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Knee & Shoulder Arthroscopy And Arthroplasty ISKSAA

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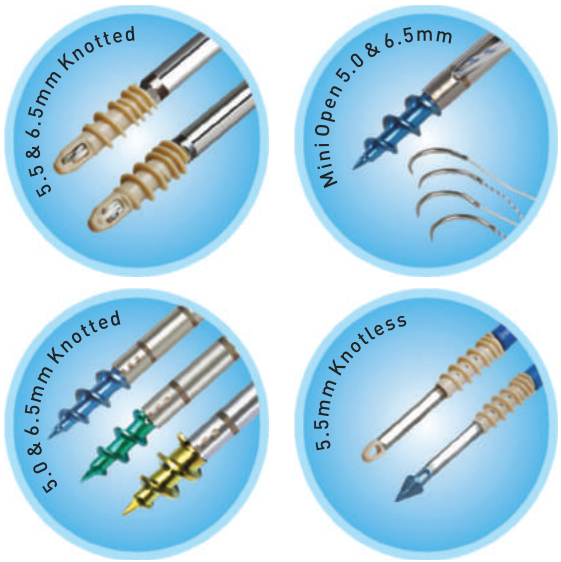

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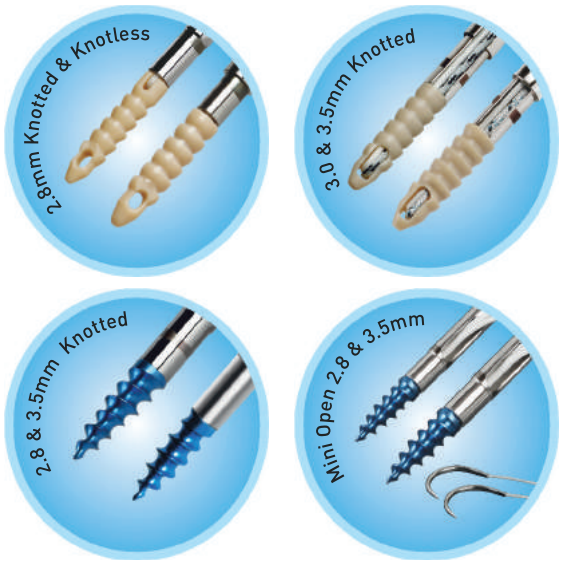

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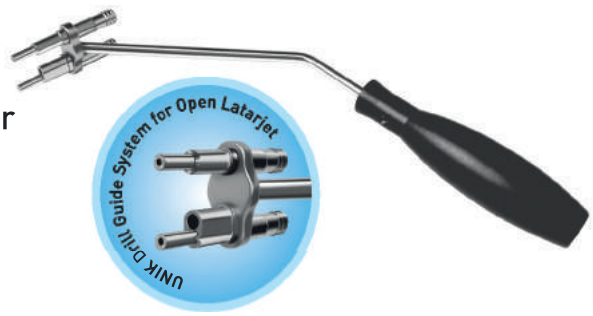

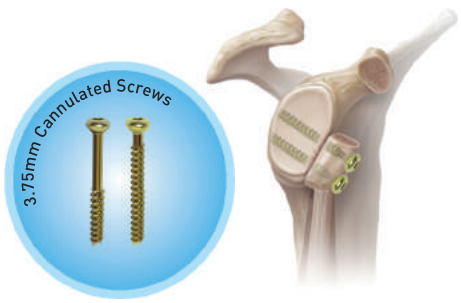

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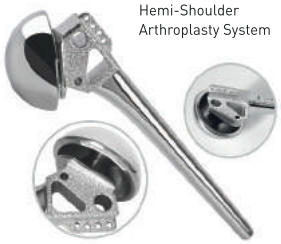

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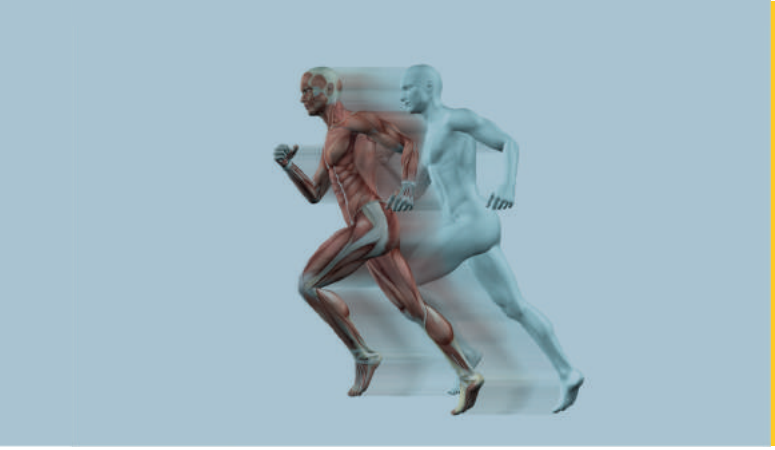

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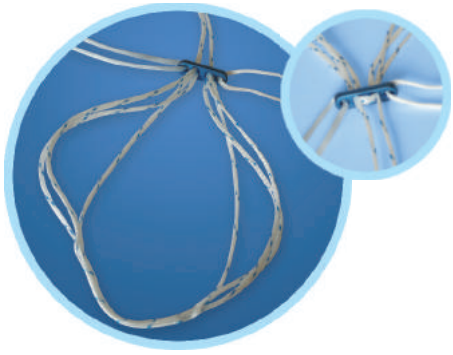

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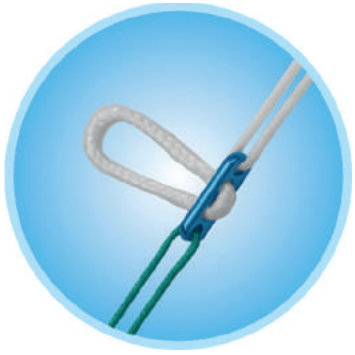

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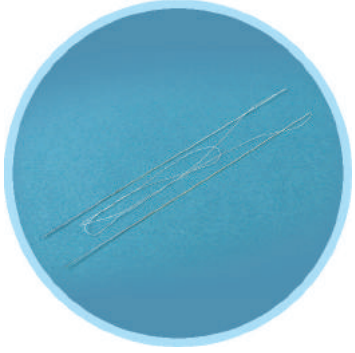

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Aims and Scope

Journal of Arthroscopy and Joint Surgery (JAJS) is committed to bring forth scientific manuscripts in the form of original research articles, current concept reviews, meta-analyses, case reports and letters to the editor. The focus of the Journal is to present wide-ranging, multi-disciplinary perspectives on the problems of the joints that are amenable with Arthroscopy and Arthroplasty. Though Arthroscopy and Arthroplasty entail surgical procedures, the Journal shall not restrict itself to these purely surgical procedures and will also encompass pharmacological, rehabilitative and physical measures that can prevent or postpone the execution of a surgical procedure. The Journal will also publish scientific research related to tissues other than joints that would ultimately have an effect on the joint function.

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Review article

Current concepts for arthroscopic ankle fusion

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ABSTRACT

Ankle arthrodesis is the gold standard treatment for end stage ankle arthritis as it provides pain relief, whilst also allowing patients to regain function and mobility. Although it is conventionally performed via an open approach, arthroscopic ankle arthrodesis (AAA) is rapidly gaining in popularity. This article reviews the current literature regarding AAA including its benefits and limitations, and various techniques used.

1. Introduction

Osteoarthritis (OA) is a common disease which accounts for significant disability and socioeconomic burden worldwide. Primary osteoarthritis of the ankle, however, is fairly rare, and represents less than 10% of patients with ankle pain, with the majority of patients being diagnosed with posttraumatic ankle arthritis (Fig. 1).[1–3] Patients with end stage ankle arthritis often present with severe pain and loss of function, which has a negative impact on their quality of life.[4] Conservative management for them includes analgesics, non-steroidal anti-inflammatory drugs (NSAIDs) and orthotic devices which aim to immobilise the ankle to provide pain-relief and support.[5] Intra-articular corticosteroid injections are also recommended by the National Institute for Health and Care Excellence (NICE) as a temporary measure, in order to provide pain relief.[6] For patients who have failed conservative treatment, ankle arthrodesis is considered to be the gold standard surgical treatment for end stage arthritis.[7]

Ankle arthrodesis provides pain relief whilst also allowing patients to regain function and mobility. Although it is conventionally performed via an open approach since the late 1800s, arthroscopic ankle arthrodesis (AAA) is now rapidly becoming the norm.[8]

2. Pre-operative evaluation

Symptomatically, patients with ankle arthritis complain of pain that is exacerbated by movements such as climbing up stairs. This is followed by ankle stiffness, locking and finally pain at rest, as the disease progresses. As stated above, the majority of patients will have had a history of trauma to the ankle joint. A thorough history helps clinicians understand exactly how much of an effect the patient's symptoms are having on his/her life, which can then guide treatment. Patients with significant co-morbidities such as diabetes, or those on long term immunosuppression may have a higher risk of complications associated with wound healing,[9] and therefore require meticulous planning prior to operative intervention.

Clinical signs suggestive of ankle arthritis include disruption of the gait cycle and patients' need to use walking aids. Examination should ascertain the degree of any valgus/varus hindfoot deformity present, and whether the deformity is correctable, in addition to the range of movement present in the tibiotalar and the subtalar joints. It is also important to assess the knee and neurovascular status of the leg, prior to deciding a management plan.

Weightbearing radiographs of the ankle joint (mortise and lateral views) form the first line investigation for patients with suspected ankle arthritis. Computed tomography (CT) is a useful tool to assess the degree of arthritis present in the ankle and surrounding joints, presence of cysts and to determine the presence of any large osteophytes which may act as barriers to performing

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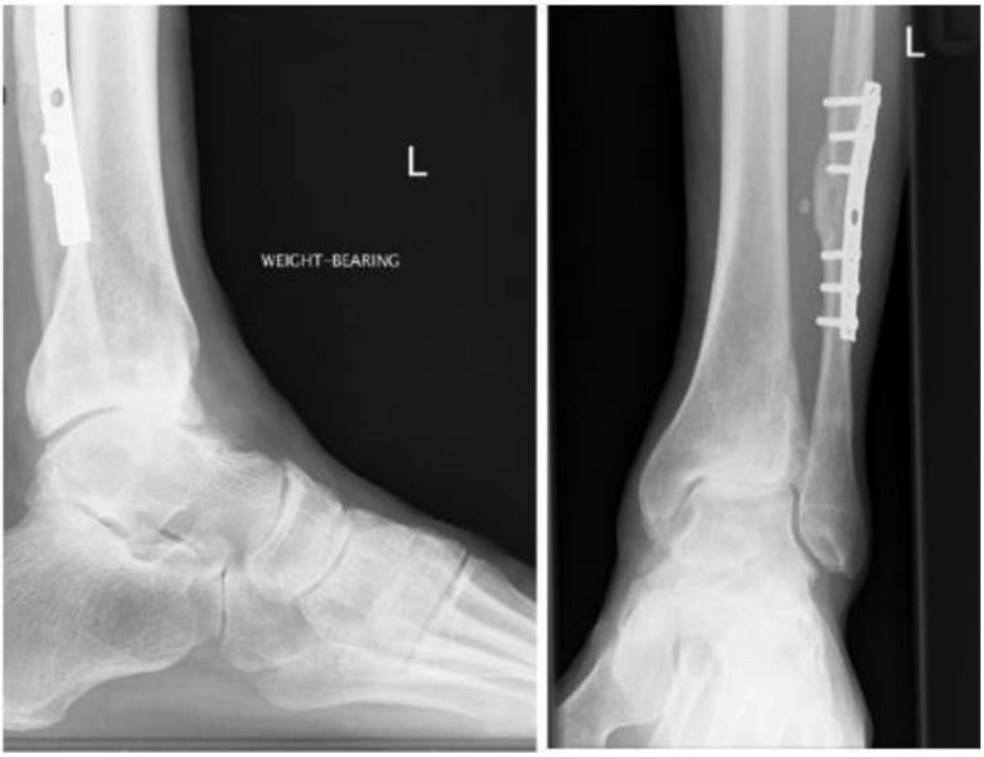

Fig. 1. Antero-posterior (AP) and lateral weight bearing radiographs of a patient (Mr X) with post-traumatic ankle arthritis. A united, high fibula fracture can be seen on the radiographs following internal fixation. There is loss of joint space, presence of anterior osteophytes and increased sclerosis of the ankle joint, confirming the diagnosis. There is a less than 15° coronal plane deformity in this case.

arthroscopic procedures.[10]

3. Indications and contraindications

AAA has gained popularity over open ankle arthrodesis due to multiple studies suggesting that it is associated with a quicker recovery period and shorter hospital stay, lower morbidity and a faster time to union than the latter.[11–13] It is most commonly performed for patients with end stage ankle arthritis. Other indications for AAA include osteochondritis of the talar dome, avascular necrosis of talus and inflammatory arthritis of the ankle joint. AAA is especially preferred for those patients with poor skin and/or those who may be more susceptible to wound related complications following surgery. It is contraindicated in patients with an active infection in the ankle joint and charcot arthropathy. In the past varus/valgus deformity of more than 15° has been considered as a relative contraindication to AAA. The rationale behind this is that a greater degree of correction in the form of osteotomies would be required to achieve joint congruency in such cases, which would not be feasible arthroscopically.[14,15] However, in recent times, AAA is being performed more and more commonly on patients with varus deformities greater than 15° with favourable results.[16–18]

4. Arthroscopic technique

4.1. Approach

AAA is most commonly performed via the standard anterior approach using anteromedial and anterolateral portals, although some authors suggest that the posterior approach may result in a higher union rate.[19] For the anterior approach, the patient is positioned supine with a thigh tourniquet. A bolster is placed underneath the thigh to flex the hip to 45°, and a non-invasive ankle distractor is attached using adjustable straps. Standard anteromedial and anterolateral portals are most commonly used, whilst taking care to avoid injuring the superficial peroneal nerve.[12]

When using the posterior approach, the patient is positioned prone with his/her foot just off the bed. A bolster or foot support is placed underneath the ankle in order to allow it to be moved freely. A thigh tourniquet is also used to provide a bloodless field for the arthroscopic procedure. Standard medial and lateral para-achilles portals are used, whilst taking care not to injure the neurovascular structures.[20]

The anterior approach is a relatively safe and reliable technique to carry out an AAA, and results in a high union rate. However, it does not allow access to approximately 10% of the posterior aspect of the ankle joint.[21] The posterior approach on the other hand allows over 95% of the joint to be debrided.[15] Moreover, it can be especially useful in cases where the patient also needs to undergo a talocalcaneal fusion in addition to a tibiotalar arthrodesis, or when large anterior osteophytes prevent access to the ankle joint through the anterior approach. However, it is only technically feasible if there is no equinus or a malunited posterior malleolus. Given the fact that the majority of patients have posttraumatic ankle arthritis, this limits the number of patients for which the posterior approach can be utilised.[22]

4.2. Debridement

Once access to the ankle joint is gained either via the anterior or posterior approach, both the tibial plafond and the talar dome need to be debrided in order to remove cartilage and restore joint alignment. Whilst it is assumed that removing less cartilage will compromise fusion rates,[8,15,22] as has been demonstrated for a

subtalar arthrodesis,[23] currently there is a dearth of literature that suggests a direct relationship between the amount of joint area debrided and ankle arthrodesis union rates. Achieving appropriate alignment of the talus within the ankle mortise is more important (Fig. 2), and it therefore may be necessary to prepare the medial and lateral gutters which may have osteophytes that interfere with joint reduction and/or deformity correction.

4.3. Fusion

In AAA, fixation is achieved by using 2 or 3 percutaneous, cannulated, large diameter (6.0–7.5 mm) screws in various configurations (Fig. 3). Currently, there is no consensus in the literature as to the number and/or screw configurations that should be used. Both cadaveric[24] and finite element analysis studies,[25] have demonstrated better mechanical stability and Goetzman et al.[26] showed a higher union rate when 3 screws were used. However, it can be technically quite difficult to insert the screws in the relatively small space available.[27] The configuration of the screws also has an impact on the time to union. Yoshimura et al.[28] revealed that not only was the time to fusion significantly shorter in patients who had had 3 screws compared to 2 screws, patients with 3 parallel, transmedial malleolar screws had an even shorter time to fusion as opposed to patients with 3 crossed transmalleolar screws. This is probably due to the fact that whilst crossed screws provide a more rigid fixation, parallel screws allow greater compression.[15]

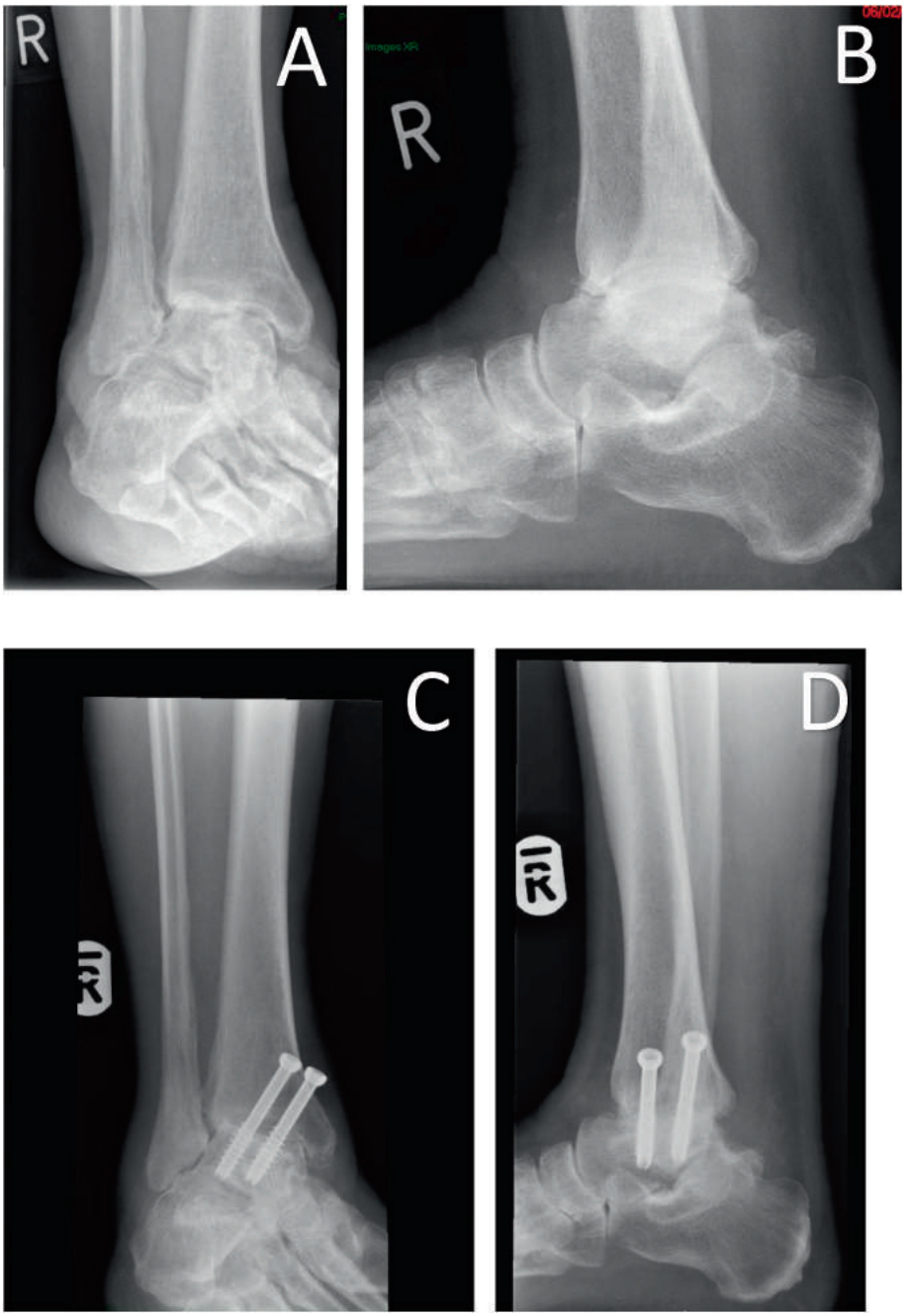

Fig. 2. (A and B): AP and lateral weight bearing radiographs of a 72 year old gentleman, demonstrating severe ankle osteoarthritis with a significant valgus deformity.Fig. 2 (C and D): AP and lateral weight bearing radiographs of the same gentleman 5 months following arthroscopic ankle arthrodesis and correction of the valgus deformity.

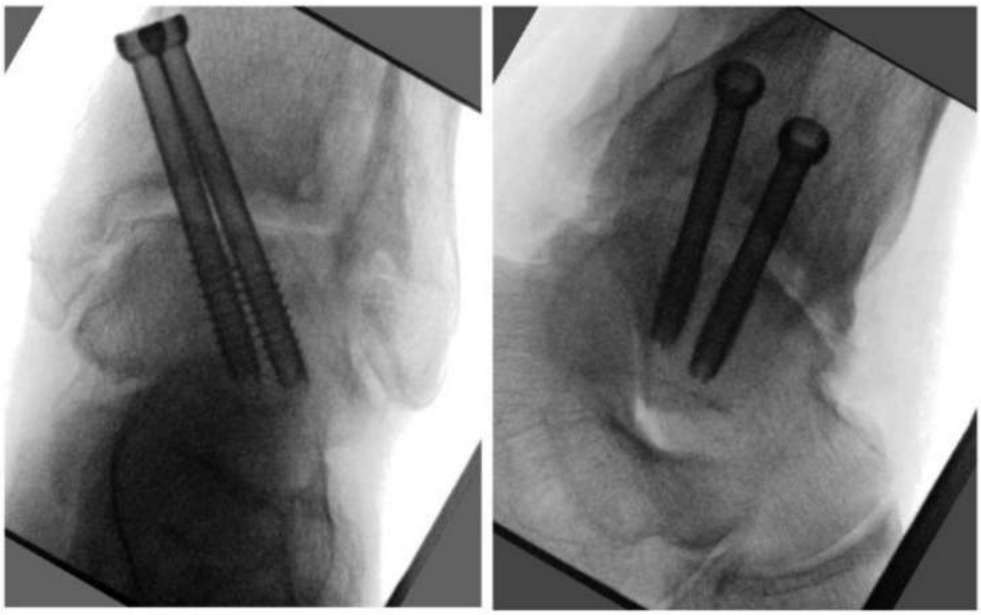

Fig. 3. Intra-operative fluoroscopy images of Mr X – AP and lateral views. 2 cannulated, parallel screws can be seen crossing the ankle joint from proximal-medial to distal-lateral.

