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MINIREVIEWS

Far lateral lumbar disc herniation part 1: Imaging, neurophysiology and clinical features

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Abstract

Far lateral lumbar disc herniations (FLLDH) represent a separate category of disc pathology which includes both intraforaminal and extraforaminal lumbar disc herniations, that are characterized by a peculiar clinical presentation, diagnostic and treatment modalities as compared to the more frequent median and paramedian disc hernias. Surgical treatment often represents the only effective weapon for the cure of this disease and over the years different approaches have been developed that can reach the region of the foramen or external to it, with different degrees of invasiveness. The diagnosis is more demanding and still underestimated as it requires a more detailed knowledge in the spine anatomy and dedicated radiological studies. Computerized tomography and in particular magnetic resonance imaging are the appropriate tools for the diagnosis of FLLDH. Despite the widespread use of these diagnostic tests, many cases of FLLDH are overlooked due to insufficiently detailed radiological examinations or due to the execution of exams not focused to the foraminal or the extraforaminal region. Neurophysiological studies represent a valid aid in the diagnostic classification of this pathology and in some cases they can facilitate the differential diagnosis with

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other types of radiculopathies. In the present study, a comprehensive review of the clinical presentation, epidemiology, radiological study and the neurophysiological aspects is presented.

Key Words: Far lateral lumbar disc herniaton; Magnetic resonance imaging diagnosis; Clinical presentation; Neurophysiology; Epidemiology

Core Tip: Far lateral lumbar disc herniations constitute a distinct category of lumbar disc herniations. Clinical presentation, diagnosis and treatment are more demanding and require specific knowledge. A comprehensive review of the clinical presentation, epidemiology, radiological study, and neurophysiological aspects is presented in the present study.

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INTRODUCTION

Approximately 10% of symptomatic lumbar disc herniations are located within the neural foramen or lateral to it. These intraforaminal and extraforaminal lumbar disc herniations, usually referred to as far-lateral lumbar disc herniations (FLLDH), can compress the spinal nerve and dorsal root ganglion leading to severe, sometimes excruciating pain that often does not respond to conservative management and requires surgery.

FLLDH represent therefore a distinct category of lumbar disc herniation, which are characterized by unique clinical manifestations and require a greater diagnostic and therapeutic effort than the more usual median and paramedian localizations of disc hernias.

In this review, we analyze the clinical features, the radiological imaging aspects and the neurophysiological characteristics.

EPIDEMIOLOGY AND CLINICAL PRESENTATION

More than 90% of lumbar disc herniations happen at the disc's posterior edge, which is located within the spinal canal. There are two types of intracanalicular herniations: median and paramedian (or postero-lateral). By impinging the nerve root in the lateral recess, shortly as it emerges from the thecal sac, they can produce radiculopathy. As a result, the root that exits the canal through the foramen of the caudal interspace at the afflicted disc is the one that is involved (*e.g.*, in the case of a far lateral L4-L5 herniation, the L4 root)[1].

FLLDH are herniations that occur outside the spinal canal, within the neural foramen (the space bounded cranially and caudally by the pedicles), or in the extraforaminal area (the space beyond the lateral margin of the pedicles).

The herniation involves the root that exits into the foramen of the same intervertebral space (*e.g.*, in the case of an L4-L5 paramedian herniation, the L4 root) (Figures 1-3).

Macnab described extraforaminal disc herniations and the associated symptoms caused by compression of the exiting nerve root in his 1971 paper about negative surgical disc space explorations in patients with radiculopathy[2].

Lateral disc herniation has different clinical features from medial disc herniation. Patients with lateral disc herniation may manifest with more severe clinical symptoms, like severe radicular pain, and motor and sensory neurologic deficits are more frequent than those with medial disc herniation. The cause is that the herniated disc

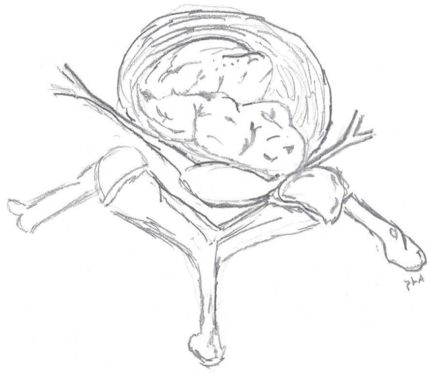

Figure 1 Artist illustration: Intraforaminal herniation compressing the nerve root and ganglion.

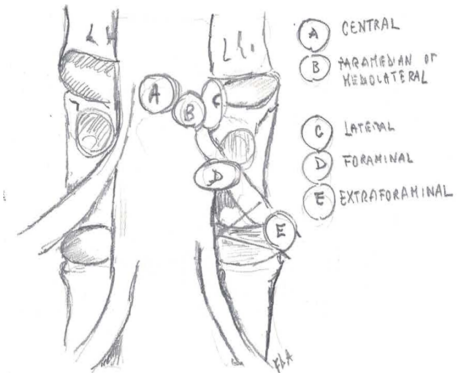

Figure 2 Schematic drawing, coronal view: Relationship between dural sac and nerve roots of disc herniations in different locations.

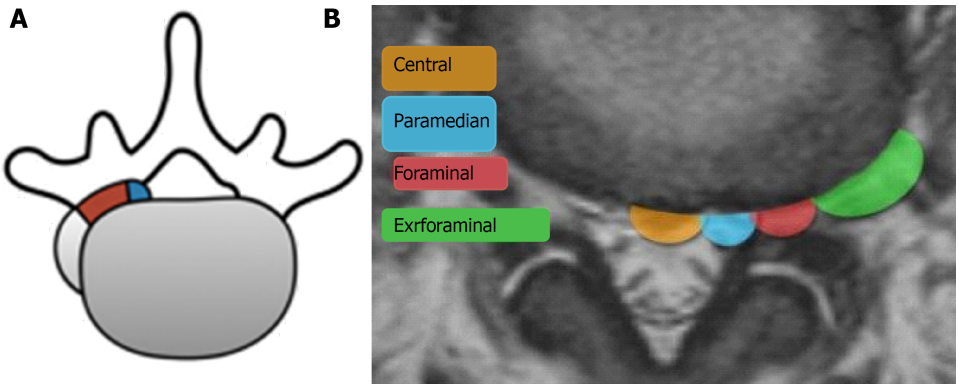

Figure 3 Schematic axial view. A: Schematic drawing, axial view: Relationship between dural sac and nerve roots of disc herniations in different locations. Blue: preforaminal. Red: intraforaminal. Grey: extraforaminal. The herniation can be combined (*e.g.* intra/extraformainal, pre/intraforaminal) (adapted from Lofrese); B: Magnetic resonance imaging schematic axial view.

fragment compresses the nerve root inside a narrow radicular foramen, resulting in direct compression of the dorsal radicular ganglion, which is a pain-sensitive structure.

In 1975, Abdullah and colleagues[3] published a detailed description of the clinical syndrome caused by FLLDH. The "extreme lateral" syndrome described by Abdullah is well defined and includes severe pain due to dorsal root ganglion involvement, as well as a higher risk of neurological deficits than common posterolateral herniations.

FLLDH is responsible for 6.5% to 12% of all lumbar disc herniations[4,5]. Intraforaminal and extraforaminal lesions appear to be almost equally common (3 percent and 4%, respectively)[6]. L3-L4 and L4-L5 are the most involved levels, followed by L5-S1. With a reported frequency of 28 percent of all FLLDH, proximal levels (L2-L3 and L1-L2) are less prevalent but comparatively more common than typical postero-

lateral herniations. The average patient age is between 50 and 78 years old, with a male to female ratio ranging from 1:1 to 2:1[7,8]. Extreme radicular pain is the most prevalent clinical manifestation, which is commonly accompanied by sensory and motor dysfunction as well as a reduced patellar reflex[9]. Back pain is a common symptom in intracanalicular herniations, but it is usually less severe. The femoral stretch test (reverse - Laségue) may show a significant positive result. By bending to the side of the lesion, radicular pain and paresthesia can be replicated, and this is thought to be a sign of intraforaminal root compression[3]. FLLDH at the L3-L4 Level, causing compression of the L3 root, result in pain in the anterior aspect of the tight. FLLDH at the L4-L5 Level, causing compression of the L4 root, are associated with pain in the anterior aspect of the tight, medial malleolus, and medial foot. FLLDH at the L5-S1 Level, where the compressed root is L5, are associated with pain in the postero-lateral aspect of the tight and leg. The clinical characteristics of postero-lateral and far-lateral herniations are summarized in Tables 1 and 2. Despite the heavy clinical manifestations of FLLDH, the natural history is favorable with a reported cure rate with conservative treatment of approximately 71%[10].

DIAGNOSTIC IMAGING

The correct surgical strategy depends on a preoperative diagnosis and thorough location of an extracanalicular herniated disc. FLLDH were difficult to detect until the advent of computed tomography (CT): In fact, root compression lies beyond the lateral extension of the subarachnoid space, therefore it cannot be seen on myelographic images[2]. Both magnetic resonance imaging (MRI) and computed tomography (CT) can now show disc herniations in intra- and extraforaminal locations in high detail. Despite advancements in neuroimaging, however, diagnosing FLLDH may be difficult. In fact, routine spine imaging is frequently limited by slice thickness and field lateral extension. Furthermore, concurrent degenerative alterations like stenosis or intracanalicular disc bulging might make radicular compression inside or laterally to the foramen difficult to visualize[11]. Osborn and colleagues discovered a 30% probability of misdiagnosis on the first CT or MR report in one study. Intracanalicular herniations, on the other hand, are rarely ignored[12]. Osteophytes, nerve root sheath pathologies (such as conjoined roots, arachnoid, perineural, and synovial cysts), and schwannomas, neurofibromas, and ectatic epidural venous plexuses are among the differential diagnoses for FLLDH[12]. When compared to the adjacent intersomatic non herniated disc, the extruded disc material is frequently hyperdense on CT images. (Figure 4). Bone windows make it easier to identify osteophytes. The herniation to the intersomatic disc is often hypointense in T1 and hyperintense in T2 on MR; osteophytes show a signal void in both sequences (Figure 5). The best imaging approach for detecting FLLDH is magnetic resonance imaging (MRI). CT detects radicular compression less reliably than MR and has lesser resolution for spinal and paraspinal soft tissues (Figures 6-8). CT imaging, on the other hand, can be effective in detecting osteophytes and calcifications[11,12]. There may be one or more of the following MR findings: (1) disc margin focal eccentricity; (2) perineural fat tissue obliteration; (3) nerve root thickness alterations; and (4) nerve root dislocation The herniated disc compresses the nerve roots directly, causing thinning, whereas edema can produce thickening. Furthermore, a closer examination usually indicates that epidural fat tissue obliteration is predominantly medial to the root in exclusively intraforaminal herniations, whereas it is observed both medially and laterally to the root in intra-extraforaminal herniations. As previously stated, standard MR examinations are frequently not focused on extraforaminal locations, and imaging this region can be particularly difficult at L5-S1 since the sacral alae and iliac bones' bony features tend to overlap. Furthermore, degenerative changes to the L5-S1 disc are common, reducing its height and making research difficult. Misdiagnosis is frequently caused by an improper MR methodology. Axial slices must be parallel to the intersomatic disc when centered on the sagittal plane. This is necessary in order to detect even minor disc margin focal eccentricities and distinguish real root dislocations from non-pathological asymmetries between the two sides' roots. In order to locate the route of roots and proximal spinal nerves, paracoronal sections (angled 15 to 30 degrees) as well as sagittal sections reaching far laterally and spanning the entire length of the foramina are necessary in the search for a far-lateral herniation[11,12]. Contrast agent administration is not usually required. Differentiating a sequestered disc fragment from other diseases such as schwannomas may need contrast-enhanced imaging. In such circumstances, fat-saturation pulse T1-weighted spin-echo sequences with axial

Table 1 Clinical differences between postero-lateral and far-lateral herniations

Clinical findings	PLH	FLH
Nerve root invovled	At the level below the disc herniation	At the same level of disc herniation
Femoral stretch test	Not always significantly reliable	Markedly positive
Lateral bending	Do not reproduce radicular symptoms	Usually reproduces pain and paresthesia
Severity of pain	Variable	Strong, related to dorsal root ganglion compression

PLH: Postero-lateral herniations; FLH: Far-lateral herniations.

Table 2 Clinical picture of postero-lateral and far-lateral herniations at different levels

Root	PLH level	FLH level	Pain/radiation/sensory involvement	Motor involvement	Deep tendon reflex	Radicular stretching test
L3	L2-L3	L3-L4	Anterior aspect of the tigh	Iliopsoas and/or quadriceps	Patellar	Femoral
L4	L3-L4	L4-L5	Anterior aspect of the tigh, medial malleolus and medial foot	Quadriceps and anterior compartment fo the leg	Patellar	Femoral
L5	L4-L5	L5-S1	Postero-lateral tigh and leg	Extensor hallucis longus and dorsiflexors	None	Lasègue
S1	L5-S1		Posterior thigh and leg, foot (plantar)	Triceps surae	Achilles	Lasègue

PLH: Postero-lateral herniations; FLH: Far-lateral herniations.

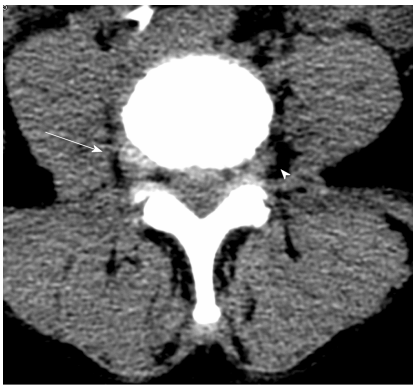

Figure 4 Computed tomography: Right intra-extraforaminal disc herniation, partially calcified (arrow). The normal course of the contralateral root is shown by arrowhead.

and sagittal T1-weighted spin-echo can be employed. The sequestered fragment normally improves in the periphery, most likely as a result of an inflammatory reaction in the surrounding area[13].

NEUROPHYSIOLOGY

Neurophysiology is a complimentary yet crucial tool in the diagnosis of FLLDH, as it aids in the differential diagnosis of radiculopathy and other disorders, as well as the verification of the implicated level. It may also reveal the extent of the damage to the brain. This evaluation is aided by a variety of ways. Electromyography, as well as findings from nerve conduction tests, H reflex, and F wave studies, are used to determine the appropriate workout. (1) signs of neurogenic injury in muscles pertaining to the same spinal root with normal (or relatively spared) findings in muscles pertaining to nearby roots; (2) involvement of the proximal part of the peripheral nervous system; and (3) exclusion of other possible sites of injury that can mimic a radicular lesion, such as the lumbo-sacral plexus or single nerves.

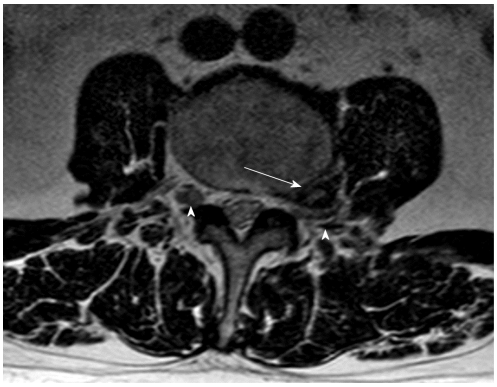

Figure 5 Magnetic resonance (T2 axial sequence): Left extraforaminal disc herniation (arrow). Nerve roots are clearly depicted (arrowheads), the left one being thinned, kinked and dislocated postero-superiorly by the herniation.

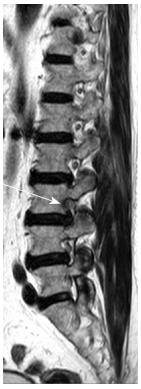

Figure 6 Magnetic resonance (T1 sagittal sequence): L3-L4 intraforaminal herniation compressing the L3 root. Perineural fat obliteration is evident.

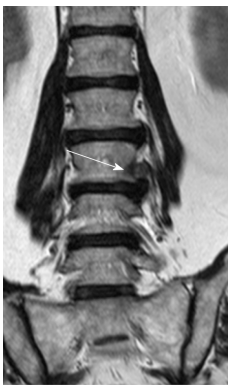

Figure 7 Magnetic resonance (T1 paracoronal sequence): Left L3-L4 extraforaminal herniation.

Electromyography

The pattern distribution of anomalies is commonly used to identify the afflicted root. As a result, needle electromyography is done on a large number of muscles, looking for anomalies in muscles belonging to a single root and normal findings in muscles belonging to other roots. Normal results in muscles innervated by distinct roots but belonging to the same nerve or plexus may also assist in distinguishing nerve or plexus injury from radiculopathy. Unfortunately, each muscle is frequently assigned to one of several nearby roots, and each root feeds multiple muscles, making differential diagnosis difficult. Because the motor regions of roots L2, L3, and L4 are significantly overlapping, this is especially noticeable when examining upper lumbar radiculopathies[14]. In such cases, assessing the paraspinal muscles can be helpful in determining the affected level. This should concentrate on the multifidus muscle,

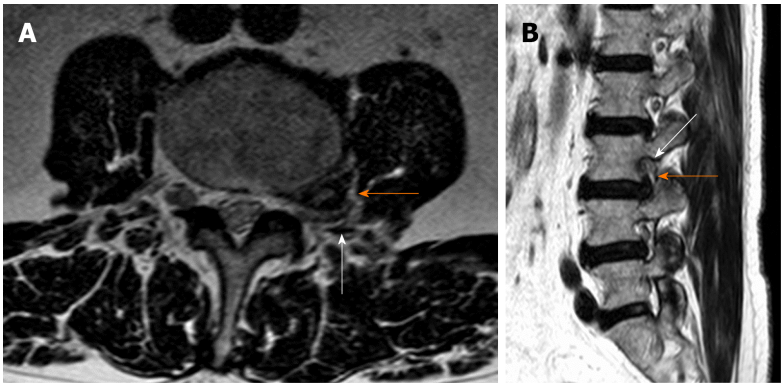

Figure 8 Axial (A) and sagittal (B) T2 magnetic resonance imaging showing a left L3-L4 extraforaminal far lateral lumbar disc herniations (orange arrow). The L3 root is severely compressed against the posterior border of the neural foramen (white arrow).

which, unlike other paraspinal muscles, is thought to be innervated by a single root [15]. In any event, there are certain limits to paraspinal muscle examination: fibrillation can be absent in paraspinal muscles in some cases of root injury, and these muscles can be difficult to assess, especially in obese individuals or those who are unable to relax the target muscles. Furthermore, after back surgery, residual neurogenic alterations due to local trauma can be found in paraspinal muscles, making postoperative testing useless[13] (Daube, 2009). Electromyography can also reveal information about the disease's progression and severity. The first expected observation after acute axonal injury is a decrease in motor unit potential (MUP) recruitment proportionate to the amount of the lesion. After 2-3 weeks, fibrillation potentials arise, and their quantity is a good measure of the amount of destroyed motor axons. Denervated muscle fibers will gradually be recruited in surviving motor units, resulting in distinct modifications in the weeks and months ahead (at first an increase in MUP duration and number of phases, and then of MUP amplitude)[16]. Increased duration and amplitude of compound potentials are a static finding that lasts indefinitely (assuming the larger motor units aren't successively harmed), therefore they shouldn't be considered indicative of continuous root injury since MUP changes are secondary to motor unit remodeling[17]. If the axonal loss is so minor that MUP changes aren't noticeable, fibrillation potentials may be the only aberrant finding in some radicular lesions[17]. Fibrillation generally fades and eventually vanishes when the motor unit remodels, but it can be recorded indefinitely in severe or continuing lesions. In isolated injuries that do not permanently damage axons, recruitment alterations can return to normal (like neurapraxic or myelin lesions). The discovery of fibrillation potentials, recruitment deficits, and MUP changes all occur at the same time, which aids in determining the initiation of injury and the severity of axonal loss. As a result, the presence of fibrillation in the lack of MUP changes usually indicates an acute injury, whereas MUP changes in the absence of fibrillation indicate a static or slowly progressive injury.

Sensory and motor nerve conduction studies

Even in the face of a clinical sensory impairment, involvement of the dorsal root between the spine and the dorsal root ganglion might spare sensory nerve action potential (SNAP) amplitudes, demonstrating radicular involvement and possibly excluding plexus or nerve lesions. Far lateral disc herniations, on the other hand, typically compress the dorsal root in the intervertebral canal and/or extraforaminal region, causing a lesion of the dorsal root ganglion or even a more distant component of the root. As a result, the amplitude of the SNAP signal may be reduced. As a result, sensory conduction tests can be deceiving, and they are insufficient to distinguish radicular from more distant sites of injury. They will, in any case, provide information that will help identify or rule out additional PNS illnesses. In muscles belonging to the afflicted root, motor conduction investigations can reveal a drop in compound muscle action potential (CMAP) amplitude, especially if the axonal loss is extensive and the muscle is weak. The CMAP and distal nerve conduction velocity can be unchanged in lesser root injuries or if the lesion does not produce axonal loss (*i.e.* in a neurapraxic lesion). It is important to remember that acute lesions involving both sensory and motor axonal loss cause changes in CMAP only after a period of time has passed (CMAP and SNAP amplitudes halve by 5-7 days after injury), *i.e.* when the nerve fiber

and the neuromuscular endplate become unexcitable due to Wallerian degeneration [18].

H reflex and F wave

The H reflex and the F wave may be relevant in the diagnosis of FLLDH on rare occasions. The H reflex is the myotactic tendon reflex's neurophysiological counterpart. It's a potential recorded from muscle fibers that's induced by electrical stimulation of a motor nerve at a lesser intensity than the CMAP[16]. It's easy to assess in the soleus muscle, and it's generally aberrant with S1 radicular lesions, but it's less reliable in other limb muscles[19]. Changes in a modified H reflex from the tibialis anterior muscle were only anecdotally linked to L4 and L5 radiculopathies (after stimulation of peroneal nerve). This explains why the H reflex isn't very useful in determining whether or not someone has FLLDH. The F wave, on the other hand, may be detected in almost all muscles. It's a minor potential measured from muscle fibers that occurs after the CMAP and is caused by anterior horn cells activating in an antidromically conducted stimulus backfiring. The F wave is a method of assessing conduction along proximal nerve segments that can be recorded from any nerve. Theoretically, clear aberrant F wave values paired with normal distal conduction parameters can detect injuries in proximal PNS sites. Unfortunately, this technique's sensitivity is poor, and normal results do not rule out a radicular lesion. Furthermore, in normal persons, the response from some nerves, such as the peroneus profundus, may be absent. As a result, the F wave's utility in the identification of radicular lesions is regarded as restricted[20]. Finally, when radiculopathy is suspected, a neurophysiological evaluation can help identify the injured root(s) and offer a semi-quantitative measurement of the root injury's size and stage. However, there are a few limitations to neurophysiological investigations in this context that must be addressed. First, neurophysiology may not be sensitive enough to rule out a radicular injury in compressive radiculopathies. Second, neurophysiological examination alone cannot determine the source of a radicular lesion, and confounding factors such as anatomical characteristics and patient comorbidities frequently prevent precise determination of the injury site[17,21].

CONCLUSION

Far-lateral disc herniations differ from their more common postero-lateral counterparts in the following ways: (1) they involve the nerve root exiting at the same level; (2) they may have a positive femoral stretch test; (3) pain and paresthesia can be reproduced by lateral bending to the side of the disc herniation; and (4) pain is often more severe than in central disc herniations, possibly due to direct compression of the dorsal root ganglion. If an appropriate procedure is followed, MR is the best imaging modality for identifying FLLDH. If an MR scan is not possible, a multi-slice CT scan is a good option. The distinction between intraforaminal and extraforaminal herniations must be correctly diagnosed before the right surgical strategy can be chosen. Despite their limitations, neurophysiological tests are a useful tool in the diagnosis and follow-up of FLLDH patients.

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MINIREVIEWS

Total hip arthroplasty in fused hips with spine stiffness in ankylosing spondylitis

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Abstract

Ankylosing spondylitis (AS) is characterized by involvement of the spine and hip joints with progressive stiffness and loss of function. Functional impairment is significant, with spine and hip involvement, and is predominantly seen in the younger age group. Total hip arthroplasty (THA) for fused hips with stiff spines in AS results in considerable improvement of mobility and function. Spine stiffness associated with AS needs evaluation before THA. Preoperative assessment with lateral spine radiographs shows loss of lumbar lordosis. Spinopelvic mobility is reduced with change in sacral slope from sitting to standing less than 10 degrees conforming to the stiff pattern. Care should be taken to reduce acetabular component anteversion at THA in these fused hips, as the posterior pelvic tilt would increase the risk of posterior impingement and anterior dislocation. Fused hips require femoral neck osteotomy, true acetabular floor identification and restoration of the hip center with horizontal and vertical offset to achieve a good functional outcome. Cementless and cemented fixation have shown comparable long-term results with the choice dependent on bone stock at THA. Risks at THA in AS include intraoperative fractures, dislocation, heterotopic ossification, among others. There is significant improvement of functional scores and quality of life following THA in these deserving young individuals with fused hips and spine stiffness.

Key Words: Ankylosing spondylitis; Total hip arthroplasty; Stiff hips; Stiff spine; Spinopelvic mobility; Functional outcome

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Grade B (Very good): B, B
Grade C (Good): 0
Grade D (Fair): 0
Grade E (Poor): 0

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Core Tip: Progressive spine stiffness associated with stiff hips in ankylosing spondylitis (AS) results in mobility restriction and reduces the quality of life in young individuals. Preoperative planning for total hip arthroplasty (THA) in AS requires spinopelvic mobility assessment. Sacral slope change is reduced (< 10 degrees) with a predominant stuck sitting pattern and posterior pelvic tilt. Care needs to be exercised to reduce acetabular anteversion preventing posterior impingement and anterior dislocation. Risks at THA in AS include intraoperative fractures, postop dislocation (1.9%), heterotopic ossification, among others, with revision-free survivorship of 82% at 20 years. Significant functional and mobility improvement justifies THA in AS with stiff hips and spine.

