soft tissue repair to some extent, but are not commonly done due the expenses involved. When done, they do not necessarily provide a clear picture of the anatomy, and can get further obscured by the presence of metallic implants and artefacts. When there is such lack of demonstrable evidence of the surgical procedure performed, it further increases the significance of proper documentation of operative notes. The operative notes therefore become the most important medicolegal document to settle any legal matter in relation to the surgical procedure [40]. It is important to list all the procedures that were performed, brief steps of the procedures, the findings encountered, any difficulties faced, and implants used. One must remember, that no matter how meticulous the procedure performed, the documentation of operatives notes is still going to be what the courts will assume being representative of what was actually performed. We would also like to mention here that the operative notes are also going to be relied upon heavily by insurance companies and are routinely reviewed before approvals for claims. An omission error of not mentioning the complete procedure or implant used can lead to insurers approving an insufficient amount. If a disputed insurance claim is being reviewed in a court of law, you can be rest assured that the operative notes will be the focal document to determining what procedure was done or which implants were used.

Intraoperative Videography

Another unique problem faced by arthroscopic surgeons is convincing the patient and patient attenders about what was encountered intra-operatively and what was done for it. A few decades back recording the arthroscopic procedure was cumbersome and there were several issues of compatibility and formatting, but today most arthroscopic systems have the provision for simultaneous recording of the arthroscopic visuals, which can be retrieved easily. They say if a picture is worth a thousand words, then a video is worth an entire book. Apart from using the video recordings for teaching purposes, technique demonstrations at medical conferences, publications and surgical review, this has also made it possible for patients to be provided a copy of the recording of the surgery. Many surgeons however would not be willing to hand over the complete video of the surgery to the patient to avoid scrutiny [41]. There may be some justification to that opinion as patients or medical professionals not trained in arthroscopy may incorrectly interpret visuals and create suspicion. The recordings are not without fallacies as well. When only still images are captured, it may be hard to orient oneself to the anatomy, and an image may not be able accurately demonstrate certain dynamic findings. Video recordings provide the entire picture, though not in its truest sense. One must remember that while video recordings of an entire procedure would demonstrate all the arthroscopic visuals seen by the surgeon, it cannot indicate the limb position, clinical assessments of stability, and steps like screw sizing and tightening that still require a 'feel' and not just visual assistance. There is also the problem that most recordings may not necessarily display the patient's name, identification number or date and time of surgery. This would make it susceptible for such videos to be mixed up with those of another patient. If the recordings are being stored, it would have to be done securely, as it contains medical information of the patient, that needs to be kept confidential.

There is no law mandating that the video recording of the surgery has to be handed over the patient, and it remains the individual surgeon's choice. Keeping these recordings could also turn out to be beneficial for the orthopaedic surgeons. It can act as a proof of the findings encountered intra-operatively and of the procedure performed. This is especially useful if there is claim of incorrect diagnosis, incorrect procedure or inadequate surgical technique made against the surgeon. But its utility in a court of law is not full proof. The validity of the video can be challenged by the counsel of the patient if it does not contain the patient details, and can easily be alleged to be of another patient. Providing the copy of the video to the patient at or before the time of discharge and documenting the same, can help indicate transparency, but does not necessarily prove authenticity. Considering all of the above, our recommendation is to store the recordings of all arthroscopic surgeries, but not necessarily handover the same to patients or attenders, or to do so only in selective cases where the surgeon believes it will do more good than harm. We do recommend that, if the patient is not under general anaesthesia during the procedure, he/she be made to view the monitor and be shown the important findings and the final status after the procedure is done.

Specific Arthroscopic Procedures

We analysed the medicolegal cases involving some common arthroscopic procedures with the aim of identifying similarities, trends and valuable lessons from it (Table 2).

Arthroscopic Anterior Cruciate Ligament (ACL) reconstruction and rotator cuff repair of shoulder were focused upon as they are among the most commonly done arthroscopic procedures of the knee and shoulder respectively

Table 2 Most common reasons for litigation following specific arthroscopic surgeries

Most common reasons for litigation following specific arthroscopic surgeries	
Anterior cruciate ligament reconstruction	Post-operative infection
	Inadequate surgical technique/graft malpositioning
	Persistent pain
Rotator cuff repair	Persistent pain
	Loss of range of motion
	Cuff weakness

[42]. With respect to ACL reconstruction, the most common cause for litigations were postoperative septic arthritis followed by the claim of suboptimal surgery [43]. Available data shows that the arthroscopy surgeon is more likely to win the malpractice suit if pain or limited range of motion is the only complaint and less likely to win if a surgical error was alleged [44]. While the mere occurrence of infection following surgery does not necessarily amount of medical negligence, the delay in identification and treatment of post-operative infection has led to the surgeon being held guilty [45]. Interestingly, cases involving the use of hamstring graft for ACL reconstruction were found to have thrice the risk of the surgeon losing the litigation than when bone- patellar tendon- bone grafts were used [46]. One important learning from many of these medicolegal cases involving ACL reconstruction is the need to set realistic expectations of the surgery for the patient [47]. We cannot emphasise enough how important proper patient counselling prior to surgery is, for establishing trust, managing patient expectations and avoiding lawsuits. In many cases the information given to the patient prior to the surgery were found to be inadequate, especially with regards to the need for post-operative rehabilitation therapy [48]. Providing comprehensive information to the patient before the surgery even improves patient satisfaction rates after surgery thereby decreasing the incidence of lawsuits [49]. When it comes to arthroscopic rotator cuff repair, the most common reason for malpractice claims were decreased range of motion, rotator cuff weakness and residual pain [50–52].

Some Indian Cases and Valuable lessons

Lastly we are going to discuss four medicolegal cases involving arthroscopy that have verdicts delivered in Indian Courts. These four cases were chosen for discussion because they are representative of the unique challenges that arthroscopy surgeons may face and have novel learnings not previously addressed in this paper. The names of the individuals and doctors have not been mentioned for the sake of anonymity. We have had to summarise the case details for the sake of brevity, but have attempted to ensure an accurate overview of the case has been given. The purpose of this discussion is not to criticise individuals or pin blame, but rather to have an insightful discussion of the case in order to take away some valuable lessons which can help the readers in their own clinical practice. One must also note the verdicts delivered in these cases are not necessarily to be taken as representative or unequivocal as they could have been/are still being challenged in higher courts.

Case 1: Before the State Consumer Disputes Redressal Commission, Punjab, verdict delivered in December 2015. { First Appeal No. 1466 of 2013} [53]

The patient approached Doctor No.1 due to pain in his left knee and was diagnosed to have left knee ACL tear, and was recommended surgery, to be performed by Doctor No.2, an arthroscopy specialist from another city. On the day of the surgery, there was a delay, and it was discovered that the complainant's name was not on the theatre list. Eventually, the surgery started, but Doctor No.2 stopped it midway, stating that there was an additional problem of Posterior Cruciate Ligament (PCL) tear in the same knee and advised the patient to come to his city for both ACL and PCL surgeries. The patient alleged incomplete surgery and requested a refund, but only a partial amount was returned. The patient filed a complaint seeking compensation. The doctors argued that there was no negligence on their part and claimed that the surgery was not completed due to the discovery of additional damage during the procedure.

The district forum delivered the verdict in favour of the patient. The reasoning given for the same by the district forum was that the additional procedure required for reconstruction of PCL was similar to ACL reconstruction, entailed a counselling or consent similar to the lines of those ACL suggesting it could have been obtained intra-operatively, and if the surgeon did not have the sufficient time for the surgery it should not have been taken up and scheduled at a different time instead. While we do not necessarily agree completely with the remarks of the forum that the PCL reconstruction did not require additional instrumentation, expertise and consent process, there are still some valuable lessons that orthopaedic surgeons can take from this case.

The first is to recognise this problem that arthroscopic surgeons often face, of encountering different problems intra-operatively than those discernable in MRI or pre-operative clinical examination. This is very common, especially with meniscal injuries of the knee. Hence we recommend that all patients be counselled pre-operatively that there is always the possibility of additional/different findings being encountered intra-operatively, that were not revealed/expected preoperatively, and secondly be prepared with a plan of action if such a situation arises. The plan of action would include establishing a policy that an attendant/family member always be available in the hospital premises at the time of the surgery. Preferably this patient representative be chosen by the patient preoperatively and be documented in the case files. Having additional instruments and implants for commonly encountered intra-op conditions would enable the additional procedure to be performed if required. When faced with such a situation intra-operatively, if equipped to perform the additional/different procedure, we recommend giving the choice to the patient and patient representatives and obtain written documentation of their preference to proceed with the procedure/defer it.

Case 2: Before the State Consumer Disputes Redressal Commission, Punjab, verdict delivered in January 2017. {First Appeal No.626 of 2014} [54]

In this case a patient had knee pain and the MRI showed a tear in the lateral meniscus. The surgeon advised the patient to undergo arthroscopic repair of the lateral meniscus. Post the surgery the patient was informed that intra-operatively the lateral meniscus was found to be normal but the ACL was torn, and hence the ACL was reconstructed. The patient claimed that the wrong surgery was done, that the lateral meniscus should have been repaired, and that there was no ACL Tear as it was not seen in the MRI. Despite the doctors' attempts at explaining to the commission that the MRI is only predictive and not as accurate as seeing the structures arthroscopically, the courts delivered a verdict against the doctor.

This case is a reversal of the previous case. Here there was a new intraoperative finding, which was treated, and yet the surgeons were held to be negligent. This reiterates the point we made earlier that when faced with new findings intra-operatively compared to what was anticipated preoperatively, there is no one option (proceeding with the new procedure or not performing the procedure) that can necessarily ensure legal safety. Instead the choice should be made by the patient and their choice among the two options should be documented in writing. There are other learning opportunities here. We believe the reason why the verdict went against the surgeon was that they had no evidence to show that intra-operatively there was an ACL tear and lateral meniscus was normal. A video recording of the surgery could have been quite useful in this case to convince the patient and the judge about the intra-operative findings.

Case 3: Before the National Consumer Disputes Redressal Commission, New Delhi, verdict delivered in October 2020. {Revision Petition No. 5028 of 2008} [55]

A patient complaining of knee pain was found to have loose bodies in the knee joint in the radiographs and MRI, and was recommended to undergo arthroscopic loose body removal by the orthopaedic surgeon. The patient filed a lawsuit against the surgeon stating that instead of an arthroscopic procedure, an open procedure (arthrotomy) was done for the loose body removal. The surgeon contested that during the arthroscopy the loose bodies were found to be quite large, measuring approximately 1 cm, and hence required to be removed by arthrotomy. The court ruled in favour of the surgeon in this case.

It is important to note here that what swung the case in the favour of the surgeon was the fact that the patient was explained before the surgery itself that if the arthroscopy was not successful, open surgery would be done and the same was documented in the case sheet. The reason we chose to discuss this case is because it deals with the scenario of having to change an arthroscopy case to an open case intra-operatively, a situation commonly encountered by arthroscopic surgeons for a host of different conditions. While it is less common for conditions of the knee, it is much more common for certain conditions of the shoulder, especially severely retracted rotator cuff tears. It is our recommendation therefore, that the informed consent form obtained for arthroscopic procedure, have it mentioned that, if it is found intra-operatively that the condition cannot be address sufficiently arthroscopically, then a mini-open/open procedure will be required.

Case 4: Before the National Consumer Disputes Redressal Commission, New Delhi, verdict delivered in October 2020 {Revision Petition No. 2195 of 2016} [56]

A patient was diagnosed to have meniscus tear based on MRI. The patient underwent an open meniscectomy. The patient claimed that this was the wrong treatment advised and performed by the surgeon, and that an arthroscopic meniscal repair should have been done instead. The court gave the verdict in favour of the surgeon.

In the previous case no.3 discussed above an arthroscopic procedure was advised, attempted and converted to an open approach. In this case however, the surgeon had advised an open procedure itself as there was no arthroscope at the hospital. So the question here was whether it was acceptable for a procedure that is routinely done arthroscopically to be done as an open procedure. The court remarked that it is not negligence for a surgeon to choose to perform a procedure as long as it is an accepted mode of treatment. While it may be inferior to arthroscopic procedure in some ways, it would still not constitute to be negligence as it was an established, accepted procedure for the treatment of meniscal tear. We must also be aware that not all medical establishments in the country have the same resources and instrumentation, and such factors also play a role in deciding the appropriateness of treatment.

We have summarised our recommendations to decrease the medicolegal risk for arthroscopic surgeries in Table 3. We believe the recommendations are practical and enforceable by individual surgeons, departments and hospitals across

Table 3 Our recommendations to decrease the medicolegal risk for arthroscopic surgeries

12 recommendations to decrease medicolegal risk for arthroscopic surgeries
Use a WHO Surgical Safety Checklist for every surgery to avoid wrong sided surgery
Cross check side of surgery with patient, case file and imaging films before incision
Give DVT prophylaxis for high risk patients like advanced age, past history of DVT, smoking and oral contraceptive use
Use prophylactic antibiotics during the perioperative period
Identify any post-operative complication early and treat it appropriately. Avoid trying to conceal the complication or dismissing it
Use good quality implants which have the necessary licences for use
Ensure operative notes are detailed and include all the procedures performed and implants used
Store video-recordings of all the surgeries if possible
Ensure patient has realistic expectations from the surgery
Explain to the patient before the surgery that the MRI and clinical examination are not always entirely accurate, and the condition can only be conclusively known after arthroscopy
When faced with an unplanned situation intra-operatively, obtain informed written consent of the patient to proceed with/defer the procedure
In the informed consent, always mention that the procedure may need to be converted to an open procedure if arthroscopic management is deemed insufficient for the case

country without requiring additional significant effort or resources. They would not only safeguard the doctors from litigation, but also help improve patient-doctor communication, increase trust and clinical outcomes.

Conclusion

Malpractice lawsuits are constantly on the rise, and arthroscopic surgeons are going to have to encounter them. It is therefore important for surgeons to be aware of some of the unique medicolegal aspects of arthroscopy. Being cognizant of these factors and incorporating the necessary changes in one's clinical practice will help prevent litigation and make the surgeon's defence much stronger in a court of law.

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REVIEW ARTICLE

There is a Minimal Difference in Ankle Functional Outcomes After Peroneus Longus Harvest: Systematic Review and Meta-analysis

A. Saoji[1] · M. Arora[2] · G. Jain[3] · T. Shukla[4]

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Abstract

Importance Recently, peroneus longus (PL) autograft as a graft choice for ligament surgeries have attracted interest due to studies showing good clinical outcomes and minimal donor site morbidity. There remain concerns related to these grafts, especially the potential impact on ankle functions.

Aims/Objective The purpose of this review and meta-analysis is to summarize the available evidence for ankle functional outcomes after PL harvest. This will provide objective clinical evidence for surgical decision making.

Evidence Review Cochrane, Embase, Medline, and Google Scholar were all searched for articles published between January 2001 and May 2021. For the aim of a systematic review, certain inclusion and exclusion criteria were adopted in accordance with PRISMA recommendations. The primary outcome measure was the assessment of ankle functional outcomes using validated instruments (such as AOFAS score, FADI score etc.)

Findings A total of twelve studies representing pooled patient populations of 537 patients were included in this review. The average follow-up duration was 17 months (range; 6–32 months) across all studies. All twelve studies assessed AOFAS score and six studies also additionally assessed FADI score. The pooled mean outcomes measured showed a slight decrease in post-operative as compared to pre-operative AOFAS and FADI score (mean difference of AOFAS 1.92, 95% CI 1.021–3.123, p value < 0.05 and mean difference for FADI 1.50, 95% CI 0.561–2.445, p value < 0.05). Though statistically significant the magnitude of variance implies minimal clinical impact.

Conclusion and Relevance This review and meta-analysis found that PL autograft harvest leads to statistically significant but minimal impact on ankle functional outcomes. This, in conjunction with various studies on ankle parameters after PL harvest, shows that PL harvest leads to minimal impact on ankle outcomes and function.

Level of Evidence Systematic review Level III.

Keywords Peroneus longus autograft · Ankle function · Anterior cruciate ligament · ACL reconstruction autograft · Systematic review · Meta-analysis

Abbreviations

ACL	Anterior cruciate ligament
HT	Hamstring tendon
PL	Peroneus longus
AOFAS	American Orthopaedic Foot and Ankle Society
FADI	Foot and Ankle Disability Index
PCL	Posterior cruciate ligament
MCL	Medial collateral ligament
LCL	Lateral collateral ligament
CI	Confidence interval

✉ A. Saoji
Saojiamit04@gmail.com

M. Arora
Manit_arora@hotmail.com

G. Jain
dr.gaurav.jain09@gmail.com

T. Shukla
Tapish.shukla20@gmail.com

1 Department of Orthopedics, Datta Meghe Institute of Medical Sciences, Jawaharlal Nehru Medical College, Sawangi Meghe, Wardha, Maharashtra, India

2 Department of Orthopedics and Sports Medicine Fortis Hospital, Mohali, Punjab, India

3 Orthopedics, GBH American Hospital, Udaipur, Rajasthan, India

4 Fortis Hospital, Mohali, Punjab, India

Introduction

Various grafts options are available for ligaments reconstruction including autografts, allografts and synthetic grafts. The ideal graft should be biomechanically similar to native ligament, be easily harvestable and have the least harvest site morbidity [1, 2]. The majority of current graft options for knee ligament surgery are knee-based grafts, namely the hamstrings, bone-patellar tendon-bone (BPTB) and quadriceps. The harvest of these knee-based grafts has several potential disadvantages, such as anterior knee pain, hamstring pain, patella fracture or quadriceps-hamstring imbalance after graft harvest [3, 4]. At present there is no ideal graft for reconstruction with each graft choice having its own limitations and advantages [1, 2]. The potential disadvantages of these knee based grafts have led to a search for non-knee based grafts.

Recently, peroneus longus autograft have become a more popular option for various ligament surgeries. Several clinical studies have shown good clinical outcomes and minimal donor site morbidity with peroneus longus autografts [5]. Rudy et al. reported no significant difference in tensile strength between the peroneus longus autograft (446.1 N ± 233.2 N) and a four-strand hamstring graft (405.8 N ± 202.9 N) with the same cross-sectional area [6].

A recent systematic review on functional outcomes of knee after peroneus longus autograft showed comparable knee functional scores compared with hamstring autograft [7]. Despite similar clinical outcomes, the popularity of peroneus longus autografts remains low due to a variety of reasons. One of the main reasons is surgical perception of graft impact on donor site with possible sequelae of impact on ankle function, local complications and possible changes in gait and biomechanics of the ankle joint.

The purpose of this review is to analyse all available evidence on the impact of peroneus longus autograft harvest on ankle functional outcomes and to provide objective clinical evidence for surgical decision making.

Methods

Criteria for Considering Studies for this Review

A comprehensive search of the published literature in PubMed, Web of Science, Cochrane Library, Ovid (MEDICINE), and EMBASE databases was performed for the period of January 2001–May 2021 according to Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines [8]. The following search phrases were used: ("Peroneus longus graft" OR "fibularis longus graft") AND (Ankle function) AND ("anterior cruciate ligament" OR "ACL reconstruction") AND posterior cruciate reconstruction or PCL reconstruction AND multiple ligament reconstruction. Various synonyms of the above ere also entered into the search systems.

Inclusion and Exclusion Criteria

All clinical studies of peroneus longus autograft which reported ankle functional outcomes with validated instruments were included in the analysis. There was no bias related to any ankle outcome used. Any study which did not report ankle functional outcome using a validated instrument was excluded from the analysis. No bias was applied to whether the study examined role of autograft in ACL, PCL multi ligament or other surgeries.

Types of Participants

All patients who underwent any ligament reconstruction with PL autograft were included. No restrictions were applied to types of ligaments tear and reconstruction that are ACL, PCL, MCL, LCL, and other surgeries.

Types of Outcome Measures

The outcomes of interest included all ankle functional outcome scores. The two most commonly used are The American Orthopedics Foot and Ankle Society (AOFAS) and Foot and Ankle Disability score (FADI). However, no bias was applied to the inclusion of ankle functional outcomes as long as they were validated instruments.

Types of Studies

The only randomised controlled studies would be taken into account in this review. The scope search was widened to include all studies, regardless of the strength of the evidence, due to the lack of studies in this category. These included non-randomized studies with more than 10 patients (comparative and single intervention groups). There were no language limits, and ways of translation were to be looked into for any included non-English research that were found. Review papers, editorials, and single case studies were also discarded, along with in vitro and animal investigations.

Search Methods for the Identification of Studies

Embase was used to create a search method that was then modified for use with other electronic databases. The searches were done from January 2001 to May 2021, covering a period of 21 years' worth of information. Using the predetermined search strategy, the following electronic databases were searched through the OVID and Cochrane Library platforms:

The Cochrane Library.

Ovid Medline, 1946 to present.

Ovid Embase, 1980 to present.

Google Scholar, 2001 to present.

Reference lists of available studies and any reviews were scanned in addition to identify further studies.

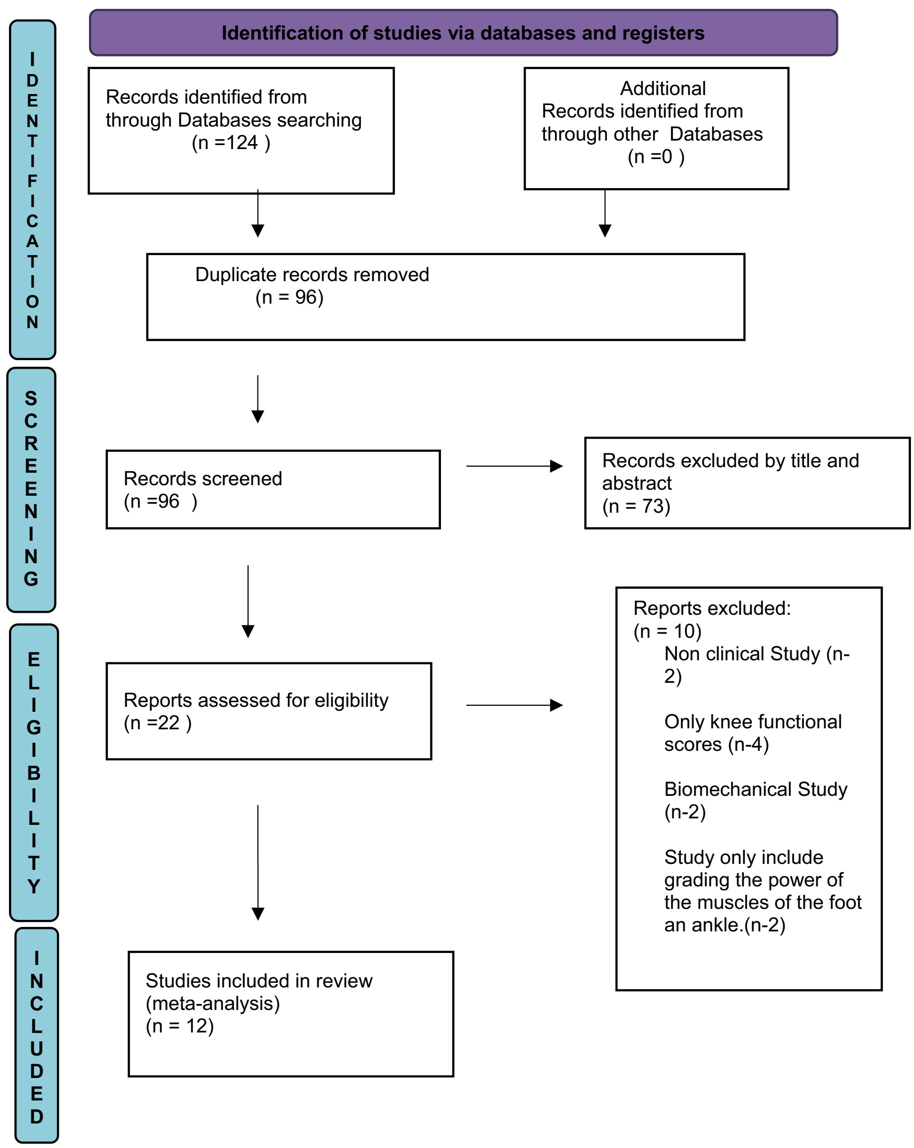
Selection of Studies

Two lead researchers (AS and MA) screened all titles and abstracts identified from the search strategy independently. If the preliminary screening revealed that the selected research were potentially relevant, full reports were requested. The evaluation was to include all complete reports that satisfy the inclusion requirements. At each level, reasons for exclusion were noted and described in a PRISMA flow diagram (Fig. 1). A third independent reviewer (GJ) was kept on standby to resolve any disputes between the primary two reviewers if they were to occur. The search methodology and study selection was conducted in accordance with PRISMA guidelines.

Data Extraction, Management and Evidence Synthesis

All relevant details from studies, including study design, patient population, and functional outcomes, was extracted using a standard data extraction table. A typical meta-analysis was conducted using patient data that had been combined and presented data. When there was a lack of data, the authors of the relevant studies were contacted and asked for

Fig. 1 PRISMA chart



the raw data. Study characteristics of the included studies are presented in Table 1.

Statistical Analysis of Data

The meta-analysis was carried out using AOFAS and FADI scores as the outcome variables. Paired comparisons of pre-operative and postoperative AOFAS and FADI scores was carried out using StatsDirect Statistical Software version 2.8.0 (http://www.statsdirect.com; 2013). Statistical significance was defined as a *p* value of less than 0.05. we used Begg nad Mazumdar' test for assessing the publication bias.

Results

A total of 12 studies meeting inclusion and exclusion criteria were included in this review representing total pooled patient population of 537 patients. The average follow-up duration was 17 months (range; 6–32 months) across all studies. All twelve studies assessed AOFAS score and six studies additionally assessed FADI score. Secondary outcomes measured in terms of VAS score in one study and Karlsson–Peterson score assessed in another study, were excluded from meta-analysis due to low frequency. All AOFAS and FADI studies were included in the meta-analysis.

Twelve studies evaluated AOFAS score in 537 patients treated with PL autograft showed significant difference in the mean pre-operative and post-operative score with a mean difference AOFAS score of 1.92 (95% CI 1.021–3.123; $p < 0.05$) There is significant heterogeneity being reported (Q Statistic—389.87, p-value < 0.001) and there is clear evidence of non-existence of publication bias (Kendall's tau = − 0.49, p-value > 0.05) which is summarised in Table 2 and Fig. 2.

Six studies evaluated FADI score in 337 patients treated with PL autograft showed significant difference in the mean pre-operative and post-operative score with a mean difference FADI score of 1.50 (95% CI = 0.561–2.445; $p < 0.05$) There is significant heterogeneity being reported (Q Statistic—354.12, p-value < 0.001) and there is clear evidence of non-existence of publication bias (Kendall's tau = − 0.58, p-value > 0.05) which is summarized in Table 3 and Fig. 3.

Discussion

PL autografts have attracted interest in recent years due to similar knee functional outcomes as compared to hamstring grafts and minimal donor site morbidity. There remains concerns related to their potential impact on ankle function, hence the necessity of this systematic review.

The main function of the peroneus longus is to evert the foot and plantar flex the first ray so there is concern of decrease in eversion strength and loss of foot arch after peroneus longus autograft harvest. Studies have shown that there was no significant difference identified in ankle eversion strength and first ray plantar flexion strength at the donor site compared to the contralateral side [10]. Fu-Dong Shi et al. also showed no difference preoperative and postoperative ankle range of motion after peroneus longus autograft harvest [20].

Another potential concern after PL harvest has been post-operative ankle stability; however, Sheo et al. showed no clinical pathological change in pre- and post operative hindfoot alignment, anterior drawer test, talar tilt test and range of ankle movements [17]. Current studies also show that minimal influence of PL autograft harvest on ankle and foot functions. Rhatomy et al. shows excellent scores of single hop test and triple hop test, as well as cross-over hop

Table 1 Study characteristics

Authors	Country	Year of publication	Cases	Male	Female	Average follow up (months)
Ravi Kumar et al. [9]	India	2020	100	80	20	12
Rhatomy et al. [10]	Indonesia	2019	31	22	9	6
Chayanin Angthong MD et al. [11]	Thailand	2015	24	15	9	12.8
Rhatomy et al. [5]	Indonesia	2019	24	20	4	12
Wu chang et al. [12]	China	2019	28	22	6	20.7
Dung Tran Trung et al. [13]	Vietnam	2019	30	19	11	6
Hong Bin Cao et al. [14]	China	2012	35	30	5	15
Riky Setyawan et al. [15]	Indonesia	2019	15	11	4	24
Rhatomy et al. [16]	Indonesia	2020	75	59	16	24
Shao et al. [17]	China	2020	21	8	13	31.8
Minggang Bi et al. [18]	China	2018	62	34	28	30 ± 3.6
Jinzhong Zhao et al. [19]	China	2011	92	31	61	24

Table 2 Meta-analysis of effect sizes of mean difference of AOFAS score

Study ID (Stratum)	*n* (Pre)	*n* (Post)	Mean difference (d)	Approx 95% CI of d		Authors
			AOFAS score	Lower	Upper	
1	100	100	2.13	1.740	2.521	Ravi Kumar et al. [9]
2	31	31	1.29	0.585	1.994	Rhatomy et al. [10]
3	24	24	4.00	2.799	5.200	Chayanin Angthong et al. [11]
4	24	24	2.70	1.499	3.900	Rhatomy et al. [5]
5	28	28	1.71	0.599	2.821	Wu Chang et al. [12]
6	30	30	0.20	− 0.516	0.916	Dung Tran et al. [13]
7	35	35	3.70	2.706	4.693	Hong Bin et al. [14]
8	15	15	5.54	3.516	7.564	Riky Setyawan et al. [15]
9	75	75	1.07	0.391	1.749	Rhatomy et al. [16]
10	21	21	0.20	− 0.655	1.055	Shao et al. [17]
11	62	62	0.30	− 0.198	0.798	Minggang Bi et al. [18]
12	92	92	0.20	− 0.209	0.609	Jinzhong Zhao et al. [19]

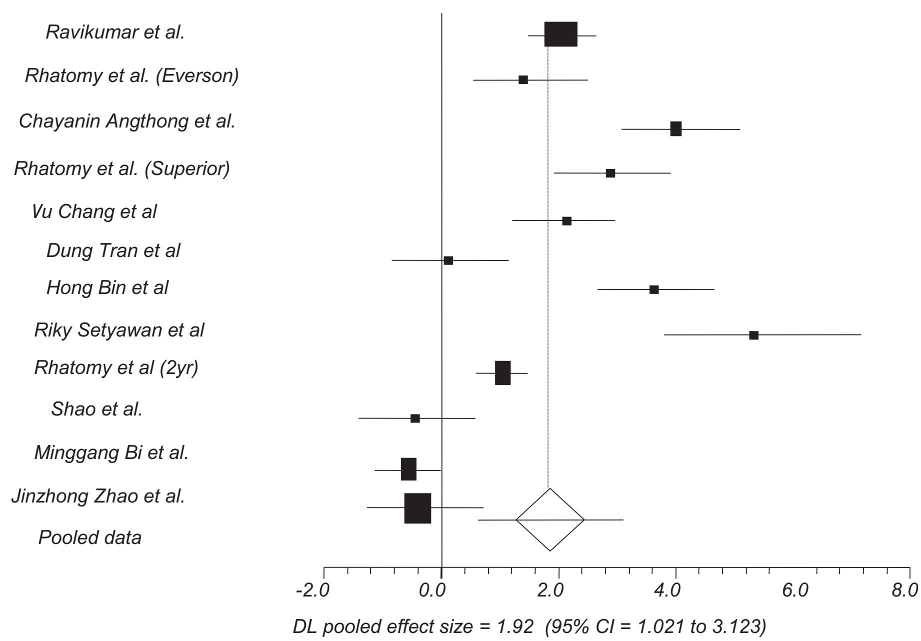


Fig. 2 Forest plot showing the effect sizes with 95% confidence interval (CI) found in the studies for mean difference of AOFS score in the meta- analysis

Table 3 Meta-analysis of effect sizes of mean difference of FADI score

Study ID (Stratum)	*n* (Pre)	*n* (Post)	Mean difference (d)	Approx 95% CI of d		Authors
			FADI Score	Lower	Upper	
1	100	100	1.02	0.432	1.608	Ravi Kumar et al. [9]
2	31	31	0.29	− 0.766	1.346	Rhatomy et al. [10]
4	24	24	2.00	0.799	3.200	Rhatomy et al. [5]
8	15	15	5.20	3.682	6.718	Riky Setyawan et al. [15]
9	75	75	0.21	− 0.469	0.889	Rhatomy et al. [16]
12	92	92	0.30	– 0.313	0.913	Jinzhong Zhao et al. [19]

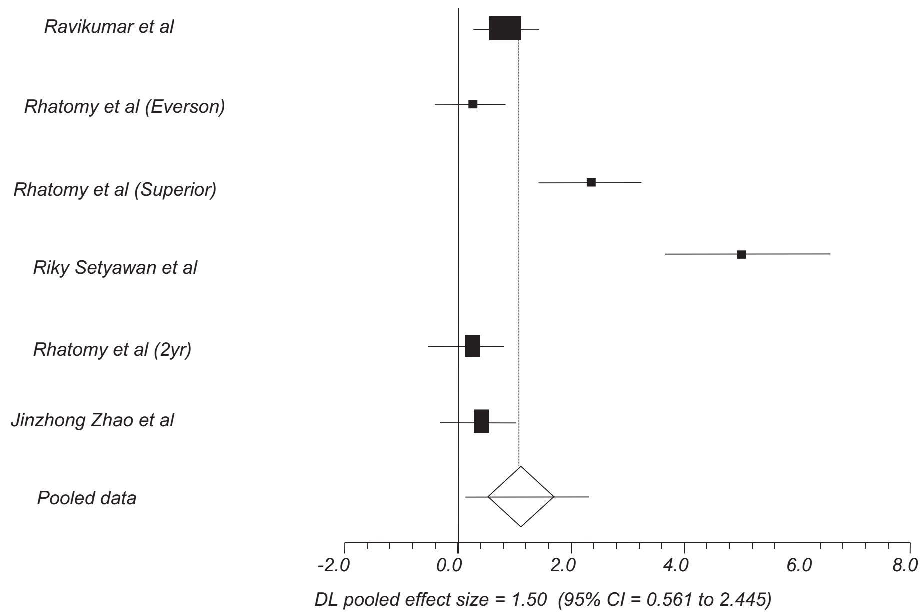


Fig. 3 Forest plot showing the Effect sizes with 95% confidence interval (CI) found in the studies for mean difference of FADI score in the meta-analysis

test and timed hop tests [16]. Further, B. L. Khajotia et al. and Kumar V. K et al. showed that the ankle functions were grossly preserved in all patients with no difference in Medical Research Council (MRC) grading of muscle power of the harvested leg compared with the contralateral leg [9, 21].

Concern about torque of ankle muscle after PL harvest, normally peak eversion force not requirement for daily activities and eversion strength is more important for rapid change of direction which mainly needed for sports activity [22]. Chayanin Angthong MD et al. measured the torque of ankle muscle using isokinetic dynamometer found that there was significantly lower peak torques of eversion and inversion on the harvested ankle compared with the contralateral ankle [11]. However, Fu-Dong Shi et al. also measured the torque of ankle using robotic dynamometer; they found that there was no statistical difference in amount of torque lost in eversion and inversion on the harvested ankle as compared with the normal ankle after 2 years of follow up [20].

The current meta-analysis shows that there is a statistically significant difference in pre-operative and post-operative ankle functional outcomes (AOFAS and FADI scores) after peroneus longus autograft harvest. Despite being statistically significant, the magnitude of the difference between preoperative and postoperative functional outcomes is small specifically 1.92 (95% CI 1.021–3.123) for AOFAS and 1.50 (95% CI 0.561–2.445) for FADI Score. This likely represents minimal clinical impact on ankle functional outcomes. These findings, in conjunction with the above literature on various ankle parameters, shows that PL autograft has minimal impact on the ankle. It is clear that PL graft harvest does not affect a range of ankle parameters as was previously postulated (range of motion, stability, movement of specific joints, power of movement etc.). This may lead to a wider acceptance of PL autografts, making the role of the present systematic review even more important. When taken in concert with the above studies, the present review shows minimal impact on clinical ankle functional outcomes after PL harvest.

The above data, in combination with available evidence of similar knee functional outcome as compared to hamstring grafts [7] shows that PL autograft is a safe and effective graft choice with comparable knee parameters to other grafts with minimal harvest site morbidity and impact on ankle functional outcomes.

Local complication like, bulging of proximal stump, numbness (sural nerve neurapraxia) found in few studies which resolved within 1–6 months.

The limitations of this systematic review and meta-analyses include the low number of studies included (12 studies) and the low level of evidence (lack of RCTs). There is a need for larger, longer and higher evidence studies to better understand the impact of PL grafts on ankle functional outcomes.

Conclusion

A total of twelve studies were includes in our systematic review and meta-analyses with a pooled population 537 patients. We found that PL autograft harvest leads to statistically significant change in ankle functional outcomes (AOFAS and FADI scores); however, the magnitude of such change is small and likely represents minimal clinical impact on ankle outcomes.

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Data availability Not applicable.

Declarations

Conflict of interest The authors declare that they have no conflicts of interest.

Ethical Approval None of the authors of this article have conducted any experiments using humans or animals.

Informed Consent No informed consent was required for this study.

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ORIGINAL ARTICLE

Inter- and Intra-observer Reliability of a New Classification System for Calcaneus Fracture Malunions: The ADEINS Classification

Rajiv Shah[1] · Siddhartha Sharma[2] · Rajeev Vohra[3] · Nikeh Shah[4] · Ankit Khurana[5]

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Abstract

Background Currently, two classification systems, namely Stephens and Sanders, based on axial CT images, and Zwipp and Rammelt, which consider deformities, are used for calcaneus malunions. Existing classifications have limitations due to their pure anatomical basis, and the complexity of the problem, involving both bone and soft tissues. As a solution, the senior author proposed a novel ADIENS classification system for calcaneal malunion, based on pain generators. This study aimed to introduce and evaluate the inter- and intra-observer reliability of a new classification system for calcaneal malunions.
Methods This retrospective cohort study included adult cases with post-traumatic calcaneus malunion. Three experienced foot and ankle surgeon volunteers underwent training session on the classification system, which classifies malunions based on *A* arthritis, *D* deformity, *E* exostosis, *I* implant issues, *N* nerve issues, and *S* soft tissue issues. Post-training, two rounds of classification exercises were conducted. Inter-rater and intra-rater agreements were determined using Gwet's AC coefficient.
Results Out of 15 cases, 6 were of Stephen and Sanders types, and 8 were of Zwipp and Rammelt types, the rest fell out of these classifications. Inter-rater agreement for ADEINS classification was noted to be 'very good' for all six domains. Intra-observer agreements were 'very good' for four out of six domains of classification and 'fair' for two domains of classification.
Conclusion Pain generators-based new ADEINS classification has demonstrated good intra- and inter-observer reliability and seemed user-friendly. However, results need to be replicated in a larger, multicentric cohort before wider clinical applicability.
Level of Evidence Level IV, retrospective study.

Keywords Calcaneus malunion · Stephens and Sanders classification · Zwipp and Rammelt classification · ADEINS classification · Pain generators

✉ Rajiv Shah
rajivortho@gmail.com

Siddhartha Sharma
sids82@gmail.com

Rajeev Vohra
vohra.r2@rediffmail.com

Nikeh Shah
nikeshreena@gmail.com

Ankit Khurana
ankit24388@gmail.com

1 Foot & Ankle Orthopaedics, Sunshine Global Hospital, Vadodara, Gujarat, India

2 Department of Orthopaedics, Postgraduate Institute of Medical Education and Research (PGIMER), Chandigarh, India

3 Amandeep Hospital, Amritsar, India

4 Indrapuri Hospital, Vadodara, India

5 BSA Medical College and Hospital, Delhi, India

Introduction

Malunions after calcaneal fractures are complex and present with a multitude of symptoms, the most common of which is pain [1–4]. Pain &&and the consequent disability in calcaneal malunions are multifactorial, and accurate recognition and documentation of pain generators in such cases are paramount [5–9]. In 1996, Stephens and Sanders introduced the first axial CT-based classification system for calcaneal malunions; however, this classification system was limited to intra-articular malunion cases only [10]. In 2003, Zwipp and Rammelt proposed a deformity-based classification system, which included six categories ranging from Type 0 to Type V and provided management guidelines on each malunion type [11, 12]. Despite these efforts, many calcaneal malunion cases are difficult to classify via the Stephens and Sanders or Zwipp and Rammelt systems. Moreover, neither of the existing classifications considers the multifactorial nature of morbidity after a calcaneal malunion, which can include arthritis of one or more joints, a variety of deformities, and nerve, implant, and soft tissue issues. Furthermore, the existing classification systems focus principally on the anatomical aspects of the calcaneal malunion, which may or may not be the source of pain in a particular patient. Considering these limitations, the senior author proposed a new classification system, referred to as the '*ADEINS*' system, which consists of six 'domains', including arthritis, deformity, exostosis, implant, neurological, and soft tissue problems. Each of the six domains represents a potential source of pain and morbidity and allows surgeons to evaluate the pathoanatomy of the malunion concerning the patient's symptoms. Hence, the present study was performed to describe the new classification system and to assess its inter- and intra-observer reliability for calcaneal malunions.

Methods

Study Design and Sample Size

This retrospective cohort study identified patients from the senior author's foot and ankle database. The study was conducted in strict accordance with the GRRAS guidelines [13]. Since the study was retrospective in nature and involved a review of radiographs and CT scans only, ethics committee clearance was not sought. To determine the appropriate sample size, we used an online calculator, which is available at https://wnarifin.github.io/ssc/sskappa.html. Assuming an expected kappa of 0.90, precision of 0.25, alpha of 95%, proportion of expected outcome as 0.5, and no dropouts, the desired sample size was determined to be 12. However, we included 15 cases, for ease of calculations.

Inclusion and Exclusion Criteria

Adult (> 18 years) patients of any gender, diagnosed with a post-traumatic calcaneus malunion were included. Patients with incomplete radiology (missing radiographs and/or CT scans) and incomplete clinical details were excluded. Patients with pathological fractures, infections, and pre-existing congenital or neurological foot deformities were excluded.

Proposed Classification System—The ADEINS Classification

Based on the extensive experience of the senior author in managing calcaneus malunions over several decades, a new classification was developed. The classification consists of six domains, each of which represents a potential pain generator in patients with calcaneus malunion. These include arthritis, deformity, exostosis, implant issues, neurological issues, and soft tissue problems. The details of this classification system are presented in Table 1.

Data Sources and Variables

The patients' clinical records were evaluated in detail and the following baseline variables were determined: (a) age, (b) gender, (c) mechanism of injury, (d) clinical examination, including the presence of heel deformity, heel height loss, and any neurological issues, (f) any soft tissue problems (e.g., claw toes). Radiographs and CT scans were also studied in detail and the following parameters were determined: (a) arthrosis of the subtalar, calcaneocuboid, ankle, talonavicular or any other foot joint, (b) deformity—varus or valgus deformity of the heel, broadening of the heel, loss of heel height, presence of horizontal talus with consequent anterior ankle impingement, (c) presence of exostosis (lateral, medial, posterior, and plantar), (d) presence of an implant. A PowerPoint slide show database was created for each case included in the study, and this consisted of anonymized radiographs, relevant CT scan images, and clinical details. The database was then used to determine inter- and intra-observer reliability of the new classification.