Crossed screws can be useful when addressing varus deformity by first inserting the lateral screw as this brings the ankle in neutral alignment (Fig. 4).

4.4. Optimum foot position

Obtaining the correct foot position during fusion of the tibiotalar joint is of paramount importance as it provides patients with a stable platform on which to mobilise on. Ideally, the ankle should be fused in a neutral position with approximately 0–5° of valgus angulation and 0–5° of external rotation. This allows for a more normal gait with the other joints of the foot compensating for the lack of movement at the ankle.[30,31] Failure to achieve this can result in patients having an abnormal gait pattern which can then lead to the development of callosities and pain.

5. Post-operative care

Traditionally, patients are kept non-weightbearing after an AAA for 6 weeks, followed by weight bearing in plaster cast, with the total duration in plaster being 3 months. Cannon et al.[34] however allowed patients without any peripheral neuropathy or pre-operative talar collapse, to fully weight bear as tolerated from day 1 following surgery, and did not find a detrimental effect on their outcomes.

6. Outcomes

Ankle arthrodesis provides significant pain relief and improvement in quality of life, as demonstrated by the improvement seen in patient reported outcome measures (PROMs) such as the ankle osteoarthritis scale (AOS), short form – 36 (SF-36), physical component summary (PCS) and foot and ankle ability measure (FAAM).[35,36] AAA does however lead to changes in the gait, resulting in a slight decrease in stride length, cadence and gait efficiency.[37] Studies have also shown that patients have a reduced ability to perform an emergency stop after ankle arthrodesis, with longer brake reaction timings compared to healthy volunteers,

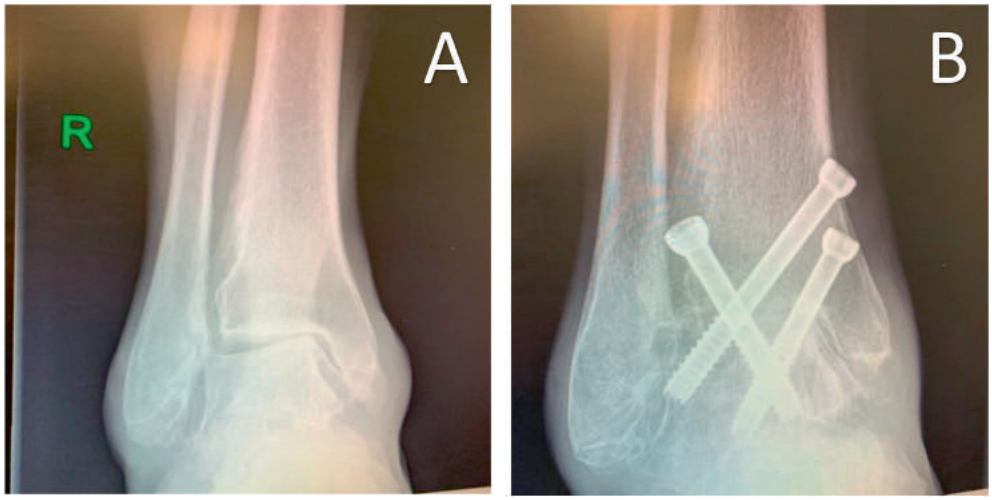

Fig. 4. (A): AP weight bearing radiographs demonstrating significant varus deformity of the right ankle Fig. 4 (B): AP weight bearing radiograph demonstrating correction of the varus deformity following AAA using 3 cross screws.

Table 1
Risk factors for delayed- and non-union following arthroscopic ankle arthrodesis. BMI – body mass index.

Local	Systemic
Open fracture leading to posttraumatic ankle arthritis	High BMI
Pre-operative coronal plane deformity	Smoking
Poor bone quality	Diabetic neuropathy
Massive bone defect	

although this does not exceed the safety criteria set by the US federal highway.[38,39]

6.1. Non union

A systematic review by Yasui et al.[13] found that the average union rate following an AAA was 94% (range, 70–100%). This was better than the 89% average union rate seen following an open ankle arthrodesis (range, 64–100%). Risk factors for delayed- and non-union included systemic and local causes as described in Table 1.

Whilst multiple studies have reported high BMI to be associated with an increased risk of delayed- or non-union, likely as a result of excessive shear strain on the ankle joint,[28,40] Goetzmann et al.[26] found no such association. Smoking also has a negative effect on union rates, as does diabetic neuropathy.[41–43] Patients with a history of an open ankle fracture resulting in post-traumatic arthritis are at a higher risk of developing a non-union, and therefore should be appropriately counselled pre-operatively.[41] Other risk factors include poor bone quality and significant bony defects, which can potentially be countered by the use of bone grafts and/or bone substitutes.[40,44] Interestingly, studies have also found that patients with a smaller pre-operative coronal plane deformity have a significantly shorter time to union as compared to those who need bigger corrections,[18,28] although Gougoulias et al.[19] reported no difference in the overall union rates. Patients with symptomatic non-unions tend to undergo revision surgeries which can either be an open ankle arthrodesis or a total ankle replacement.[45] Low intensity pulsed ultrasound (LIPUS) treatment, which has helped achieve fusion in small foot joints, has not been hugely successful in treating non-unions of ankle arthrodesis.[46]

6.2. Revision surgery

Literaure suggests that apart from symptomatic non-unions, approximately 9–31% of patients tend to undergo revision surgery following an AAA for removal of prominent screws.[11,47] Most techniques involve placing at least one compression screw from the medial tibial border to the lateral aspect of the talus, *trans*-articularly. This can result in the screw head being quite prominent and causing discomfort. One way of tackling this issue is to use headless compression screws which allow the entire screw length to be buried in the bone, thus preventing the need for revision surgery for prominent metalwork. However, it has been suggested that headless screws produce less inter-fragmentary compression compared with headed screws.[47]

Table 2
Complications following arthroscopic ankle arthrodesis.

Complications following arthroscopic ankle arthrodesis
Infection – superficial or deep
Deep Vein thrombosis
Pulmonary embolism
Changes in gait
Metalwork prominence
Non-union
Mal-aligned ankle joint

Table 2 shows the complications that can occur after an AAA. There are also cases of patients complaining of persistent pain in the foot. This was initially thought to be as a result of the development of subtalar and chopart joint arthritis following an AAA, as these joints compensate for the lack of movement at the ankle joint.[18] However, a systematic review by Ling et al.[48] has disproven this theory, suggesting that the arthritis in adjacent joints probably pre-existed. Interestingly, a higher rate of adjacent joint arthritis has been found in patients following an open ankle arthrodesis (OAA) compared with AAA.[13]

7. Advantages of AAA

In addition to offering a high union rate as stated above (Fig. 5), AAA is also a cost-saving procedure compared to OAA. Patients with AAA have a significantly shorter hospital stay, which is likely a result of them being in less pain due to the limited soft tissue disruption involved in the technique over OAA.[11,49] Zvijac et al.[44] have reported performing AAA as a day case procedure and in future this is likely to be the trend.[44] Moreover, there is significantly less blood loss and a shorter time to union in AAA than OAA, again due to the limited periosteal stripping needed and preservation of blood supply.[12,49,50] Unsurprisingly, multiple studies have shown better AOS scores at the 1 year postoperative mark.[50–52] Despite this, no significant difference has been seen in terms of infection and complication rates, or incidence of revision arthrodesis after AAA or OAA.[13,52,53] Table 3 summarises the advantages and disadvantages of AAA compared with OAA.

8. Drawbacks of AAA

As stated above, traditionally AAA is not used for patients with moderate to severe coronal plane deformities,[14,15] with the rationale being that an open procedure will allow for better visualisation and correction of the deformity with osteotomies.[13] However, in a study by Yang TC et al.,[54] no significant difference in union rate and PROMs was found between patients who had had AAA for mild or severe coronal plane deformities. Similarly, other groups too demonstrated achieving near-normal tibiotalar alignment for patients with severe coronal plane deformities and AAA.[18,52] Townshend et al.[52] suggest that the coronal plane deformity is often a result of the talus tilting within the ankle mortise, and not due to the deformity being within the tibia or talus. This can therefore be corrected intra-operatively, without the need for major bone resection or osteotomies.

9. AAA versus total ankle replacement (TAR)

Another treatment option for treating end-stage ankle arthritis is a TAR. A multicentre, prospective cohort study found that TAR demonstrated significant improvement in PROMs compared with ankle arthrodesis. Although the patients undergoing a TAR had an increased number of complications and required more revision surgeries, no significant difference was found between the 2 groups when adjusted for age, sex, BMI and comorbidities.[35] These findings echoed those by Veljkovic et al.[36] who too found significantly improved AOS and higher rate of revision surgery for patients with TAR compared with AAA or OAA.

10. Conclusion

AAA is a safe and reliable treatment option for patients with

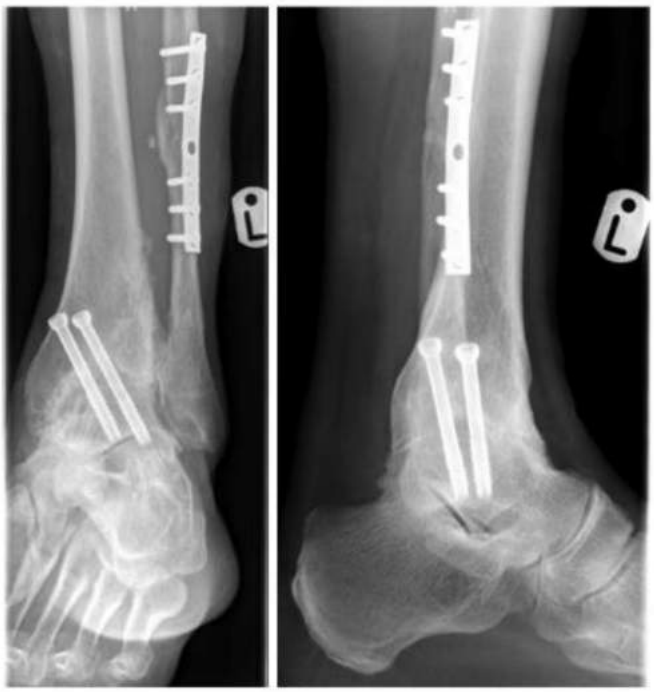

Fig. 5. AP and lateral weight bearing radiographs of Mr X 4 years following an AAA. Union is demonstrated in all 4 cortices on the 2 radiographs.

end-stage ankle arthritis, including those with severe coronal plane deformities. It can be performed either via the anterior or the posterior approach, depending on where in the ankle the pathology lies. It is associated with a shorter hospital stay and a shorter time to union when compared with OAA, and has a high union rate.

We certify that we have participated sufficiently in the intellectual content, conception and design of this work or the analysis and interpretation of the data (when applicable), as well as the writing of the manuscript, to take public responsibility for it and have agreed to have our name listed as a contributor. We believe the manuscript represents valid work. Each author confirms they meet the criteria for authorship as established by the ICMJE. Neither this manuscript nor one with substantially similar content under our authorship has been published or is being considered for publication elsewhere, except as described in the covering letter. We certify that all the data collected during the study is presented in this manuscript and no data from the study has been or will be published separately. We attest that, if requested by the editors, we will provide the data/information or will cooperate fully in obtaining and providing the data/information on which the manuscript is based, for examination by the editors or their assignees. Financial interests, direct or indirect, that exist or may be perceived to exist for individual contributors in connection with the content of this paper have been disclosed in the cover letter.

Table 3
Advantages and disadvantages of AAA compared to OAA.

Advantages	Disadvantages
High union rate	Surgeon learning curve
Shorter time to fusion	Addressing large coronal plane deformity
Shorter hospital stay	and bone defects are relative contraindications
Less intra-operative blood loss	for AAA as compared to OAA
Better outcome scores	

Sources of outside support of the project are named in the cover letter.

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Review article

Current concepts in total ankle arthroplasty

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ABSTRACT

Ankle arthrodesis has for decades been the 'gold standard' treatment for end-stage ankle arthritis. Total ankle arthroplasty (TAA) surgery, first introduced in the early 1970's, was initially plagued with poor outcomes and high complications, leading understandably to limited uptake. Since then, their design has evolved tremendously, and with it, there has been renewed interest in its role in the surgical management of end-stage ankle arthritis. In this article we discuss the current clinical evidence for TAA, its indications and contra-indications for use, its outcomes and results, the role of concomitant surgical procedures, complications and comment on areas of further study required.

1. Introduction

The prevalence of ankle arthritis ranges from 9 to 15%,[1] with an estimated 29,000 patients in the United Kingdom (UK) referred to specialist foot and ankle (F&A) clinics yearly.[2] Whilst ankle arthrodesis, has for decades been the 'gold standard' surgical management for end stage arthritis, and is still widely practiced within the UK, the use of total ankle arthroplasty (TAA) as treatment for end stage ankle arthritis has steadily increased from 402 primary implants/year in 2010 to 974 primary implants/year in 2019.[3]

2. Indications

The primary indication for TAA is end-stage ankle arthritis. Unlike for hip or knee arthritis, where primary osteoarthritis (OA) is the most common cause of end stage arthritis, for ankle arthritis, post-traumatic is the most common cause (54–78%).[4,5] Approximately 20–28% of post-traumatic causes are following chronic ligamentous injuries, with 72–80% following fracture. Idiopathic or primary OA accounts for only 9–19% of cases of ankle arthritis, with rheumatoid arthrosis (RA) accounting for 5.5–14.5% of cases.[4,5]

Historically, the ideal patient for TAA has been a middle-aged or elderly patient with symptomatic end-stage ankle arthritis, a well aligned ankle and hindfoot, reasonable preservation of ankle movement that includes neutral dorsiflexion, no ankle ligament instability and sufficient bone stock to fit the implants (no large tibiotalar cysts, osteonecrosis, collapse of the talus or malleolus bone erosion).

Patients with arthritic change in adjacent joints, such as the ipsilateral hindfoot or midfoot, may arguably benefit more from TAA than from ankle arthrodesis. Some authors have shown high rates of adjacent joint arthrosis following ankle arthrodesis,[6] with between 7.7% and 8.6% of these cases sufficiently clinically symptomatic to require further surgical fusion of the adjacent joints within 5–15 years.[7,8] In contrast, others report much lower rates of adjacent joint surgical fusion (1.8–3.9%) following TAA.[9,10] Similarly TAA may be favoured for patients with a prior arthrodesis. Rates of adjacent hindfoot joint non-union following prior ankle joint arthrodesis have been reported to approach 40%.[8]

Historically, the presence of coronal plane deformity >15° has been considered a contraindication to TAA, though this is now being challenged. Several recent studies have shown that for patients with varus deformities >20°, or valgus deformity >15°, good results following TAA can be achieved, although frequently they require various concomitant procedures.[11,12]

Contra indications can be either absolute or relative. Absolute contraindications would include active or recent infection, Charcot neuroarthropathy, severe peripheral vascular disease, avascular necrosis of the talus affecting more than 50% of the body, poor quality soft tissue envelope and lower limb neurological dysfunction. Relative contra indications would include younger age, high physical demands and severe lower extremity malalignment. Obesity has been shown in one study to increase revision rates,[13] though other studies have reported it not to increase risk of

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Table 1
National Joint Registry (NJR) cumulative results from various countries. ** This is cumulative 9 year survivorship. (10 year rate is not yet published).

	Total number in database	Mean age at time of surgery/years	Number of primary TAA/year	Cumulative 5 Year survival/%	Cumulative 10 Year survival/%
UK	6589	68.5	974	93.6	90.3**
Australia	2564	66.9	284	90.0	83.8
New Zealand	1737	66.5	118	91.3	84.2
Sweden	1230	–	53	85	74
Norway	1310	60.1	40	–	–

Table 2
Survivorship rates from single centre specialized units. Infinity is a new implant, so no longer term data on survivorship is yet available.

Study: Number n; Average length follow-up/years	Implant	5 Year survival/%	10 Year survival/%
Townshend et al.[22] n = 503; 1.4 yrs	Infinity	99.0[a]	–
Penner et al.[23] n = 67; 3.0 yrs	Infinity	97.0[b]	–
Clough et al.[24] n = 200; 15.8 yrs	STAR	90.4	82.8
Daniels et al.[25] n = 111; 9.0 yrs	STAR	92.2	88.0
Clough et al.[26] n = 118; 5.1 yrs	Zenith	91.2	–
Bianchi et al.[27] n = 62; 3.5 yrs	Box	91.9	–
Koo et al.[28] n = 55; 5 yrs	Salto	93.4	–
Barg et al.[29] n = 722; 6.3yrs	Hintegra	94	84
Yang et al.[30] n = 210; 6.4yrs	Hintegra	91.7	–

[a] Survivorship at average 1.4 year follow-up.
[b] Survivorship at average 3 year follow-up.

complications, infection or implant failure.[14,15] Similarly diabetes has been reported to confer increased risk of late revision (risk of clinical failure at 5 years; 21% v 11.6%) or infection, especially in those with poor glycaemic control,[16] though other studies report no increased risk.[17]

3. Results

The National Joint Registry for England, Wales, Northern Ireland and the Isle of Man (NJR) has been collecting data on ankle replacements since 2010, with the 2020 report including 6589 primary ankle replacements, with 12 different implants reported.[3] The median age of patients at surgery is 68.5 years, the average BMI 30.0, with 92% of cases performed for osteoarthritis and 5% for rheumatoid arthritis.[3] There are several national joint registries now publishing recent cumulative 5 and 10 year survivorship results for TAA,[3,18–21] which are listed in Table 1.

In comparison to the national registries, results from single centre specialized units are often better. Table 2 reports the literature results from various single centres for the most common implants performed in the UK in 2019 (67.7% Infinity, 8.7% STAR, 7.6% Box, 6.0% Zenith, 1.1% Hintegra and 0.9% Salto).

Survivorship data for the early implant designs is less than that for current designs. The Swedish NJR has reported 10 year TAA survival data of 69% for early prosthesis designs (CI 64–73%) and 84% for current prosthesis designs (CI 79–88%).[20] Barg et al.[29] in their study of 722 ankles with 3 generations of Hintegra prosthesis reported 10 year survival rates of 61% for the first generation prosthesis, compared to 90% for the latest 3rd generation prosthesis. These improvement in outcome are, in part, be due to better prosthesis designs including instrumentation, but may also be due to improving surgical experience, more careful patient selection, and an improved understanding of the role of balancing the ankle and foot.

The Australian NJR has reported higher rates of revision for mobile bearing prostheses (7.5% at 3 years) compared to fixed bearing prosthesis (3% at 3 years).[18] Both the Australian and New Zealand NJR[18,19] report higher rates of revision in patients <55 years of age (14.5% at 5 years) compared to patients 64–75 years of age (6.5%–9.7% at 5 years).

Table 3
Patient Reported Outcome Measures (PROMS) scores following TAA across a range of prostheses, following medium to long term follow-up.[a]

Study Number n; Average length follow-up/years	Implant	AOFAS	MOXFQ	FFI	AOS pain	SF36 physical	VAS
Halai et al.[12] n = 100; 5.1 yrs	Hintegra + STAR+ Mobility				52.5–28	32 – 41	
Penner et al.[23] n = 67; 3.0 yrs	Infinity			43.4–21.8	59.1–24.4	33.7–45.9	
King A et al.[31] n = 40; 2 yrs	Infinity + Zenith		63.9–15.0				
Clough T et al.[24] n = 200; 15.8 yrs	STAR	38.0 – 61.0					
Daniels T et al.[25] n = 111; 7.6 yrs	STAR				56.3–19.8	29.6–39.1	
Bianchi et al.[27] n = 62; 3.5 yrs	Box	35.1–78.0					6.8–2.0
Yang HY et al.[30] n = 210; 6.4 yrs	Hintegra	52.0–86.0			61.1–15.6	41.5–65.0	7.0–2.0
Koo et al.[28] n = 55; 4.6 yrs	Salto	??? – 71.5					???- 1.9
Stewart et al.[32] n = 72; 6.8 yrs	Salto Talaris	43.4–79.4				45.1–69.8	7.0–1.2

[a] ??? No pre-operative PROMS scores. AOFAS American Orthopaedic Foot Ankle Society Ankle-Hindfoot score; MOXFQ Manchester Oxford Foot Questionnaire; FFI Foot Function Index; AOS pain Ankle Osteoarthritis Scale (pain); SF36 physical Short Form 36 (physical); VAS Visual Analogue Score.

Table 4
Frequency of concomitant procedures with TAA across larger studies.

	Daniels[25] STAR; n = 111	Yang[30] Hintegra n = 210	Bianchi[27] Box; n = 62	Townshend[22] Infinity; n = 503	Penner[23] Infinity; n = 67
Overall frequency of concomitant procedures; %	61.3%	75.2%	24.2%	33.1%	70.1%
Gastrocnemius release/TA lengthening; %	45.0	25.2	14.5	15.5	49.3
Lateral ligament reconstruction; %	6.3	16.7	1.6	3.6	6.0
Deltoid release; %		23.3		3.0	3.0
Medial ligament reconstruction; %	4.5	1.4		–	
Subtalar fusion; %	13.5		4.8	1.2	6.0
Triple fusion; %	10.8		1.6	–	
T/Navicular fusion; %	0.9			1.6	3.0
Calcaneal osteotomy; %	5.4	1.9	1.6	3.4	3.0
Midfoot fusion; %	7.2			0.2	7.5
Midfoot reconstruction; %	4.5			–	3.0
Removal of hardware; %	9.9			5.0	17.9

There have been numerous different patient reported outcome measures (PROMS) used to document clinical outcomes following TAA across a range of prostheses (Table 3). All confirm significant improvements PROMS scores, pain reduction and patient satisfaction before and after TAA surgery.[12,23–25,27,28,30–32]

4. Concomitant procedures

Since patients with end stage ankle arthritis often present with concomitant hindfoot or midfoot pathology, this may need addressing the time of TAA surgery. Rates of concomitant procedures range from 24 to 75%. Common concomitant procedures performed and rates are listed in Table 4.