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INTRODUCTION

Ankylosing spondylitis (AS) belongs to the spondyloarthropathy group of disorders affecting the young with progressive stiffness of the spine and hip joints. Inflammation of the spine leads to progressive changes with ankylosis and decreased spinal mobility [1,2]. Chronic inflammation in AS of unknown etiology leads to progressive involvement of the spine, hips, knees, shoulders, among other joints[2-5]. Sacroiliac joints are involved in 100% of AS, followed by lumbosacral spine and cervical spine[4, 6]. Hip disease is evident in 19%-36% of AS[4], and shoulder involvement is seen in 20% of the disease[7]. Small joints of the hand are rarely involved[6]. Early hip involvement is marked by synovitis with synovial thickening and increased synovial fluid, as evidenced) by magnetic resonance imaging even in asymptomatic hips with AS[8]. Hip involvement with inflammation and edema is accompanied by involvement of the sacroiliac joint, symphysis pubis and shoulders. Subcortical edema in AS is typical with inflammation of the insertion sites of the tendons, ligaments and capsule, referred to as enthesitis[4]. Inflammation with pathological new bone formation is characteristic of AS with hip and spine involvement. The hip joint radiographs reveal concentric osteoproliferation and acetabular erosion[4]. Synovial and capsular inflammation responsible for pain and decreased movement, with other incompletely specified mechanisms, eventually leads to hip degeneration in AS[4,8]. The hip disease progression seems more significant in males with younger age of onset, eventually requiring total hip arthroplasty (THA)[9-12]. Duration of hip disease in AS is reported as 10-20 years, which is less than duration of AS with spine involvement[4,5,13]. Younger age of onset is associated with more hip disease[4]. Disability is predominantly due to decreased mobility resulting in stiffness and activity restriction. Hip disease is seen largely in the younger age group with significant functional impairment[4,14]. Most AS hips have fixed deformities with stiff spines and loss of spinopelvic mobility. THA improves functional outcome in these patients with significant activity limitations and progressive stiffness in their spine and hips.

THA in AS provides significant improvement in the range of movement with marked improvement in function and mobility[15]. However, the associated risks for consideration are heterotopic ossification (HO), reduced range of movement and re-ankylosis after THA in AS[11].

EPIDEMIOLOGY

The estimated prevalence of Ankylosing Spondylitis (AS) globally is 0.1%-1.4%[16,17] Mean prevalence of 17.6 per 10000 has been reported in Asia[16], with approximately 0.31% (11 to 37.1 per 10,000) reported in China and 7 to 9.8 per 10000 in India[18]. Approximately 25%-50% of patients have hip joint involvement[19], with bilateral hip

disease seen in 50%-90% of in AS[12,15,20,21]. Hip involvement in AS varies from 24%-36% according to data reported from Belgium, Spain and South America[4]. Functional impairment predominantly due to hip disease in AS is evident from functional indicator scores such as the Bath Ankylosing Spondylitis Functional Index [1,4]. The Bath Ankylosing Spondylitis Disease Activity Index and other indicators are used in the assessment of functional impairment due to hip disease in AS[4]. Hip involvement presents with varying degrees of stiffness, with bony ankylosis seen in about 40% at THA[22].

CONSIDERATIONS FOR THA IN AS

Progressive hip stiffness is seen in AS results in loss of function and limitation of activities of daily living. Hip stiffness combined with spine stiffness results in significant reduction of mobility. The progressive disease leads to fixed deformities of the hip. The fused hips at THA have flexion, abduction or extension deformities[11,23,24]. The individuals are unable to sit comfortably due to the absence of a normal spinopelvic mobility pattern that occurs from standing to sitting position.

AS with restricted spine and hip mobility presents with advanced disease for THA due to various social and other reasons. There is a significant reduction in the range of movement in these affected hips with fixed flexion and rotational deformities. AS with fused hips and stiff spines causes significant activity restriction and loss of function. The indication for THA is a significant loss of mobility rather than pain[15].

AS patients for THA need preoperative assessment and anesthetic evaluation for optimal perioperative care[15]. Airway, respiratory and cardiovascular status needs preoperative assessment. The medical management with disease-modifying antirheumatic drugs, such as anti-tumor necrosis factor alpha agents, must be stopped with rheumatology input and restarted later to minimize risks associated with wound healing reported at 0.9%[15].

Fused hips with AS have a loss of spinopelvic mobility from the stiffness of the spine and this needs to be recognized before THA for adequate preoperative planning. Preoperative templating is essential to plan for correct acetabular component size and restoration of the hip center. THA with cementless fixation would achieve a good outcome[11,23,25,26], however, cemented fixation would be required in hips with capacious femoral (Dorr C) and poor bone stock[15,21,27]. Cementless acetabular components may require additional screw fixation. Cementless fixation preserves bone stock which, would help in future revisions[15]. The bone stock could be compromised due to significant hip and spine stiffness with prolonged restriction of mobility. Comparison for both cemented and cementless fixation at THA have shown good long-term survivorship in AS[17,28].

APPROACHES FOR THA IN AS

THA in stiff hips with AS have fixed deformities[23]. Flexion deformity is the most common[3,10,11], and an extension abduction deformity occurs rarely[24]. External rotation deformities also coexist indicating contracture of the internal rotators and posterior capsule. The surgical approach for THA should ensure the release of the tight capsular tissue and soft tissue to enable full correction at THA. The flexion deformity would require a comprehensive anterior release while the abduction extension deformities would require the release of the lateral structures including the Iliotibial band

The posterior approach has been the most common in AS[11,15]. The lateral approach has also been used for THA in AS and has been advocated for its lower dislocation rates[29,30]. The modified lateral approach would not compromise the abductors further especially in AS, and this would ensure a comprehensive release in these fused hips with flexion deformity[29-32]. Anterior approach has been reported with favorable outcomes in AS with stiff hips[33,34].

The surgical approach chosen should ensure complete release to correct the fixed deformity in these fused hips without compromising the inherently weak abductors [15]. Trochanteric osteotomy aiding exposure has been associated with increased risk of HO. This approach has been gradually abandoned, although it improves exposure [11,15].

FUSED HIPS

AS with progressive hip stiffness and bilateral hip involvement present as fused hips at THA. Hips with ankylosis require *in situ* femoral neck osteotomy, identification of acetabular margins, reaming into the femoral head and identification of true acetabular floor to achieve correct acetabular component placement (Figures 1 and 2). Femoral neck osteotomy needs to be done with care to prevent damage to the greater trochanter and the posterior acetabular margin[15]. Identification of the true floor is aided by the pulvinar tissue, with care exercised not to medialize the acetabulum[23]. Hip fusion could present with proximal migration of the hip center requiring restoration of the hip center. Subtrochanteric femoral shortening may be required in fused hips with a high hip center[35] (Figures 3 and 4).

SPINE STIFFNESS WITH FUSED HIPS

Spinopelvic movement from standing to sitting is determined by three factors, which include the lumbar spine, spinopelvic mobility and hip flexion[36,37]. Spinopelvic mobility is dependent on sagittal pelvic movement as the anterior pelvic tilt, with lumbar lordosis in the standing position changes to the posterior tilt in the sitting position[38]. Spinopelvic mobility is an essential component in preoperative THA planning, which could lead to early or delayed complications[38-43]. Spinopelvic mobility patterns have also been well described, with recommendations for acetabular component placement at THA[38,39,44]. The preoperative assessment for THA includes a radiological spine assessment, especially with concurrent spinal involvement.

The spine in AS is stiff, and the normal change from sitting to standing is dependent on all three factors that are affected in AS. The change in sacral slope from sitting to standing (< 10 degrees) conforms to the stiff spine pattern[36-38,43]. The stuck sitting pattern with posterior pelvic tilt is common in AS (Figure 5). The stuck standing pattern is not infrequent in AS, as the lumbar spine stiffness may occur with lordosis (Figure 6).

Spine stiffness and altered spinopelvic mobility coexistent with hip disease in AS at THA has been described[41]. Spinopelvic mobility is gradually lost in these young individuals, with the stiffness of both hips and spine causing significant activity restriction. The posterior pelvic tilt with low pelvic incidence had marginal change (< 10 degrees) before and after THA (Figures 5 and 6) conforms to the stiff pattern. The spinopelvic mobility pattern would fall into the rigid unbalanced category[45].

The stiff spine requires preoperative assessment to evaluate change with THA[36,37,43,46]. Hu *et al*[47] have recommended correction of thoracolumbar kyphosis before THA. However, most AS individuals with stiff hips and spines undergo THA to achieve improvement in mobility and function. The understanding of the normal hip spine relationship and the different patterns brings out the importance of acetabular component anteversion in THA[36,38-40,45]. Progressive loss of spine mobility is common in AS with the loss of normal spinopelvic mobility. Spine stiffness with stiff hips in AS contributes to loss of spinopelvic mobility from sitting to standing. Preoperative assessment includes lateral radiographs of the lumbosacral spine in sitting and standing positions to evaluate the spinopelvic mobility pattern. Preoperative sitting radiographs may not be possible in AS with stiff hips, as these individuals with significant spine stiffness are often unable to sit with the thighs parallel to the floor.

Acetabular anteversion of 15-25 degrees needs to be reduced in these hips with decreased spinopelvic mobility[17,48]. Posterior pelvic tilt with spine stiffness has an associated risk of posterior impingement with subsequent anterior dislocation. Care should be taken to avoid excessive anteversion as this would increase the risk of posterior impingement and anterior dislocation[42,49]. The normal change in inclination and anteversion from sitting to standing is absent[38-40]. Dual mobility hips have been recommended for fused hips associated with a stiff lumbar spine and posterior pelvic tilt to reduce the risk of impingement and dislocation[38,40].

PROTRUSIO

Protrusio in stiff hips is not uncommon in AS. The reason for the medialization of the femoral head beyond the ilioischial line is not fully understood[21,50,51]. Protrusio has

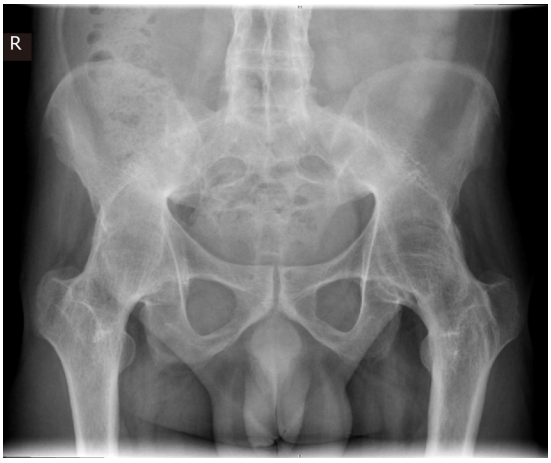

Figure 1 Bilateral fused hips with ankylosing spondylitis in a 43-year-old male at total hip arthroplasty-pre op.

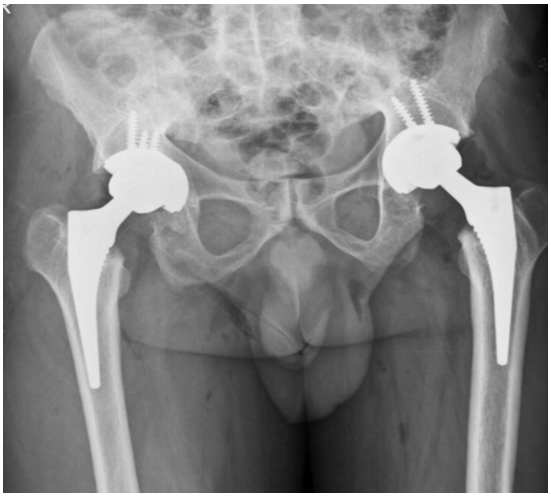

Figure 2 Bilateral fused hips-post op bilateral total hip arthroplasty (Pre op Figure 3) with cementless fixation in 43-year-old male.

been reported in about 17% of hip disease with AS[50]. Preoperative planning includes templating and medial defect bone grafting with reverse reaming for the protrusio with cementless acetabular components. Dislocation of the femoral head during THA in these cases could be challenging, and osteotomy of the neck and head removal may be necessary to avoid intraoperative fractures. The acetabular floor is prepared with caution to prevent medialization, and hip center restoration is essential with autogenous bone grafting and primary cementless acetabular fixation[52] (Figure 7). The protrusio in these hips may present with proximal migration and resorption of the femoral head as well.

FUNCTIONAL OUTCOME

THA in AS with stiff hips restores mobility with significant improvement in activity limitation. The mobility is restored with a significant increase in range of movement and good functional outcome[12,21,25,26,33]. Thirty-six item Short Form Survey scores and health-related quality of life are significantly affected in AS[53]. Functional scores have shown significant improvement for bilateral THA with an average change in HSS scores by 60.6 points reported[15]. Harris Hip Score showed improvement from 48 to 73 and 53 to 82 for historical and recent data in the same series[17] (Table 1). The improvement in functional outcome and quality of life have supported the increased incidence of THA in these stiff hips in AS.

Table 1 Comparison of outcome of total hip arthroplasty in ankylosing spondylitis

Ref.	Patients (Hips)	Follow up in mo	Pain relief (%)	Final MHHS	ROM score/ Mean flexion	Approach	Complications (%)
Bisla *et al*[58], 1976	23 (34)	42.5	91	NS	ROM-3	NS	5.88
Resnick *et al* [59], 1976	11 (21)	36	NS	NS	NS	NS	30 re-ankylosis; 6/20 hips
Williams *et al* [60], 1977	56 (99)	36	NS	NS	NS	NS	10
Baldursonn *et al* [61], 1977	10 (18)	45.6	94	NS	Flexion-90	NS	0
Shanahan *et al* [62], 1982	12 (16)	89	94	NS	NS	NS	6.25
Finsterbush *et al* [63], 1988	23 (35)	90	NS	NS	Flexion-86	NS	14.28
Walker *et al*[9], 1991	19 (29)	58	97	NS	ROM-4	NS	15; 3 hips re-ankylosis
Gualtieri *et al* [64], 1992	39 (73)	90	89	NS	NS	NS	0
Brinker *et al*[10], 1996	12 (20)	75	90	89.1	ROM-4	Posterior, Lateral	0
Sochart *et al*[55], 1997	24 (43)	276	100	NS	ROM-4	NS	27.9
Lehtimaki *et al* [56], 2001	54 (76)	240	NS	NS	NS	NS	3.94
Joshi *et al*[27], 2002	103 (181)	120	96	NS	NS	Lateral, Hardinge	10.5
Kim YL *et al* [65], 2007	12 (24)	132	NS	82.3	NS	Lateral	12.5
Bhan *et al*[11], 2008	54 (92)	102	62	82.6	ROM-4	Posterior	14
Li *et al*[66], 2009	24 (39)	36	NS	91	ROM-4	Posterolateral	2.5
Tang *et al*[12], 2000	58 (95)	135.4	94	88.8	ROM-4.2	Posterior	20
Bangjian *et al* [54], 2012	12 (24)	50.4	100	86.25	Flexion-84	Posterolateral	8.3; 2 intraoperative femur fractures; 2 osteolysis, polyethylene wear
Malhotra *et al* [67], 2012	23 (32)	42	NS	87.1	ROM-4	Posterior	3.1
Siavashi *et al* [68], 2014	77 (NA)	12	NS	88.22	ROM-5	Posterior, lateral	20.8
Xu *et al*[26], 2017	54 (81)	42	NS	86.1	Flexion-82.5	Posterolateral	0
Guo *et al*[69], 2019	26 (31)	46.5	80.6	87.1	Flexion90.8	Smith Peterson; lateral, Posterior	1 dislocation; Closed reduction; 12.9% HO
Bukowski BR *et al*[17], 2021	219 (309)	16 yr (192 mo)	NS	76	NS	Transtrochanteric (45%); Posterior (25%); Anterolateral (29%)	17.5% at 20 yr

Complications as percentage. Revision, dislocation, fractures, infection. HO: Heterotopic ossification; ROM: Reduced range of movement; MHHS: Modified Harris Hip Score; NS: Not specified.

COMPLICATIONS

AS with stiff hips could present with poor bone stock due to prolonged immobility and stiffness. Care needs to be exercised during THA to prevent intraoperative fractures reported at 4.3%[11,15,27,54]. Wu *et al*[33] reported 1 case of greater

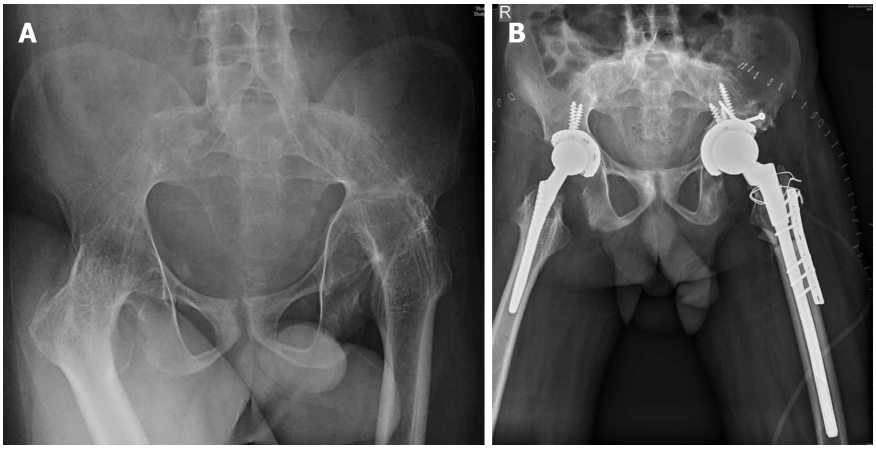

Figure 3 Bilateral fused hips and ankylosing spondylitis in a 31-year-old male. A: Proximal migration of the left hip with femoral head and acetabular type 3b acetabular deficiency; B: Bilateral total hip arthroplasty with left hip femoral shortening. Acetabulum medial wall fracture, defect managed with bone graft and screws for superior augmentation. Sacral slope wire for proximal femur incomplete split, femur plate for additional rotational stability.

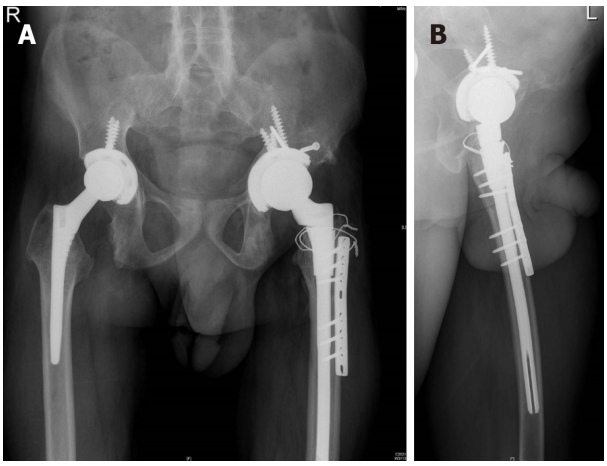

Figure 4 Follow up bilateral fused hips total hip arthroplasty in 31-year-old male with proximal migration left hip (pre op Figure 3). A: 15 mo follow-up with osteotomy site union, acetabulum graft well united; B: Lateral view confirming osteotomy site union.

trochanter fracture in their series with DAA for THA in AS. Fracture risk is associated with cementless fixation with inadequate bone stock. Fractures have been reported at femoral stem insertion managed with wiring and delayed weight bearing[15]. Bukowski *et al*[17] reported 3 proximal femur fractures and 1 acetabular fracture treated with femur wiring and acetabular component retention in their series. Hips for THA with poor bone stock and wide femoral canal (Dorr C) should be planned for cemented fixation. The identification of the medial wall during acetabular preparation and reaming is crucial in achieving the ideal component position at THA in fused hips. Restoration of the hip center with vertical and horizontal offset is essential in achieving THA with a good functional outcome.

Dislocation is a common mode of failure after THA in AS, with earlier reports of 3%-5% at 10 years[11]. Dislocation after THA in AS has been reported at 1.75% managed by closed reduction with successful outcome[15] (Figure 8). Eight dislocations requiring closed reduction were reported in a series of 309 AS hips[17]. Tang *et al*[12] reported 2 (2 out of 3) anterior dislocations in their series with posterior approach THA, attributed to hip hyperextension. Dislocation has been reported by Bhan *et al*[11] at 4.3% with the posterior approach and Joshi *et al*[27] reported a rate of 2.2% with the lateral approach. Wu *et al*[33] had reported two dislocations in the posterolateral approach when compared to DAA in their series. Cumulative dislocation requiring open or closed reduction has been reported at 1.9% at 2 years and 10 years and 2.9% at 20 years[17]. Dislocation was predominantly posterior with one out of three hips requiring revision with a constrained liner[17].

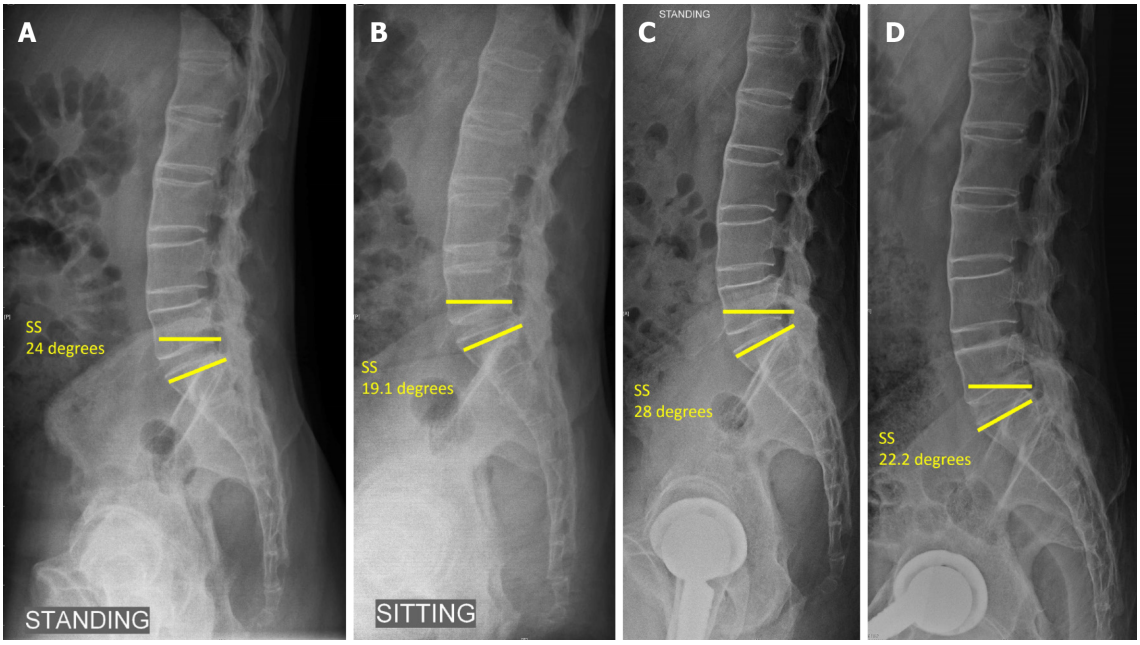

Figure 5 Lateral lumbosacral spine radiographs. A: Pre op standing; B: Sitting compared to; C: Post op standing; D: Sitting showing the change in sacral slope < 10 degrees with reduced sacral slope indicating posterior pelvic tilt and stuck sitting pattern in ankylosing spondylitis (sacral slope < 30 degrees on sitting and standing typical of stuck sitting pattern). SS: Sacral slope.

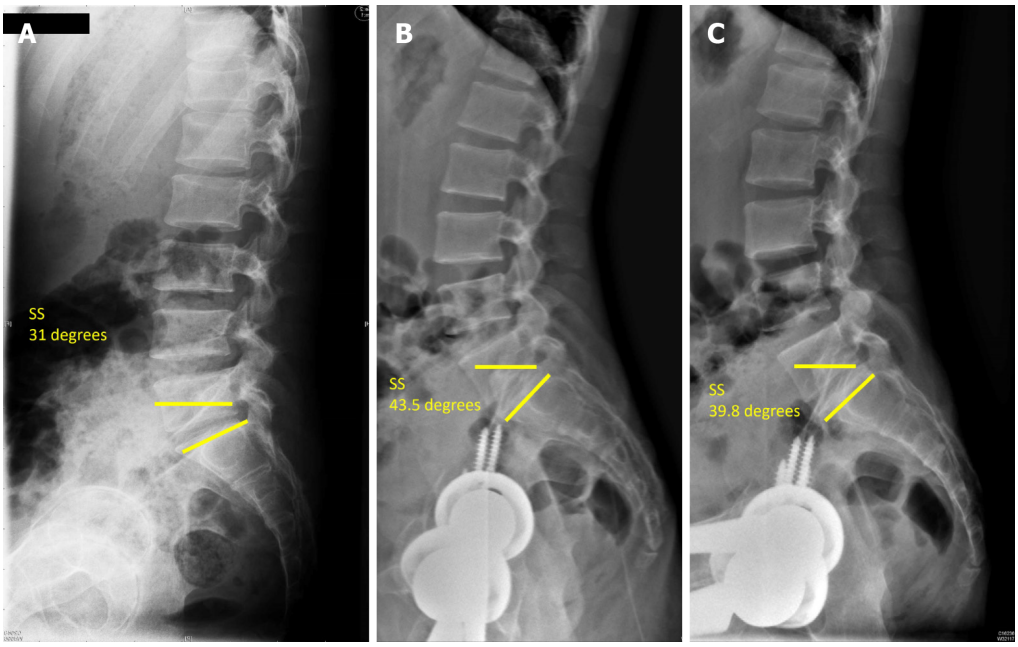

Figure 6 Spinopelvic mobility in a 51-year-old male with flexion deformity and inability to sit comfortably prior to total hip arthroplasty, pre op and 29 mo post bilateral total hip arthroplasty ankylosing spondylitis. A: Pre op sacral slope (SS) standing; B: Post total hip arthroplasty SS standing; C: Sitting SS > 30 degrees sitting and standing demonstrates the stuck standing pattern. SS: Sacral slope.

The other complications reported included superficial wound infections requiring oral antibiotics in five hips and hematoma formation in five hips in THA for AS[17].

Nerve injuries have been reported with a slightly higher incidence (2.6%) after bilateral THA for AS[15]. Neuropraxia of the femoral, sciatic and peroneal nerves have been reported with recovery rates between 3 wk and 6 mo.

Long-term survivorship following THA in AS has been reported as 92%-100% at 10 years, with rates falling to 66%-81% at 15 years[12,27,55,56]. Aseptic loosening requiring revision in AS has been reported at 9.7%, 14% and 11% at 16-, 9- and 5-year follow-up, respectively[11,17,21]. Cemented fixation in AS had longer survivorship with lower revision rates compared to cementless fixation, which was considered to

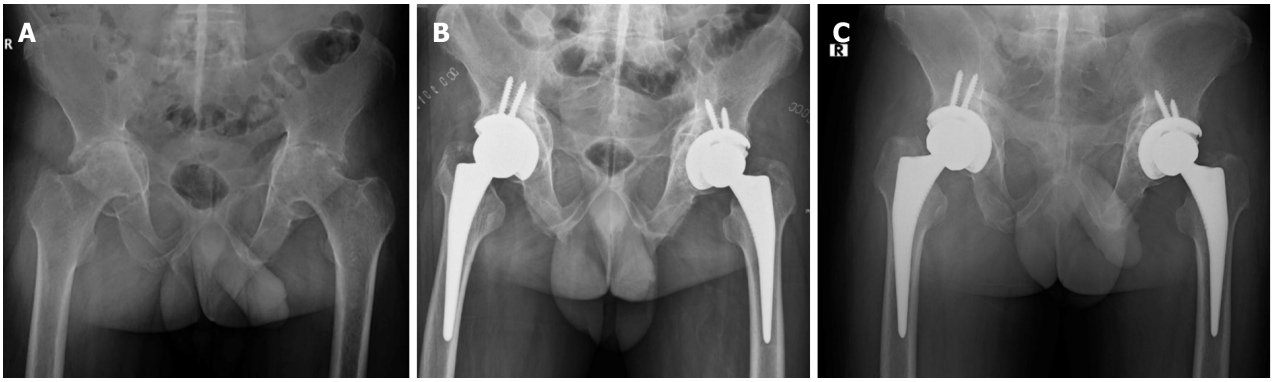

Figure 7 Bilateral hip protrusion in 48-year-old male with ankylosing spondylitis and fused sacroiliac joints. A: Pre op bilateral stiff hips; B: Post op total hip arthroplasty with bone grafting (autograft) reverse reaming for graft impaction; C: 1-year follow-up with graft integration.