Table 1 The ADEINS classification system for calcaneus malunions

Domain	Description	Evaluated on
Arthritis	Radiological and/or clinical arthritis of the subtalar, calcaneocuboid, ankle and midfoot joints	Clinical examination, radiographs, and CT scans
Deformity	Varus or valgus heel, broadening of the heel, heel height loss with or without horizontal talus resulting in anterior ankle impingement	Clinical examination, radiographs, and CT scans
Exostosis	Lateral, medial, posterior or plantar exostosis	Clinical examination, radiographs, and CT scans
Implant	Presence of an implant resulting in pain or discomfort	Clinical examination, radiographs, and CT scans
Neurological issues	Injury to the sural nerve, posterior tibial nerve, tarsal tunnel syndrome, etc	Clinical examination, NCV, MRI
Soft tissue issues	Soft tissue problems secondary to the initial trauma or malunion, including claw toes	Clinical examination and/or radiographs

Table 2 Baseline demographics

Variable	Value
Age	38 (24–49)
Gender	
Male	12
Female	3
Side	
Right	10
Left	5
Mechanism of injury	
Fall from height	11
Road accident	4
Stephen and Sanders classification	
I	0
II	0
III	6 (9 cases could not be classified)
Zwipp and Rammelt classification	
0	0
I	2
II	6
III	0
IV	0
V	0 (7 cases could not be classified)
ADEINS classification	
AD	1
AE	2
ES	1
ADE	5
ADES	2
ADEN	1
ADNS	1
ADENS	1
ADEINS	1
Arthritis	
Subtalar	14
Calcaneocuboid	3
Talonavicular	2
Ankle	1
Subtalar + calcaneocuboid	3
Subtalar + calcaneocuboid + talonavicular	2
Subtalar + calcaneocuboid + talonavicular + ankle	1
Deformity	
Varus	11
Valgus	1
Heel shortening	9
Claw and hammer toes	5
Exostosis	
Lateral	12
Medial	2
Plantar	4
Posterior	2
Lateral + medial	1
Lateral + posterior	1

Table 2 (continued)

Variable	Value
Lateral + plantar	1
Lateral + medial + plantar	1
Implant issues	1
Neurological issues	
Sural	3
Posterior tibial	4
Sural + posterior tibial	3
Soft tissue issues	
Peroneal tendon dislocation	2
Heel fat pad atrophy	1
Complex regional pain syndrome	1

Table 3 Classification of calcaneus malunion cases under all three classifications

Case number	Stephens and Sanders classification	Zwipp and Rammelt classification	ADEINS classification
1	Not classifiable	Not classifiable	ADEN
2	Type III	Type II	AD
3	Not classifiable	Type I	AE
4	Type III	Type II	ADE
5	Not classifiable	Not classifiable	ADES
6	Not classifiable	Not classifiable	ADENS
7	Not classifiable	Not classifiable	ADNS
8	Not classifiable	Not classifiable	ADEINS
9	Type III	Type II	ADE
10	Not classifiable	Type I	AE
11	Type III	Type II	ADE
12	Not classifiable	Not classifiable	ES
13	Type III	Type II	ADE
14	Not classifiable	Not classifiable	ADES
15	Type III	Type II	ADE

Table 4 Results of inter-rater agreement for different domains of the ADEINS classification for calcaneal malunions

Domain	Percentage agreement	Gwet's AC	95% confidence intervals	*P* value
Arthritis	100	1	1–1	< 0.0001
Deformity	86.7	0.85	0.65–1	< 0.0001
Exostosis	86.7	0.85	0.65–1	< 0.0001
Implant issues	86.7	0.85	0.65–1	< 0.0001
Neurological issues	95.6	0.93	0.76–1	< 0.0001
Soft tissue issues	91.1	0.82	0.56–1	< 0.0001

All results calculated from Round 1

Inter-rater Agreement of the Proposed Classification System

Three experienced, fellowship-trained foot and ankle surgeons who voluntarily agreed to participate were chosen for determining the inter- and intra-observer reliability of the proposed classification. A training session was conducted, and the classification was described in detail. The raters were given three example cases to demonstrate their understanding of the classification system and to provide opportunities for clarification. No further clarifications were allowed thereafter. Subsequently, a dataset of 15 patients with calcaneal malunion was provided to each rater, and they were asked to classify each case as per the proposed classification system. The observers were not allowed to discuss their responses with each other. Responses were collected through pre-piloted, anonymized web-based surveys (Google Forms). Two weeks after the first round, the three raters were asked to rate the same dataset; however, the order of cases was randomly rearranged to prevent any recall bias.

Statistical Analysis

The assessment of inter-rater and intra-rater agreement was conducted using the percentage of agreement and Gwet's AC coefficient. The traditional method of determining inter-rater agreement, Cohen's Kappa coefficient, can sometimes provide a misleading estimate of agreement when the prevalence of an outcome is low. This phenomenon, known as the "Kappa Paradox," is avoided using Gwet's AC coefficient, which is not affected by the prevalence of outcome variables [14]. The Gwet's AC coefficient was rated on a scale of − 1 to 1, with values ranging from "very good" (0.81–1.00), "good" (0.61–0.80), "moderate" (0.41–0.60), "fair" (0.21–0.40), to "poor" (less than 0.20), as per the recommendations of Altman. 95% confidence intervals and *P* values were reported for all estimates, and *P* values less

Table 5 Results of the intra-rater agreement for different domains of the ADEINS classification for calcaneal malunions

Observer	Domain	Percentage agreement	Gwet's AC	95% confidence intervals	*P* value
Observer 1	Arthritis	93.3	0.93	0.77–1	< 0.0001
	Deformity	93.3	0.93	0.77–1	< 0.0001
	Exostosis	93.3	0.93	0.77–1	< 0.00011
	Implant issues	0.73	0.65	0.24–1	0.004
	Neurological issues	93.3	0.89	0.63–1	< 0.0001
	Soft tissue issues	86.7	0.74	0.36–1	0.001
Observer 2	Arthritis	93.3	0.93	0.77–1	< 0.0001
	Deformity	1	1	1–1	< 0.0001
	Exostosis	86.7	0.83	0.54–1	< 0.0001
	Implant issues	93.3	0.91	0.70–1	< 0.0001
	Neurological issues	86.7	0.76	0.40–1	0.001
	Soft tissue issues	93.3	0.88	0.60–1	< 0.0001
Observer 3	Arthritis	1	1	1–1	< 0.0001
	Deformity	80	0.72	0.35–1	0.001
	Exostosis	0.93	0.93	0.77–1	< 0.0001
	Implant issues	93.3	0.91	0.70–1	< 0.0001
	Neurological issues	86.7	0.76	0.39–1	0.001
	Soft tissue issues	86.7	0.73	0.35–1	< 0.0001

than 0.05 were considered significant. The data analysis was performed using Stata MP version 17.0.

Results

Baseline Demographics

A total of 18 patients were included in the study. Of these, 3 were used to train the observers and 15 were used for agreement analysis. The mean age of patients was 38 years. Most of the patients were males, the right side was commonly involved, and the most common mechanism of injury was fall from a height. Six cases had Stephen and Sanders Type III malunion. Six cases had Zwipp and Rammelt Type II malunion, and two cases had Type I malunion. Nine cases fell out of Stephens and Sanders types and seven cases fell out of Zwipp and Rammelt types. Arthritis of the subtalar joint was noted in 14 cases, arthritis of the calcaneocuboid joint was noted in 3 cases, talonavicular joint arthritis was noted in 2 cases, and ankle arthritis was found in 1 case. Three cases had combined subtalar and calcaneocuboid arthritis, and one case had arthritis of subtalar, calcaneocuboid plus talonavicular joints. One case had arthritis of the ankle, subtalar, talonavicular, and calcaneocuboid joints. Deformity and exostosis were noted in 12 cases with lateral, medial, plantar, posterior, and a combination of exostosis. Implant issues were noticed in one case, neurological issues in four cases, and soft tissue issues were noted in four cases (Table 2 and Table 3).

Agreement Analysis

Inter-rater agreement was noted to be 'very good' for all six domains of the classification. Intra-observer estimates of the agreement were 'fair' for the 'implant' and 'soft tissue issues' domains for observer 1, 'neurological issues' domains for observer 2, and 'deformity', 'neurological issues' and 'soft tissue issues' domains for observer 3. All other estimates of the intra-observer agreement were deemed to be 'very good' (Tables 4, 5).

Example Case

Thirty-seven-year old female sustained a fall from height 7 years back and had a right sided comminuted intra-articular calcaneus fracture (Fig. 1a and b). The patient was treated with a passage of Steinman pin in calcaneus supported with a below knee plaster cast. She presented after 7 years after injury with complaints of anterior as well as lateral ankle and foot pain, limp, and inability to carry out routine activities. Radiological investigations revealed a malunited calcaneus fracture with lateral wall exostosis, subtalar arthritis, varus of heel, and dorsiflexed talus in ankle mortise. The patient also had painful claw toe deformities (Fig. 2). The patient was classified as type ADES where A was for subtalar arthritis, D was for deformities like talar dorsiflexion and heel shortening, E was for lateral wall exostosis, and S was for soft tissue problems like claw toes. Surgical intervention in the form

Fig. 1 (**a**) Anteroposterior radiograph of right ankle and comparative axial radiograph of both heels of a patient demonstrating right sided malunited calcaneus fracture with heel varus and heel shortening deformity. Lateral weight-bearing radiograph (**b**) of the same patient showing the horizontal position of talus in ankle mortise

of lateral wall exosectomy, open tendoachilles lengthening, iliac crest grafts-assisted distraction subtalar fusion, and claw toe correction (Fig. 3a and b) was carried out. The patient did well and could carry out all activities of daily living with an improved post-operative AOFAS score of 80 from a pre-operative score of 24.

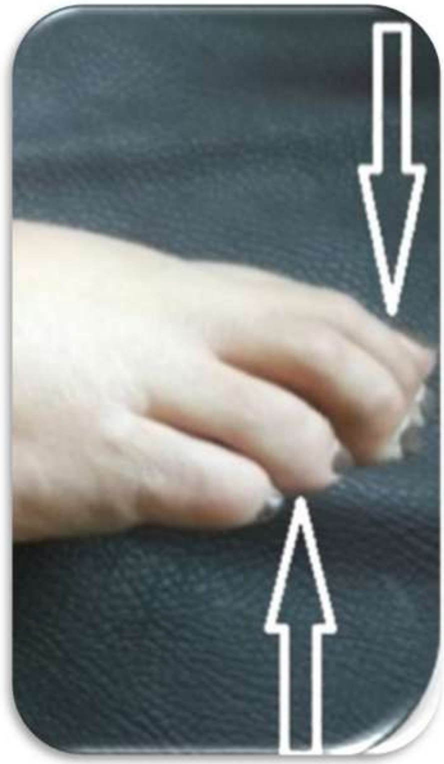

Fig. 2 The clinical picture of the same patient shows claw toe deformities of all four lesser toes

Discussion

The morbidity and disability in calcaneus malunions are complex and multifactorial. Several studies have documented the presence of a variety of complications including arthritis of the subtalar and calcaneocuboid joints, deformities such as heel varus, heel valgus, heel shortening, dorsiflexion of the talus, and lateral translation of the heel, as well as multidirectional exostoses, and nerve problems like sural and posterior tibial neuralgia. Uncommon complications such as heel fat pad atrophy, compartment syndrome residues, equinus contracture, arthritis of midfoot joints, and reflex sympathetic dystrophy have also been reported. Management of post-surgical malunions presents a unique challenge due to implant-related issues [1–9].

Two classifications with suggested management plans for calcaneus malunions have been described in the current literature. In 1996, Stephens and Sanders proposed an axial CT scan-based classification system for calcaneus malunions, which was based on a study of 23 cases. The authors classified calcaneus malunion into three types and suggested a management plan for each type. Type I was characterized by lateral wall exostosis with no or far lateral arthrosis of the subtalar joint and was advised to be managed with lateral

Fig. 3 **a** shows intraoperative pictures of open tendoachilles lengthening, iliac crest graft and claw toe correction. Postoperative axial and lateral radiographs (**b**) of the same patient demonstrating distraction subtalar fusion carried with the use of three cannulated cancellous screws. Note that restoration of heel height, correction of heel varus and heel broadening, and talar inclination correction is achieved

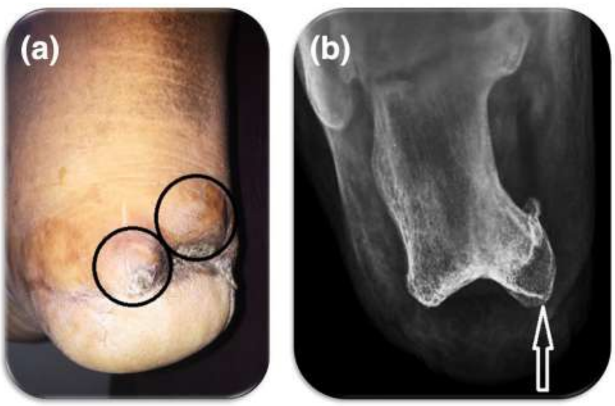

Fig. 4 Clinical (**a**) and axial radiograph (**b**) of an extra-articular calcaneus malunion case which fell out of the Stephens and Sanders classification system b. Circles (**a**) are demonstrating prominent exostosis

wall exosectomy and peroneal tendon decompression. Type II was characterized by arthritic involvement of the subtalar joint and was proposed to be treated with in situ arthrodesis of the subtalar joint. Type III had additional varus or valgus malpositioning of the heel along with subtalar joint arthritis and was suggested to be treated with subtalar arthrodesis and an osteotomy. This classification did not include extra-articular malunion cases [9, 10].

In 2003, Zwipp and Rammelt proposed a more comprehensive classification system based on deformities in a review article. Six types of deformities were described, ranging from Type 0 to Type V, with accompanying treatment guidelines. Type 0 was for extra-articular or intra-articular malunion cases without joint involvement and was proposed to be treated with either a corrective osteotomy or bone resection. Type I was characterized by subtalar incongruence without any hindfoot varus or valgus and was similar

Fig. 5 Sagittal CT image (**a**) of a calcaneus malunion case with calcaneocuboid joint arthritis which fell out of the Zwipp and Rammelt classification system. Postoperative lateral radiograph of the same case (**b**) is showing fusion of calcaneocuboid joint with cross screws

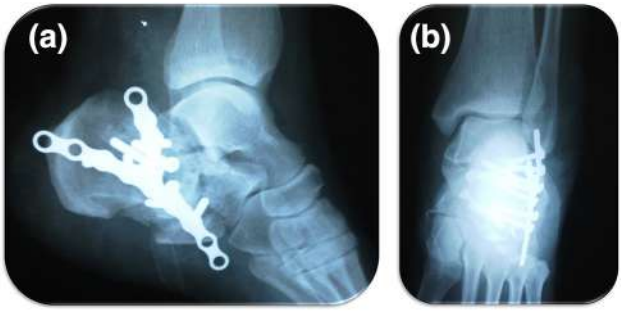

Fig. 6 Lateral (**a**) and AP (**b**) radiographs of a calcaneus malunion case who had sural as well as posterior tibial nerve problems. The case remained unclassified under both Stephens and Sanders and Zwipp and Rammelt classification systems

Fig. 7 Anteroposterior and lateral radiograph of operated cases of calcaneus malunion with an impinging implant which fell out of both Stephens and Sanders and Zwipp and Rammelt classification systems

to Type II of the Stephens and Sanders classification and was proposed to be treated with in situ arthrodesis of the subtalar joint. Type II was similar to Type III of the Stephens and Sanders classification with the same treatment plan. Type III malunion cases had additional shortening of the heel and were advised to be treated with subtalar distraction bone block arthrodesis. Type IV was characterized by an additional translation of the heel and was treated with corrective osteotomy through the original fracture plane and subtalar arthrodesis. Type V had an additional tilt of the talus into the ankle mortise and was treated with sequential correction of the talus and calcaneus with double approaches, anterior for the ankle and lateral for the subtalar joint [11, 12].

A review of these classification systems reveals several limitations. The Stephens and Sanders classification only includes intra-articular calcaneus malunions and does not cover extra-articular malunion cases (Fig. 4a and b). It only focuses on issues of the subtalar joint, leaving aside issues of the calcaneocuboid joint, deformities like heel

Fig. 8 Lateral radiograph of a calcaneus malunion case with gross Achilles shortening, as shown by lines depicting the axis of the calcaneus. The case fell out of both Stephens and Sanders and Zwipp and Rammelt classification systems

shortening, talar dorsiflexion, heel translation, and equinus contracture, as well as nerve problems, and exostosis other than lateral wall exostosis. The Zwipp and Rammelt classification system provides a comprehensive categorization of extra-articular malunions and most deformities, as well as multidirectional exostosis. However, several issues are not addressed by this classification, such as calcaneocuboid arthritis (Fig. 5a and b), nerve problems (Fig. 6a and b), and implant-related issues (Fig. 7). Moreover, uncommon conditions like equinus deformity (Fig. 8), peroneal tendon subluxation and dislocation, reflex sympathetic dystrophy, and heel fat pad atrophy are not included in the Zwipp and Rammelt classification (Fig. 9a and b).

Given these limitations, the senior author developed the 'ADEINS' classification system that is patient centric and can allow individualization of treatment protocols. The term ADEINS is an acronym and serves as a useful mnemonic to remind surgeons of the multifaceted nature of calcaneal malunions. Domain ***A*** includes common joint arthritides such as subtalar and calcaneocuboid, as well as uncommon arthritides of the ankle, talonavicular, and midfoot joints. Domain ***D*** encompasses all common deformities, such as heel varus, talar dorsiflexion, and equinus, as well as uncommon deformities like heel valgus and toe deformities due to healed compartment syndrome. Domain ***E*** encompasses exostosis, which is often associated with severe complications, such as peroneal tendon impingement and plantar heel pain. Domain ***I*** encompasses implant-related issues, such as impingement from retained implants. The "Implant" domain does not refer to merely the presence of an implant, but to implant-related pain generators. Stated in other terms, this pain is directly attributed to the implant. In this study, the three observers were presented with case details which

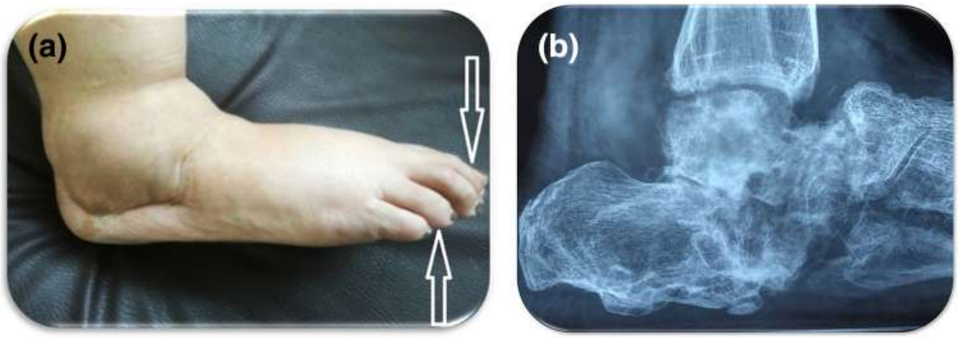

Fig. 9 Clinical (**a**) and radiological (**b**) picture of a case with smashed heel fat pad with chronic regional pain syndrome (CRPS). The case fell out of both Stephens and Sanders and Zwipp and Rammelt classification systems

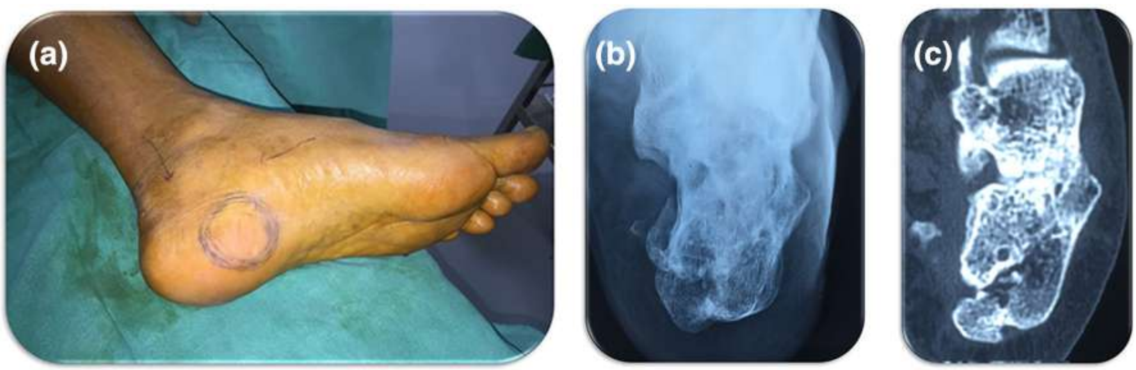

Fig. 10 ADEINS type AE where a clinical picture (**a**) shows a circle marked over painful plantar exostosis. An axial radiograph (**b**) and CT image (**c**) confirm the presence of subtalar arthritis (A) and plantar exostosis (E)

included history, examination, X-rays, and CT scans. Hence, some observers may have graded implant as a pain generator, and others may have not. This is the potential source of disagreement. However, it should be noted that 87% of the times, the observers agreed on implant-related issues, which does indicate that these issues are relatively easy to pick up. Domain ***N*** encompasses nerve problems secondary to surgical interventions. Finally, Domain ***S*** encompasses soft tissue problems like equinus contracture, peroneal tendon problems, heel fat pad atrophy, and reflex sympathetic dystrophy. The 'ADEINS' classification system allows for multiple permutations and combinations. For example, a patient with painful subtalar arthrosis and subfibular impingement due to a lateral wall exostosis would be classified as '*AE*' (Fig. 10a, b and c). Similarly, a patient with subtalar arthritis, calcaneocuboid arthritis, heel varus deformity, lateral wall exostosis, and hammer and mallet toe deformities would be classified as '*ADES'* Fig. 11. The current classification has been made entirely around surgical decision-making. By identification of pain generators, appropriate surgical interventions can be planned. Presence of multiple pain generators, deformity and arthrosis of multiple joints renders a poor prognosis. Hence, this classification helps in decision-making as well as prognostication. With regard to soft tissue problems, the authors plan to come up with subcategories in a larger, future study. However, at the moment, this is the only classification which forces surgeons to think of soft tissue problems related to calcaneal malunions.

The present study has several noteworthy strengths, including adherence to the GRRAS guidelines [13], a case series encompassing both typical and atypical manifestations of calcaneal malunion, and assessment by three experienced foot and ankle surgeons with fellowship training. Despite these strengths, the study has the significant limitation of limited sample size, and it has not yet compared the reliability of this classification system to the other two existing classification systems. The authors plan to address these limitations in future studies with a larger sample size.

Conclusion

The recently introduced 'ADEINS' classification system shows promise in identifying pain generators and sources of morbidity in patients with calcaneal malunion. It is a patient-focused approach, rather than an anatomy-focused one, enables surgeons to personalize treatment plans. The system has demonstrated satisfactory inter- and intra-rater reliability, but further validation by other research groups and comparison with established classification systems is

Fig. 11 CT scan pictures (**a**) of type ADES demonstrating subtalar plus calcaneocuboid joint arthritis (A). Comparative axial radiographic images (**b**) show shortening of the heel (D) with lateral wall exostosis (E). The clinical picture (**c**) demonstrates a hammer toe deformity of the second toe and a mallet toe deformity of the third toe (D). The patient also had an equinus contracture with midfoot cavus (S)

necessary before making recommendations for its routine clinical utilization.

Funding No funding in any form was received for this study.

Data availability statement Not applicable.

Declarations

Conflict of Interest The authors have no conflicts of interest to declare relevant to this article's content.

Ethical Approval Since the study was retrospective in nature and involved a review of radiographs and CT scans only, ethics committee clearance was not sought.

Informed Consent For this type of study, informed consent is not required.

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ORIGINAL ARTICLE

Role of Biplane Double-Supported Screw Fixation (BDSF) in Management of Fracture Neck Femur and Its Comparison with Conventional CC Screw Fixation

Sahil Garg[1] · **Gyaneshwar Tank**[1]

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Abstract

Background The aim of this study is to evaluate comparative biomechanical fixation provided with the BDSF method with the conventional CC screw fixation for treatment of femoral neck fractures with three parallel cannulated screws.

Methods This is a prospective cohort study. There were two teams of surgeons out of which one team operated the patients with BDSF technique and second with conventional CC screw fixation technique; thus, the patients were randomly distributed into two groups. Patients were included in the study as per the following inclusion and exclusion criteria.

Results Union was achieved in 15 (83.33%) patients managed by conventional CC screw technique, while union was achieved in 11 (91.67%) patients managed by BDSF technique in the present study. The average Harris hip score in present study was 90 score in patients managed by BDSF technique, while the average Harris hip score in present study was 80 score in patients managed by BDSF technique.

Conclusion Both BDSF and conventional CC screw fixation are good fixation methods for fracture neck of femur. But functional outcome and fracture union rates are better with BDSF Technique. Although, there are some minor problems noted in BDSF technique such as outer cortical fracture at the entry point of beam screw and opening up of anterior cortex of oblique fracture patterns. Thus, BDSF method provides reliable fixation in which early mobilization and partial weight bearing of the patient may be allowed.

Keywords HHS · BDSF · CC

Introduction

Hip fractures are increasingly being common and these comprises of high operative workload of orthopedic trauma unit. Understanding of this fracture is important as the incidence of the fracture in elderly population in our society is rising exponentially and management still remains challenging to orthopedic surgeons. Fracture neck femur still remains the "unsolved fracture" today. We can say that this fracture is endemic disease in elderly population having tremendous impact on our health care system.

There have been marked improvements in implant design, surgical techniques, patient care, and rehabilitation since last decades. We have done this study to understand the biomechanics of various implants and surgical techniques to manage the fracture and prevent complications (Figs. 1 , 2).

Previous decades have seen multiple implants available for the management of fracture neck femur are: (i) Multiple Moore pins or C.C. screws, (ii) fixed angle nail, (iii) sliding hip screw with or without derotation screw.

There are many controversies in deciding the treatment algorithm for management like, timing of surgery, open versus closed reduction, the choice of implant for internal fixation, the capsular tamponade, internal fixation versus arthroplasty, THR versus bipolar, and bipolar versus unipolar. In our study, we focused on comparing the biomechanics and results of biplane double-supported screw fixation (BDSF) versus conventional C.C. screw fixation. In both systems, the cannulation allows use of guide wires which enables use of guide system which helps to achieve parallel placement of screws (Fig. 3).

From the study by different surgeons in the world, it has been found that biplane double-supported screw fixation

✉ Sahil Garg
garg777sahil@gmail.com

1 L.L.R.M. Medical College, Meerut, U.P., India

(BDSF) can increase fixation stability and it has demonstrated a high reproducibility when the standard surgical procedure as described is followed. This new concept of positioning the screws in two planes makes it possible to place three cannulated screws at steeper angles to the anatomical axis of femur which in turn improve their beam function and cortical support [1]. The critical element in fracture stability is the density of the bone. Multiple screw fixation technique in itself is not free from disadvantages. Various study shows neck length is best achieved with sliding hip screw. Biomechanically, fixation is less rigid with cannulated screws when compared with sliding hip screw. Sliding hip screw buttresses better in cases with posterior comminution. The sliding hip screw also has multiple disadvantages. We have focused our study and discussion on multiple cannulated screw fixation techniques.

Hence, we have conducted this study to evaluate comparative biomechanical fixation provided with the BDSF method with the conventional CC screw fixation for treatment of femoral neck fractures with three parallel cannulated screws.

Materials and Methods

The study was conducted in the Department of Orthopaedics at L.L.R.M. Medical College, Meerut during 2018-20. The patients attending OPD, Emergency and IPD of SVBP Hospital and operated for fracture neck femur were taken up

Figs. 1, 2 Pre-operative image intensifier picture

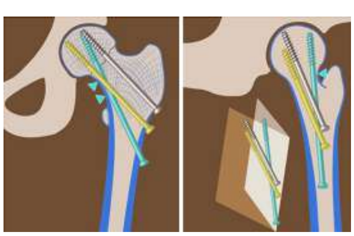
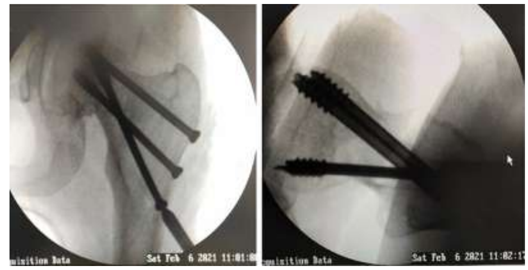


Fig. 3 The original described method BDSF



Figs. 4, 5 Post-operative image intensifier picture

Figs. 6, 7 Post-operative X-ray picture on follow-up

for the study. Clearance from the institutional ethical committee was taken. Procedure includes positioning of patient supine on the fracture table. Lateral incision is performed at the level of the lower border of the greater trochanter. Closed reduction maneuver Whitman's method was used (Figs. 1 and 2). Guidewires were positioned as distal at 150'-165' angle, middle at 130'-140' angle proximal parallel to 2nd middle wire as per the original described method (Fig. 3). The middle and proximal screws were placed first and then foot traction is released. Finally, the distal screw is placed (Figs. 4 and 5). Post-op care and follow-up include pain relief, wound dressing at 3rd post op day, and stitches removal at 2 weeks. We followed our patients at 1 month, 3 months, 6 months, 9 months, and 1 year with X-rays (Figs. 6 and 7) we focused on comparing the biomechanics and results of biplane double-supported screw fixation (BDSF)functional assessment (Figs. 8 and 9) using Harris hip scoring. Clinical and radiological outcome was assessed. Full weight-bearing mobilization was started at 8-12 weeks.

Study Design

It is a prospective cohort study. There were two teams of surgeons out of which one team operated the patients with BDSF technique and second with conventional CC screw fixation technique; thus, the patients were randomly distributed into two groups. Patients were included in the study as per the following inclusion and exclusion criteria.

Inclusion Criteria

Patients agreed with and signed the informed consent form.

- Garden stages I–IV fracture of neck femur
- Age
- < 60 years with any type of fracture of neck femur and age > 60 years with undisplaced type of fracture of neck femur

Exclusion Criteria

- Patients with legal incompetence
- Pediatric fractures
- Patients with delayed presentations
- Patients with fracture neck of femur with hip dislocation
- Age > 65 years, displaced.
- Patients with active sepsis of the hip joint and systemic sepsis.
- Intravenous drug abusers.
- Patients anesthetically unfit for surgery.
- Bone diseases or neuromuscular disorders.

All the patients based on the inclusion and exclusion criteria were taken for the study. History was taken from the patients regarding mode of injury, time since injury, and any chronic illness like hypertension, diabetes mellitus, coronary artery disease, COPD, tuberculosis, stroke, osteoporosis, etc. Diagnosis was made on the clinical and radiological ground. All patients were examined clinically and investigated for preanesthetic checkup (Figs. 8, 9).

Study Group

We divided our patients in two groups:

Group A includes treatment by BDSF technique.

Group B includes treatment by conventional CC screw fixation technique.

Figs. 8, 9 Functional outcome in patient at follow-up

Observation and Results

This study was conducted during 2018–20 on 35 patients who presented with fracture neck of femur and were treated with internal fixation (osteosynthesis). Amongst them, 5 patients were lost to follow-up and did not complete one year mandatory follow-up period. Hence for the study, remaining 30 patients were analyzed, 12 with BDSF and 18 with conventional CC screw.

The study comprised 12 males (40%) and 18 females (60%), of age group 15–62 years, the mean age being 40.93 years. They were grouped age and gender wise. Out of 30 patients, 2 patients were in garden type 1, 6 patients in garden stage 2, 12 patients in garden type 3, and 10 patients in garden type 4.

Most of the patients (26.67%) were in their fourth and fifth decades, 3 (10%) patients (male 1, female 2) in 10–20 years group, 6 (20%) in 21–30 group (male 1, female 5), 4 (13.33%) in 31–40 group (male 3, female 1), 8 (26.67%) in 41–50 group (males , female 5), 8 (26.67%) in 51–60 group (male 4, female 4), 1 (3.3%) in 61–70 group (male 0, female 1). Incidentally, 12 (40%) fractures were on the left side and 18 (60%) were on the right side. 16 (53.33%) fractures were sustained in road accidents, and 14 (46.67%) were sustained due to trivial injury.

In the present study, pre-reduction and post-reduction Garden index was calculated on AP skiagram under the supervision of guide and co-guide.

In all patients treated by either BDSF or conventional CC screw fixation, the GAR index improved in post-reduction X-ray as shown in Table 1.

In pre-reduction Garden index, it was observed that 9 patients (30%) had Garden index between 141 and 150; 17 patients (56.67%) had Garden index between 151 and 160; while the remaining 4 patients (13.33%) had Garden index between 161 and 170.

Similarly in post-reduction, 5 patients (16.67%) had Garden index between 151 and 160; while the remaining 25 patients (83.33%) had Garden index between 161 and 170.

In this study, in conventional CC screw fixation patients, Harris Hip Score evaluated at 6th month for 14 patients was

Table 1 Relation between Garden alignment (GAR) index and number of patients

Garden index	No of patients
Pre-reduction	
141–150	9
151–160	17
161–170	4
Post-reduction	
151–160	5
161–170	25

Table 2 Harris hip score and trends at six-month follow-up

Garden Stage	BDSF	CCS
1	90–100	90–100
2	80–89	80–89
3	80–89	70–79
4	70–79	<70

Table 3 Degree of residual pain score (RPS) at 6 months

Garden staging	BDSF	CCS
1	Grade 1–2	Grade 1–2
2	Grade 1–2	Grade 1–2
3	Grade 1–2	Grade 2–3
4	Grade 1–2	Grade 2–3

80–89 points. 4 patients achieved fair HHS. As per garden staging, the HHS score is mentioned in Table 2.

Residual pain score as per garden staging system in the follow-up patients is mentioned Table 3.

The above Table 4 shows residual pain score grades in both methods employed.

Mobility score in follow-up visit as per garden staging is mentioned in Table 5.

Table 6 shows the mobility scores in both the methods employed.

VAS score in follow-up visit as per garden staging is mentioned in Table 7

Table 8 shows the VAS scores in both the methods employed.

Complications: There were no significant complications in the study except for the discussed below.

Non-union and Osteonecrosis of Femoral Head

In our study, there is non-union and osteonecrosis of femoral head in 18% of patients managed by conventional CC screw fixation, while there is non-union in 8% of patients managed by B.D.S.F technique.

Table 5 Mobility score in follow-up visit as per garden staging

Garden staging	BDSF	CCS
1	Grades 8–9	Grades 8–9
2	Grades 8–9	Grades 8–9
3	Grades 8–9	Grades 6–7
4	Grades 8–9	Grades 6–7

Table 6 Mobility score at 6 months

Procedure	Grades 0–1	Grades 2–3	Grades 4–5	Grades 6–7	Grades 8–9
B.D.S.F	0	0	0	0	12
Conventional CC screw fixation	0	0	0	13	5
Total	0	0	0	13	17

Discussion

Femoral neck fracture in elderly poses a great challenge in their treatment and rehabilitation. To avoid complications associated with long-term immobilization, internal fixation of these fractures has been accepted as the standard procedure. Successful treatment of femoral neck fracture depends on many factors such as age of the patient, general health status, medical co-morbidities, and their influence on the mobility and balance of the elderly patient, besides the commonly observed delay in surgical treatment due to financial and social reasons. Identification of possible causes of the fracture itself being unstable, situations beyond the control of surgeon, Osteopenia, age-, and gender-related variation may not allow the for ideal healing. The varus collapse, implant cut-out in head region, and intraarticular penetration remain the major causes of unacceptable outcome in failures. Various factors have been studied such as age and sex distribution, mode of trauma, and associated co-morbidities in this study along with method of fixation.

In our study, the mean age of the patients in the present study was 40.933 years as shown in Table 9. Females outnumbered males with 60% of female patients in the current

Table 4 Residual pain score grades in both methods employed

Procedure	Grade 6	Grade 5	Grade 4	Grade 3	Grade 2	Grade 1
B.D.S.F	0	0	0	0	4	8
Conventional CC screw fixation	0	0	0	9	9	0
Total	0	0	0	9	13	8

Table 7 VAS score in follow-up visit as per garden staging

Garden staging	BDSF	CCS
1	Grades 0–2	Grades 0–2
2	Grades 0–2	Grades 3–5
3	Grades 0–2	Grades 3–5
4	Grades 3–5	Grades 6–8

Table 8 VAS score at 6 months

Procedure	Grades 0–2	Grades 3–5	Grades 6–8	Grades 9–10
BDSF	4	8	0	0
Conventional CC screw fixation	3	11	4	0
Total	7	19	4	0

study. Road Traffic Accident (RTA) set-up was the most common mode of trauma in the present study accounting for 53.33% of cases. High velocity trauma is the commoner cause of this fracture in the younger population. The high incidence of patients with RTA in the current study indicates the sample size to be comprising of predominantly younger population. The patients in elderly age group have higher number of associated medical co-morbidities mostly diabetes mellitus and hypertension. 40% of patients in the present study were associated with medical illness, most of which were diagnosed at the time of admission to the hospital. This highlights the fact that early mobilization is the key to prevent worsening of medical co-morbidities in patients suffering from fracture neck of femur. The average time between injury and surgery in the present study was 5.33 days as illustrated in Table 10. The delay in surgery in the present study in comparison with most studies is accounted by the concomitant association of various medical illnesses and other social and financial reasons. It is interesting that many patients were diagnosed to have medical illness only on hospitalization for this fracture. Table 10 shows comparison of present study with other authors.

Table 9 Average age of patient sustaining femoral neck fracture

Authors	Number of patients	Average age (years)
Filipov et al.	88	76.9
Garden et al.	111	67.2
Satish et al.	64	60
Tidermark et al.	102	80
Blomfeldt et al.	60	84
Guruswami et al.	395	73.9
Current study	30	40.93

Table 10 Trauma surgery interval

Authors	Trauma surgery interval
Satish et al.	2 days
Blomfeldt et al.	2.75 days
Guruswami et al.	1.54 days
Garden et al.	3.68 days
Current study	5.33 days

Table 11 Duration of surgery in various studies

Authors	Number of patients	Average duration of surgery (minutes)
Filipov et al.	88	39
Blomfeldt et al.	60	19
Tidermark et al.	102	20
Current study	30	65

Table 12 Percentage of union achieved in various studies

Authors	Total number of patients	Union (%)
Filipov et al.	88	98.86 BDSF
Blomfeldt et al.	60	86.67 CCS
Garden et al.	111	81 CCS
Current study	30	83.33 BDSF + CCS

Table 13 Average time of union in weeks

Authors	Average time to union (weeks)
Satish et al.	10
Guruswami et al.	14.28
Current study	13.72

The average operating time was 65 min with a range of 50–90 min (Table 11). The variation in operating time was mainly influenced by whether the patient was operated by a trainee resident or a consultant and its other causes have not been compared with other works. Union was achieved in 83.33% patients in the present study which is comparable to rates reported in literature as shown in Table 12. Out of which union was achieved in 91.67% patients operated

Table 14 Harris hip score in various studies at one year

Authors	Number of patients	Mean HHS
Filipov et al.	88	84.26
Lee et al.	102	86.6
Current study	30	91.13

by BDSF technique, while union was achieved in 83.33% patients operated by conventional CC screw fixation technique. The average time to clinico-radiological union in current study was 13.72 weeks with a range of 9–19 weeks, which was comparable to that reported in literature in various series depicted in Table 13.

The average time to clinico-radiological union in BDSF techniques is 12 weeks, with a range of 9–15 weeks. The average time to clinico-radiological union in conventional CC screw fixation techniques is 14.92 weeks, with a range of 11–19 weeks.

Harris hip score was developed in 1969 to assess the outcome following total hip arthroplasty [2]. It consists of eight questions and a physical examination. It has been used in a number of studies over the years for both fixation and arthroplasty, and has been shown to have high reliability and validity.

Table 14 shows that the average Harris hip score in the current study was 91.13, with 56.67% of total patients in excellent grade and 43.33% in good grade at one year. Mean HHS in patients treated by BDSF technique is 95.83, while Mean HHS in patients treated by conventional CC screw fixation technique is 88.27.

Most of the cases in the present study were unstable in which the outcome of deliberate valgus reduction in femoral neck fractures was analyzed to have diminished rates of screw cut-out and facilitate consolidation. Hence, we advocate anatomical reduction, if not valgus reduction in femoral neck fractures to achieve reliable functional and radiological outcomes.

Various studies has revealed fixation of fracture neck femur by conventional method has failure rate to be as high as 20–42% [3] . Reason for this failure is due to the entry point of the screws, which lies in cancellous region of proximal femur such that inter-fragmentary compression is achieved intra-operatively, so this amount of inter-fragmentary compression is not achieved in this osteoporotic bone which leads to high failure in conventional CC screw fixation 8.

Biplane double-supported screw fixation method (BDSF) is superior in this regard as it takes purchase of distal screw in cortical bone and proximal screws lie in different plane with that of distal screw.

The distal screw is the beam screw which transmits weight from head of femur to femur diaphysis directly reducing stress in cancellous proximal femur. Biplane arrangement allows enough space in neck and femur head for screw placement. Due to increased distance between entry points of proximal and distal screws, the forces are spread over large area of proximal femur which in turn reduces the incidence of fracture subtrochanteric femur which is common with conventional CC screw fixation. Placement of guidewire need to be learnt with time.

Conventional CC screw fixation and BDSF methods are similar in terms of learning curve, cost, operative time, and operation theater set-up.

Conclusion

Both BDSF and conventional CC screw fixation are good fixation methods for fracture neck of femur. But functional outcome and fracture union rates are better with BDSF Technique. Although, there are some minor problems noted in BDSF technique such as outer cortical fracture at the entry point of beam screw and opening up of anterior cortex of oblique fracture patterns. Thus, BDSF method provides reliable fixation in which early mobilization and partial weight bearing of the patient may be allowed. In our study, the sample size is small and long-term follow-up is lacking. So, other studies by different authors having large sample size and longer follow-up are required to establish BDSF method as a standard method of fixation for fracture neck of femur.

Declarations

Conflict of Interest The authors declare that they have no conflict of interest.

Ethical Approval This article does not contain any studies with human or animal subjects performed by the any of the authors.

Informed Consent For this type of study informed consent is not required.

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ORIGINAL ARTICLE

Surgical Residents´ Results Seem to be Non-Inferior Comparing to More Experienced Surgeons in Femoral Neck Fracture Osteosynthesis

Nora Forsbacka[1] · **Terhi Kolari**[2] · **Marjo Talme**[3] · **Ville Bister**[4,5,6]

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Abstract

Purpose of the Study Femoral neck fracture osteosynthesis is usually performed by using dynamic hip screw (DHS) or multiple parallel cannulated screws (MCS). In orthopedic surgery training, certain hip fractures are one of the most common operations performed by residents. It has been questioned, whether residents can provide as safe treatment and patient outcomes as those of more experienced surgeons. The aim of this study was to evaluate the effect of surgical experience on risk of complications by comparing the surgical performance and clinical outcomes in femoral neck osteosyntheses between surgical residents and orthopaedic surgeons.