The more one drifts from the ideal indication of neutral coronal plane ankle and hindfoot alignment, the higher the rates not only of concomitant procedures at the time of TAA surgery, but also the higher the rate of later supplementary procedures required. Lee et al. reported 60% rate of concomitant procedures in patients with pre-operative >15° varus deformity. There was a 54% complication rate in this severe varus group, compared to 39% complication rate in the group <15° group.[11] Daniels et al.[12] reported on a cohort of patients with >15° valgus, finding 80% underwent concomitant procedures at the time of surgery (compared to 26% of patients in whom the pre-operative deformity was <15° valgus). Also more underwent secondary procedures post-operatively (36% v 14%). Thus, it should be at least understood that the further one strays from the 'ideal indication', the more adjunct procedures, and probable secondary procedures, that are required to neutralize the confounding variables and balance the ankle, thus making a technical challenging operation even more demanding, and thus incorporating more risk for the patient.

Table 5
Complication rates following TAA.

Complication	Literature % Range
Overall complications	13.5%–54.5%
Intra-operative fracture: Medial	3.1–9.7
Intra-operative fracture: Lateral	0.05–2.1
Post-operative Fracture Early (<4 months)	1.5
Post-operative Fracture Late (>4 months)	2.0–5.0
Malpositioning	1.1–6.0
Wound Problems	0.9–14.7
Superficial infection	1.3–7.2
Deep Infection	0.5–5.7
Aseptic Loosening	3.2–19.0
Polyethylene fracture/dislocation	0–14.0
Edge Loading	2.5–23.0
Gutter pain	2.0–23.5
Residual pain	3.5–60.0
Stiffness	0–1.8
Soft tissue injuries (nerve/tendon)	0.5–15.3
Subsidence	0.9–46.0
Venous Thromboembolic Events	0–4.8
Chronic Regional Pain Syndrome (CRPS)	0–4.4
Amputation	0.4–2.6

5. Complications

There is a wide variation in the reported rate of complications associated with TAA surgery, ranging from 13.5% to 54.5%.[33] These are listed, with the quoted incidences in Table 5. Clough et al. reported, in their series of 278 TARs in 251 patients, that 82.9% of these complications did not lead to further surgery or any untoward sequalae with relation to implant longevity.[33]

6. Conclusions

TAA has become a viable option in the surgical treatment for end stage ankle arthritis. Improvements both in prosthesis design and surgical experience have gradually improved implant survivorship and outcomes, with many studies now confirming overall high patient satisfaction and functional outcome following the procedure. However, this report highlights potential complications associated with TAA surgery and emphasizes the importance of informed consent. TAA should be performed by those adequately trained and experienced in the technique, and a clear consent process should be undertaken.

Intra-operative X-ray guidance seems to reduce complications, improve implant alignment and may have a role in the future of TAA surgery. The impact of pre-operative diagnosis (OA/RA), diabetes and obesity on long term implant survivorship remains controversial and deserves further study. Similarly the role of fixed bearing versus mobile bearing implant designs and the relevance of young age at the time of implantation to implant survival also requires further analysis.

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Review article

Current concepts review: Management of Achilles tendinopathy overview

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ABSTRACT

Achilles tendinopathy can be a debilitating condition affecting 2–3 in 1000 of the population, rising to 1 in 20 in runners. A variety of non-operative and operative treatments are available for both insertional and non-insertional tendinopathy. This review summarises the current management options of these different pathologies.

1. Introduction

Achilles tendinopathy can be a debilitating condition affecting 2–3 in 1000 of the population,[1] rising to 1 in 20 in runners.[2] A variety of non-operative and operative treatments are available for both insertional and non-insertional tendinopathy. This review summarises the current management options of these different pathologies.

2. Background

The Achilles tendon is the largest tendon in the body.[3] It is the amalgamation of the soleus and gastrocnemius muscles, both of which contribute roughly 50% of the tendon. The soleus muscle consists mainly of slow twitch fibres, thought to be responsible for maintenance of posture and stance, whereas the gastrocnemius is comprised predominantly of fast twitch fibres and is therefore involved in exercise and movement.[4] In 1992, Clain and Baxter[5] divided Achilles tendinopathy into insertional and non-insertional, highlighting the differences in aetiologies of these separate pathologies, and, consequently, the difference in management. Since their review, many more treatment modalities have evolved.

Distinction should be made between chronic and acute tendinopathy. Acute presentation may be inflammatory in nature and therefore may respond to anti-inflammatory treatments and rest. In contrast, chronic tendinopathy is a process of degeneration, as opposed to inflammation, so treatments targeting inflammation are largely redundant.

3. Insertional Achilles tendinopathy

The aetiology of insertional Achilles tendinopathy can be wide ranging. Systemic patient factors include older age, diabetes, higher body mass index, hypertension, steroid use and genetic susceptibility,[6–8] so it would follow that correction of these factors, for example weight loss, could assist in management. Local contributary factors include overuse, inflammatory arthropathy and altered biomechanics, for example hindfoot malalignment. Altered biomechanics is also associated with non-insertional tendinopathy.[9] Mechanical overload of the tendon confers stress at different parts of the tendon insertion footprint; the superficial tendon fibres experience increased axial stress because of the line of pull of the gastrocnemii, whereas the deep fibres experience compressive forces throughout the dorsi- and plantarflexion cycle.[10]

Aside from the insertion of the tendon itself, other local anomalies can contribute to tendinopathy, namely retrocalcaneal bursitis or a Haglund deformity (a calcaneal prominence which may cause friction and impaired blood flow around the tendon).

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These two are often seen hand in hand, and together are known as Haglund's syndrome. Calcification of the tendon itself may occur, resulting in an enthesophyte, or intrasubstance calcification. The precise mechanism of calcification in this setting is unknown, but Oliva and colleagues suggested one of three mechanisms; reactive, whereby the tendon is adapting to stress, endochondral ossification, whereby ossification of fibrocartilage evolves over time, or metaplasia of tendon cells into osteogenic cells.[11],Fig. 1, Fig. 2, Fig. 3.

4. Management

Physiotherapy and orthotics. Non-invasive measures include rest, activity modification and physiotherapy. Insertional tendinopathy tends to affect patients after physical activity, or first thing in the morning (so called start-up pain), so managing activity may confer some level of symptom management. Physiotherapy can play a role, particularly calf stretches and eccentric loading exercises, although the benefit of these exercises is generally greater in the treatment of non-insertional tendinopathy.[12] An orthotic such as a heel cup or heel raise allows the hindfoot to adopt a more plantarflexed posture, so reducing stress on the tendon insertion.

Interventional (or medical) management options are limited in insertional tendinopathy. Non-steroidal anti-inflammatory medications (NSAIDs) may be of use for symptom control, but will not assist with the pathology. In some cases, steroid injection into a retrocalcaneal bursa may reduce symptoms in this region, and can also be useful in isolating symptoms and predicting a response to surgery.

Extra-corporeal shock wave treatment (ECSWT). Rompe et al.[13] reviewed ECSWT in both insertional and non-insertional tendinopathic settings. Their small study compared eccentric exercises with ECSWT and found that ECSWT conferred an improvement in pain scores at four months onwards, however there was a high crossover rate between the study groups. These findings echoed those of Furia[14] and Wiegerinck[15] who described high patient satisfaction with ECSWT. ECSWT is used more often in the non-insertional Achilles tendinopathy setting (see later), but remains an option prior to consideration of surgery.

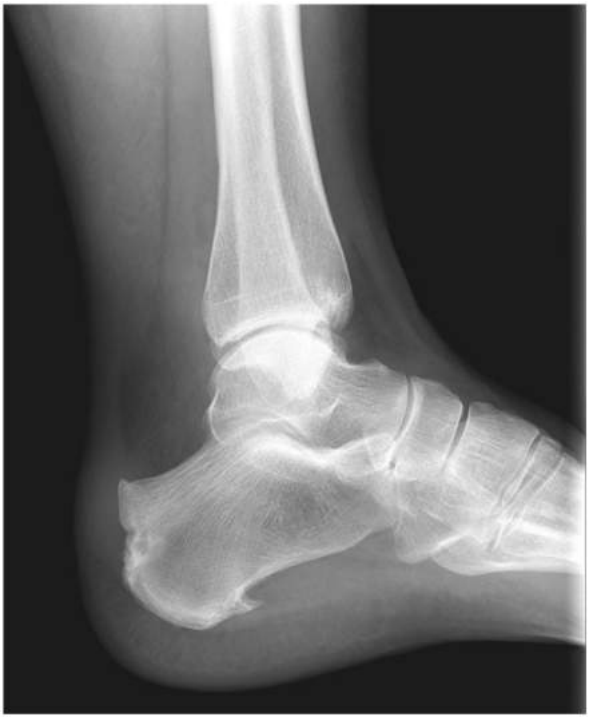

Fig. 1. Radiographic lateral image of foot, demonstrating Haglund deformity.

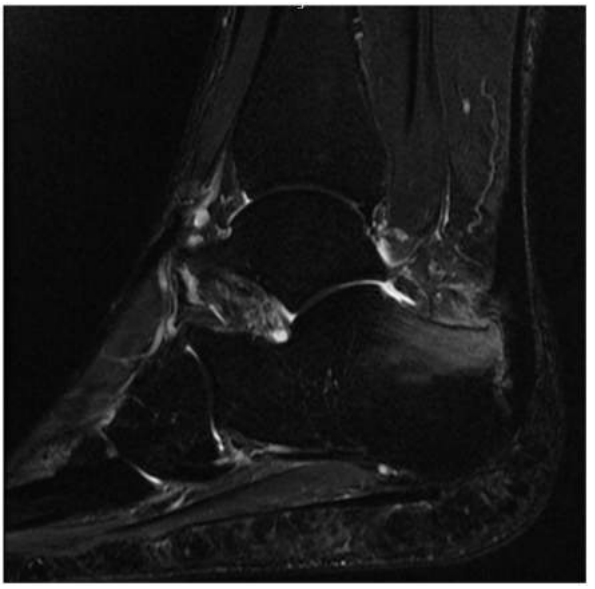

Fig. 2. Sagittal T2 weighted Magnetic Resonance Image (MRI) demonstrating Haglund deformity with oedema.

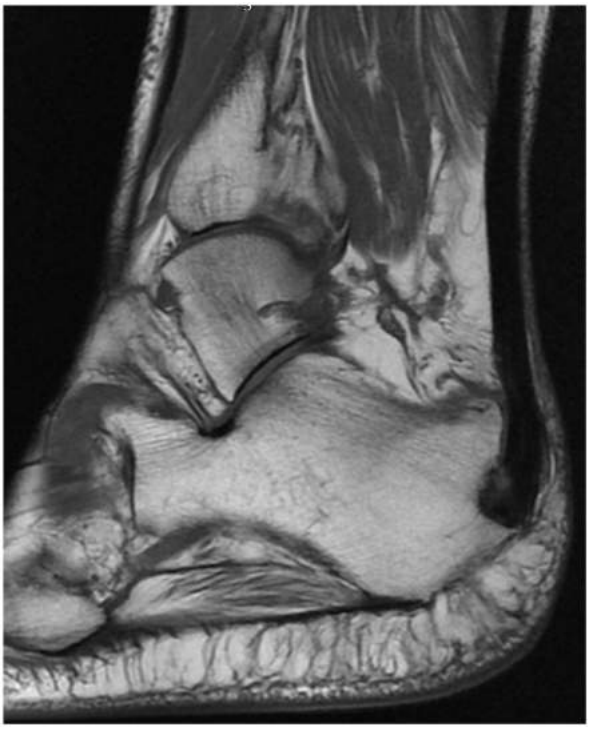

Fig. 3. Sagittal T1 weighted MRI demonstrating enthesophyte and Haglund deformity.

Operative intervention. Surgical management will be dictated by the underlying pathology, and should be reserved for cases that do not respond to non-operative measures.[16] Surgical targets include excision of a retrocalcaneal bursa, resection of a Haglund's deformity (calcaneoplasty),[17] and debridement of the diseased portion of tendon, often with complete detachment and

subsequent repair.[18] Augmentation of the repair may be required, in which case a flexor hallucis longus (FHL) tendon transfer can be employed.

Calcaneoplasty. Excision of a retrocalcaneal bursa and resection of a Haglund's deformity may be performed open or endoscopically. Both of these approaches have been shown to improve symptoms, with fewer complications and higher patient satisfaction generally seen in endoscopic groups.[17] This technique leaves the footprint of the tendon insertion untouched. Jerosch found the endoscopic technique conferred good results in patients who had experienced temporary relief of symptoms following pre-operative steroid injection.[19] This group stated that this technique should not be used in patients whose radiographs identified calcification in the Achilles insertion itself, and that those patients should be additionally treated with debridement of the tendon. Nevertheless, in cases of isolated Haglund's syndrome, this is a good surgical option for management. A pre-operative steroid injection can indicate a patient's future response to surgery.

Tendon debridement and reattachment. In some cases, the Achilles tendon requires detachment from the calcaneal insertion to allow a thorough debridement, followed by reattachment. A needle can be used to identify areas of softened, thickened or calcified tendon.[18] Up to 50% of the tendon can be resected from the footprint safely, without the need for post-operative immobilisation.[20] Sometimes, however, the calcification can be imbedded within the central portion of the tendon and the only way of accessing it is via complete detachment. Following resection, the calcaneal tendon footprint is prepared using a nibbler and anchors, or transosseus sutures, are placed in the calcaneum. Several repair systems are available and so consideration has been given to single row versus double row fixation, number of anchors, and knotless versus knotted anchors. Barg reviewed a number of anchor-repair studies in 2019 and found overall that single row was just as successful as double row repair during load to failure studies. The commonest mode of failure was a knot pulling through the tendon itself.[21] There has been further evolution of anchor fixation, with newer devices available that allow a larger footprint, are knotless, and spread the stress over a larger area of distal tendon. Knotless systems have the advantage of reducing bulky suture material that may irritate the soft tissues at the back of the heel. Excellent results have been reported using these devices, particularly with early return to mobilisation.[22]

Calcaneal osteotomy. With advances in endoscopic calcaneoplasty, it is thought that rates of calcaneal osteotomy for treatment of insertional tendinopathy are decreasing,[6] however recent studies continue to support its use. A dorsal closing wedge osteotomy (a Zadek osteotomy) can be performed to alter the position of the Haglund's deformity, preventing it abutting the tendon and reducing tension on the tendon itself. First described in 1939[23], it continues to show good results,[24] although some authors have described high complication rates. Recently, a percutaneous method of Zadek osteotomy has been shown effective, with minimal complications.[25]

Tendon transfer. In failed or resistant cases, or in cases where more than 50% of the Achilles tendon has been released, the FHL tendon can be used to augment the repair or reconstruct.[26] Other tendon transfers have been described, for example peroneus brevis or flexor digitorum longus (FDL), however these have drawbacks in terms of biomechanics (line of pull) and strength.[6] In 2015, Hunt prospectively reviewed patients randomised to receive FHL transfer versus control in insertional Achilles reconstructive cases. They found that although pain and complications were the same in both groups, plantarflexion strength was improved in the FHL transfer group.[27] So, although FHL transfer conferred good results, they suggested it need not be routinely performed in lower functional demand patients. Clearly FHL transfer will be required for resistant or previously failed cases where the tendon has essentially become redundant, but in patients where augmentation is the indication for FHL transfer, it could be reserved for higher functioning patients only.

5. Non-insertional Achilles tendinopathy

Non-insertional tendinopathy differs from insertional tendinopathy in a number of aspects, most obviously it's location; it is mid-substance, usually located 2–6 cm proximal to the calcaneal insertion. The anatomy of the Achilles tendon is such that conditions are ripe for tendinosis development at this location; the tendon fibres twist through a 90° trajectory before inserting into the calcaneum, meaning that stress here can be high.[28] This unique twist is thought to allow a mechanical advantage in terms of lengthening.

Blood supply to the Achilles tendon is via the posterior tibial artery. Vascularity varies with age, but the most avascular portion of the tendon is in this mid-substance area,[28] in the same region as the twist in tendon fibrils described above. This relative avascularity, combined with the stress associated with the twist of the fibres, contributes to the development of tendinopathy at this location.

Other associated aetiological factors include increasing age, overuse, an abnormal response to injury, as well as the use of quinolone antibiotics.[29,30]

6. Management

Activity modification. The mainstay of treatment in non-insertional tendinosis is non operative. Up to three quarters of patients will exhibit some self-limitation of the disease, so non-operative management in the first instance is favourable.[30] Rest is first line management, with a minimum of six weeks' refrain from provocative activity,[29] although some athletes can continue with limited, rather than complete cessation, of exercise.[31] NSAIDs do not have a role in management of non-insertional tendinopathy due to its degenerative nature; in fact, it has been suggested that NSAIDs may be harmful due to a reduced pain-mediated inhibitory response.[30] A previous Cochrane review suggested next to no benefit from NSAID use.[32]

Physiotherapy. Eccentric exercises appear to confer the most benefit to non-insertional tendinopathy sufferers. The mechanism by which this works at a cellular level is not fully understood, although many theories have been suggested.[33,34] The most commonly accepted view is that this exercise causes microtrauma to the tendon, stimulating it to heal. The review by O'Neill et al.[35] outlines several theories as to why this specific manoeuvre works, including tendon structural adaptation, neuromuscular modulation and changes in muscle-tendon stiffness, however the authors conclude that the relationship between this dynamic exercise and tendon recovery is not clear cut. Nevertheless, it appears to work.

Injected therapies. Moving to interventional therapies, a plethora of options are available. Many injection therapies have been described, including high volume injection, platelet-rich plasma (PRP), sclerosing agents, autologous blood, local anaesthetic and glycosaminoglycans. There has been a move away from steroid injection into the tendon, given the risk of tendon rupture. Injected therapies may offer relief via one of two mechanisms; i) agents that impede vascularity to allow repair (high volume injection, sclerosing agents) and ii) agents that promote repair directly (PRP, autologous blood, glycosaminoglycans).

In their meta-analysis, Kearney et al. found no strong evidence

for any of these interventions long term, with the only evidence suggesting a short term relief of symptoms and return to activity.[36] One tendon rupture was seen in a steroid injection group.

PRP and high volume image guided injections (HVIGI) are probably the more commonly utilised injections given in UK practice. HVIGI involves the injection of a large volume of normal saline (eg 40 mls) and local anaesthetic, with or without a small quantity of steroid. The injection is administered between Kager's fat pad and the anterior Achilles tendon, avoiding the tendon itself, and is thought to cause a disruption of the small blood vessels and accompanying neurological bundles which penetrate the Achilles tendon from the paratenon, thus improving pain. In their small cohort study, Humphrey et al. found a statistically significant improvement in pain scores in patients undergoing HVIGI, albeit with short follow up.[37] Chaudhry also reports that HVIGI provided better outcomes compared with dry needling.[38]

PRP injections have been used to provide a biological treatment to tendon repair. Together with the aforementioned Cochrane review (Kearney et al.), Zhang et al. conducted a meta-analysis specifically looking at PRP use for non-insertional Achilles tendinopathy.[39] Their review, which included only four studies of adequate power, found no significant improvement in pain scores, so they did not suggest use of PRP for Achilles tendinopathy. It may be that variable effects are seen depending on age and gender of the patient; Abate et al. found that modestly better results were seen in patients receiving PRP who were younger and male, however these results were not replicated across all patients.[40]

Topical Glycerl trinitrate (GTN). GTN patches have historically been used for other tendinopathic areas, for example the rotator cuff. Mechanism of action is thought to be the effect on local nitrous oxide (NO) levels. No clear evidence exists to show a beneficial response to topical GTN, with side effects of headache appearing to preclude longer term use.[41,42]

Extra-corporeal shock wave treatment (ECSWT). As mentioned with insertional tendinopathy, ECSWT is more commonly used to treat non-insertional tendinopathy. Postulated theories behind its mechanism of action include a short term analgesic effect due to alteration of neuron cell membrane permeability, and a long term response on account of microtrauma and stimulation of healing.[43,44] A Cochrane review in 2013 found that overall ECSWT was beneficial in both insertional and non-insertional tendinopathy, albeit with only six studies included in that meta-analysis. Four of the six studies reported statistically significant improvements in pain. Four of the five studies that investigated function reported improvements in functional outcome.[43] Other studies have shown it is beneficial in comparison to observation alone.[44]

Operative intervention. Surgical options are only employed in recalcitrant cases of non-insertional tendinopathy given the high rates of success with non-operative management and sometimes spontaneous resolution. Surgery may involve gastrocnemius recession, Achilles tendon adhesiolysis, debridement, augmentation or reconstruction.

Gastrocnemius recession. A number of approaches for gastrocnemius recession have been described. Good outcomes have been seen in cases of recalcitrant non-insertional tendinopathy treated with gastrocnemius recession alone. Low complication rates have been reported, likely due to the proximal nature of the incision.[45,46] One recent study found that not only did pain and function scores improve, magnetic resonance imaging (MRI) findings of tendinopathy also improved one year following surgery.[47] Given this is a relatively small and well tolerated procedure, gastrocnemius recession can be a successful first step for operative management.