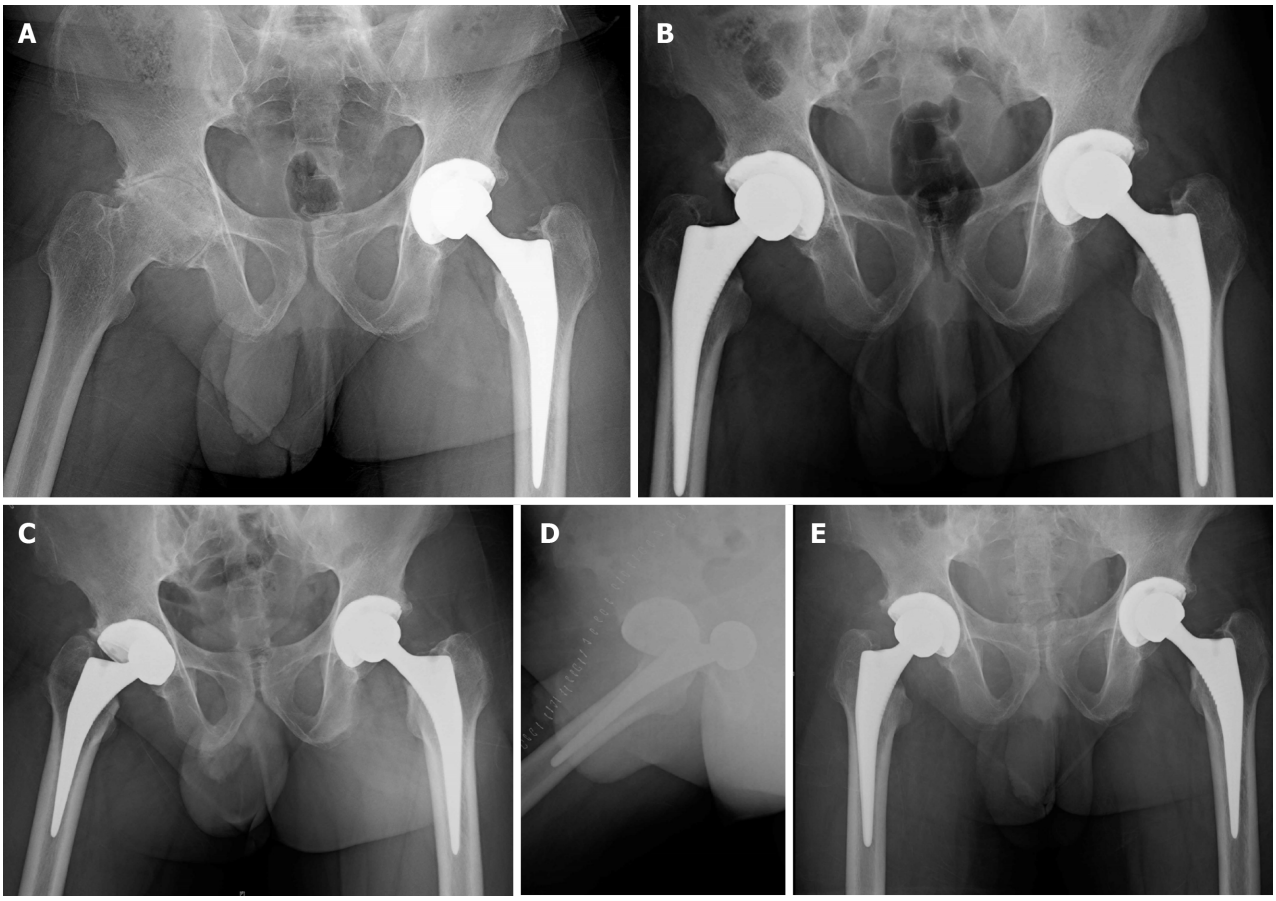

Figure 8 Left total hip arthroplasty with right hip arthritis in a 34-year-old male with ankylosing spondylitis. A: Pre op stiff right hip; B: Post op right total hip arthroplasty; C: With dislocation at day 5 following a fall; D: Lateral view; E: 1-year follow-up after closed reduction.

have better results[17,28].

HETEROTOPIC OSSIFICATION

The incidence of HO in AS after THA has been reported at 11%-13%, with findings of Brooker class 1 in most hips[21,28]. Brooker 3 or 4 (Figure 9), referred to as clinically relevant HO, was seen in 8% of hips[17]. Data in the literature suggest incidence of HO following THA in AS is 9%-77%[9,10]. Re-ankylosis has also been reported with significant HO following THA in AS associated with a reduced range of movement. Trochanteric osteotomy approach has been attributed to increased incidence of HO and re-ankylosis in earlier reports[3,11,57]. HO following THA in AS is probably due

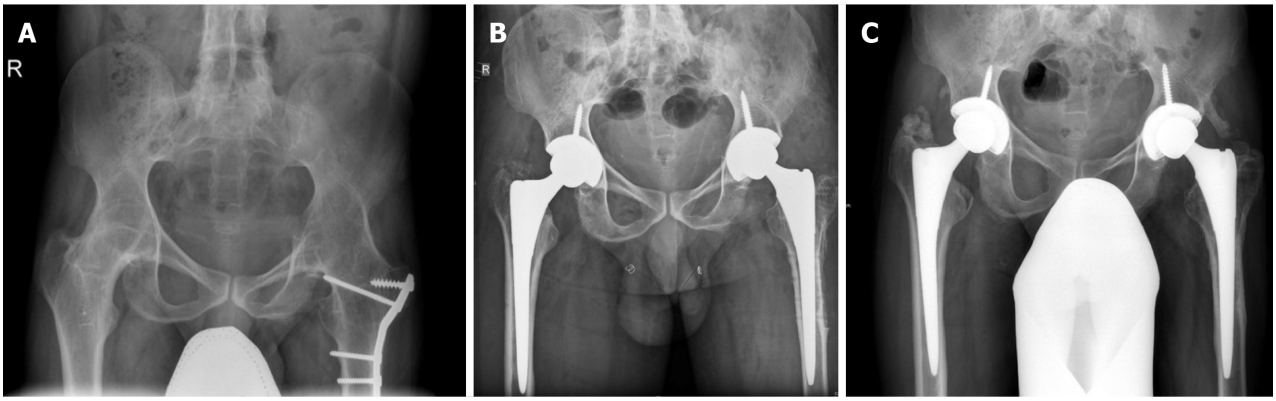

Figure 9 Bilateral hip ankylosis in a 33-year-old male with ankylosing spondylitis. A: Pre op total hip arthroplasty, 12-year post op fracture fixation left proximal femur; B: Post op bilateral total hip arthroplasty; C: Follow-up with Brooker grade 3 heterotopic ossification left hip and good hip function (Harris hip score improved from 34 to 81 at 24 mo follow-up).

to chronic inflammation seen in the joint as well as the surrounding tissues with varying degrees of stiffness. Indomethacin plays an effective role in HO treatment and prevention in these cases[21]. Careful soft tissue handling and copious lavage to ensure removal of excess bone debris before closure after THA play a significant role in HO prevention in these stiff hips.

CONCLUSION

AS with stiff hips and spine have reduced mobility and function. THA enhances movement and functional activity with significant improvement in outcome. The spinopelvic mobility pattern in AS belongs to the stiff category with minimal change from sitting to standing (< 10 degrees). Preoperative sitting and standing spine lateral radiographs are essential for assessment. THA for fused hips in AS requires *in situ* femoral neck osteotomy, identification of the true acetabular floor and restoration of hip center, vertical and horizontal offset. Cementless and cemented THA have shown good long-term results. Care should be taken to avoid increased anteversion to avoid posterior impingement and anterior dislocation in fused hips with posterior pelvic tilt. Functional outcome significantly improves in these stiff hips. Risks with THA in AS includes intraoperative fractures (4.3%), dislocation (1.9% to 2.9 %), HO (13%), along with other factors including re-ankylosis (6%) and aseptic loosening (14%).

Stiff hips with spine stiffness in AS warrant THA with knowledge of spinopelvic mobility and overall risks to improve long-term functional outcomes.

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ORIGINAL ARTICLE

Basic Study

Assessing the accuracy of arthroscopic and open measurements of the size of rotator cuff tears: A simulation-based study

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Author contributions: Kitridis D wrote the manuscript and conducted the statistical analysis; Alaseirlis D designed and coordinated the study; Malliaropoulos N interpreted the data; Chalidis B conducted the literature search; McMahon P and Debski R performed the experiments, acquired and analyzed data; Givissis P supervised the paper; all authors read and approved the final manuscript.

Institutional review board statement: Not Applicable for the current simulation-based study. No patients or animals were involved.

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Abstract

BACKGROUND

Arthroscopic procedures are commonly performed for rotator cuff pathology. Repair of rotator cuff tears is a commonly performed procedure. The intraoperative evaluation of the tear size and pattern contributes to the choice and completion of the technique and the prognosis of the repair.

AIM

To compare the arthroscopic and open measurements with the real dimensions of three different patterns of simulated rotator cuff tears of known size using a plastic shoulder model.

METHODS

We created three sizes and patterns of simulated supraspinatus tears on a plastic shoulder model (small and large U-shaped, oval-shaped). Six orthopaedic surgeons with three levels of experience measured the dimensions of the tears arthroscopically, using a 5 mm probe, repeating the procedure three times, and then using a ruler (open technique). Arthroscopic, open and computerized measurements were compared.

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RESULTS

A constant underestimation of specific dimensions of the tears was found when measured with an arthroscope, compared to both the open and computerized measurements (mean differences up to -7.5 ± 5.8 mm, $P < 0.001$). No differences were observed between the open and computerized measurements (mean difference -0.4 ± 1.6 mm). The accuracy of arthroscopic and open measurements was 90.5% and 98.5%, respectively. When comparing between levels of experience, senior residents reported smaller tear dimensions when compared both to staff surgeons and fellows.

CONCLUSION

This study suggests that arthroscopic measurements of full-thickness rotator cuff tears constantly underestimate the dimensions of the tears. Development of more precise arthroscopic techniques or tools for the evaluation of the size and type of rotator cuff tears are necessary.

Key Words: Shoulder; Arthroscopy; Simulation model; Rotator cuff tear; Supraspinatus tear; Cuff tear size

Core Tip: The intraoperative evaluation of the rotator cuff tear size and pattern contributes to the choice of the technique and the prognosis of the repair. The purpose of the study was to determine the accuracy of arthroscopic measurement of the tears' size comparing them with the open technique. A constant underestimation of specific dimensions of the tears was found when measured with an arthroscopic probe compared to the open measurements.

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INTRODUCTION

Rotator cuff (RC) tears are the most common tendon injury in adults, often resulting in debilitating symptoms related to both daily and sports activities[1-3]. After the failure of conservative regimens, these patients are usually treated with surgical repair of the tear[1]. Arthroscopy is the preferred surgical option for rotator cuff repair, giving a better intraoperative evaluation of the dynamic shoulder anatomy, preserves the muscle integrity, is associated with lower postoperative morbidity, and provides equal or better results compared to open techniques[4,5].

Repair techniques are based on many factors including patient characteristics, muscle quality, mobility of the tendons, and intraoperative evaluation of the size of the tear[4,6-9]. Therefore, accurate intraoperative measurement of the size of the rotator cuff tear is crucial. Especially in certain techniques such as superior capsule reconstruction, precise measurements of the tears' dimensions are crucial for the correct sizing of the graft[10-12]. Previous studies have compared magnetic resonance imaging (MRI) measurements with arthroscopic evaluation, and focused on the MRIs ability to detect shoulder pathology in general, and not on the arthroscopic accuracy to evaluate the dimensions of different types of rotator cuff tears[13-15].

Our purpose was to compare the arthroscopic and open measurements with the real dimensions of three different patterns of simulated rotator cuff tears of known size using a plastic shoulder model. We utilized surgeons of three different levels of experience and compared the accuracy between them. The hypothesis of our study was that the size of a rotator cuff tear can be estimated accurately and equally with both arthroscopic and open techniques. To our knowledge, there is currently no research implementing this study design.

MATERIALS AND METHODS

The study took place at the Musculoskeletal Research Center in Pittsburgh, PA, USA. A plastic shoulder model (ALEX shoulder model, Sawbones Inc, Vashon, WA, Figure 1), a 30-degree arthroscope (Linvatec, Largo, FL) through the posterior portal, and a high-definition video system were utilized. Three sizes and patterns of full-thickness rotator cuff tears (a small U-shaped, a larger U-shaped, and a crescent-type, Figure 2) were created using computer software. Dimensions close to the cut-off point of medium and large tears (3 cm) were chosen, according to the DeOrio and Cofield classification system (Table 1)[16]. The simulated tear patterns were printed on paper with adhesive backing and placed in the location of the soft tissue element of the model simulating the supraspinatus tears location. The simulated tears with these computerized measurements had a precision of 0.1 mm.

Six orthopaedic surgeons were enrolled in the study and they were blinded to the computerized measurements: two senior residents with fellowship training, two fellows and two senior staff surgeons, all of the Sports Injuries and Shoulder Surgery Department. We asked them to measure the dimensions of the tears arthroscopically, repeating the procedure three times at weekly intervals. Viewing was from the lateral portal and measuring from the lateral portal, constantly. We used a probe calibrated in 5mm intervals and with a 5 mm tip, reflecting the usual practice. During all arthroscopic measurements, the shoulder model was completely covered, so the observers could not have direct vision of the simulated tears (Figure 1B). When all arthroscopic measurements were completed, the shoulder model was uncovered and the plastic cover was also removed. Each surgeon used a surgical ruler for a single measurement to simulate the open technique.

Statistical analysis

The mean differences between the arthroscopic measurements of the tears compared to the open and computerized measurements were calculated. Comparisons between the overall mean differences between the groups in pairs, using Wilcoxon signed ranks test, with $P < 0.016$ as the level of significance using the Bonferroni correction were then performed.

Subsequently, the subgroups of the separate dimensions' measurements were evaluated, using Wilcoxon signed ranks test, with $P < 0.05$ as the level of significance. Finally, the measurements between the surgeons with the different levels of experience were compared using Wilcoxon signed ranks test, with $P < 0.016$ as the level of significance using the Bonferroni correction.

The mean value of the three consecutive arthroscopic measurements were used for the analyses that was then performed with the Statistical Package for Social Sciences (SPSS, IBM) software version 24.

RESULTS

Arthroscopic vs computerized measurements

A statistically significant underestimation of the dimensions of the tears when measured arthroscopically was observed ($P < 0.001$) (Table 2). The largest mean differences of the separate measurements were -7.6 ± 5.8 mm in the contour length of the small U-shape tear, -4.5 ± 3.1 mm in the anterior to posterior height of the crescent-type tear, and -3.1 ± 3.1 mm in the contour length of the large U-shaped tear (Table 3). All mean differences were negative (Table 3), showing the constant underestimation of the dimensions. The accuracy of the arthroscopic measurements was 90.5%.

Arthroscopic vs open measurements

The overall mean difference between arthroscopic and open measurements confirmed the trend of underestimation of the dimensions, when measured arthroscopically ($P < 0.001$) (Table 2). The differences between separate measurements were all negative, and some of them were statistically significant (Table 3).

Open vs computerized measurements

The overall mean difference between open and computerized differences was smaller than between arthroscopic and computerized; -0.4 ± 1.6 mm *vs* -2.4 ± 3.2 mm. The difference was statistically significant for the corrected level of significance between the groups ($P < 0.016$), but we considered the mean value of 0.4 mm clinically insigni-

Table 1 The dimensions of the simulated tears measured by the surgeons (Layouts in Figure 2)

ID	Description	Standardized technique	Computerized dimensions (mm)
A1	Basis length	Anterior to posterior	15.2
A2	Contour length	Anterior to posterior	53.5
A3	Height	Medial to lateral, most distal length	22.9
B1	Basis length	Anterior to posterior	20.3
B2	Contour length	Anterior to posterior	31.9
B3	Height	Medial to lateral, most distal length	10.2
C1	Medial contour length	Upper in Figure 2	31.9
C2	Lateral contour length	Lower in Figure 2	31.6
C3	Medial to lateral height	Short height in Figure 2	7.6
C4	Anterior to posterior height	Long height in Figure 2	31.0

Table 2 Overall mean difference between the groups of measurements

Groups	mean difference, mm	*P*[1] value
Arthroscopic *vs* computerized	-2.4 ± 3.2	< 0.001
Arthroscopic *vs* open	-2 ± 2.6	< 0.001
Open *vs* computerized	-0.4 ± 1.6	0.014

[1]Wilcoxon signed ranks test, level of significance $P = 0.016$ (Bonferroni correction).

Table 3 Comparison of mean differences between arthroscopic versus computerized, and arthroscopic and open measurements in millimeters (mean ± SD)

Dimension	Arthroscopic *vs* computerized	*P*[1] value	Arthroscopic *vs* open	*P*[1] value
A1	-0.5 ± 1.2	0.92	-0.3 ± 1.2	0.92
A2	-7.6 ± 5.8	0.03	-3.7 ± 4.9	0.12
A3	-2.1 ± 2.7	0.17	-2.0 ± 2.5	0.14
B1	-2.3 ± 1.9	0.03	-1.9 ± 1.9	0.04
B2	-3.1 ± 3.1	0.12	-3.2 ± 2.3	0.04
B3	-0.7 ± 0.8	0.05	-0.5 ± 0.8	0.20
C1	-1.8 ± 1.6	0.05	-2.5 ± 2.4	0.05
C2	-1.8 ± 1.8	0.05	-2.8 ± 2.1	0.03
C3	-0.1 ± 0.5	0.91	-0.3 ± 0.4	0.18
C4	-4.5 ± 3.1	0.03	-3.1 ± 3.5	0.06

[1]Wilcoxon Signed Ranks Test, level of significance $P = 0.05$.

ficant for the surgical decision-making. The accuracy of the open measurements was 98.5%.

Precision between surgeons with different levels of experience

No significant differences were observed between the senior staff surgeons and the fellows ($P = 0.07$). On the contrary, the senior residents reported smaller tear dimensions when compared both to the staff surgeons and the fellows ($P < 0.001$ for both comparisons). Measurements with the open technique were precise among all surgeons ($P = 0.96$), showing excellent inter-observer reliability.

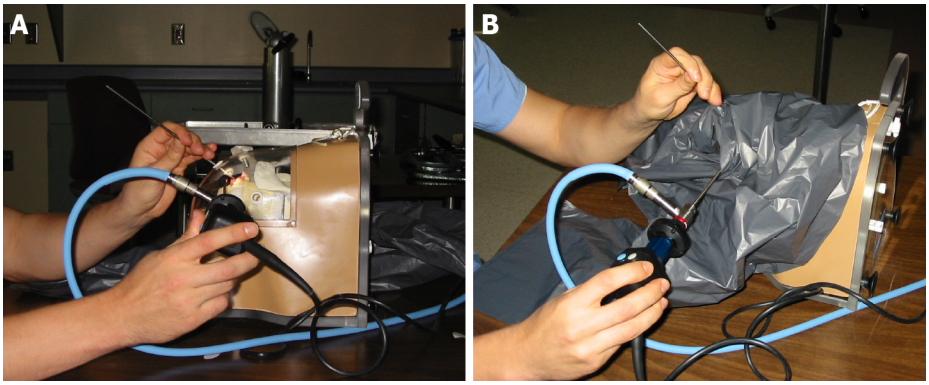

Figure 1 The ALEX plastic shoulder model. A: The model used for the procedures; B: The shoulder model covered for obstructing direct vision.

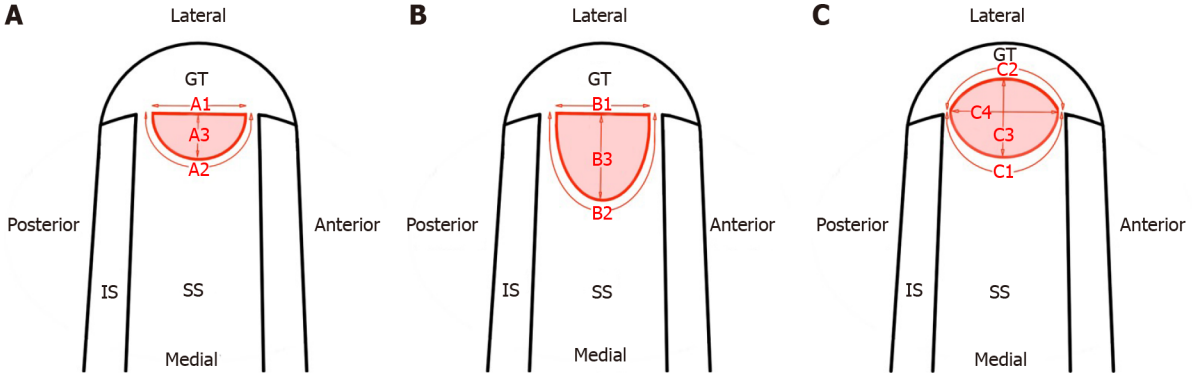

Figure 2 Three pattern of supraspinatus tears were created using computer software and were printed on paper with adhesive backing. A: Small U-shaped; B: Larger U-shaped; C: Crescent-type. The dimensions of the tears are reported in Table 1. GT: Greater tuberosity; IS: Infraspinatus; SS: Supraspinatus.

DISCUSSION

Surgeons of three different levels of experience were found to constantly underestimate given dimensions of simulated rotator cuff tears with the arthroscopic technique. We utilized three common patterns of rotator tears (a small U-shaped, a larger U-shaped, and a crescent-type). We observed a constant underestimation of the dimensions of the tears when measured with a standard 5 mm probe arthroscopically.

We observed mean differences up to 7.5 mm when comparing the separate measurements of the tears' dimensions compared to the computerized measurements. The accuracy of the arthroscopic and open measurements was 90.5% and 98.5%, respectively. When comparing the different levels of experience, the senior residents reported smaller tear dimensions when compared both to the staff surgeons and the fellows. It seems that more experienced surgeons tend to be more accurate, although the underestimation is constant to all levels of experience, implicating that the instrumentation used is not suitable for precise measurements. Measurements with an open technique were both accurate and precise.

There are numerous studies considering the intraoperative evaluation of the size of the tear as a factor influencing the choice of the most indicated repair technique and the outcomes of the repair. Park *et al*[4] reported that large-to-massive tears (> 3 cm) repaired with double-row fixation had significantly improved outcomes in terms of functional outcomes in comparison with those repaired with single-row fixation. Duquin *et al*[7] analyzed data from 23 studies and found re-tearrates significantly lower for double-row repairs when compared with single-row, especially for tears greater than 5 cm. A summary of meta-analyses reported that six meta-analyses found double row repair to be superior for tears greater than 3 cm, and recent studies also report that larger tears size increases re-tear risk[9,17-19]. Of course, several other factors influence the surgeon's decision-making of the appropriate surgical technique, including patient characteristics, muscle quality, and mobility of the tendons, as mentioned before[4,6-9]. However, recent research has shown that the rotator cuff tear size at the time of surgery significantly affects supraspinatus integrity in the long-term,

thus greatly influences the prognosis of clinical and functional outcomes and patient satisfaction[20]. Moreover, in certain techniques such as superior capsule reconstruction for irreparable rotator cuff tears or reinforcement of cuff repair, precise measurements of the tears' dimensions are crucial for the technique per se[10,11].

In the current study, we observed a constant underestimation of the tears' dimensions with mean differences up to 7.5 mm, when measured arthroscopically. These differences could lead to inappropriate selection of procedures during surgery and affect the patients' outcomes and prognosis. Our results agree with Bryant *et al* [21], who reported arthroscopic measurements to have a 12% underestimation of the tear size compared to measurements with an open technique.

Previous studies have compared MRI measurements with the arthroscopic evaluation of rotator cuff tears and reported high sensitivity and specificity both for full and partial thickness tears[13,14]. However, Bryant *et al*[21] reported magnetic resonance imaging to underestimate the size of rotator cuff tears by 30%. Additionally, Eren *et al*[14] found significantly larger measurements during surgery when compared with MRI.

In our study, arthroscopic and open techniques were compared but the accuracy and precision were also determined. Combined with the three different levels of experience of the surgeons and the common clinical use of the 5 mm probe, our procedure is very close to daily routine surgical practice.

Limitations of the study

We used a relatively small sample size. The rationale for the sample selection was that separate measurements for ten specific tear dimensions provided a total of sixty observations in each group (arthroscopic, open, and computerized measurements), which were enough to draw conclusions. Secondly, the measurements were conducted in a plastic simulation shoulder model and not in real patients so that comparisons could be made to computerized measurements.

CONCLUSION

This study suggests that arthroscopic measurements of full-thickness rotator cuff tears constantly underestimate the dimensions of the tears. This underestimation, especially of specific dimensions (contour length of the small U-shape tear, anterior to posterior height of the crescent-type tear, and contour length of the large U-shaped tear), could lead to false documentation during surgery, unreliable prognostic suggestions, and even postoperative failures. Measurements with an open technique were accurate and precise. These observations raise the need for the development of better arthroscopic tools and techniques for the evaluation of the size of the rotator cuff tears.

ARTICLE HIGHLIGHTS

Research background

Arthroscopic procedures are commonly performed for rotator cuff pathology. The intraoperative evaluation of the tear size and pattern contributes to the choice and completion of the technique and the prognosis of the repair.

Research motivation

The accuracy of common arthroscopic instruments to evaluate the dimensions of different types of rotator cuff tears is not yet evaluated.

Research objectives

The purpose of the current study was to compare the arthroscopic and open measurements with the real dimensions of three different patterns of simulated rotator cuff tears of known size using a plastic shoulder model.