Methods All patients with femoral neck fracture admitted to Helsinki and Uusimaa Hospital District (HUS) Hyvinkää Hospital from 2011 to 2016 were collected as research material. 88 hip fractures (87 patients) treated with DHS or MCS osteosyntheses were included in this study. The patients were divided into 2 groups, based on the surgeon's experience: an orthopedic surgeon group ($n = 68$) and a surgical resident group ($n = 20$). All data from complications, reoperations, and the duration of operations were collected.

Results There was no significant difference in characteristics of operated patients between orthopaedics and residents group. There was no significant difference in complications or re-operations between groups ($p = 0.4$, $p = 0.2$). Surgical residents had statistically longer surgical time (mean 76 min, 95% CI 62.92 min, mean 46 min, 95% Cl 42.51 min; p-value < 0.001). Still surgical time was not a risk factor for complication (p-value 0.5).

Conclusion Our results show that surgical residents´ outcomes in femoral neck fracture osteosynthesis seem to be as favorable as those of orthopedic surgeons; the operations just last slightly longer.

Keywords Femoral neck fracture · Osteosynthesis · Surgical experience · Surgical training

✉ Nora Forsbacka
Nora.Forsbacka@Tyks.fi

Terhi Kolari
terhi.kolari@utu.fi

Marjo Talme
marjo.talme@hus.fi

Ville Bister
ville.o.bister@hus.fi

1 Turku University Hospital Trauma Unit, Turku University Hospital, Turku, Finland

2 Department of Biostatistics, University of Turku, Turku, Finland

3 Helsinki University Hospital, Hyvinkää Hospital, Hyvinkää, Finland

4 Helsinki University Hospital Trauma Unit, Töölö Hospital, Helsinki, Finland

5 Department of Surgery, Clinicum, Faculty of Medicine, University of Helsinki, Helsinki, Finland

6 Peijas Hospital, Vantaa, Finland

Introduction

Osteosynthesis is used with certain types of femoral neck fracture. Patients are typically younger with undisplaced fractures, while retaining the patient's own hip joint is a priority [1]. Osteosynthesis, also known as internal fixation, is usually performed with either dynamic hip screws (DHS) or multiple parallel cannulated screws (MCS). Multiple-screw fixation is less invasive and retains more viable bone [2, 3] than does DHS fixation, which appears to be biomechanically more stable [4–6]. The optimal treatment for intracapsular hip fracture has been controversial [7–9].

Operative treatment of hip fracture is one of the most common procedures during orthopedic surgery training. Residents are also vital to the clinical workforce in hospitals and provide a large portion of the daily patient care. Surgical training aims to prepare residents to provide high-quality care, and it requires appropriate amounts of hands-on experience in the operating room. Whether residents can provide treatment as safe and patient outcomes as favorable as those of more experienced surgeons has been questioned.

To evaluate the risks and quality of treatment, researchers have defined learning curves from various surgical procedures. These describe either the minimum time of training or number of surgeries a surgical trainee needs to be able to achieve the required quality of treatment and minimal risk for complications. Van der Leeuw et al. [10] concluded in a systematic review including nearly 100 studies that patient care appears to be safe and equal in quality when delivered by residents. Of course, complications can still appear regardless of the experience of the surgeon performing the operation.

Femoral neck fracture operations include risks of complications, such as infections and surgical site hematomas. Femoral neck fractures, treated with osteosynthesis, can sometimes cause non-union, implant failure, bone misalignment or femoral head avascular necrosis (AVN) [1, 11]. Rare complications of surgical treatment include sciatic nerve injuries and iatrogenic fractures.

In the review by van der Leeuw et al. [10] examining treatment outcomes with residents, only 7 studies were of orthopedic residents; only one of these studies covered hip fractures [12]. The study examined whether the complication and mortality rates for hip fracture patients were higher with less experienced residents and included both femoral neck fractures and intertrochanteric fractures in the analysis. There was no mention about the surgical treatment used. The overall mortality rate was slightly higher in teaching than in nonteaching hospitals (3.7% vs. 3.6%). In contrast, the complication rates showed no differences between teaching and nonteaching hospitals.

To our knowledge, no studies have evaluated the impact of surgical expertise on the outcomes of femoral neck fracture osteosynthesis. The aim of this study was to evaluate the effect of surgical experience on the risk of complications by comparing the surgical performance and clinical outcomes between surgical residents and orthopedic surgeons.

Materials and Methods

This was a retrospective single center study, conducted at Helsinki and Uusimaa Hospital District (HUS) Hyvinkää Hospital, Finland. HUS Hyvinkää Hospital is a public hospital (Level III trauma center) providing 24/7 traumatological treatment to a population of 190,000, which is approximately 4% of the population in Finland.

Patients with hip fracture treated with osteosynthesis were selected for the study from the period January 1st 2011 to December 31st 2016. This included 361 patients, of which 87 were treated with DHS or MCS osteosynthesis and had an International Classification of Diseases (ICD-10) S72.0 femoral neck fracture diagnosis (exclusion criteria are seen in Table 1). One patient had both hips operated (two different injuries), therefore the study included total of 88 operated femoral neck fractures.

The surgical information program Centricity Opera provided data about the surgeon and duration of the surgery. The patients were divided into 2 groups: surgeries performed by orthopedic surgeons (n = 68) and those performed by residents (n = 20). Both orthopedic and resident groups had 9 different surgeons (total of 18). The number of operations per surgeon in this study was on median 8.5 (range 2 to 13) in the orthopedic group and on median 2 (range 1 to 5) in the resident group. Residents operated 15 hips independently and 5 hips under senior supervision but also in those cases the resident was the primary surgeon. Due to very

Table 1 Exclusion criteria

Exclusion criteria	n
Total	361
Pertrochanteric	109
Other osteosynthesis or arthroplasty	154
Died before operation	2
Non-operative treatment	1
Re-operation	2
Age under 16 yrs	4
Treatment in other hospital	1
Primary x-rays not available	1
Included patients	**87**
Included hip fractures	**88***

*One patient had both hips operated (two different injuries) small amount of operations under supervision, we decided to include these 5 operations to the resident group as a whole. Regarding this study, previous experience of these operations (DHS or MCS osteosynthesis) is approximately over 10–20 in the orthopedic group and 0–5 in the resident group.

Tobacco and alcohol consumption were also recorded. The patient was recorded as a heavy user if there was a history of several hospital visits for alcohol intoxication.

Postoperative recordings and X-rays were used to determine the implementation and success of the treatment, as well as possible complications. The complications included infections requiring hospitalization, hematomas of the surgical site requiring reoperation, and AVN changes. Fixation material failures were included as complications. If a fracture gap was still visible in the control x-rays after a 6-month follow-up period, it was considered a non-ossification and included as a complication.

Possible reoperations due to complications or treatment failure were recorded. These included also osteosynthesis conversion to arthroplasty. The follow-up period was 2–5 years.

Statistical Analysis

The clinical characteristics were summarized with counts (n). The associations between the categorical data were analyzed with Fisher's exact test. Survival analysis was performed to investigate complication and the need for reoperation. The patients were allocated into groups by the surgeon performing the operation.

First, univariate analyses for the cumulative percentages of complication and reoperation need were estimated, using the Kaplan–Meier technique, and the differences between the orthopedic and resident groups were tested, using the log-rank test. Second, more complicated models with multiple factors were performed with Cox's proportional hazard models. Differences between the orthopedic and resident groups were quantified by calculating hazard ratios (HRs) with 95% confidence intervals (95% CIs), using Cox's regression models. The validity of proportional hazards assumption was assessed both visually and numerically, and no marked deviations for assumptions were observed. The initial model included the surgeon performing the operation, osteosynthesis method, tobacco, alcohol, patient age, gender, and Garden classification; nonsignificant factors were gradually omitted.

The operation times between the operator groups were compared with one-way analysis of variance (ANOVA). All tests were performed as two-sided with a significance level set at 0.05. The statistical computations were performed, using SAS Systems for Windows, Version 9.4 (SAS Institute Inc., Cary, NC, USA).

Results

The majority of patients were female, and the mean age of the whole study population was 69.7 (sd 17.1) years. Sex or patient age showed no significant differences between groups (p-values 0.8, 0.9). 44 patients used tobacco and 15 were heavy users of alcohol. There were no significant differences in patient intoxicant use between the orthopedic and resident groups (p-values 0.6, 0.7). If a patient used alcohol, the same patient was also more prone to use tobacco (p-value < 0.001). The clinical characteristics are shown in Table 2. There were no significant differences in Garden classification or anatomical fracture types between the operating groups (p-value 0.3 and 0.8).

In all, 68 hips were operated by the orthopedic surgeon group and 20 the resident group; 47 hips were treated with a DHS and 41 with screws. The plate sliding screw, i.e. the DHS group, also included patients who had a single antirotation screw installed in addition to the plate sliding screw. The orthopedic surgeon group had 35 DHS and 33 MCS osteosyntheses, while the resident group had 12 DHS and 8 MCS fixations. There were no significant differences between the groups by used osteosyntheses (p-value 0.4).

In all, 22 patients had some complications, of which 19 required reoperations. In the orthopedic group, 19 patients had complications and 17 patients were reoperated. In the resident group, 3 patients had complications and 2 had to be reoperated. All of the postoperative x-rays were accepted by senior surgeons and their colleagues during the primary ward treatment period, and there were no early reoperations because of poor reduction or suboptimal

Table 2 Clinical characteristic

Clinical characteristics	Total	OS	Rs	p-value
All patients (n)	87	67	20	
Female (n)	53	40	13	0.8
Age (mean)	69.7	69.8	69.2	0.9
Tobacco (n)				0.6
No	43	35	8	
Yes	22	16	6	
N/A	22	16	6	
Alcohol (n)				0.7
No	32	24	8	
Yes	15	13	2	
N/A	40	30	10	
Smoking + alcohol combination (n)				1.0
No	24	19	5	
Yes	9	7	2	

OS Orthopedic surgeons, *Rs* Residents, *N/A* not applicable fixation. There were no statistically significant differences in complications or reoperations between the groups (p-values 0.4, 0.15).

Significant differences were observed in the duration of surgeries. The operating mean time in the orthopedic group was 46 min (95% CI 42,51 min) and in the resident group 76 min (95% CI 62,92 min) (p-value < 0.001). Duration of surgery was not a risk factor for complication or reoperation (p-value 0.3).

Alcohol consumption was a risk factor for reoperation (log-rank test p-value = 0.03, Cox's proportional hazard HR = 2.64, 95% CI 0.96, 7.27, p-value 0.06). However, the analyses of tobacco and alcohol use were limited due to missing data. Of the 33 patients having information on their intoxicant and tobacco use, 7 of those 9 who used both tobacco and alcohol had complications and/or reoperation, while 12 of 24 nonusers had complications and/or reoperation (p-value 0.24).

The other clinical characteristics (patient age, gender, and Garden classification) were not statistically associated with complication or reoperation (p-values 0.1, 0.9, 0.1).

Overall, there were no infections requiring hospitalization in either of the osteosynthesis groups. In the orthopedic group 8 and in the resident group 1 fracture remained unossified. At follow-up, fixation failed in 7 patients, all of whom were in the orthopedic group, while 2 cases of AVN developed in the orthopedic group and 1 in the resident group. Both groups had one for other complications, see Table 3.

Table 3 Surgical expertise

Surgical expertise	OS	Rs	p-value
Osteosynthesis (n)	68	20	
DHS	35	12	0.4
MCS	33	8	0.4
Duration of surgery, mean (min)	46	76	< 0.001
Complication (combination)	19 (30%)	3 (15%)	0.4
Infection	0	0	
Non-union	8 (12%)	1 (5%)	
Fixation failure*	7 (12%)	0	
AVN	2 (3%)	1 (5%)	
Other**	2 (3%)	1 (5%)	
Reoperation	17 (25%)	2 (13%)	0.15

OS Orthopedic surgeon, *Rs* Resident, *DHS* dynamic hip screws, *MCS* multiple parallel cannulated screws, *AVN* avascular necrosis

*Fixation material such as screws or collum blade movement in follow-up

**Surgical site hematoma, delayed ossification, long-term pain

Discussion

Femoral neck fractures treated with osteosyntheses such as DHS or MCS are relatively small surgical procedures but have risk of reoperation due to complications such as non-union, mechanical failure, or AVN [1, 11, 13]. Although MCS fixation may have some benefits compared with DHS, it also seems to have a higher risk of conversion to hemi/total hip arthroplasty [14]. Recently, it has also been suggested that elderly patients may benefit from primary hemiarthroplasty in comparison to those using MCS when improved mobility and risk for reoperations are considered [15].

Postoperative infections range from 0 to 10% after internal fixation of femoral neck fracture [2]. In our study, there were no infections leading to hospitalization or even emergency department/out-patient clinic visits. Minor wound problems or superficial wound infections treated at the primary health care level may possibly have been present without the need for surgical intervention. Our results showed slightly higher rates of non-union and AVN than previously reported [14]. There were 4 patients who had problems with recovery (malunion or non-union), but never went through a reoperation because of their poor overall condition. In more complex surgeries there is a learning curve with both complications and surgical time [16–19]. Low number of repetitive procedures has led to consider different training methods like virtual reality [20].

Quality improvement efforts in surgery have largely focused on reducing the risk of complications after surgical procedures. Whether residents can provide as safe treatment and patient outcomes as favourable as those from more experienced surgeons has often been questioned. Sometimes the longer surgical time may take the glory away from successful outcomes. In our study, the surgical time was longer in the residents' group, as expected. More experienced surgeons operate faster than early-state residents [16, 21], and there is also a learning curve up to at least 20 to 30 operations when considering the duration of surgery [19, 22]. However, perhaps the most important finding was that this increase in surgical time seemed not to be associated with more unfavourable patient outcomes. The same conclusion was also previously made with intertrochanteric nailing with simple fracture patterns [23]. Surgical time can impact the effectiveness and costs of surgery, but without surgical training, there will be no future experienced surgeons. Longer surgical times can also affect the complication rates, including postoperative infections, when approximately 2 h is exceeded [24]. With femoral neck fracture osteosynthesis it is rarely a problem, since the surgical time ranges from approximately

30 min to 90 min [25]. In our study, residents performed 20 (23%) of these femoral neck osteosynthesis operations, which is already slightly higher than the reported amounts in Norway (13.5%) [25]. We must still bear in mind that not all surgeries are suitable for inexperienced surgeons. Displaced fracture patterns and more seldom-performed operations may lead to poorer results [26].

Our patients were younger on average (69.7 years) than in previously reported hip osteosynthesis studies [14, 25] so the results of complication rates are not directly comparable. Although we had limited data on alcohol and tobacco consumption, the results are leaning towards a larger material studied in general surgery revealing that combined consumption is more likely to lead to complications, readmissions, and reoperations [27].

This study has strengths and some limitations. This was a single center study of all operated femoral neck fracture patients in HUS Hyvinkää Hospital from the selected period of 6 years. The teaching methods and unit traditions stayed the same, and patient chart review could be done in detail. The research design was retrospective and the number of operated fractures (n = 88) was relatively limited. When making further conclusions, one has to bear in mind that the research population should have been larger. In this case, it would have needed either longer period of time for data collection or data combination with another hospital. We must also acknowledge that surgical training variates around the world and surgical residents' operating results may also vary.

We evaluated the effect of a surgeon's expertise on the outcome and safety of femoral neck fractures treated with osteosynthesis. Considering the equal complication profile in this study, it may be possible to offer residents further opportunities to perform the operation. Our results show that femoral neck fracture osteosynthesis seems to be non-inferior in the hands of surgical residents.

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Declarations

Conflict of Interest No competing interests.

Ethical Approval As a retrospective study, an ethical approval was unnecessary.

Informed Consent All authors made significant contributions to the study and have approved the final manuscript.

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ORIGINAL ARTICLE

Locked Tension Band Wiring: A Modified Technique for Olecranon Fractures—A Multicenter Study Comparing Clinical Outcomes and Complications with Conventional Methods

Yutaro Kuwahara[1] · Yasuhiko Takegami[2] · So Mitsuya[3] · Katsuhiro Tokutake[4] · Kenichi Yamauchi[3] · Shiro Imagama[2]

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Abstract
Purpose Tension band wiring is the standard treatment for olecranon fractures, but it is associated with high rate of implant-related complication. To reduce this high complication rate, we developed a modified technique, locked tension band wiring (LTBW). The aim of this study was to investigate whether LTBW reduces complication and reoperation rates compared to conventional methods (CTBW).
Methods We identified 213 olecranon fractures treated with tension band wiring: 183 were treated with CTBW, and 30 were treated with LTBW, and patients in each group were selected using propensity score matching. We evaluated operation time, intraoperative bleeding, complication and reoperation rates, the amount of Kirschner's wire (K-wire) back-out, and Mayo Elbow Performance Index (MEPI). Complications included nonunion, loss of fracture reduction, implant failure, infection, neurological impairment, heterotopic ossification, and implant irritation. Implant removal included at the patient's request with no symptoms.
Results We finally investigated 29 patients in both groups. The mean operation time was significantly longer in the LTBW (106.7 ± 17.5 vs. 79.7 ± 21.1 min; $p < 0.01$). Complication rates were significantly lower in the LTBW than the CTBW group (10.3 vs. 37.9%; $p = 0.03$). The rate of implant irritation was more frequent in the CTBW, but there was no significant difference (3.4 vs. 20.7%; $p = 0.10$). Removal rate was significantly lower in the LTBW (41.4 vs. 72.4%; $p = 0.03$). The mean amount of K-wire backout at last follow-up was significantly less in the LTBW (3.79 ± 0.65 mm vs. 8.97 ± 3.54 mm; $p < 0.01$). There were no significant differences in mean MEPI at all follow-up periods (77.4 ± 9.0 vs. 71.5 ± 14.0; $p = 0.07$, 87.4 ± 7.2 vs. 85.2 ± 10.3; $p = 0.40$, 94.6 ± 5.8 vs. 90.4 ± 9.0; $p = 0.06$, respectively).
Conclusion Our modified TBW significantly increased operation time compared to conventional method, but reduced the complication and removal rate and had equivalent functional outcomes in this retrospective study.

Keywords Tension band wiring · Olecranon fracture · Mayo Elbow Performance Index · Modified surgical technique · Complication · Implant irritation

Introduction

Olecranon fractures are relatively common fractures that reportedly account for approximately 10% of all upper extremity fractures [1]. Tension band wiring (TBW) is widely used for displaced olecranon fractures that utilize Kirschner's wire (K-wire) and flexible wire. Previous studies showed that TBW achieved good clinical outcomes but a high complication and reoperation rate and the most frequent complication was reported the implant irritation [2–4]. The main cause of this high rate of complications is thought to be due to the K-wire migration pulled by the triceps. Mitsuya et al. first reported a simple modified method called locked

✉ Yasuhiko Takegami
takegami@med.nagoya-u.ac.jp

1 Department of Orthopaedic Surgery, Orthopaedic Registrar, Nagoya University Graduate School of Medicine, Nagoya, Japan

2 Department of Orthopaedic Surgery, Nagoya University Graduate School of Medicine, 65 Tsurumai-cho, Showa-ku, Nagoya 466-8550, Japan

3 Department of Orthopaedic Surgery, Toyohashi Municipal Hospital, Toyohashi, Japan

4 Department of Hand Surgery, Nagoya University Graduate School of Medicine, Nagoya, Japan

tension band wiring (LTBW) which the proximal part of the TBW was locked by wrapping it with flexible wires and the method showed significantly less amount of K-wire backout compared with conventional TBW (CTBW) in their retrospective study [5]. Authors considered it effective to reduce the implant irritation and have reported that LTBW achieved postoperative complication rate equivalent to locked plate for simple olecranon fractures with the same database of this study in a previous report. [6]

The purpose of this study was to establish the efficacy of our modified TBW as a treatment method for olecranon fractures. To achieve our goal, we compared (1) the frequency of complications and reoperations, and (2) the functional outcomes between LTBW and CTBW. We hypothesized that LTBW would reduce postoperative implant-related complications and reoperation rates compared to CTBW.

Materials and Methods

Locked Tension Band Wiring

All patients who received LTBW were operated in the supine position. An "S" shaped posterior approach with a medial arc from the triceps to the ulna was used to prevent skin contracture. The ulnar nerve was routinely identified but not dissected or transposed. A 1.5-mm K-wire was inserted perpendicular to the ulna approximately 30 mm distal to the fracture site. Using the K-wire as a foothold, we reduced and held the fragments with one- or two-point reduction forceps.

Two 1.5-mm K-wires were placed in parallel and bi-cortically. A 1.0-mm flexible wire was placed and fastened in a figure-of-eight configuration using the double-knot method. At this point, the proximal ends of the K-wires were bent at a right angle, their bent portions overlapped on top of each other, and then cut to leave approximately 1 mm from the overlapping portions. The K-wires and figure-of-eight wire were lifted slightly off the triceps using an elevator, and the proximal bent portions of the K-wires and figure-of-eight wire were coiled and fixed with a 0.5-mm flexible wire. The proximal portions of the K-wires were not embedded in the triceps brachii tendon but only hammered into them. The figure-of-eight wire was re-tightened at the fastener, and the fracture was compressed, following which the excess metal wire was cut to reduce skin irritation. Finally, we confirmed that the fracture was correctly restored under fluoroscopy and that internal fixation was completed (Fig. 1).

Subjects

Data from the hospitals of a trauma research group were extracted for this study. This registry collects data about all orthopedic trauma patients referred to participating hospitals, with data having been registered annually since 2014. Thirteen hospitals participating in the database were all associated with the Department of Orthopedic Surgery of our university, and 63 orthopedic surgeons perform the surgery at these hospitals.

All eligible patients were registered using an opt-out consent process. Patients were provided with a letter and a brochure informing them that they had been registered, the purpose of the registration, and the procedure to remove themselves from the registry. The registry received ethical approval from all participating institutions, and this study received institutional ethical approval (reference number 2020–564).

We extracted data from the database on 475 patients who were treated with surgery for olecranon fractures from 2014 to 2019. We only included patients with simple olecranon fractures (Mayo type IIA) treated by a team that included at least one trauma or elbow orthopedic surgeon with more than 10 years of experience. We excluded patients (a) treated with other than TBW, (b) with open fractures, and (c) followed up for less than 6 months (Fig. 2).

Clinical Evaluation

The following demographic data were extracted for each patient: (a) background factors: age, sex, body mass index (BMI), and Charlson's comorbidity index (CCI) [7]; (b) injury factors: injury mechanism, injury side (dominant arm or not), and Mayo classification [8]; and (c) operation factors: operation time and intraoperative blood loss from medical records in each participating institution. High-energy trauma was defined as anything worse than a fall from a second floor or traffic accidents between pedestrians or motorcycles and automobiles, whereas low-energy trauma was defined as a fall from a standing position [9]. Operation time was measured from skin incision to wound closure, and blood loss was calculated from gauze and suction.

We evaluated postoperative complications, reoperation, and K-wire backout from patients' medical records and radiographic data. Postoperative complications included the loss of fracture reduction, irritation by the implants, superficial or deep infection, heterotopic ossification [10], and neurological damage. Superficial or deep infection was determined according to the criteria of Horan et al. [11] The occurrence of any sensory or motor disturbance, or numbness was defined as neurological impairment [12]. Implant removal due to patient request without any symptoms was included in this study. The amount of K-wire backout was measured by the distance between the proximal surface of the ulna and proximal K-wire prominence in lateral radiographs. [13]

The main surgeon assessed the Mayo Elbow Performance Index (MEPI) at 3-, 6-, and 12-month postoperative follow-ups. MEPI assesses pain, range of motion, stability, and

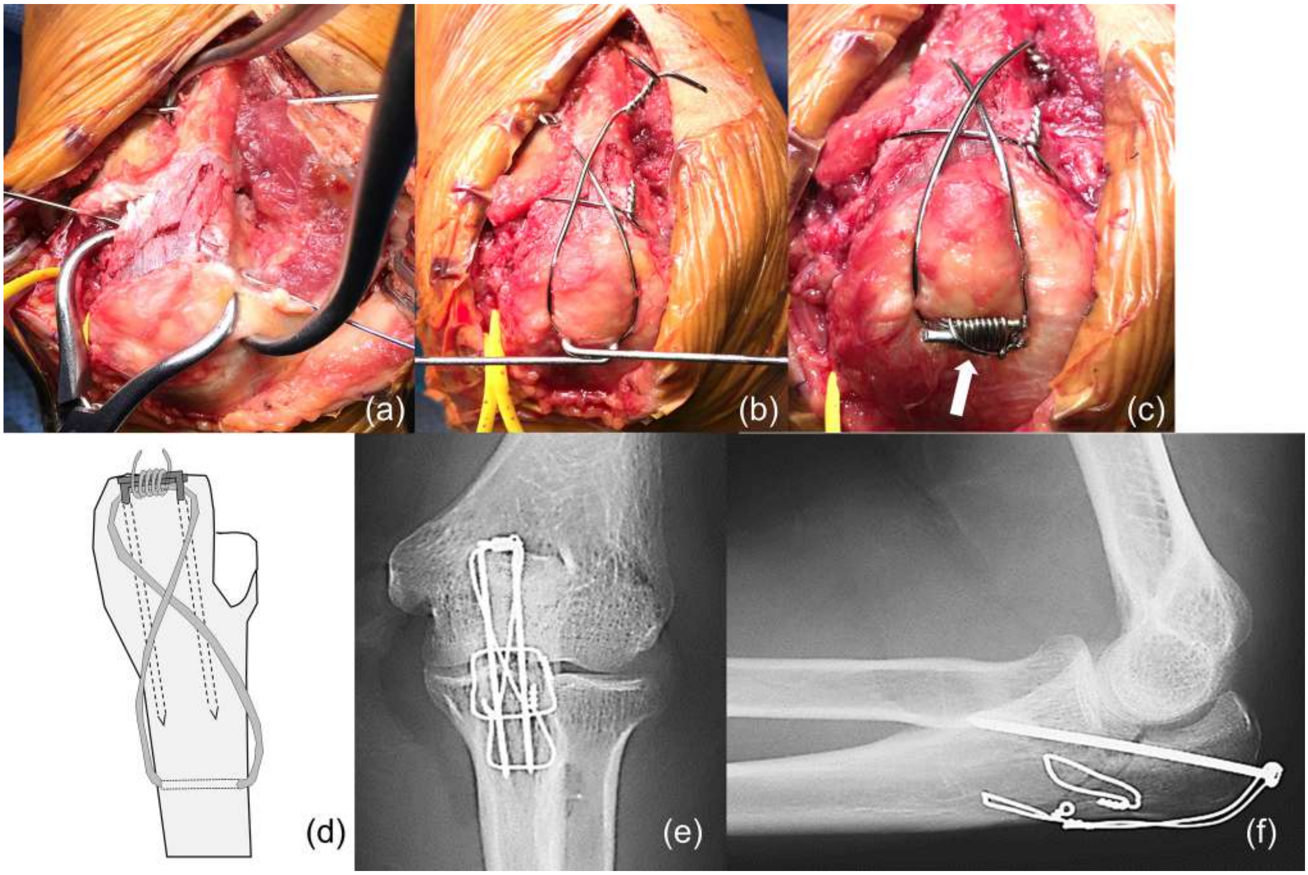
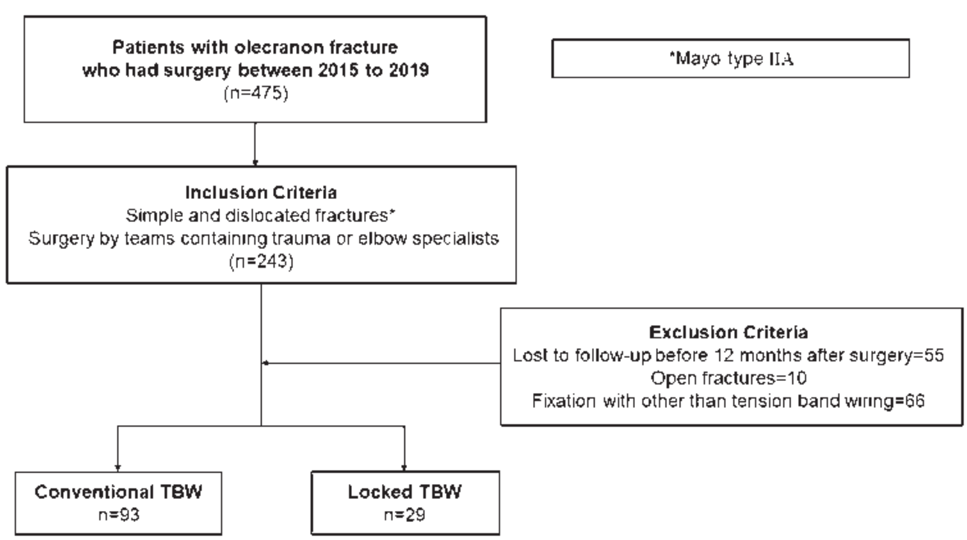


Fig. 1 Surgical procedure for locked tension band wiring: **a** The fracture was crimped using pointed reduction forceps and tension band wiring in a double knot according to the AO surgical reference. **b** The proximal end of the K-wires was bent at a right angle. **c**, **d** An elevator was used to create a gap between the bent portion of the K-wires and the figure-of-eight wire, and the triceps. The proximal bent portions of the K-wires and the figure-of-eight wire were coiled and fixed with a 0.5-mm flexible wire (white arrow). **e**, **f** Postoperative X-rays indicated that the proximal end of the K-wires and the figure-of-eight wire were fixed with the flexible wire. In this case, there were multiple bone fragments, so additional flexible wire was used for the circular wiring to improve stability (color figure online)

Fig. 2 Patient flow in this study. We only included patients with simple and displaced olecranon fractures (Mayo IIA) treated by a team that included at least one trauma or elbow orthopedic surgeon with more than 10 years of experience. Patients with open fractures and those treated with other than tension band wiring (TBW) were excluded. We identified 122 patients with olecranon fractures treated with TBW: 93 were treated with a conventional TBW method, and 29 were treated with locked TBW



ability of daily function (combing hair, eating by oneself, self-hygiene management, and putting on shirts and shoes). [14]

Statistical Analysis

Categorical data were compared between the two groups using Fisher's exact test. Welch's T-test was performed for the analysis of all continuous variables. Radiographic assessment was reviewed by two orthopedic trauma surgeons (YK, SM). We calculated intraclass correlation coefficients (continuous variable) and Kappa coefficient (categorical data) for inter-observer reliability, which were 0.76 and 0.81, respectively. We evaluated missing MEPI data by a multiple imputation method using the Expectation–Maximization with Bootstrapping algorithm [15]. The logistic regression model was used to calculate the odds ratio (OR) with a 95% confidence interval (CI) for risks of symptomatic removal. The significance level was set at $P < 0.05$. All statistical analyses were performed using EZR (Jichi Medical School, Tochigi, Japan). [16]

Results

We investigated 29 and 93 patients with LTBW and CTBW, respectively. The mean follow-up period was 13.1 ± 2.5 months (range, 6–24 months). The baseline characteristics of the patients and their fractures are presented in Table 1. The mean age in the LTBW group was slightly older than that in the CTBW group, but the difference was not significant (67.0 ± 11.9 vs. 60.8 ± 18.5; $p = 0.090$). The proportion of smokers was significantly higher in the LTBW group (mean 34.5% vs. 15.1%; $p = 0.032$).

Operative time was significantly longer for LTBW than CTBW (mean 107.7 ± 20.2 vs. 79.3 ± 30.2 min; $p < 0.001$). The rate of postoperative complications was significantly lower in the LTBW group than in the CTBW group (10.3% vs. 30.1%; $p = 0.048$). Two out of 29 patients in the LTBW group (6.9%) complained of implant irritation and 23 out of 93 patients (24.7%) in the CTBW group, and the difference was significant ($p = 0.032$). Three patients experienced implant failure and two out of them were performed re-implantation surgery. Two patients in the CTBW group developed postoperative infection. One was a superficial infection that was treated with antibiotics for a week, and the other was a deep infection that received implant removal. The reoperation rate in the LTBW group was lower than that in the CTBW group, but there was no significant difference (10.3% vs. 25.8%; $p = 0.122$). The most common reason for reoperation was implant irritation. Three patients experienced early postoperative superficial infection, two patients were cured with intravenous antibiotics only without reoperation, and one patient in the CTBW group required implant removal (Table 2). The mean back out of K-wires in the LTBW group at the last follow-up was significantly less than that in the CTBW group (3.7 ± 0.5 vs. 5.2 ± 1.9

Table 1 Patient demographics

	CTBW	LTBW	*p*.value
Number, *n*	93	29	
Age, years, mean ± SD	60.8 ± 18.5	67.0 ± 11.8	0.090
Sex, M/F, *n*	29/64	14/15	0.120
BMI, kg/m^2, mean, (range)	21.7 ± 4.0	23.3 ± 3.2	0.043
Charlson comorbidity score, *n* (%)			0.586
Low (0)	64 (68.8)	17 (58.6)	
Median (1–2)	22 (23.7)	10 (34.5)	
High (3–4)	1 (1.1)	0 (0.0)	
Very high (≥ 5)	6 (6.5)	2 (6.9)	
Smoking, *n* (%)	14 (15.1)	10 (34.5)	0.032
Injury mechanism, *n* (%)			0.331
Low energy	67 (72.0)	24 (82.8)	
High energy	26 (28.0)	5 (17.2)	
Injury at dominant side, *n* (%)	39 (41.9)	14 (48.3)	0.668

SD Standard deviation, *BMI* Body mass index, *CTBW* conventional tension band wiring, *LTBW* locked tension band wiring

Table 2 Intraoperative and postoperative outcomes

	CTBW	LTBW	*p*. value
Number, *n*	93	29	
Operation time, min, mean ± SD	79.3 ± 30.0	107.7 ± 20.2	< 0.001
Complication*, *n* (%)	28 (30.1)	3 (10.3)	0.048
Implant failure, *n* (%)	2 (2.2)	0 (0.0)	1.000
Infection, *n* (%)	2 (2.2)	1 (3.4)	0.560
Neurological symptoms, *n* (%)	1 (1.1)	0 (0.0)	1.000
Heterotopic ossification, *n* (%)	1 (1.1)	0 (0.0)	1.000
Irritation, *n* (%)	23 (24.7)	2 (6.9)	0.038
Reoperation, *n* (%)	24 (25.8)	3 (10.3)	0.122
Removal, *n* (%)	66 (71.0)	12 (41.4)	0.007
Patients' request, *n* (%)	42 (63.6)	10 (83.3)	
Irritation, *n* (%)	22 (33.3)	2 (16.7)	
Infection, *n* (%)	1 (1.5)	0 (0.0)	
Implant failure, *n* (%)	1 (1.5)	0 (0.0)	
Postoperative K-wire displacement, mm, mean (SD)	2.0 ± 0.9	2.9 ± 0.4	< 0.001
K-wire displacement at last follow-up, mm, mean (SD)	5.2 ± 1.9	3.7 ± 0.5	< 0.001

SD standard deviation, *CTBW* conventional tension band wiring, *LTBW* locked tension band wiring

*There are some duplications in number of complications mm, $p < 0.001$). The mean postoperative K-wire backout at the last follow-up was associated with a high risk of symptomatic implant removal in the logistic regression analysis (OR, 1.32; 95% CI 1.01–1.71; $p = 0.039$).

The mean MEPI at 3 months was 71.4 ± 14.1 (range 40–85) in the LTBW group versus 81.4 ± 18.1 (range 30–100) in the CTBW group, which was significantly different ($p = 0.012$). However, there were no significant differences in the mean MEPI at 6 and 12 months between the two groups (84.8 ± 8.7 vs. 89.8 ± 13.5; $p = 0.087$ and 95.2 ± 6.4 vs. 92.4 ± 9.9; $p = 0.186$, respectively) (Fig. 3). There was a significant difference in mean pain scores at 3 months (32.1 ± 10.1 vs. 24.0 ± 7.5 points; $p < 0.001$).

Discussion

Our modified method, LTBW, decreased the complication and removal rates compared to CTBW in our retrospective cohort. Powell et al. reported that the complication rate of TBW was 33.3%, and the removal rate of TBW for hardware irritation was 27.1%. Rantalaiho et al. [17] showed 148 of 387 patients (48.8%) had early complications and 129 of 387 patients (33.3%) had removal surgery of implant. Tan et al. [18] showed the removal rate due to symptomatic hardware was 21.6%. The complication rate of CTBW in our study (30.1%) was comparable to that in these studies, and the implant removal rate related to symptomatic implants in this study was 24.7% in CTBW and 10.3% in LTBW, which was comparable to that in previous studies (20–50%). [2–4, 17–19]

The theory of the LTB is that the union of the K-wires and figure-of-eight wire at the proximal end is expected to reduce back-out because the compressive force of TBW is used to stabilize the K-wires. Previous studies using a cable system, which was thought to have the same effect as LTBW, showed significantly fewer implant-related complications than CTBW [3, 20]. However, the price of the initial implant for the cable pin system is much higher than that of the LTBW in our country (mean $744 vs. $47, respectively). Kinik et al. reported that their self-locking tension band wiring, in which the proximal K-wire ends were bent to form a loop and the figure-eight wire passed through them, resulted in no adverse event in their case-series study [21]. These results suggested that locking the K-wire proximal ends and the figure-eight wire reduced the implant-related complications compared with CTBW.

Early postoperative MEPI in LTBW was worse than that in CTBW. The difference in pain score was a major factor in the poor early postoperative MEPI in LTBW. The K-wire proximal ends were bent along the fibers of the triceps in CTBW so that the K-wires can be embedded in the triceps. However, this is impossible with LTBW because the proximal ends of the K-wires are bent perpendicular to the fibers of the triceps and are hammered into the triceps. The distance from olecranon to the proximal K-wires in LTBW was significantly more than that in CTBW (2.9 ± 0.4 vs. 2.0 ± 0.9; $p < 0.001$). Therefore, LTBW is considered to have greater irritation to the triceps muscle or posterior elbow by the proximal K-wire ends, which

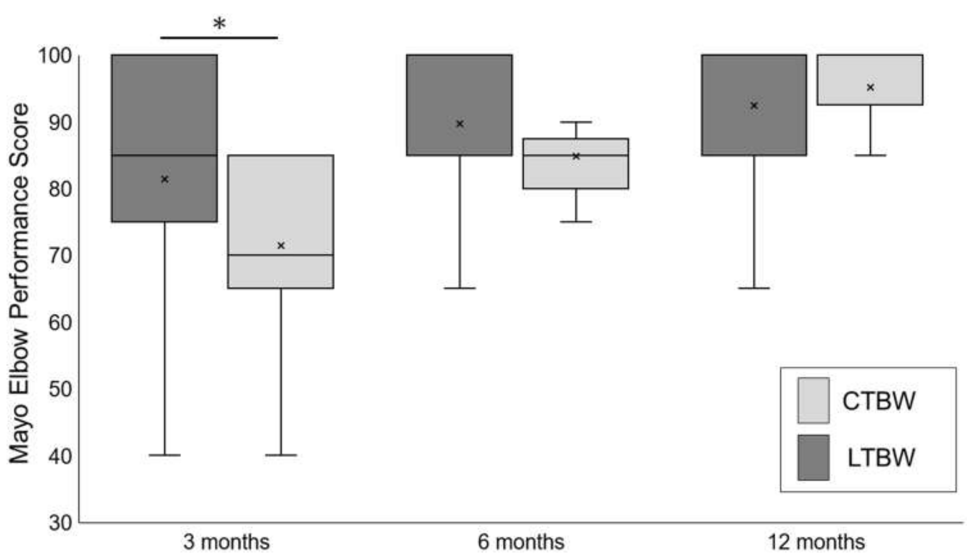


Fig. 3 Box plots for Mayo Elbow Performance Index (MEPI) at 3, 6, and 12 months by intervention group. Boxes show upper and lower interquartile ranges with the median indicated by the black horizontal line, and dots in boxes represented the mean. * indicates a significant difference between the two groups. MEPI in LTBW was significantly lower than that in CTBW at 3 months (71.4 ± 14.1 vs. 81.4 ± 18.1; $p = 0.012$). There was no significant difference in MEPI between the two groups at 6 and 12 months (84.8 ± 8.7 vs. 89.8 ± 13.5; $p = 0.087$ and 95.2 ± 6.4 vs. 92.4 ± 9.9; $p = 0.186$, respectively). CTBW, conventional tension band wiring, *LTBW* locked tension band wiring

might have caused more pain. However, there was no significant difference in MEPI between LTBW and CTBW and the authors have never observed the triceps injuries at the time of implant removal. The implant can be removed by cutting a part of the distal flexible wire and pulling it out proximally; therefore, there is virtually no possibility of damaging the triceps muscle during removal.

This study has some limitations. This study was retrospective, therefore it could have an inherent risk of observer and selection bias, including the potential for missing data and the inability to control confounding variables. LTBW was performed only by two of the authors (YK and SM) and their colleagues. Although TBW was performed by skilled trauma or elbow orthopedic surgeons, the skill of the surgeon might have affected the outcome. To further reduce the α error, the authors did not collect the LTBW data directly. This study had a short follow-up period (6 months or more). Chalidis et al. [22] showed that 48.8% of patients with olecranon fractures had a degenerative articular change in their long-term study. Therefore, long-term prospective studies are required to demonstrate the efficacy of LTBW. The protocols for outpatient care, postoperative rehabilitation, and reoperation were not standardized and followed the policies of the attending physicians and institutions in the present study. This study included hospitals that did not have facilities for adequate postoperative rehabilitation by occupational therapists, which is also the case with the main institution of the LTBW group; if they were standardized, the results could be affected. The mean age in the LTBW group was higher than that in the CTBW group, which was not significantly different, and it might result in a higher tolerance for hardware irritation. However, the mean age of patients who underwent implant removal was 62.9 ± 17.8 and that of patients who did not was 59.6 ± 15.7, and the difference was not significant ($p = 0.375$). The total removal rate was higher than that reported in previous studies (LTBW: 41.4%, CTBW: 71.0%) [2–4]. These results might be due to the fact that implants were removed 1 year after surgery or after bone union, and some insurance coverage included removal of implants even if asymptomatic in our country. To ensure that all cases were considered, patients who underwent implant removal for potential irritation were not excluded from the study even if they did not exhibit specific symptoms noted by their surgeon. The present study showed that the implant removal rate, including patient preference, was significantly lower in LTBW than in CTBW.

Conclusion

We introduced a modified technique for olecranon fractures, and locked tension band wiring. This retrospective study showed that LTBW significantly reduced the complication rates, removal rates, and the amount of K-wire migration compared to CTBW, but significantly increased surgery time. We believe that prospective studies such as randomized controlled trials and comparative studies with locking plates are needed to further demonstrate the efficacy of our modified TBW.

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Author Contributions YK: data collection and assessment, study design, and writing the paper. YT: manuscript preparation, study and conception design. SM: conception design. KT: manuscript preparation and study design. KY: data collection and assessment, and manuscript preparation. SI: conception design and guarantor.

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Data availability Data supporting the findings of this study are available from the corresponding author upon reasonable request.