Tendon debridement. Open surgery utilises a midline posterior longitudinal incision, with adhesiolysis, or stripping, of the paratenon, which is thought to disrupt the neuro-vascularisation,[6] in much the same way as in HVIGI. Thickened or softened areas of tendon are debrided using longitudinal incisions, with subsequent side-to-side repair. Endoscopic surgery also can provide adequate adhesiolysis and debridement, using only small skin incisions. Success rates of open, minimally invasive and endoscopic surgeries have all been shown to be good, sitting in the region of 70–100%.[6,48] Complication rates are highest in open surgery and include skin necrosis, infection, haematoma, scar formation, sural nerve injury and venous thromboembolism.[49] Lower complication rates are seen in endoscopic surgery.[48,50]

Plantaris release. Recent interest has turned to the plantaris tendon, the vestigial tendon that runs medially alongside the calf and Achilles tendon. Patients with non-insertional tendinopathy often present with pain and swelling localised to the medial side, corresponding to the location of the plantaris tendon, so attention has turned to releasing this tendon, alone or as part of a surgical debridement. A small number of studies have investigated isolated plantaris release in a minimally invasive manner. All have shown that patients had a significant improvement in symptoms, with minimal complications, so releasing plantaris would appear to be a useful adjunct in the surgical management of non-insertional tendinopathy cases.[51–53]

FHL transfer. In cases where more than 50% of the mid-substance tendon is debrided, again, it is considered necessary to augment the tendon repair, usually with an FHL tendon transfer. A previous cadaveric study has demonstrated that load to failure was improved with FHL transfer, even when only 25% of the tendon had been debrided, and therefore supports the belief that augmentation is certainly required in cases where more than 50% tendon debridement has been performed.[54] In some cases, complete excision of the tendon may be required, in which case a tendon transfer is indicated to maintain function. Martin et al. investigated FHL transfer in patients undergoing complete tendon excision and found that pain scores improved in 95% of patients, with good functional results, albeit with around 30% loss of strength in plantarflexion. It is worth noting that the mean age of participants in their study was 58 years, so they recommended this approach for older patients, with a direct Achilles tendon repair and augmentation with FHL for younger patients.[55]

What is clear from the literature is that a combination of surgical techniques is employed, so teasing out the precise surgical intervention that is responsible for the best outcome is challenging. Table 1.

7. Summary

There is no overwhelming consensus on the best treatment options for both insertional and non-insertional Achilles tendinopathy, as suggested by the myriad of treatment options available. Previous meta-analyses support the use of eccentric exercises, ECSWT or a combination of both as first line non operative management in non-insertional tendinopathy, but inclusion of small studies with lots of interventions in these reviews can introduce bias and cloud the conclusions.[1] Surgical management will be dictated by the underlying pathology in the case of insertional tendinopathy, whereas a combination of surgical targets may be useful in non-insertional cases, with transection of the plantaris tendon proving a useful adjunct. In the authors' experience, surgery for non-insertional tendinopathy should be reserved for only the most resistant cases that have not responded to non-operative management including eccentric exercises and HVIGI or PRP injections.

Table 1
Summary of treatment options for insertional and non-insertional Achilles tendinopathy.

	Insertional	Non-insertional
Activity therapy, Physiotherapy, Orthotics	Rest Activity modification Calf stretches Eccentric loading exercises[a] Heel raise/cup	Eccentric loading exercises
Medical/Interventional	NSAIDs[b] ECSWT	ECSWT High volume injection PRP injection Other injectables (see main text)
Surgical	Combination of: Excision of retrocalcaneal bursa Resection of Haglund's deformity Debridement (detachment and reattachment) of diseased tendon Augmentation of tendon, for example using FHL	Combination of: Adhesiolysis Tendon debridement Tendon repair or direct reinforcement Plantaris release Gastrocnemius recession (Strayer, Baumann) Reconstruction, for example using FHL

[a] Eccentric exercises more beneficial in the management of non-insertional tendinopathy, but can still be suggested.
[b] NSAIDs may only confer mild symptom relief.

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Review article

Current concepts review of hallux valgus

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ABSTRACT

Hallux valgus is a complex three-dimensional deformity. Surgical correction of the hallux valgus is technically demanding and has a significant risk of recurrence and complications. There is a learning curve associated with the operative technique. The aim of the realignment procedures include.

- Re-positioning the first metatarsal head over the sesamoids
- Restoring the intermetatarsal and hallux valgus angles to normal levels
- A congruous metatarsophalangeal joint

Great toe metatarsophalangeal fusion offers an effective salvage option for recurrent hallux valgus and severe deformities. Clinical and radiological examination aid choice of operative management of the deformity of the great toe. Different techniques may be prioritised according to the patient's presentation.

1. Introduction

Hallux valgus is one of the most common forefoot pathologies encountered in orthopaedic practice. The latin word 'bunion', meaning a 'turnip', does not do justice to this complex deformity. Hallux valgus is a complex three-dimensional deformity commonly associated with deformities of the lesser toes. Using CT scans, up to 87% of hallux valgus cases have been shown to present with a pronated metatarsal bone, which highlights the multiplanar nature of the deformity.[1]

The terminology of 'hallux abducto-valgus' was first coined by the German surgeon, Carl Hueter, who described it as a lateral deviation of the great toe at the metatarsophalangeal joint.[2] Various factors have been linked to the causation of hallux valgus, such as: tight footwear, familial predisposition, hyperlaxity, pes planus, neuromuscular disorders (e.g., cerebral palsy) and a tight Achilles tendon.[3–13]

Females are more affected than males (15:1) and more often, require operative intervention. High heeled, tight fitting shoes and higher incidence of hyperlaxity may be contributory factors for this association.[14–18]

2. Pathogenesis

The first ray is the main weight bearing ray of the foot and helps maintain the medial arch of the foot. Thus, the integrity of the first metatarso-phalangeal joint stabilisers is extremely important to enable optimal weight bearing through the first ray. Stephens[17] has described the steps that lead to the formation of the hallux valgus deformity.[11,17] (Fig. 1).

1. The medial capsule, medial collateral ligament and the medial metatarso-sesamoid ligament fail first allowing the first metatarsal head to migrate medially and drift off the sesamoids.
2. Being tethered to the sesamoids and the adductor hallucis: the proximal phalanx moves laterally.
3. The crista on the plantar surface of the first metatarsal head slowly gets eroded allowing the metatarsal head to move further medially.
4. The axis of the flexor and extensor hallucis moves lateral to the metatarsophalangeal joint exaggerating the abduction force on the hallux.
5. The abductor hallucis migrates plantar to the metatarsophalangeal joint and hence cannot oppose the hallux valgus deformity. It also pulls the proximal phalanx into pronation.

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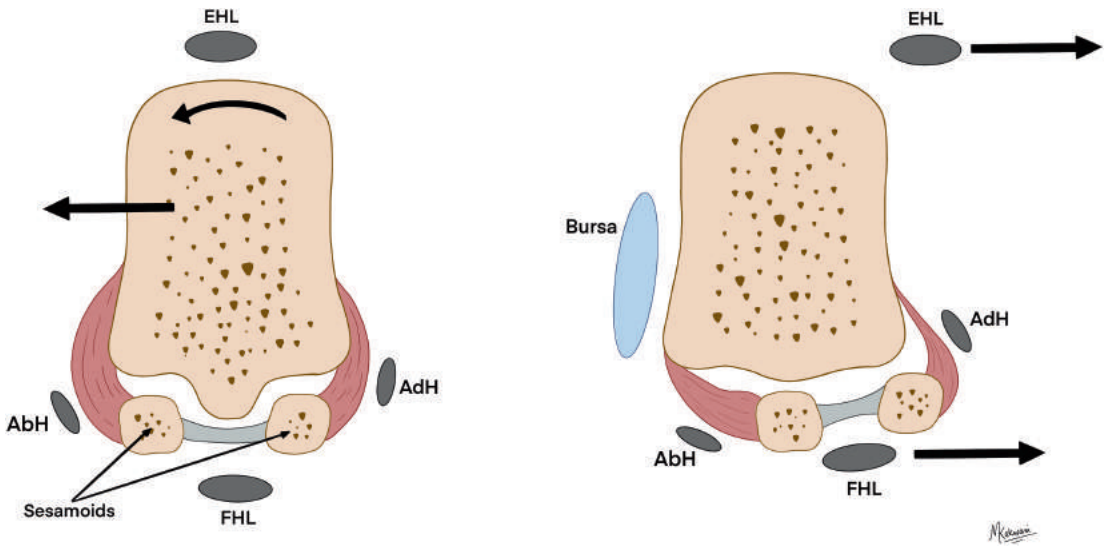

Fig. 1. Pathogenesis of hallux valgus adapted from Perera et al.[11]

6. The bursa overlying the first metatarsal medial eminence can thicken due to friction against the footwear.
7. The elevation of the first metatarsal head due to its medial migration can lead to transfer metatarsalgia.
8. The plantar metatarsal artery to the great toe follows a tortuous course between the two heads of the flexor hallucis brevis. In hallux valgus, this course is made further tortuous, and part of the pain experienced by the patient may be due to the ischaemic effects.[19]

3. Clinical examination and conservative management

3.1. Clinical examination

The commonest presentation of hallux valgus, in addition to the obvious deformity: is inability to find appropriate footwear; pain on the medial eminence of the metatarsal head; pain on weight-bearing and deep, aching pain from arthritis affecting the metatarsophalangeal joint. Some patients experience a neuralgic type of pain due to pressure on the dorsomedial cutaneous nerve.

A thorough history (including family history), physical examination and weightbearing radiographs of the foot (anteroposterior and lateral views) are recommended.

The physical examination would include examination of the following: the gait, the extent of the hallux valgus deformity, its correctability and the range of motion in the great toe metatarsophalangeal joint. The deformity is often exaggerated on weight bearing. The great toe is often pronated with callosity under the medial-plantar aspect of the first metatarsal head. Soft corns may be present between the lesser toes along with the lateral deviation of lesser toes.

Examination of the first tarsometatarsal joint for laxity/instability[20] and if positive, assessment for the Beighton score is advisable.

The intermetatarsal spaces are examined for presence of interdigital neuromas. Common associations are hammer toe deformities of the lesser toes, callosities under the second and third metatarsal head (suggesting transfer lesions) tightness of the Achilles tendon and pes planus.

The footwear may show a bulge in the region of the first metatarsal medial eminence.

3.2. Radiological MANAGEMENT

Weightbearing antero- posterior and lateral radiographs of the foot will help define the severity of the deformity, as well as, assisting in preoperative planning. The angles generally calculated are the hallux valgus angle (HVA), the intermetatarsal angle (IMA) and the distal metatarsal articular angle (DMAA) (normal $< 10^{\circ}$) (Fig. 2/Table 1). The congruity of the metatarsophalangeal joint is also noted, in addition to, the degree of arthritis affecting the great toe metatarsophalangeal joint.[26]

It is important to consider the intra-observer and inter-observer variability during radiological assessment. Evidence supports that the calculation of the hallux valgus angle and the intermetatarsal angle is highly reliable. However, this is not the case for the calculation of the distal metatarsal articular angle, which remains a challenge.[27–31]

3.3. Conservative MANAGEMENT

Management of the hallux valgus begins with conservative options including: activity modification, soft, comfortable wide toe-box shoes, spacers between the big toe and the second toe, avoidance of tight fitting and high-heeled shoes.[21]

Orthotics may be beneficial in reducing the pain experienced by the patient, although, they have not been proven to help prevent the progression of hallux valgus.[22,23]

In a randomised controlled trial comparing surgery v/s orthosis v/s watchful waiting, at one year follow-up, the percentage of patients who felt improvement in their pain symptom were 83%, 46%, and 24% in the surgery, orthosis, and control groups, respectively.

Number of painful days, cosmetic disturbance, and footwear problems were least and functional status and satisfaction with treatment were best in the surgical group.[24,25]

Non-operative treatment using foot orthosis for hallux valgus patients: there was no change in the hallux valgus or intermetatarsal angles seen over the 24-month follow-up period, in the study published by Nakagawa and colleagues.[22] These results were corroborated by Reina and colleagues.[23]

4. Operative management

Surgical correction for cosmetic deformity only is not advisable.

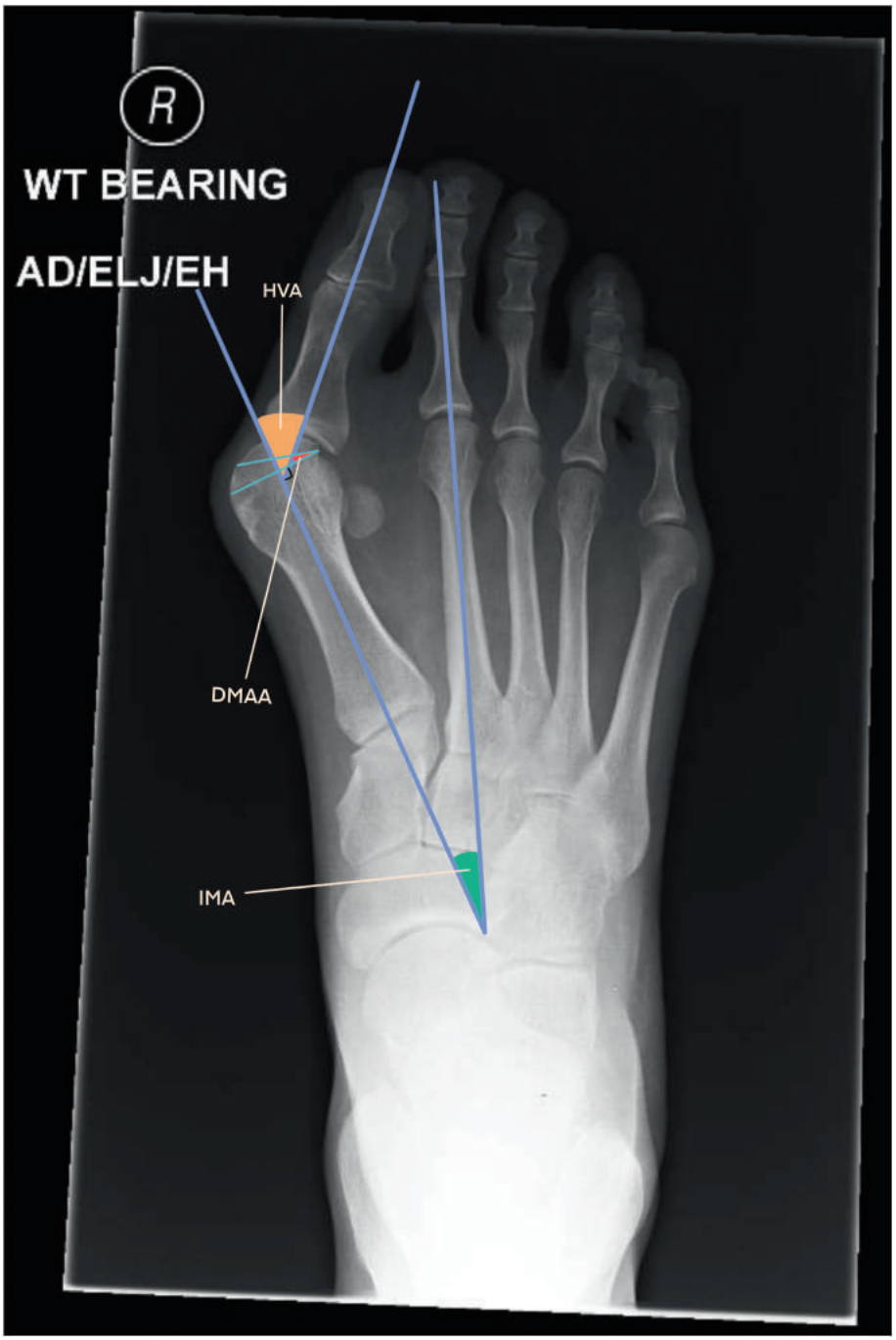

Fig. 2. Weight bearing foot anteroposterior radiograph demonstrating HVA/IMA/DMAA. Adapted from Robinson and Limbers.[26]

Table 1
Measured angles and their corresponding level of deformity. Adapted from Robinson and Limbers.[26]

Severity of Deformity	Hallux Valgus Angle (HVA)	Intermetatarsal Angle (IMA)
Normal	Less than 15°	Less than 9°
Mild	Up to 19°	Up to 13°
Moderate	20–41°	14–20°
Severe	More than 40°	More than 20°

The main indication for operation is pain, which is not resolved by conservative methods of management. The pain is generally over the bunion region or sometimes under the second metatarsophalangeal joint.

More than 100 operations have been described for correction of hallux valgus which can be broadly categorised as follows:

- Distal soft tissue procedures
- First metatarsal osteotomy, which can be either distal, shaft or proximal osteotomy
- Proximal phalangeal osteotomy
- Fusion of the first metatarsophalangeal joint
- Fusion of the first tarso-metatarsal joint
- Excision arthroplasty (Kellers)

4.1. PROM score

Patient-reported outcome measures (PROMs) are helpful to judge the patient satisfaction following any intervention.[32] Pain and disability are subjective to the patient and an improvement in PROM scores indicates the extent to which the procedure has helped resolve the patient's complaint. Several foot and ankle PROM scores have been established. For hallux valgus correction, the commonly used patient reported outcomes are: SF-16 (short form (SF) questionnaire), MOXFQ (Manchester-Oxford foot questionnaire), SEFAS (self-reported foot and ankle score), EQ5D (EuroQol- 5 Dimension), NRS (numeric rating scale), VAS (visual analogue scale) and FAOS (foot and ankle outcome score).[33]

The scoring systems aim to demonstrate changes in the patient's quality of life, pain and disease-specific outcomes. For the purpose of assessing the patient's general quality of life, SF-16 & EQ5D are preferred. For pain and disability outcomes: VAS and NRS are useful for objective measurement. Whilst, for disease-specific outcomes: MOXFQ, FAOS and SEFAS are recommended. Previously the AOFAS score was predominantly used to assess the success of the hallux valgus operative treatment. However, due to the partial clinician-reported element involved, it cannot be considered as a true PROM score. Instead, the MOXFQ and SEFAS are preferred for these purposes, based on current data.[33,34]

4.2. Simple bunionectomy

Simple bunionectomy i.e., excision of the medical eminence and medical capsular plication is rarely performed due to a high recurrence rate and poor patient satisfaction outcomes.[35]

4.3. Distal soft tissue procedures

Modification of the McBride procedure involves excision of the medial eminence, lateral capsular & adductor release and medial capsular plication.[36]

Mann and Coughlin[37] reported improvement of the hallux valgus angle by around 14° and intermetatarsal angle by 5° using distal soft tissue procedures. However, they also found an incidence of hallux varus in 11% of cases.

4.4. Osteotomies

Osteotomies of the first metatarsal generally involve lateral translation of the metatarsal head to reduce the intermetatarsal angle and to reposition the metatarsal head over the sesamoids. Depending on the severity of the hallux valgus deformity, a distal metatarsal osteotomy may be effective for mild to moderate deformities. Metatarsal shaft osteotomies are utilised for moderate to severe hallux valgus deformity. For severe deformities, proximal metatarsal osteotomy/Lapidus type fusion are preferrable (Fig. 3).

It is important to preserve the vascularity of the first metatarsal head to avoid avascular necrosis of the metatarsal head. Blood supply to the metatarsal is predominantly through the planter leash of vessels entering at the level of the metatarsal neck. The length of the first metatarsal should be maintained as shortening can lead to transfer metatarsalgia. Effective dorsiflexion of the first metatarsal during the osteotomy can offload the first metatarsal and again, lead to transfer lesions.

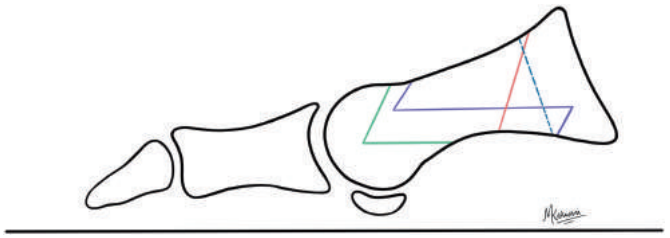

Fig. 3. Illustration demonstrating distal chevron, scarf, Ludloff and proximal metatarsal osteotomies.

The goal of these realignment procedures includes:

1. Re-positioning the first metatarsal head over the sesamoids
2. Restoring the intermetatarsal and hallux valgus angles to normal levels
3. A congruous metatarsophalangeal joint

4.4.1. Distal chevron v-shaped osteotomy

A chevron v-shaped distal first metatarsal osteotomy, is performed for mild to moderate Hallux Valgus deformities. The distal chevron osteotomy can also be combined with lateral soft tissue release (release of the lateral metatarsal sesamoid ligament ± adductor hallucis). On an average up to 50% displacement of the metatarsal is possible whilst maintaining the stability. The fixation (if needed) can be done with various methods such as screw, Kirchner wire or bioabsorbable fixation. Some authors recommend an extended plantar limb of the chevron osteotomy.[38,39] This has an advantage of increased contact surface area for bony union and for fixation of the osteotomy.

Schneider et al.[40] found that chevron osteotomies led to consistently excellent outcomes. The 10-year follow up study acknowledged an improvement of 46.5 points in the AOFAS-score. The first metatarsophalangeal angle was improved from 27.6° to 14.0° postoperatively. Meanwhile, the intermetatarsal angle reduced from 13.8 to 8.7 postoperatively. Only one revision procedure was required to solve the painful return of the deformity in the cohort of 112 patients.

Giotis et al.[41] achieved excellent outcomes with the modified chevron osteotomy in female athletes. All of the patients involved in the study were able to resume with their athletic activities by 12 weeks. An improvement in the AOFAS score from 47.4 to 96.3 by the end of the 2-year study period summarised the successful outcomes. The procedure also led to good cosmetic results (95% of patients). Radiological correction of the metatarsophalangeal and interphalangeal angles was evident with the decrease of 15.6° and 4.1° seen, respectively.

In a randomised controlled trial, Resch et al.[42] compared distal metatarsal osteotomy with or without adductor tenotomy in 106 feet. The clinical appearance and radiographic results were better in the group with adductor release, but the patient satisfaction rates were similar. The main complication of distal metatarsal Chevron osteotomy is osteonecrosis of the metatarsal head and recurrence of the deformity. This can be avoided by having the planter limb proximal to the planter metatarsal artery branches, as well as, avoiding passing the saw beyond the lateral first metatarsal cortex and the lateral capsule.[43]

Resch et al.[44] did a randomised control trial using 99mTc-methylene diphosphonate scintigraphy to demonstrate that

adductor tenotomy performed with a distal Chevron osteotomy does not cause an increased threat to the vascularity of the first metatarsal head, as compared to, distal chevron osteotomies performed without a lateral soft tissue release.[45] Shariff et al.[46] performed a similar study and found that 7.7% cases had abnormal scans on scintigraphy post chevron osteotomy but none of those patients showed any clinical signs of avascular necrosis.

The radiographic and clinical results of a prospective controlled study by Windhagen et al.[47] showed that degradable magnesium-based screws were equivalent to titanium screws for the treatment of mild hallux valgus deformities using chevron osteotomy.