Research methods

Three sizes and patterns of simulated supraspinatus tears on a plastic shoulder model (small and large U-shaped, oval-shaped) were created. Six orthopaedic surgeons with three levels of experience measured the dimensions of the tears arthroscopically, using a 5 mm probe, repeating the procedure three times, and then using a ruler (open

technique). Arthroscopic, open and computerized measurements were compared.

Research results

A constant underestimation of specific dimensions of the tears was found when measured with an arthroscope, compared to both the open and computerized measurements. No differences were observed between the open and computerized measurements. The accuracy of arthroscopic and open measurements was 90.5% and 98.5%, respectively. When comparing between levels of experience, senior residents reported smaller tear dimensions when compared both to staff surgeons and fellows.

Research conclusions

This study suggests that arthroscopic measurements of full-thickness rotator cuff tears constantly underestimate the dimensions of the tears. This underestimation could lead to false documentation during surgery, unreliable prognostic suggestions, and even postoperative failures.

Research perspectives

Development of more precise arthroscopic techniques or tools for the evaluation of the size and type of rotator cuff tears are necessary.

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ORIGINAL ARTICLE

Case Control Study

Role of biomechanical assessment in rotator cuff tear repair: Arthroscopic *vs* mini-open approach

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Abstract

BACKGROUND

Rotator cuff (RC) tears are one of the most frequent pathologies within the shoulder girdle. Hand dominance and older age are associated with RC tears. Two different surgical procedures, the mini-open (MO) and all-arthroscopic (AA) approach, represented the standard of treatment.

AIM

To compare the clinical and biomechanical outcomes of two surgical techniques (AA *vs* MO procedure) performed to address the painful shoulder syndrome with partial or total supraspinatus tendon tear.

METHODS

Eighty-eight participants, 50 following RC repair with AA and 38 with MO approach, were recruited in the present cross-sectional case-control study (ORTHO-SHOULDER, Prot. 0054602). All patients underwent postoperative clinical evaluation for pain (Visual analogic scale), impairment, and disability (disability of the arm, shoulder, and hand) and limitation in daily activity (Constant-Murley score). Patients' shoulder mobility was also assessed in our

statement: The study was approved by the Local Ethical Committee (ORTHO-SHOULDER, n. 6480, Prot. n. 0054602).

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Laboratory of Functional Movement through a wearable inertial sensor and surface electromyography to monitor kinematics and muscle activity during the movement on the frontal (abduction/adduction) and sagittal (flexion-extension) planes.

RESULTS

No statistically significant differences between the two procedures were observed in either main clinical score or range of motion. A significant increase in velocity during the movement execution and a higher contribution of upper trapezius muscles were found in the AA group compared with MO patients.

CONCLUSION

In terms of clinical scores, our findings were in line with previous results. However, the use of technology-based assessment of shoulder mobility has revealed significant differences between the two techniques in terms of mean velocity and pattern of muscle activation.

Key Words: Rotator cuff tear; Arthroscopic; Mini-open; Wearable sensors; Surface electromyography

Core Tip: Wearable technologies could be useful in clinical practice since they could provide clinical information during the performance of a motor task. The present work represents a preliminary attempt in making use of novel wearable technologies in common clinical practice.

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INTRODUCTION

An important group of the population suffers from shoulder pain due to acute or chronic tendon injuries. It is becoming a considerable cause of work disability. Rotator cuff tendinopathy and tears (RCTs) are the most common lesions. After the supraspinatus tendon, the most common injured structure of the rotator cuff (RC) complex, the biceps tendon is the second most commonly injured structure, as it is an element of compensation of the abnormal forces. Biceps' tears predispose the patient's rotator cuff to subsequent instability and further subscapularis tendon tears. Multi-tendon shoulder injuries, moreover, complicate the process of diagnosis, treatment, and rehabilitation[1,2]. The overall prevalence of RC abnormalities, regardless of symptoms, ranged from 9.7% in patients younger than or equal to 20 years and increased to 62% in patients aged 80 years and older ($P < 0.001$)[3]. Many RCTs also cause restriction of shoulder function. Surgical repair of the RC is a cost-effective solution for all populations and reduces the societal burden of the disease. The choice of surgery varies from surgeon-to-surgeon with arthroscopy more common at the present time. Mini-open (MO) technique has represented the gold standard for years, with a 90% success rate[4], since it guaranteed stronger suture fixation and a shorter learning curve[5]. However, the development of dedicated surgical instruments and improvement of the surgical technique have allowed surgeons to perform all-arthroscopic (AA) techniques in rotator cuff repair surgery[6]. The ideal repair of the RC tear must have the potential to withstand physiological loads while allowing simultaneous healing to occur. Currently, no significant superiority of one procedure has been demonstrated over the other[3,7,8], although RCTs in evaluating short- and long-term outcomes of both approaches are limited[9]. Recently, Liu and colleagues performed a RCT in 50 patients who had undergone AA repair and 50 patients who had undergone

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MO repair with a minimum 1-year follow-up. They concluded that the AA procedure has better recovery at short-term follow-ups, while both techniques are equivalent regarding long-term outcomes[10].

Motion analysis techniques can provide a more thorough description of 3-dimensional kinematics and offer a noninvasive, dynamic, quantitative alternative to radiographic methods. Motion analysis has been widely used to assess the motor abilities of people with neurological and musculoskeletal impairments[11]. To our knowledge, there is limited study regarding what biomechanical effect RTC tears have on different motion tasks and muscle activities after surgical treatment of RC tears. In 2007, Pearsall *et al*[12] prospectively evaluated patients who underwent a "mini-open" repair *vs* a completely arthroscopic technique for small to large size rotator cuff tears. They found no statistical difference in outcome between the two groups, indicating that either procedure was efficacious. In 2017, Fritz *et al*[13] applied a quantitative, validated upper extremity model to assess the kinematics and muscle activity of the shoulder following repair of the supraspinatus RC tendon compared to that in healthy shoulders in different activities of daily living (ADLs). They found that the RC repair group participants could accomplish the ADLs within the same time frame and through thoracolumbar joint kinematics, similar to those in the healthy shoulder group participants.

Wearable sensors are acquiring more and more influence in the diagnostic and rehabilitation field to assess the motor abilities of aging populations[14]. In a recent systematic literature review, Carnevale *et al*[15] analyzed the wearable systems for monitoring shoulder kinematics and their applicability in clinical settings and rehabilitation. However, to date, no studies have been carried out with wearable technologies in the assessment of quantitative functional recovery of RC tear healing. The present paper aims at comparing the clinical and biomechanical outcomes of two surgical techniques (AA *vs* MO procedure) to address the painful shoulder syndrome with partial or total supraspinatus tendon tear.

MATERIALS AND METHODS

Study population and design

A total of 88 participants, 50 following RC repair with AA and 38 with MO, were recruited for this study. Each participant provided written informed consent to participate in the study approved by the Local Ethical Committee (ORTHO-SHOULDER, n. 6480, Prot. n. 0054602).

Inclusion criteria were: (1) Aged between 40-years-old and 70-years-old; (2) absence of shoulder pathology in the contralateral side; and (3) surgical procedure between January 2018 and October 2019. Exclusion criteria were: (1) Neurological impairments; (2) other pathological conditions that limited shoulder stability; and (3) previous surgical procedures on the ipsilateral side.

Surgical treatments

The surgeries were performed by single senior shoulder surgeons experienced in both the AA and MO repair techniques. In the case of arthroscopic surgery, the patient is positioned in lateral decubitus with the affected upper limb maintained by dedicated support. The arthroscope was placed in the subacromial space through a standard posterior portal; lateral and posterolateral accessory portals were subsequently established. The tear was adequately mobilized and repaired by attaching the supraspinatus to the prepared greater tuberosity using the single-row repair technique with a suture anchor. The procedure usually starts with the evaluation of the shoulder using the SCOI 15 points exam. The number of anchors and sutures used depended on the tear size and pattern. In the case of mini-open surgery, the patient is positioned in a beach chair position. The approach begins with a 5-cm lateral incision at the anterior border of the acromion. The fibers of the deltoid muscle are split by blunt dissection, and maximal visualization was established using a soft tissue retractor. It is very important not to damage the axillary nerve running close to the distal edge of the incision and to minimize detachment of deltoid muscle fibers from the lateral part of the acromion. A partial bursectomy is performed using dissection scissors. The rest of the procedure is basically the same for both techniques[10]. Both groups used the same rehabilitation protocol.

Follow-up procedures

Each participant underwent concurrent, synchronized motion and electromyography (EMG) analysis. Postoperative outcome measurements were collected by two medical doctors and a bioengineer.

The primary outcome measures were the Constant-Murley score (CMS), the visual analogue scale (VAS) and, the disability of the arm, shoulder, and hand (DASH) score [16,17]. Secondary outcome measures were the biomechanical parameters in terms of the Range of Motion (ROM), quality of movement (velocity and acceleration), and muscle activation.

Biomechanical assessment

Kinematics and EMG data of patients were collected in our Laboratory of Functional Movement through the "Shoulder mobility" protocol. Tasks were explained clearly. The beginning and the end were signaled orally by the researcher to all participants. They were told to perform the movements to the highest position they could reach their preferred speed. They were placed standing in a neutral position to perform shoulder abduction in the coronal plane and shoulder flexion in the sagittal plane. They were told to perform both tasks with the elbow extended, the wrist in a neutral position, and the palm of the hand toward the midline at the beginning and end of the movement. They performed two series of five repetitions of both tasks, with a break of about 3 min between each series.

Upper arm active movements were detected with a wireless inertial sensor (BTS G-Sensor, BTS SpA, Milano, Italy), positioned on the arm aligned with the humerus at the level of the lateral epicondyle. The sensor, which communicates with the receiving unit (personal computer) *via* a Bluetooth link, was used for kinematic information, and BTS EMG-Analyzer software was used for data recording, processing, reporting, and storage. The same software also integrated data from four surface EMG [sEMG, BTS FREEEMG 1000 (BTS SpA, Milano, Italy)] attached to selected muscles according to SENIAM recommendations[18]. Muscle activity was assessed in the injured upper limb muscles (Biceps Brachialis Caput Longus, Upper Trapezius, Deltoid Anterior, Infraspinatus). To detect signals, adhesive Ag/AgCl electrodes (Kendall™ ECG Electrodes H124SG) with an effective diameter of 10 mm and an inter-electrode distance of 20 mm (center to center) were used. Proprietary algorithms fuse sensor data at 200 Hz. After positioning electrodes, patients were instructed to execute the two movements at their natural pace with the inertial sensor synchronized with EMG to identify the different cycles and phases of respectively abduction/adduction and flexion/extension.

ROM (°), acceleration (m/s^2), and velocity (v, m/s) were extracted for each cycle in both forward and return direction from the inertial sensor, in the same way muscle activity has been quantified as root mean square (RMS, uV) and percentage of activation with respect to the peak dynamic value of the cycle (%) for each cycle in both directions.

Statistical analysis

SPSS v23.0 was used for all statistical computations. A P value of ≤ 0.05 was considered statistically significant. Descriptive statistics (mean ± SD) were calculated for age, height, weight, and body mass index (BMI). Standard procedures were used to calculate means and SDs. The Kolmogorov–Smirnov test showed a normal distribution of the data ($P > 0.05$). Independent t-tests have been used to compare the two surgical treatments (arthroscopic *vs* mini-open), while the mixed ANOVA test has been performed to understand if there is an interaction between the two treatments (between factor, arthroscopic *vs* mini-open) on the response of different muscles (within factor) for the selected body plane.

The Pearson χ^2 test was used for between-group comparisons. The Fisher exact test was used for group comparisons when appropriate. Correlation between clinical and self-reported outcomes and biomechanical variables was calculated by Pearson's correlation (r) and P value.

RESULTS

Socio-demographic characteristics of the study sample were shown in Table 1. Eighty-eight patients were finally enrolled in the study [female = 37 (42.1%), mean age = 59.3-years-old] with mean follow-up of 13 mo. Fifty-one patients presented a RC injury on the right side. Fifty patients underwent arthroscopic repair [female = 20 (40%), mean

Table 1 Characteristics of the sample (*n* = 88)

Characteristics	mean ± SD
Age (yr)	59.27 ± 8.94
BMI (kg/m^2)	28.06 ± 4.58
Gender (Female), *n* (%)	37 (42.05)
Affected Side (Right), *n* (%)	51 (57.95)
Surgical treatment, *n* (%)	
AA	50 (56.8)
MO	38 (43.2)
Follow up (mo)	13.62 ± 5.08
VAS	3.16 ± 2.7
CMS	69.5 ± 14.41
DASH	23.01 ± 21.07
SF-12, *n* (%)	
Physical	43.31 (9.53)
Mental	46.53 (11.88)

AA: All-arthroscopic approach; BMI: Body mass index; CMS: Constant-Murley score; DASH: Disability of the Arm, shoulder, and hand; MO: Mini-open approach; SD: Standard deviation; SF-12: The 12-item short form survey; VAS: Visual analogic scale.

age = 58.5-years-old] and 38 underwent repair with a mini-open incision [female = 14 (36.8%), mean age = 60.3-years-old]. At the time of the examination, almost all the patients reported low pain scores and good health status. No differences emerged between groups in terms of demographic features (age, gender, BMI, and affected side).

Table 2 summarized the main results in terms of comparisons of clinical, self-reported, and biomechanical outcomes between the two surgical procedures. Clinical scores (CMS, DASH, and VAS) did not differ significantly between groups as either self-reported health status ($P > 0.05$).

A strong inverse correlation has been found among the two clinical scores of shoulder abilities ($r = -0.63$, $P < 0.01$): lower level of pain and improved ability to carry out the normal daily activities of the patient (increasing CMS scores) were associated with a lower level of shoulder impairment (decreasing DASH scores). Furthermore, only the DASH score was positively related to pain level (VAS, $r = 0.68$) and both physical and mental components of SF-12, indicating that lower levels of shoulder impairment were associated with lower pain and better health status.

Significant differences emerged in terms of mean activation of the upper trapezius muscle in both abduction and flexion movements. In the AA group, the trapezius muscle was more active than the MO group during both the forward and return phase of both abduction and flexion movements, thus indicating a significant contribution of this muscle in joint mobility and stability.

However, no significant differences were found between groups in the post-operative range of motion either in sagittal (abduction, $P = 0.41$) or frontal planes (flexion-extension, $P = 0.34$). Moreover, we observed a significant difference between groups in the average velocity required to complete the flexion movement either in the forward or return phase. Patients who were treated with the MO surgery reported significantly lower velocity in the execution of the movement than patients in the AA group. A possible explanation may be found in the different contributions of observed muscles' recruitment during the movement: in the AA group, the deltoid anterior and upper trapezius showed a high percentage of mean activation, while in the MO group, the deltoid anterior contributed more than fifty percent of the overall activation.

An overview of the mean contribution of each recorded muscle during the movement is shown in Figure 1. The results of mixed ANOVA revealed that significant interactions were present between the adopted surgical procedure and the contribution of muscles (%) in both abduction ($F_{1.618} = 3.707$, $P = 0.05$) and flexion ($F_{2.035} = 8.732$, $P < 0.01$) movements. In the abduction movement, the activation of the deltoid

Table 2 Clinical, self-reported health and biomechanical outcomes according to the surgical treatment

	AA (*n* = 50)	MO (*n* = 38)	*P* value
Clinical score			
VAS	3 (2.62)	3.37 (2.97)	0.78
CONSTANT	65 (10.32)	75.12 (17.38)	0.14
DASH	24.12 (20.59)	21.63 (23)	0.81
Self-reported health measures			
$SF\text{-}12_{PH}$	43.17 (9.41)	43.5 (10.34)	0.94
$SF\text{-}12_{ME}$	48.86 (9.86)	43.63 (14.16)	0.37
Biomechanical tests			
ROM_{ABD}	110.88 (21.9)	120.76 (27.91)	0.41
$RMS_{ABD,F,TRAP}$	125.78 (77.49)	54.52 (58.25)	0.05[1]
$RMS_{ABD,R,TRAP}$	59.5 (30.42)	28.34 (26.39)	0.04[1]
$PERC_{ABD,BBCL}$	8.23 (2.64)	19.23 (12.15)	0.04[1]
$PERC_{ABD,TRAP}$	35.99 (14.39)	19.57 (15.97)	0.04[1]
ROM_{FLEX}	127.95 (25.55)	141.75 (33.51)	0.34
$VEL_{FLEX,F}$	73.97 (31.74)	46.26 (16.04)	0.03[1]
$VEL_{FLEX,R}$	88.65 (30.9)	56.13 (23.72)	0.03[1]
$RMS_{FLEX,F,TRAP}$	91.19 (49.57)	41.35 (45.43)	0.04[1]
$RMS_{FLEX,R,TRAP}$	47.15 (24.04)	22.99 (19.58)	0.04[1]
$PERC_{FLEX,DLTA}$	43.18 (6.9)	58.65 (9.6)	< 0.01[1]
$PERC_{FLEX,TRAP}$	29.97 (11.21)	14.2 (9.04)	< 0.01[1]

[1]Significant differences. ABD: Abduction; F: Forward; R: Return; BBCL: Biceps brachialis caput longus; CMS: Constant-Murley score; DASH: Disability of the arm, shoulder, and hand; DLTA: Deltoid anterior; ME: Mental components; PERC: Peak dynamic value of the cycle; PH: Physical component; RMS: Root mean square; ROM: Range of motion; SF-12: The 12-item short form survey; TRAP: Upper trapezius; VAS: Visual analogic scale; VEL: Velocity; FLEX: Flexion.

anterior was significantly higher than other muscles while the contribution of upper trapezius and infraspinatus muscles did not show any difference between each other. Similar results were found in the flexion movement, where the percentage activation of the deltoid anterior was significantly higher than other contributions.

DISCUSSION

Rotator cuff tears are the most common shoulder injury. Treatment options include nonoperative management, arthroscopic debridement with a biceps tenotomy, or tenodesis, partial repair, complete repair, muscle-tendon transfer, superior capsular reconstruction, patch augmentation, and reverse total shoulder arthroplasty[19]. The treatment can be performed with two different approaches: Mini-open (MO) or all-arthroscopic (AA) technique. The ideal repair of the RC tear should withstand the physiological loads while allowing simultaneous tendon healing to occur. Recently, Liu *et al*[10] performed an RCT in 50 patients who had undergone AA repair and 50 patients who had undergone MO repair with a minimum 1-year follow-up. They concluded that the AA procedure has better recovery at short-term follow-ups, while both techniques are equivalent regarding long-term outcomes. Although there is still an open debate on the superiority of surgical treatment over the other[20,21], few attempts have been made in promoting the use of motion capture technologies to analyze kinematics and muscle activity of shoulder mobility in the postoperative phase, especially with the advancing in wearable devices.

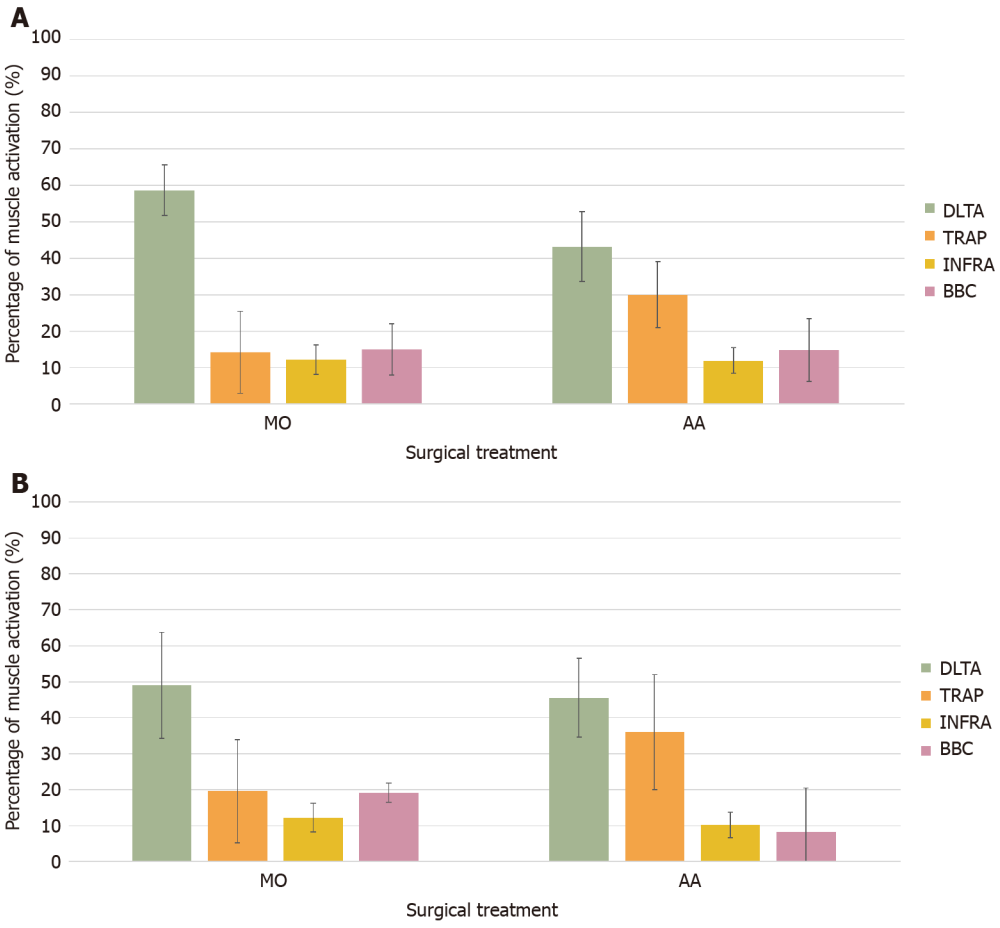

Figure 1 Bar plots of the percentage of activation of all selected muscle. A: During flexion/extension movements for the two surgical treatments; B: During abduction/adduction movements for the two surgical treatments. AA: All-arthroscopic approach; BBC: Biceps brachialis caput longus; DLTA: Deltoid anterior; INFRA: Infraspinatus; MO: Mini-open approach; TRAP: Upper trapezius.

The present cross-sectional study enrolled a sample of patients who had undergone AA/MO repair with a minimum 1-year follow-up. Patients were then evaluated using both clinical and biomechanical tests to assess whether there were relevant effects of the surgical treatment on the selected outcomes.

Our findings reported no statistically significant difference in terms of clinical scores and joint excursions after RC repair, in line with what emerged from previous studies [10,12,21]. However, significant differences emerged in terms of other kinematic factors and muscle activation. Patients treated with the MO surgery reported significantly lower velocities in the execution of the movement compared with the AA group. The upper trapezius muscle in the AA group showed higher mean activation (RMS) than the MO group during both the forward and return phases of both abduction and flexion movements. Furthermore, in the AA group, deltoid anterior and upper trapezius showed a higher percentage of mean activation, while in the MO group deltoid anterior contributed more than fifty percent of the overall activation.

While different normalization processes and range of movement prevent direct comparison with the current study, previous EMG research during coronal plane abduction indicates that high contraction intensities throughout the abduction movement in healthy subjects were seen for glenohumeral and scapulothoracic prime movers such as anterior and middle deltoid, supraspinatus, serratus anterior, rhomboids, and upper, middle, and lower trapezius[22].

Rehabilitation probably plays a role in the increased ROM and muscular strength, due to the position and kinematics of the scapula. They can influence patient symptoms. Consequently, motivation and cooperation during the rehabilitation process can influence the results[23].

Previous investigations on the role of shoulder muscles in flexion and abduction movements have been carried out mostly in healthy subjects[24,25] showing that deltoids were the largest muscle contributor to humeral elevation during flexion tasks, while trapezius and serratus anterior combined to do more work than deltoids for every task including flexion.

CONCLUSION

Wearable technologies could support clinical practice since they provide clinical information during the performance of a motor task, and their adoption should grow in shoulder evaluation and therapy. The present work represents a preliminary attempt at promoting novel wearable technologies in clinical practice. We compared the postoperative effects of two surgical treatments through clinical scores, standardized protocol, and wearable sensors. Our findings were almost in line with previous investigations regarding clinical scores. However, our analysis highlighted a different response in muscle activation during the shoulder movement in both flexion/extension and abduction/adduction. A significant interaction effect emerged for mean activation of deltoid anterior and upper trapezius with surgical procedure, thus indicating that the adopted treatment influenced the functional recovery of the joint. Further studies with larger samples are needed to confirm our findings and open new scenarios in surgical planning and rehabilitation of shoulder instability.

ARTICLE HIGHLIGHTS

Research background

Rotator cuff (RC) tears are one of the most frequent pathologies within the shoulder girdle. Hand dominance and older age are associated with RC tears. Two different surgical procedures, the mini-open (MO) and all-arthroscopic (AA) approach represented the standard of treatment.

Research motivation

To understand if AA and MO procedures provide comparable clinical results in the repairment of RC tears.

Research objectives

The present paper aims at comparing the clinical and biomechanical outcomes of two surgical techniques (AA *vs* MO procedure) to address the painful shoulder syndrome with partial or total supraspinatus tendon tear.

Research methods

Eighty-eight participants, 50 following RC repair with AA and 38 with MO approach, were recruited in the present cross-sectional case-control study. All the patients underwent postoperative clinical evaluation for pain, impairment, and disability and limitation in daily activity.

Research results

No statistically significant differences between the two procedures were observed in either main clinical score or range of motion. A significant increase in velocity during the movement execution and a higher contribution of upper trapezius muscles were found in the AA group compared with MO patients.

Research conclusions

In terms of clinical scores, our findings were in line with previous results. However, the use of technology-based assessment of shoulder mobility has revealed significant differences between the two techniques in terms of mean velocity and scheme of muscle activation.

Research perspectives

Further studies with larger samples are needed to confirm such findings and open new scenarios in the surgical planning and the rehabilitation of shoulder instability.

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ORIGINAL ARTICLE

Retrospective Study

Rates of readmission and reoperation after operative management of midshaft clavicle fractures in adolescents

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Institutional review board statement: This study is a database study using data obtained from the Healthcare Cost and Utilization Project (HCUP). Therefore, no IRB approval letter was required.

Informed consent statement: This retrospective study was IRB exempt and no signed consent forms were required.

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

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Abstract

BACKGROUND

The national rates of readmission and reoperation after open reduction internal fixation (ORIF) of midshaft clavicle fractures in adolescents is unknown.

AIM

To determine rates of and risk factors for readmission and reoperation after ORIF of midshaft clavicle fractures in adolescents.

METHODS

This retrospective study utilized data from the Healthcare Cost and Utilization Project State Inpatient Database for California and Florida and included 11728 patients 10–18 years of age that underwent ORIF of midshaft clavicle fracture between 2005 and 2012. Readmissions within ninety days, reoperations within two years, and differences in patient demographic factors were determined through descriptive, univariate, and multivariate analyses.