Declarations

Conflict of interest No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article.

Ethical approval This article does not contain any studies with human or animal subjects performed by any of the authors.

Informed consent For this type of study informed consent is not required.

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ORIGINAL ARTICLE

CT-Based Micromotion Analysis After Locking Plate Fixation of AO Type C Distal Radius Fractures

Eva Lundqvist[1,2] · Henrik Olivecrona[3] · Per Wretenberg[1,2] · Marcus Sagerfors[1,2]

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Abstract

Background Volar locking plate fixation (VLPF) is the most common method for operative fixation of distal radius fractures (DRF). The dorsal ulnar corner (DUC) can be difficult to stabilize as the fragment is small and not exposed when using the volar approach. The purpose of this study was to study fracture fragment migration after VLPF of AO type C DRF, using a volume registration technique of paired CT scans with special focus on the DUC fragment.

Materials and Methods This pilot study included ten patients with AO type C DRF, all operated with VLPF. The primary outcome was radiographic outcome. Postoperative and 1-year scans were compared and analyzed. Fragment migration was assessed with CT-based micromotion analysis (CTMA), a software technique used for volume registration of paired CT scans.

Results All plates were stable over time. Two patients showed signs of screw movement (0.2–0.35 mm and 0.35–> 1 mm respectively). Postoperative reduction was maintained, and there was no fragment migration at the 1-year follow-up except for one case with increased dorsal tilt. The DUC fragment was found in 8/10 cases, fixated in 7/8 cases, and not dislocated in any case at the 1-year follow-up.

Conclusion The CTMA results indicate that variable-angle VLPF after AO type C DRF can yield and maintain a highly stable reduction of the fracture fragments. The DUC fragment remained stable regardless of the number of screws through the fragment. CT volume registration can be a valuable tool in the detailed assessment of fracture fragment migration following volar plate fixation of DRFs.

Keywords Articular · Distal radius fractures · Computed tomography · Dorsal ulnar corner · Internal fixation · Micromotion analysis · Volar locking plate · Outcomes · Trauma · Wrist

Introduction

Distal radius fractures (DRFs) are common, comprising 18% of all fractures among adults in an orthopedic trauma unit, and their incidence is increasing due to an aging population [1, 2]. There has been a shift during recent decades from non-operative and other operative treatments toward volar plate fixation aimed at restoring the anatomy and improving the clinical and radiographic outcome [3, 4]. The volar locking plate has shown good clinical and radiographic outcomes, even for AO type C fractures [5, 6]. It allows early mobilization, which is beneficial for early return of function. Known complications include tenosynovitis, tendon rupture, and median nerve irritation [7]. The frequency of hardware removal is 15–30% [7, 8]. However, concerns have been raised that a single volar locking plate may not be sufficient for complex intra-articular AO type C fractures involving the dorsal ulnar corner (DUC) [9, 10]. The DUC plays a critical role in the DRUJ, anchoring the dorsal distal radioulnar ligament as well as providing dorsal rim stability and preservation of appropriate dorsal tilt [9]. To prevent postoperative displacement of the fragment, stabilization with at least one screw through the volar locking plate has been proposed; however, the size of the DUC fragment is often small [10].

CT-based micromotion analysis (CTMA) is an image post-processing volume registration technique used for

✉ Eva Lundqvist
eva.lundqvist@oru.se

1 Faculty of Medicine and Health, Örebro University, Örebro, Sweden

2 Department of Orthopedics and Hand Surgery, Örebro University Hospital, Södra Grev Rosengatan, 70185 Örebro, Sweden

3 Department of Molecular Medicine and Surgery, Karolinska Institute, Stockholm, Sweden

analyzing and measuring migration between two CT examinations [11]. The registration (i.e., bringing the images into spatial alignment) and calculation are based on the relative micromotion between two rigid bodies, such as non-deforming bone and the implant. The method has shown the clinically relevant precision comparable to radiostereometric analysis (RSA) [11–13]. RSA was introduced in 1974 and is considered the gold standard for assessment of implant migration [14]. However, it requires specialized equipment, trained staff, and strict patient positioning during the examination, and so new methods have been developed. The volume registration technique has been used to analyze motion between the scaphoid and the lunate during the dart-throwing motion, and to analyze triquetral motion after lunocapitate arthrodesis [15, 16], but to our knowledge has not been used to assess fracture fragment migration in DRFs.

In this study, we used CTMA for the first time in a clinical setting in patients surgically treated for AO type C DRF. The aim of this study was to evaluate Computed Tomography Micromotion Analysis (CTMA) in a clinical setting for follow-up of surgically treated AO type C distal radius fracture patients.

Materials and Methods

This prospective study was conducted at the Department of Orthopedics and Hand Surgery, Örebro University Hospital, a tertiary referral center in Sweden. The study was approved by the Swedish Ethical Review Authority (EPM, 2019-04377). All patients gave written informed consent before participation, according to the Helsinki declaration [17]. The study was registered in the Swedish research database FoU in Sweden (www.researchweb.org/is/sverige, ref: 272589). The sample consisted of 10 adult patients with AO type C fractures treated with variable-angle volar locking plates (TriMed, Santa Clarita, CA, USA) between March 25th and October 28th 2020. The plate is made in stainless steel and allows for placement of 3–7 screws in the radius shaft (3.2 mm) and double rows of 2.3 mm locking screws distally with up to 30° optional angulation. Inclusion and exclusion criteria are presented in Table 1. All operations were performed by hand surgeons.

Surgical Technique

Surgery was performed according to department routine under general anesthesia with a brachial plexus block and tourniquet. A volar central incision was made to visualize the volar ulnar portion of the distal radius, and the carpal tunnel was opened through the same incision since the volar corner often is involved in AO type C fractures. The volar portion of the distal radius was exposed between the finger flexors ulnarly, and the median nerve and the thumb flexor radially. The pronator quadratus was divided with a central split. The central incision provides a good visualization of the volar lunate facet, also called the critical corner, and facilitates fixation of the DUC fragment [18]. The volar cortex was reduced, and the volar plate was placed (Fig. 1). The pronator quadratus was repaired using resorbable sutures if feasible.

All patients were seen by a hand therapist on the first day postoperatively for instructions regarding exercises to reduce edema and active finger range of motion exercises. After two weeks with a cast, an orthosis was used for an additional two weeks. Gentle mobilization was initiated two weeks postoperatively. The orthosis was removed during active wrist and finger range of motion exercises. After three months, clinical

Table 1 Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
Age 18–80 years	Previous fracture of the same wrist
Operation within 14 days from injury	Bilateral fractures
AO type C with one or more of the following:	Other concomitant fractures
> 20° dorsal angulation of the distal radial articular surface	Open fracture
> 2 mm ulnar plus	Fracture extending to the diaphysis
> 1 mm incongruence in the radiocarpal joint	Ongoing chemotherapy or radiotherapy
> 1 mm incongruence in the distal radioulnar joint	Metabolic diseases that affect bone
	Dementia
	Mental illness
	Alcohol or drug abuse
	Difficulty understanding Swedish
	Severe neurological disease
	Severe cardiopulmonary disease
	Associated injuries (e.g., ligament injury or other factures in hand/arm)

Fig. 1 Pre- and intraoperative radiographs. Patient number 6

outcome measurements and radiographic evaluation were performed. There were no further load restrictions if the fracture was considered healed. Fracture healing is of today not properly defined and relies on different criteria including mechanical stability [19].

In case of an associated ulnar styloid fracture, the stability of the distal radioulnar joint (DRUJ) was evaluated intraoperatively after plate fixation of the DRF. If DRU instability was found, the styloid was fixated with a 2.0 mm locking ulna hook plate (DePuy Synthes, West Chester, PA, USA).

Clinical Evaluation

At the 1-year follow-up, a hand therapist performed clinical measurements including wrist range of motion (ROM), hand grip strength, visual analog scale (VAS) pain scores, and patient-reported outcome measurements (PROMs).

Validated Swedish translated versions of the Patient-Rated Wrist Evaluation (PRWE) score and the short version of the Quick Disabilities of the Arm Shoulder and Hand (QuickDASH) questionnaire were used [20, 21]. The PRWE is a 15-item questionnaire with a maximum score of 100, where 0 represents no pain or disability in activities of daily living. The QuickDASH questionnaire evaluates a patient's upper extremity disability during the last week. An eleven-item questionnaire is used to calculate a score ranging from 0 to 100, where 100 represents the most severe disability and symptoms.

Wrist ROM (flexion, extension, radial deviation, ulnar deviation, and pronation and supination (degrees)) was evaluated using a goniometer according to guidelines from the Swedish National Quality Registry for Hand Surgery [22].

Hand grip strength in kg was measured with a Jamar Hand Dynamometer (Biometrics Ltd, Newport, UK). The mean value of three measurements was calculated [22]. For right-handed patients, correction of grip strength was calculated as a percentage of the strength on the uninjured side according to the 10% rule [23].

Pain was evaluated both at rest and during activity using the VAS pain score (0 = no pain, 10 = worst imaginable pain).

Radiographic Evaluation and Motion Analysis

The AO classification of the DRFs was assessed by the operating surgeon using preoperative radiographs and intraoperative findings.

CT scan examination was performed preoperatively, postoperatively within 2 days after surgery, and 1 year postoperatively. Double examinations were performed on the first five patients at the postoperative scans, to assess the reliability of the method. The data volumes were acquired according to the protocol used for standard imaging of the wrist (Somatom Definition Flash, Siemens Healthineers, Germany, Erlangen/Forchheim. kV 100, Effective mAs 100, slice thickness/overlap 0.6/0.4 mm, Kernel Br58).

Batra radiographic score was calculated and assessed on postoperative radiographic examinations (anteroposterior and lateral views). The measurements were performed by a single hand surgeon. This score includes radial angle, radial length, volar tilt, and articular incongruency and congruency of the DRUJ. The parameters were summarized and graded in four categories: excellent (90–100), good (80–89), fair (70–79), or poor (< 70) [24].

Postoperative and 1-year follow-up CT examinations were assessed and analyzed. Presence of a DUC fragment was assessed, and the number of screws in each DUC fragment was measured, as was the length of the screws in relation to the distance between the volar and dorsal cortex of the distal radius at the sigmoid notch. Finally, articular incongruence (step off or gap formation) was assessed.

Paired CT volumes were analyzed using the image post-processing volume registration tool CTMA (Sectra CTMA, Sectra, Linköping, Sweden). This tool provides a method for graphically visualizing and numerically calculating the motion in space between two rigid bodies based on CT volume registration [19]. These can be non-deforming bone or an implant. In our setting, the volar plate and the radial shaft proximal to the fracture can be considered rigid bodies, but the individual distal fracture fragments cannot, since remodeling is expected to occur.

First the double examinations were studied, and then the postoperative examination was registered to the 1-year examination. The plate was registered (brought into spatial alignment), and the appearance of the radius proximal to the fracture was examined in 3D and 2D images. Thereafter, the radius proximal to the fracture was registered. Two points, one proximal and one distal on the plate, were chosen as measurement points of the plate relative to the radius. The system by default also gives the movement at a center of mass point. Thereafter the movements of the distal fracture fragments were visualized in multiplanar reconstruction overlay images aligned along the long axis of the radius.

Movement of the screws relative to the plate was analyzed by the CTMA software, using color mapping (intervals: < 0.2 mm, 0.2–0.35 mm, > 0.35 mm).

Results

All 10 patients completed the 1-year follow-up. Demographic characteristics are presented in Table 2. The ulnar styloid was operatively stabilized in one patient. Clinical outcome measures are presented in Table 3.

Registration of the plate showed excellent (< 0.2 mm) overlapping of the surface of the plate. There were no signs of plate deformity over time. After registration of the plate, the radius proximal to the fracture was also aligned, indicating that all plates were stable over time. However, two patients (nos. 8 and 10) showed signs of screw movement (Figs. 2, 3).

Radiographic results are presented in Table 4. The median postoperative Batra score was 88 (range: 64–100). Seven of the 10 cases had a good to excellent Batra score. There was no case with articular incongruence > 1 mm postoperatively. No fragment migration was detected at the one-year follow-up, except for one case (no. 8) with increased dorsal tilt. A DUC fragment was found in 8/10 cases, fixated in 7/8, and not dislocated in any of the cases at the 1-year follow-up. The DUC fragment was fixated with 1–3 screws in each fragment. The median screw length was 82.6% (range: 64.2–126.5%) of the depth (distance between volar and dorsal cortex) of the distal radius. Of the screws in the DUC-fragments, there was one case (no. 8) with dorsal screw penetration. (Figs. 4, 5, 6, 7, 8, 9, 10, 11).

Complications

There was no mechanical failure resulting in secondary surgery. There was no patient with load restrictions after the 3-month follow-up, no postoperative infections, and no cases of tendon rupture or complex regional pain syndrome. Plate removal was performed in one patient due to suspicion of intra-articular screw penetration.

Table 2 Demographic data

Male/female	Age, median (range)	Side fractured, right/left	Hand dominance, right/left	DRF AO type, A/B/C
3/7	54.5 (20–63)	2/8	9/1	0/0/10

Table 3 Outcome 1 year postoperatively

Outcome measure	Injured side, median (range)	Percentage of uninjured side, median (range)
Pronation (degrees)	75 (70–85)	94 (82–108)
Supination (degrees)	80 (65–90)	100 (76–117)
Dorsal extension (degrees)	55 (35–75)	89 (54–115)
Volar flexion (degrees)	70 (45–85)	80 (64–100)
Radial deviation (degrees)	25 (20–30)	100 (80–167)
Ulnar deviation (degrees)	35 (20–50)	100 (63–133)
Grip strength (kg)	23.9 (13.1–57.5)	76 (65–104)
Grip strength (kg), corrected		83 (66–116)
VAS at rest (cm)	0.0 (0.0–0.0)	
VAS during activity (cm)	0.1 (0.0–2.5)	
PRWE (points)	4.0 (0.0–11.0)	
QuickDASH (points)	2.3 (0.0–13.6)	

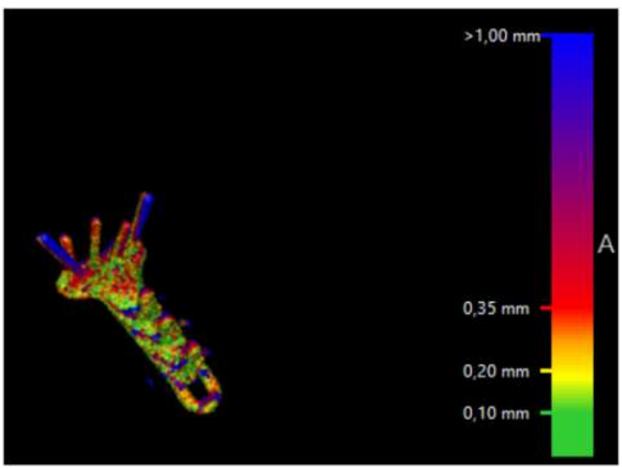

Fig. 2 Alignment result with color mapping. Patient no. 8 with screw migration

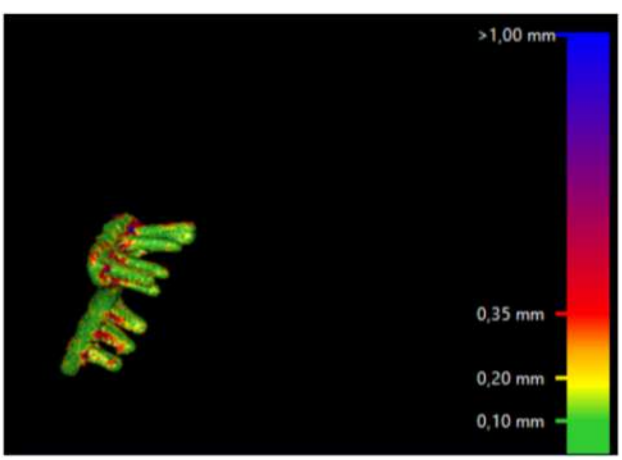

Fig. 3 Alignment result with color mapping. Patient no. 2 without screw migration

Discussion

In this study, we confirmed the usability of CTMA in a clinical setting and were able to distinguish motion in the injured part of the distal radius over time in patients operated for a DRF. The postoperative reposition was maintained and there was no fragment migration at the 1-year follow-up, except for one case with increased dorsal tilt. The DUC fragment was not displaced in any of the cases at the 1-year follow-up. Our findings, using a volume registration technique, indicate that a volar locking plate can yield and maintain a stable fixation of the fracture fragments including the DUC fragment.

This study included 10 cases, as it was a pilot study using CTMA for assessing radiographic outcome after DRF. The number of patients is a limitation and the results, therefore, may not be generalized.

In the present study, 8/10 patients with AO type C DRF had a DUC fragment; this is in line with previous studies showing that the DUC is involved in 87% of all AO type C3 fractures [10]. Bain et al. [25] demonstrated that the DUC is frequently involved in intra-articular DRF as one of the main sites when studying fracture pattern. Miyashima et al. found the mean size of the fragment to be 9 × 8 × 11 mm, occupying 50% of the DRU joint [10]. The DUC fragment can be challenging to reduce and capture because of its size and dorsal location. In the present study, the DUC fragment was fixated in 7/8 cases, with 1–3 screws in each DUC fragment, and the median screw length was 82.6% of the depth of the distal radius. In a recent randomized study including 150 patients with AO type C DRF treated with either volar locking plate or combined plating, the radiographic results were similar between the treatment groups and there was no case of re-displacement or mechanical failure after surgery [6].

In the present study, one of the 10 patients underwent hardware removal before the 1-year follow-up, due to

Table 4 Radiographic results

Patient no	Postoperative articular incongruence, > 1 mm	Maintained reduction at 1 year	Screw migration > 0–0.2 mm at 1 year	DUC fragment present	Number of screws in DUC fragment	Screw length, % of the depth of the distal radius		
						Screw 1	Screw 2	Screw 3
1	No	Yes	No	Yes	2	98.9%	85.6%	
2	No	Yes	No	Yes	3	73.7%	64.2%	70.6%
3	No	Yes	No	Yes	2	89.0%	81.4%	
4	No	Yes	No	Yes	1	71.0%		
5	No	Yes	No	No				
6	No	Yes	No	Yes	2	71.3%	90.0%	89.3%
7	No	Yes	No	Yes	0			
8	No	No	0.35– > 1 mm	Yes	1	126.5%	74.5%	
9	No	Yes	No	No				
10	No	Yes	0.2–0.35 mm	Yes	2	91.2%	82.6%	

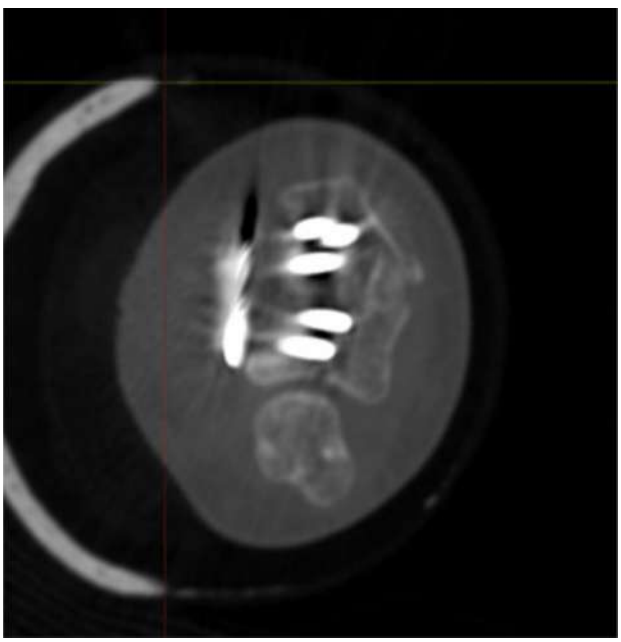

Fig. 4 Postoperative scan of patient no. 2, with DUC fragment outlined

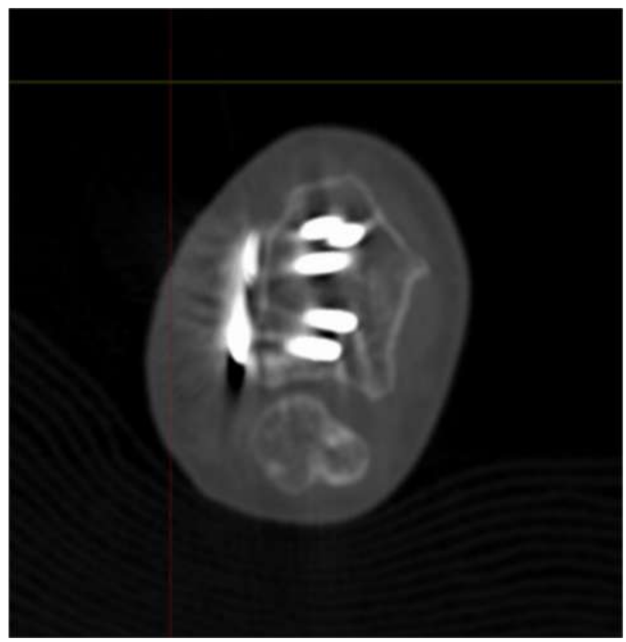

Fig. 5 One-year follow-up of patient no. 2, with no migration/dislocation of the DUC fragment

suspicion of intra-articular screw penetration at the postoperative CT scan. Analysis of screw length regarding the DUC fragment showed that 1 of the 15 screws through the DUC fragment had penetrated the dorsal cortex. The subchondral screws are also important to support the articular surface after DRF. A biomechanical study concluded that locked unicortical distal screws of at least 75% of the length of the bone width can produce construct stiffness similar to bicortical fixation in extra-articular DRF, and at the same time avoid extensor tendon injuries [26]. This is not the case in intra-articular DRF with dorsal fragments or dorsal comminution. The DUC fragment is often small, and if the screws are too short, the fragment will not be captured. Too short screws will not give adequate fixation, and too-long screws mean dorsal prominence and penetration with risk of extensor tendon injury [27]. Ohno et al. [28] found that even when downsizing subchondral screws by 2 mm to prevent dorsal screw penetration, 9.6% of the patients still showed penetration during surgery or at the final follow-up. Detection of screw prominence and penetration is crucial, but difficult in the operating room. Conventional anteroposterior and lateral views are not sufficient to detect penetration [27], and so additional or alternative views and modalities are needed. Our findings show that the DUC fragment remained

Fig. 6 Postoperative scan of patient no. 2, with a dorsal fragment

Fig. 7 One-year follow-up of patient no. 2, with remodulation of the dorsal cortex

Fig. 8 Postoperative scan of patient no. 3, with a < 1 mm gap in the articular surface

Fig. 9 One-year follow-up of patient no. 3, with remodulation of the articular surface

stable when stabilized by a single locking screw, and in one case with no locking screw. The reason for this is not entirely clear, but one explanation may be that stabilizing all the structures surrounding the DUC provides sufficient stability.

Movement of the distal screws in relation to the plate was minimal in 8/10 patients (< 0.2 mm) and more than 0.2 mm in the remaining two. Loosening of the polyaxial locking interface may result in loss of reduction, which was the case in one of these two patients (dorsal tilt). The strength of the locking interface of the variable-angle locking plate differs between implants, and an increase in the

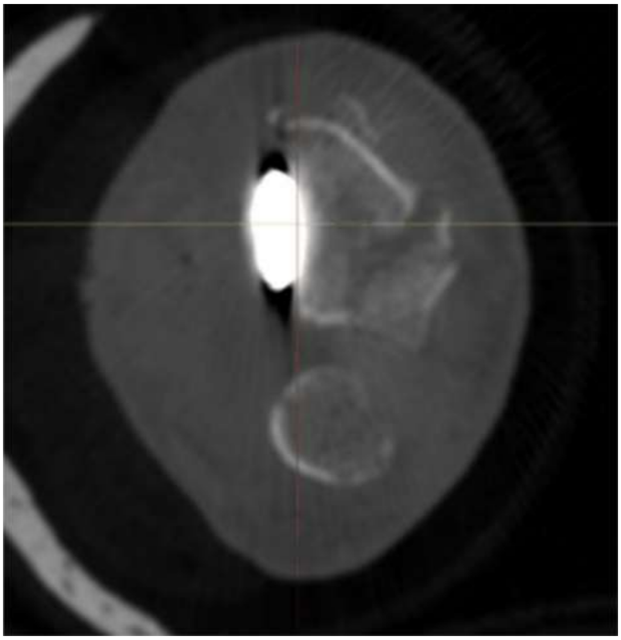

Fig. 10 Postoperative scan of patient no. 6, with DUC fragment outlined

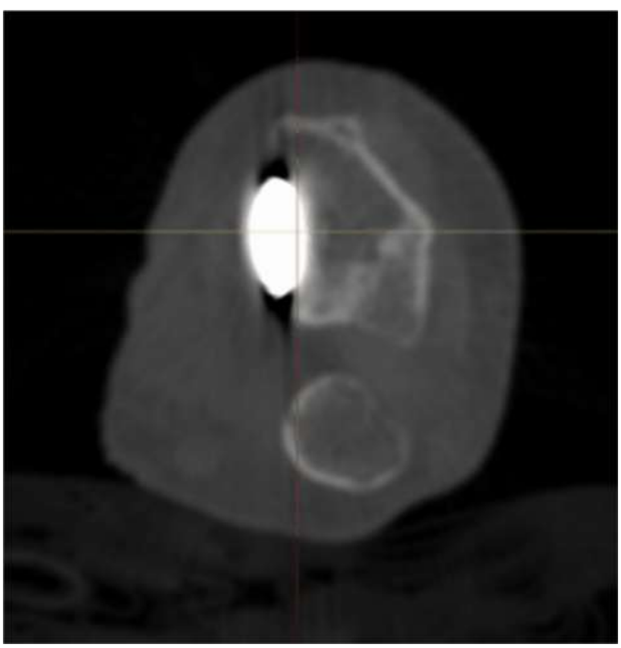

Fig. 11 One-year follow-up of patient no. 6, with no migration/dislocation of the DUC fragment

screw locking angle causes a reduction of strength which depends on the implant [29]. In our case, the loosening of the distal screws may have resulted from a technical error, such as incomplete locking of the screws to the plate.

This study showed no cases with incongruency in the articular surface on the postoperative radiographs, which is encouraging. Articular incongruence, with step or gap, predicts posttraumatic arthritis (PA), but the association between PA and PROMs is still unclear. However, wrist ROM is negatively affected by PA [30]. In this study, the clinical and functional results regarding pain, PROMS, wrist ROM, and grip strength were comparable to previous studies regarding AO type C DRF fixated with volar locking plate with 1-year follow-up [6].

As a next step, a larger cohort of patients treated surgically for a DRF would be needed to follow with CTMA for a longer time period to assess a relationship between fracture fragment movement and clinical outcomes. Given that the correlation between radiographic outcome and clinical outcome after a DRF is poor, it can be debated whether DRF patients benefit from radiographic follow-up. Nevertheless, AO type C DRFs represent the most complex fractures in the large group of patients. We believe these patients need optimal follow-up to facilitate postoperative rehabilitation. To our knowledge, the method of CT volume registration has not been used for DRF before; however, it seems to be suitable for assessing fragment size and migration, especially of key fragments of biomechanical importance to the wrist.

In conclusion, the findings in this study suggest that a variable volar locking plate can yield and maintain a stable reduction and fixation of the fracture fragments after AO type C DRF, including the DUC fragment. Further studies are warranted to determine the role and clinical significance of the DUC fragment. CTMA can be a valuable tool in the assessment of intra-articular DRFs.

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Data availability The data that support the findings of this study are available from the corresponding author, EL, upon reasonable request.

Declarations

Conflict of Interest Dr Olivecrona is occasionally engaged by Sectra as an independent consultant for software development. The authors declared no other potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Ethical Approval The study was approved by the Swedish Ethical Review Authority (EPN, 2019-04377).

Informed Consent For this type of study, informed consent is not required.

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ORIGINAL ARTICLE

Longitudinal Experience and Determinants for Common Mental Health Problems, Phantom Limb and Functional Outcome in Lower Limb Amputees

Uttam Chand Saini[1] · Shubhankar Bu[1] · Himanshu Bhayana[1] · Mandeep Singh Dhillon[1] · Aseem Mehra[2]

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Abstract

Background Amputation of a limb is equivalent to loss of a person's life. Psychological aspects are essential factors in dealing with the disability and functional outcome is a significant concern. Longitudinal studies have not examined the experience and determinants of common mental health problems and functional outcome in lower limb amputees.

Materials and Methodology A total of 103 lower limb amputees were recruited and followed up for 6 months. Patients were assessed on Hospital Anxiety and Depression Scale (HADS) and Social Functioning (SF-36) Quality of life, semi-structured clinical interview for psychiatric disorders and phantom limb at baseline (in hospital), at 2 weeks, 3 months and 6 months, respectively after discharge. Holistic care was provided through psychological counselling, supportive sessions, medications if required, rehabilitation counselling, prosthesis implantation, and treatment as usual.

Results Holistic care resulted in a statistically significant reduction in anxiety, depression and overall psychiatric morbidity as measured on HADS ($p < 0.001$). There was a significant improvement in all the domains of SF-36 (p -< 0.001) except the role of limitation due to physical activity. The intervention also resulted in a statistically significant reduction in the presence of phantom limbs.

Conclusion Amputees should be provided holistic care under one roof, which was found to be very useful in treating psychiatric morbidity, social functioning and quality of life.

Keywords Amputation · Psychiatric Morbidity · Social functioning · Quality of life

Introduction

Amputation of a limb is either losing a leg, arm, or part of these limbs due to various reasons like traumatic injury, burns, peripheral vascular disease, infection, etc. [1]. Amputation can lead to permanent disability, significantly impacting an individual's life and quality of life. Amputation of any limbs is associated with psychological problems and different levels of physical impairment [2]. In traumatic injuries, lower limb amputation accounted for more than three-fourths (approx. 73.5%) of all limb losses [3]. Amputation incidence in different countries varies from 1.2 to 4.0 per 10,000 persons [4, 5]. The loss of a limb can lead to Anxiety, Depression, poor quality of life, social discrimination and suicidal ideation amongst amputees. The prevalence of psychiatric disorders in amputees ranges from 32 to 84% [6, 7], with a prevalence of depression and anxiety disorder ranging from 10.4 to 63% [8, 9] and 3.4%–10%, respectively [7, 9]. Only a few longitudinal studies evaluated the rate of Depression and Anxiety over a period of time and reported that prevalence of these disorders decreases with time [10–12]. In the previous studies, being female, young, low education, poor social support, unemployed, and having

✉ Aseem Mehra
aseemmehra86@gmail.com

Uttam Chand Saini
doc.uttamsaini@gmail.com

Shubhankar Bu
vegetass93@gmail.com

Himanshu Bhayana
Himanshu.Bhayana.mamc@gmail.com

Mandeep Singh Dhillon
drdhillon@gmail.com

[1] Department of Orthopaedics, PGIMER, Chandigarh, India

[2] Department of Psychiatry, PGIMER, Chandigarh, India

below-knee amputation were some of the factors associated with psychological symptoms.

Most studies are cross-sectional studies conducted at different periods after amputation with different scales and treatment settings. Only a few studies are available which evaluated the patients prospectively and assessed the prevalence of psychiatric disorders. The study conducted by Srivastava et al. (2010) [10], evaluated 50 consecutive patients admitted to artificial limb centres and showed significant differences in scores on HADS before and after therapy [10]. In another study conducted by Kashif et al. [12], 40 patients with limb amputations were examined. The findings of the study showed that 29 (72.5%) of the amputees had psychiatric disorders, which reduced significantly to 20 (50%) after therapy.

The previous studies reported a very high prevalence rate of psychiatric disorders at different periods after amputation. The previous studies highlighted the importance of early intervention to improve the quality of life. In addition, the presence of psychiatric disorders is also an obstacle to providing the prosthesis or successful use of the prosthesis. However, to date, no studies evaluated the patients to assess the impact of early intervention from the day of amputation. With this background, the current study focussed to assess the impact of early intervention in patients with lower limb amputations over a period of 6 months.

Materials and Methodology

Study Design and Sampling Technique

The study was a longitudinal prospective study conducted at a tertiary care hospital in northern India. The sampling technique was consecutive. The Institute ethic committee approved the study.

Study Site

Emergency Trauma Clinic of a tertiary care hospital.

Sample Size

The sample size was calculated as per the Fisher formula, considering a confidence interval of 95%, with a precision of 10%, and proportion of patients reaching to designated clinic more than 10,000. The sample size came out was 96. We included a total of 106 participants considering a drop out of 10% at 6 months. At the 6 months, 103 patients were included in the present study.

Inclusion Criteria

For this study, those participants who were ≥ 18 years, either gender, able to understand the Hindi/Punjabi/English included. Those who were suffering from intellectual disability, had significant cognitive decline, acute debilitating physical illness, refused to give consent and had a past history of psychiatric disorder were excluded from the present study. The study sample comprised 103 patients.

Procedure

The first amputee clinic of India was started in 2021 in our institute i.e. "PGI Amputee Clinic". The motive of the clinic was to provide comprehensive care to post-trauma amputees in collaboration with various aspects of multidisciplinary care. The specialist, including an orthopaedic surgeon, Psychiatrists, Psychologists, physiotherapists, occupational therapists, prosthetists and nursing care, started to provide holistic care under one roof. The concept of this clinic was not only to provide care after the trauma but also to care for them after surgical recovery by providing psychological help, occupational training, appropriate prosthesis etc. and to follow the patients till the potential return of the amputee as a normal lifestyle to the maximum extent.

In the present study, those with roadside accidents or traumatic injuries presented with lower limb injuries to the emergency trauma clinic. They were assessed by the orthopaedician and based on the clinical evaluation and with a mangled extremity severity score (MESS score of > 10), selected for amputation were registered under the special clinic "PGI Amputee Clinic". After the amputation, patient and their family member were assessed by the psychiatrist, psychologist and social worker within 24 h to look for any psychological or social problem.

Before recruitment in the present study, informed consent was obtained from the participants. Patients were assessed on the Hospital and Anxiety Disorder Scale (HADS), Short form-36 (SF-36) Quality of Life Survey and for presence of phantom limbs with semi-structured clinical interview for presence of psychiatric disorder. In the present study, all the patients and their caregivers received counselling sessions, supportive session and psycho education about the follow-up status, consequences in future, implantation of the prosthesis, rehabilitation process, and financial help if anyone required, apart from regular nursing care along with the treatment as usual. Those patients who were found to be suffered from psychiatric or physical disorders were offered treatment and started on medications as per the need of patient by following the institute protocol. All the patients were called for follow-up in the "PGI amputee Clinic" after two weeks from the day of discharge. At 2 weeks, patients were assessed by the orthopeadician, psychiatrist, psychologist, physiotherapist and another specialist. The same instruments were applied, i.e. HADS and SF-36, along with clinical assessment for phantom limb and presence/prognosis of psychiatric disorder. Those patients who did not come on the follow-up date were contacted over the phone. These patients were provided with another follow-up date within one week.

Similarly, patients were followed up at 3 months and 6 months from the day of discharge. At 3 months and 6 months, patients were also assessed for prosthesis implantation. If the patient found to be suitable for prosthesis implantation, an artificial limb was implanted or planned based on the clinical outcome (Fig. 1).

Instruments used in the present study

Sociodemographic Profile

A basic information sheet which includes information about the subject's age, gender, marital status, educational qualifications, locality, current work profile etc..

Using a semi-structured interview, based on the available information from the patient, family members, and mental status examination, psychiatric diagnosis was made as per the International Classification of Diseases, 10th revision (ICD-10) criteria by the qualified psychiatrist, and if required, the patients were started on treatment. In addition, participants were evaluated on following instruments.

Hospital Anxiety and Depression Scale (HADS) [13]

This tool was initially developed by Zigmond and Snaith in 1983 and is used for assessing the severity of Anxiety and Depression and evaluating the risk for these disorders. This scale is more suitable for patients with physical disabilities. This scale is a 4-point Likert-type scale, which includes 14 items, of which seven items each for Anxiety and Depression. Higher the score higher the risk of Anxiety and Depression. A total subscale score of ≥ 8 points indicates the presence of considerable symptoms of Anxiety or Depression. This scale is validated in Indian languages too [14, 15].

Short form-36 (SF-36) Quality of Life Survey

Ware and Sherbourne [16] developed this scale to evaluate quality of life. The tool consists of 36 items assessing eight aspects of health: vitality, physical functioning, bodily pain, general health perceptions, physical role functioning, emotional role functioning, social role functioning, and mental health. The scores are transformed to range from zero, where the respondent has the worst possible health, to 100 where the respondent is in the best possible health. It is a validated tool for the population with mobility-related or musculoskeletal-related disorders [17].

Statistical Analysis

Statistical Package for the Social Sciences, Windows version 22 (SPSS-22, SPSS Inc., Chicago) was used for analysis. Continuous variables were analyzed in the form of mean and standard deviation (SD). Frequencies, along with percentages, were calculated for categorical variables. Comparisons were done using Chi-square test. An association of Depression, Anxiety and quality of life, clinic and demographic variables was studied by using Pearson's product-moment correlations and Spearman rank correlations. Repeated Measure ANOVA was used to determine whether or not

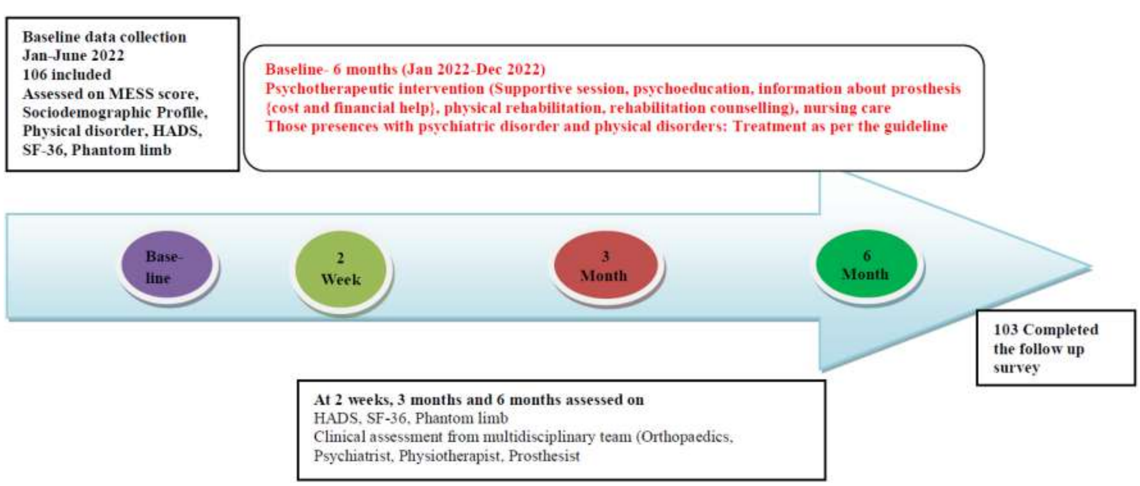

Fig. 1 Timeline of baseline and follow-up surveys in relation to amputation of lower limb and prevention measures in “PGI Amputee Clinic”

there was a statistically significant difference between the means score of HADS and SF-36 was there at different period of time i.e. from baseline assessment to 6 months.

Results

A total of 103 participants were recruited in the present study; mean age was 37.7 (SD-14.6) yrs.

Majority were male (87.4%), on paid employment (95.1), and from middle socioeconomic status (83.5%). Approximately two-thirds were single (69.9%) and from joint/extended families (61.2%). A little more than half (53.4%) were from a rural background, as depicted in Table 1.

As shown in Table 2, majority of them presented with roadside accident injury (83.5%) and had grade 3 C level of injury (72.8%). More than half of them underwent above-knee amputation (52.5%). 38.8% reported the use of the substance, rest of the details are provided in Table 2.

Table 1 Sociodemographic profile of study participants (N-103)

Variables	Frequency (%)/mean (SD)
Age (years)	37.7 (14.6)
Category of age	
Young adults (18–24 years)	23 (22.3%)
Adults (Millennials) (25–44)	48 (46.6%)
Middle age (45–59)	22 (21.4%)
Older adults (≥ 60 years)	10 (9.7%)
Gender	
Male	90 (87.4)
Female	13 (12.6)
Marital status	
Married	31 (30.1)
Currently single (separated/widowed/divorced)	72 (69.9)
Number of years of education	8.2 (4.2) (range: 0–15)
Socioeconomic status	
Lower	14 (13.6)
Middle	86 (83.5)
Upper	3 (2.9)
Type of family	
Nuclear	40 (38.8)
Non-nuclear (joint/extended)	63 (61.2)
Locality	
Rural	55 (53.4)
Urban	48 (46.6)
Employment	
On paid employment	98 (95.1)
Unemployed	5 (4.9)

Table 2 Clinic profile of study participants (N-103)

Variables	Frequency (%)/mean (SD)
Mode of injury	
Roadside accident	86 (83.5)
Machine cut injury	7 (6.8)
Crush injury	5 (4.9)
Train accident	3 (2.9)
Gunshot injury	2 (1.9)
Area of the limb involved	
Below knee	60 (58.3)
Above knee	43 (41.7)
Gustilo Anderson's grading of injury	
Grade 3B	28 (27.2)
Grade 3C	75 (72.8)
Pulse was present at the initial evaluation	
Yes	28 (27.2)
No	75 (72.8)
Distal neurovascular deficit	
Present	101 (98.1)
Absent	2 (1.9)
Final level of amputation#	
Above knee	54 (52.5)
Below knee	49 (47.5)
Substance use/abuse*	
Present	40 (38.8)
Absent	63 (61.2)

*Alcohol-37 (35.9%); Tobacco-25 (24.3%)

#Amputation after reconstruction surgery if any one required following first surgery

On the HADS, 9 were identified with anxiety syndrome at the baseline, and this number was reduced to zero at 6 months. On HADS, 100 were identified with depressive syndrome and reduced to 10 by 6 months, as depicted in Table 3. The overall score on HADS at the baseline was 21.8 (SD-3.5) and decreased to 6.9 (SD-3.1). The overall score on SF-36 at the baseline was 25.8 (SD-5.2), which increased to 60.9 (SD-4.3) at 6 months, as shown in Table 3. Rest of the details are provided in Table 3.

Repeated measure ANOVA test was done to assess the impact of intervention at different periods of time.