4.4.2. Wilson procedure

The Wilson procedure involves an oblique, extra-articular cut along the first metatarsal bone.[48,49] The prospective randomised trial, conducted by Klosok et al.,[48] comparing Chevron versus Wilson metatarsal osteotomy for hallux valgus, found that the Wilson procedure provided better appearance of the foot after correction of the deformity. However, when compared to chevron osteotomies, the latter enabled patients to mobilise and resume activities of daily living sooner. Similar outcomes were seen when the Wilson procedure was compared with the Mitchell osteotomy.[50] Patient satisfaction was greater with the Mitchell osteotomy because of better stability and less risk of complications such as post-operative metatarsalgia as well as shorter rehabilitation time.[50]

Other operations are recommended instead of the Wilson procedure because of the increased risk of metatarsalgia due to an average shortening of 8.5 mm of the metatarsal bone.[51] Usually, greater than 5 mm of shortening is shown to have a strong correlation with development of metatarsalgia.[52] Hence, proving to be a substantial disadvantage of the technique.[53]

4.4.3. Mitchell osteotomy

Mitchell's osteotomy, although first described by Hawkins et al.,[54] bears his name after he described his results on more than 400 such osteotomies.[55] It is a double step-cut osteotomy through the neck of the first metatarsal, displacing the head fragment laterally and plantar.

Mitchell osteotomies are slowly falling out of favour, by many surgeons, due to the greater loss of metatarsal length during the procedure.[56] As mentioned earlier, excessive decrease in metatarsal length may lead to transfer metatarsalgia.

Level 3 evidence by Heerspink et al.[56] showed that around double the number of patients in the study developed secondary metatarsalgia following the Mitchell procedure (24%) compared to chevron osteotomy (14%). The prevention of post-operative metatarsalgia is an important factor for patient satisfaction and thus should not be underestimated when selecting the operative treatment.

4.4.4. Scarf osteotomy

The 'Z' shaped scarf osteotomy comprises of a longitudinal transverse cut, a distal dorsal limb and a proximal planter limb at 60° to the longitudinal cut. This is an inherently stable osteotomy and allows for significant displacement of the metatarsal. It is able to reduce the intermetatarsal angle significantly and is generally stabilised with two screws across the shaft of the metatarsal. The procedure is technically demanding with a learning curve and can have significant complications of up to 11%.[57–59]

It stands at risk of troughing which effectively dorsiflexes the metatarsal head.[57] **(**Fig. 4**)** The incidence of guttering can be reduced by having the transverse longitudinal cut parallel to the floor, rather than along the long axis of the metatarsal or using a rotational scarf osteotomy when permissible according to the DMAA.

Multiple studies comparing scarf and chevron osteotomies in moderate and severe hallux valgus have concluded that both the scarf and chevron osteotomy techniques are equally effective at managing the hallux valgus deformity. The correction of HVA, IMA and outcome scores were similar in both these groups. However, almost all these studies expressed preference for the chevron osteotomy technique because of its less invasive method, whilst maintaining good correction of the IMA and HVA.[38,39,60–66] However, a systematic review and meta-analysis by Smith, showed a statistically significant increase in the correction of the 1–2 IMA in favour of the scarf osteotomy compared with the chevron osteotomy.[67]

4.4.5. Minimally invasive chevron akin osteotomy

This involves percutaneous metatarsal neck chevron osteotomies using a low speed, high torque burr. The disadvantage is the shortening of the metatarsal, but it allows a large translation of the metatarsal head laterally and percutaneous stabilisation. Risks include dorsal malunion of the metatarsal head and transfer metatarsalgia.

Jowett and Bedi[68] found a significant improvement ($p < 0.001$) in AOFAS scores post-minimally invasive chevron akin osteotomy from 56 to 87 points. The mean hallux valgus angle was improved from 29.7° to 10.3° postoperatively. Additionally, postoperatively the intermetatarsal angle was reduced from 14.0° to 7.6°. The majority of patients (87%) were satisfied with their results, although, 14% of the entire cohort (15 of 106) necessitated revision surgery.

These positive results were corroborated by Redfern et al.[69] who found 82% were pleased with the procedure. They also reported an improvement in the AOFAS score from 39.3 preoperatively to 89.9 postoperatively.

Both minimally invasive and open chevron osteotomy were shown to reduce the angular deformity in hallux valgus patients in the randomised control trial including 47 patients. In regard to, the patient outcomes: Visual Analog Scores (VAS) of pain, the American Orthopaedic Foot and Ankle Society (AOFAS) forefoot score, radiographic outcome measures and the range of motion (ROM), the trial found no significant difference. Although, concerning patient satisfaction, the minimally invasive technique was significantly better received ($P = 0.022$).[70] In a comparison study, Frigg et al.[71] found no advantage in favour of minimally invasive chevron osteotomy compared to a scarf osteotomy except for a shorter scar. A 10-degree increased extension of metatarsophalangeal joint found in the minimally invasive group was attributed to the 3 mm shortening of the metatarsal caused by the burr.

In a systematic review of complications following minimally invasive chevron osteotomies, the main complications found were joint stiffness in 18.47%, followed by recurrence and shortening of first metatarsal, both in 15.2%.[72]

4.4.6. Proximal first metatarsal osteotomies (Table 2)

Proximal first metatarsal osteotomy can be used in moderate to severe hallux valgus. They have a higher complication rate with up to 5 mm of metatarsal shortening associated with proximal closing wedge osteotomies.[73,74] The medial opening wedge osteotomies cause elongation of the metatarsal and hence tighten up the medial soft tissue structures. They require a bone grafting and can have a risk of dorsal malunion in up to 38%.[75] A separate series comprising of 187 feet treated with proximal oblique closing wedge osteotomy recorded removal of hardware in 12.3% for symptomatic hardware & transfer metatarsalgia in 4.8%.[74]

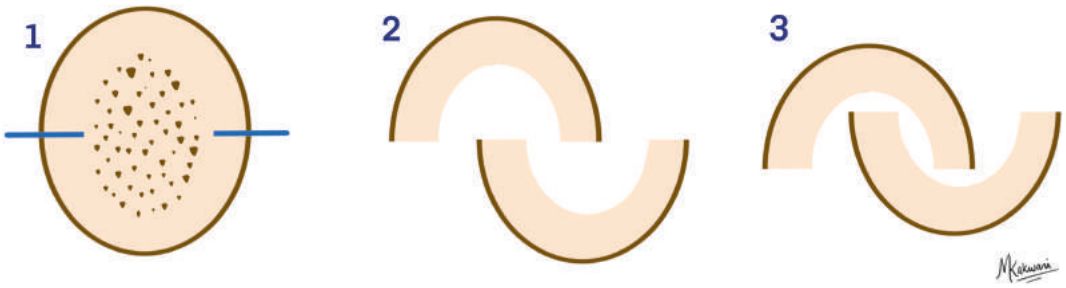

Fig. 4. Troughing of scarf osteotomy.

4.4.7. Proximal oblique (ludloff) osteotomy

The modified Ludloff osteotomy is an oblique osteotomy that begins 2 mm distal to the metatarso-cuneiform joint on the dorsal aspect extending distally and inferior to the planter cortex. The osteotomy forms at an angle of around 30° to the metatarsal. The initial metatarsal osteotomy cut should extend only two-thirds the length of the metatarsal, maintaining the distal plantar cortex intact. Once the proximal screw is placed across the osteotomy, the distal bone cut is completed. Rotation of the metatarsal osteotomy occurs around a single axis point established by the more proximal screw. The osteotomy is further stabilised with screws or plate dorsally.[76,77] Chiodo et al.[77] demonstrated a mean improvement in the first/second intermetatarsal angle from 31° to 11° and the American Orthopaedic Foot and Ankle Society (AOFAS) hindfoot score improved from 54 to 91 in their series. In a large series of 326 feet, Neufeld et al.[78] were able to allow immediate weight bearing post-surgery by using a dorsal locking plate to stabilise the osteotomy. Jo et al.[79] also recommended use of a dorsal plate in patient with rheumatoid arthritis or low bone mineral density.

The major risk of this osteotomy is the possibility of dorsal malunion. However, it is mechanically more stable than proximal chevron or crescentic osteotomies.

4.4.8. Proximal crescentic osteotomy

Coughlin et al.[5] described crescentic osteotomies of 1 cm distal to the tarsal metatarsal joint using a crescentic saw blade with concavity proximal. This allows rotation of the metatarsal shaft and can be stabilised with any internal fixation device. The procedure leads to minimal shortening of the first metatarsal but has a dorsal malunion rate of up to 17% with transfer metatarsalgia.[80,81]

The randomised control trial by Wester et al.[82] compared crescentic and open wedge metatarsal osteotomy, and showed that they are both effective in addressing the symptoms associated with hallux valgus and improving the patients' visual analogue & AOFAS score. The difference between the angular measurements of the deformity (IMA and HVA) in the two groups were insignificant. They found no statistical difference in the length of the first metatarsal using the open wedge osteotomy compared to the crescentic osteotomy.[82]

4.4.9. Proximal chevron osteotomy

A proximal chevron osteotomy involves not only lateral translation of the first metatarsal head fragment but also incorporates an open wedge principle. It provides a lot of surface contact area for the osteotomy to heal but has up to 17% risk of dorsal malunion.[81,83–85]

The randomised control trial by Lee et al.[86] suggested that distal Chevron osteotomy with a distal soft-tissue procedure was as effective and reliable as proximal Chevron osteotomy with a distal soft-tissue procedure for simultaneous correction of bilateral moderate to severe hallux valgus in 50 patients (100 feet).

Table 2
Comparing proximal metatarsal osteotomies, a systematic review by Schuh et al.[87] The difference in IMA was not statistically significant.

	Correction of HVA	Correction of IMA	Major complication rate
Proximal closing wedge	19.6°	8.2°	15.7%
Proximal opening wedge	16.2°	7.2°	14.3%
Ludloff	22.4°	8.2°	17.5%
Proximal crescentic	23.3°	9.2°	11.7%
Proximal chevron	21.0°	7.2°	6.1%

4.4.10. Akin osteotomy

In patients with hallux valgus inter-phalangeus, the metatarsal osteotomy is generally combined with a medial closing wedge osteotomy of the base of the proximal phalanx.[88–90]

The osteotomy can be stabilised with sutures, threaded K wires (if an intact lateral cortex is maintained) or screws. It is important to acknowledge that the base of the proximal phalanx is concave and hence the osteotomy must be distal enough to avoid an intra-articular extension of the osteotomy into the metatarso-phalangeal joint.

4.5. Arthodesis

4.5.1. First metatarsophalengeal joint arthodesis

Indications: Hallux valgus with rheumatoid arthritis, recurrent hallux valgus, severe hallux valgus deformity, hallux valgus associated with hallux rigidus and hallux valgus secondary to neurological conditions.

This operation reduces the intermetatarsal angle by retention of the adductor pull on the proximal phalanx. It has up to 10% risk of non-unions.[91]

In comparison between scarf osteotomy and metatarsophalangeal fusion for hallux valgus correction, the improvement in pain scores and global satisfaction were similar in both groups but the scarf group was better in the functional/sports activity (hiking) scores & mental health component of SF36.[92]

In a biomechanical gait study, Ballas et al.[93] found that the patients who underwent Scarf osteotomy had a gait pattern and propulsive force, similar to that of their non-operated foot.

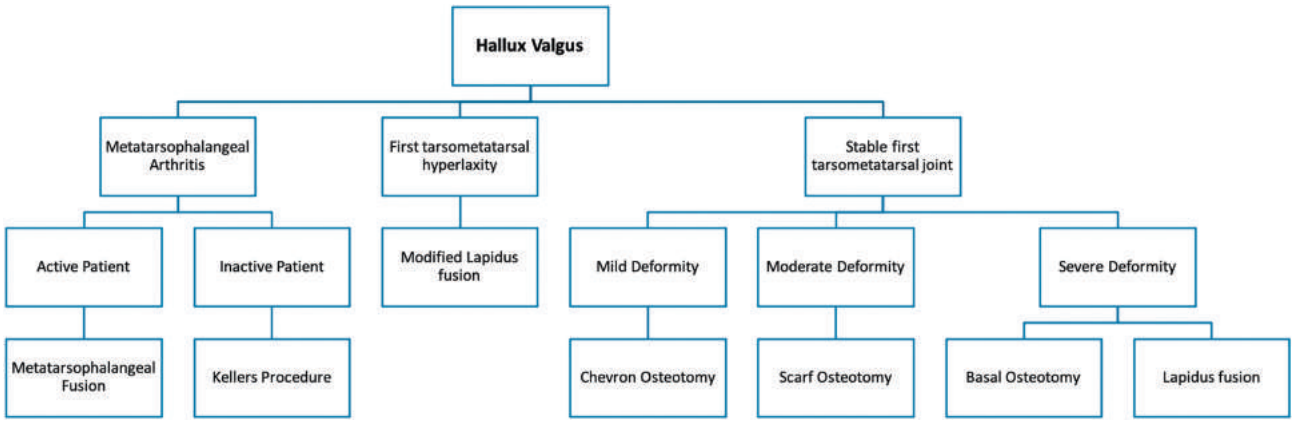

Fig. 5. Author's algorithm regarding surgical management of hallux valgus.

Whereas the patients who underwent arthrodesis of the first metatarsophalangeal joint did not totally recover the propulsive forces of the forefoot. The complication rates were similar in both groups.[92,93]

4.5.2. First tarsometatarsal joint arthodesis

Also referred to as the modified Lapidus procedure.

Indications: severe hallux Valgus, instability of the first tarsometatarsal joint, hyperlaxity metatarsus primus varus and recurrent hallux valgus.

Sangeorzan and Hansen[94] achieved a 75% success rate with the modified lapidus procedure when it was the primary operative treatment used for the correction of hallux valgus. They also reported an approximate 5 mm decrease and 4-mm increase in metatarsal length without and with bone graft, respectively.

Complications often occur with the Lapidus procedure due to its challenging technique. Examples include symptomatic hallux varus, recurrence of hallux valgus deformity, deep vein thrombosis and failure of fixation. Stiffness may also be considered as an additional complication and is experienced by 58% of patients in the retrospective study by Kopp et al.[95] However, they also found that in the majority of cases (90%) of patients were satisfied with their foot function after the operation and 86% were happy with the cosmetic appearance of the foot.[95] Non-union rates of 10–12% have been published with the modified Lapidus procedure.[96,97]

In terms of recurrent hallux valgus, the operative treatment is more complex. Using the Lapidus procedure in the revision surgery, Ellington et al.[98] were able to achieve better radiological correction of the deformity and 87% of patients obtained excellent results. The rates of non-union were also low in this case series.[98]

4.5.3. Kellers procedure

This involves resection of the proximal third of the proximal phalanx of the great toe. This allows decompression of the joint, as well as relaxation of the tight lateral soft tissue structures and correction of the deformity. It has a high rate of recurrence and cock-up deformity, with a reduction in the range of movement of the metatarsophalangeal joint. Another issue associated with Keller's procedure is the significant loss of function of the great toe, which no longer has sufficient contact with the ground during the heel rise phase of gait, leading to transfer metatarsalgia. This procedure is best reserved for physically inactive patients.[90,99,100] Salvage following a failed Keller's procedure is difficult due to the shortening and the loss of bone stock of the proximal phalanx.[101–103]

4.5.4. Rehabilitation following surgical correction of hallux valgus

In our institution, post-surgical correction of hallux valgus, patients are allowed to heel weight bear in a wedge (under the heel) shoe/flat dressing shoe for the first 6 weeks. They are advised to elevate the foot most of the time for the first 2 weeks to reduce swelling and allowing the wounds to heal. Patients can usually walk normally after 8–12 weeks. Driving generally permissible after 8 weeks following right foot surgery, when the patient can safely perform an emergency stop.[104]

5. Summary

Hallux valgus is a complex three-dimensional deformity. Surgical correction of the hallux valgus is technically demanding and has a significant risk of recurrence and complications (Fig. 5). There is a learning curve associated with the operative technique. The aim of the realignment procedures include:

1. Re-positioning the first metatarsal head over the sesamoids
2. Restoring the intermetatarsal and hallux valgus angles to normal levels
3. A congruous metatarsophalangeal joint

Great toe metatarsophalangeal fusion offers an effective salvage option for recurrent hallux valgus and severe deformities.

Our results echo the literature evidence of 85% of patients being satisfied and having a good clinical result at 5-year review. Ten percent of patients are less satisfied, and in 5% the results are poor.[90]

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Review article

The management of talar osteochondral lesions - Current concepts

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ABSTRACT

Osteochondral lesions of the talus (OLTs) are a common complication following trauma, involving both the articular cartilage and the underlying subchondral bone, with variable aetiologies and often presenting with non-specific symptoms. Diagnosis of OLTs requires a combination of clinical assessment and imaging and despite many different treatment options, there is no generalised consensus regarding which option is the most effective. Left untreated, OLTs risk progressing to osteoarthritis. Acute non-displaced OLTs can be treated non-operatively. However, OLTs refractory to non-surgical care for three to six months may be suitable for surgical care. In these cases, conservative treatments are often unsuccessful, particularly for larger and more severe defects and so the majority require surgical intervention. Although bone marrow stimulation techniques remain the "gold standard" for lesions <150 mm^2, there still requires a need for better long term clinical data and cost-benefit analyses compared with other treatment options. Biological attempts at either regenerating or replacing the articular cartilage are however demonstrating some promising results, but each with their own advantages and disadvantages. In this review, we summarise the clinical management of OLTs and present the current concepts of different treatment regimes.

1. Introduction

Osteochondral lesions of the talus (OLTs), also known as talar osteochondral defects, include many varieties of pathologies such as osteochondritis dissecans, transchondral fractures and osteochondral fractures. In general, OLTs refer to any defect of the ankle articular cartilage and underlying subchondral bone.[1] OLTs are mainly associated with trauma, with the majority of defects occurring in young people aged between 20 and 40 years, following ankle sprains or fractures.[2] They can be diagnosed by plain radiography, computerized tomography (CT), magnetic resonance imaging (MRI) and arthroscopy; OLT classifications among these diagnostic techniques also vary.[3] Patients with symptomatic OLTs will normally suffer from prolonged pain, swelling, locking and catching of the ankle joint. Acute non-displaced OLTs can be treated non-surgically with successful results in up to 50% of cases.[4,5] Due to the low healing capacity of articular cartilage, conservative treatments such as immobilisation, rest and restriction of activities do not have a good performance in ankle restoration in late stage symptomatic OLT patients.[6] Untreated OLTs may contribute to the development of early-stage osteoarthritis (OA) and lead to the severe disability.[7,8] Bone marrow stimulation is still a gold standard among surgical interventions for lesions <150mm^2, but it cannot promise good long-term results.[1,9] Newer, novel cell-based therapies are developing rapidly, aiming for safe, cost-effective and improved long-term results.

2. Aetiology

The aetiology of OLTs is still controversial but are more common in young and active patients (20–40 years old) following an ankle sprain or trauma.[2,10] It is widely accepted that OLTs are caused by both traumatic and nontraumatic events with up to 50% of ankle sprains and over 70% of ankle fracture cases leading to the

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development of osteochondral lesions.[7,11] A study by Tol et al. (2000),[12] demonstrated 93% of patients with lateral lesions had a history of trauma, compared to only 62% with medial lesions. According to Berndt and Harty,[13] the mechanism of injury in lateral lesions, is associated with ankle joint dorsiflexion and inversion, while in medial lesions it is associated with ankle plantarflexion and inversion. OLTs without trauma history could possibly be caused by repetitive microtrauma, ischemia, subsequent avascular necrosis, genetic predisposition and endocrine or metabolic factors.[14]

Depending on their anatomical location, OLTs are divided into different types. Posteromedial and anterolateral OLTs were traditionally thought to be the most common OLTs.[13] Raikin et al. (2007) examined 424 patients by MRI based on a 9-zone anatomic grid system (Fig. 1), and found that the majority of lesions (53%) were located in zone 4 (centromedial), and that the second most common lesion location was zone 6 (centrolateral).[15] Another study, however, demonstrated the opposite with regards symptomatic and operatively treated lesions, with the centrolateral region being twice as common as the centromedial region of the talar dome.[16] Despite this, these studies demonstrate that the centrolateral and centromedial areas of the talar dome are the most common locations for OLTs. In addition, it has been shown in several studies that medial lesions are generally larger and deeper while lateral lesions are smaller and shallower.[13,15,16] However, lateral lesions tend to be more symptomatic than medial lesions, possibly due to the higher baseline contact pressure found in the centrolateral area compared to the centromedial area of the ankle joint.[16]

It has been demonstrated that the posteromedial and anterolateral regions of the talar dome have the thickest articular cartilage, as evidenced by quantitative cartilage thickness measurements of 12 cadaveric ankle joints by high resolution stereophotography.[17] The authors of this study have related this finding to an adaptive response of the tissue in this region to the greatest mechanical stress, and claimed that these results are consistent with the most common sites of OLTs.[17] However, other studies suggest that the posterolateral region of the talar dome has the thickest articular cartilage and that the anterolateral region has the thinnest articular cartilage, as assessed by confocal microscopy and MR imaging with 3D modelling respectively.[18,19] Further, Sugimoto et al. (2005) concluded that articular cartilage in the medial corner of the talar dome showed the greatest thickness, while the lateral gutter of the talar dome showed the least thickness, as assessed radiographically.[20] Taken together, although there is no complete agreement on the thickness of cartilage in specific regions, the cartilage thickness has been shown to vary in all studies across the talar dome, and its relationship with the mechanism of OLT development requires further investigation.