RESULTS

In total, 3.29% (n = 11) of patients were readmitted within 90 d to a hospital at an average of 18.91 ± 18 d after discharge, while 15.87% (n = 53) of patients underwent a reoperation within two years at an average of 209.53 ± 151 d since the index surgery. The most common reason for readmission was a postoperative infection (n < 10). Reasons for reoperation included implant removal (n = 49) at an average time of 202.39 ± 138 d after surgery, and revision ORIF (n < 10) with an average time of 297 ± 289 d after index surgery. The odds of reoperation were

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higher for females ($P < 0.01$) and outpatients ($P < 0.01$), while the odds of reoperation were lower for patients who underwent surgery in California ($P = 0.02$).

CONCLUSION
There is a low rate of readmission and a high rate of reoperation after ORIF for midshaft clavicle fractures in adolescents. There are significant differences for reoperation based on patient sex, location, and hospital type.

Key Words: Adolescent; Clavicle fracture; Reoperation; Readmission

Core Tip: There is a low rate of readmission and a high rate of reoperation after open reduction internal fixation for midshaft clavicle fractures in adolescents. There are significant differences for reoperation based on patient sex, location, and hospital type.

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INTRODUCTION

In the past decade, there has been a shift in the paradigm for the treatment of clavicle fractures[1]. In both adolescents and adults, the trend has been towards increasing rates of operative management[1-4]. In the pediatric population, demand for return to sport and year-round sporting activity have also made surgical management a more popular treatment option[3]. However, it is unclear if the literature supports the superiority of open reduction internal fixation (ORIF) to nonoperative management in the management of closed midshaft clavicle fractures in adolescents. Recent studies have shown improved outcomes with ORIF in skeletally mature patients[5-7]; however, studies in adolescent patients have shown no difference in functional outcomes[8,9]. Recent literature also suggests surgical complication rates ranging from 21%-86% with close to 50% of patients requiring a second surgery for implant removal [10-12]. To our knowledge, there are no studies that have examined the rates of readmission and reoperation after ORIF of midshaft clavicle fractures in adolescents.

The purpose of this paper is to determine the rates of 90-d readmission and two-year reoperation after surgical management of midshaft clavicle fractures in adolescents. We hypothesized that the rates of readmission and reoperation would be low after surgical management of clavicle fractures in adolescents.

MATERIALS AND METHODS

The Healthcare Cost and Utilization Project (HCUP) State Inpatient Database (SID) was evaluated for the years 2005-2012. This database, sponsored by the Agency for Healthcare Research and Quality, provides publicly available all-payer statewide data related to inpatient discharge records from community hospitals in participating states [13]. At the time of data collection, 48 States and the District of Columbia provide inpatient data to HCUP[14]. Data for this study were obtained from the Florida (2005-2012) and California (2005-2009) HCUP SID. These states were chosen due to the availability of data over consecutive years, which allowed for a comprehensive review of ninety-day readmissions and two-year reoperations. This study was exempt from Institutional Review Board oversight.

International Classification of Diseases, 9th Revision Clinical Modification (ICD-9 CM) diagnosis codes, and the current procedural terminology (CPT) codes were used to identify adolescent patients between the ages of 10 and 18 inclusive, who presented

with a midshaft clavicle fracture and underwent an ORIF from January 1, 2005 to December 31, 2012 (ICD-9-CM 79.39, CPT: 23515). Data collection included patient age, sex, race, insurance type, hospital type, and income percentile. We determined the rates of readmission within ninety-days and reoperation within two-years. We compared demographic and socioeconomic factors to determine predictors of readmission and reoperation.

Statistical methods

Descriptive statistics were performed including *t*-test and χ^2 analysis to determine statistical significance of adolescent reoperation rates. Multivariate logistic regression was used to compare differences between patients that did or did not require a readmission, and patients that did or did not require a reoperation. Specific predictor variables that were controlled for and analyzed included patient sex, age, race, payer type, hospital type, and state. All statistical analysis was performed using SAS Studio statistical software. Statistical significance was set at $P < 0.05$.

RESULTS

Overall, 11728 adolescent clavicle fractures were analyzed between 2005-2012 in Florida and 2005-2009 in California. Within this cohort, there were 334 clavicle fractures that were managed operatively (2.8%). The surgical cohort consisted of 80.5% ($n = 265$) male and 19.5% ($n = 64$) female patients, and the mean age at time of injury was 16.0 ± 1.7 years (Range: 10-18 years). In total, 3.3% ($n = 11$) of patients were readmitted within 90 d to a hospital at an average of 18.9 ± 18 d after discharge, while 15.9% ($n = 53$) of patients underwent a reoperation within two years at an average of 209.5 ± 151 d since the index surgery.

Of the 334 patients who underwent clavicle ORIF, only 11 patients were readmitted within 90 d after discharge, and the most common reason was a postoperative infection ($n < 10$). Per database reporting restrictions, there is insufficient data for additional analysis.

The most common reason for reoperation was removal of implant (92.5%, $n = 49$) at an average of 202.4 ± 138 d after index surgery. The second most common reason for reoperation was revision ORIF (7.6%, $n = 4$) at an average of 297 ± 289 d after index surgery. There were a greater number of male patients who underwent ORIF (68% *vs* 32%, $P = 0.01$) compared to females, and there were more reoperations in the state of Florida compared to California (98% *vs* 2%) ($P < 0.01$) over the study period (Table 1). There were no significant differences in age, race, payer type, median income quartile, and hospital type observed in patients who did or did not have a reoperation within two years ($P > 0.05$). In the multivariate analysis, female patients had greater odds of undergoing reoperation compared to male patients [odds ratio (OR) = 3.49 (1.66-7.33), $P < 0.01$], and patients in California had lower odds of having a reoperation than patients in Florida [OR = 0.08 (0.01-0.66), $P = 0.02$] (Table 2). Additionally, it was demonstrated that patients who had their index surgery at an outpatient center had greater odds of having a reoperation when compared to patients who had their index surgery at a community hospital [OR = 10.76 (2.04-56.83), $P < 0.01$].

DISCUSSION

Recent literature has suggested improved functional outcomes after ORIF for displaced midshaft clavicle fractures in adults[5]. However, these studies have not focused on pediatric or adolescent patients, and the superiority of surgical management in these patients is unclear. There has also been a recent increase in the rates of surgical management of midshaft clavicle fractures in adolescents, and it is important that we understand the rates and reasons for readmission and reoperation after surgery[2,4]. A few studies have described such rates, but these studies have been limited by small samples sizes. To our knowledge, this is the first study to investigate these factors using a large database[12,15-17].

In this study, we found a low rate of readmission but a significantly high rate of reoperation after surgical management of midshaft clavicle fractures in adolescents. Although rates of readmission were low, the most common reason for readmission was postoperative infection. In a previous study by Li *et al*[12], 2/85 pediatric patients experienced a wound dehiscence or infection after ORIF. The rate of readmission is

Table 1 Adolescent fracture demographics: Reoperation *vs* no reoperation

Predictor variables		Cohort proportion (%)	Cohort total (*n*)	Cohort proportion (%)	Cohort total (*n*)	*P*-value
Sex	Male	0.68	36	0.83	229	0.01
	Female	0.32	17	0.17	47	
Race	White	0.79	42	0.78	209	0.86
	Hispanic	0.13	7	0.12	31	
	Black	0.04	2	0.05	14	
	Other	0.02	1	0.05	13	
Payer type	Commercial	0.74	39	0.62	175	0.47
	Medicaid	0.19	10	0.24	67	
	Self-pay	0.02	1	0.06	17	
	Other	0.06	3	0.08	22	
State	CA	0.02	1	0.20	55	< 0.01
	FL	0.98	52	0.80	226	
Median income quartile	0-25th (%)	0.16	7	0.20	42	0.64
	26th-50th (%)	0.34	16	0.34	70	
	51st-75th (%)	0.28	13	0.29	61	
	76th-100th (%)	0.23	11	0.16	34	
Hospital type	Academic	0.04	2	0.07	19	0.07
	Children's	0.00	0	0.02	6	
	Community	0.75	40	0.77	215	
	County	0.13	7	0.14	38	
	Outpatient	0.08	4	0.01	3	
Age	Mean	15.87 ± 1.8	53	16.08 ± 1.7	281	0.41

likely low after surgical management of midshaft clavicle fractures in adolescents, but additional multicenter studies are needed to validate these results.

Most reoperations were performed due to removal of implant (n = 49; 92.45%). This finding is comparable to other reports in the literature. For example, Vander *et al*[15] reported 17.6% of adolescent patients underwent implant removal after the operative treatment of a closed midshaft clavicle fracture. This instrumentation removal rate is much lower compared to other studies that have reported rates ranging from 41%-59% [12,15-17]. Reasons for these differences could be related to population differences and differences in regional surgical practice and trends. Overall the high rate of reoperation (15.9%) found among adolescents surgically treated for midshaft clavicle fractures is similar to the reoperation rate reported by Kruppa *et al*[18] among children and adolescents surgically treated for femoral shaft fractures (14.3%).

We found significant differences in patients that did or did not undergo a reoperation. We found that female adolescents had a 249% greater odds of undergoing reoperation, which contrasts with findings published by Li *et al*[12]. In the adult literature, female sex has been identified as a risk factor for implant removal after ORIF[19,20]. Reasons for this difference have been postulated to relate to a thinner physique and implant irritation with clothing[19-21]. Thus, this may explain why adolescent females were more likely to undergo reoperations in this study. We also found that patients who had their initial surgery performed at an outpatient center had a higher likelihood to undergo reoperation. Additionally, patients in Florida had a higher likelihood to undergo reoperation. Such differences may reflect differences in regional practice and require further investigation.

The results from this study have several implications to clinical practice. First, it provides surgeons with a general idea of the rates of readmission and reoperation after surgical management. Secondly, it allows surgeons to adequately counsel patients regarding risk factors for reoperation. Surgeons may want to consider such characteristics when counseling patients and parents prior to ORIF to ensure no additional

Table 2 Adolescent fracture demographics: Multivariate analysis

Predictor variables	Odds ratio	95%CI	*P* value
Sex			
Female *vs* male	3.49	1.66-7.33	< 0.01
Race			
Black *vs* white	1.03	0.20-5.19	0.97
Hispanic *vs* white	1.23	0.45-3.37	0.69
Other *vs* white	0.52	0.06-4.50	0.55
Payer type			
Commercial *vs* self-pay	4.70	0.52-42.17	0.17
Medicaid *vs* self-pay	4.67	0.49-44.93	0.18
Other *vs* self-pay	2.96	0.24-37.06	0.40
State			
CA *vs* FL	0.08	0.01-0.66	0.02
Hospital type			
Academic *vs* community	0.55	0.11-2.75	0.46
Children's *vs* community	< 0.01	0.01 < x < 999	0.98
County *vs* community	0.92	0.36-2.33	0.86
Outpatient *vs* community	10.76	2.04-56.83	< 0.01
Age	0.91	0.75-1.10	0.33

concerns arise if a reoperation is later needed. For example, it is more likely that female patients will undergo removal of implant after surgical management. Finally, these results provide the framework for additional research to investigate geographic differences and differences in rates based on hospital setting.

Several limitations were present. Given the nature of database studies, we were limited to the data available and did not have access to clinical or radiographic outcomes or patient-reported outcome measures, which may be valuable in future studies. Additionally, we are unable to clearly investigate reasons for readmission and reoperation due to limitations of the database. We were also unable to determine how many patients had implant-related complaints *vs* elective implant removal, which may have been recommended by the pediatric surgeon[12]. This study was also limited to two states (California and Florida) due to the lack of data available over consecutive years in the remaining states. Additional studies are needed to understand the applicability of the results nationally and improve the generalizability of these results. As this study is unable to comment on long-term outcomes, future prospective studies are needed to review short, mid, and long-term outcomes, patient reported outcomes, and complications. Despite these limitations, this study is the first to our knowledge to explore readmission and reoperation rates among surgically treated clavicle fractures in adolescents using a large database cohort.

CONCLUSION

In conclusion, the rates of readmission are low after surgical management of midshaft clavicle fractures in adolescents. However, the rates of reoperation are relatively high, and removal of implant remains the primary reason for reoperation. Rates of reoperation significantly differ based on sex and the geographic location of the index surgery. Future multicenter prospective studies are needed to further investigate these findings and ultimately decrease the need for readmission and reoperation after surgical management of midshaft clavicle fractures in adolescents.

ARTICLE HIGHLIGHTS

Research background

In the past decade, there has been a shift in the paradigm for the treatment of clavicle fractures. In both adolescents and adults, the trend has been towards increasing rates of operative management.

Research motivation

It is unclear if the literature supports the superiority of open reduction internal fixation (ORIF) to nonoperative management in the management of closed midshaft clavicle fractures in adolescents.

Research objectives

The primary objective of this paper is to determine the rates of 90-d readmission and two-year reoperation after surgical management of midshaft clavicle fractures in adolescents.

Research methods

This retrospective study utilized data from the Healthcare Cost and Utilization Project State Inpatient Database for California and Florida and included patients 10–18 years of age that underwent ORIF of midshaft clavicle fracture between 2005 and 2012.

Research results

In total, 3.29% (n = 11) of patients were readmitted within 90 days to a hospital at an average of 18.91 ± 18 d after discharge, while 15.87% (n = 53) of patients underwent a reoperation within two years at an average of 209.53 ± 151 d since the index surgery. The most common reason for readmission was a postoperative infection (n < 10). Reasons for reoperation included implant removal (n = 49) at an average time of 202.39 ± 138 d after surgery, and revision ORIF (n < 10) with an average time of 297 ± 289 days after index surgery. The odds of reoperation were higher for females (P < 0.01) and outpatients (P < 0.01), while the odds of reoperation were lower for patients who underwent surgery in California (P = 0.02).

Research conclusions

There is a low rate of readmission and a high rate of reoperation after ORIF for midshaft clavicle fractures in adolescents. There are significant differences for reoperation based on patient sex, location, and hospital type.

Research perspectives

Future studies are needed to understand the applicability of the results nationally and improve the generalizability of these results. Additional prospective studies are needed to review short, mid, long-term outcomes, patient reported outcomes, and complications for the patient population.

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ORIGINAL ARTICLE

Retrospective Study

Surgical treatment outcome of painful traumatic neuroma of the infrapatellar branch of the saphenous nerve during total knee arthroplasty

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Abstract

BACKGROUND

Development of infrapatellar saphenous neuroma (ISN) is a well-recognized reason for knee pain following total knee arthroplasty (TKA). So far, very few studies have addressed the development of painful ISN after TKA and its impact on functional outcome and patient satisfaction.

AIM

To present the results of surgical treatment for ISN after primary TKA, the level of pain relief, and the improvement of knee motion and function.

METHODS

Fifteen patients (13 women, 2 men) with persistent medial pain for more than six months after primary TKA, due to osteoarthritis, underwent surgical excision of ISN. ISN diagnosis was confirmed with the presence of Tinel's sign along the course of the infrapatellar branch of the saphenous nerve and with pain relief after selective nerve block using local anesthetic. Component loosening, malalignment, instability and infection were excluded systematically in all patients as a source of pain. Pain relief in terms of visual analog scale (VAS), active knee range of motion (ROM), and the Knee Society Score (KSS) for pain and function were evaluated preoperatively and at least six months postoperatively.

RESULTS

The mean patients' age was 71.3 ± 5.4 years old. The mean interval between TKA and neuroma excision was 10 mo (range, 6 to 14 mo), while the mean follow-up was 8 mo (range: 6 to 11 mo). All 15 patients experienced almost complete immediate pain relief and resolution of allodynia and hyperesthesia after surgery. Pain on the VAS scale improved from 8.6 ± 1.3 preoperatively to 0.8 ± 0.9 at the final follow-up (P = 0.001). KSS pain and function scores were improved from 49.3

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± 5.9 and 62.7 ± 12.8 before surgery to 91.8 ± 4.2 and 75.3 ± 11.3 after surgery, respectively (P = 0.001 and P = 0.015). Active knee ROM was also increased postoperatively from 96 ± 4 to 105 ± 6 degrees (P = 0.001). There were no complications and no further operations required.

CONCLUSION
ISN should be considered a potential cause of persistent pain following TKA. Neuroma excision not only provides immediate pain relief and resolution of symptoms but may also improve the knee range of motion.

Key Words: Total knee arthroplasty; Infrapatellar branch of saphenous nerve; Neuroma; Neurogenic pain; Knee osteoarthritis

Core Tip: Development of infrapatellar saphenous neuroma after total knee arthroplasty should be considered a potential reason for persistent pain in an otherwise non-infected, well-fixed, and well-aligned joint. Before total knee arthroplasty, patients should be warned for the risk of nerve injury and neuroma formation. Neuroma excision provides excellent pain relief and improves knee function and range of motion.

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INTRODUCTION

Postoperative pain after total knee arthroplasty (TKA) is a complex and multifactorial issue. Infection, loosening, instability, component malalignment, poor ligament balance, and complex regional pain syndrome may lead to knee pain, stiffness, and poor functional outcome[1,2].

Although very rare, the development of infrapatellar saphenous neuroma (ISN) is a well-recognized factor of knee pain following not only TKA but also patellar and hamstring tendon harvest during anterior cruciate ligament reconstruction, open and arthroscopic repairs, tibial nailing, and vascular surgery of the lower extremity[3,4]. The prevalence of postoperative infrapatellar branch of the saphenous nerve (IPSN) damage has been reported to range between 0.5 to 53%[4] and may be apparent up to 9.7% and 21% of patients after primary and revision TKA, respectively[5], causing neuralgia or hypersensitivity, paresthesia, and loss of sensation at the medial joint area [4].

The IPSN is a purely sensory nerve that derives from the saphenous nerve. The latter arises as a division of the femoral nerve and leaves the adductor canal between the tendons of gracilis and semitendinosus[6]. It then divides into the main saphenous branch, which continues down to the ankle, and the IPSN that crosses the inferior knee from medial to lateral and innervates the skin below the patella as well as the anterior inferior knee capsule[3]. During TKA, the nerve is inevitably sectioned during the midline skin incision and anteromedial approach. Medial retractors, knee position in flexion, and a thigh tourniquet may further increase the tension over the course of the nerve and impede uneventful recovery[7]. Although the area of postoperative hypesthesia at the distribution of IPSN is usually decreased during the time, a painful neuroma can occur and further surgical intervention may be required[8]. The risk is even higher when the nerve is traumatized close to its origin and before its terminal branches[9].

So far, very few studies have addressed the issue of the development of painful ISN after TKA, and no clear evidence regarding its importance on functional outcome and patient satisfaction exists. In the current clinical study, we present the results of

surgical treatment of ISN after primary TKA. The level of pain relief and improvement of knee motion and function are also described.

MATERIALS AND METHODS

Between 2012 and 2018, 2054 patients underwent primary TKA due to osteoarthritis in our department. Patients with previous open knee operations and skin incisions were excluded from further evaluation. All operations were performed using a thigh tourniquet and a standard midline skin incision with a medial parapatellar knee approach were applied. Twenty-nine patients (1.4%) complained of postoperative medial knee pain that was frequently accompanied by burning and tingling sensation, hyperesthesia, and allodynia after the index procedure.

All patients were evaluated with X-Rays, computed tomography (CT) scan, and bone scan to exclude any component malalignment and/or implant failure. Infection was also ruled out performing erythrocyte sedimentation rate and C-reactive protein blood tests as well as knee aspiration. The joint fluid sample was sent to laboratory for culture and evaluation of synovial white blood (WBC) and its proportion of polymorphonuclear (PMN) cells according to the criteria for the diagnosis of periprosthetic joint infection as proposed by the Musculoskeletal Infection Society and the International Consensus Meeting[10]. WBC > 3.000 cells/μL and PMN > 80% were considered indicative for knee infection and additional diagnostic and operative procedures were performed[10].

The diagnosis of ISN was based on the presence of Tinel's sign along the course of IPSN and confirmed with an injection of 1 mL lidocaine 1% and 2 mL ropivacaine 0.2%. In case of pain relief, the patient was suggested to follow a protocol that included injection with betamethasone acetate/betamethasone sodium phosphate (Celestone Chronodose) at the neuroma site and pregabalin intake (50 mg or 75 mg three times per day).

Fifteen patients (13 women, 2 men) failed to respond to conservative treatment (partial or temporary resolution of symptoms) and therefore required neuroma excision. The latter occurred *via* medial skin incision following the course of IPSN and the area of greatest tenderness that was marked before surgery (Figure 1). After dissection of the subcutaneous soft tissues, the nerve was explored and a neuroma surrounded by scar tissue was identified (Figure 2 and Figure 3). The fibrous nodule containing the neuroma was removed. The nerve was sharply transected approximately 1-2 cm proximal to the neuroma and its proximal stump was buried to adjacent soft tissues to prevent recurrence (Figure 4). Postoperatively, no restrictions in terms of motion and weight-bearing were applied and patients were encouraged to perform knee flexion and extension exercises and gradually increase their activity level. Pregabalin was continued to a lower dose of 25 mg two or three times per day for one more month.

Active knee range of motion (ROM), visual analog scale (VAS) for pain, Knee Society Score (KSS) for pain and function were evaluated before and at least 6 mo after neuroma excision[11]. Interpretation of the VAS change scores was based on the minimum clinically important difference (MCID) for adequate pain control of -3 (in a VAS scale from 0 to 10)[12,13].

Mean preoperative and follow-up values were compared with Wilcoxon signed ranks test. The level of significance was set at $P < 0.05$ and SPSS software version 24 was used.

RESULTS

The mean patients' age was 71.3 ± 5.4 years old. The mean interval between TKA and neuroma excision was 10 mo (range, 6 to 14 mo) and the mean follow-up was 8 mo (range: 6 to 11 mo). Patients' demographics are presented in Table 1.

All patients experienced almost immediate and complete pain relief and resolution of allodynia and hyperesthesia after surgery (Table 2). Mean pain relief in terms of VAS exceeded the MCID for adequate pain control (mean difference -7.8 ± 1.9, $P = 0.001$). Only two patients reported some residual numbness that gradually resolved during the time but didn't cause any functional deficit.

The KSS pain and function scores were significantly improved from 49.3 ± 5.9 and 62.7 ± 12.8 before surgery to 91.8 ± 4.2 and 75.3 ± 11.3 after surgery, respectively ($P = 0.001$ and $P = 0.015$). Active knee ROM was also increased postoperatively from 96 ± 4

Table 1 Patients' demographics

Patient No.	Gender	Age, yr	Height, m	Weight, kg	BMI	Interval from TKA to neuroma excision, mo	Follow-up, mo
1	F	70	1.56	68	27.9	10	6
2	F	72	1.53	72	30.8	8	8
3	F	69	1.65	82	30.1	13	7
4	M	76	1.75	95	31.0	9	11
5	F	65	1.58	70	28.0	8	9
6	F	71	1.67	83	29.8	11	8
7	F	74	1.53	51	21.8	9	7
8	F	70	1.55	69	28.7	6	9
9	F	57	1.68	81	28.7	11	6
10	M	72	1.71	85	29.1	11	7
11	F	70	1.53	73	31.2	6	8
12	F	79	1.57	65	26.4	10	10
13	F	72	1.54	50	21.1	13	8
14	F	79	1.54	79	33.3	10	6
15	F	74	1.52	76	32.9	14	10
mean ± SD		71.3 ± 5.4	1.59 ± 0.08	73.3 ± 12.1	28.7 ± 3.5	10 ± 2	8 ± 2

F: Female; M: Male; BMI: Body mass index; TKA: Total knee arthroplasty.

Table 2 Pain relief, range of motion, and functional outcomes

VAS for pain		Active ROM (degrees)		KSS pain		KSS function
Postoperative	Preoperative	Postoperative	Preoperative	Postoperative	Preoperative	Postoperative
0.8 ± 0.9	96 ± 4	105 ± 6	49.3 ± 5.9	91.8 ± 4.2	62.7 ± 12.8	75.3 ± 11.3
[a]P = 0.001		[a]P = 0.001		[a]P = 0.001		[a]P = 0.015

[a]Wilcoxon signed ranks test.
VAS: Visual Analog Scale; ROM: Range of motion; KSS: Knee Society Score.

to 105 ± 6 degrees (P = 0.001) (Table 2).

There were no complications and no further operations required.

DISCUSSION

Iatrogenic injury of IPSN is a rare cause of postoperative pain and stiffness after TKA. The diagnosis is one of the exclusion as no specific clinical and laboratory findings can accurately diagnose the condition. Periprosthetic joint infection, malalignment, and ligamentous instability should be ruled out before the suspicion of neuroma development is taken into consideration[1]. The presence of positive Tinel's sign along the course of the nerve and the marked improvement of the symptoms of more than 50% after diagnostic injection can confirm to a great extent the neurogenic source of pain and disability. So far, very few studies with a small number of patients and case reports have described the impact of the development of ISN on knee function after TKA and the results of conservative or surgical treatment.

Conservative management is usually the first approach utilized, including local injection of analgesics, corticosteroids, and physical therapy[14]. However, the published results are quite conflicting regarding their efficacy in alleviating pain and improving knee function. Clendenen *et al*[7] found that local treatment with

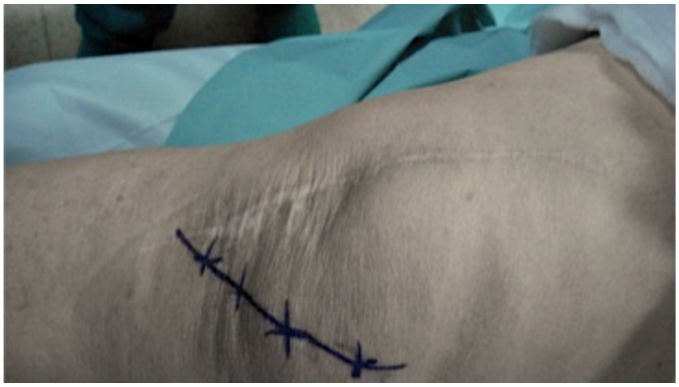

Figure 1 Postoperative neuroma in a 76 years-old patient after total knee arthroplasty (Case 4). Medial side knee incision following the course of infrapatellar branch of the saphenous nerve.

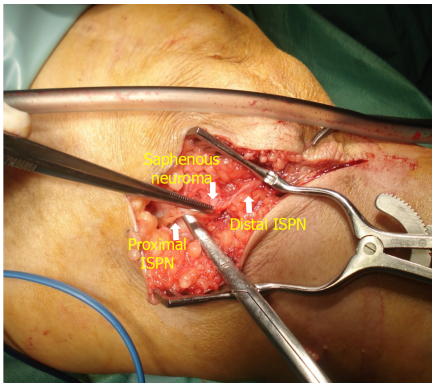

Figure 2 Surgical exploration revealed neuroma of the infrapatellar branch of the saphenous nerve. ISPN: Infrapatellar branch of the saphenous nerve.