In terms of anxiety disorder, we can see that there was a statistically significant difference in mean score of an anxiety disorder (on HADS) pre-intervention compared to 2 weeks ($p < 0.001$), 3 months ($p < 0.001$) and 6 months ($p < 0.001$). Even from the "Mean Difference (I-J)" column, we can see that the overall mean score of anxiety disorder was significantly reduced from baseline to 6 months, as mentioned in Table 4. The same has been plotted in Fig. 2

Table 3 Psychological morbidity and health-related quality of life at different periods of time

Variables	Baseline (N-103)	At 2 weeks (N-103)	At 3 months (N-100)	At 6 months (N-100)
Hospital anxiety and depression scale (HADS)				
Anxiety syndrome				
Present	9 (8.7)	69 (67.0)	6 (6.0)	–
Absent	94 (91.3)	34 (33.0)	94 (94.0)	100 (100)
Severity of anxiety				
Normal	9 (8.7)	69 (67.0)	94 (94.0)	100 (100)
Borderline abnormal	83 (80.6)	34 (33.0)	6 (6.0))	–
Abnormal	11 (10.7)	–	–	–
Overall score on the Anxiety domain	8.5 (1.4)	6.6 (2.1)	4.4 (3.2)	1.9 (1.2)
Depressive syndrome				
Present	103 (100)	44 (42.7)	12 (12.0)	10 (10)
Absent	–	59 (57.3)	88 (88.0)	90 (90)
Severity of depression				
Normal	00	59 (57.3)	88 (88.0)	90 (90)
Borderline	15 (14.6)	27 (26.2)	12 (12.0)	9 (9)
Abnormal	88 (85.4)	17 (16.5)	–	1 (1)
Overall score on the depression domain	13.3 (2.7)	7.9 (2.1)	6.4 (1.5)	4.9 (2.4)
Overall score on HADS	21.8 (3.5)	14.5 (3.5)	10.8 (3.2)	6.9 (3.1)
Phantom limb pain				
Present	101 (98.1)	100 (97.1)	53 (53)	10 (10)
Absent	2 (1.9)	3 (2.9)	47 (47)	–
Short-form health-related quality of life (SF-36)				
Physical functioning/Vitality	0.0	9.4 (9.8)	34.4 (14.1)	49.4 (17.5)
Role functioning/physical	0.0	0.0	1.0 (100)	1.0 (7.1)
Role functioning/emotional	55.3 (38.1)	72.5 (36.6)	93.9 (21.4)	99.7 (3.3)
Energy/fatigue	19.7 (6.8)	38.8 (8.1)	53.6 (10.6)	61.9 (6.9)
Emotional well-being	49.1 (7.1)	62.6 (8.7)	68.4 (8.3)	76.9 (6.2)
Social functioning	53.4 (9.6)	70.1(13.1)	79.1 (11.1)	91.2 (7.3)
Pain	21.8 (9.5)	21.8 (9.5)	64.2 (11.1)	86.4 (11.9)
General Health	32.1 (12.1)	45.1 (14.1)	46.8 (7.9)	47.7 (7.9)
Health change	1.2 (5.4)	16.5 (17.1)	33.8 (12.9)	34.5 (12.2)
Overall score on SF36	25.8 (5.2)	34.9 (6.6)	52.7 (5.5)	60.9 (4.3)
Semi-structured clinical interview based on ICD-10				
At least on psychiatric disorder				51 (49.5%)
Depressive disorder				15 (14.6%)
Anxiety disorder				7 (6.8%)
Delirium				13 (12.6%)
Substance abuse				40 (38.8%)

In terms of depression, as measured on HADS, there was a statistically significant difference in mean score of depression at the baseline (pre-intervention) compared to 2 weeks ($p < 0.001$), 3 months ($p < 0.001$) and 6 months ($p < 0.001$). Even from the "Mean Difference (I-J)" column, it is evident that the overall mean score of the depressive syndrome was significantly reduced from baseline to 6 months as mentioned in Table 5. The same has been plotted in Fig. 3

Overall score decreased significantly with time, i.e. from baseline to 6 months, as evident in Fig. 4 (Table 5).

Table 4 Pairwise comparison of anxiety disorder at different periods of time

(I)Factor 1	(J)Factor1	Mean difference (I-J)	Std error	Sig (*p*-value)	95% confidence interval for difference	
					Lower bound	Upper bound
1	2	1.990	0.251	< 0.001*	1.315	2.665
	3	4.140	0.282	< 0.001*	3.381	4.899
	4	6.580	0.174	< 0.001*	6.111	7.049
2	3	2.150	0.283	< 0.001*	1.387	2.913
	4	4.590	0.225	< 0.001*	3.985	5.195
3	4	2.440	0.248	< 0.001*	1.772	3.108

*$p < 0.05$

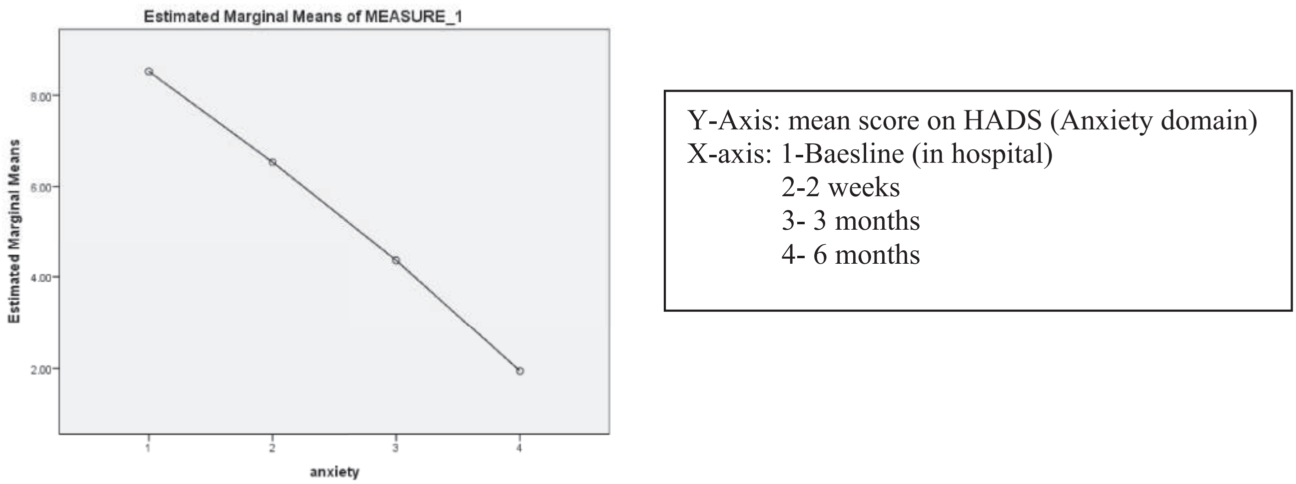

Fig. 2 Changes in the level of anxiety from baseline to follow up i.e. 6 months

In terms of social functioning of quality of life, there was a statistically significant difference in the overall mean score of SF-36 at the baseline (pre-intervention) compared to 2 weeks ($p < 0.001$), 3 months ($p < 0.001$) and 6 months ($p < 0.001$). Even from the "Mean Difference (I-J)" column, it is evident that the overall mean score of the depressive syndrome significantly increased from baseline to 6 months, as mentioned in Table 6 (Fig. 5).

Sub-domain of SF-36

In terms of the role of limitations due to physical health, no significant differences were noted in the overall mean score at the different periods of time.

In terms of pain, there were no significant differences noted in the mean score of change of pain from baseline to

Table 5 Pairwise comparison of depression

(I)Factor 1	(J)Factor1	Mean Difference (I-J)	Std error	Sig (*p*-value)	95% confidence interval for the difference	
					Lower bound	Upper bound
1	2	5.330	0.307	< 0.001*	4.504	6.156
	3	6.860	0.315	< 0.001*	6.013	7.707
	4	8.330	0.339	< 0.001*	7.417	9.243
2	3	1.530	0.255	< 0.001*	0.843	2.217
	4	3.000	0.277	< 0.001*	2.255	3.745
3	4	1.430	0.267	< 0.001*	0.752	2.188

*$p < 0.05$

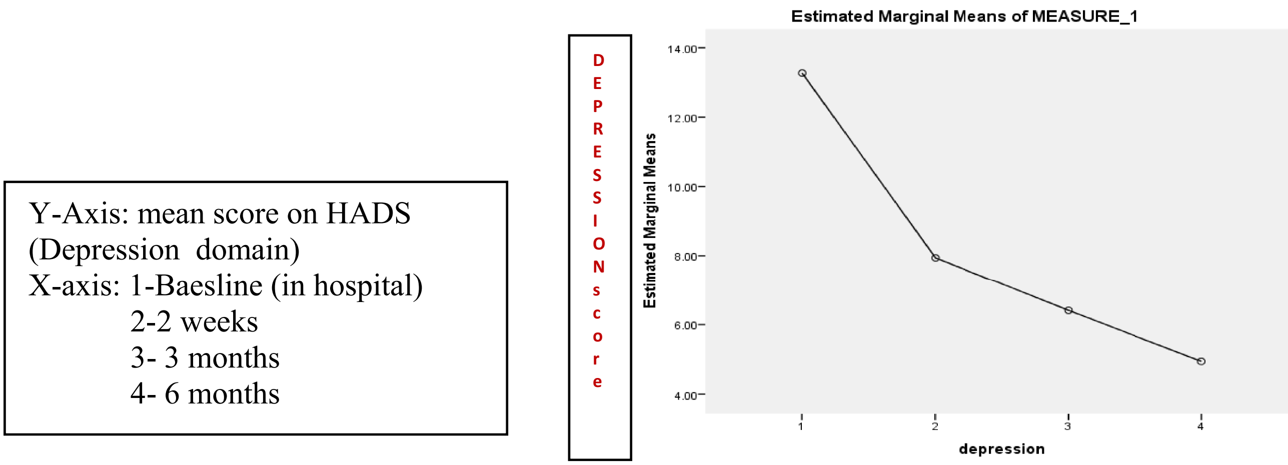

Fig. 3 Changes in the level of depression from baseline to follow up i.e. 6 months

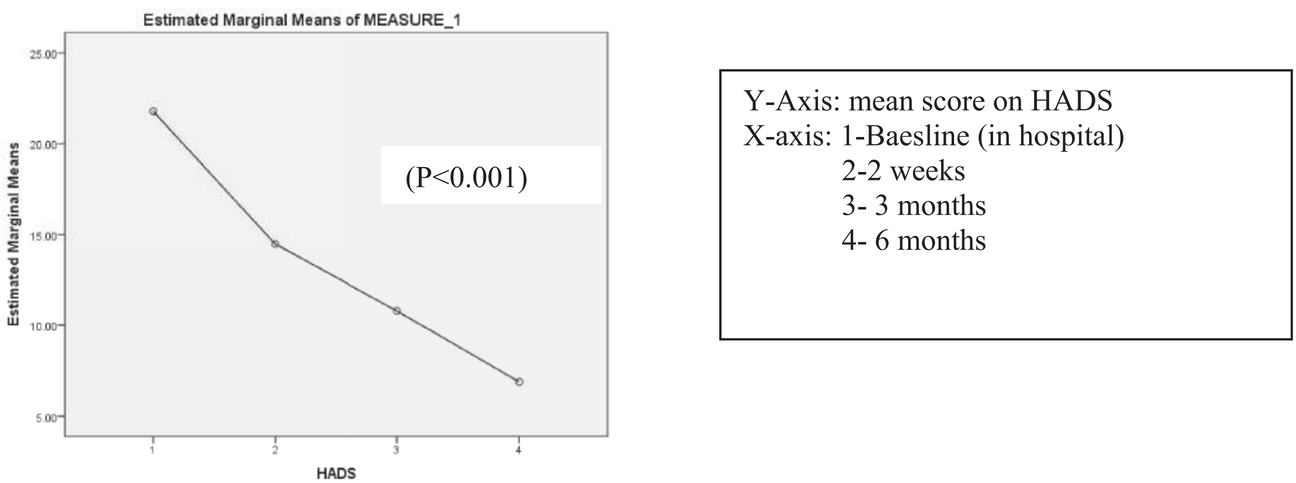

Fig. 4 Changes in the overall score of HADS from baseline to follow up i.e. 6 months

2 weeks, however, thereafter, significant differences were noted in the mean score of change in pain from baseline to 3 months ($p < 0.001$) and 6 months ($p < 0.001$) from 2 weeks to compare with 3 ($p < 0.001$) and 6 months ($p < 0.001$), respectively.

In terms of change in general health, significant differences in the mean score of change in general health were noted at different periods.

Rest of the domain showed a significant difference in change in the mean score over a period of time i.e. from baseline to 2 weeks ($p < 0.001$), 3 months ($p < 0.001$), 6 months ($p < 0.001$) and so on.

Correlates of Social functioning, as Measured on SF-36 and Anxiety and Depression, Measured on HADS at Different Time Points After Amputation

In-Hospital Evaluation (At the Baseline)

Those who were middle-aged and older adults (> 45 years) reported more of anxiety symptoms compared to those with younger adults (x^2-10.066; p-0.018). Those who were from rural areas scored statistically significantly higher score on HADS (x^2-2.732; p-0.007) and subdomain of HADS, i.e. anxiety (x^2-2.484; p-0.015), and depression (x^2-2.204; p-0.030) compared to those belongs to urban locality. Those from extended/joint family setup

Table 6 Pairwise comparison of social functioning (SF-36) quality of life

(I)Factor 1	(J)Factor1	Mean Difference (I-J)	Std error	Sig.[a] (p-value)	95% confidence interval for difference	
					Lower bound	Upper bound
1	2	− 9.195	0.815	< 0.001*	11.388	7.001
		− 26.862	0.801	< 0.001*	29.020	24.704
	4	− 35.046	0.706	< 0.001*	36.949	33.144
2	3	− 17.667	0.864	< 0.001*	19.950	15.340
	4	− 25.881	0.757	< 0.001*	27.891	23.812
3	4	− 8.184	0.646	< 0.001*	9.924	6.644

[a]Adjusted for multiple comparisons: Bonferroni; *the mean significant difference is at 0.05

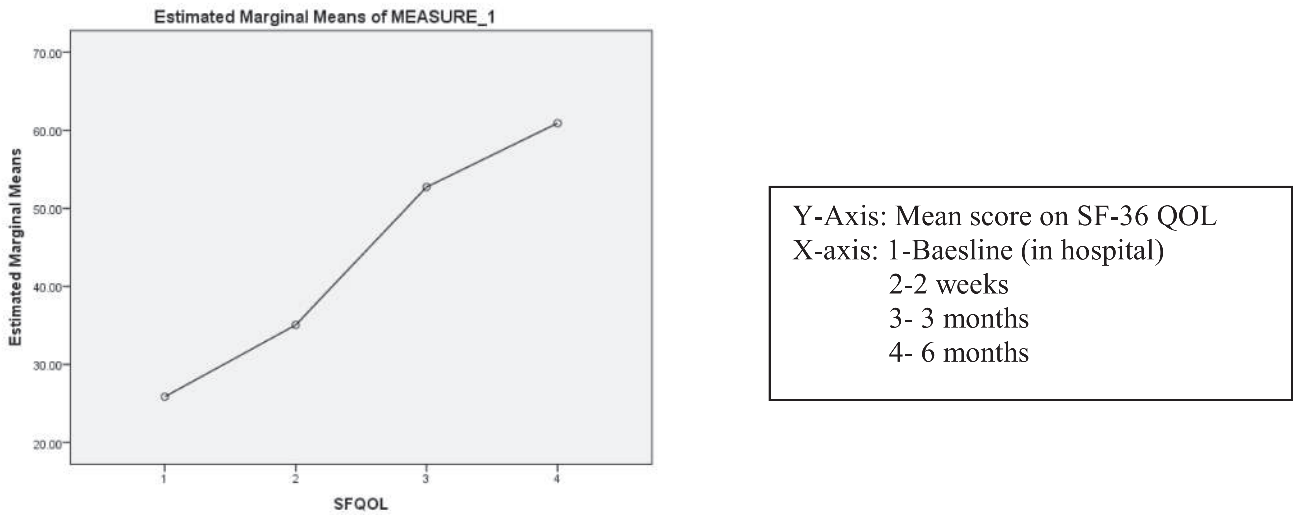

Fig. 5 Change in the social functioning from baseline to follow up i.e. 6 months

scored statistically significantly higher overall scores on HADS (x^2-2.090; p-0.039).

Those from lower socioeconomic status scored significantly higher score on HADS (x^2-2.475; p-0.015) and anxiety domain of HADS compared to those from middle socioeconomic status(x^2-2.678; p-0.009).

2 Weeks After Amputation

Those from lower socioeconomic status scored significantly higher score on HADS (x^2-2.239; p-0.027) and anxiety domain of HADS compared to those from middle socioeconomic status (x^2-2.192; p-0.031). Those with below-knee amputation scored significantly higher score on HADS (x^2-2.283; p-0.025) and depression domain of HADS (x^2-2.476; p-0.015) compared to those with above-knee amputation.

3 Months After Amputation

Females reported significantly better health change than males (x^2-2.003; p-0.048).

6 Months After Amputation

No significant correlation was seen between sociodemographic, clinic variables and psychiatric morbidity, except those who returned to work or re-employed reported significant improvement in health and social functioning compared to those who did not return to work ($p < 0.001$).

At 6 months, successful prosthetic implantation was done for 24 patients (23.3%). When a comparison was made with those who did not get the prosthetic implantation, it was found that those with prosthetics had significantly better social functioning compared to another group (t-2.606; p-0.011). In other domains, no significant differences were noted.

Discussion

Amputation means a loss and psychological reactions to loss lead to bereavement, as equivalent to the grief experienced by a person who loses their near-dear ones. These reactions are manifested in different forms like anxiety disorder, depression, suicidal ideation, poor quality of life etc. In the present study, a total 103 amputees were studied for a period of 6 months. The mean age was 37.7 years. The findings are more or less comparable with the previous studies [10, 12, 18]. The middle age population is more prone to roadside accidents because they are the breadwinner for the family, earning population, working in different industries and using motor vehicles more frequent as a mode of transport.

On HADS, 85.4% were at risk of depressive disorder and 10.7% at a risk of anxiety disorder. While on the basis of semi-structured clinical interviews (ICD-10), overall, 49.5% had a presence of at least one psychiatric disorder. 38.8% had presence of substance use/abuse, 14.6% had a presence of depression, and 12.3% had delirium.

The overall prevalence of psychiatric disorders was 49.5% in the present study. The prevalence of psychiatric disorders in the existing literature in amputees was reported in a range of 32–84% [6, 7, 19], similar to the present study. The reasons for inconsistent findings may be because different instruments were used with different cut-off scores to diagnose the psychiatric disorder. Second, studies were done at different periods after amputation from 3 months to 2 years [6–9, 12]. The advantage of the present study is that diagnosis was made by a trained psychiatrist based on the clinical interview. In the present study, the most common diagnosis was substance abuse/dependence, and it was difficult to compare the findings with the previous studies. No studies have evaluated the presence of substance abuse/dependence. Most of the studies focused on depression or anxiety disorder. Hence, this study also highlights the importance to evaluate for the presence of substance use so that early intervention can be provided. Second, substance use can be one of the reasons for poor adherence to the treatment, poor adaptation to the prosthesis or difficulty in integrating into society. Substance use can be one of the reasons for traumatic events, which can be prevented by educating society or implementing effective policies. The prevalence of depression and anxiety disorder was 14.6% and 6.8%. The present study's findings align with previous studies [7–9]. From the findings, it could be said that depression is an almost invariable concomitant of a disabling physical illness, either as an organic symptom or emotional consequence.

All the patients, whether they had psychiatric morbidity or not, received counselling regarding the traumatic event they underwent, along with education about the prosthesis implantation, rehabilitation counselling, muscle strengthening exercises and financial aids for poor patients with treatment as usual. Those with the presence of primary psychiatric disorders received active intervention in the form of psychotropics with psychotherapeutic intervention. After that, it was seen that after treatment there was a significant difference across all the domain of HADS (Includes Depression and Anxiety). There was a statistically significant increase in the score of all the domains of SF-36 except role functioning in physical form. The finding indicates the effectiveness and usefulness of holistic care, including psychotherapeutic, rehabilitation, physicist, and nursing care, in ameliorating amputees' psychological and physical distress. The present study's findings agree with the previous studies [9, 10, 12].

Limitations of the Study

The study was limited to lower limb amputees and with traumatic events only. The sample size was small, and the follow-up period should be longer to retain the complete functionality in daily life. Future should be large with qualitative in nature would provide more comprehensive details. The studies should be multicentric with a larger sample size and for a longer period. Other confounding variables like personality traits, social supports, emotional maturity and knowledge of prosthesis implantation were not taken in to account.

Conclusion

The present study highlights the high incidence of psychiatric disorders in a patient with amputees. In view of the same, it is suggested that psychiatric evaluation and management should be an integral part. The study's findings reinforce the need for psychological assessment and intervention along with good nursing care, rehabilitation counselling, financial aid, and good nursing care should be from day one. There should be a holistic approach with interdisciplinary management under one roof for the patient with amputees. As evident in the present study, the holistic approach restores patients in handling day-day life.

Data availability statement The authors confirm that the data supporting the findings of this study are available within the article.

Declarations

Conflict of Interest None.

Ethical Considerations Institute Ethics Committee approved the study.

Informed consent Written informed consent was obtained from the selected participants.

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ORIGINAL ARTICLE

Rotational Assessment of Thoracolumbar/Lumbar Curves According to Lowest Instrumented Vertebra Level

Hakan Serhat Yanik[1] · Ismail Emre Ketenci[1]

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Abstract

Background It is not clearly defined in the literature how the lowest instrumented vertebra (LIV) selection effects the rotation of lumbar vertebrae at fused and unfused levels in thoracolumbar/lumbar (TL/L) curves. The aim of this study was to evaluate the rotational profile of structural TL/L curves, corrected with rod derotation manoeuvre, according to LIV level.

Methods 82 consecutive AIS patients with structural TL/L curves who were treated with long segment posterior instrumentation and fusion were retrospectively evaluated. Patients were divided into three groups according to LIV level: lower end vertebra (LEV) group (32 patients), LEV−1 group (23 patients) and LEV + 1 group (27 patients). Cobb angles of structural curves, coronal and sagittal balance were evaluated with direct roentgenograms. Rotation of upper end vertebra, apical vertebra, LIV−1, LIV and LIV + 1 was evaluated with computerised tomography. Clinical outcomes were assessed using SRS-22 questionnaire.

Results Mean follow-up time was 31 months (range 24–42 months). Preoperative LIV rotation was measured as 16.03°, 16.08° and 12.68° in LEV, LEV-1 and LEV + 1 groups, which changed postoperatively as 13.36°, 16.52° and 9.74° respectively. Postoperative LIV−1, LIV and LIV + 1 rotation values were significantly higher in LEV−1 group compared to LEV + 1 group. None of the patients developed coronal or sagittal imbalance. No significant differences were observed between the groups in terms of SRS-22 scores.

Conclusions Axial rotation of LIV and vertebrae adjacent to LIV is higher when the fusion is stopped at LEV−1. However, higher rotation does not seem to cause poor radiologic and clinical outcomes in the last follow-up.

Keywords Adolescent idiopathic scoliosis · Axial rotation · Rod derotation · Lower end vertebra · Lowest instrumented vertebra · Computerised tomography

Introduction

Adolescent idiopathic scoliosis (AIS) is the deformity of the spine in coronal, sagittal and transverse planes. Former instrumentation systems, such as Harrington and Cotrel–Dubousset systems, addressed only coronal or coronal–sagittal planes respectively. With the use of segmental pedicle screw instrumentation and derotational manoeuvres better, three-dimensional correction has been achieved in AIS surgery [1].

Correction in transverse plane is particularly important since it enables better coronal plane correction, decreases thoracic and lumbar hump deformities, improving cosmetic and satisfaction outcomes [1, 2]. Beside apical rotational correction, it is also important to stop the instrumentation distally at a vertebra with an acceptable amount of rotation [3]. It has been shown that higher lowest instrumented vertebra (LIV) rotation can cause postoperative lumbar curve progression and coronal decompensation [4]. Rotation of unfused lumbar vertebrae can also increase postoperatively [5].

A few studies evaluated the rotation of instrumented and uninstrumented vertebrae pre- and postoperatively [5, 6]. Many criteria have been defined for LIV selection including its rotation in standing and bending radiographs [7].

✉ Hakan Serhat Yanik
dr.serhatyanik@hotmail.com

Ismail Emre Ketenci
emreket@yahoo.com

1 Department of Orthopedics and Traumatology, Haydarpasa Numune Education and Research Hospital, Tibbiye Caddesi No:23, Uskudar, 34668 Istanbul, Turkey

However, it is not clearly defined in the literature how the LIV selection effects the rotation of lumbar vertebrae at fused and unfused levels. Our aim in this study was to evaluate the changes in the rotation of strategic vertebrae of the structural lumbar curves, corrected with rod derotation (RD) manoeuvre, according to LIV selection. We hypothesised that stopping the fusion more caudally would better correct the rotational deformity.

Materials and Methods

Patients and Groups

82 consecutive AIS patients with structural lumbar curves who were treated with long segment posterior instrumentation and fusion, and who were available for postoperative computerised tomography (CT) imaging were included into this study, and were retrospectively evaluated. Patients who had congenital or neuromuscular scoliosis, who underwent prior spine surgery and who were over 20 years were excluded.

Preoperatively, LIV was selected according to the criteria defined by Trobisch et al. [7]. However, final LIV decision was made intraoperatively, in order to leave one more mobile segment, if possible. With correction manoeuvres, the disc below LIV tried to be levelled. The most cranial vertebra which enabled to achieve this goal was selected as LIV. Three groups occurred according to LIV level: lower end vertebra (LEV) group (32 patients), LEV−1 group (23 patients) and LEV + 1 group (27 patients).

Surgical Technique

Senior surgeon performed all operations. After a standard posterior midline incision, exposure was performed, and polyaxial pedicle screws were inserted bilaterally at every level of the thoracic and lumbar curves by freehand technique. After posterior release with wide facetectomies, first precontoured rod was inserted to the convex side of the lumbar curve and the deformity was corrected using RD manoeuvre. Second precontoured rod was inserted with the help of in situ benders. Compression and distraction manoeuvres were performed to further correct the deformity. Under fluoroscopic control, the alignment of the disc below LIV was assessed. If it was not parallel, instrumentation was extended one level distally using new longer rods. After a thorough decortication, allograft was placed for fusion. Neuromonitorization was used in all surgeries. Operation times were also noted.

Radiographic and Clinical Outcome Measurements

Radiographic measurements were performed on whole spine standing anteroposterior (AP) and lateral radiographs (Fig. 1) as well as CT. For all patients, postoperative

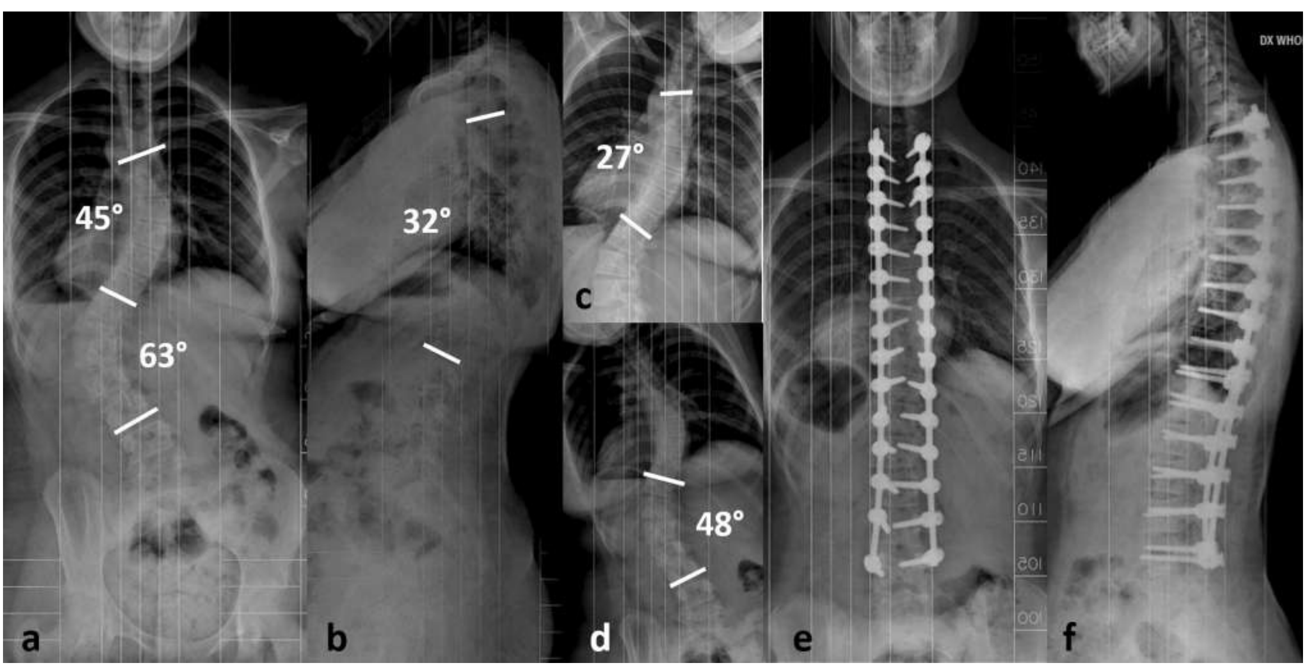

Fig. 1 **a**, **b** Anteroposterior and lateral radiographs of 15-year-old girl with Lenke 6C scoliosis, showing 45° of main thoracic, 63° of lumbar curves and 32° of thoracic kyphosis. **c**, **d** Right and left bending radiographs show that both curves are structural. **e**, **f** Postoperative radiographs in the last follow-up showing T2–L4 fusion. The patient was fused to LEV + 1

assessment was made in the final follow-up (minimum two years). Measurements were performed by two blinded orthopaedic surgeons who were not in the operative team.

Parameters examined on coronal plane were scoliosis angles of thoracic and lumbar curves which were measured with Cobb method. Coronal balance was measured as the perpendicular distance between C7 plumb line and central sacral vertical line (C7PL–CSVL). Coronal imbalance was defined as C7PL–CSVL distance of more than 20 mm. Curve flexibility was measured with bending AP radiographs. Risser grade was evaluated on standing AP radiographs using the routine technique. Sagittal parameters examined were thoracic kyphosis (T5–T12), lumbar lordosis (L1–L5) and sagittal balance as C7 plumb line.

Measurements of rotational parameters were performed on axial CT images. Thin-cut (0.6 mm) axial images were available for all thoracic and lumbar levels. Analyses were performed on true axial images which were reconstructed according to the tilt of each strategic vertebra in coronal and sagittal planes. Strategic vertebrae were selected as the upper end vertebra (UEV) and apical vertebra (AV) of lumbar curve, the vertebra one-level cranial to LIV (LIV−1), LIV and the vertebra one-level caudal to LIV (LIV + 1). The analysed image of each vertebra should include both pedicles and junction of the inner surface of the laminae. The angle between the long axes of the vertebra and sagittal plane was defined as vertebral rotation angle (Fig. 2 and Fig. 3).

Preoperatively and at two-year follow-up, Scoliosis Research Society (SRS)-22 questionnaire was used to evaluate clinical outcomes, which were completed by face-to-face interview.

Statistical Analyses

SPSS for Windows (Version 21.0; IBM Corp., Armonk, NY, USA) was used for statistical analysis. During the comparison between groups, ANOVA test was used for parametric values, and Kruskal–Wallis test was used for non-parametric values. During the comparison between preoperative and postoperative values, Student's *t* test was used for parametric values, and Mann–Whitney *U* test was used for non-parametric values. A *p* value less than 0.05 was considered statistically significant. The interobserver reliability was estimated using intraclass correlation coefficients (ICCs) for two observers.

Results

Demographic data, curve flexibility and Risser grades were similar between groups (Table 1). Surgical times did not also show significant differences. Mean follow-up time was 31 months (range 24–42 months). Preoperative and postoperative radiographic values in coronal and sagittal planes are given in Table 2. Whilst preoperative TL/L curve Cobb angle of LEV−1 group was significantly lower than LEV and LEV + 1 groups, postoperative TL/L curve Cobb angle of LEV + 1 group was significantly lower than LEV−1 group.

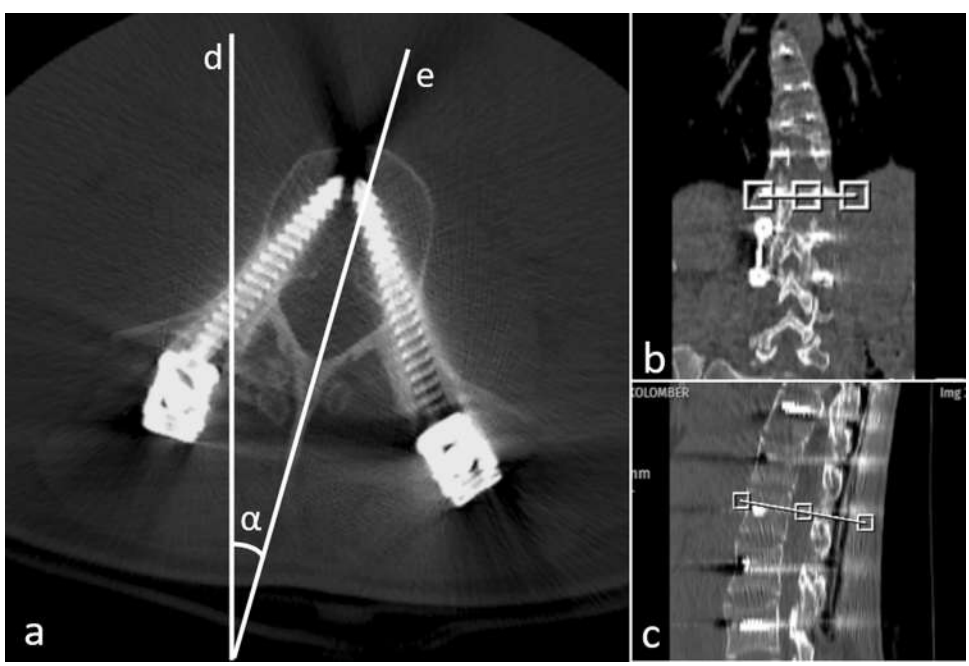

Fig. 2 **a**, **b**, **c** The true axial plane of the vertebra is determined according to its tilt in sagittal and coronal planes. The vertebral rotation angle α is the angle between the lines d (sagittal plane) and e (long axis of the vertebra)

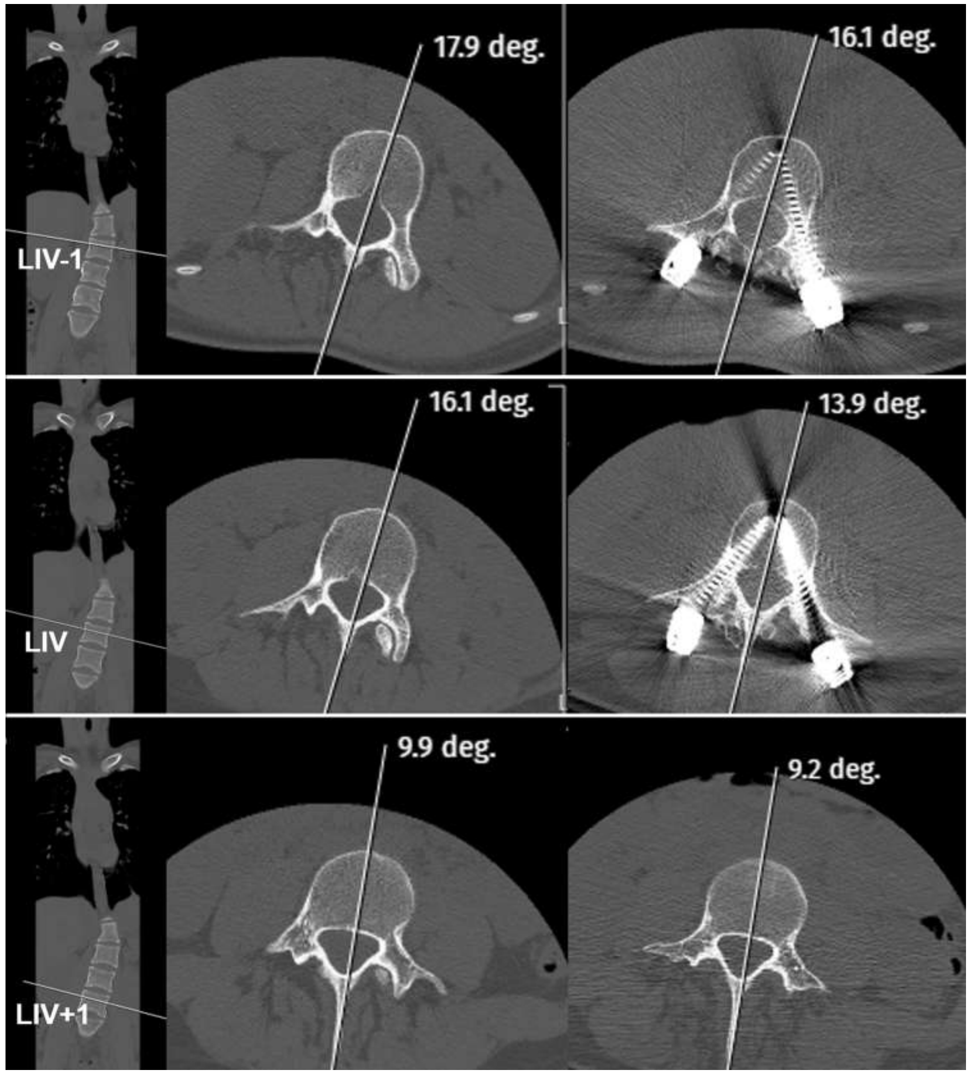

Fig. 3 Preoperative and postoperative rotations of LIV−1, LIV, and LIV + 1 of a patient from LEV group

Table 1 Demographic values, curve characteristics

Variables	LEV group $n = 32$	LEV−1 group $n = 23$	LEV + 1 group $n = 27$	p
Age (mean ± sd)	14.7 ± 1.72	14.8 ± 1.53	15.1 ± 1.68	0.758
Gender (male/female)	7/25	5/18	7/20	0.425
Lenke curve type (3C/5C/6C)	15/4/13	12/6/5	6/7/14	
TL/L curve flexibility (%)	41.38 ± 13.76	42.56 ± 8.93	39.27 ± 12.62	0.186
Risser grade (Range 0–5)	3.5 ± 0.8	3.7 ± 0.6	3.6 ± 0.7	0.684

LEV lower end vertebra, *TL/L* thoracolumbar/lumbar

Preoperative and postoperative rotational angles of strategic vertebrae are given in Table 3. Apical vertebral (AV) rotation decreased significantly in LEV and LEV + 1 groups postoperatively. On the contrary, AV rotation increased in LEV−1 group postoperatively; however, the increase was insignificant. Rotation angles of LIV−1, LIV and LIV + 1 slightly decreased postoperatively in LEV and LEV + 1 groups. However, these angles increased in LEV-1 group insignificantly. Postoperative LIV−1 and LIV rotation values were significantly higher in LEV−1 group compared to LEV + 1 group. Postoperative LIV + 1 rotation values were significantly higher in LEV−1 group compared to LEV and LEV + 1 groups.

No significant differences were observed between the groups in terms of all subgroups and total scores of SRS-22 (Table 4). There were no intraoperative or postoperative complications. None of the patients developed coronal or sagittal imbalance in the last follow-up.

Table 2 Preoperative and postoperative values in coronal and sagittal planes

Variables	LEV group	LEV−1 group	LEV + 1 group	*p*
Preoperative MT cobb angle (°)	51.42 ± 9.12	49.63 ± 13.57	47.42 ± 15.89	0.865
Postoperative MT Cobb angle (°)	12.51 ± 4.42	13.27 ± 7.47	9.83 ± 4.8–95	0.296
p	< 0.001*	< 0.001*	< 0.001*	
Preoperative TL/L cobb angle (°)	49.37 ± 7.25	41.56 ± 5.78	53.75 ± 13.46	0.007*
Postoperative TL/L cobb angle (°)	11.56 ± 2.72	12.97 ± 2.85	9.59 ± 4.84	0.015*
p	< 0.001*	< 0.001*	< 0.001*	
Preoperative C7PL-CSVL (mm)	21.6 ± 11.2	19.3 ± 12.9	23.2 ± 10.4	0.596
Postoperative C7PL-CSVL (mm)	9.1 ± 5.2	10.6 ± 4.3	8.7 ± 3.6	0.473
p	< 0.001*	0.006*	< 0.001*	
Preoperative T5–T12 TK (°)	27.3 ± 4.9	29.4 ± 6.3	30.2 ± 5.7	0.792
Postoperative T5–T12 TK (°)	29.8 ± 5.2	31.2 ± 4.6	31.9 ± 6.1	0.635
p	0.824	0.783	0.891	
Preoperative L1–L5 LL (°)	50.3 ± 11.9	48.6 ± 12.5	52.5 ± 16.8	0.593
Preoperative L1–L5 LL (°)	50.9 ± 14.7	50.3 ± 13.7	49.4 ± 14.7	0.682
p	0.946	0.767	0.723	
Preoperative C7-PL (mm)	− 12.3 ± 21.2	− 11.7 ± 24.6	− 14.6 ± 19.5	0.515
Preoperative C7-PL (mm)	− 10.7 ± 19.3	− 9.2 ± 21.7	− 12.6 ± 22.4	0.487
p	0.715	0.693	0.646	

LEV lower end vertebra, *MT* main thoracic, *TL/L* thoracolumbar/lumbar, *C7PL-CSVL* C7 plumb line-central sacral vertical line, *TK* thoracic kyphosis, *LL* lumbar lordosis

*p < 0.05, statistically significant difference

Table 3 Preoperative and postoperative values in transverse plane

Variables	LEV group	LEV−1 group	LEV + 1 group	*p*
Preoperative UEV Rot (°)	7.94 ± 6.82	9.75 ± 4.27	8.92 ± 3.43	0.486
Postoperative UEV Rot (°)	1.65 ± 2.32	1.93 ± 4.35	2.43 ± 4.17	0.694
p	< 0.001*	< 0.001*	< 0.001*	
Preoperative AV Rot (°)	21.18 ± 4.21	16.87 ± 5.03	22.24 ± 6.12	0.033*
Postoperative AV Rot (°)	15.74 ± 4.35	18.93 ± 5.87	14.76 ± 8.15	0.285
p	0.001*	0.312	0.024*	
Preoperative LIV−1 Rot (°)	18.32 ± 3.29	16.46 ± 3.72	16.52 ± 6.26	0.293
Postoperative LIV−1 Rot (°)	15.65 ± 3.42	17.58 ± 6.39	11.86 ± 5.49	0.022*
p	0.017*	0.453	0.081	
Preoperative LIV Rot (°)	16.03 ± 2.37	16.08 ± 4.45	12.68 ± 6.58	0.075
Postoperative LIV Rot (°)	13.36 ± 4.12	16.52 ± 6.47	9.74 ± 5.18	0.039*
p	0.053	0.864	0.213	
Preoperative LIV + 1 Rot (°)	10.61 ± 3.54	12.56 ± 4.14	7.29 ± 4.64	0.005*
Postoperative LIV + 1 Rot (°)	10.29 ± 2.74	15.73 ± 6.87	7.01 ± 3.78	0.002*
p	0.692	0.185	0.798	

LEV lower end vertebra, *UEV Rot* upper end vertebra rotation, *AV Rot* apical vertebra rotation, *LIV Rot* lowest instrumented vertebra rotation

Discussion

Correcting the transverse plane deformity is as important as coronal and sagittal plane correction in AIS surgery, in order to obtain satisfying cosmetic outcomes as well as to decrease the risk of unfused curve progression and coronal or sagittal imbalance [1–6]. Manoeuvres to correct the axial rotation evolved throughout time. Distractive forces applied in Harrington instrumentation have not been shown to correct transverse plane. Rotational component of scoliotic deformity was first addressed with Cotrel–Dubousset instrumentation, which used the RD technique [8]. Correction amounts of AV rotation

Table 4 Comparison of clinical outcomes

SRS scores	LEV group	LEV−1 group	LEV + 1 group	*p*
Preoperative activity	4.2 ± 0.5	4.1 ± 0.7	4.2 ± 0.4	0.715
Postoperative activity	4.3 ± 0.6	4.3 ± 0.5	4.1 ± 0.7	0.582
Preoperative pain	4.4 ± 0.2	4.2 ± 0.6	4.5 ± 0.4	0.672
Postoperative pain	4.2 ± 0.7	4.3 ± 0.3	4.4 ± 0.5	0.496
Preoperative self-image	3.7 ± 0.5	3.8 ± 0.7	3.6 ± 0.5	0.592
Postoperative self-image	3.8 ± 0.8	4.0 ± 0.6	3.9 ± 0.4	0.638
Preoperative mental health	4.1 ± 0.4	3.9 ± 0.6	4.2 ± 0.4	0.487
Postoperative mental health	4.0 ± 0.3	4.0 ± 0.8	4.1 ± 0.7	0.827
Preoperative satisfaction	4.1 ± 0.7	4.0 ± 0.3	4.2 ± 0.6	0.625
Postoperative satisfaction	4.2 ± 0.6	4.1 ± 0.8	4.1 ± 0.4	0.816
Preoperative total	4.2 ± 0.5	4.1 ± 0.7	4.0 ± 0.8	0.741
Postoperative total	4.1 ± 0.7	4.2 ± 0.4	4.0 ± 0.5	0.653

SRS scoliosis research society

are around 15% with RD [9, 10]. Our overall AV rotation correction was 14.2%, which was consistent with the literature. However, when we further analyse the rotation according to LIV level, AV rotation decreased 26.1% in LEV and LEV + 1 groups, whilst it increased, although insignificantly, 16.5% in LEV−1 group. This may be related to the use of longer lever arms in LEV and LEV + 1 groups to apply stronger derotation force on AV. Better AV rotational correction amounts have been reported with direct vertebral rotation (DVR) in several studies [1, 10, 11]. However, DVR has also some disadvantages, such as hypokyphotic effect on sagittal profile and increased surgical time and blood loss [10].