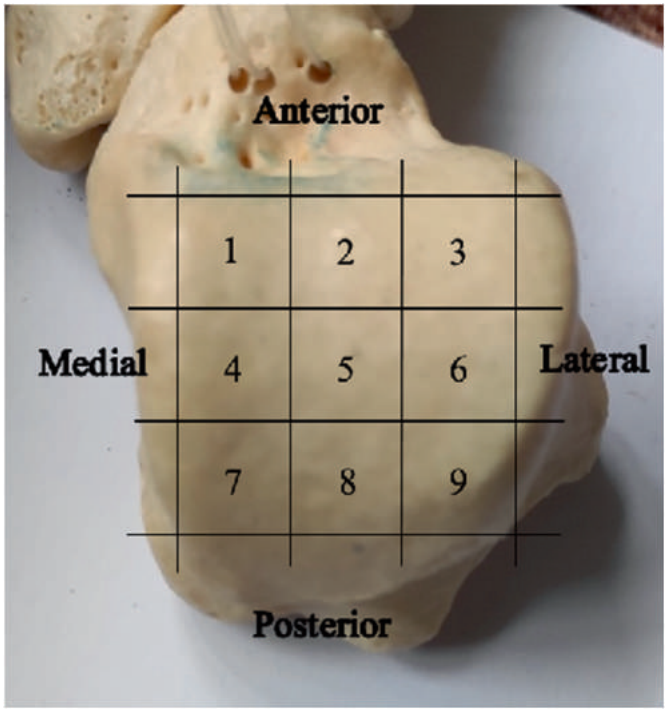

Fig. 1. Anatomical 9 zone grid system of the talar dome.[15] The talar dome is divided into 9 equal zones, with zones 1, 2 and 3 located anteriorly and zones 3, 6 and 9 located laterally.

Compared to the knee, the ankle is anatomically different: it has a smaller articular contact area than the knee, and over 60% of the talar dome is covered by hyaline cartilage. Ankle cartilage has a higher dynamic stiffness due to the higher proteoglycan content, which contributes to stability when weightbearing or loading.[21] The average cartilage thickness of the ankle is almost two folds thinner than the knee, however a study showed that the ankle has a relatively higher proportion of the superficial zone of cartilage, which indicates that ankle has stronger protection than the knee when weightbearing.[22] In addition, ankle articular cartilage has undetectable levels of matrix metalloproteinase-8 (MMP-8) compared to knee articular cartilage, reducing endogenous degradation of extracellular matrix proteins.[23] From a biomechanical point of view, the main movements of the ankle joint are rolling and rotating, while the knee experiences higher shear forces from its rolling, sliding and rotating movements.[24] Although the development of ankle OA is considered to be associated with untreated OLTs,[7,8] the incidence of OA in the ankle is relatively low; around 15% of adults are affected by OA worldwide, however, only 1% of this is ankle OA.[25] In a 21-year follow up study, Bauer et al. (1987) found that only two out of 30 patients' OLTs had progressed on to develop OA.[26] According to Günther et al. (1998), 67% of knee OA cases were primary origin,[27] while Valderrabano et al. (2008) reported that primary ankle OA only accounts for 9% of cases, whilst 78% of OA cases were posttraumatic.[25] In conclusion, the ankle develops less OA than the knee,[28] with ankle OA developing mainly posttraumatically and knee OA developing idiopathically.[24]

3. Diagnosis and evaluation

Pain, swelling and stiffness are the most common complaints of presenting patients with OLTs, occurring particularly with high levels of activity such as sport, but rarely present at rest.[29] Occasionally, there may also be mechanical symptoms present such as locking and catching.[3] Patients will often relate the pain experienced to a history of either a single trauma or recurrent sprains. Often the initial OLT is misdiagnosed as an ankle sprain.[30] Chronic OLTs present with non-specific symptoms, in these cases, physical examination may show an effusion, decreased range of motion, general tenderness, and pain with inversion or dorsiflexion.[29] In general, patients often describe a deep-seated pain with more chronic OLTs compared with a more superficial pain with synovitis.[31] Of course, the absence of physical signs and symptoms on examination does not exclude the presence of OLTs, highlighting the importance of further clinical imaging investigations being required to confirm OLT diagnosis.[31]

Imaging modalities most commonly utilised in the clinic for the identification and diagnosis of OLTs include plain radiography, MRI and CT, each with their own benefits, drawbacks and classification systems (Table 1). Initially, plain radiographs are often used upon first presentation usually taken in anterior-posterior (AP) mortise

Table 1
Overview of the classification systems used across the different assessment modalities used in the diagnosis of OLTs. OC = osteochondral fragment; SCB = subchondral bone.

X-Ray	MRI	CT	Arthroscopy	
Berndt and Harty[13]	Hepple[34]	Ferkel[36]	ICRS[37]	Cheng-Ferkel[38]
I – subchondral compression	1 - articular damage only	I - cystic lesion, intact overlying articular cartilage	1 – superficial zone softening or fissure	A – smooth and intact cartilage, but soft
II – partially detached OC fragments	2a – Articular cartilage damage with subchondral fracture (- odema)	IIA – cystic lesion with articular surface communication	2 – lesions extend <50% depth	B – rough articular surface
III – fully detached OC fragments	2b – Articular cartilage damage with subchondral fracture (+odema)	IIB – overlying non-displaced OC fragment	3 – lesions extend >50% depth but not into SCB	C – fissures and fibrillations present
IV – displaced OC fragments	3 – detached non-displaced OC fragment	III – non-displaced OC fragment with lucency	4 – lesion extends into the SCB	D – cartilage flap or exposed SCB
	4 – detached and displaced OC fragment	IV – displaced OC fragment		E – loose, non-displaced fragments
	5 – subchondral cysts			F – displaced fragment

view and lateral weight-bearing views of the ankle. In the acute injury a trauma series is often taken. Radiographs have relatively low sensitivity and are often unclear, missing over 40% of cases.[31,32] The Berndt and Harty radiography score is a 4-stage classification system that assesses the initial subchondral compression (stage I) and osteochondral fragments being either partially detached (stage II), completely detached (stage III) or displaced (stage IV; Table 1).[13]

MRI is more able to clearly visualise soft tissues such as articular cartilage, synovium and tendons, making it advantageous in detecting and characterising OLTs.[31] It is often the imaging modality of choice following inconclusive plain radiographs or continuation of symptoms. However, MRI is less able to assess bony changes and can make it difficult to fully assess the true status of the subchondral bone and the exact lesion dimensions.[33] OLTs on MRI are classified according to the 5-stage Hepple MRI classification system,[34] where stage 1 is articular cartilage damage only, stage 2 is cartilage damage with subchondral fracture (this is further categorised as either acute (2a) or chronic (2b) dependent upon the presence of oedema), stages 3 and 4 include detached non-displaced and displaced osteochondral fragments, respectively and stage 5 is the presence of subchondral cysts (Table 1).

CT on the other hand provides a far superior assessment of the subchondral bone compared to MRI and can therefore more accurately predict the depth of the OLT unless it is an early lesion, which is characterised by changes in the articular cartilage.[35] Performing a CT scan can provide the surgeon with the finer details required for accurate surgical planning.[35] OLTs on CT are classified according to the Ferkel system where stage I is the presence of a cystic lesion but with intact overlying articular cartilage,[36] stage IIA is where the cystic lesion communicates with the articular surface and stage IIB includes an overlying non-displaced osteochondral fragment, stage III is a non-displaced fragment with lucency beneath it and stage IV is a displaced fragment (Table 1).

Arthroscopy is also an effective method for visualising and investigating OLTs. The ability to assess the entire joint in addition to probing the lesion can provide the most comprehensive evaluation in deciding the most appropriate treatment regime. Arthroscopic evaluation of OLTs uses the International Cartilage Repair System (ICRS) grading,[37] which is a standardised grading system. Grade 1 lesions involve the superficial zone with softening or fissure, Grade 2 lesions extend less than 50% of the depth, Grade 3 greater than 50% in the depth but not to the subchondral bone as in Grade 4 (Table 1). Cheng-Ferkel grading is another arthroscopic grading system used in OLT evaluation, Grade A lesions present smooth and intact cartilage with a soft or ballottable arthroscopic appearance, Grade B lesions show a rough surface, Grade C lesions appear fibrillations or fissures, Grade D lesions have a flap present or bone exposed, Grade E lesions are loose and normally show non-displaced fragments and displaced fragments present in Grade F lesions (Table 1).[38]

4. Treatment and outcomes

The goal of any treatment strategy of course is to diminish debilitating symptoms such as pain and swelling and to improve function. The effectiveness of each strategy, however, is variable and often the strategy adopted is based not only on the type and size of the defect but also preferences of the treating clinician. In acute non-displaced OLTs injuries conservative methods of treatment are usually considered with the intention of reducing the load on the damaged cartilage to resolve bone oedema or encourage healing of any detached fragments.[39] Methods include rest and/or restriction of activities with or without the use of non-steroidal anti-inflammatories (NSAIDs), short-term immobilisation in a cast or boot for approximately 6 weeks, followed by physiotherapy and progressive weight-bearing with a slow return to previous activities.[1,29] Such conservative techniques are effective in only ~50% of cases.[39] Chronic symptomatic OLTs, acute fragmented OLTs and those refractory to conservative management should be considered for surgical intervention.[1] Acute displaced, symptomatic OLTs can be treated by open or arthroscopic methods, whereas large OLTs are usually fixed using headless cannulated screws or absorbable pins. Access to the ankle is restricted and this may require either a medial or lateral malleolar osteotomy for access. Small or fragmented lesions can simply be excised (Fig. 2). Symptomatic OLTs that are chronic or refractory to non-surgical measures should be considered for surgical intervention. Surgical interventions to treat OLTs are most commonly performed as arthroscopic interventions. The majority of procedures treat the OLTs through debridement of any damaged hyaline cartilage and underlying subchondral bone. The 'gold standard' treatment for lesions <150 mm^2 remains microfracture,[1,9] which involves creating small holes in the subchondral bone to create a new blood supply, also resulting in innate mesenchymal stem or stromal cells (MSCs) entering the defect from the subchondral blood/marrow and stimulating healing of the cartilage. Microfracture benefits patients who require quick return to function, as this procedure requires early mobilisation of the joint through its' associated recommended rehabilitation programme.[40] Optimal clinical improvements of microfracture (based on Visual Analogue Scale (VAS) and American Orthopaedic Foot and Ankle Society (AOFAS) score) have been demonstrated at 24 months post-operatively.[41] Recently published findings from both Kim et al. (2019) and Choi et al. (2020) indicate that microfracture results in mid-term improvements.[41,42] When assessing 70 patients, 85% of patients showed some improvement 6 months after their microfracture, for whom their symptoms did not worsen from baseline at 3 years post-operatively.[41] Further, in a study of 156 patients (165 ankles) improvement or maintenance of pain and

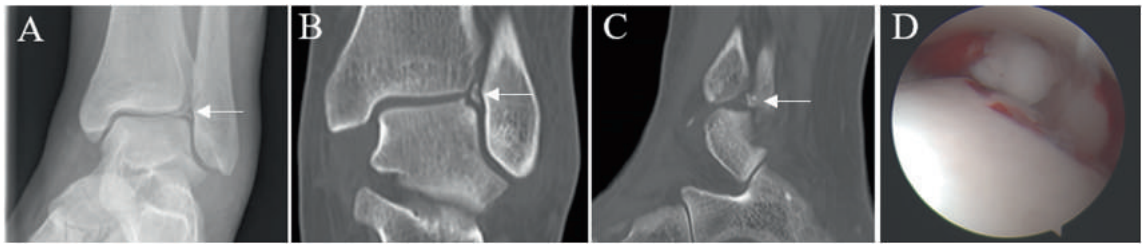

Fig. 2. 22-year-old female case presenting with an acute injury, with a history of a fall from a horse. X-ray (A) and CT (B–C) imaging demonstrated lateral talar dome OLTs (arrow). OLT fragment was excised arthroscopically (D).

functional scores (AOFAS; VAS; Short Form-36) compared with baseline scores could be demonstrated up to six years post-operatively.[42] There does appear to be an inverse relationship between the size of the lesion and the outcome following microfracture. The critical size of the defect appears to be those that are less than 150 mm^2.[41,43] Interestingly, a systematic review of 70 patients indicated that microfracture might also be effective as a treatment for non-primary OLTs.[44]

In patients where lesions are observed within the subchondral bone but the hyaline cartilage is intact, retrograde drilling can be offered with the aim of treating the subchondral lesion whilst preserving overlying cartilage.[45] In the retrograde drilling procedure, articular cartilage is selected for entry into the talus and then a guidewire is directed into the lesion in a retrograde direction under x-ray control. This can also be under computer navigation to place the guide wire and direct the location of drilling.[45]

Other interventions used to treat OLTs include those in which osteochondral transplants are inserted into small defect. These can be in the form of Osteochondral Autograft Transfers or Osteochondral Allograft Transplantations (OATs). In either of these procedures, non-weight bearing cartilage and subchondral bone is harvested as a cylindrical plug which is matched in size and area to the problem defect. To treat larger defects, mosaicplasty can be performed in which multiple smaller osteochondral (OC) plugs are taken and inserted into the defect(s).[46] For defects that are less than 1 cm^2, OATs are more commonly used in which the OC plugs are harvested from the patient themselves. Where defects are larger than 2 cm^2, OATs are carried out using arthrotomy. This relies on the harvest of OC plugs from cadaveric donors and subsequent sterilisation of the tissue prior to being transplanted into the patient's defect site. OATs have long been turned to as a surgical option for the treatment of OLTs, with these surgeries having been performed widely since 1992.[47] A number of systematic reviews have recently been published which aimed to determine the clinical outcomes following OATs in the ankle.[48] Pereira et al. (2021), found that in 12 studies, yielding 191 patients, there were no short-term complications following fresh OATs and that the graft survival rate was 86.6% (assessed by AOFAS and VAS score).[48] Autologous osteochondral transplants were also concluded to have good clinical outcomes (AOFAS, MRI and radiographs) at a mean of 62.8 months follow-up, although donor site morbidity was demonstrated in 18 of the 500 study participants.[49]

More recently, surgeons have been investigating the potential of another allogeneic tissue donor source which uses particulated juvenile articular cartilage (PJAC).[50] These juvenile grafts are taken from donors typically younger than 13 years old. The only commercial graft available for this procedure at present, is DeNovo NT Natural Tissue Graft (Zimmer, Warsaw, IN, USA), marketed as a pre-packaged allograft consisting of immature chondrocytes in their innate extracellular matrix. These grafts can be used to treat focal defects up to 2 cm^2 with fibrin used to adhere the allograft in place. Similar to osteochondral allograft transfer, this procedure benefits from removing the possibility of donor site morbidity that comes from an autologous tissue transfer procedure.[51] PJAC treatment has been reported to produce articular cartilage, which is more akin to native tissue.[50] Aldawsari et al. (2021), found that of the published 10 studies of PJAC radiological and clinical outcomes included in their systematic review, PJAC demonstrated promising functional outcomes, with MRIs demonstrating some filling of the OLTs.[52] However, there was some disparity in cartilage repair between studies and a consistent lack of repair in the subchondral bone and subchondral lamina.[52] Furthermore, a comparative study found PJAC had no advantage over microfracture based on patient reported outcomes.[53]

Cell-based surgical interventions are regenerative medicine methods used to biologically regenerate the cartilage rather than replace it. Techniques include autologous chondrocyte implantation (ACI), autologous matrix-induced chondrogenesis (AMIC), platelet-rich plasma (PRP) and bone-marrow aspirate concentrate (BMAC). These treatment modalities are often used following a failed microfracture.[54] ACI is a long-established 2-stage procedure initially developed for chondral/osteochondral lesions in the knee,[55] that, in the ankle, involves harvesting macroscopically normal hyaline cartilage either from the anterior talus or detached osteochondral fragments.[56,57] Previously, harvests for ankle ACI have been obtained from the knee, with limited donor-site morbidity.[58,59] Chondrocytes are enzymatically extracted from the cartilage and culture-expanded *in vitro* prior to being re-implanted into the defect some 3–4 weeks later, beneath either a periosteal patch or a commercially available type I/III collagen patch.[60] Alternatively, extracted chondrocytes can be cultured directly on the collagen patch, a procedure known as matrix-assisted ACI, or MACI. Pagliazzi et al. (2018) demonstrated a significant improvement in the patient AOFAS score at 7 years (87.2 ± 14.5 months) following the ACI.[61] Despite the recent technical appraisal by the National Institute for Clinical Excellence (NICE) approving the use of ACI in the knee,[62] the same cannot be said for the ankle. Current guidelines state that ACI will not be routinely commissioned due to lack of evidence of the clinical effectiveness of this therapy in the ankle, so it remains a clinical trial/efficacy study line of treatment only at present (within the UK at least).

To eradicate the need for a 2-stage procedure, the AMIC technique offers a promising, cost-effective alternative that was originally developed for the treatment of defects in the knee.[63] The technique consists of performing a microfracture followed by securing a commercially available type I/III collagen patch over the defect with the aim of not only trapping any MSCs entering the defect area through the bleeding process, but also providing a scaffold on which the cells may adhere and proliferate.[64] It has been suggested that transforming growth factor beta (TGF-beta) present in the fibrin glue used to adhere the patch may enhance MSC chondrogenic differentiation.[65] However, a recent systematic review of AMIC in the talus concluded that more clinical studies are

required to validate the efficacy and safety of this technique.[66] Complete defect filling was demonstrated in 88% of patients (n = 33) treated with AMIC when assessed by MRI, along with reduction in pain and improvement in function at 4.7 (mean; range, 2.3–8.0) years post-operatively.[67] A systematic review of 13 papers, further confirmed the efficacy of AMIC,[66] as did another of 15 studies with outcomes up to five years post-operatively.[68]

There has been increasing interest in recent years with regards to a biological therapy for OLTs utilising PRP, either autologous or allogenic, which can either be administered directly to the lesion or via intra-articular injection.[69,70] PRP is rich in various growth factors and cytokines such as TGF-beta, platelet-derived growth factor (PDGF), insulin-like growth factor (IGF) I and II, fibroblast growth factor (FGF) and vascular endothelial growth factor (VEGF) which are believed to enhance the natural healing response by promoting MSC differentiation and cartilage formation.[71–73] The use of PRP to treat OLTs has also been systematically reviewed and was concluded to result in significantly reduced pain and improved function in comparison with microfracture alone.[73] Despite being a promising treatment option, to date, there is limited clinical evidence for the use of PRP and an absence of a standardised preparation technique prior to application.[74]

BMAC is a type of biological adjuvant used for one-step cartilage repair of OLTs, in the most recent decade.[75] BMAC consists of different types of stem cells and progenitor cells such as MSCs and haematopoietic progenitor cells (HPCs), which have the potential to repair injured hyaline cartilage. BMAC also contains an abundance of growth factors and cytokines which may contribute to the cartilage regeneration process.[76] In BMAC therapy, bone marrow aspirate is collected from the patient's iliac crest, the white cells in the marrow including MSCs, HPCs and all other immune cell fractions are concentrated with the aid of commercial kits, and injected directly into the patient's OLT, combined with a biological scaffold, such as a hyaluronic acid and fibrin gel.[77] Unlike the two-stage procedure of ACI, BMAC therapy can be achieved during a single surgical operation, and does not require *in vitro* cell culture, which significantly lowers the financial burden (as BMAC is not considered an advanced therapy medicinal product by regulators), and avoids the heterogeneity caused by inconsistent cell culture protocols between laboratories. However, BMAC therapy still lacks standardisation; there is no defined protocol for bone marrow aspirate collection and concentration, and the scaffolds used in the treatment vary.

BMAC has been demonstrated to have good long-term results in the treatment of both OLTs and OA.[77–79] In one of these studies patients receiving BMAC therapy demonstrated significantly increased AOFAS scores, decreased Ankle Osteoarthritis Scale (AOS) pain and disability subscales and high patient satisfaction after 24 months and 10 year follow-up.[77] Interestingly, two studies both reported that the AOFAS score increased greatly in the first 24 months post-operatively, but after 48 months the AOFAS score was slightly decreased, yet remained significantly higher than the pre-operative score.[77,78] The reason behind this still needs further investigation.

5. Conclusion

In conclusion, there are several conservative and surgical approaches currently used to treat OLTs. All of these procedures have pros- and cons- and a decision has to be made based upon the likely efficacy compared with the potential risks e.g. donor site morbidity or risks associated with multiple surgical procedures. The judgement of which approach is most suited to each patient depends on the specific presentation of the defect e.g. size, site (contained or uncontained) depth and cyst presence. Moreover, for certain demographics of patient there will be greater impetus on choosing an approach which will allow for rapid return to normal physical activity, such as athletes. There remains a need to better predict which procedure is most likely to benefit an individual, perhaps through the use of imaging or fluid biomarkers, to ensure that repair of OLTs can be achieved as quickly as possible preventing further damage to the joint and the likelihood of developing OA.

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Declarations of competing interest

None.

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Research paper

Distal tibial osteotomy for varus ankle arthritis: A meta-analysis and systematic review

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ABSTRACT

Joint preserving surgical options are essential in modern orthopaedic care. The aim of this study was to review current literature about distal tibial osteotomies for varus osteoarthritis of the ankle joint. A clinical librarian searched electronic from inception to August 2019 using standard terms. Studies that assessed distal tibial osteotomy outcomes (clinical, radiological and complications) in the treatment of varus ankle osteoarthritis with a minimum of one-year follow-up. The search identified 968 studies. Duplicates (225) were removed. On applying inclusion/exclusion criteria to title and abstract review 686 papers were excluded. 57 full-texts were reviewed and a further 45 were excluded. Twelve papers underwent quality assessment and finally only nine included. The nine papers underwent full data extraction and inclusion within the study. Pain scores (VAS) improved in all studies examined. Mean pooled pre-operative VAS was 7.0 and post-operative VAS was 2.5. These results were for 166 ankles. Mean pooled Pre- and post-operative AOFAS scores available for nine studies showed an improvement from 57.7 to 83.6 for 242 ankles. Satisfaction rates were 89.1% from four studies, including 92 ankles. Out of the total number of osteotomies (242) there were four (1.7%) patients who underwent total ankle arthroplasty and five (2.1%) who had arthrodesis at mean follow-up of 45 months (range; 21–99). Distal tibial osteotomy can provide significant pain relief and improvement in functional scores. Satisfaction is high with a low level of complications. It is a viable option for joint preservation in carefully selected patients.

1. Introduction

Joint preservation has become a key facet in the management of joint arthritis as surgeons and patients wish to retain native joints. Cartilage regeneration techniques are possible but have been shown to have a guarded prognosis in a degenerative joint.[1–3] As a result, realignment osteotomy has had an upsurge in recent years, particularly around joints such as the knee. Realignment osteotomy aims to improve symptoms by altering the mechanical axis of a joint. It does this by redistributing load away from degenerative areas of articular cartilage onto intact areas. It has even been shown to stimulate cartilage regeneration.[4,5]

Osteotomy for ankle arthritis remains an infrequent option undertaken for ankle arthritis. Takakura et al. first described distal tibial osteotomy (DTO) to treat varus ankle osteoarthritis in 1995.[6] It is aimed at treating intermediate ankle osteoarthritis defined as stage 2, 3a or 3b according to the modified Takakura system.[6,7] Often this cohort can be complicated by concurrent ankle instability and sequelae of trauma.