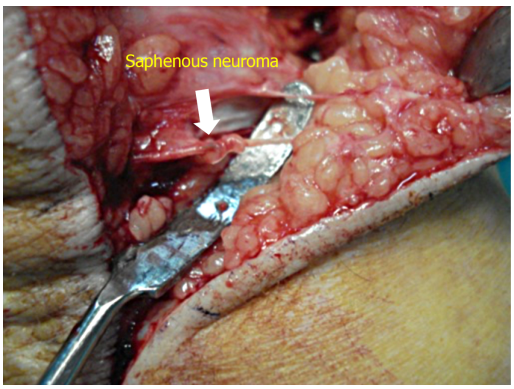

Figure 3 Development of painful saphenous neuroma in a 79 years-old patient after primary total knee arthroplasty (Case 12). The damaged and degenerated nerve was surrounded by scar tissue.

hydrodissection of the IPSN from the adjacent interfascial planes followed by corticosteroid injection was effective in reducing persistent medial knee pain after TKA in nine out of 16 patients (VAS score of 0 or 1) with one (eight patients) or two (one patient) procedures. Three patients reported less pain improvement to VAS levels of 3 to 4. Of the remaining four patients, two did not have improvement with VAS scores of 8, and two underwent subsequent radiofrequency ablation of the IPSN with resolution of pain in one patient. Similarly, Shi *et al*[14] found that after ultrasound-guided local treatment by hydrodissection and corticosteroid injection of ISN, the median numeric VAS pain score was improved from 9 (range, 5 to 10) to 5 (range, 0 to 10) at both one-month and midterm follow-up ($P < 0.001$). The authors reported that females and a previous TKA revision were associated with less pain relief and poor results. On the

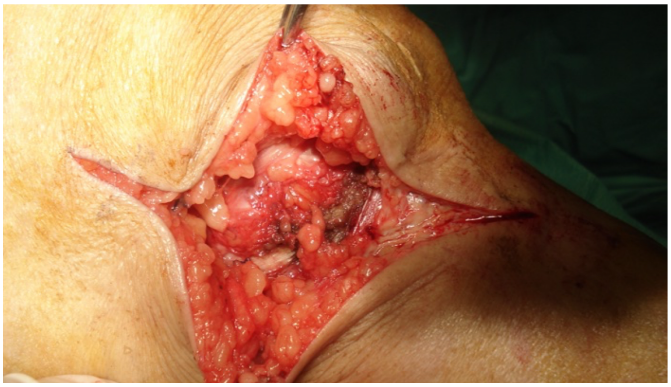

Figure 4 The fibrous nodule containing the neuroma was removed and the nerve was sharply transected approximately 1-2 cm proximal to the neuroma. Its proximal stump was buried to adjacent sift tissues to prevent recurrence.

other hand, Worth *et al*[15] reported no significant resolution of pain after local injection of the saphenous nerve in 14 patients with prior knee surgery.

In case of failed conservative treatment, surgical intervention with neurolysis, neurectomy, and selective knee denervation are utilized. The proximal nerve stump is cauterized and buried deeply in the adjacent tissues to prevent recurrence[9]. Nahabedian *et al*[16] excised 62 nerves in 25 patients including the IPSN in 24 cases. Complete pain relief was obtained in 11 patients (44%), partial pain relief in 10 patients (40%), and no pain relief in 4 patients (16%). The overall patient satisfaction rate was 84% (21 out of 25 patients) and none reported a worse outcome after surgery. Shi *et al*[1] performed selective denervation in 50 patients suffering from neuroma pain after TKA. The procedure was applied not only to IPSN but also to the other sensory nerves around the knee according to symptoms and Tinel's sign location. Thirty-two patients (64%) rated their outcome as excellent, 10 (20%) as good, 3 (6%) as fair, and 2 (4%) reported no change. The mean VAS pain score was improved from 9.4 ± 0.8 preoperatively to 1.1 ± 1.6 postoperatively ($P < 0.001$). The mean Knee Society Scores was also increased from 45.5 ± 14.3 before surgery to 94.1 ± 8.6 after surgery ($P < 0.0001$). Three patients (6%) required a second neurectomy due to recurrent pain. In our series of 15 patients, exclusive denervation of IPSN was associated with statistically significant pain resolution (mean VAS increase -7.8 ± 1.9) and improvement of knee function (KSS pain and function scores increased from 49.3 ± 5.9 and 62.7 ± 12.8 to 91.8 ± 4.2 and 75.3 ± 11.3, respectively) and range of motion (from 96 ± 4 to 105 ± 6 degrees).

The common applied medial parapatellar approach in TKA may increase the likelihood of the development of ISN[9]. James *et al*[2] performed a clinical study in primary TKA patients to identify the location of the IPSN and determine whether it could be transected during a standard medial arthrotomy. They found that the nerve was, on average, between 2.58 and 3.06 cm below the inferior pole of the patella. No demographic predictors of nerve location were found, including sex, height, and BMI. Kartus *et al*[17] reported that the IPSN passes through the area between the apex of the patella and the tibial tubercle in 59 of 60 examined specimens and the distance from the apex of the patella to the IPSN or its uppermost branch was 30 mm. Kerver *et al*[18] in a cadaveric study identified that anatomic variation of topographic anatomy of IPSN is high and the nerve is at risk for iatrogenic damage in any anteromedial knee surgery, especially when longitudinal incisions are made.

The current study has certain limitations. Firstly, it represents a case series study with a relatively small sample size and no control group. It is also a single institution's report, with scarce literature to provide an adequate comparison of data. On the other hand, it contains a homogenous group of patients that underwent only primary TKA with the same type of knee approach.

CONCLUSION

Iatrogenic injury of IPSN may cause persistent pain after TKA in an otherwise non-infected, well-fixed, and well-aligned joint. Therefore, and before TKA, patients should be warned of the risk of nerve injury and neuroma formation. After confirmation of the diagnosis with local anesthetic infiltration of the painful site, neuroma excision provides excellent pain relief and can improve the knee function and range of motion.

ARTICLE HIGHLIGHTS

Research background

Development of infrapatellar saphenous neuroma (ISN) is a well-recognized source of knee pain after total knee arthroplasty (TKA).

Research motivation

So far, very few studies have addressed the issue of the development of painful ISN after TKA, and no clear evidence regarding its importance on functional outcome and patient satisfaction exists.

Research objectives

The current clinical study aims to evaluate the results of surgical treatment of ISN after primary TKA, the level of pain relief, and the improvement of knee motion and function.

Research methods

This study is a clinical series of 15 patients (13 women, 2 men) with persistent pain for more than six months after primary TKA due to osteoarthritis, who underwent surgical excision of ISN. Active knee range of motion (ROM), visual analog scale (VAS) for pain, Knee Society Score (KSS) for pain and function were evaluated before and at least 6 mo after neuroma excision, with a mean follow-up of 8 mo (range: 6 to 11 mo).

Research results

The mean patients' age was 71.3 ± 5.4 years old. The mean interval between TKA and neuroma excision was 10 mo (range, 6 to 14 mo). All patients experienced almost immediate and complete pain relief and resolution of allodynia and hyperesthesia after surgery. Mean pain relief in terms of VAS exceeded the MCID for adequate pain control (mean difference -7.8 ± 1.9, P = 0.001). Only two patients reported some residual numbness that gradually resolved during the time but didn't cause any functional deficit. The KSS pain and function scores were significantly improved from 49.3 ± 5.9 and 62.7 ± 12.8 before surgery to 91.8 ± 4.2 and 75.3 ± 11.3 after surgery, respectively (P = 0.001 and P = 0.015). Active knee ROM was also increased postoperatively from 96 ± 4 to 105 ± 6 degrees (P = 0.001). There were no complications and no further operations required

Research conclusions

Iatrogenic injury of IPSN may cause persistent pain after TKA in an otherwise non-infected, well-fixed, and well-aligned prosthetic joint. Neuroma excision can provide excellent pain relief and improve the knee function and range of motion.

Research perspectives

Further clinical studies are required to identify the predisposing factors for development of traumatic ISN during TKA as well as the optimal treatment approach of postoperative neurogenic pain around the knee joint area.

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ORIGINAL ARTICLE

Prospective Study

Arthroscopic *vs* open ankle arthrodesis: A prospective case series with seven years follow-up

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Author contributions: Morelli F, Princi G did work design; Princi G, Cantagalli MR, and Rossini M did data acquisition; Princi G did data analysis; Princi G, Cantagalli MR, Rossini M, Caperna L and Mazza D drafted the work; Morelli F, Princi G, Caperna L, Mazza D and Ferretti A did critical revision for important intellectual content; All authors did final approval of the version to be published.

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Abstract

BACKGROUND

The osteoarthritis of the ankle, although less common than other joints, is associated with severe functional limitation. Surgical options are ankle arthroscopic debridement, osteotomies, ankle arthrodesis and ankle arthroplasty. Ankle arthroplasty is increasingly used thanks to the new implants design, but ankle arthrodesis still represents the most used technique and it can be performed arthroscopically or with an open procedure.

AIM

To compare mid-term results of arthroscopic *vs* open ankle arthrodesis of patients affected by end-stage ankle arthritis.

METHODS

This study enrolled 23 patients, which underwent ankle arthrodesis. The patients were divided into 2 groups: group A (open procedure; n = 11) and group B (arthroscopic procedure, n = 12), the two groups were homogeneous with regard to age and body mass index (P = 0.347). The American Orthopaedic Foot and Ankle score (AOFAS), Freiburg Ankle score (FAS) and visual analogue scale for pain intensity were evaluated preoperatively, at six months and at final follow-up of 7.6 years in group A and 7.3 years in group B (P = 0.364).

RESULTS

Patients in the arthroscopic group showed better results at six-month follow-up compared to the open group at the AOFAS (group A, 62.2; group B, 78.5; $P < 0.05$) and the FAS (group A, 61.1; group B, 70.3; P = 0.015) scores. Pain relief was achieved in both groups at six-month follow-up (group A, 1.4; group B, 0.9; P = 0.162). Both open and arthroscopic groups showed improved clinical outcomes

from baseline to final follow-up ($P > 0.05$). Hospital stay was shorter in group B than in group A ($P = 0.001$). More complications were reported in the open group than in the arthroscopic group ($P = 0.459$).

CONCLUSION

The arthroscopic and the open arthrodesis are valid and safe options for the treatment of ankle arthritis on the basis of clinical outcomes at 7 years follow-up. Moreover, the arthroscopic treatment shows faster improvement at six-month follow-up in comparison with the open group.

Key Words: Ankle; Osteoarthritis; Arthrodesis; Arthroscopy; Arthroplasty; Surgery

Core Tip: Purpose of this study is to evaluate arthrodesis as surgical treatment in patients with end-stage ankle osteoarthritis. The open procedure is compared with the arthroscopic procedure, evaluating the medium to long-term results through The American Orthopedic Foot and Ankle score, Freiburg Ankle score and visual analogue scale for pain intensity. Bone fusion timing is analyzed utilizing X-rays. The results suggest that both treatments are valid and safe, and that the arthroscopic procedure shows faster improvements in the medium term. It is also interesting to note that the group treated with arthroscopic procedure in the medium term control, has a shorter hospital stay and a better union rate.

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INTRODUCTION

End-stage ankle arthritis is a clinical condition associated with pain and severe function limitation. The ankle joint, even though subjected to more weight-bearing force per square centimeter and to injury than any other joint, is relatively less affected by osteoarthritis, up to nine times lower than knee and hip[1]. The most frequent cause of ankle arthritis is post-traumatic, which includes almost 80% of all osteoarthritis of this joint[2-4]; more rarely other clinical diseases as arthropathies, infections, tumors and neuropathic arthropathies are involved. Initial management of ankle arthritis consist of conservative options: first-line consist of weight management, exercise, braces, orthoses, and assistive devices, followed by adjunction of pharmacologic agents (non-steroidal anti-inflammatory drug) and intra-articular injection (corticosteroid, hyaluronic acid, *etc*)[5]. In case of failure of conservative treatment, surgery is indicated. Possible surgical options are ankle arthroscopic debridement, osteotomies, ankle fusion and tibio-talar arthroplasty. Despite the development of new implant designs for ankle replacement that are improving its utilization and outcome, arthrodesis still represents the main surgical method to treat ankle arthritis, offering safe and stable results as regards in pain and function[6-9].

Ankle fusion is indicated for end-stage arthritis, residual joint destruction after infection, avascular talar necrosis, Charcot neuroarthropathy, and total ankle replacement failure[8]. For many years ankle arthrodesis has been considered a reliable procedure and for many authors it is still the reference standard for the treatment of end-stage ankle arthritis[10]. Success rate ranging from 80% to 100% has been reported for isolated tibio-talar fusion with patient satisfaction rates around 80% [11,12].

Since the first description by Schneider[13] in 1983, arthroscopic ankle arthrodesis has seen increase in popularity and utilization because of numerous advantages. Several studies in literature in fact, show reduced postoperative pain and a lower use of painkiller drugs[14,15], as well as decreased morbidity, duration of hospitalization,

presented data are anonymized and risk of identification is low.

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lower infection rate and more rapid return to daily activities[16,17], preserving a better fusion rate and time to union[18]. Moreover, with arthroscopic procedure the indication for arthrodesis can be extended to patients with high wound complications risk such as diabetes or skin problems.

The purpose of the present study was to compare two cohorts of patients who were managed with either an open or an arthroscopic arthrodesis for the treatment of end-stage ankle arthritis: clinical outcome, morbidity and length of hospital stay are reported for both groups.

MATERIALS AND METHODS

This is a comparative case series. Between June 2008 and January 2012, forty patients (40 ankles) with end-stage ankle arthritis that needed ankle fusion surgery, were selected for this prospective study. Institutional review board approval was granted, and informed consent was obtained from all study participants.

Decision on which surgical procedure to be utilized was based on the grade of varus or valgus malalignment of the involved ankle. Therefore patients were divided in two groups: In group A (open procedure), were included patients with end-stage ankle arthritis with severe varus or valgus deformity (≥ 10°); in group B (arthroscopic procedure) those with minor ankle malalignment (< 10°).

Exclusion criteria were the following: diabetes mellitus, Charcot neuroarthropathy, osteomyelitis, previous total ankle arthroplasty, subtalar arthritis requiring fusion at same time of the tibio-talar procedure, neurological diseases.

Following the aforementioned criteria, we enrolled 23 patients (23 ankle) for this study, 11 patients in group A and 12 patients in group B. No significant difference were found between the two groups regarding average age (respectively 67.0 ± 2.6 and 64.6 ± 1.9), body mass index (BMI, 23.6 ± 1.0 and 23.8 ± 1.0), sex (open group shows 8 male/3 female and arthroscopic group 5 male/7 female) and dominant side (8/3 and 9/3). Details of all demographic data are shown in Table 1.

Seventeen patients were excluded from further analysis: 7 patients with incomplete clinical follow-up, 7 patients performed triple arthrodesis, 3 patients affected by diabetes mellitus.

All patients had a minimum follow-up of 5 years and mean FU of 7.4 years.

Analyzing the etiology of the ankle arthritis, the two groups showed comparable data. The main cause was post-traumatic, that include 72.7% (8 patients) and 83.3% (10 patients) of the cases respectively in group A and in group B. In the open group, we found out a similar percentage of idiopathic arthritis compared to the arthroscopic group (group A, 9.0%, 1 patient; group B, 8.5%, 1 patient); two patients of group A were affected by Rheumatoid arthritis (18.1%) counter to 1 in the arthroscopic group (8.5%).

Surgical procedures

In the open group the approach entailed a longitudinal lateral incision combined with an ancillary antero-medial incision to obtain a good congruence of bone surfaces. The lateral dissection included osteotomy and removal of the cortical portion of the distal fibula, with subsequent placement of the remaining lateral aspect of the distal fibula and onlay graft before wound closure. All of the residual cartilage and subchondral bone was removed from the distal tibia, talar dome, lateral talus and medial gutter. The deformity was corrected with planar cuts to place the foot and the ankle in a neutral fusion position. The subchondral plate was preserved unless the deformity required planal resection, after which the subchondral plate was fenestrated and drilled, and fish scaled with a curved osteotome. The desired position of fusion was then ensured by means of direct visualization and fluoroscopy, after which the fusion was stabilized in 7 cases with 2 or 3 large diameter (≥ 6.5 mm) cannulated screws, interfragmentary compression screws reinforced with the before mentioned fibular onlay graft. In 4 cases the IOFIX (Extremity Medical, New Jersey, United States) system was used.

Arthroscopic procedure was performed with anteromedial and anterolateral portals using noninvasive distraction. Adequate inflow was achieved with use of a 2.9 mm arthroscope within a 4.0 mm fenestrated cannula or a 4.0 mm arthroscope with a 5.5 mm fenestrated cannula and a pump with 30 mmHg of inflow pressure at the surgeon's discretion. After removal of articular cartilage, the subchondral bone was prepared with a 2 mm drill and osteotome or high-speed burr. Osseous contours were preserved, and fusion sites were stabilized with two or three compression screws (7

Table 1 Demographic data

Variable	Group A (open) *n* = 11	Group B (arthroscopic) *n* = 12	*P*
Average age ± SD	67.0 ± 2.6	64.6 ± 1.9	0.162
Sex (M/F)	8/3	5/7	0.219
BMI ± SD	23.6 ± 1.0	23.8 ± 1.0	0.347
Dominant side (R/L)	8/3	9/3	0.952
Affected side (R/L)	7/4	5/7	0.390
Hospital stay (d) ± SD	5.4 ± 0.8	3.6 ± 0.5	**0.001**[b]
Follow-up (yr) ± SD	7.6 ± 1.1	7.3 ± 1.1	0.364
Device (screws/IOFIX)	7/4	7/5	0.390

[b]$P < 0.05$.

Boldface indicates statistical significance. BMI: Body mass index.

cases) or with the IOFIX system (4 cases).

Postoperative protocol

The same postoperative protocol was used for both groups. After surgery, patients were managed with ankle immobilization in a below-the-knee plaster cast without weight-bearing for the first six weeks. Progressive weight-bearing was allowed from seventh to twelfth week, when the cast was removed. Anti-thrombotic prophylaxis protocol was performed for 6 wk with enoxaparin 4000 UI/die.

Outcomes evaluation

Clinical evaluation was obtained using the American Orthopaedic Foot and Ankle score (AOFAS)[19], Freiburg Ankle score (FAS)[20] and visual analogue scale (VAS) for pain evaluation that were collected pre-operatively, at six months and at final follow-up.

Demographic data were collected preoperatively. Secondary outcome measures also included length of the hospital stay and radiographic evaluation. Antero-posterior, lateral radiographs and Saltzman view were made at baseline, monthly until bone healing at the arthrodesis site was achieved, at sixth-month and at final follow-up[21-23] (Figures 1 and 2).

To eliminate interobserver variability, all radiographic measurements were completed by a single independent radiographic reviewer who was blinded to the treatment. The alignment was measured using the ruler application in the Centricity Enterprise Web V2.1 PACS viewing system (GE Healthcare, Chalfont St. Giles, Buckinghamshire, United Kingdom).

Statistical analysis

The data were analysed by using IBM SPSS Statistics for Windows, version 23.0 (IBM Corp., Armonk, N.Y., United States). All the data was first analysed for normality of distribution using the Kolmogorov–Smirnov test. Continuous variables were expressed as mean ± SD, categorical variables displayed as frequencies and the appropriate parametric (student *t* test) or non-parametric test (Mann–Whitney U test or χ^2 test) was used to assess the significance of the differences between groups. All of the intergroup comparisons were two-sided and statistical significance was set at $P < 0.05$.

RESULTS

The study sample consisted of twenty three patients allocated in two groups: group A (open procedure group; $n = 11$) and group B (arthroscopic procedure group; $n = 12$). The groups were homogeneous with regard to age, BMI, dominant side and fixation device ($P > 0.05$) (Table 1).

Clinical outcomes intergroup comparison at baseline, at six months and final follow-up are reported in Table 2.

Table 2 Clinical outcomes

Variable	Group A (open) *n* = 11	Group B (arthroscopic) *n* = 12	*P*
AOFAS ± SD			
Pre-operative	33.6 ± 11.7	32.1 ± 4.1	0.411
Six months	62.2 ± 3.2	78.5 ± 3.9	**0.00001**[b]
Final follow-up	79.3 ± 3.6	81.3 ± 3.7	0.462
FAS ± SD			
Pre-operative	44.1 ± 6.9	48.8 ± 2.9	0.244
Six months	61.1 ± 6.1	70.3 ± 2.8	**0.015**[b]
Final follow-up	74.7 ± 2.7	75.8 ± 2.7	0.593
Pain VAS ± SD			
Pre-operative	4.3 ± 0.7	4.3 ± 0.6	0.903
Six months	1.4 ± 0.4	0.9 ± 0.4	0.162
Final follow-up	0.8 ± 0.6	0.6 ± 0.4	0.507
Bone fusion (wk) ± SD	15.1 ± 1.1	11.2 ± 0.7	**0.00001**[b]
Complications	1 nonunion, 2 wound dehiscence	1 screws removed	0.459

[b]$P < 0.05$.

Boldface indicates statistical significance. AOFAS: American Orthopaedic Foot and Ankle score; FAS: Freiburg Ankle score; VAS: Visual analogue scale.

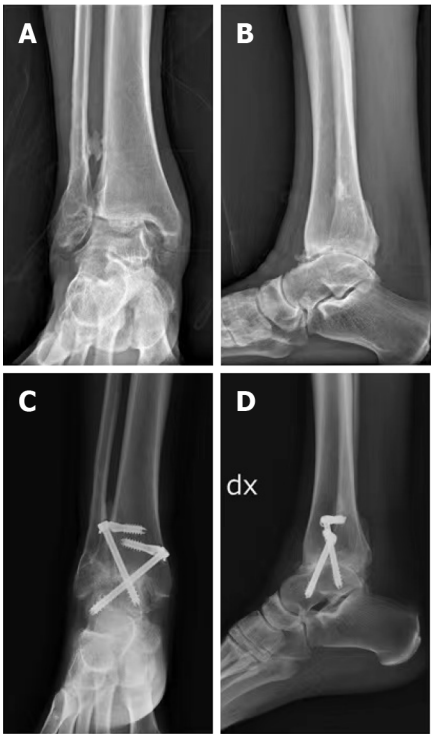

Figure 1 X-rays (IOFIX system). A and B: Preoperative, anterior-posterior (AP) and lateral (L); C and D: 6 mo follow-up, AP and L.

Average preoperative AOFAS was 33.6 in group A and 32.1 in group B ($P = 0.411$); at six-month follow-up results showed significant differences between the two groups, the mean score was 62.2 in group A and 78.5 in group B ($P = 0.00001$); at final follow up, AOFAS average score was 79.3 in the open group and 81.3 in the arthroscopic group ($P = 0.462$).

The FAS increased in group A from 44.1 at baseline to 61.1 at six months, and to 74.7 at final follow-up; in group B it increased from 48.8 at baseline, to 70.3 at six months,

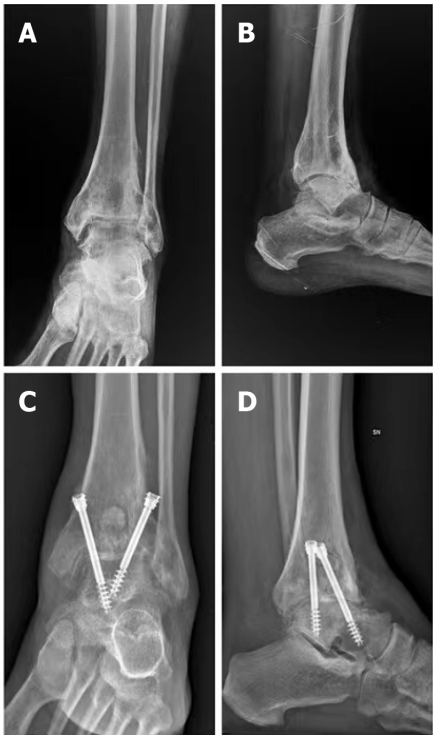

Figure 2 X-rays (screw fixation). A and B: Preoperative, anterior-posterior (AP) and lateral (L); C and D: 6 mo follow-up, AP and L.

and to 75.8 at final follow-up. Results were statistically significant at six-month follow-up (P = 0.015), no statistical significance was found neither at baseline (P = 0.244) nor at final follow-up (P = 0.593).

The preoperative VAS score was 4.3 in group A and 4.3 in group B (P = 0.903); Pain relief was achieved in both groups at six-month follow-up, VAS score was 1.4 in the open group and 0.9 in the arthroscopic group (P = 0.162). The average score at final follow was 0.8 in group A and 0.6 in group B (P = 0.507).

The patients which underwent open surgery stayed in the hospital for an average of 5.4 d, whereas patients treated arthroscopically for 3.6 d (P = 0.001).

Statistical significance was found in bone fusion time, ten patients out of eleven in group A achieved satisfactory consolidation in 15.1 wk at X-ray evaluation with a union rate of 90.9%. All patients in group B (100%) showed good consolidation at 11.2 wk (P = 0.00001).

One patient in group A underwent revision surgery for symptomatic nonunion within twenty-four months from first surgery. In one patient of group B screws were removed three years after surgery due to pain and discomfort. We reported two cases of wound dehiscence in the open group that were successfully treated with medical therapy.

DISCUSSION

Ankle arthrodesis is considered a safe option for surgical management of end-stage ankle arthritis with good clinical results even compared with total ankle arthroplasty [5]. To authors' knowledge there were few clinical studies comparing mid-term results between arthroscopic ankle arthrodesis (AAA) and open ankle arthrodesis (OAA); our average follow-up of 7.4 years can be considered a long-term follow-up compared with literature.

Clinical results reported by other authors are good both for AAA and OAA with slightly better results for OAA although often not statistically significant[9]. Many authors considered it as relative contraindication for arthroscopic ankle arthrodesis a large coronal plane deformity)[15,24]. Townshend *et al*[25], however, achieved technical success for coronal plane deformities up to 30° with arthroscopy and up to 36° for open arthrodesis. They also evaluated the results of open and arthroscopic ankle arthrodesis in a comparative case series with two years follow-up. They reported significantly greater improvement in the ankle osteoarthritis scale at one and two

years and shorter hospital stay in the arthroscopic group. Those data are partially congruent to our results. We found better clinical results for arthroscopic procedure at six months, but similar results at final follow-up between two groups.