Other than AV, we measured the rotation amounts of some strategic vertebrae, in order to reveal the rotational profile of structural TL/L curves. Therefore, we included Lenke type 3C, 5C and 6C curves. The rotation of UEV decreased in all three groups significantly. This may be due to its location, which is in the transition zone from thoracic to lumbar curve. Derotation forces from both thoracic and lumbar parts of the rods effect on UEV. Although insignificantly, LIV−1, LIV and LIV + 1 rotation values increased in LEV−1 group, whilst they slightly decreased in LEV and LEV + 1 groups. This may also be explained with the longer lever arm effects mentioned previously. Postoperative rotation of LIV and LIV + 1 was significantly higher in LEV−1 group compared to other two groups. Postoperative LIV rotation is particularly important because it effects spontaneous correction of unfused segments in coronal and transverse plane as well as clinical outcomes [4, 12, 13]. In our study, higher rotational values of LIV and LIV + 1 in LEV−1 group did not cause curve progression or decreased clinical outcomes. We think that poor results in terms of radiologic and functional outcomes occur when too much derotation force is applied on LIV, which may increase stress on adjacent discs and unfused segments. This effect has been discussed in previous studies [3, 14]. It has been suggested that fusion should be extended to LEV + 1 if LEV has a preoperative rotation of grade-II or more [3]. According to our study, it can be deduced that rotation of LIV should not be corrected aggressively if the fusion is stopped proximal to LEV, where preoperative rotation is relatively high. With polyaxial screws and RD manoeuvre, we were not able to correct LIV rotation especially in LEV−1 group. This created a smooth passage from fused to unfused segments in terms of rotation, which prevented possible future decompansation.

The challenge in distal fusion level selection in AIS surgery is deciding between more correction in three planes and sparing more mobile segments. Leaving more mobile segments may be easier with DVR especially in selective fusion of thoracic curves with better spontaneous lumbar curve correction [1]. Rotation of unfused vertebrae can be increased or decreased after DVR according to different studies [5, 6]. Chang et al. demonstrated that long-term outcomes of selective fusion of thoracic curves corrected with sufficient DVR are satisfactory although rotation of unfused levels was not measured in this study [13]. Correction of structural TL/L curve rotation with DVR has been also studied [15, 16]. Huang et al. demonstrated that correction of apical rotation in Lenke 5C curves was better with DVR than with RD [15]. On the other hand, DVR has been shown to be ineffective in decreasing lumbar prominence in TL/L curves [16]. As mentioned previously, with RD, rotation of instrumented vertebrae is corrected less than with DVR. However, as far as we know, no study has evaluated the rotation of adjacent unfused vertebra using CT in AIS corrected with RD. Therefore, we cannot draw a conclusion from the literature how stopping the fusion proximally or distally affects the rotation of unfused segments after RD. According to our study, in mild to moderate curves, selection of LIV as LEV−1 does not seem to cause poor radiologic and clinical outcomes after a relatively short follow-up period, although higher axial rotation was observed in LIV and LIV + 1 in LEV−1 group. However, longer follow-up time may be needed to make a better conclusion about this issue.

Axial rotation of vertebrae can be measured with several different techniques with variable amount of reliability [17]. CT is one of the most reliable methods to measure vertebral rotation [10]. Although rotation can be changed in supine position, this effect can be underestimated [18]. Exposure to radiation is another disadvantage of CT. We tried to minimise it with using low dose CT scan.

To the best of our knowledge, this is the first study in the literature to compare the axial rotation of lumbar vertebrae according to LIV selection. Furthermore, also no study has evaluated the rotation of the vertebrae adjacent to LIV in structural TL/L curves corrected with RD. Other strong point is the uniformity of the patient group and surgical technique. All patients had structural TL/L curves and they were operated by a single spinal surgeon at the same hospital. One of the limitations is the retrospective nature of the study. The number of the patients is relatively low due to the limited number of patients with postoperative CT images. Our mean follow-up period of 31 months may be too short for occurance of complications, such as curve decompensation, adding-on, or coronal and sagittal imbalance.

In conclusion, LIV level is a determinant factor for postoperative rotation of fused and unfused vertebrae. Stopping the fusion proximally, such as at LEV−1, to save more mobile segments is an option if intraoperative coronal alignment is satisfactory because higher axial rotation does not seem to cause poor radiologic and clinical outcomes. The critical point in this case is not to perform aggressive derotation force, in order to create a smooth passage to unfused segments, which is possible with RD technique. Fusion can be extended to LEV or LEV + 1, if a near neutral vertebra is to be achieved.

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Data Availability Data generated or analyzed during this study are available from the corresponding author upon reasonable request.

Declarations

Conflict of ınterest Hakan Serhat Yanik and Ismail Emre Ketenci declare that they have no conflict of interest.

Ethical approval Institutional Review Board approval was obtained.

Informed consent All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2008 (5). Informed consent was obtained from all patients for being included in the study.

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ORIGINAL ARTICLE

The Effect of Indirect Decompression Through Extraforaminal Interbody Fusion for Degenerative Lumbar Disease

Josef Vcelak[1] · Adam Kral[1] · Andrea Speldova[1] · Ladislav Toth[1]

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Abstract

Purpose Extraforaminal lumbar interbody fusion as with other methods that involve the mechanism of indirect decompression, the discussion not only focuses on the benefit of minimizing the risk of thecal sac injury and postoperative scarring, but also on the risk of insufficient decompression in the affected neural structures during the reduction of the affected segment.

Methods Eighty-two patients presenting with degenerative lumbar disease with segmental instability underwent ELIF combined with transpedicular fixation and circumferential fusion. Clinical and radiographic evaluations were performed.

Results The mean ODI significantly improved from 63.4 preoperatively to 32.3 1 year postoperatively. The mean VAS back pain significantly improved from 5.95 to 2.63 postoperatively and VAS (leg pain) improved from 6.04 to 2.44. The mean CSA increased from 103 mm^2 preoperatively to 169 mm^2 postoperatively. The median extension ratio of CSA was 33%. Disc height, segmental disc angle, and lumbar lordosis also improved significantly. Only three (3.7%) patients were revised using direct central decompression due to neurologic deterioration.

Conclusion Spinal stenosis was resolved successfully by indirect decompression through extraforaminal interbody fusion via a transmuscular limited approach.

Keywords ELIF · Extraforaminal lumbar interbody fusion · FLIF · Far lateral lumbar interbody fusion · Circumferential fusion · Indirect decompression · Transmuscular approach · CSA for thecal sac

Introduction

Transforaminal lumbar interbody fusion (TLIF), first described in the 1990s, has gained popularity and is currently considered the standard for the treatment of lumbar degenerative disease [1]. The method involves the direct decompression of a stenotic segment and also a circumferential fusion with possible reconstruction of translation or sagittal deformity. The development of this method is discussed mainly with regard to the invasiveness of the approach and the extent of decompression in the area of the articular processes [2–4]. Modifications to the TLIF method, such as extraforaminal lumbar interbody fusion (ELIF) and far lateral interbody fusion (FLIF), take advantage of the possibility of the transmuscular approach and limited resection of only upper articular process of the distal vertebra and dissection of the intervertebral disc in a safe Kambin's triangle [5]. The advantage of the method is the small "foot print" of the surgery, reduced blood loss, shorter hospitalization time, and minor ischemia of postural muscles. As with other methods that involve the mechanism of indirect decompression, the discussion not only focuses on the benefit of minimizing the risk of thecal sac injury and postoperative scarring but also on the risk of insufficient decompression in the affected neural structures during the reduction of the affected segment [6].

The aim of this retrospective study is to assess the clinical and radiological outcomes of patients who have been operated on the basis of the principle of indirect decompression according to the ELIF method. The work has the following objectives. First, to evaluate the clinical outcomes of said surgical method for treating degenerative disease of the lumbar spine, including surgery complications that required revision surgery. Second, to define postoperative development of the spinal canal space for neural structures after the application of surgical methods that utilize the principle of

✉ Josef Vcelak
josef.vcelak@post.cz; ort@bulovka.cz; ortbul@ipvz.cz

[1] The Orthopaedic Clinic of the 1st Medical Faculty, Charles University, Prague, The University Hospital Bulovka, Budínova 2, 180 81 Prague 8, Czech Republic

indirect decompression and to assess parameters of height with regard to the intervertebral space and restoration of the lumbar lordosis shape.

Materials and Methods

The study was performed with the approval of the institutional ethics committee of the university hospital. The retrospective study assessed the radiological and clinical outcomes of patients operated according to the ELIF method in one institution by two experienced surgeons from January 2015 to December 2020. In total, 82 patients were included in the cohort (41 women, 41 men), with an average age of 60.5 years, on whom a total of 90 lumbar segments were operated. Indications for the procedure included spinal stenosis related to instability or deformity based on degenerative disc disease, spondylolisthesis, degenerative scoliosis, and revision surgery after a previous decompressive intervention. Instability was assessed based on criteria of dynamic flexion–extension X-rays originally defined by White and Panjabi [7] and static MRI scans [8, 9]. The inclusion criteria of the method were based on the requirements for indirect decompression: 1. no paralysis or severe leg pain at rest; 2. no cauda equina syndrome; and 3. the absence of free disc fragments on MRI. The exclusion criteria included the following: 1. malignancies; 2. infection; 3. other neurological diseases; 4. trauma; 5. spondylolisthesis > grade II; 6. fusion level > 3; and 7. Cobb angle > 30°. Demographic data are listed in Table 1.

All patients were uniformly treated by interbody fusion according to the ELIF method, complemented by posterior transpedicular instrumentation and lateral fusion. The double incision technique via the transmuscular approach was used originally. Our modification of the method consists of a central skin incision, followed by a bilateral section of lumbodorsal fascia. Subsequently, with blunt dissection via Wiltse's transmuscular approach using an expandable retractor, we expose the facet joint and transversal processes of the affected segment. The interlaminar space remains hidden under the multifidus muscle. On the symptomatic side, we then resect the lateral two-thirds of the superior articular process of the distal vertebra with dissection in the lateral foraminal exit zone of Kambin's triangle. The integrity of the spinal canal remains intact with preserved flavum ligament, inferior articular process, and rest of the superior articular process. Gradually, we withdraw the root sheath and expose the intervertebral disc posterolateraly. The disc is subsequently resected, including decortication of the endplates, and the implantation of an intervertebral cage (straight-shape) with autologous spongioplasty. The sizing of the cage is on average 2–4 mm larger than preoperative disc height with slight lordotisation of the segment. The surgery is then finished with transpedicular instrumentation and lateral fusion via resection and decortication of the transverse processes bilaterally and facet on the contralateral side with subsequent autologous spongioplasty.

Table 1 Demographic patient's data

	Number	%
Number of patients	82	
Total number of lumbar levels	90	
L1/2	3	3.33%
L2/3	11	12.22%
L3/4	14	15.56%
L4/5	51	56.67%
L5/S1	11	12.22%
Male:Female	1:1	
Age (years)	60,45 ± 10,57	
Preoperative diagnosis		
Degenerative disc disease	23	28.40%
Spondylolisthesis	28	34.57%
Degenerative scoliosis	5	6.17%
FBBS	25	30.86%
Spinal canal stenosis		
Schizas A	0	0.00%
Schizas B	16	19.75%
Schizas C	56	69.14%
Schizas D	9	11.11%

Clinical outcomes were compared with the preoperative assessment and 1 year post-surgery. The Oswestry Disability Index (ODI) (0–100 points) and visual analog pain scale (VAS), separately for back and limb pain, were used for the clinical evaluation. The necessity of revision surgery due to complications was also recorded 1 year post-surgery.

MRI scans were obtained before surgery and then at least 1 year post-surgery. The examination was always performed when there were radiographic signs of healed spondylodesis. The cross-sectional areas of the thecal sac were measured in T2-weighted images on axial sections at the mid-level of the intervertebral disc. The severity of lumbar spinal stenosis was evaluated quantitatively in T2-weighted images using the Schizas classification. The stenosis classification was defined: Grade A (no stenosis); Grade B (moderate stenosis; rootlets occupy the whole of the thecal sac; some cerebrospinal fluid (CSF) is still present); Grade C (severe stenosis; no rootlets can be recognized; homogenous gray signal of thecal sac with no visibility of CSF; epidural fat present posteriorly); Grade D (extreme stenosis, in addition no epidural fat present posteriorly). A simple X-ray image was used to assess disc height, segmental lordosis, and lumbar lordosis prior to surgery and 1 year post-surgery according to the methodology [10, 11]. The healing of the circumferential fusion, migration of the interbody cage, and release or failure of the transpedicular instrumentation were also recorded.

A *P* value < 05 was considered significant. An analysis of categorical variables was performed on the basis of Student's pair *t*-test. Comparisons between quantitative parameters were performed by t-test after assessment of normal distribution and homoscedasticity.

Results

All 82 patients were operated without any major complications. No thecal sac injury, cerebrospinal fluid leak, or injury to the nerve root was reported. Indirect decompression was achieved radiologically in all operated segments. The average duration of surgery of one segment using circumferential fusion was 96.9 min (range 60 to 135) with an average estimated blood loss of 236.4 mL (range 50 to 350). A total of 9 revision surgeries in 9 patients (11.1%) were performed in the evaluation interval (1 × transpedicular screw malposition, 2 × interbody implant's migration, 2 × superficial infection, 1 × deep infection) (Fig. 1a,b). In 3 patients (3.7%), the neurological finding worsened in the postoperative period, which required subsequent central decompression with subsequent neurologic adjustment. Spondylolisthesis combined with critical stenosis Schizas grade D was the issue in all the cases.

Both clinical assessments, the ODI and VAS, were improved in all patients at 12 months postoperatively ($P < 0.001$). The recovery rate assessed according to the ODI changed from preoperative 63.35 ± 8.62 to 32.27 ± 11.61 1 year postoperatively (49.06%) (Fig. 2). The VAS (back pain) decreased from preoperative 5.60 ± 0.83 to 3.16 ± 0.81 (43.57%) (Fig. 3), with VAS (leg pain) improved from 6.04 ± 1.45 to 2.44 ± 0.71 1 year postoperatively (59.6%) (Fig. 4). The clinical results are summarized in Table 2.

Indirect neural decompression was achieved successfully at all levels radiologically. The preoperative cross-sectional area of the thecal sac on T2-MRI scans was 103.1 ± 58.4 mm^2 and had improved to 169.1 ± 56.5 mm^2 1 year postoperatively ($P < 0.001$). The mean change was 66.0 mm^2 and the median CSA extension ratio was 64.1% (Fig. 5).

The disc height also improved significantly ($P < 0.001$). The preoperative diameter was 5.43 ± 2.08 mm and increased 1 year postoperation to 10.45 ± 1.28 mm with a median extension of 92%. Segmental lordosis changed from preoperative 14.91° ± 8.73 to 19.90° ± 9.76 1 year postoperatively with lordosis change of 25.1%. Lumbar lordosis increased after surgery from preoperative 44.72 ± 12.3 to 46.20 ± 11.88 postoperatively with a lumbar lordosis change of 1.51 ± 7.03%. The radiographic results are summarized in Table 3.

Discussion

All 82 patients operated by indirect decompression, on the basis of circumferential fusion according to the ELIF method combined with transpedicular fixation, were successfully treated without any severe neurological complications. The

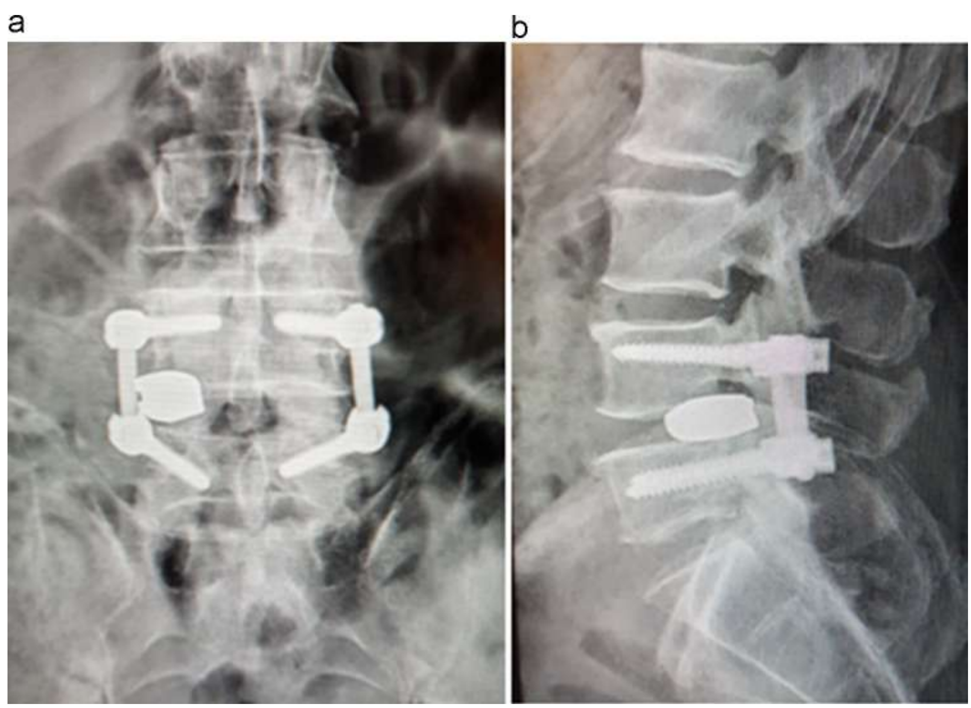

Fig. 1 **a**, **b** Interbody implant's migration

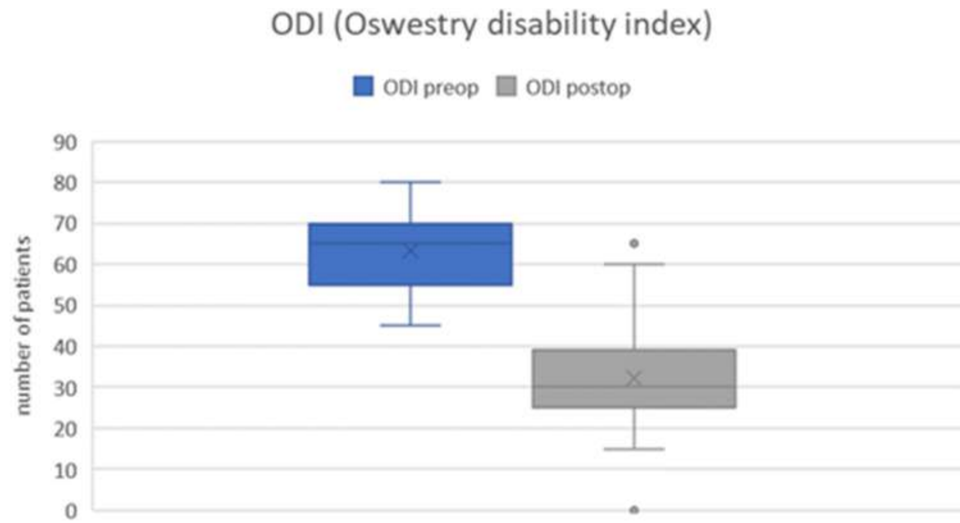

Fig. 2 Graf (ODI clinical patient's assessment)

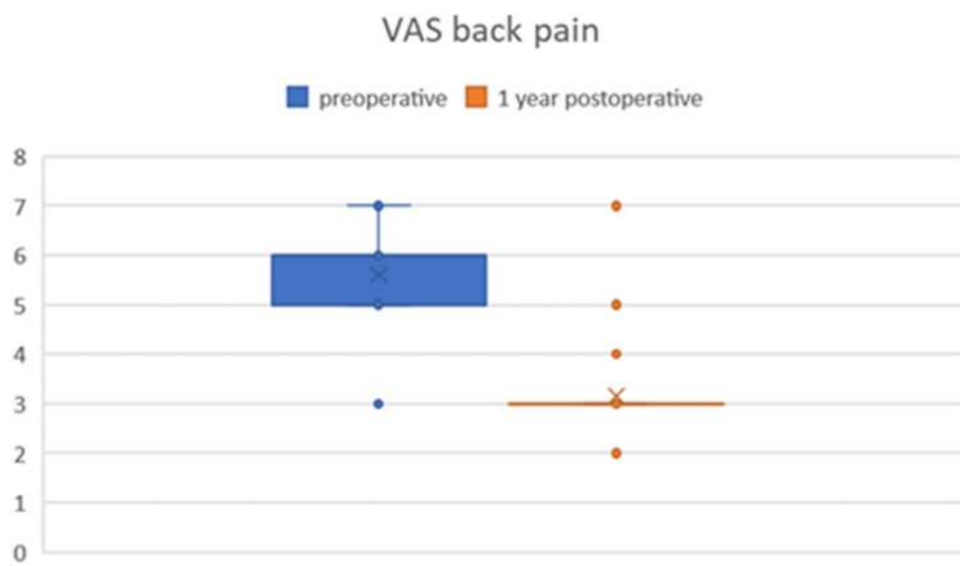

Fig. 3 Graf (VAS—back pain clinical patient's assessment)

study demonstrated a significant improvement in clinical outcomes in the postoperative period. Radiological assessment of the 1 year post-surgery showed that direct decompression according to the ELIF method led to enlargement of the spinal canal space and also improvement of the sagittal profile of lumbar lordosis. Only 9 patients (11.1%) underwent revision surgery during the evaluated time period due to complications related to the method, of which 3 (3.7%) patients required reoperation in the early postoperative period due to worsened neurological conditions. These patients were treated by direct central decompression of the spinal canal with subsequent complete clinical restoration. These were always patients with critical stenosis Schizas grade D combined with spondylolisthesis. Partial reduction of the deformity in the terrain of critical stenosis could impair the spinal canal compression and according to our results is a relative contraindication for the indirect decompression.

The described surgical method utilizes a limited transmuscular approach originally described by Wiltse using expandable retractors. We abandoned the original double-incision technique and now use the common central skin incision. The reason for this is mainly the rare necessity to add central direct decompression in the second period, and also further revision surgeries due to degeneration of the adjacent segment. Transmuscular access is mainly compared to the central approach when applying the TLIF method in the therapy of degenerative disease. Zairi [4] compares central and transmuscular mini-open TLIF in a group of 100 patients. He reports significantly lower perioperative blood loss and shorter hospitalization time. No significant difference in the clinical evaluation according to ODI or VAS

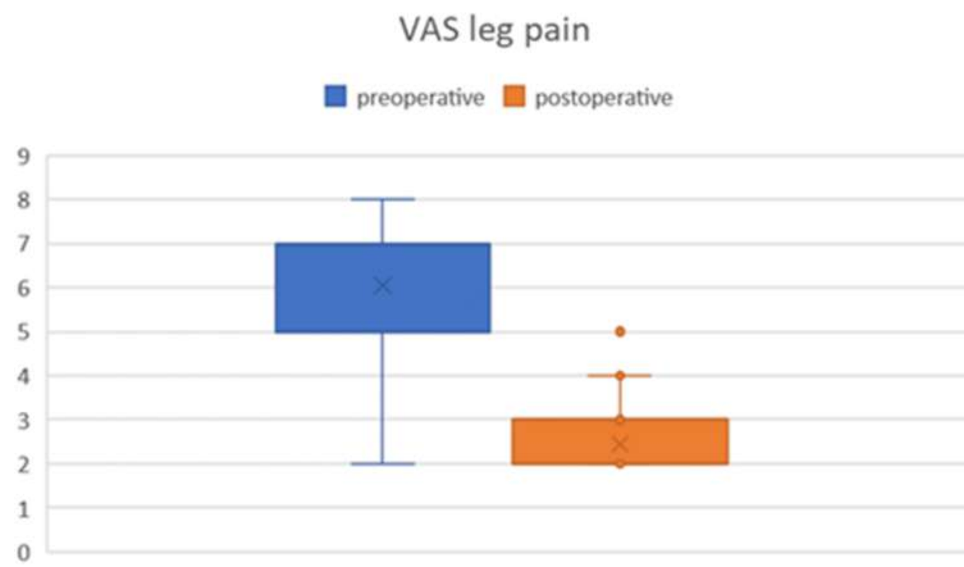

Fig. 4 Graf (VAS—leg pain clinical patient's assessment)

Table 2 Clinical results data (ODI, VAS back pain, VAS leg pain)

	Preoperative	Postoperative 1y	Change	Change %	*p*-value
ODI	63.35 ± 8.62	32.27 ± 11.61	– 31.08 ± 14.05	– 49.06%	$P < 0.0001$
VAS (back pain)	5.60 ± 0.83	3.16 ± 0.81	– 2.44 ± 1.04	– 43.57%	$P < 0.0001$
VAS (leg pain)	6.04 ± 1.45	2.44 ± 0.71	– 3.60 ± 1.47	– 59.60%	$P < 0.0001$

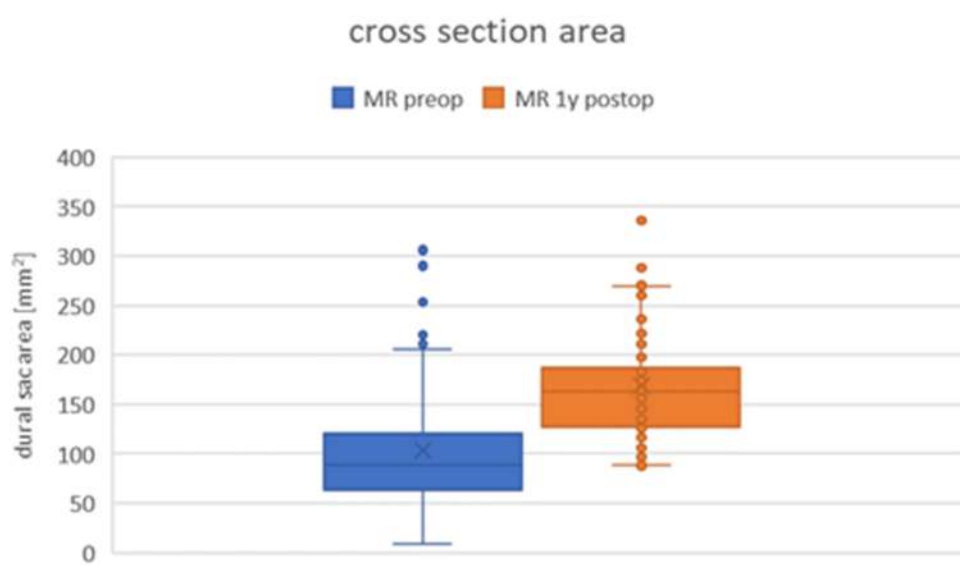

Fig. 5 Graf (CSA for thecal sac patient's radiographic assessment)

Table 3 Radiographical results data (CSA for thecal sac, disc height, segmental lordosis, lumbar lordosis)

	Preoperative	Postoperative (1 year)	Change	% change	*P*-value
CSA of thecal sac [mm^2]	103.1 ± 58.4	169.1 ± 56.5	66.0 ± 33.1	64.00%	$P < 0.001$
Disc height [mm]	5.43 ± 2.08	10.45 ± 1.28	5.02 ± 1.94	92.00%	$P < 0.001$
Segmental lordosis [°]	14.91 ± 8.73	19.90 ± 9.76	5.00 ± 4.12	25.13%	$P < 0.001$
Lumbar lordosis [°]	44.72 ± 12.3	46.20 ± 11.88	1.51 ± 7.03	3.25%	$P = 0.05$

was found. Li [12] uses the "channel" technique of dilation of postural muscles in the mini-open TLIF direct muscle approach. He measured differences in the postoperative levels of creatine phosphokinase compared to the central approach. No differences in the postoperative levels between the two methods were found, as was the case with regard to the clinical evaluation of the patients. In contrast, significant differences were found in the time duration of surgery and blood loss in favor of the transmuscular approach.

The ELIF surgical method uses the principle of indirect decompression by limited resection of the superior articular process of the distal vertebra technique with subsequent dissection in the safe space of the Kambin's triangle and proximal retraction of the root sheath [5, 13]. This procedure reduces the risks of injury to the neural structures and also their postoperative scarring. Indirect decompression of the spinal canal is achieved by reduction of the bulging disc and elongation of the hypertrophic ligamentum flavum. The effect of indirect decompression is studied mainly in association with methods of lateral and anterior lumbar intervertebral fusion, such as extreme lateral interbody fusion (XLIF/LLIF), oblique lateral interbody fusion (OLIF), and anterior lumbar interbody fusion (ALIF). Oliveira [14], in his study of 21 patients treated with stand-alone LLIF, demonstrated improvement of all radiological parameters, with a 41.9% increase in DH parameter, 33.1% increase in central canal diameter, and 24.7% increase in foraminal area. Fujibayashi [15] demonstrated the effect of indirect decompression according to the OLIF method and posterior transpedicular fixation. In a group of 28 patients, he operated a total of 39 lumbar spine segments. He found an increase of 30.3% in the spinal canal area CSA in primary surgeries and 7.1% in revision surgeries. The DH parameter in the group increased by 82.3% and the segmental disc angle (SDA) increased from 3.5° preoperatively to 7.9° postoperatively. Kono [16], when comparing direct decompression according to the mini-TLIF method and indirect according to the XLIF method, achieved a significant increase in SAC in both operated groups; TLIF showed a higher increase (from 33.3 to 131.1 mm^2) than XLIF (26.4 to 55.4 mm^2). In his study, Nakashima [17] compares parameters of the spinal canal area over time post-LLIF surgery. He noticed an immediate increase of SAC from 62.0 ± 32.4 mm^2 preoperatively to 86.8 ± 41.8 mm^2 (140%) 2 weeks post-surgery, with further improvement 6 months after surgery (107.4 ± 47.1 mm^2 (173.3%)), 1 year after surgery (117.4 ± 47.4 mm^2 (189.4%)), and 2 years after surgery (126.2 ± 46.8 mm^2 (203.6%)). The author demonstrated chronological improvement of the spinal canal area by continual atrophy of the ligamentum flavum. Other authors describe the mechanism of these anatomical changes on the basis of the loss of mechanical stress due to immobilization of the segment. The levels of inflammatory cytokines, the interleukin (IL)-6, transforming growth factor (TGF)-β 1, and matrix metalloproteinase (MMPs), gradually reduce. These changes macroscopically reduce fibrosis, elastic fibers, and chondrogenesis of the ligamentum flavum, which, in combination with reduced disc bulging, further remodel the spinal canal [18–20].

The authors using various techniques of indirect decompression related to the stabilization of lumbar spine segments showed good clinical postoperative outcomes [21–24]. Clinical outcomes are evaluated in relation to the development of radiographic parameters and also in relation to the size of the preoperative stenosis. Although Nakashima [25] noticed clinical postoperative improvement, he did not prove there was a correlation between the further development of the clinical and radiological presentation in the postoperative observation period. He also confirms an increased risk of the manifestation of postoperative neurological deficit when using indirect decompression in higher stages of stenosis Schizas grade D. Li [22] reports that an advanced grade of stenosis is a relative contraindication for the use of indirect decompression. In his study of 181 treated spinal segments according to the LLIF method, involving a total of 18 patients with Schizas grade D stenosis, he achieved an improvement in the ODI from a preoperative value of 43.3 ± 7.32 to a postoperative 22.56 ± 8.63, with postoperative complications present in a total of 7 patients. Derman [26], in his study of 568 patients operated according to the ALIF and LLIF methods, re-operated on a total of 23 patients (4%) in the early postoperative period due to the failure of indirect decompression. Older age, ossification of the posterior longitudinal ligament, preoperative motor deficit, spondylolisthesis of a higher grade, and obesity were reported to be risk factors. Malham [27] revised 9% of the patients in the second period by direct decompression, adding bony lateral recess stenosis to the list of risk factors. Khalsa [28], in his study of 295 patients, confirmed good clinical results of indirect decompression in patients with preoperative pain of the lower limbs, which subsides at rest with the abdomen in the prone position.

The benefit of the ELIF method is the possibility of achieving circumferential fusion of the segment in combination with transpedicular fixation and lateral fusion. Indications with benefits and disadvantages of indirect decompression overlap with other methods. Using this method, Kurzbuch [29] confirms, in a study of 100 patients, a good clinical effect in 92% of the patients and healing of spondylodesis in 99% of the patients 5 months after surgery. In a group of 12 patients treated according to the ELIF method, Lee [5] demonstrated clinical improvement in all patients; from preoperative ODI 76.78 to 29.91 postoperatively, with complications manifesting in three patients. Shibayama [13] minimized access using the assistance of a microendoscope, achieving good results in all 55 patients.

Our study evaluates the clinical and radiographic effect of the ELIF method, as well as the development of spinal canal size and sagittal spine profile parameters. This method of using the less invasive transmuscular approach and the principle of indirect decompression is used less compared to other methods of interbody fusion. Additional information on the method's outcomes may contribute to further therapy of degenerative spine disease. However, the study has certain limitations. These include the retrospective design of the study and the statistically borderline number of patients for evaluation. The study also only evaluated the ELIF method with regard to the invasiveness of the transmuscular approach and the subsequent effects of indirect decompression in radiological assessment. During the same time period, other methods for treating the degenerative disease of the lumbar spine using direct decompression of the spinal canal were also performed in our facility, with indications for these surgeries coinciding with the indication for indirect decompression according to the ELIF method. The treatment method was therefore the choice of the surgeon, subject to the previously specified limitations of indirect decompression. At the same time, the certain heterogeneity of the cohort according to the diagnosis and level of dysfunction might have further biased the final clinical and radiological evaluation. To further deepen knowledge of the benefits, drawbacks, and limitations of indirect decompression according to the ELIF method, it is appropriate, in the future, to use a prospective evaluation of a group of patients to compare it with other methods for treating degenerative disease of the lumbar spine. In addition, more clinical studies are necessary to specify appropriate indications of the ELIF method.

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Author's contributions All authors contributed to the study conception and design. Material preparation, data collection, and analysis were performed by Josef Vcelak, Adam Kral, Adrea Speldova, and Ladislav Toth. The first draft of the manuscript was written by Josef Vcelak and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

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Data availability Not applicable.

Declarations

Conflict of interest All authors declare, that they have no relevant or non-financial interests to disclose. All authors certify that they have no affiliations with or involvement in any organization or entity with any financial interest or non-financial interest in the subject matter or materials discussed in this manuscript.

Ethics approval The study was performed with the approval of the institutional ethics committee of the university hospital (University Hospital Bulovka, Prague, Czech Republic, 1 July 2022). This study was performed in line with the principles of the Declaration of Helsinki.

Consent to participate and to publish Informed consent was obtained from all individual participants included in the study.

Research involving human participants and/or animals Not applicable.

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ORIGINAL ARTICLE

Expert Consensus on Best Practices for Optimal Wound Closure in Total Knee Arthroplasty: A STRIDE Initiative for Orthopedic Surgeons of India

Rajesh N. Maniar[1] · Bharat Mody[2] · Hemant M. Wakankar[3] · Indrajit Sardar[4] · Neeraj Adkar[5] · Rajkumar Natesan[6] · Sameer Ali Paravath[7] · Sanjay Pai[8] · Unmesh S. Mahajan[9]

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Abstract

Background Wound closure in joint replacement surgeries is crucial for postoperative rehabilitation. Despite substantial advances in total knee arthroplasty (TKA), no guidelines/recommendation or consensus practice statement available internationally or nationally around the optimal method of wound closure. The study aimed to develop evidence-based consensus on current practices, and proposed adoption of advanced wound closure initiatives.

Methods From Nov 2020 to Jan 2021, a group of 12 leading orthopedic surgeons from India met virtually under the Success in Total joint replacement through Recommendation In wounD closure (STRIDE) initiative. Expert committee used Delphi method to evaluate definitional statements that were identified through a comprehensive review of the published literature. Over three rounds of iterative voting, revision, and exclusion, the expert panel provided recommendations based on their clinical expertise and scientific evidence. Statements that reached ≥ 80% agreement was considered as "consensus". A survey poll was conducted following each round to add or suggest changes to the statements.

Results General recommendations include marking the arthrotomy before incision, placing the knee in flexion (less than 90°) for re-approximation during arthrotomy closure. The barbed suture can be a good alternative to traditional sutures for providing water-tight capsule closure and topical skin adhesives (TSAs) to staples for minimizing hospital visits and improving patient satisfaction.

Conclusion This consensus provides interim guidance and practical references to orthopedic surgeons of India enabling easy access to evidence-based healthcare solutions for TKA wound closure. These recommendations need to be periodically reviewed in light of emerging evidence.

Keywords Polydioxanone (PDS) · Barbed suture · Stratafix symmetric · Topical skin adhesive (TSA) · Surgical site infection (SSI) · Total knee arthroplasty (TKA) · Wound closure

Introduction

Total knee arthroplasty (TKA) and total hip arthroplasty (THA) are considered as the most common joint replacement surgeries and a well-established surgical option for various underlying indications [1]. Despite the successes and its rapid adoption, about 1 in 5 patients undergoing TKA are dissatisfied from the outcome of the surgery with dissatisfaction rates estimated to be approximately 20% [2, 3]. This is attributed mainly to the development of complications, unexplained pain, and limited function. Furthermore, the incidence of wound complications following TKA ranges from 0.33 up to 2% in the western literature [4, 5] which is a particular concern considering the substantially increasing TKA use and the aging population.

Despite the availability of multiple techniques and materials, selecting the optimum wound closure device and method needs to be evaluated on basis of patient outcome. There has been an ongoing debate regarding the optimal position of the knee during the closure for optimal soft-tissue repair and postoperative range of motion (ROM) which is closely linked to the patient's functional recovery. The availability of wound closure recommendations in TKA are currently lacking, particularly in the Indian scenario. STRIDE under expert panel from India aims to understand the current

Extended author information available on the last page of the article

practice and gaps; and recommend (1) factors to be considered in wound closure in TKA, (2) wound closure practices of panel members, and (3) their perspective on newer wound closure technologies which could be adopted for wound closure in total knee surgeries.

Materials and Methods

The STRIDE initiative was established (Success in Total joint replacement through Recommendation In wounD closurE) involving 12 experts in total hip and knee replacement representing public and private hospitals across India. Three virtual meeting were held virtually over 3 months from November 2020 to January 2021. A pre-meeting preparation was done prior to each meeting.

A literature search was performed using PubMed and Google scholar to distill the existing evidence. Published global and Indian literature was shared with every member ahead of each meeting. Based on the evidence available, a preliminary questionnaire with the list of statements was developed which was then circulated via e-mail among the expert panel 4 weeks before the meeting. A three-step Delphi process was undertaken to assess the extent of agreement and resolve disagreement on an issue. A threshold of $\geq 80\%$ agreement was considered as "consensus", while the agreement outside the range were considered as "no consensus". Detailed method flow chart of STRIDE methodology is outlined in Fig. 1.

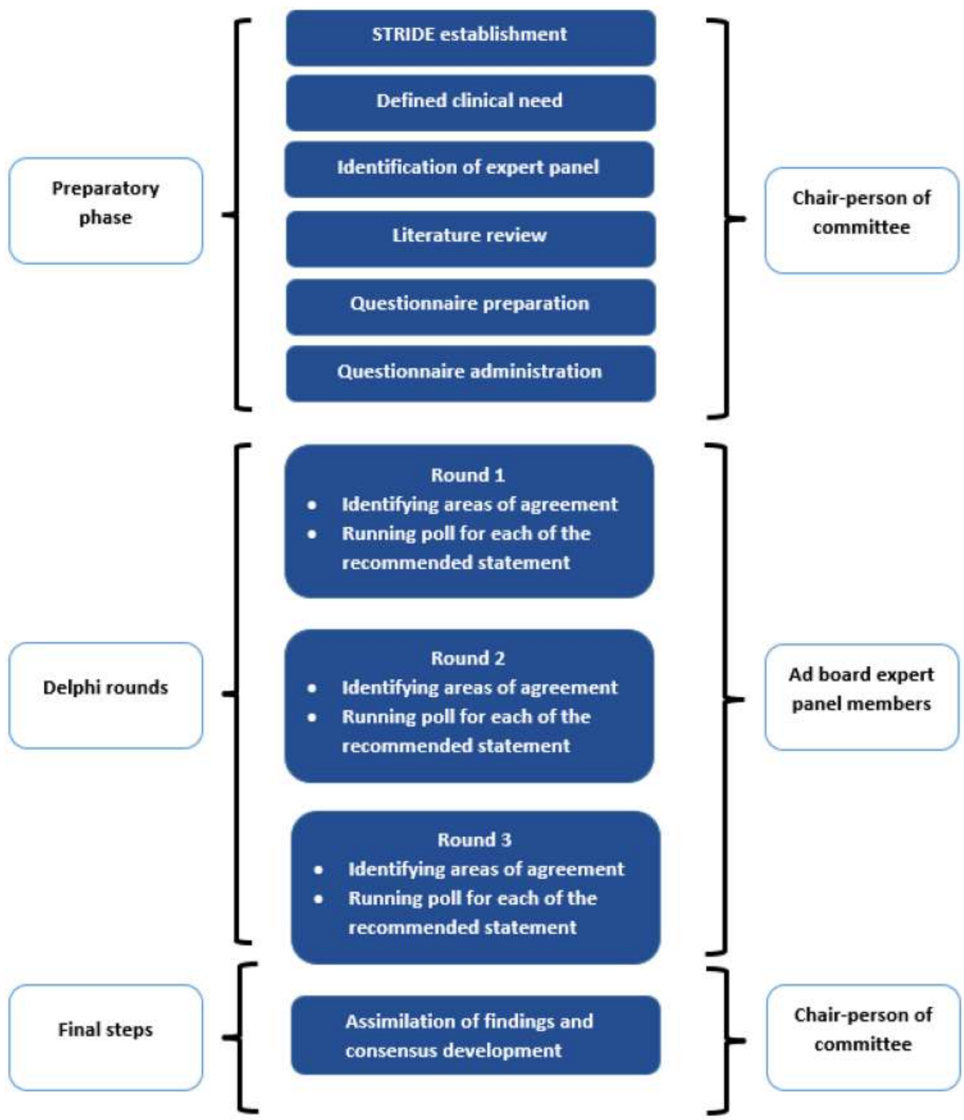


Fig. 1 Delphi process flow chart and the responsibility of individual panel committee during each phase of consensus process

Results

The expert group recommendations to guide orthopedic surgeons to implement in clinical practice are summed up in Table 1, and are discussed in detail below.