Traditional extra-articular, or supra-malleolar, osteotomy aimed to correct overall alignment. However, it has been shown to be less effective in stage 3b disease and where pre-operative talar tilt is $< 5°$.[7–9] Following this the intra-articular, or plafondoplasty, osteotomy was developed to correct the centre of rotation at the level of the deformity. It aimed to tackle the issue of intra-articular varus deformity and prevent recurrent varus deformity.[10]

The aim of this meta-analysis and systematic review was to

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appraise current literature about distal tibial osteotomies for varus osteoarthritis of the tibio-talar joint.

2. Methods

Prior to this review being conducted a thorough literature and Cochrane review search were conducted to ensure no similar studies had been undertaken. The PROSPERO database was then reviewed to ensure no similar study was currently being conducted.

2.1. Systematic review meetings

A series of systematic review meetings were arranged 4–8 weeks apart. All contributors and authors to the research were invited. Meeting 1 involved reviewing and agreeing the research protocol, outcomes to be investigated, finalising literature search terms and inclusion/exclusion criteria. Meeting 2 involved reviewing the studies excluded upon title and abstract review, identifying full-texts to request and confirming quality assessment tool to be used. Meeting 3 was used to present the excluded studies with reasons for exclusion, present the data extraction from included studies and associated themes and conclusions. These meetings allowed there to be a consensus opinion of all authors with every decision made.

2.2. Literature search

An experienced clinical librarian searched electronic databases Medline, Ovid EMBASE, CINAHL and Cochrane CENTRAL from inception to August 2019. Search terms used were “distal osteotomy”, “tibia” and “osteotomy” (Divall, P. Evidence search: Distal tibia osteotomy; University Hospitals of Leicester NHS Trust; August 28, 2019). We did not exclude for language initially and made all attempts to find translated versions of relevant studies. There were no restrictions upon date of publication or journal of publication.

Inclusion criteria were studies that assessed distal tibial osteotomy clinical outcomes (pain visual analogue scores and/or American Orthopaedic Foot and Ankle Score) in the treatment of varus ankle arthritis with a minimum of one-year follow-up.

Exclusion criteria were non-human studies, case reports, and publications pertaining to surgical techniques/biomechanics/personal opinion.

The bibliographies of all relevant articles were searched for studies missed in the electronic search and manual searching for the most recent relevant publications was undertaken.

2.3. Quality assessment

Two independent reviewers (RSA, GP) assessed the quality of the studies. Quality assessment was undertaken using the Modified Coleman Criteria (Appendix A). The Coleman Criteria has two parts. The first consists of assessing the study patients and methodology review and the second involves assessment of outcomes used. The Coleman Criteria were adjusted to accommodate the predicted low number osteotomies in studies and the robustness of objective and subjective outcomes to be investigated. An absolute score was obtained and used to scrutinise the overall quality, and eligibility, of the study. Studies scoring less than 40% were excluded based on their quality.

2.4. Data extraction & analysis

Data extraction was undertaken by two researchers (RSA, GP) independently and cross-referenced for disparities. Outcomes extracted included pain visual analogue scores, patient satisfaction and American Orthopaedic Foot & Ankle Score (AOFAS). Pre- and post-operative outcomes were recorded where possible. Clinical and radiological complications were also recorded.

2.5. Radiological analysis

Weight bearing radiographs were utilised in all studies. The medial distal tibial surface angle (TAS) and the talar tilt (TT) were assessed on the mortise view (Fig. 1). The tibial lateral surface angle (TLS) was assessed on the lateral view.

2.6. Statistical analysis

Statistics were combined across cohort studies to calculate mean results, both pre- and post-operatively, and improvements in outcomes.

All statistical analysis was performed using Excel spreadsheets

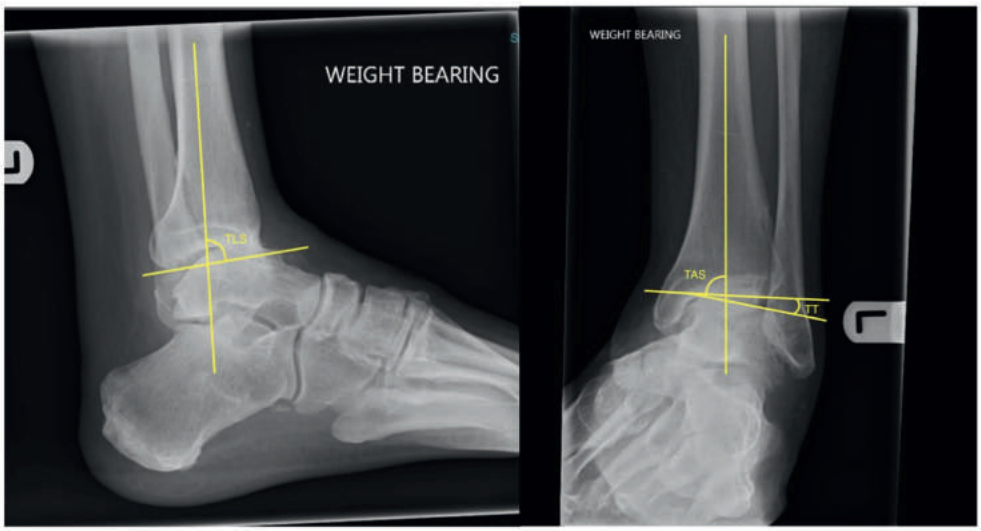

Fig. 1. Radiological measurements. TLS = Tibial lateral surface angle; TAS = Tibial anterior surface angle; TT = Talar tilt.

with standard formulations.

Review Manager (RevMan) [Computer program]. Version 5.3. Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2014 was used to conduct meta-analysis.

3. Results

The search identified 968 studies; 964 from the database search and a further four on reviewing references and individual electronic hand searches. 225 duplicates were then removed leaving 743 studies undergoing title and abstract review. Following title and abstract review 686 papers were excluded when applying inclusion/exclusion criteria. 57 full-texts went onto to be assessed and a further 45 were excluded upon closer review as further exclusion criteria were found. 12 papers underwent quality assessment using Modified Coleman criteria (Appendix A). Three studies did not satisfy this quality assessment and were excluded. Finally, nine papers underwent full data extraction and inclusion within the study. Fig. 2 shows the PRISMA flowchart of our review. Table 1 shows the characteristics of included final nine studies.

3.1. Patient demographics

242 osteotomies, in 235 patients, were included in the analysis. 59% were female. Mean age was 53.2 years (range; 17–79).

3.2. Pain

Pain scores improved in all studies examined. Pain Visual Analogue Scores (VAS) from 0 to 10 were used. Mean pooled pre-operative VAS was 7.0. Mean pooled post-operative VAS was 2.5. Resulting in a 4.5 point improvement in 166 ankles.

Meta-analysis of four studies demonstrated an improvement in pain VAS of 4.16 points (95% CI; 3.80–4.53). Results are shown in Fig. 3.

3.3. American orthopaedic foot & Ankle Score (AOFAS)

Mean pooled Pre- and post-operative AOFAS scores were available for all nine studies. There was an improvement from 57.7 to 83.6 for 242 ankles. Resulting in a 25.9 point improvement.

Six studies could be involved in the meta-analysis and demonstrated a 22.59 points (95% CI; 20.74–24.44) improvement in AOFAS (Fig. 4).

3.4. Satisfaction

Satisfaction rates were 89.1% from four studies, including 92 ankles.

3.5. Radiology

Radiological findings were reported in all nine studies. Mean pooled mean data is presented in Table 2.

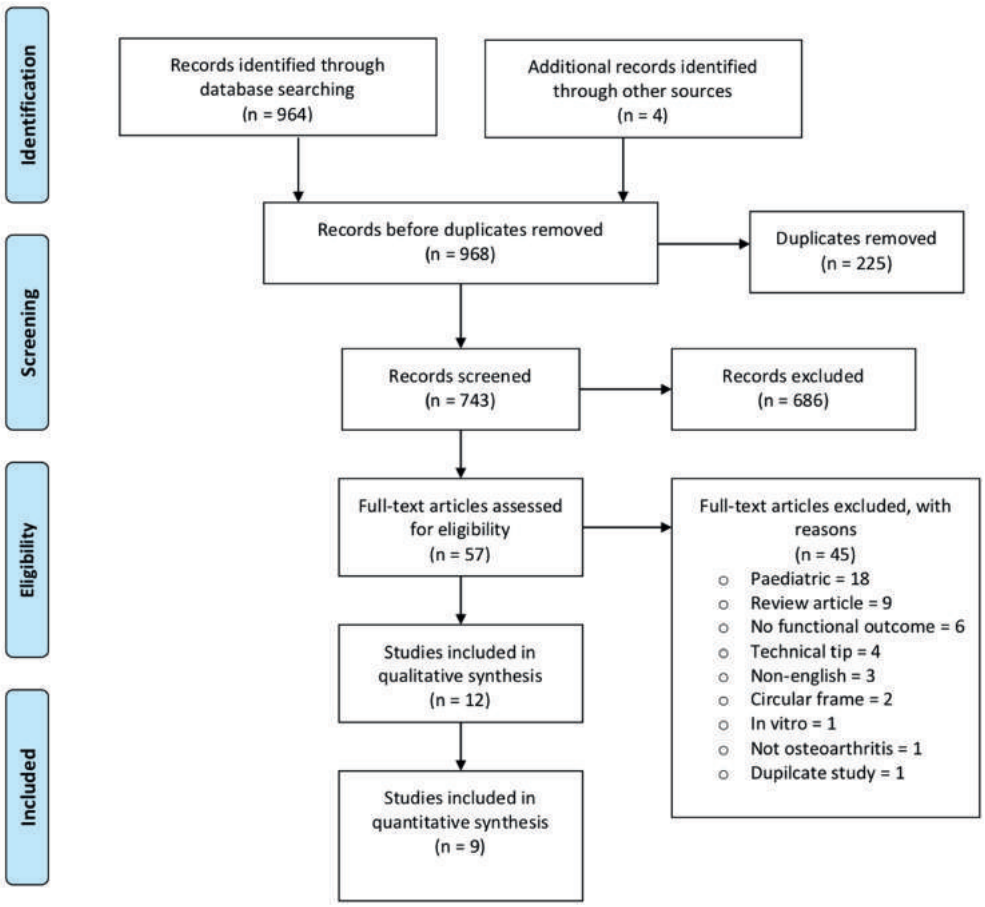

Fig. 2. PRISMA flowchart.

Table 1
A table to show the details of the studies included.

Author	Year	No. of Feet	Gender (M:F)	Mean Age (range)	Mean Follow-Up (months)	Minimum Follow-Up (months)	Intervention	Fibular Osteotomy	Modified Coleman Score
Xu et al. [20]	2019	21	3:18	54 (39–61)	88	61	Horizontal medial opening	None	43
Kim et al. [7]	2019	58	27:26	54 (39–68)	62	48	Oblique medial opening	None	60
Hintermann et al. [4]	2017	20	12:8	44 (17–60)	71	48	Horizontal medial opening + Plafondoplasty	25%	66
Jung et al. [6]	2017	22	6:16	56 (34–72)	25	12	Oblique medial opening	100%	49
Hongmou et al. [5]	2016	41	14:27	51 (32–71)	37	17	Horizontal medial opening	50%	50
Kobayashi et al. [8]	2016	27	6:19	63 (28–79)	27	14	Horizontal medial opening	None	50
Ahn et al. [1]	2015	18	3:15	57 (49-64	34	24	Oblique medial opening	None	56
Mann et al. [12]	2012	19	14:5	48 (32–63)	59	14	Plafondoplasty	None	46
Lee et al. [10]	2011	16	7:9	55 (44–75)	28	12	Oblique medial opening	100%	47
TOTAL		**242**	**92:143**						

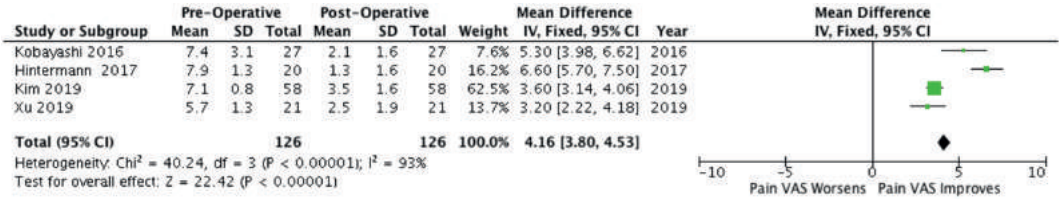

Fig. 3. A forest plot to show the results of studies for meta-analysis for pain visual analogue scores.

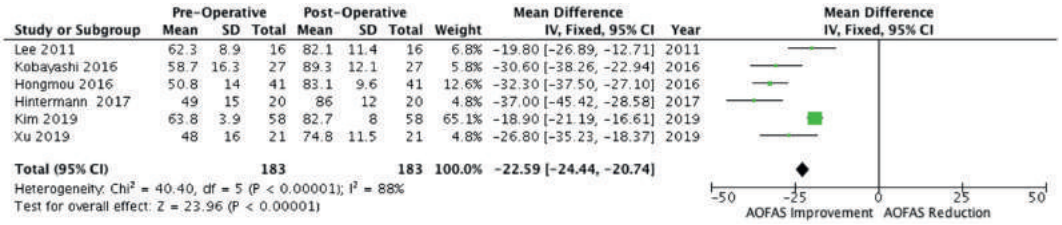

Fig. 4. A forest plot to show the results of studies for meta-analysis for AOFAS.

Table 2
A table demonstrating the mean pooled pre- and post-operative radiological parameters.

	Number of Osteotomies	Pre-Operative	Post-Operative
Talar Tilt (TT)	203	6.5	3.0
Tibial Anterior Surface (TAS)	222	83.9	91.5
Tibial Lateral Surface (TLS)	222	79.6	81.8

3.6. Complications

Out of the total number of osteotomies (242) there were four (1.7%) patients who underwent total ankle arthroplasty and five (2.1%) who had arthrodesis at mean follow-up of 46 months (range; 25–99). There were no reported cases of non-union. Other highlighted complications are shown in Table 3.

4. Discussion

We present the results of a systematic review and meta-analysis of distal tibial osteotomies undertaken for varus ankle osteoarthritis in 242 cases across nine studies. There are significant improvements in pain visual analogue scores (VAS), American Orthopaedic Foot & Ankle Scores (AOFAS) and a satisfaction rate of 89%. A failure rate of 3.7% was noted at almost 4 years post-procedure.

Table 3
Complications following distal tibial osteotomy.

Complication	Number	Percentage
Routine removal of metalwork	40	16.5
Implant related pain	12	5.0
Failure	9	3.7
Sub-fibular pain	5	2.1
Delayed Union	3	1.2
Haematoma	2	0.8
Loss of correction	1	0.4
Infection	1	0.4

Clinical improvements were noted across all studies. Hintermann et al. demonstrated the greatest reduction in pain VAS (6.6 point improvement) and a 37 point increase in AOFAS.[11] The smallest improvement in pain VAS were noted by Xu et al. at 3.2 points.[12] This correlated with an AOFAS improvement of 26.8 points. The lowest improvement in AOFAS was shown by Ahn et al. at 10.6 points.[13] However, improvements in pain VAS and AOFAS were statistically significant for all studies included in the review. Publication bias can play a role in the presentation of these results. It is unlikely that a unit/journal would publish not significant results for a retrospective review of their cases.

Unstable varus ankles often demonstrate dysplasia of the medial malleolus. This phenomenon occurs over time and eventually the medial aspect of the medial malleolus is no longer vertical. This causes widening of the mortise and we are aware of the negative effect of even minimal talar displacement leading to reduced contact area.[14,15] This reduced contact area will accelerate any degenerative joint disease. This highlights the importance of achieving a stable well-fitted mortise to protect the tibio-talar joint. The arguments upon the best way to achieve this continue with some authors stating the need to correct this deformity at the centre of rotation angle (CORA).[10] This can only be performed with an intra-articular osteotomy (plafondoplasty) as compared to a conventional (horizontal/oblique) osteotomy in the supra-malleolar region. The ultimate aim remains to shift joint stresses on to a preserved part of the tibiotalar joint.[16]

Within our study there were multiple methods of performing distal tibial osteotomy. Four studies used an isolated medial oblique opening osteotomy and three studies used an isolated medial horizontal opening osteotomy.[5,8,12,13,15,17] The remaining studies used an isolated plafondoplasty[10] or double osteotomy (horizontal and plafondoplasty).[2,11] Fruitful comparison between these osteotomy types was not possible in this review due to the small numbers. The use of a fibular osteotomy varied also with two studies using it in all case.[5,8] Two studies using it in 25–50% of cases.[11,17] Hongmou et al. studied the effect of fibular osteotomy in their retrospective review and found no difference in functional outcomes in either group but did note fibular osteotomy improved radiological parameters.[17]

The rate of concurrent lateral ligament reconstruction also varied. Mann et al. felt a lateral ligament reconstruction was important to protect the osteotomy and prevent recurrence of the deformity.[10] Conversely some authors believe that bony correction alone should be enough to treat this degenerative pathology and hence did not undertake any ligament reconstructions.[18] Other authors went on a case-by-case basis and reconstructed lateral ligaments in the presence of residual laxity.[11] The exact decision-making process around which patients received concurrent lateral ligament reconstructions was unclear and this may help direct future research.

TAS angle pre-operatively was 83.9° across all studies but there remains debate as to what the surgical target is. It is agreed that overcorrection is ideal with options varying from 93 to 94°; 95° or 96–98°.[6–8] The mean post-operative TAS was 91.5° (range 88.3–99.6). Increasing the TAS too high can cause sub-fibular pain. At what stage this occurs is unknown. This complication was only reported in two studies. Lee et al. had sub-fibular pain in 25% and their post-operative TAS was 99.6°.[8] Kobayashi et al. had sub-fibular pain in 4% and their post-operative TAS was 95.0°.[15] These studies were the two highest post-operative TAS angles. We would recommend aiming for a post-operative TAS of 93–95° in order to create an overcorrection to improve results but prevent sub-fibular pain. There also needs to be some agreed radiological measurement method. This was highlighted in the measurement of talar tilt where there was a mean range from 3.4° to 13° between studies. Potentially this could be as a result of anatomical variation and disease severity but more likely it is due to variability in measurement methods.

In an early study evaluating DTO, Tanaka et al. reported that it was not indicated in stage 3b ankles. However, in this review there were at least 19% of cases at stage 3b. Indeed one study just included stage 3b ankle.[12] This did not appear to adversely affect clinical outcomes (Table 4). However, two studies included patients with stage 1 ankles and these two studies boasted two of the three largest improvements in AOFAS.[10,11] This may suggest that selecting patients early, or late, may not be an issue and can still result in large improvement in functional scores.

Table 4
A table to show the pre-operative Tanaka stage and clinical improvements in studies.

Study	Osteotomy Type	Stage 1	Stage 2	Stage 3a	Stage 3b	Pain VAS Improvement	AOFAS Improvement
Hintermann et al. [4]	Horizontal + Plafondoplasty	15%	30%	45%	10%	6.6	37.0
Hongmou et al. [5]	Horizontal	0	34%	46%	20%	–	32.3
Mann et al. [12]	Plafondoplasty	21%	5%	53%	21%	–	32.0
Kobayashi et al. [8]	Horizontal	0	33%	41%	26%	5.3	30.6
Xu et al. [20]	Horizontal	0	0	0	100%	3.2	26.8
Jung et al. [6]	Oblique	0	27%	68%	5%	5.4	26.4
Ahn et al. [1]	Oblique	0	17%	72%	11%	4.0	10.6

We accept limitations in our study. The basis of the study is around compiling data from multiple cohort studies to gain strength in evidence. Of the nine studies included, seven were conducted in the Far East (Japan, China, South Korea) versus two Western studies (Switzerland, USA). This adds questions as to the transferrable nature of the results to the Western population. The Western studies contained proportionally more males (67% vs 34%) than the Far Eastern studies and this could contribute to outcome differences. Though, the Far East lifestyle does demand a higher range of motion than Western life.[19] As a result, we feel the functional scores and satisfaction rates would be under-estimated rather than over-estimated from the Far Eastern studies. There is also doubt to the radiological parameter aims in the Far Eastern cohort compared to Western cohort. Secondly, there was a variety in osteotomy techniques and adjuncts to the procedure. In premise all patients had a DTO but the orientation (horizontal, oblique, plafondoplasty) and adjuncts (ankle arthroscopy, micro-fracture, lateral ligament reconstructions, calcaneal osteotomy) differed. Meta-analysis was not possible across all outcomes and all studies due to the heterogeneity of data presentations within publications. Many lacked the inclusion of standard deviations for outcomes.

5. Conclusion

We conclude that distal tibial osteotomy provides good pain relief and functional improvements at medium-term follow-up across patients with Takakura stage 2–3b disease.

Author contribution

Randeep S. Aujla – Concept, Data collection, Data Analysis, Production of manuscript. Ganapathy Perianagyam – Data collection, Data Analysis, Production of manuscript. Bobby M. Siddiqui – Data collection, Data Analysis, Production of manuscript. Pip Divall – Performed literature search, Production of manuscript. Maneesh Bhatia – Concept, Production of manuscript.

Funding

None.

Ethical approval

N/A.

Informed consent

N/A.

Declaration of competing interest

Each author certifies that he or she has no commercial associations (eg, consultancies, stock ownership, equity interest, patent/licensing arrangements, etc) that might pose a conflict of interest in connection with the submitted article.

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None.