Woo *et al*[26] demonstrated that patients who underwent arthroscopic ankle arthrodesis reported a higher SF-36 score on physical functioning at 6 mo and higher AOFAS at 24-mo, the analysis of VAS scores demonstrated significant less pain during the perioperative period compared with the open group and no significant difference among the two groups at 6 and 24 mo. In this study, it is shown an improvement at 6 mo at the AOFAS (P = 0.00001) and at the FAS (P = 0.015) and at final follow-up at the AOFAS (P = 0.462) and at the FAS (P = 0.593); the VAS showed that pain relief was achieved in both groups at six-month (P = 0.162) and at final follow-up (P = 0.507).

A systematic review by Park *et al*[27] reported that the mean AOFAS score was statistically significant greater in the arthroscopic group at 6 and 12 mo, and a greater improvement in the AOS scores at 1 and 2 years in the arthroscopic group with statistical significance. The SF-36 mental component summary the scores at 1 and 2 years were without a statistical difference greater in the arthroscopic group, The SF-36 physical component summary scores were higher in the arthroscopic group at 1 and 2 years, but the difference was only statistically significant at 1 year.

This study showed that complication rates were overall higher in the group A (27%; 1 revision and 2 wound dehiscence) than in the group B (8%; 1 screws removed) in accordance with the systematic review by Park *et al*[27] in which the most common reoperation was screw removal (open group, 5.1%; arthroscopic group, 9.5%) and the second most common was re-arthrodesis (open group, 2.5%; arthroscopic group, 4%). Another study by Woo *et al*[26] did not reported postoperative complications in the arthroscopic group, but complication rate was 20% in the open group, 16% of these required revision surgery. Quayle *et al*[18] identified that open ankle arthrodesis and a low BMI were the strongest predictors of developing a complication.

Ogilvie-Harris *et al*[15] reported prospectively collected data on nineteen arthroscopic arthrodesis and demonstrated an average length of stay of only one day. Zvijac *et al*[28] reported an average duration of hospitalization of 3 d for open arthrodesis and 1 d for arthroscopic procedure. Similarly, in our results the arthroscopic group showed shorter hospitalization time (P = 0.001).

Time of consolidation of the arthrodesis is a key factor for the success of this surgical technique. Myerson *et al*[16] and other authors reported that traditional open arthrodesis requires approximately 14 wk to achieve satisfactory consolidation[9,18,26,27,29]. On the other hand, regarding arthroscopic procedure, there was no consensus on the fusion timing; Collman *et al*[30] reported that arthroscopic procedures required an average 47 days to achieve bone fusion, while Glick *et al*[31] reported an average time to fusion of 9 wk. A systematic review and meta-analysis by Honnenahalli Chandrappa *et al*[32] showed that the fusion rate was significantly lower in the open group than in the arthroscopic group. Moreover, it has been shown by Collman *et al*[30] and Winson *et al*[33] that arthroscopic ankle arthrodesis achieves high union rates, facilitates short time to union, and permits rapid patient mobility. In this study, the open group required approximately 15 wk to achieve satisfactory consolidation of the fusion at X-ray evaluation with a rate of 90.9% and the arthroscopic group required approximately 11 wk, with a fusion rate of 100%. The pre-operative hindfoot alignment and the shorter time to fusion in the arthroscopic group, could explain the better clinical results compared with open procedure. In this study, the improvement in clinical outcomes was greater and more rapid in the arthroscopic group than in the open treatment group, with maximum improvement achieved at six months follow-up. The arthroscopic arthrodesis is less invasive than open procedure and there is less soft-tissue disruption associated which may reduce the degree of permanent functional impairment of joints and soft tissues adjacent to the arthrodesis site. Furthermore, It appears to allow more rapid activation of the bone-healing cascade, leading to more rapid bone healing and fast functional improvements[25].

The present study is limited by a lack of randomization, a large number of patients lost at final follow-up, and a small sample. Patients were not consecutive, and, in the early period, an open technique was preferred for some of the more difficult cases at the center at which the arthroscopic procedures were performed. Secondly, we did not evaluate the postoperative alignment, furthermore there was no intermediate follow-up between six-month and final follow up.

The main finding of the present study was that ankle arthrodesis is a safe and effective procedure to treat end-stage arthritis with long-term good clinical outcomes, but arthroscopic procedures had a more rapid improvement, with maximum achieved by six months.

CONCLUSION

In this comparative case series, it has been shown that both open and arthroscopic ankle arthrodesis were associated with good clinical outcomes at a long term follow-up on the basis of validated outcome measures. The arthroscopic treatment group showed a more rapid improvement of clinical scores at six months in comparison with the open group, beyond that a shorter hospital stay and a better union rate.

ARTICLE HIGHLIGHTS

Research background

Ankle arthrodesis is a commonly used treatment for end stage ankle arthrosis. There are two different surgical approaches: open arthrodesis and arthroscopic arthrodesis.

Research motivation

To compare the results of arthroscopic arthrodesis *vs* open arthrodesis and evaluate the different efficacy of these surgical approaches.

Research objectives

The aim of the study was to analyze the medium and long term results of the two surgical treatments using the clinical evaluation scales for the ankle.

Research methods

Patients treated with open and arthroscopic technique were divided into two groups. To evaluate the surgical treatments we used The American Orthopaedic Foot and Ankle score (AOFAS), Freiburg Ankle score (FAS) and visual analogue scale for pain intensity. This study enrolled 23 patients which were evaluated preoperatively, at six months and at final follow-up (7 years).

Research results

Arthroscopic treatment shows better results at six months with the AOFAS and FAS. The decrease of pain at six months is present in both groups. At the final follow up both treatments show good clinical results. To be noted is the data relating to hospital stay, which appears to be lower for arthroscopic treatment.

Research conclusions

There are no differences between open and arthroscopic treatments at clinical results at a medium to long term follow-up, and in both cases it was possible to achieve excellent results.

Research perspectives

In perspective, despite being a medium-long term follow up, it is possible to re-evaluate the same court of patients at a greater distance to verify the stability of these results.

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ORIGINAL ARTICLE

Randomized Controlled Trial

Decision aids can decrease decisional conflict in patients with hip or knee osteoarthritis: Randomized controlled trial

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Informed consent statement: No additional invasive diagnostic interventions or invasive treatments were performed. For this study a waiver for informed consent was obtained.

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Abstract

BACKGROUND

The interest in shared decision making has increased considerably over the last couple of decades. Decision aids (DAs) can help in shared decision making. Especially when there is more than one reasonable option and outcomes between treatments are comparable.

AIM

To investigate if the use of DAs decreases decisional conflict in patients when choosing treatment for knee or hip osteoarthritis (OA).

METHODS

In this multi-center unblinded randomized controlled trial of patients with knee or hip OA were included from four secondary and tertiary referral centers. One-hundred-thirty-one patients who consulted an orthopedic surgeon for the first time with knee or hip OA were included between December 2014 and January 2016. After the first consultation, patients were randomly assigned by a computer to the control group which was treated according to standard care, or to the intervention group which was treated with standard care and provided with a DA. After the first consultation, patients were asked to complete questionnaires about decisional conflict (DCS), satisfaction, anxiety (PASS-20), gained knowledge, stage of decision making and preferred treatment. Follow-up was

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carried out after 26 wk and evaluated decisional conflict, satisfaction, anxiety, health outcomes (HOOS/KOOS), quality of life (EQ5D) and chosen treatment.

RESULTS
After the first consultation, patients in the intervention group (mean DCS: 25 out of 100, SD: 13) had significantly (*P* value: 0.00) less decisional conflict compared to patients in the control group (mean DCS: 39 out of 100, SD 11). The mean satisfaction score for the given information (7.6 out of 10, SD: 1.8 *vs* 8.6 out of 10, SD: 1.1) (*P* value: 0.00), mean satisfaction score with the physician (8.3 out of 10, SD: 1.7 *vs* 8.9 out of 10, SD: 0.9) (*P* value: 0.01) and the mean knowledge score (3.3 out of 4, SD: 0.9 *vs* 3.7 out of, SD: 0.6) (*P* value: 0.01) were all significantly higher in the intervention group. At 26-wk follow-up, only 75 of 131 patients (57%) were available for analysis. This sample is too small for meaningful analysis.

CONCLUSION
Providing patients with an additional DA may have a positive effect on decisional conflict after the first consultation. Due to loss to follow-up we are unsure if this effect remains over time.

Key Words: Decision aid; Decisional conflict; Shared decision making; Anxiety; Hip osteoarthritis; Knee osteoarthritis

Core Tip: Patients with knee or hip osteoarthritis provided with an additional decision aid appear to have less decisional conflict, more knowledge about their treatment, more satisfaction with the given information by their physician and therefore more satisfaction with their physician after their first consultation with the physician.

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INTRODUCTION

For patients with knee or hip osteoarthritis (OA) there are multiple treatment options. These treatment options vary from lifestyle adjustments to surgery. When a patient has radiographically end-stage OA combined with a lot of pain, other forms of treatment including physical therapy and corticosteroid injections have been unsuccessful, the choice for a knee or hip arthroplasty seems obvious. However, surgery comes with multiple risks and a period of rehabilitation, which are important factors for patients considering total joint arthroplasty. In the stages before end-stage OA, the choice of treatment is demanding because the results of conservative and operative treatment are comparable[1]. Therefore, in the treatment of OA it is preferable to use shared decision making. Physicians need to give complete, correct and neutral information about the possible treatments to aid the patient in making a shared decision[2]. Furthermore, it is necessary that patients share their own values about the benefits, risks and side effects of a treatment. Due to limited time during clinical visits and the complexity of the information, in many cases it is difficult to establish clear communication between the physician and the patient to make a shared decision. Therefore, it is difficult for the patient to define their values, and this can lead to worse outcomes of the surgery, followed by disappointment, and sometimes regret [3]. Decision aids (DAs) have been developed to support the decision-making process and provide evidence-based information to the patient[4,5]. A DA should be used as an addition to the information explained by the physician, not as a substitution for medical consultation[6]. On top of that with a DA the patient can reread the given information at home.

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Positive effects of DAs related to decisional conflict and knowledge are reflected in previous studies[7,8]. Achaval *et al*[7] investigated the effect of an education booklet, video booklet and decision tool on the decisional conflict among patients with knee OA. It showed a significant overall reduction in decisional conflict. A recent systematic review by Riddle *et al*[8] looked primarily at the effect of DAs on patients' knowledge considering total knee arthroplasty. They found a positive effect on the knowledge of patients, but no effect on patients' anxiety, satisfaction or decisional conflict.

The primary objective of this study is to investigate if a DA reduces decisional conflict in patients choosing treatment for knee and hip OA after the first consultation with their physician. The secondary objective is to investigate if providing patients with a DA increases satisfaction, gained knowledge, influenced stage of decision making, preferred treatment or decreased anxiety after the first consultation and if it reduces decisional conflict, decreases anxiety, increases knowledge, satisfaction, quality of life or physical function and changes preferred treatment at enrollment after 26 wk of follow-up.

MATERIALS AND METHODS

Study design and participants

A multicenter unblinded randomized controlled trial (RCT) was carried out at four secondary and tertiary referral centers in the Netherlands after approval of the Institutional Research Board. Patients were included when they met the following inclusion criteria: Adult patients (18 years or older), newly diagnosed with OA of the knee or hip, Dutch fluency and literacy, and first consultation by an orthopedic surgeon for the complaint.

Study setting

Patients received the diagnosis OA of the knee or hip at one of the participating centers. After the first consultation, patients were asked if they wanted to participate in this trial. When this was the case, the patients were randomized by a computer-generated randomization sequence by one of the research fellows into the control group or intervention group. The control group was treated with standard care. This consists of a thorough case history, physical examination, an X-ray of knee or hip followed by explanation about treatment options for OA. The intervention group was also treated with standard care and received an online DA for their specific diagnosis (knee or hip OA) after the first consultation.

An implementation workshop was conducted prior to the start of this trial to support the treating physicians in using the DAs. In total 14 physicians received the implementation workshop and the included patients. The online DAs were developed by patients and physicians according to the International Patient Decision Aids Standards and based on a previous study, carried out by this research group, assessing patients and physicians needs when deciding about the optimal treatment[3,9]. The DA consists of 5 steps comparing operative treatment, defined as total joint prosthesis, with non-operative treatment, defined as lifestyle advice, painkillers and corticosteroid injections (Supplementary material).

Outcome measures

Our primary outcome was the difference in decisional conflict after the first consultation (mean: 11 d, range: 5-11) measured through the Decisional Conflict Scale (DCS)[10]. The DCS is a validated and reliable questionnaire that consists of 16 questions, divided into 3 categories: a) the level of uncertainty, b) factors contributing to uncertainty such as feeling uninformed, unclear about personal values, or unsupported in decision-making and c) effective decision making such as feeling the choice is informed, values-based, likely to be implemented, and expressing satisfaction with the choice. The total score ranges from 0 (no decisional conflict) to 100 (highest level of decisional conflict).

Our secondary outcomes were satisfaction, anxiety, gained knowledge, stage of decision making, preferred treatment options and if a final choice was made after the first consultation. At 26 wk (mean: 50 wk, range: 26-91) we evaluated differences in decisional conflict, satisfaction, anxiety, final choice, health outcomes and quality of life. The satisfaction questionnaire consisted of three questions to measure patients' satisfaction with the given information, the clinic and the physician. Patients could score each question from 0 (no satisfaction) to 10 (complete satisfaction). As outcome measurement for anxiety, we used the short Pain Anxiety Symptoms Scale (PASS-20)

questionnaire to measure patients' pain-related anxiety and fear. It consisted of 20 questions with a score ranging from 0 (no anxiety and fear) to 100 (extreme anxiety and fear)[11]. The knowledge questionnaire consisted of 4 questions and was used to measure the patients' knowledge of treatment options and risks. The score ranged from 0 (no correct answers) to 4 (all correct answers). The decision questionnaires contained 2 separate questionnaires. One questionnaire inquired what phase of decision making patients were in and which treatment they preferred. The second questionnaire was to determine whether patients had made their definitive decision. Health outcomes measured by the Hip Disability and Osteoarthritis Outcome Score (HOOS) and the Knee Injury and Osteoarthritis Outcome Score (KOOS)[12,13]. Both questionnaires include questions about patients' symptoms, pain, activity limitations in daily life, sport, recreation and quality of life. The EuroQol 5 Dimensions (EQ-5D) questionnaire was used to measure health-related quality of life[14]. It consisted of 5 questions concerning mobility, self-care, usual activities, pain /discomfort and anxiety/depression.

Statistical analysis

We calculated a sample size of 128 patients to identify an effect size of 0.5 SD on the decisional conflict scale with a type 1 error (0.05) and type 2 error (0.20) based on a two-tailed prediction. To report continuous data, we used mean and SD when the group was normally distributed. To compare the control and intervention group we used the Student t-test for continuous dependent variables and dichotomous independent variables when normally distributed. In the case of skewed data, we used the Mann-Whitney U-test. For ordinal data the Kruskal Wallis test was used. We investigated the association between continuous dependent and continuous independent variables in bivariate analysis using Spearman correlation. Associations with a *P* value less than 0.05 were considered statistically significant

RESULTS

Participants

Between December 2014 and January 2016, 145 patients were eligible to participate in this study. Sixty-nine patients were assigned to the control group and 76 patients to the intervention group. Of these 145 patients, 4 patients in the control group and 10 patients in the intervention group did not complete the first questionnaires resulting in a total of 131 participants. Fifty-six patients, 29 in the control group and 27 in the intervention group, did not respond at follow-up (Figure 1).

The control group comprised of 30 men and 35 women, who were on average 66-years-old (SD: 10). The intervention group comprised 33 men and 33 women, who were on average 68-years-old (SD: 11). The baseline demographics are shown in Table 1.

After first consultation

When we compared the total DCS after the first consultation, the total DCS of the intervention group (mean: 25) was significantly ($P = 0.00$) lower than the total DCS in the control group (mean: 39). This means there was significantly less decisional conflict in the intervention group. The intervention group had significantly lower DCS-subscales (information, values clarity, support, uncertainty, and effective decision making) than the control group (Table 2).

Patients in the intervention group scored significantly higher on the knowledge scale than the patients in the control group ($P < 0.01$), they were significantly more satisfied with the given information (mean: 8.6 *vs* mean: 7.6; $P < 0.001$) and their physician (mean: 8.9 *vs* mean: 8.3; $P = 0.01$) compared to the patients in the control group. There was no significant difference in satisfaction with the visit to the outpatient clinic ($P = 0.30$) and anxiety ($P = 0.29$).

Follow-up at 26 wk

Only 75 of 131 patients (57%) were available for analysis at this follow-up point. This sample was too small for meaningful analysis.

Table 1 Baseline characteristics of the patients, *n* (%)

	Without DA	With DA
Sex		
Male	30 (46)	33 (50)
Female	35 (54)	33 (50)
Age (yr; mean ± SD)	66 ± 10	68 ± 11
Level of education		
Pre-vocational secondary or secondary vocational education	15 (23)	22 (33)
Senior general secondary education	10 (16)	8 (12)
Pre-university education	30 (46)	24 (37)
Higher professional education or university	8 (12)	10 (15)
Unknown	2 (3)	2 (3)
Duration of pain in d (mean ± SD)	47 ± 75	55 ± 76
Marital status		
Single	13 (20)	16 (24)
Unmarried	8 (12)	8 (12)
Married	37 (57)	30 (45)
Divorced	2 (3)	1 (2)
Widowed	4 (6)	9 (14)
Unknown	1 (2)	2 (3)
Working status		
Working, full time	8 (12)	16 (24)
Working, part time	12 (18)	7 (10)
Sickleave	2 (3)	1 (2)
Retired	36 (55)	34 (51)
Unemployed, able to work	3 (5)	1 (2)
Unemployed, unable to work	3 (5)	3 (5)
Unknown	1 (2)	4 (6)
Location		
Left hip	10 (15)	9 (14)
Right hip	24 (37)	15 (23)
Both hips	6 (9)	3 (5)
Left knee	13 (20)	13 (20)
Right knee	9 (14)	18 (26)
Both knees	3 (5)	6 (9)
Unknown	0 (0)	2 (3)
Had non-operative treatment before		
Yes	18 (28)	25 (38)
No	47 (72)	39 (59)
Unknown	0 (0)	2 (3)
Hospital		
Hospital 1	2 (3)	9 (14)
Hospital 2	23 (35)	21 (32)

Hospital 3	27 (42)	26 (39)
Hospital 4	13 (20)	10 (15)

DA: Decision aid.

DISCUSSION

Our research shows that patients using a DA in making a shared decision had significantly less decisional conflict, increased satisfaction with the given information and the treating physician after their first consultation and more knowledge about their given treatment.

In previous studies, low decisional conflict was related to DCS scores of 25 or lower. Scores of 39 and higher were related to higher mental conflict which can result in delays in decision making[10,15]. The finding that patients provided with a DA experienced less decisional conflict after the first consultation compared to patients treated without a DA is in concordance with previous studies[6]. The systematic review by Stacey *et al*[16] included 105 studies comparing treatment with DAs to usual care. Sixty-three of the 105 studies used the DCS. A significant average decrease in the level of decisional conflict was observed in the DA group.

In the systematic review by Stacey *et al*[5], the level of satisfaction with the given information and the treating physician at enrollment seems to be positively influenced by DAs. Eleven studies measured satisfaction with the decision-making process, 4 measured satisfaction with the given information and 1 measured satisfaction with participating in the decision making. In these 16 studies, mixed outcomes were found for satisfaction, but none of the studies showed significantly less satisfaction in the DA group. A possible explanation for the positive effect of the DA on the level of satisfaction with the given information could be that patients were able to repeat the information that was given by the physician by reading the DA and have a better recollection. This could also make the patient feel more satisfied with the physician. A crucial factor in patients' satisfaction with their treating physician is how they communicate. An essential part of communication is how the physician provides information about treatments. If the patient is more satisfied with the information because of the DA, this could influence the satisfaction with the physician in a positive way[17-19].

The finding that DAs did not have an effect on the level of anxiety is also accordant with previous studies[5]. Thirty-one studies measured anxiety, and none of these studies showed differences in the effect on patients stated anxiety after one month, three months or one year. Our expectation was that if a patient knows more about potential risks then they might be more anxious. This was not seen in our results.

A well-designed DA should be substantiated by evidence-based research. This means that if one of the treatments has better results this will be seen in the DA. However, every treatment has disadvantages, which will also be reflected in the DA. It is then up to the patient to decide if the advantages are more important than the disadvantages. This means that after the implementation of a DA the preference for a certain treatment can change.

The positive effect of DAs in our results supports the use of DAs in clinical practice. It can help physicians to inform their patient in a better, easier and more complete way. For example, with knee OA, not many patients decide during the first consultation that they are ready for a total knee arthroplasty. In the majority of cases there will be a second and a third consultation. If the orthopedic surgeon provides the patient with a DA in the first consultation, the patient will return better informed. The orthopedic surgeon will have more time to personalize the consultation instead of giving only basic information about the treatments. The patient can ask more specific questions to support their decision. In this way, consultations can be more efficient, and this will be of benefit to the patient and the physician.

Further research is required to determine the positive effect on patients and physicians. In addition, the effect of individualized DAs and their cost-effectiveness should be investigated.

The strength of this study is that this RCT was performed in secondary as well as tertiary referral centers.

The first limitation of this study is the high loss to follow-up at 26 wk (Figure 1). After 26 wk, 56 patients (43%) did not respond during the follow-up period. Additionally, the initial follow-up period was set at 26 wk after the first consultation.

Table 2 Outcomes after the first consultation, *n* (%)

	Without DA	With DA	*P* value
Decisional conflict scale (mean, SD)			
Informed subscore	39 (20)	32 (20)	0.03
Values clarity subscore	50 (22)	25 (16)	0.00
Support subscore	45 (16)	27 (13)	0.00
Uncertainty subscore	35 (15)	23 (16)	0.00
Effective decision subscore	28 (13)	20 (15)	0.00
Total score	39 (11)	25 (12)	0.00
Satisfaction (mean, SD)			
Information	7.6 (1.8)	8.6 (1.1)	0.00
Visit outpatient clinic	8.0 (1.7)	8.3 (1.5)	0.30
Physician	8.3 (1.7)	8.9 (0.9)	0.01
Anxiety (mean, SD)	23 (19)	20 (17)	0.29
Knowledge (mean, SD)	3.3 (0.9)	3.7 (0.6)	0.01
Stage of decision making			0.11
Have not begun to think about the treatment options	2 (3)	1 (1.5)	
Have not begun to think about the treatment options, but I am interested to do so	6 (9)	0 (0)	
I am considering the treatment options now	9 (14)	10 (15)	
I am close to selecting an option	1 (2)	3 (4.5)	
I have already made a decision, but am still willing to reconsider	10 (15)	15 (23)	
I have already made a decision and I am unlikely to change my mind	37 (57)	37 (56)	
What treatment option do you prefer?			0.46
Watchful waiting	3 (5)	5 (8)	
Lifestyle changes	3 (5)	1 (2)	
Physiotherapy	13 (20)	22 (33)	
Painkillers	3 (5)	3 (5)	
Corticosteroid injection	12 (18)	7 (11)	
Prosthesis	27 (41)	26 (38)	
Other	4 (6)	2 (3)	
Did you make a final choice			0.84
Yes	51 (78)	50 (76)	
No	14 (22)	16 (24)	
If yes, what did you choose			0.26
Watchful waiting	2 (4)	4 (8)	
Lifestyle changes	3 (6)	1 (2)	
Physiotherapy	8 (16)	16 (32)	
Painkillers	2 (3)	1 (2)	
Corticosteroid injection	11 (22)	6 (12)	
Prosthesis	25 (49)	21 (42)	
Other	0 (0)	1 (2)	

DA: Decision aid.

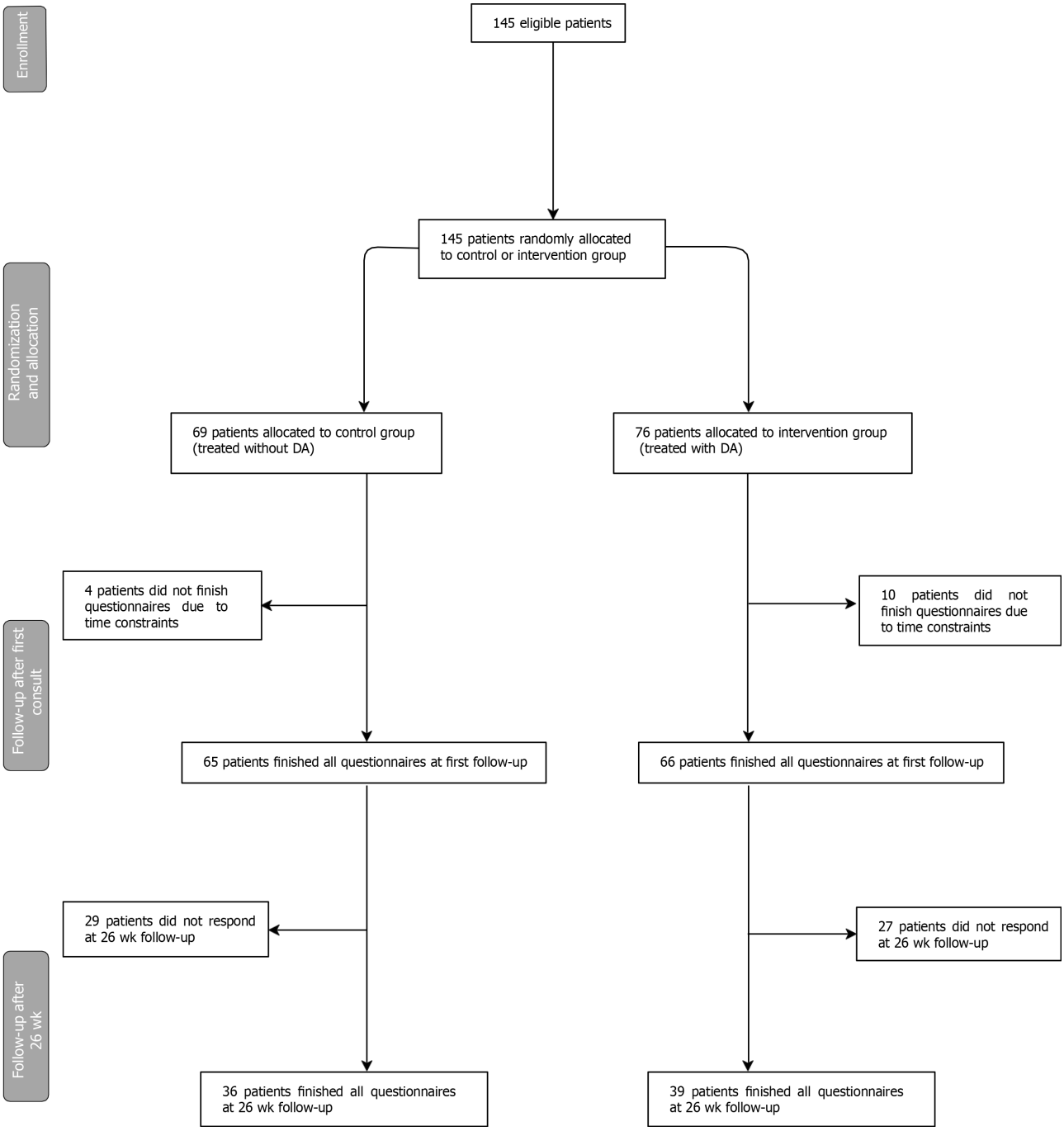

Figure 1 Flow of the patients in the study.