Goals for Optimal Wound Closure

The importance of meticulous wound closure in TJA is often stressed in the orthopedic literature. Majority of the expert panel (78%) strongly agreed that wound closure affects the outcome of the surgery and patient satisfaction, emphasizing the need for a meticulous technique and optimal strategy concerning the wound infection and post-surgical complications. During the poll, experts univocally agreed that surgeons must follow Halsted's six steps in the principles of surgery: (a) gentle tissue handling; (b) strict aseptic technique; (c) sharp surgical dissection of tissues; (d) careful hemostasis; (e) avoidance of tension on skin closure; and (f) obliteration of dead space. Evidence suggests that the failure to observe the above principles can have complications, ranging from poor cosmesis and patient dissatisfaction to deep implant infection or failure [6, 7]. The expert panel outlines the following goals for obtaining optimal wound closure in TKA, consistent with the goals discussed by Lyons et al. [8].

Table 1 Expert group recommendations for wound closure in TKA

I. Goals for optimum wound closure in TKA
To minimize dead space formation
Achieving good soft tissue tension and a watertight closure
Preventing infection or scarring
Maximizing functional recovery and Patient satisfaction
Cosmesis—another consideration to achieve patient satisfaction
Cost-effective (minimizing the cost)
Reduction in overall closure time and post-operative pain
II. Capsular closure/Fascia Closure
Divide capsular closure into 2 parts i.e., distal: capsule, thick material, and proximal: quadriceps
Mark arthrotomy with 4 marks before incision to help ensure flexor apparatus is approximated appropriately throughout the length
Incision of 2 mm from the musculotendinous junction of vastus medialis can be considered
Keep knee flexion in the range 60° to 110°* (* Varies from surgeon to surgeon. Majority of the expert panel prefer lesser than 90° flexion of the knee during capsular closure)
III. Suture materials in capsular closure
Advanced Capsular closure devices: Consider Barbed sutures
Other Conventional Suture materials: Slowly absorbable monofilament suture recommended for extended wound support and to minimize risk of wound infection, e.g., Polydiaxanone sutures (PDS)
Triclosan Coated Suture: WHO statement recommends use of TCS suture to reduce risk of SSI irrespective of the type of surgery
IV. Capsular suturing techniques
A combination of continuous and interrupted techniques in capsular closure can be considered for higher capsular closure security
Interrupted suturing provides better tension distribution, watertight seal and improved perfusion
Avoid over-tightening of tissues when using conventional sutures may produce ischemic areas of lateral blood flow
Barbed sutures may be considered as they minimize the incision gap and provide optimum tension across the closure
The incidence of leakage at the capsular layer may be of special importance to surgeons and barbed sutures might be helpful in reducing it
VII. Subcutaneous closure (i.e., Fascial layer closure)
Around 60° flexion can be considered for subcutaneous closure
The closing of both deep and superficial fascia is recommended to avoid the creation of dead space
Absorbable interrupted stitches are fine, but one can consider to use continuous barbed sutures
VIII. Subcuticular and skin closure
Around 60° flexion can be considered for skin closure
Technique of subcuticular closure should be running closure to enable robust perfusion and for speed
Poliglecaprone 25 (MONOCRYL) is recommended for a subcuticular layer
Use of advanced products such as topical skin adhesives (DERMABOND Prineo) is recommended
If stapling is performed, staple spacing should be sufficient to allow optimal oxygenation (~ 6 mm or more). Care should also be taken for proper midline alignment of the staples equidistant from the wound edge

Capsular Closure

Overview

As patients do ROM exercise, capsules may be subjected to extremely high tensile force. Over the past years, studies provided substantial evidence that can effectively decrease anterior knee pain and promote the early recovery of ROM. Results from two meta-analysis studies indicate that positioning the knee in flexion was associated with significantly lesser total blood loss, minimal need for blood transfusion, and improved ROM in the early postoperative period [9, 10].

Knee Positioning

A mean knee flexion between 100° and 110° is adequate for most of the daily activities. Closing the knee in deep flexion (90°–120°) results in re-aligning and less stretching of the soft tissues, ultimately minimizing patient discomfort and possible prevention of extensor mechanism shortening [11]. Another key point is that knee closure in full extension results in decreased postoperative ROM and increased anterior knee pain [12]. The exact knee flexion position for joint and wound closure varied amongst panel members and the panel recommended knee flexion angles between 60° and 110°.

Appropriate Suture Material Selection for Capsular Closure

The expert panel highlighted the use of absorbable sutures over non-absorbable sutures. According to the literature, polydiaxanone monofilament slowly absorbable suture (PDS) showed low reactivity and extended wound support [16]. Medium absorbable suture such as Polyglactin 910 (VICRYL) might lose their tensile strength early and lead to dehiscence which must be avoided. At 4 weeks, Polyglactin 910 (VICRYL) retain only 25% of their strength while 50% is necessary throughout the critical wound healing period (which is about 3–4 weeks). In such cases where the surgeon expects a longer period to heal, the use of slowly absorbable material is suggested.

Various international guidelines including WHO, CDC and NICE have recommended triclosan coated sutures (TCS) in reducing Surgical Site Infection risk. A double-blind randomized controlled trial on THA and TKA did not show any benefit of TCS compared to standard sutures [17]. However, a subsequent meta-analysis of 25 randomized controlled trial established superiority of TCS compared to standard sutures in reducing surgical site infections (RR = 0.73, 95% CI 0.65–0.82) [18, 19]. Based on the possible benefits of triclosan-coated sutures in reducing surgical site infections, they may be considered to be used. A cost-effectiveness analysis may be required to understand the extent of benefits with TCS in the Indian context.

Techniques of Suturing

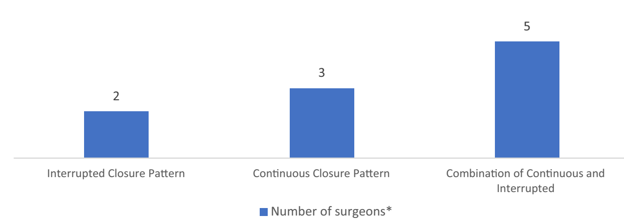
Several advantages and disadvantages for continuous and interrupted suture patterns have been well documented in the literature [20]. Traditionally, knee arthrotomy closure is achieved using an interrupted suture pattern. Expert suggest that a combination of continuous and interrupted sutures are the most preferred techniques in their routine practice (Fig. 2) when traditional sutures are used.

Use of Advanced Capsular Closure Techniques

The influence of barbed sutures in obtaining optimal wound closure has been well described in the literature. In a recent meta-analysis [21], authors support the use of barbed suture (i.e., symmetric barbed sutures, Stratafix®, Symmetric PDS Plus Knotless Tissue Control Device Ethicon) for capsular closure as an alternative to conventional sutures. With current limited evidence on the use of barbed suture for capsular closure highlights the following clinical benefits a. reduced incidence of leakages, i.e., more watertight closure b. faster closure time c. higher wound holding strength, to support the extreme tension during post-op exercise (d) consistent tension across incision (equal tension distribution due to continuous technique) (e) fewer chances of blood supply compromise (i.e., no need to pull up strongly) [22].

Barbed sutures when used in TKA to close the high-tension capsular layer, provide superior tissue-holding capacity compared to traditional absorbable suture. Barbed suture is found to close the wounds substantially faster compared to interrupted technique, resulting in significant time saving in the OR [13]. Evidence from published randomized controlled trials and observational studies suggests that barbed sutures can reduce the closure time to enhance surgery efficiently [14, 15].

However, in addition to recommendations (Table 1) that details the content and usage of barbed sutures, expert panel



* 10 out of 12 expert panel votes were obtained

Fig. 2 Preferred suturing technique for capsular closure based on expert consensus expressed interest for more robust clinical evidence and emphasized the need for further research to conclusively establish patient and economic benefits with use of barbed sutures.

Subcutaneous Closure (i.e., Fascial Layer Closure)

A layer between the knee joint capsule and skin can lead to the creation of dead space which facilitates hematoma and seroma formation [23]. Thus, most panel members recommend the closing of both deep and superficial fascia to avoid the creation of dead space. An angle of around 40°–60° flexion can be considered for fascial closure.

Conventionally, closure of fascial layer is performed using absorbable sutures placed in an interrupted manner. However, data on the outcomes of applying barbed sutures for fascial closure after knee replacement have shown to improve cost-effectiveness, reduced operation time and the reduced rate of wound complications [24, 25].

Dermal Closure

Subcuticular Closure

Subcuticular closure is needed to improve cosmesis and to provide water-tight closure. According to the experts, the technique of subcuticular closure should be running closure. Subcuticular closure with absorbable sutures has gained considerable momentum with the justification of less time spent and better cosmetic appearance. As per the poll results, the majority of expert panel (88%) agreed that subcuticular suturing must be considered based on the recent evidence, and the continuous suture technique helps provide robust perfusion around the suture site and saves time. Infrequently, well approximated subcuticular closure is used as the only dermal closure method, and not followed by formal skin closure.

Skin Closure

Traditionally, different methods used for skin closure are staples and sutures. The use of staples or sutures may result in the chances of unraveling, splitting, and might lead to bacterial colonization. Further concerns on staples include poorer cosmesis, increased pain while removing, and low precision wound approximation. Suturing can address the shortcomings of staples but is a time-consuming closure technique. Based on this, expert panel suggests that wound closure materials for the skin should facilitate wound and tissue healing; and prevent or reduce potential wound complications. Skin closure devices such as topical skin adhesives (DERMABOND Prineo), absorbable monofilament Poliglecarone 25 (MONOCRYL) sutures can reduce the shortcomings of staples and provide better patient outcome.

Advances in Skin Closure

Topical skin adhesive (TSA), a new device in skin closure, uses two components that allow high strength, desired wound healing, and watertight and yet flexible antimicrobial barrier. TSA was found to distribute tension more evenly and tend to be stronger than the average strength of staples and sutures. Being a transparent barrier without dressing requirement, and having the property of sloughing off by own, topical skin adhesives enable teleconsultation and tend to reduce hospital visits. A study showed improved patient satisfaction with the use of TSA compared to conventional staples mainly due to improved cosmesis [26]. In the interest of relevance, expert panel recommend considering TSAs as an alternative to other conventional skin closure methods. However, more robust clinical evidence to reinforce the use of TSA is needed as it is a comparatively newer technique. The cost-effectiveness of this method in the Indian scenario also needs to be evaluated especially for resource-constrained settings [27].

Furthermore, an improved dressing can enhance the healing process, helps in reducing infection, and pain, thus optimizing the quality of the outcome. An ideal wound dressing material should consist of mentioned features as follows: (a) control the moisture around wound, (b) biocompatible and biodegradable, (c) easily changed and removed, (d) minimize wound necrosis, (e) low skin adherence and (f) removing exudate.

Limitations Systematic literature review with stringent criteria for levels of evidence was not performed. Second, although our expert panel comprised representatives across the nation, only experts from the orthopedic community were included, and no multidisciplinary panel involving patient-advocacy experts, and a recovered patient to speak on behalf of patients was included.

Conclusion

In this initiative, we sought to address the gaps in obtaining optimal wound closure by providing a consensus of various practice options within TKA. Placing the knee in flexion (lesser than 90°) is recommended practice for accurate re-approximation. Barbed sutures can be considered over conventional sutures for high-tension areas like capsules. Closure of fascial layer, prior to skin closure is recommended to obliterate a potential dead space. Running subcuticular stitch is recommended prior to skin closure with staples or Ethilon sutures. TSA can be considered as an alternative to staples.

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Data Availability Not applicable.

Declarations

Conflict of interest Rajesh N. Maniar, Bharat Mody, Hemant M. Wakankar, Indrajit Sardar, Neeraj Adkar, Rajkumar Natesan, Sameer Ali Paravath, Sanjay Pai, Unmesh S. Mahajan declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest. On behalf of all authors, the corresponding author states that there is no conflict of interest.

Ethical approval The views and opinions expressed in the article are solely of the authors as named above, and are based on their independent professional judgement.

Ethical standard statement This article does not contain any studies with human participants or animals performed by any of the authors.

Informed consent Formal consent is not required for this type of study.

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Authors and Affiliations

Rajesh N. Maniar[1] · Bharat Mody[2] · Hemant M. Wakankar[3] · Indrajit Sardar[4] · Neeraj Adkar[5] · Rajkumar Natesan[6] · Sameer Ali Paravath[7] · Sanjay Pai[8] · Unmesh S. Mahajan[9]

✉ Rajesh N. Maniar
drmaniar@jointspeciality.com

Bharat Mody
joints.mody@gmail.com

Hemant M. Wakankar
hwakankar@gmail.com

Indrajit Sardar
indrajit@hotmail.com

Neeraj Adkar
knee.expert@gmail.com

Rajkumar Natesan
drrajkumarn@gmail.com

Sameer Ali Paravath
drsameeralip@gmail.com

Sanjay Pai
sanjaypaiortho@gmail.com

Unmesh S. Mahajan
unmeshmahajan@hotmail.com

1 Department of Orthopedics, Lilavati Hospital, Bandra West, Mumbai, Maharashtra 400050, India

2 Welcare Hospital, Vadodara, Gujarat, India

3 Department of Joint Replacement & Reconstruction, Deenanath Mangeshkar Hospital, Pune, Maharashtra, India

4 Department of Orthopedics, Nightingale Hospital, Kolkata, West Bengal, India

5 Department of Orthopedics, SaiShree Hospital for Special Surgery, Pune, Maharashtra, India

6 Department of Orthopedics, Ganga Hospital, Coimbatore, Tamil Nadu, India

7 Centre for Bone, Joint and Spine, Meitra Hospital, Calicut, Kerala, India

8 Department of Orthopedics, Apollo Specialty Hospital, Bangalore, Karnataka, India

9 Department of Orthopedics, Mahajan Ortho and Surgical Hospital, Nagpur, Maharashtra, India

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ORIGINAL ARTICLE

Influence of Lateral Retinacular Release in Realigning the Patella Between Varus and Valgus Knees in Primary Total Knee Arthroplasty

Palanisami Dhanasekararaja[1] · Dhanasekaran Soundarrajan[1] · James B. Jisanth[1] · Natesan Rajkumar[1] · Shanmuganathan Rajasekaran[1]

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Abstract

Purpose Our study aims to find the role of lateral retinacular release (LRR) on realigning the patella in knees with maltracking during primary total knee arthroplasty. We also compared the patellar morphological factors between the varus and valgus knees on predicting the need for LRR.

Methods We have retrospectively analyzed the incidence of LRR in consecutive 152 primary TKA (124 patients) from May 2018 to December 2018. We have evaluated the preoperative radiological parameters like Wiberg's patellar morphological type, patellar angle, sulcus angle, patellar width and thickness, preoperative patellar tilt and patellar shift, lateral patellofemoral angle and congruent angle. Post-operatively, patellar shift and patellar tilt were measured. Multivariate regression analysis was used to find the association of LRR with the individual radiological parameters.

Results There was no statistical difference in the postoperative patellar shift and tilt between lateral released and non-released groups, suggesting realignment of the patella after LRR ($p > 0.05$). The morphological parameters like patellar shift, lateral patellofemoral angle and congruent angle were significantly increased in valgus knees compared to varus knees ($p < 0.05$). The preoperative patellar shift of > 3.5 mm have a specificity of 93.7% and a negative predictive value (NPV) of 92.7%, congruent angle > 16° have a specificity of 85.3% and NPV of 4.2% in varus knees in predicting LRR.

Conclusion Radiological parameters of patellar maltracking like increased patellar tilt and lateral patellar shift get corrected postoperatively after performing the lateral release. Patella with Wiberg type 3 morphology, patellar shift > 3.5 mm and congruent angle > 16° in axial view tend to have an increased chance of lateral retinacular release.

Keywords Patellar maltracking · Lateral retinacular release · Total knee arthroplasty · Patellofemoral complications

Introduction

Advances in the prosthetic design reduced the patellofemoral complications to about 2–8% after total knee arthroplasty (TKA) [1–3]. Still, it accounts for the important cause of patient dissatisfaction and causes of early failure after TKA. Optimal patellar tracking is one of the important factors which influences patient satisfaction after TKA and postoperative functional outcome [3]. Postoperative patellar tracking is influenced by prosthetic design, rotation and alignment of the femoral and tibial component, overstuffing of the anterior compartment, angle of patellar resection and most notably balance of peripatellar soft tissues [3, 4].

The lateral retinacular release (LRR) helps to balance the lateral patellar maltracking due to excess soft tissue tension. Even though the frequency of LRR significantly reduced over time, some patients still require LRR for balancing the

✉ Dhanasekaran Soundarrajan
soundarortho@gmail.com

Palanisami Dhanasekararaja
dhanasekararaja@gmail.com

James B. Jisanth
drjisanth@gmail.com

Natesan Rajkumar
drrajkumarn@gmail.com

Shanmuganathan Rajasekaran
rajasekaran.orth@gmail.com

[1] Department of Orthopaedics, Ganga Hospital, 313, Mettupalayam Road, Coimbatore 641 043, India

peripatellar soft tissues [4]. There is controversy regarding morbidity associated with LRR. Literature is varied with some studies [5–7] claiming the procedure is innocuous, whereas others showing LRR is associated with complications like hemarthrosis, infection, avascular necrosis and patellar fracture [6, 8–10].

Few studies [4, 11, 12] identified the preoperative radiological factors which influenced the patellar maltracking during total knee arthroplasty. The literature regarding the comparison of the preoperative morphological factors of the patella which can influence patellar maltracking between the varus and valgus knees is sparse. Thus, the presence of a preoperative radiological indicator which would suggest the need for the lateral release can help in better preoperative planning and avoid lateral release in those who do not actually require it.

Our study aims to find the role of LRR in realigning the patella in knees with maltracking during primary total knee arthroplasty. We also compared the patellar morphological factors between the varus and valgus knees on predicting the need for LRR. We hypothesize that LRR helps to realign the patella in knees with maltracking and we can preoperatively predict the need for LRR by analyzing the patellar morphological parameters.

Patients and Methods

After getting consent from the institutional review board, we retrospectively collected data of 152 consecutive primary TKA of 124 patients from May 2018 to December 2018. Among the 124 patients, 28 patients underwent bilateral TKA. Exclusion criteria were non-standardized radiographs, non-availability of pre or postoperative axial view, revision surgery and previous surgery in the same limb. Posterior stabilized knees, either PFC Sigma (Depuy, Indianapolis, IN) or Genesis II (Smith & Nephew, Memphis, TN) were used. Institutional ethical committee approval was obtained for the study and conducted in compliance with the Helsinki declaration.

Radiographic Assessment

Long leg alignment film including hip, knee and ankle were taken in a single film for all the patients. Weight-bearing anteroposterior, lateral and axial radiographs were done preoperatively. The axial radiographs were taken at 30 degrees knee flexion using a standardized frame pre and postoperatively. Picture Archiving and Communication Systems 3.0 software used for radiographic measurements and magnification corrections were digitally performed.

We have analyzed preoperative parameters like patellar morphological type, patellar angle, patellar width, patellar thickness, patellar lateral facet width, patellar facet thickness, preoperative patellar tilt and patellar shift, lateral patellofemoral angle, sulcus angle and congruent angle. Postoperatively, patellar shift and patellar tilt were measured to find the realignment after doing LRR.

The patellar morphology is graded into three types by Wiberg classification [13] in the axial view. In type 1, equal medial and lateral facets and both are slightly concave. In type 2, the medial facet is smaller than the lateral facet the and medial facet is concave. In type 3, the medial facet is small, convex and more vertical. The variant types include cobblestone and pebble types (Fig. 1).

The patella angle is the angle between the two tangents drawn along the medial and lateral facets [14]. The patella width measured between the medial and lateral most points on the patella. The patella thickness measured between the upper and lowest point on the patella perpendicular to the patellar width line [14]. The patella lateral facet width is the

Fig. 1 Axial radiographs showing various Wiberg's morphological types of patella

distance between the line measuring patellar thickness and the lateral pole of the patella [14] (Fig. 2).

The sulcus angle measures the angle between the lateral and medial femoral condyle [15]. The normal sulcus angle is approximately 140°. Congruence angle is the angle between one line bisecting the sulcus angle and another to the apex of the patella [15]. The average congruence angle is -6 degrees and measures primarily subluxation. Normally the line through the apex should be medial to the bisector and is taken as positive. If the line through the apex is passing laterally the angle is taken as negative. Lateral patellofemoral angle calculated between two lines. One line connecting the highest points of the medial and lateral facets of the trochlea and another tangent to the lateral facet of the patella [16] (Fig. 2). In normal knees, this angle should open laterally.

The patellar shift is measured between the deepest point on the femoral sulcus and the median ridge of the patella [4, 12, 15]. Lateral patellar displacement is taken as positive. Normal value is 0.3 mm ± 2.5 mm. The patellar tilt is defined as the angle between a line from the anterior limits of the femoral condyles and the equatorial line of the patella preoperatively [4, 15] (Fig. 2). A tilt angle between 0 and 5 degrees is normal, 5 to 10 degrees is borderline, and an angle greater than 10 degrees is considered abnormal. Lateral patellar tilt is taken as positive.

Postoperatively, patellar tilt is calculated between a line from the anterior limits of the femoral condyles and a line drawn through the prosthesis-bone interface of patella. Patellar shift measured between the center of the patella and a line drawn through the central area of the femoral condyles (Fig. 3).

Surgical Technique

Conventional total knee arthroplasty done for all the knees. Proper care was taken to place the femoral and tibial components in correct rotation and alignment. Intraoperatively patellar tracking was evaluated using the no thumb technique with trial implants in place. If there is patellar maltracking, the tourniquet deflated after implanting the final components and patellar tracking is evaluated again from full extension to full possible flexion. A grading system was devised by Maniar et al. [17]. was used to grade the patellar tracking and lateral release was done for all those

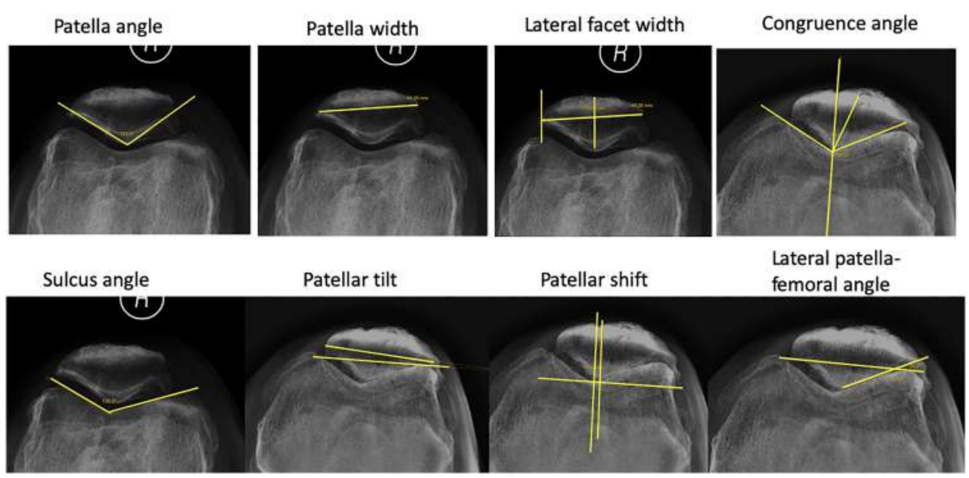

Fig. 2 Axial radiographs showing various preoperative radiographic measurements of patellar morphology (details in the text)

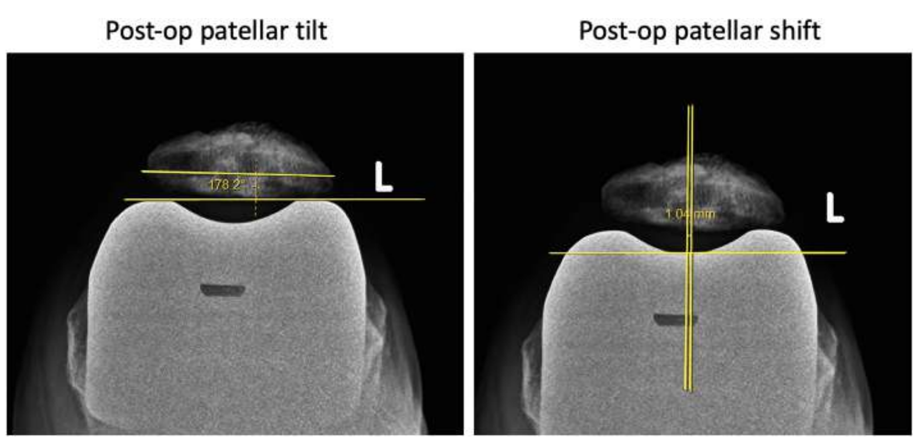

Fig. 3 Axial radiographs depicting the measurement of postoperative patellar tilt and shift

with grade 2 and above of patellar maltracking. The lateral release was done using the outside-in technique [17] (Fig. 4). The lateral skin flap is raised to expose the lateral retinaculum. The graded release was done and patellar tracking was checked at each stage to prevent over-release (Fig. 5). If the release involves the superior patellar border, the ligation of the superior lateral genicular artery was done.

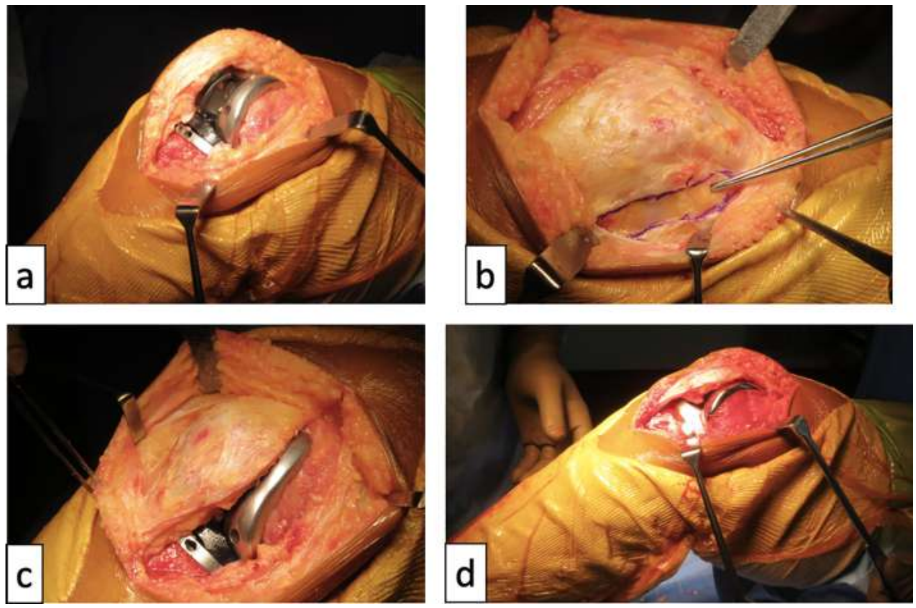

Fig. 4 Intraoperative picture showing **a** patellar maltracking on knee flexion **b** lateral retinacular release by outside-in technique **c** correction of patellar maltracking on graded lateral retinacular release **d** congruent patellar tracking after lateral retinacular release

Fig. 5 **a** Preoperative radiographs showing tricompartmental osteoarthritis with patellar maltracking in the axial view **b** postoperative radiographs showing neutral alignment with optimal patellar tracking after lateral retinacular release

Statistical Analysis

Statistical software used to analyze data were MS Excel, SPSS for Windows Inc. Version 22. Chicago, Illinois. Descriptive statistics were reported as mean (SD) for continuous variables, frequencies (percentage) for categorical variables. Multivariate analysis and multiple regression analysis were carried out to find the patellar morphological factors between the varus and valgus knees on predicting the need for LRR. Conventional statistical analysis methods, such as t-tests were used to compare the means between two related groups. Chi-Square at a 5% level of significance was used to find statistical significance. Sensitivity, specificity, positive predictive value, negative predictive value was calculated to find out the diagnostic accuracy.

Table 1 Distribution of morphological characteristics among the total knees observed ($N = 152$)

Variable	Types		*p* value
	Valgus ($n = 46$) *n* (%)	Varus ($n = 106$) *n* (%)	
Side			
Right	26 (56.5)	56 (52.8)	0.67
Left	20 (43.5)	50 (47.2)	
Surgical approach			
Medial parapatellar	36 (78.3)	106 (100)	
Lateral parapatellar	10 (21.7)	0 (0)	**0.000***
Patellar resurfacing			
Yes	33 (71.7)	48 (45.3)	
No	13 (28.3)	58 (54.7)	**0.002***
Lateral release			
Yes	22 (47.8)	11 (10.4)	
No	24 (52.2)	95 (89.6)	**0.000***
Patellar morphology			
1	10 (21.7)	22 (20.8)	
2	16 (34.8)	47 (44.3)	
3	20 (43.5)	27 (20.8)	0.077
Cobble stone	0 (0)	1 (0.9)	
Pebble	0 (0)	9 (8.5)	

*Significant (p<0.05)

Results

The mean age of the patients was 62.3 ± 8.1 years. Wiberg's type 3 patella predominated in valgus knees (43.5%), whereas type 2 morphology predominated in the varus group (44.3%). LRR was done in 47.8% of knees ($n = 22$) in valgus knees and 10.4% of knees ($n = 11$) in the varus group (Table 1).

Congruent Angle in Predicting LRR Between Varus and Valgus Knees

The average congruent angle was $12.9 \pm 16.4°$ in valgus knees compared to $-0.55 \pm 18.6°$ in the varus knees ($p < 0.001$) (Table 2). The average congruent angle for patients who underwent lateral release was $17.1 \pm 20.6°$ compared to $-2.6 \pm 17.3°$ ($p < 0.001$) in those who didn't undergo lateral release in the varus group (Table 3,4). The average congruent angle for patients who underwent lateral release was $18.3 \pm 16.2°$ compared to $8 \pm 15.5°$ ($p = 0.03$) in those who didn't undergo lateral release in the valgus group (Table 5). The congruent angle of > 16° had a specificity of 85.2% and negative predictive value (NPV) of 94.2% in varus knees and specificity of 66.7% and NPV of 66.7% in valgus knees in predicting the need for lateral release (Table 6).

Table 2 Various morphological measurements of patella between varus and valgus knees ($N = 152$)

Sl.no	Patella morphology	Valgus ($n = 46$)	Varus ($n = 106$)	*p* value
1	Patellar angle	116.90 ± 10.0	122.60 ± 14.4	**0.016***
2	Patellar width	47.9 ± 5.1	47.9 ± 5.6	0.976
3	Patella thickness	23.3 ± 3.3	22.4 ± 3.8	0.167
4	Patella lateral facet width	28.1 ± 4.7	28.9 ± 4.0	0.295
5	Patella facet thickness	12.1 ± 2.6	11.4 ± 2.9	0.126
6	Patellar tilt	6.24 ± 6.2	6.61 ± 5.3	0.708
7	Lateral patella-femoral angle	28.23 ± 6.7	22.29 ± 6.1	**< 0.001***
8	Sulcus angle	124.36 ± 7.8	123.98 ± 14.1	0.865
9	Congruent angle	12.95 ± 16.4	− 0.55 ± 18.62	**< 0.001***
10	Patellar shift	1.75 ± 2.3	− 0.69 ± 5.4	**0.004***
11	Postoperative patellar tilt	0.039 ± 5.5	1.96 ± 6.2	0.073
12	Postoperative patellar shift	2.39 ± 3.49	3.31 ± 4.1	0.190

*Significant (p<0.05) (Angles given in degrees and linear measurements given in millimetres)

Table 3 Multivariate regression analysis to predict the need between patellar resurfacing, Wiberg's patellar morphology and lateral release in the varus and valgus knees ($N=152$)

Sl. no	Variable	Lateral release ($n=33$)	Lateral release not done ($n=119$)	OR	95% CI	p value
1	**Patellar resurfacing** (Valgus $n=46$)					
	Yes	18 (54.54)	15 (45.46)	2.7	(0.69–10.54)	0.153
	No	4 (30.77)	9 (69.23)	1		
2	**Patellar resurfacing** (Varus $n=106$)					
	Yes	9 (18.8)	39 (81.3)	6.46	(1.32–31.55)	**0.010***
	No	2 (3.4)	56 (96.6)	1		
3	**Patellar morphology** (Valgus $n=46$)					
	1	3 (30)	7 (70)	1		
	2	8 (50)	8 (50)	2.33	(0.43–12.39)	0.424
	3	11 (55)	9 (45)	2.85	(0.57–14.32)	
4	**Patellar morphology** (Varus $n=106$)					
	1	0 (0)	22 (100)			**0.005***
	2	2 (4.3)	45 (95.7)	–	–	
	3	6 (22.2)	21 (77.8)			
	Others	3 (30)	7 (70)			

*Significant (p<0.05)

Table 4 Patella Morphology Measurements in varus group between LRR done and not-done groups ($n=106$)

Sl. no	Patellar morphology	Lateral release done (11)	Lateral release not done (95)	r	p value
1	Patella angle	129.76 ± 14.15	121.77 ± 14.31	− 0.17	0.08
2	Patellar width	49.4 ± 4.5	47.8 ± 5.7	− 0.09	0.38
3	Patella thickness	21.7 ± 3.0	22.5 ± 3.9	0.06	0.51
4	Patella lateral facet width	29.3 ± 4.4	28.8 ± 4.0	− 0.03	0.71
5	Patella facet thickness	10.9 ± 2.9	11.4 ± 2.9	0.05	0.63
6	Patellar tilt	6.33 ± 6.9	6.64 ± 5.1	0.02	0.85
7	Lateral patello-femoral angle	20.36 ± 5.4	22.51 ± 6.2	0.05	0.23
8	Sulcus angle	128.22 ± 7.9	123.49 ± 14.5	− 0.02	0.29
9	Congruent angle	17.16 ± 20.6	− 2.60 ± 17.34	− 0.32	**< 0.001***
10	Patellar shift	2.3 ± 2.7	− 1.0 ± 5.5	− 0.19	**0.05***
11	Postoperative patella tilt	− 0.18 ± 2.8	2.21 ± 6.4	0.12	0.23
12	Postoperative patellar shift	0.7 ± 2.1	3.61 ± 4.1	0.22	**0.03***

*Significant (p<0.05)

Patellar Shift in Predicting LRR Between Varus and Valgus Knees

The average preoperative patellar shift was 1.8 ± 2.3 mm in valgus knees compared to − 0.7 ± 5.4 mm ($p=0.004$) in varus knees (Table 2). The average preoperative patellar shift for patients who underwent lateral release was 2.3 ± 2.7 mm compared to − 1 ± 5.5 mm ($p=0.05$) in those who did not undergo lateral release in varus knees (Table 4). The average preoperative patellar shift for patients who underwent lateral release was 2.7 ± 2.5 mm compared to 0 ± 1.9 mm ($p=0.007$) in those who did not undergo lateral release in valgus knees (Table 5). The preoperative patellar shift of > 3.5 mm had a specificity of 93.7% and NPV of 92.7% in varus knees and specificity of 91.7% and NPV of 62.9% in valgus knees (Table 6).

Preoperative Patellar Parameters in Predicting LRR

Lateral patellofemoral femoral angle was significantly higher in valgus group 28.2 ± 6.7 compared to varus group 22.3 ± 6.1 ($p<0.001$). A higher lateral patellofemoral angle indicates that the patella is tilted more medially. However, on analyzing valgus and varus groups separately there was no

Table 5 Patella Morphology Measurements in the valgus group between LRR done and not-done groups ($n=46$)

Sl.no	Patella morphology	Lateral release done (22)	Lateral release not done (24)	r	p value
1	Patella angle	113.91 ± 11.2	119.65 ± 8.0	0.28	**0.05***
2	Patellar width	4.93 ± 0.4	4.66 ± 0.5	− 0.26	0.08
3	Patella thickness	2.48 ± 0.34	2.20 ± 0.3	0.42	**0.003***
4	Patella lateral facet width	2.88 ± 0.4	2.75 ± 0.5	− 0.14	0.35
5	Patella facet thickness	1.33 ± 0.3	1.10 ± 0.22	− 0.45	**0.002***
6	Patellar tilt	8.29 ± 6.0	4.36 ± 5.8	− 0.32	**0.03***
7	Lateral patella-femoral angle	28.5 ± 7.5	27.97 ± 6.0	− 0.04	0.79
8	Sulcus angle	121.09 ± 5.6	127.35 ± 8.5	0.40	**0.006***
9	Congruent angle	18.34 ± 16.2	8.01 ± 15.47	− 0.32	**0.03***
10	Patellar shift	2.7 ± 2.5	0.0 ± 1.9	− 0.39	**0.007***
11	Postoperative patellar tilt	− 1.37 ± 5.85	1.33 ± 5.10	0.24	0.10
12	Postoperative patellar shift	1.9 ± 3.8	2.9 ± 3.1	0.15	0.30

*Significant (p<0.05)

Table 6 Validity of lateral release with preoperative patellar shift and congruent angle between varus and valgus knees ($N=152$)

Variable	Lateral release	Lateral release not done	OR	95% CI	Validity
Preop patellar shift (valgus knee $n=46$)					
> 3.5 mm	9	2	7.61	(1.42–40.80)	Specificity = 91.67%, NPV = 62.86%
< 3.5 mm	13	22	1		Sensitivity = 40.91%, PPV = 81.82%
Preop patellar shift (varus knee $n=106$)					
> 3.5 mm	4	6	8.47	(1.92–37.26)	Specificity = 93.68%, NPV = 92.71%
< 3.5 mm	7	89	1		Sensitivity = 36.36%, PPV = 40%
Congruent angle (valgus knee $n=46$)					
> 16°	14	8	3.50	(1.03–11.79)	Specificity = 66.67%, NPV = 66.67%
< 16°	8	16	1		Sensitivity = 64%, PPV = 63.34%
Congruent angle (varus knee $n=106$)					
> 16°	6	14	6.94	(1.86–25.87)	Specificity = 85.26%, NPV = 94.19%
< 16°	5	81	1		Sensitivity = 54.55%, PPV = 30%

statistically significant difference in the lateral patellofemoral angle between the knees that required and those which did not require lateral release (Tables 4, 5).

There was no statistically significant difference between preoperative patellar tilt in valgus and varus groups (Table 2). It was 6.2 ± 6.2 in the valgus group and 6.6 ± 5.3 the in varus group ($p=0.708$). There was a statistically significant difference in patellar tilt between the need for lateral release in valgus group ($p=0.03$) (Table 5), but not in the varus group ($p=0.85$) (Table 4).

Patellar angle was significantly higher in varus group (122.6 ± 14.4) compared to valgus group (116.9 ± 10) ($p=0.016$). There was no statistically significant difference between the two groups for other preoperative patellar measurements like patellar width, patellar thickness, patella lateral facet width, patella facet thickness and sulcus angle (Table 2).

Patellar Resurfacing Vs LRR Between Varus and Valgus Knees

Among the valgus group, 54.5% of knees who underwent patellar resurfacing needed lateral release while 30.7% of knees which didn't undergo patellar resurfacing needed lateral release ($p=0.08$) (Table 3). In the varus group, 18.8% of patients who underwent patellar resurfacing needed lateral release while only 3.4% of knees which didn't undergo patellar resurfacing needed lateral release which was statistically significant ($p=0.01$) (Table 3).

Change in Patellar Parameters After LRR

In the varus group, the postoperative patellar shift was 0.7 ± 2.1 mm in the lateral release group while it was 3.61 ± 4.1 mm in the non-lateral release group ($p=0.03$)

(Table 4). In the varus group, knees that underwent lateral release had a preoperative patellar shift of 2.3 ± 2.7 mm which got reduced to 0.7 ± 2.1 mm postoperatively ($p = 0.13$). In the valgus group, the postoperative patellar shift was 1.9 ± 3.8 mm in the lateral release group and 2.9 ± 3.1 mm in the non-lateral release group ($P = 0.3$) (Table 5). In valgus group, knees that underwent lateral release, the preoperative patellar shift was 2.7 ± 2.5 mm which got reduced to 1.9 ± 3.8 mm postoperatively ($P = 0.43$) (Table 5).

Discussion

The key findings of our study are radiological parameters of patellar maltracking like increased patellar tilt and lateral patellar shift get corrected postoperatively after performing the lateral release. The morphological variations in the patella occur depending on the coronal malalignment. Wiberg's type 3 patella predominated in valgus knees and type 2 morphology predominated in the varus group. The patellar morphological parameters like increased congruent angle, patellar shift and lateral patellofemoral angle were found significantly associated with valgus knees which can predict patellar maltracking. Patella with Wiberg type 3 morphology, patellar shift > 3.5 mm and congruent angle > 16° in axial view tend to have an increased chance of lateral retinacular release.

Lateral release of the tight lateral retinaculum during TKA is one well-described option in the literature to avoid patellar maltracking. This has been reported as being performed in 3.8–45% of patients [3, 5, 12]. But this procedure is not entirely without complications which include increased intraoperative blood loss, accidental damage to lateral retinacular vessels leading to a compromised blood supply to the patella, patellar necrosis, patella fracture, reduced transcutaneous oxygen tension, wound healing issues and knee pain [6, 8–10]. Hence, preoperative prediction of lateral release helps to anticipate the tight lateral structures and avoid unnecessary lateral release.

Reduction in postoperative patellar tilt and shift was observed in both varus and valgus groups and this reduction was more marked in the groups which underwent a lateral release. Chia et al. [4]. also found a significant reduction in the patellar tilt and shift after lateral release. Lateral release helps in correcting the increased lateral patellar shift present preoperatively in valgus and varus knees and is an effective method for preventing lateral patellar maltracking after TKR.

Alterations in coronal alignment can affect the progression of osteoarthritis in medial and lateral patellar facets [18]. In our study, we could observe a difference in patellar morphology in varus and valgus knees. Patellar instability is more commonly seen in valgus knees. Many of these patients can have tightness in the lateral retinaculum, chronically dislocated patella and a smaller lateral femoral condyle. Like other studies [4, 12, 19], we also found the incidence of lateral release during TKA is significantly higher in valgus knees compared to varus knees.