However, eventually, the mean follow-up period was 350 d, thus closer to 52 wk than the anticipated 26 wk. Although the loss to follow-up in both groups was approximately the same, no conclusion can be drawn from the follow-up results. The loss to follow-up was due to time constraints, even though great effort was made to try and contact these patients.

The second limitation was the exclusion of 14 patients, 4 patients in the control group and 10 patients in the intervention group, who did not complete the questionnaires after the first consultation due to time constraints at the outpatient clinic.

The third limitation was that knee or hip OA patients may experience different levels of decisional conflict related to their stage of the OA. We did not categorize patients into different stages of OA. However, due to randomization we expect that patients with varying stages of OA were equally divided over both groups.

CONCLUSION

Providing patients with an additional DA may have a positive effect on decisional conflict after the first consultation. Due to loss to follow-up we are unsure if this effect remains over time.

ARTICLE HIGHLIGHTS

Research background

Shared decision making has become more popular over the years. A decision aid (DA) can help the patient and the physician with the shared decision making process in case a diagnosis has multiple treatment options.

Research motivation

To determine if DAs can help in optimizing orthopedic healthcare we provide to patients with hip or knee osteoarthritis (OA).

Research objectives

The objective of this study was to determine the influence of a DA on decisional conflict in patients that require treatment for hip or knee OA.

Research methods

A multi-center unblinded randomized controlled trial was conducted in which we compared decisional conflict in patients with hip or knee OA. The control group was treated with standard care, and the intervention group was treated with standard care and was provided with a DA.

Research results

In the intervention group, we observed a significant decrease in decisional conflict after their first consultation with the physician. At 26 wk the sample was too small for analysis due to excessive loss to follow-up.

Research conclusions

Patients with hip or knee OA choosing treatment seem to have less decisional conflict after their first consultation with their physician when treated with an additional DA.

Research perspectives

In further research we should investigate the cost-effectiveness of decision aids and the satisfaction among physicians.

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SYSTEMATIC REVIEWS

Intraosseous device for arthrodesis in foot and ankle surgery: Review of the literature and biomechanical properties

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Abstract

BACKGROUND

Arthrodesis is the surgical fusion of a diseased joint for the purposes of obtaining pain relief and stability. There have been numerous fixation devices described in literature for foot and ankle arthrodesis, each with their own benefits and drawbacks.

AIM

To review the use of intraosseous devices in foot and ankle surgery.

METHODS

There were 9 papers included in the review (6 clinical and 3 experimental studies) all evaluating arthrodesis in the foot and ankle using the IOFIX device (Extremity Medical™, Parsippany, NJ, United States). Outcome scores, union rates, as well as complications were analysed.

RESULTS

IOFIX appears to be safe and effective in achieving arthrodesis of the 1st metatarsophalangeal, and talonavicular joints with early rehabilitation. In comparison to plate/screw constructs there were fewer soft tissue complications and issues of metalwork prominence. Cadaveric and biomechanical studies on the use of intramedullary fixation for fusion of the tarsometatarsal and ankle joint showed decreased load to failure, cycles to failure and stiffness in comparison to traditional fusion methods using plates and screws, however IOFIX devices produced higher compressive forces at the joint.

CONCLUSION

We describe the reasons for which this biomechanical behavior of the intraosseous fixation may be favorable, until prospective and comparative studies with larger

Peer-review model: Single blind

Peer-review report's scientific quality classification
Grade A (Excellent): 0
Grade B (Very good): B
Grade C (Good): 0
Grade D (Fair): D
Grade E (Poor): 0

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sample size and longer follow-up confirm the effectiveness and limitations of the method.

Key Words: Intra-osseous fixation; Foot; Ankle; Arthrodesis; Biomechanical; IOFIX

Core Tip: Numerous fixation devices have been described in literature for foot and ankle arthrodesis. This review article looked into the use of an intraosseous device IOFIX. Outcome scores, union rates, as well as complications described in 9 related publications were analysed. IOFIX appears to be safe and effective in achieving arthrodesis of the 1st metatarsophalangeal and talonavicular joints with early rehabilitation. However, cadaveric and biomechanical studies on the use in tarsometatarsal and ankle joint showed some concerns for which further clinical trials are required.

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INTRODUCTION

Arthrodesis is the surgical fusion of a diseased joint for the purposes of obtaining pain relief and stability. The fundamental principles of arthrodesis include (1) Adequate exposure and preparation of joint surfaces; (2) Coaptation of the surfaces; and (3) Rigid fixation of the surfaces until union[1,2].

Compression, rigidity and co-aptation are interrelated. With perfect co-aptation and compression, significant rigidity can be achieved. Compression neutralises the shear and bending forces. This in turn prevents separation of the surfaces. When compression is applied across an arthrodesis, the pressure is initially concentrated on the uneven areas of the cut surfaces. The resulting osteoclastic resorption brings the surfaces into closer co-aptation. Under the influence of moderate dynamic compression, osteoblastic stimulation occurs resulting in union across the arthrodesis[1]. However, excessive compression leads to bone resorption[2]. The ideal arthrodesis should therefore have moderate compression and near perfect coaptation. Decreased stiffness of fixation and micro-motion improve union provided the magnitude of strain and force of application are not excessive[3,4].

In foot and ankle surgery, common joints where arthrodesis is performed include ankle, subtalar (ST), talonavicular (TN), calcaneocuboid (CC), tarsometatarsal (TMT) and the 1st metatarsophalangeal (MTP) joint. There have been numerous fixation devices such as compression screws, staples, locking and nonlocking plates, as well as combined fixation of screws, staples, and/or plates described in literature each with their own benefits and drawbacks.

The IOFIX (an Intra-Osseous FIXation device, Extremity medical, New Jersey, United States) is a fixed angle device consisting of a "Post" and a lag screw. The "Post" is inserted parallel to the joint surface. The "post" has an eyelet in its head through which a lag screw can be passed across the arthrodesis site at a 60° angle (Figures 1 and 2A). The lag screw gets engaged in the morse taper of the eyelet resulting in a more uniform compression across the fusion site. Since the entire construct is embedded in the bone there is less risk of soft tissue irritation and prominence of metalwork. Furthermore, in comparison with a plate and screw construct there is less soft tissue damage and periosteal damage needed to prepare the articular surfaces and apply the implant.

There have been a number of publications in literature regarding the use of the Intraosseous devices in different joint arthrodesis[5-12]. The aim of this article is to review these publications, assess the overall efficacy of the device across the various joints that are commonly arthrodesed in foot and ankle surgery and correlate the results with its biomechanical properties.

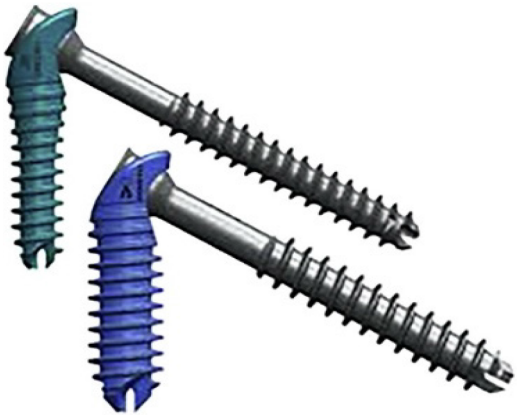

Figure 1 IOFIX device with post (6.5/6.9 mm diameters) and lag screw (4.3/5 mm diameters).

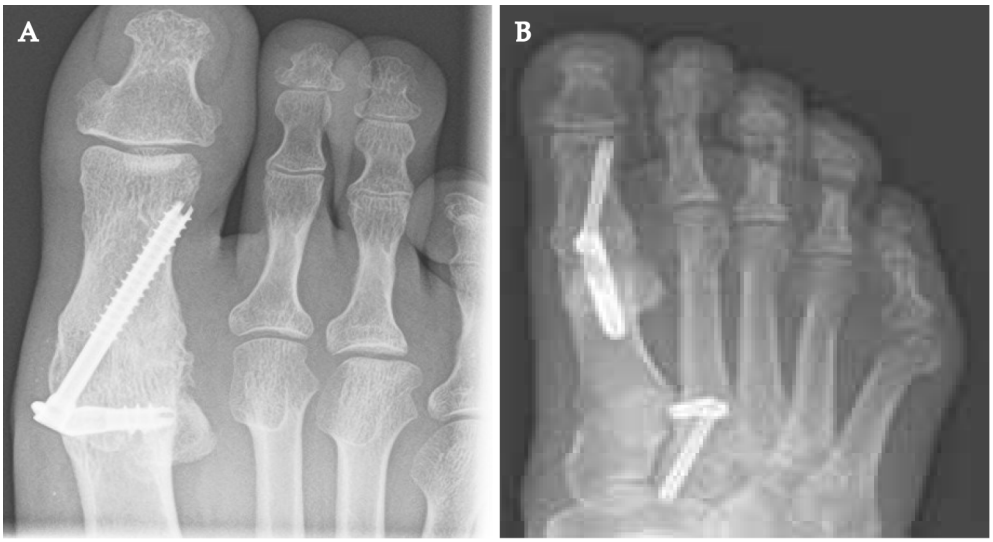

Figure 2 X ray. A: Final position of IOFIX implant; B: Post-operative x ray of a 1st metatarsophalangeal joint fusion using an Intramedullary device at 12 wk.

MATERIALS AND METHODS

A literature search was done in several databases; PubMed Central, Cochrane Central and MEDLINE. The search was restricted to articles in English language. Only fully published studies with details of the use of intra osseous devices were included. Key words used in search were "Intra osseous fixation", "foot", "ankle" and "arthrodesis".

Data extracted included study design, selection criteria, population demographics, type of intervention, initial and final outcome scores, union rates, as well as complications if any. Results of all the included studies were described in a table format. Key outcomes assessed were union rates, patient reported outcome scores and complications.

RESULTS

There have been 9 publications on this topic[5-13] (Table 1). Six of these were clinical studies (5 on 1st MTP joint and 1 on TN joint). Two were cadaveric (1 each on ankle and TMT joint) and one was a synthetic bone study (TMT joint). All the clinical studies had patient reported outcome scores as well as arthrodesis union rates reported.

Radiographic union of the fusion site was defined by observing complete callus or trabeculation across 3 cortices. Position of fusion of the 1st MTP joint was assessed by analysing the intermetatarsal angle, hallux valgus angle (HVA), and 1st MTP joint dorsiflexion angle (DA) using weightbearing anteroposterior and lateral views of the foot.

Table 1 Characteristics of included studies

No	Ref.	Joint arthrodesed	Number of joints	Follow up (mo)	Outcome
1	Segal *et al*[5], 2020	1st MTP joint	30	36	Mean postop AOFAS score: 80.5
2	Patel *et al*[6], 2019	1st MTP joint	54	12	Mean MOXFQ improved from 46.4 to 18.4
3	Singhal *et al*[7], 2018	1st MTP joint	21	28	Mean MOXFQ improved from 49.7 to 17.9
4	Drampalos *et al*[8], 2017	1st MTP joint	12	15	Mean AOFAS score improved from 29.4 to 73.3
5	Drampalos *et al*[9], 2016	1st MTP joint	23	19	Mean AOFAS score improved from 29 to 75.4
6	Shymon *et al*[10], 2016	Talonavicular	12	12	VAS pain level decreased from 7.3 to 2.1
7	Parker *et al*[11], 2014	Tibio talar joint	10 cadaveric		Higher forces within the arthrodesis (3.95 kg *vs* 2.35 kg) in IOFIX
8	Burchard *et al*[12], 2018	1st MTP joint	9 synthetic		Lower load to failure and less stiffness in IOFIX
9	Roth *et al*[13], 2014	1st MTP joint	7 cadaveric		Lesser cycles to failure in IOFIX

VAS: Visual analogue scale; MTP: Metatarsophalangeal.

1st MTP joint (clinical study)

Segal *et al*[5] from Tel Aviv, Israel, conducted a retrospective review on union rates following the use of IOFIX. Standard operative technique was used. The study included 30 cases with an average follow up of 36.2 ± 12.31 mo. Plain radiographic studies were taken at 6 wk, 3–6-12 mo, and at 24 mo when applicable. Clinical union was when the patients could fully bear weight on their feet without pain, and had no pain when applying external force on the 1st MTP joint. Radiographic union was obtained in 28 (93.33%) patients. None of the patients requested removal of hardware due to prominence. The mean postoperative AOFAS score[14,15] was 80.5 ± 10.87. One patient had asymptomatic nonunion. One patient underwent repeat surgery for symptomatic nonunion but still did not go on to union. There were no cases of loss of position or implant breakage.

Patel *et al*[6] from London, United Kingdom, analysed 54 feet for clinical and radiological union with a minimum follow up of 1 year. Patients were allowed to fully bear weight in a rigid-soled shoe with 2 crutches to assist walking immediately after surgery. Arthrodesis was achieved in 52 (96.3%) feet at a mean of 61 ± 16 d. Nonunion was observed in 2 (3.7%) feet with one person opting for repeat surgery using a dorsal plate. There were 2 (3.7%) superficial wound infections that responded to oral antibiotics without further complications. Removal of implant due to metalware impingement on soft tissues was performed in 3 (5.6%) feet after union. The mean Manchester-Oxford Foot Questionnaire score[16] improved from 46.4 ± 13.3 to 18.4 ± 9.4 ($P < 0.001$) at latest follow-up. There were no cases of loss of position or implant breakage.

Singhal *et al*[7] from Liverpool, United Kingdom, did a retrospective review of 21 patients with a mean follow up of 28 mo. Postoperatively patients were allowed to heel weight bear in a firm soled sandal with the aid of crutches. Complete fusion of the 1st MTP joint was achieved in twenty (95%) patients. One patient had a non-union and another patient developed a delayed union. The non-union was revised 14 mo after the initial procedure with a locking plate and bone graft and this has gone on to unite. The mean preoperative MOXFQ score improved from 49.7 (95% confidence interval: 46-52) to 17.9 (95% confidence interval: 12-22), $P < 0.05$.

Drampalos *et al*[8] from Manchester, United Kingdom, published their results on twelve consecutive patients operated with this method. Postoperatively, a C-slab was applied, followed by immediate heel weight bearing in stiff soled shoe. After 6–12 wk, the patients were allowed unrestricted activities provided a satisfactory progression of fusion was evident on radiographs. The mean follow up was 15 mo. Fusion of the MTP joint was obtained in 11 toes (91%). The AOFAS score improved significantly from a preoperative mean of 29.4 (range 10–54), to a postoperative mean of 73.3 (range 59–90) ($P < 0.0001$). The patient with nonunion had only minor improvement from the procedure with persisting symptoms but did not want a revision surgery. There was one patient diagnosed with transfer metatarsalgia who had a malalignment with a

HVA of 4°. This patient had a poor improvement of the AOFAS score (from 30 preoperatively to 59 after the operation) but was still satisfied with the result.

In another series, Drampalos *et al*[9] from Manchester, United Kingdom, reviewed the results of arthrodesis of the 1st MTP joint in 23 patients using the IOFIX or HALUX (Extremity Medical, Parsippany NJ, a similar intramedullary device with an anchored post and a lag screw) (Figure 2B). Patients were followed up for a mean of 19 mo. The mean AOFAS score improved from 29 to 75.4 ($P < 0.0001$) and the mean VAS for pain improved from 8.1 to 2.4 ($P < 0.0001$). Twenty (86%) of the patients were satisfied with the outcome. Twenty-one (91%) of the patients achieved arthrodesis. 2 patients underwent revision surgery for failed fusion (HALUX) and infected non-union (IOFIX).

Talonavicular joint (clinical study)

Shymon *et al*[10] from California, United States, investigated postoperative bony union and functional outcomes of 12 consecutive patients who underwent TN arthrodesis with the IOFIX device. Surgical indications included posttraumatic arthritis, rheumatoid arthritis, and idiopathic arthritis. Post operatively, a short leg, well-padded splint was applied. Patients were advised to be non–weight bearing. At 1 wk, they were placed in a controlled ankle movement boot and allowed to weight bear if pain allowed it. Patients were followed up for a minimum of 1 year. The VAS pain level decreased from 7.3 ± 0.9 preoperatively to 2.1 ± 0.7 postoperatively ($P < 0.001$) and the SF-12 physical component improved from 27.9 ± 4.2 preoperatively to 42.2 ± 3.5 postoperatively ($P < 0.001$). Radiographic union was achieved in all the 12 patients at 9.6 ± 0.4 wk. Three patients had a superficial wound infection that resolved with oral antibiotics for 10 d. On average, patients were able to weight bear by 3.5 wk (range 2.2-5.5 wk)

Tibiotalar joint (cadaveric study)

Parker *et al*[11] from London, United Kingdom, conducted a cadaveric experiment on 10 ankles where they compared the magnitude and distribution of force created across an ankle arthrodesis between IOFIX and traditional AO 6.5 mm cancellous partially-threaded bone screws (Figure 3). The soft tissues from the ankles were removed and the articular surfaces of the distal tibia and talus were prepared with a 2.5 cm wide saw to create uniformly flat arthrodesis cuts. The 10 ankles received both treatments in a randomized fashion in order to allow direct comparisons between repeated measurements. Compression forces were measured using a Tekscan/Iscan (Tekscan Inc. South Boston MA, United States) pressure transducer calibrated to display force in kilograms (kg) and contact area in cm^2 and inserted into the arthrodesis.

The IOFIX created significantly higher median average forces within the arthrodesis (3.95 kg compared with 2.35 kg, $P \leq 0.01$). The IOFIX also created a more uniform pressure across the arthrodesis as well as a higher median average uniform contact area (3.41 cm^2 *vs* 2.42 cm^2, $P \leq 0.03$).

1st TMT joint (in vitro study & cadaveric study)

Burchard *et al*[12] from Witten, Germany, conducted an experimental study using 9 synthetic bones to study the use of a medial locking plate (Double bridge plate® (Konigsee Implantate GmbH, Allendorf, Germany), a plantar locking plate (PEDUS L Plantar Lapidus Plate® (Axomed GmbH, Freiburg, Germany), or an intraosseous locking device [IOFIX (Extremity Medicals, Parsippany, United States)] in 1st TMT joint arthrodesis. They looked into the difference in the initial compression of the osteosynthesis as well as loss of stability and load to failure. The highest initial compression force was provided by the IOFIX implant (131 ± 55 N), followed by the medial locking plate (87 ± 51 N) and the plantar plate (3 ± 1 N). The stiffness provided by the plantar plate was superior compared to both of the other fixation methods (*vs* medial plate $P \leq 0.000$, *vs* IOFIX $P \leq 0.000$). Load to failure was in the following order: (1) IOFIX (173 ± 8 N); (2) Medial plate (324 ± 24 N); and (3) Plantar plate (377 ± 41 N).

Roth *et al*[13] from Mainz, Germany, performed a study on 7 pairs of freshly frozen cadaveric feet to compare the intra- medullary implant IOFIX (Extremity Medical TM, Parsippany, NJ, United States) with plantar locking plate (Wright Medical Technology, Inc, Arlington, TX, United States) in osteosynthesis of the 1st TMT joint. Cycles until failure, failure load, displacement, and plantar gapping were recorded. On average the plates failed after 7517 cycles and a maxi- mum load of 167.1 N while the screw and post implants failed on average after 2946 cycles and a maximum load of 68.6 N. After 8167 cycles 50% of the plates had failed while the same failure rate was observed after 2269 cycles in the IOFIX group. Initial and final stiffness were all higher on average in

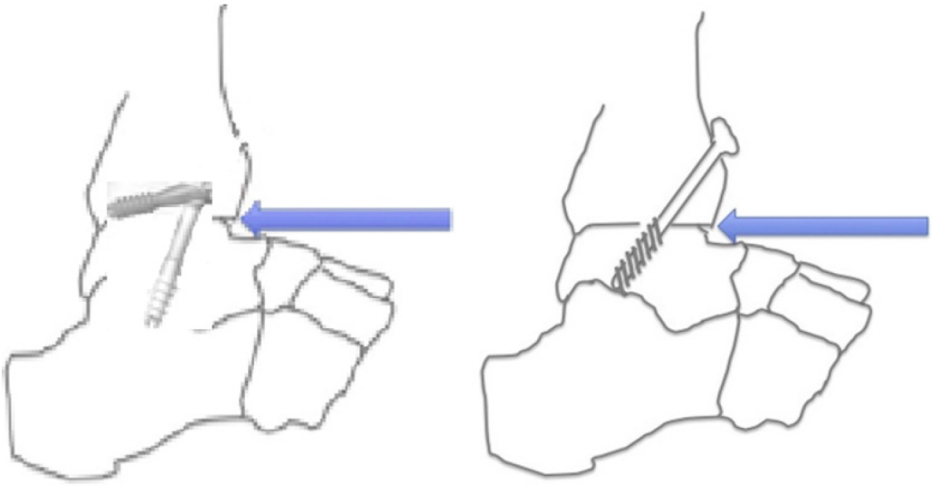

Figure 3 Diagrammatic representation of IOFIX and cancellous screws used in tibiotalar joint arthrodesis.

the plate-treated group than in the screw and post group.

DISCUSSION

The majority of studies on the use of intraosseus fixation devices for arthrodesis involve the first MTP joint and it is considered that the type of implant used to stabilise the fusion site influences the outcome. In general literature the union rates of primary first MTP joint arthrodesis has been excellent and reported to be up to 100% [17]. Patient's satisfaction after MTP arthrodesis varies from 78% to 93%[18-20]. Larger implants have a higher rate of successful fusion but they also have higher implant removal rate, up to 30%, due to nonunion, malalignment, pain and hardware impingement of the soft tissues[21-23]. The intraosseous advantages of IOFIX include the facts that it is of "low profile" and provides uniform compression with a stable fixation[24]. In the series of studies reviewed, IOFIX appears to be safe and effective in achieving arthrodesis of the first MTPJ and immediate weightbearing can be allowed. Concerns have been raised about the cost of the IOFIX implant[5]. However, with the reduced requirement for further surgery and excellent union rates, the pros could outweigh the cons.

The TN arthrodesis study[10] suggests that the IOFIX device improves patient outcomes with a quick return to weight bearing. Historically, post-TN arthrodesis nonunion has been reported in up to 37% of cases of rheumatoid arthritis[25]. In this study, that included 3 patients with rheumatoid arthritis, there were no cases of nonunion.

The experimental study on ankle arthrodesis[11] showed that the IOFIX exhibited a more uniform contact area. The AO lag-screw and washer tended to concentrate stress nearest where it was inserted. Bone resorption in areas of high peak contact stress within an arthrodesis may lead to progressive loss of bone interdigitation, gapping and non-union at the interface. Therefore, theoretically, IOFIX has an advantage over the lag screw fixation methods. But there were no clinical studies available.

In the TMT studies[12,13], IOFIX demonstrated the highest initial compression force of the three tested implants but the load to failure, cycles to failure and stiffness were significantly lesser. The plantar locking plate showed the best overall stability and stiffer construct during cyclic weight-bearing simulation. This does not necessarily mean higher union rates when a plate is being used. In case of a fracture or a fusion there is a range of instability/rigidity which may be tolerated in different biomechanical scenarios. A fusion may be achieved despite instability (or decreased stiffness) while minimal instability may be detrimental in rigidly fixed constructs with small gaps.

The Perren's theory of strain describes the minimum and maximum degrees of rigidity which will be tolerated leading to primary bone healing and induction of callus formation[26]. The decisive factor for tissue differentiation is deformation or strain of the repair tissue and not rigidity/mobility. While tissue strain relates with mobility, it depends even more so on the distance between the movement of the

opposing surfaces. The biological parameters of damage to the blood supply and bone necrosis emphasize the importance of avoiding extensive periosteal stripping and contact of the implant with bone. A balance between rigidity, compression and co-aptation is probably more important. Primary union is seen when rigid stabilisation with perfect co-aptation and minimal interfragmentary motion is applied. Osteoclasts make up the head of a "cutting cone", followed by capillaries and then osteoblasts which lay down the osteoid to fill the "cutting cone". Small gaps are filled by woven bone which later remodels to lamellar bone. There is no external callus and bone strength is not restored for many months. However, in less rigidly fixed fractures, external callus is seen and bone is remodelled quicker in accordance with Wolff's law and Perrens's strain theory[3]. The intraosseous device offers an advantage in this regard. Further research and clinical data is necessary to study the efficacy of IOFIX in TMT fusions. The senior authors of our team have used the IOFIX device for 1st TMT joint fusions with encouraging results and is in the process of publishing them.

The limitation of this review is the few papers available on the device. There were also no clinical papers on the use of intraosseous devices in joints other than the 1st MTPJ and a single article on the talonavicular joint.

CONCLUSION

The intraosseous fixation device IOFIX reviewed in our study appears to be a safe and effective device to achieve arthrodesis with the advantages of early weight bearing. They provide good patient reported outcomes satisfaction and bone union as well as avoiding prominent hardware complications and soft tissue irritation. However, further prospective and comparative studies with larger sample size and longer follow-up are needed to confirm these findings.

ARTICLE HIGHLIGHTS

Research background

Numerous fixation devices have been described in literature for foot and ankle arthrodesis. Each of these devices have their own benefits and drawbacks

Research motivation

This review article looked into the use of an intraosseous device IOFIX. Since the entire construct of IOFIX is embedded in the bone, there is less risk of soft tissue irritation and prominence of metalwork.

Research objectives

Outcome scores, union rates, as well as complications associated with the use of IOFIX was looked into.

Research methods

Fully published studies with details of the use of intra osseous devices were included in the study. These were identified by a search through available English literature. Nine related publications were identified and analysed.

Research results

In comparison to plate/screw constructs there were fewer soft tissue complications and issues of metalwork prominence. It also provided adequate compression across the arthrodesis site.

Research conclusions

IOFIX appears to be safe and effective in achieving arthrodesis of the 1st metatarsophalangeal and talonavicular joints with early rehabilitation. However, cadaveric and biomechanical studies on the use in tarsometatarsal and ankle joint showed some concerns with decreased load to failure and cycles to failure.

Research perspectives

Further clinical trials are required. Prospective and comparative studies with larger sample size and longer follow-up could confirm the effectiveness and limitations of

the method.

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