The incidence of Wiberg type 3 morphology in the valgus group was 43.5% compared to 25.5% in varus group. There was no statistical correlation between Wiberg's patellar morphology and lateral release in the valgus group. But in varus group, knees with type 3 patella morphology had a statistically significant chance of requiring lateral release. (Table 3). Wiberg type 3 patella with lateral facet arthritis has an increased chance of patellar maltracking and lateral release during TKA.

Our study specifically analyzed between varus and valgus knees and found that the knees which required a lateral release had a significantly higher positive value for both patellar shift and congruent angle. Both these parameters indicate the relative position of the patella compared to the trochlear groove. A higher positive value indicates that the patella is more laterally placed and are more prone to develop patellar maltracking. This might explain the higher incidence of lateral release in valgus knees (43.5%) compared to varus knees (10.4%). Some studies [4, 12] also showed lateral patellar shift significantly associated with lateral retinacular release. These results indicate that preoperative congruent angle and patellar shift can be used as predictors for requiring lateral release during TKA.

There is a positive correlation between patellar resurfacing and lateral release in varus knees. This may be attributed to the fact that the patella which had more extensive osteoarthritis may have an increased instability associated with it leading to the requirement of both patellar resurfacing and lateral release. Our study also had several limitations. The patellar tracking after TKA depends on multiple factors like component position and alignment. We have not evaluated the relation of component rotation by computed tomography, but great care was taken to placing the component in correct rotation and alignment. We have not quantified the magnitude of coronal deformity which might influence the postoperative patellar tracking.

Conclusion

Lateral retinacular release helps in correcting the radiological parameters of patellar maltracking like increased lateral patellar shift and tilt and is an effective method for realigning the patella during TKA. The preoperative patellar shift of > 3.5 mm and congruent angle of > 16° can be used as preoperative predictors for lateral release. The incidence of lateral release during TKA is significantly higher in valgus knees compared to varus knees.

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Data availability Our data will be available upon request and described in detail in the tables.

Declarations

Conflict of Interest Palanisami Dhanasekararaja,, Dhanasekaran Soundarrajan, James B Jisanth, Natesan Rajkumar and Shanmuganathan Rajasekaran declare that they have no conflict of interest.

Ethical Standard Statement This article does not contain any studies with human or animal subjects performed by the any of the authors.

Informed consent in Studies with Human Subjects All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2008. Informed consent was obtained from all patients for being included in the study.

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ORIGINAL ARTICLE

ACL Volume Measurement Using a Multi-truncated Pyramid Shape Simulation

Takanori Iriuchishima[1] · Bunsei Goto[1]

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Abstract

Purpose The purpose of this study was to measure anterior cruciate ligament (ACL) volume in a newly reported multi-truncated pyramid shape simulation using axial magnetic resonance imaging (MRI) for the detailed knowledge of the ACL anatomy.

Methods Fifty subjects (27 female and 23 male, average age: 23 ± 7.8) visiting our clinic with knee pain and in whom MRI showed no structural injury were included in this study. Using the axial image of the MRI, four deferent levels of the cross-sectional area of the ACL were measured. ACL height was measured as the distance between the most proximal and distal slices of the MRI. ACL volume was calculated using a multi-truncated pyramid shape simulation. Femoral intercondylar notch height, area, and trans-epicondylar length (TEL) were also measured using MRI.

Results The measured top, proximal 1/3, distal 1/3, and bottom of the ACL cross-sectional area were, 36.8 ± 10.7, 59.9 ± 15.4, 66.4 ± 20.8, and 107.3 ± 21.1mm^2, respectively. ACL height was 26.3 ± 3.9 mm. Using these data, the calculated ACL volume was 1755 ± 874mm^3. Significant correlations were observed between ACL volume and notch height, area, and TEL.

Conclusion Similar ACL volume with previous reports was obtained in this simple and easy multi-truncated pyramid shape simulation from axial MRI evaluation. Significant correlation was observed between ACL volume and knee bony morphology. The ability of surgeons to measure ACL volume simply and effectively can be useful for the detailed ACL anatomical knowledge, and also for prediction and prevention of ACL injury.

Level of evidence: IV, Case series.

Keywords Anterior cruciate ligament · Anatomy · Volume · Anterior cruciate ligament reconstruction

Introduction

Prevention of anterior cruciate ligament (ACL) injury is essential for both subjects who perform sports activity and the clinicians who treat them [1, 2]. When ACL injury occurs, ACL surgery often becomes necessary. This requires a recovery time of approximately 1 year [2–4], during which time athletes are unable to participate in sporting activity. Time loss of such substantial duration can have a significant economic impact for such athletes [2]. Although several factors related to the incidence of ACL injury, such as joint laxity, knee alignment, gender, and knee morphology [5] have been identified, greater clarity is needed in order to predict and prevent the occurrence of ACL injury.

Same with the anatomical factors such as tibial posterior slope or femoral intercondylar notch size [5], the size of the native ACL is one of the reported factors related to the incidence of ACL injury [6–10]. It has been reported that subjects with ACL injury exhibit small native ACL volume compared to ACL intact subjects [6, 10]. However, measuring the native ACL volume without special 3D-software is difficult in daily clinical settings [11, 12]. The ability to measure native ACL volume more easily would help clinicians predict and prevent the occurrence of ACL injury with greater accuracy. Recently, Iriuchishima et al. reported that the complicated shape of the femoral intercondylar notch volume can be calculated using a truncated pyramid shape simulation [13]. In their method, femoral intercondylar notch morphology is simulated as a truncated pyramid, the volume of which can be measured and similar notch volume with

✉ Takanori Iriuchishima
sekaiwoseisu@yahoo.co.jp

[1] Department of Orthopedic Surgery, Kamimoku Spa Hospital, Minakami, Japan

previous reports was obtained. Their study revealed a significant difference in notch volume between ACL injured and ACL intact subjects. As ACL volume calculation is normally calculated using the manually segmented cross-sectional area and the height of the ACL, even in evaluations utilizing 3D software [11, 12, 14, 15], we hypothesized that this truncated pyramid shape simulation could also be used for ACL volume measurement, because the truncated-pyramid shape simulation is also calculated with manually segmented cross-sectional area and height.

The purpose of this study was to measure ACL volume using a multi-truncated pyramid shape simulation and to reveal the size correlation between ACL volume and knee bony morphology. The hypothesis of this study was that the ACL volume could be measured using this multi-truncated pyramid shape simulation with results similar to previous reports concerning ACL volume, and that correlation would be found between ACL volume and knee bony morphology. For clinical relevance, the ability to measure complicated ACL volume simply and accurately using normal knee magnetic resonance imaging (MRI) would greatly assist clinicians to obtain the detailed knowledge of the ACL anatomy. And considering that the small ACL size is the risk of ACL injury [5, 8], the measurement of the ACL volume would be also useful in the prediction and prevention of ACL injury when the ACL volume is small in size.

Materials and Methods

Fifty subjects (27 female and 23 male) under 50 years of age visiting our clinic from January to December 2021 with knee pain were included in this study (average age: 23 ± 7.8). No structural injury was revealed by MRI in any of the subjects. The main diagnosis were, synovitis, tendinitis, arthritis, and joint effusion. The exclusion criteria were: subjects over 50 years of age, subjects with knee osteoarthritis more severe than grade II on the Kellgren–Lawrence grading scale, and history of knee trauma. No more subjects' selection except the inclusion and exclusion criteria has been performed. Informed consent was obtained from all subjects before data collection. This research has been approved by the IRB of the authors' affiliated institutions.

MRI

MRI of the knees was taken after their initial submission (Vantage Titan 3 T, Toshiba medical systems, Tokyo, Japan). Using the axial slice of the T2 image of the knee, four deferent levels of the cross-sectional area (most proximal: S1, proximal 1/3: S2, distal 1/3: S3, and the most distal: S4) of the ACL were measured. Axial slice distance of the MRI was 2 mm. Firstly, axial MRI slice with most proximal (S1) and distal (S4) level of Blumensaat's line were decided. And then, the axial slices 1/3 (S2) and 2/3 (S4) of the Blumensaat's line were determined. ACL height (h) was measured using the sagittal slice, and corresponded to the distance between the most proximal and the most distal axial slices of the ACL. ACL volume was calculated using a multi-truncated pyramid shape simulation [13]. In this simulation, as the ACL is regarded as a multi truncated-pyramid, its volume is mathematically calculated using the formula: Total volume (mm^3) = V1: $h/3(S1+S2+\sqrt{(S1\ S2)})/3$ + V2: $h/3(S2+S3+\sqrt{(S2\ S3)})/3$ + V3: $h/3(S3+S4+\sqrt{(S3\ S4)})/3$ (Fig. 1).

Using the axial slice exhibiting the longest medial and lateral femoral epicondyle length (trans-epicondylar length: TEL), the TEL, axial femoral condyle area and notch width index (NWI) were measured following the previously reported methods using a PACS system [16, 17]. NWI was measured as the notch outlet length/bicondylar length. The distance between the most proximal and the most distal points of the Blumensaat's line was regarded as the femoral intercondylar notch height and measured.

Two independent observers with over 20 years experiences as knee surgeon performed the measurements of the ACL parameters three times of each, and the average amount were calculated. The inter-and intra-observer reliability of the ACL cross-sectional area, height and the volume measurement were evaluated.

Statistical Analysis

Collected data are presented as the mean with standard deviation. A Pearson's coefficient correlation test was performed to reveal the correlation between ACL volume and knee bony morphology (axial notch area, notch height, TEL, and NWI). For the statistical analysis, SPSS software was used (Ver 19.0, SPSS Inc., Chicago, IL). Data are regarded as significant at a P-value of less than 0.05 ($p < 0.05$).

Results

The measured S1, S2, S3, and S4 of the ACL cross-sectional area were 36.8 ± 10.7, 59.9 ± 15.4, 66.4 ± 20.8, and $107.3 \pm 21.1 mm^2$, respectively. ACL height was 26.3 ± 3.9 mm. Using these data, the calculated ACL volume V1, V2, V3, and the total volume were 426 ± 213, 564 ± 292, 764 ± 380, and $1755 \pm 874 mm^3$, respectively (Table 1). The inter- and intra-observer reliability of the S1, S2, S3, S4, ACL height, and ACL volume measurement were, 0.85 and 0.88, 0.85 and 0.86, 0.88 and 0.9, 0.82 and 0.82, 0,88 and 0,92, 0.81 and 0.86, respectively (Table 1).

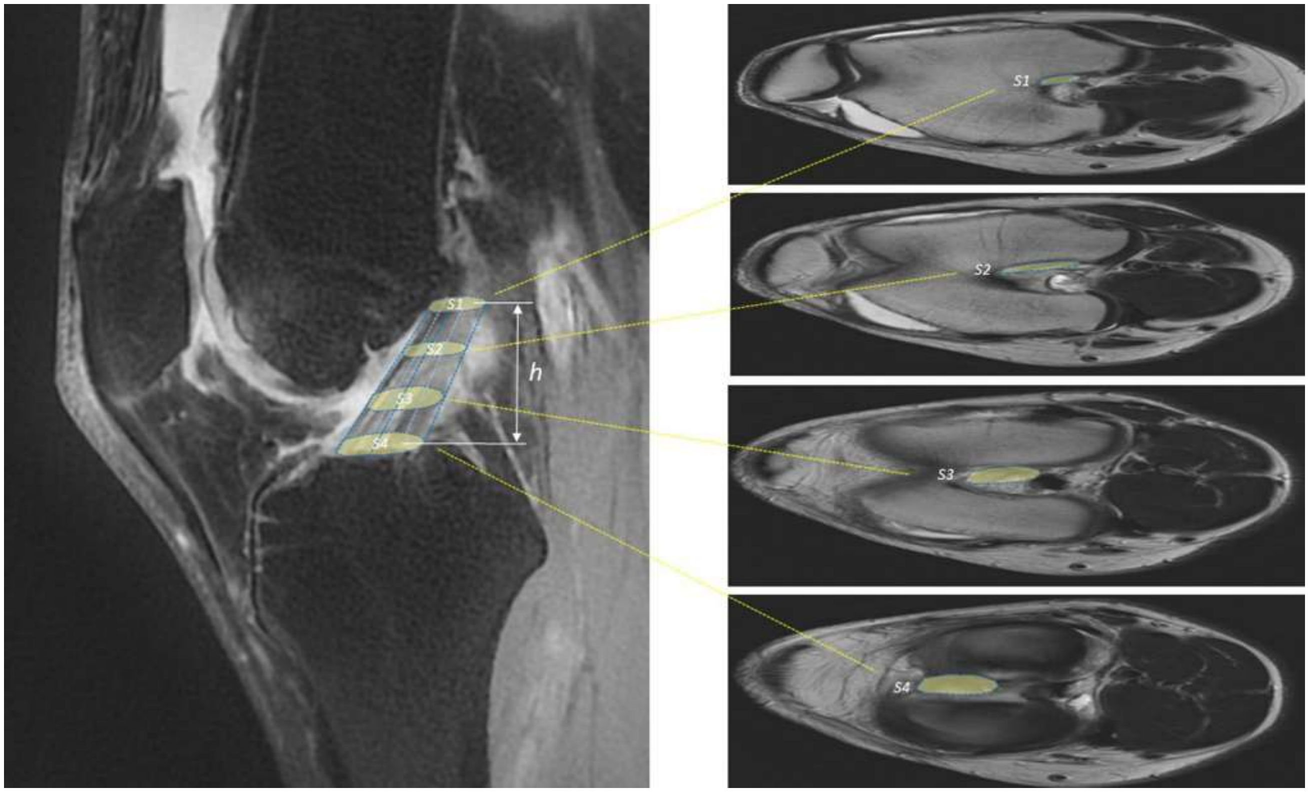

Fig. 1 Multi-truncated pyramid shape simulation for the measurement of ACL volume. Using axial knee MRI images including the most proximal (S1), proximal 1/3 (S2), distal 1/3 (S3), and most distal ACL (S4) cross-sectional area, each cross-sectional area was measured. ACL height (h) was measured as the distance between the axial slice including S1 and S4. ACL volume was simulated using the formula: Total volume (mm^3) = V1: $h/3(S1 + S2 + \sqrt{(S1\ S2)})/3$ + V2: $h/3(S2 + S3 + \sqrt{(S2\ S3)})/3$ + V3: $h/3(S3 + S4 + \sqrt{(S3\ S4)})/3$

Table 1 Measured ACL cross-sectional area, height and simulated ACL volume

Measured and simulated ACL morphology		
ACL cross sectional area		Inter and intra observer reliability
S1	$36.8 \pm 10.7\ mm^2$	0.85, 0.88
S2	$59.9 \pm 15.4\ mm^2$	0.85, 0.86
S3	$66.4 \pm 20.8\ mm^2$	0.88, 0.9
S4	$107.3 \pm 21.1\ mm^2$	0.82, 0.82
ACL length	26.3 ± 3.9 mm	0.88, 0.92
ACL volume	$1755 \pm 874\ mm^3$	0.81, 0.86

Table 2 Correlation between ACL volume and knee bony morphology

Correlation between ACL volume and knee bony morphology		
Knee bony morphology	Pearson's coefficient correlation	*P*-value
NWI	0.032	N.S
Notch outlet area	0.585	0.001
Notch height	0.629	0.000
TEL	0.786	0.000

Significant correlation was observed between ACL volume and notch outlet area, notch height, and TEL

NWI Notch width index, *TEL* Trans-epicondylar length

Measured axial notch area, notch height, TEL, and NWI were $468 \pm 98mm^2$, 26 ± 5 mm, 79.2 ± 7.2 mm, and $29.8 \pm 3.7\%$, respectively. Significant correlation was observed between ACL volume and axial notch area (Pearson's coefficient correlation: 0.585, $p = 0.001$), notch height (Pearson's coefficient correlation: 0.629, $p = 0.000$), and TEL (Pearson's coefficient correlation: 0.786, $p = 0.000$) (Table 2).

Discussion

The most important finding of this study was that ACL volume can be measured in a simple multi-truncated pyramid shape simulation using just ordinary MRI images. The measured ACL volume was significantly correlated with knee bony morphology. Measuring the ACL volume, and when small volume of ACL was found, it can be useful for the prediction and prevention of potential ACL injuries.

Although several studies have evaluated the native ACL size in subjects with ACL tear [7, 8, 10, 14], such evaluations are relatively problematic, because the intact ACL does not exist in knees with ACL tear. In order to determine the native ACL size in subjects with ACL tear, the contra-lateral knee MRI must be evaluated [8, 14]. It has been reported that the size of the ACL is correlated with the incidence of ACL injury [6–8, 11, 18, 19]. Same as the previously reported anatomical factors such as large tibial posterior slope or small femoral intercondylar notch size [5], small ACL size is one of the risk factors for ACL injury [6, 20]. Wang et al. reported that subjects with narrow ACL width have greater anterior tibial knee laxity and suggested a correlation between this circumstance and ACL injury [15]. Sturnick et al. reported that a decrease in ACL volume is correlated with a high incidence of ACL injury [5]. Measuring ACL volume is relatively difficult, especially in clinical settings, and not many studies have evaluated the difference in ACL volume between ACL tear and ACL intact subjects [10, 14, 15]. In this study, ACL volume was measured using a multi-truncated pyramid shape simulation. In this method, ACL volume can be measured using just normal MRI. In this study, direct validation of ACL cross-section, height, and the volume cannot be performed. To validate the ACL morphology, ACL have to be resected, and the size have to be measured. It is impractical in the clinical situation. As alternated of the direct validation, ACL mid-substance cross-sectional area and the volume were compared with previous reports. The native ACL footprint and mid-substance anatomy have been evaluated in numerous studies. In a systematic review from Kopf et al. [21], the femoral and tibial ACL footprint area was reported to be 83–196.8mm^2, and 114–229mm^2, respectively. Recently, it has been reported that the ACL footprint can be divided according to the mid-substance insertion and fan-like extension fibers [22, 23]. When only the mid-substance insertion is evaluated, the femoral footprint area is approximately half of the whole ACL footprint [23]. Evaluating the mid-substance cross-sectional area of the ACL, Iriuchishima et al. reported the cross-sectional area to be 46.9mm^2 [24], and Fujimaki et al. reported it to be approximately 40mm^2 [25]. Evaluating ACL length in cadaveric studies, Zantop et al. reported an average intraarticular ACL length of 31 mm [26], and Fujimaki et al. reported an average length of 24.3–31.1 mm [25]. The results of this study indicate that S1 can be regarded as close to the femoral ACL mid-substance insertion, S2 and S3 as the measurement of the cross-sectional area, and S4 as similar to the tibial ACL footprint. Although many of ACL footprint or mid-substance cross-section anatomy have been published [21–26], only few studies have reported on ACL volume. Normally, cadaveric specimens were fixed with formalin, and therefore, the size of soft tissue is underestimated when compared with in vivo condition [22–24]. Chaudhari et al. reported that the contra-lateral ACL volume in ACL tear and ACL intact subjects was 1921 mm^3, and 2151 mm^3, respectively [7]. Cone SG et al. conducted a systematic review concerning ACL morphology [8]. They found that studies reporting ACL volume were less common than those reporting ACL length and area. In their systematic review, the summarized ACL volume from five studies was 854–1858mm^3. In the present study, ACL volume, calculated using a multi-truncated pyramid shape simulation, was 1755mm^3, which was similar to previous studies [8]. In this study, not only the measured cross-sectional area but also ACL length, and calculated ACL volume were similar to previous anatomical studies, and therefore, this simple and easy multi-truncated pyramid shape simulation using normal MRI image can be considered as an useful method for the ACL volume evaluation.

Several parameters of the knee bony morphology have been reported to have correlation with the incidence of ACL injury [12, 13, 16–18, 22, 27]. Femoral intercondylar notch morphology is the most evaluated parameter exhibiting such correlation [5]. Small notch width index is commonly known to be a high-risk factor of ACL injury [5]. Recently, Iriuchishima et al. reported a significant difference in femoral intercondylar notch volume, measured using a truncated-pyramid shape simulation, between ACL tear and ACL intact subjects [13]. In their study, femoral intercondylar notch volume was found to be significantly smaller in the ACL tear group. In the present study, the simulated ACL volume also exhibited significant positive correlation with knee bony morphology. Previous studies have reported that the size of the ACL is larger in large knees [22, 24]. The significant correlation between knee morphology and ACL volume found in the present study indicates that this multi-truncated pyramid shape simulation provides an accurate reflection of native ACL anatomy.

The limitations of this study were: (1) unhealthy subjects were evaluated in this study. Although no structural tear was observed in the MRI, the subjects who visited our clinic suffered from knee pain, which may introduce some bias. Healthy knees should be evaluated in future studies. (2) Only Asian subjects were included in this study. Knee size has a strong correlation with body size, and subjects of other ethnicities should be evaluated in future studies. (3) ACL volume was simulated using a mathematical formula alone in this study. Volume measurement using 3D-image software would be a better method providing better accuracy [11, 12]. A comparison between multi-truncated pyramid shape simulation and 3D-image software simulation should be attempted in the future. (4) Direct validation of the ACL morphology could not be performed in this study. Although, measured ACL cross-sectional area, height, and the calculated ACL volume were all similar with previous studies, and the inter- and intra-observer reliability of this study were relatively consistent, direct validation should be performed in the future plans.

Conclusion

In conclusion, for clinical relevance, ACL volume can be measured using a newly investigated multi-truncated pyramid shape simulation with ordinary MRI. The ACL volume measured in the present study was similar to that of previous anatomical studies. Measuring the ACL volume can help clinicians to obtain the detailed knowledge of the ACL anatomy. This newly investigated multi-truncated pyramid shape simulation method makes the surgeons possible to easily measure the complicated ACL image in the clinical settings. Furthermore, considering that the small ACL size is one of the risk factors of the ACL injury [5, 8], when the small volume of ACL is found in the clinical situation, subjects should be informed the risk of ACL injury for the prevention of it.

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Declarations

Conflict of Interest Takanori Iriuchishima: No conflict of interest was existed on this study.
Bunsei Goto: No conflict of interest was existed on this study.

Ethical Approval This study was approved by the ethics committee of the Kamimoku Spa Hospital: ID KH04001.

Informed Consent Informed consent was obtained from all subjects included in this study.

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ORIGINAL ARTICLE

A New Concept of Using Femoral Condyles Surface for Femoral Component Alignment During Total Knee Arthroplasty: A Technical Note

Mohammad Mahdi Sarzaeem[1] · Farzad Amouzadeh[1] · Bentolhoda Salehi[2] · Mohammad Movahedinia[3,5] · Mohammad Soleimani[4]

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Abstract

Background Orthopedic surgeons favor an intramedullary guiding system on the femoral component during total knee arthroplasty (TKA); nevertheless, improper positioning of the entry point affects the final alignment. We have designed a new femoral cutting system for TKA that uses the distal and posterior femoral condyles as reference points for the setting of the cutting system regardless of the femoral canal. This study aims to evaluate the outcomes of this new guiding system.
Methods We enrolled a series of 75 consecutive knees undergoing TKA. The alpha, gamma, and hip–knee–ankle (HKA) angles were assessed three months postoperatively. Also, surgical time and intraoperative blood loss were recorded for all patients.
Results Fifteen patients underwent TKA using the mechanical alignment (MA) strategy, and 60 underwent kinematically aligned (KA) TKA. Both groups showed normal coronal and sagittal alignment 3 months postoperatively. The mean intra-operative blood loss was 213.11 ± 52.73 ml, which was not different between the two groups (n.s.). The mean surgical time was 43.12 ± 11.62 min, which was significantly shorter in the KA-TKA (41.11 ± 3.77 min) than in the MA-TKA (49.34 ± 4.56 min) ($P < 0.001$).
Conclusion Using the new guiding system with good femoral alignment, we introduced the easily palpable and available condylar surface as a new landmark for cutting the distal femur in TKA.
Level of Evidence IV.

Keywords Total knee arthroplasty · Femoral alignment · Kinematic · Mechanical

Introduction

Proper femoral component alignment, e.g., rotation and angulation, is crucial in patellar tracking and ligament balancing during total knee arthroplasty (TKA) [1–3]. Malalignment of the femoral component leads to functional impairment and decreased long-term survival [4–6]. More than 3° of implant varus or valgus malalignment to the neutral mechanical axis results in early component failure [7]. Alignment guiding systems are designed to ensure accurate component position [8].

Although surgeons prefer intramedullary (IM) guiding on the femur [9, 10], improper positioning of the intramedullary rod's entry point affects the femoral component position and limb alignment [11]. Individual variations, including a wide canal or excessive femoral bowing, may also result in alignment errors if the surgeon is unaware preoperatively [11]. Moreover, the IM guiding system damages the cancellous bone and intramedullary vessels, which may lead to fat embolism and post-operative blood loss [12]. Despite all limitations, the IM guiding system is still the technique of choice for femoral component insertion during TKA due to its usability and early evidence of its superiority over extramedullary systems [9, 10, 13].

Although recent studies using new extramedullary guiding systems have shown accurate distal femoral resection and optimized femoral alignment [8, 14–17], the greatest obstacle to using the extramedullary femoral guiding system is the absence of palpable landmarks. Furthermore, the extramedullary systems introduced so far need the whole limb in the surgical field and expose the patient and the

Extended author information available on the last page of the article

surgeon to X-rays to find the femoral canal. Moreover, they are all based on the mechanical alignment (MA) concept and are unusable in kinematic alignment (KA) surgeries.

To overcome these limitations, we have designed a new femoral cutting system for TKA that can be used based on both the KA and MA concepts. This new guide uses the distal and posterior femoral condyles as references for the setting of the cutting system regardless of the femoral canal. This reference is more palpable than the IM canal, eliminating concerns about the IM guide's entry point position and angulation. The routine surgical field is adequate for this new guide, sparing surgeons from additional exposure or off-field landmarks.

We hypothesized that considering the surface of the femoral condyles as a reference during TKA using our new guide can simplify the surgical procedures with accurate alignment in both KA- and MA-TKA. This study aimed to evaluate this novel distal femoral cutting system regarding the restoration of the alignment, surgical time, and intraoperative blood loss.

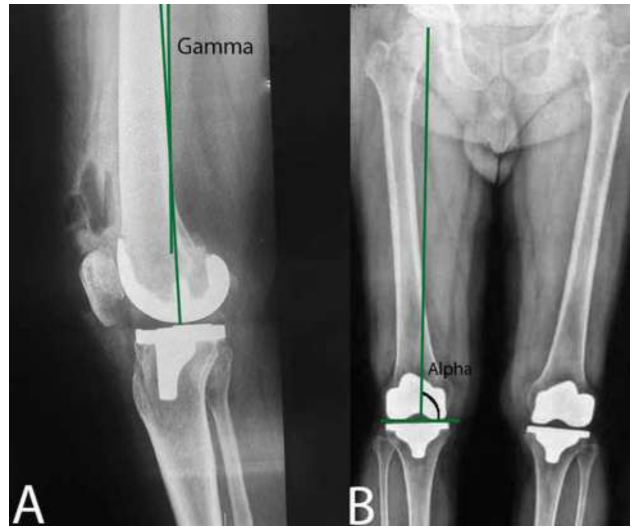

Fig. 1 Postoperative standing alignment radiography showing the gamma (**A**) and alpha angles (**B**)

Materials and Methods

We studied 75 consecutive TKAs between April 2021 and April 2022. The need for Ethics Committee approval was waived as the procedure has been performed routinely. Inclusion criteria were age > 40 years, knee osteoarthritis, and being a candidate for primary TKA. Exclusion criteria were previous TKA, neuromuscular disease, acute lumbar pathology, and knee infection.

All patients underwent standing lower limb radiography preoperatively and 3 months postoperatively per the hospital protocol. The alpha, gamma, and hip–knee–ankle (HKA) angles were assessed 3 months postoperatively. Surgical time and intraoperative blood loss were recorded for all patients. The gamma angle was measured in sagittal images as the angle between the line perpendicular to the distal femoral component and the anatomical femoral axis (Fig. 1A). The alpha angle was measured in coronal images as the medial angle between the line parallel to the femoral condyles and the femoral mechanical axis (Fig. 1B).

Prosthesis from two manufacturers (Stryker, Kalamazoo, MI, USA; and NexGen LPS Flex, Zimmer Biomet Inc., Warsaw, IN, USA) was used for cruciate-retaining cemented TKA without patellar resurfacing. The choice between prostheses was not random and was based on availability.

After anesthesia and high thigh tourniquet inflation, subvastus arthrotomy was performed through a midline incision. Administering intraoperative tranexamic acid and analgesics was the same for all patients. No surgical drains were used, and the tourniquet was deflated after wound closure. Tourniquet time was regarded as surgical time. The same anticoagulant prophylaxis was started for all patients the day after surgery. Intraoperative blood loss was measured considering suctioned blood volume and swabs used during surgery.

KA-TKA

We used a new guiding system for femoral cutting. The device relies on intra-articular landmarks, readily available in the standard surgical field for TKA procedures. The device includes a base, a cutting guide, and a mounting mechanism. The base consists of two contact areas that are perpendicular to each other: the planar surface of the base extending from the distal end to the proximal end, and two projections extending from the distal end of the base that slide under the posterior condyles and come in contact with them. The base also includes two spacers with a ruler in 1-mm increments, one on each lateral side of the base, for adjusting a cut thickness difference between the femoral condyles. Each spacer is held in place by a pin. The mounting mechanism is configured to releasably couple the cutting guide to the base and includes an adjustment guide with a ruler in millimeter increments for adjusting the position of the cutting guide from the base and also the thickness of the distal femoral cut. The mounting mechanism is fixed to the cutting guide using a screw tight fastener and to the base using two rods (Fig. 2). When the tibia is flexed 90°, the planar surface of the base engages the distal surfaces of the medial and lateral condyles using the spacers, while the two projections align with the posterior surfaces of the medial and lateral condyles perpendicular to the base planar surface. Only one possible position is precisely perpendicular to the posterior condylar surface (Fig. 3).

Fig. 2 The newly introduced guide for femoral cutting during TKA. Asterisk: the base; thick arrow: mounting mechanism; thin arrows: projections; dashed arrow: spacer; double arrow: cutting guide; arrowhead: rod; circle: screw tight fastener

Fig. 3 When the tibia is in 90° of flexion, the new femoral cutting system engages the distal condyles by the planar surface of the base (asterisk) and its spacers (white arrow) in both coronal **A** and sagittal **B** planes. In this position, the two projections (not seen here) align with the posterior surfaces of the medial and lateral condyles perpendicular to the base planar surface. **C** Then, the base will be released using the mounting mechanism (arrowhead), and the cutting guide (black arrow) remains on the anterior cortex, just perpendicular to the posterior condyle surface

Based on the KA concept, the cartilage loss of femoral condyles to reach the subchondral bone was evaluated as 2 mm, while a 1-mm bone cut was considered for saw thickness. A 2-mm spacer in the cutting guiding system compensated for this cartilage loss in condylar areas. Then, it was placed precisely in contact with the posterior and distal condyles.

This proper contact of the cutting guiding system to the distal and posterior surfaces ensures proper cutting of the distal femur precisely perpendicular to the posterior cortex of the femoral shaft. Bone cut in the distal femur was measured the same as the femoral component thickness based on the KA concept. The femoral sizing was done by posterior reference cutting guiding system, and the posterior condyles cut was done in 0˚ rotation. Other stages of surgery were the same as Howells' technique [18].

MA-TKA

The guide used in this study was designed for KA-TKA. However, we used it for MA-TKA in patients with > 10°

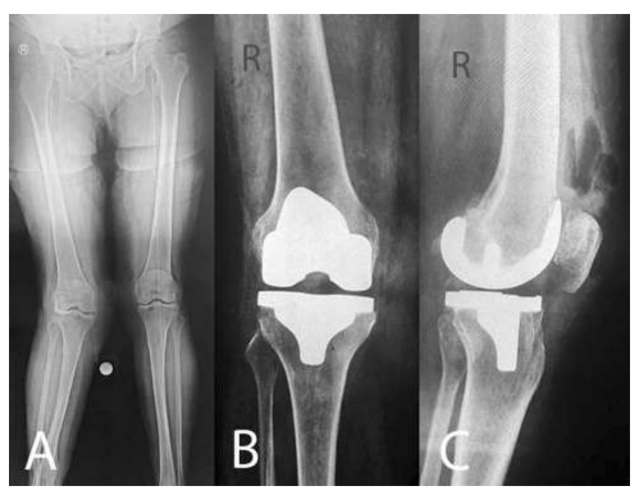

Fig. 4 **A** A 65-year-old woman with right knee osteoarthritis and valgus deformity > 10° **B**, **C** underwent TKA using the new guide according to the mechanical concept

of valgus and > 25° of varus deformities (Fig. 4). Lateral distal femoral angle (LDFA) was considered as a reference when we tried to cut the distal femur, so that the LDFA became 90°. For this purpose, each 1-mm cut was considered to modify 1° of LDFA, e.g., if the LDFA was 82°, the distal cut of the medial condyle should be 8 mm more than the lateral condyle. Considering 9 mm for the thickness of the femoral prosthesis and 1 mm for the saw thickness, the medial and lateral condyles were cut by 9 mm and 1 mm, respectively. In this method, relying only on LDFA without using an anatomical axis, the distal femoral cut is easily and accurately possible, even in severe deformities with difficult and imprecise determination of the femur angles.

For surgeons not obtaining long-alignment radiographs to evaluate LDFA, the guide can be set for the same amount of cut in medial and lateral condyles. After checking the alignment during surgery, it could be adjusted for a 1-mm or 2-mm valgus or varus cut. This can be very effective in cases where there are severe deformities caused by previous surgeries (Fig. 5).

Statistical Analysis

Data were analyzed using SPSS version 19 (IBM Corp., Armonk, NY). The Kolmogorov–Smirnov test evaluated the normal distribution of variables. Parametric data were expressed as mean ± standard deviation (SD) and analyzed by independent *t* test. Nonparametric data were analyzed using the Mann–Whitney *U* and Chi-square tests. A *P* value < 0.05 was considered statistically significant.

Results

Seventy-five patients were enrolled in the study. Of whom, 62 (82.66%) were female. The mean age was 69.12 ± 4.28 years, and the mean BMI was 28.16 ± 2.73 kg/m^2. Fifteen patients underwent TKA using MA, and 60 patients underwent KA-TKA.

The mean preoperative hemoglobin level was 12.91 ± 1.45 g/dL. A mean of 2.4 ± 0.3 g/dL decrease in hemoglobin level was observed 72 h postoperatively. The mean intraoperative blood loss was 213.11 ± 52.73 ml. No patients required blood transfusion. The mean surgical time was 43.12 ± 11.62 min (Table 1). Both groups showed normal coronal and sagittal alignment 3 months postoperatively (Table 2).

Discussion

Currently, surgeons use extramedullary guiding systems for proximal tibial resection, while there are several choices for distal femoral resection, e.g., IM or extramedullary cutting guides, and technology-assisted TKA. Although the technology-assisted TKA (e.g., computed navigation and robotic

Fig. 5 **A**, **B** An 83-year-old man with severe lateral femoral bowing and isthmus stenosis from a previous fracture filled with a femoral nail. **C**, **D** The left knee underwent TKA using the new guide without touching the canal with good alpha and gamma angles. **E** The alignment was correct

Table 1 Comparison of mechanical alignment with kinematic alignment-TKA regarding blood loss and surgical time

Variable	MA	KA
Preoperative hemoglobin (g/dL)	12.89 ± 2.12	12.97 ± 0.85
Postoperative hemoglobin at day 3 (g/dL)	10.17 ± 2.15	10.64 ± 1.44
Intraoperative bleeding volume (ml)	227.05 ± 36.18	204.26 ± 68.92
Surgical time (min)	49.34 ± 4 56	41.11 ± 3.77

MA Mechanical alignment, *KA* kinematic alignment

Table 2 Radiographic measurements in patients 3 months postoperatively

Measurement	MA	KA
Alpha angle	90.02 ± 0.99	90.14 ± 1.21
Gamma angle	2.10 ± 0.93	2.00 ± 1.04
HKA angle	0.39 ± 2.66	1.03 ± 2.13

MA Mechanical alignment, *KA* kinematic alignment, *HKA* hip–knee–ankle

surgery) can overcome the limitations of IM cutting femur system [19], these technologies have inherent shortcomings, such as higher cost and longer learning curve. Furthermore, proper sagittal positioning of the femoral components using computer navigation can be imprecise [20]. Currently, surgeons are more inclined to use IM guides [9, 10].

These methods are inaccurate and require additional exposure in the surgical field to both the patient and the surgeon. Using the condylar surfaces as landmarks for cutting the distal femur in TKA has not previously been explored. In this study, the femoral condyles were used as reference surfaces to cut the distal femur perpendicular to the femoral shaft's posterior cortex. This study introduces the femoral condyles as reference surfaces for cutting the distal femur. These intra-articular landmarks are easily palpable and available in the standard surgical field, making KA- or MA-TKA convenient and fast with satisfactory femoral alignment.

The effort to make extramedullary guides popular is due to their advantages, e.g., lower post-operative fat embolism and perioperative blood loss [12]. Also, extramedullary systems are currently the choice in severe lateral femoral bowing, femoral malunion, stenosis from a previous fracture, or filling of the isthmus of the IM canal by orthopedic devices (e.g., ipsilateral total hip arthroplasty) [9, 10, 21].

The main drawback of extramedullary guides is more femoral malalignment than IM systems [9, 10, 13, 22], which has been minimized with the development of new extramedullary systems [8, 14–17]. However, the difficulty and time-consuming nature of using existing extramedullary systems make surgeons reluctant to use them.

Extramedullary guiding systems consist of a long rod at the anterior cortex of the femur [8, 14–17]. Besides, current extramedullary guides are based on the MA concept [8, 14–16]. The new guiding system can be used for both MA- or KA-TKA. We used the KA concept for most TKAs due to its ease of use and superiority [23], while MA-TKA was reserved for valgus > 10° or varus > 25°. We found acceptable alignment for both techniques. Recent systematic reviews have shown no clinical or radiological differences between patients undergoing MA- or KA-TKA [23–25].

The guide is designed to align the femoral component precisely in the coronal and sagittal plane without penetrating the femoral canal. Although there is no consensus on the optimal sagittal positioning of the femoral component, most surgeons agree on a gamma angle of about 0–3° of flexion [2]. In this study, the sagittal positioning of the femoral component was about 2° of flexion.

We found a mean blood loss of 213.11 ml, which was less than other studies [14, 26, 27]. Many factors affect the bleeding, including the subvastus approach, not using a drain, and the amount and method of administering tranexamic acid. These may explain our low rate of bleeding. However, our results are in line with the hypothesis that extramedullary guiding systems reduce intraoperative blood loss and transfusion rate. Also, many factors affect the surgical time, and the time reported in this study is relatively short [28, 29].

Limitations

This study was not without limitations. First, this study is not a comparison between the guiding systems used in this study with other extramedullary or IM systems, and thus, despite the satisfactory results, accurately inferring the superiority of this method over other methods is not possible. Second, including patients with a severe deformity for MA-TKA may have influenced the conclusion. Third, we used two different prostheses, and the choice between them was not random, which could affect the results.

Conclusion

This study shows that the novel guide for femoral cutting during TKA is reliable, though future comparative studies are suggested. Using this new guide, we introduced the easily palpable and available condylar surfaces as a new landmark for cutting the distal femur in TKA. The posterior and distal condyles of the femur were used as the reference surface to cut the distal femur precisely perpendicular to the femoral shaft's posterior cortex.

Author Contributions MMS designed the study and invented the new device used in it and was the main surgeon of the patients. He carried out the post-operative visits and has given final approval of the version to be published. FA and BS participated in the study drafting and design. Amouzadeh helped Sarzeem during surgery and post-operative visits and participated in data gathering. MM carried out data analysis and wrote the first draft. MS contributed to the first draft of the manuscript and revised it critically for important intellectual content. All authors read and approved the final manuscript.

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Data Availability The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Declarations

Conflict of Interest All authors declared no conflict of interest.

Ethical Approval and Consent to Participate There was no need for this study to be reviewed and approved by an ethics committee as the procedure has been performed routinely for years.

Informed Consent For this type of study, informed consent is not required.

Consent for Publication Not applicable.

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Authors and Affiliations

Mohammad Mahdi Sarzaeem[1] · Farzad Amouzadeh[1] · Bentolhoda Salehi[2] · Mohammad Movahedinia[3,5] · Mohammad Soleimani[4]

✉ Mohammad Movahedinia
mmvn93@gmail.com

Mohammad Mahdi Sarzaeem
mmsarzaeem@gmail.com

Farzad Amouzadeh
Farzad90am@gmail.com

Bentolhoda Salehi
Hoda.7575@gmail.com

Mohammad Soleimani
mohammad.soleimani.md@gmail.com

[1] Imam Hossien Hospital, Shahid Beheshti University of Medical Sciences, Tehran, Iran

[2] Medicine Faculty, Kerman University of Medical Sciences, Kerman, Iran

[3] Department of Orthopedics and Traumatology, Shahid Beheshti University of Medical Sciences, Tehran, Iran

[4] Department of Epidemiology, School of Public Health, Iran University of Medical Sciences, Tehran, Iran

[5] Bone Joint and Related Tissues Research Center, Akhtar Orthopedic Hospital, Sharifi Manesh Street, Shariati Street, Tehran, Iran

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LETTER TO THE EDITOR

Letter to the Editor: Importance of Peroneal Fascia Closure in Peroneal Longus Graft Harvest

Manit Arora[1]

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The peroneus longus graft (PLG) has long been used in the setting of various ligament surgeries as a reliable autograft. Its use in primary ACL surgery has garnered much attention in recent years. Proponents of its use argue that donor site morbidity is low after PL harvest, as has been shown by our recent systematic review and meta-analysis [1]. Critics raise concerns about its impact on ankle strength, gait patterns and eversion of the foot. A common stigma related to its use is the perception of 'ankle and foot pain and swelling' after PLG harvest.

At our high volume centre for PLG harvest, the early days of PLG usage were a learning curve. Part of this learning curve was the incidence of post-operative ankle swelling at (3–6) week follow-up which persisted for 3 months in approx. 10% of patients. Initially, we hypothesized that the swelling maybe secondary to dependent edema from our delayed weight bearing protocol post-ACL surgery, however, the initiation of venous pump on weight bearing should lead to immediate dissipation of symptoms.

In the search for answers, we examined our harvest technique and reviewed the anatomy of the PL [2, 3]. The peroneal longus and brevis are covered by their common investing fascia at the level of graft harvest site, approximately 2 cm above the tip of the fibula. It is here that we incise the fascia in a longitudinal manner to facilitate access to the peronei.

Incision of this fascia creates an effective dead space where post-operative bleeding will accumulate and lead to ankle swelling. We modified our technique to address this concern and now close the peroneal fascia at the time of layer closure with simple interrupted absorbable sutures. This seals the dead space and theoretically should reduce swelling even in a position of dependence. Since the last 2 years, we have been using this modification [4] and have found that the rate of post-operative swelling, with no change in our delayed weight bearing protocol, has come down significantly. We now see post-operative ankle swelling in less than 0.5% of our patients at the 6-week follow-up.

We believe that this simple step of peroneal fascia closure is important to reduce ankle site morbidity and should be a part of PLG harvest.

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✉ Manit Arora
manit_arora@hotmail.com

[1] Department of Orthopaedics and Sports Medicine, Fortis Hospital, Mohali, Punjab, India