Appendix A. Part A and B of the modified methodology score used to assess distal tibial osteotomy literature

Part A (60%)		Score
1. Study Size (joints) (10)	31–50	10
	21–30	7
	11–20	4
	<10	0
2. Mean Follow-up (10)	>85	10
	61–84	8
	37–60	6
	24–36	4
	<24, not stated or unclear	0
	If minimum <24	−1
3. Type of Study (methodology) (15)	Randomized controlled trial	15
	Prospective cohort study	10
	Prospective/Retrospective Mixed	5
	Retrospective cohort study	0
4. Diagnostic certainty (underlying aetiology e.g. degenerative/inflammatory/post trauma) (5)	In all	5
	>80%	3
	<80%	0
5. Post-operative Rehabilitation (5)	Well described	5
	Not adequately described	3
	Protocol not reported	0
6. Surgical technique (5)	Detailed	5
	Brief	3
	Nil	0
7. Number of Interventions (10)	One in all	10
	Multiple but consistent in all	5
	Unclear/unreported/multiple and different	0
Part B (40%)		
1. Outcome Criteria (11)	Clearly defined outcome(s)	2
	Timing of outcome assessment clearly stated	1
	Visual analogue scores used	2
	PROM used	2
	Overall Satisfaction	2
	Radiological Assessment	2
2. Procedure for assessing outcomes (6)	Clearly Defined Method and timepoint	2
	Objective assessment with arthroscopy	2
	Multiple/Independent observers	2
3. Description of Subject Selection from population (11)	Inclusion criteria reported and unbiased	3
	Recruitment rate reported >80%	3
	“Consecutive” series	2
	Recruitment not reported	0
	All eligible subjects accounted for in methodology	3
4. Complications recorded (6)	All with explanations	6
	Selected complications reported	4
	Incomplete record	2
	None	0
5. Revisions recorded (6)	Method of failure(s)	3
	Time to failure(s)	3
	No Failures in Study	2

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Research paper

A comparative study between intralesional platelet rich plasma injection and extracorporeal shockwave therapy for the treatment of plantar fasciitis

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ABSTRACT

Purpose: Plantar Fasciitis is a widely prevalent condition and is extremely disabling if it remains unresolved. Despite many available treatment modalities, the management of recalcitrant cases is still a dilemma. We conducted this study to evaluate and compare the role of two novel modalities: Intralesional PRP (Platelet Rich Plasma) injection and Extra Corporeal Shockwave Therapy (ESWT) for the management of this condition.

Methods: 60 patients with a clinical diagnosis of recalcitrant plantar fasciitis were randomized into 2 groups; PRP Group (n = 30) and ESWT Group (n = 30). In PRP group patients received 3 intralesional injections of PRP and in ESWT group 3 sessions of Extra Corporeal Shockwave Therapy were administered. The Primary outcome measures were Visual Analogue Scale (VAS) score, American Orthopaedic Foot and Ankle Society (AOFAS) Ankle-Hindfoot Score, Roles and Maudsley Index and Heel Tenderness Index (HTI). The secondary outcome measures were complications. The patients were followed up for a period of 6 months and evaluated for various scores.

Results: At 6 months follow-up, significant results were found only on VAS score for both groups (p-value <0.05). However, both modalities resulted in significant clinical improvement with no complications reported. No statistically significant differences were reported between the two test groups.

Conclusions: Both autologous PRP and ESWT can become extremely useful modalities for management of recalcitrant cases of plantar fasciitis with no known adverse effects.

1. Introduction

Being the most common cause of inferior heel pain in adults, plantar fasciitis is estimated to affect almost 10% of the general population.[1] It is characterized by a self-limiting course and as many as 90% of the patients can be successfully treated with conservative measures.[1,2] However, the remaining patients enter a state of recalcitrant painful heel syndrome[3] which is extremely difficult to treat. The successful management of this condition has been an area of focus since long.

The etiology of plantar fasciitis is poorly understood and likely multifactorial. Various predisposing factors have been suggested including minor trauma, excessive foot protonation, obesity, jobs that require prolonged standing and running, tightness of the Achilles tendon and intrinsic foot muscles, and inappropriate footwear.[4] The diagnosis of plantar fasciitis is usually made possible with an elaborate clinical examination.[5]With the chronicity of this condition, a thickening of the fascia may be found on ultrasound examination.[6,7]

A large number of conservative treatments for plantar fasciitis have been advised which include physiotherapy, plantar-fascia-stretching exercises, icepacks, night splints, inserts, shoe modification & nonsteroidal anti-inflammatory drugs (NSAIDs).[7]Intralesional steroid injections as well as surgical treatments like fasciotomy or endoscopic release of plantar fascia etc. have been described for recalcitrant cases,[8] but such traditional treatments for plantar fasciitis do not have predictive results and have potential downfalls.

Extracorporeal shock wave therapy (ESWT) and injection of

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platelet rich plasma (PRP) are two such modalities that have a role in the management of recalcitrant cases of plantar fasciitis. Extracorporeal shock waves are focused, single pressure pulses of microseconds duration. They have traditionally been used as one of the most effective approaches to the treatment of renal calculi. More recently, ESWT has been used in the treatment of a number of musculoskeletal conditions such as plantar fasciitis, at doses of 10–20% of those used in lithotripsy of renal calculi.[9,10] ESWT was approved by FDA in 2007 for recalcitrant cases of plantar fasciitis in which conventional treatment has not been effective.[11] Shockwaves cause mechanical tissue disruption, the repair of which is the theoretical basis for the neovascularization process and subsequent pain relief following ESWT.

Platelet Rich Plasma (PRP) can be defined as the volume of plasma fraction from autologous blood with a platelet concentration above baseline count (150,000 platelets/cu. Mm). In the last 10 years there has been an increased use of platelet rich plasma (PRP) for a myriad of enthesopathies.[12] This is attributed to the capacity of autologous platelets to stimulate a healing response when injected intra-lesionally. The rationale for the use of PRP is to stimulate the natural healing cascade and tissue regeneration by a "supra-physiologic" release of platelet derived factors directly at the site of injection.[13]

For most Patients of plantar fasciitis, the condition resolves with the traditional forms of treatment[1,2,13] but there is a subset of patients who continue to suffer and the treatment for this group can be difficult and dissatisfying. Patient as well as doctor dissatisfaction led to a search for an alternative mode of treatment and both ESWT and autologous PRP injections have shown promising results in recent years.[14,15]

Although many studies have documented the efficacy of both these modalities when used individually, no conclusive treatment guidelines are available. This study was aimed to prospectively evaluate and compare the efficacy of these two modalities when used for the treatment of plantar fasciitis.

2. Materials and methods

A prospective randomized comparative study was conducted involving 60 patients with a clinical diagnosis of recalcitrant plantar fasciitis. The diagnosis was purely clinical, one of the most consistent features being tenderness at the attachment of plantar fascia at tuberosity of calcaneum. No imaging modality such as radiograph, ultrasonography or magnetic resonance imaging was used to diagnose plantar fasciitis. Patients who failed to respond after minimum 3 months of conservative treatment were included. All cases with Bilateral plantar fasciitis/traumatic injury/arthritis/local infection/tumor were excluded from the study.

The study was approved by the institutional ethics committee. A written informed consent was taken from the patients who fulfilled the criteria. A detailed clinical history was taken and examination was performed. The base line characteristics of the patients such as age, weight, height, BMI, gender and any co-morbidity were recorded.

Patients were subjected to computer generated randomization and were allocated to either PRP injection receiving Group (PRP Group, n = 30) or Extracorporeal Shockwave Therapy Group (ESWT group, n = 30).

2.1. PRP group

Patients in this group received PRP injections prepared by using patients own blood. Each patient received 3 injections at 1 month interval each.

2.1.1. PRP preparation technique

Under all aseptic conditions, 11 ml of patient's blood was collected in a sterile syringe using 18-gauge needle and then transferred to BD Vacutainers® containing buffered sodium citrate 3.2% as anticoagulant. The tubes were placed snugly in the centrifugation machine and centrifuged at a frequency of 800 Hz for 8 min. The centrifuged product then gets separated into a basal layer containing RBCs, a Buffy coat containing leucocytes at the junction, platelets just above it, and Platelet Poor Plasma from downwards above. PRP was extracted from the interface of the 2 layers using sterile syringe and cannula.

A fraction of PRP sample, along with patient's unprocessed blood sample was analysed for platelet count assessment and to evaluate the platelet count amplification.

2.1.2. Administration of PRP

Patient was instructed to lie prone. After primary preparation of the site, painting and draping was done. The injection point was identified by palpation as the point of maximum tenderness which was usually at the origin of the plantar fascia on the medial tubercle of the calcaneum under aseptic precautions. The site was approached from the medial side of the foot but near the plantar surface with a 20–22 gauge needle and 3 ml PRP was injected (Fig. 1).

Non-Steroidal anti-inflammatory drugs (NSAIDs) were not prescribed for pain relief. They were advised to wear comfortable shoes and avoid all running and other high impact activities for 10 days. A standardized stretching program for the Achilles tendon and the plantar fascia was given to all patients. No additional treatment was permitted during the study periods, including NSAIDs, orthoses, and night splints.

2.2. ESWT group

Patients in this group were treated with extracorporeal shockwave therapy. Each patient received 3 sessions of ESWT with 1month interval. Procedure was performed in the physiotherapy section of our institute and the shockwave device used was the Swiss DolorClast® (EMS Electro Medical Systems; USA).

2.2.1. Procedure of ESWT

Patient was instructed to lie down in prone position. After localization of the affected area by patient biofeedback, the region was marked and coupling gel was applied. Two thousand impulses with a frequency of 8 Hz and application pressure of 4 bar was delivered. As in PRP Group, no additional treatment was permitted during the study period, including NSAIDs, orthoses, and night splints (Fig. 2).

All patients were first evaluated on day 3 and then at 2 weeks for the inspection of the application area in both groups. Subsequently patients were reviewed at 1 month and 2 month for the application of either PRP injection or ESWT session and also for assessment of various scores. Further follow up visits were held at 3 months and 6 months.

2.3. Outcome measures

The primary outcome measures were the Visual Analogue scale (VAS) score, Roles and Maudsley score, American Orthopaedic Foot and Ankle Society (AOFAS) score and Heel tenderness index. The secondary outcome measures were platelet amplification achieved and any complications.

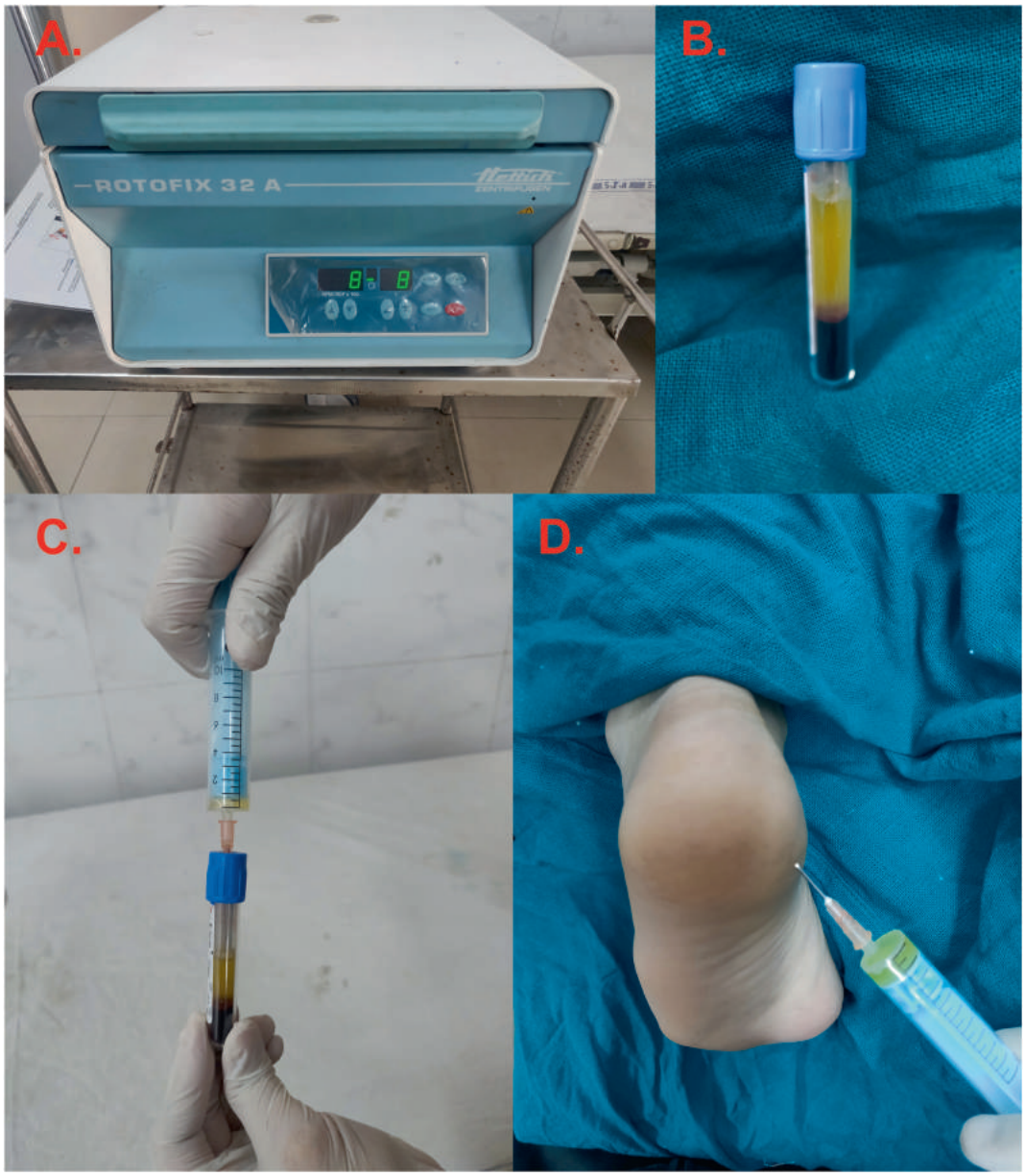

Fig. 1. A) Blood centrifuges at 800 rpm for 8 min in centrifugation machine. B) Basal layer containing RBCs, a Buffy coat containing leucocytes at the junction, platelets just above it. C) PRP extracted from the interface of the 2 layers using sterile syringe. D) PRP injection at point of maximum tenderness over medial side of heel.

2.4. Statistical analysis

The data was managed using Microsoft Excel and Statistical testing was conducted using SPSS 26.0. Continuous variables are presented as mean ± SD, and categorical variables are presented as absolute numbers and percentage. The comparison of normally distributed continuous variables between the groups was performed using Student's *t*-test. Nominal categorical data between the groups were compared using Chi-squared test or Fisher's exact test as appropriate. For non-normally distributed data (Duration of symptoms, Duration of conservative treatment received), Mann Whitney *U* test was used. The level of clinical significance was set at $p \leq 0.05$ with a confidence interval of 95% for all tests.

3. Results

The demographic data in both groups was comparable with no significant differences in age, gender, BMI and side involved. The pre-intervention characteristics such as duration of illness and duration of medical treatment received also did not show any significant differences between the 2 groups (Table 1).

There were four pain and functional scores utilized for assessment of the patients. The scores in the follow up were compared with the pre-intervention scores and the trend studied in both the groups, to understand the effect of treatment on pain and functional parameters.

3.1. VAS score

The baseline VAS of both groups was comparable. The mean VAS

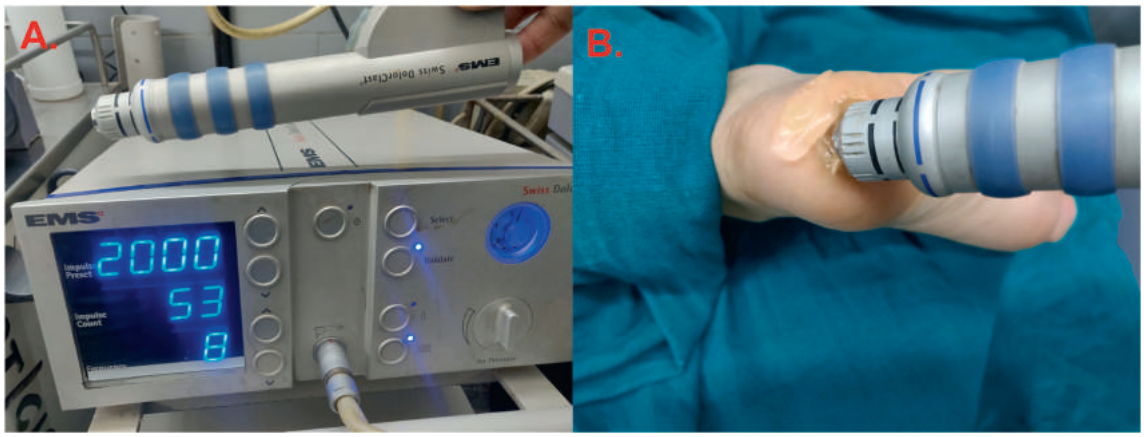

Fig. 2. A) ECSWT machine. B) Therapy with two thousand impulses with a frequency of 8 Hz.

Table 1
Demographic Data of the study groups.

	PRP GROUP MEAN ± SD	ESWT GROUP MEAN± SD	p VALUE
AGE (years)	35.83 ± 7.94	38.70 ± 10.60	0.241
GENDER (F/M)	15/15	14/16	0.796
BMI	26.40 ± 2.86	25.41 ± 3.60	0.244
SIDE INVOLVED (L/R)	15/15	16/14	0.796
DURATION OF ILLNESS (months)	12.53 ± 5.24	11.66 ± 4.76	0.629
DURATION OF MEDICAL TREATMENT RECEIVED (months)	6.70 ± 2.82	6.76 ± 3.10	1.000

improved in both groups after initiation of treatment with greater improvement seen in PRP Group as compared to ESWT group. At 1st month ($p = 0.036$), 2nd month ($p = 0.022$) and 6th month ($p = 0.018$) follow-up this difference was found to be statistically significant with greater improvement reported in the PRP Group.

3.2. AOFAS score

The AOFAS score at baseline in both groups was found to be comparable ($p = 0.263$). The score improved with each follow up visit and reached a mean of 81.79 ± 4.10 in PRP Group and 82.75 ± 3.95 in ESWT group at last follow up at 6 months which shows that improvement has occurred in both groups. However, between the two groups the difference in scores was not statistically significant at any point of time (Table 2).

3.3. Roles and Maudsley scale

At baseline (day 0) patients reporting 'poor' on this scale comprised the majority in both groups (56.7% in group-1 and 63.3% in group 2), while patients who reported 'satisfactory' comprised the remaining (43.3% in group 1 and 36.7% in group-2). No patients reported 'good' or 'excellent' at baseline visit. These finding were comparable in both groups ($p = 0.470$).

At 1st follow up visit (1st month) the proportion of patients reporting 'poor' decreased in both groups (13.3% in group-1 and 13.3% in group-2) while those reporting 'satisfactory' increased in both groups (83.1% in group-1 and 86.7% in group-2). Although there was an improvement in symptoms in both groups this difference between the 2 groups was not statistically significant ($p = 0.612$).

Table 2
VAS and AOFAS scores of the two study groups.

VAS of the two study groups VAS	PRP Group (n = 30) Mean±SD	ESWT group (n = 30) Mean±SD	p value
Day 0	7.07 ± 0.842	7.44 ± 0.847	0.102
1 month	5.52 ± 1.022	6.0 ± 0.62	0.036
2 month	4.45 ± 0.948	5.0 ± 0.784	0.022
3 month	3.17 ± 0.928	3.48 ± 0.643	0.156
6 month	2.21 ± 0.819	2.74 ± 0.813	0.018
AOFAS score of the two study groups			
AOFAS Score	PRP Group (n = 30) Mean±SD	ESWT group (n = 30) Mean±SD	p value
Day 0	44.48 ± 10.81	47.54 ± 9.48	0.263
1 month	56.83 ± 7.03	58.75 ± 6.55	0.290
2 month	65.90 ± 6.64	67.64 ± 7.14	0.343
3 month	75.41 ± 6.80	77.21 ± 6.01	0.295
6 month	81.79 ± 4.10	82.75 ± 3.95	0.374

Table 3
Heel Tenderness Index score comparison.

Heel Tenderness Index score comparison between the study groups			
HTI Score	PRP Group (n = 30)	ESWT group (n = 30)	p value
	Mean±SD	Mean±SD	
Day 0	2.59 ± 0.50	2.64 ± 0.49	0.667
1 month	2.17 ± 0.47	2.14 ± 0.36	0.790
2 month	1.62 ± 0.49	1.93 ± 0.26	0.005
3 month	0.86 ± 0.64	0.86 ± 0.45	0.973
6 month	0.62 ± 0.68	0.64 ± 0.49	0.887

Similarly at 2nd, 3rd and 6th month the proportion of patients showing 'good' and 'excellent' results increased in both groups although the difference was not statistically significant.

3.4. Heel Tenderness Index (HTI) score comparison

The Heel Tenderness Index scores at baseline in both groups were comparable. The score improved in both groups and at last follow up visit it was recorded to be 0.62 ± 0.68 in group-PRP and 0.64 ± 0.49 in group-ESWT. This implies that improvement occurred in both groups but the difference in improvement between the 2 groups was not statistically significant except at 2nd month when it was found to be statistically significant ($p = 0.005$). (Table 3).

3.5. Platelet amplification

In majority of our samples the platelet amplification was between 2.6 and 3.5 and only in about 3% samples the amplification was greater than 3.5 times. In our study the mean platelet amplification was found to be 3.06 ± 0.294. This implies that the platelet count in PRP was on an average 3.06 times the platelet count in blood.

3.6. Complications

No complications were reported in any patient in either groups in our study demonstrating that both procedures are well tolerated and are extremely safe.

4. Discussion

Plantar fasciitis is a common clinical problem with many available treatment modalities.[1,2,7] In over 80% of cases, symptoms can be resolved with simple non-operative measures, but those who fail to respond develop intractable plantar fasciitis, which is extremely difficult to treat. For such patients' options include corticosteroids injections which offer a quick fix for pain relief in the early phase but have serious concerns of recurrence of pain.[16] In chronic cases, surgery is the last resort with unpredictable results and it comes with its risk of complications inherent to any surgical procedure.

Recent years have seen an increase in the use of newer modalities like autologous PRP injections and extracorporeal shockwave therapy to treat the patients with recalcitrant plantar fasciitis.[14,15]

PRP contains a concentrated amount of platelets than whole blood. Within platelets powerful growth factors, including platelet-derived growth factor (PDGF), transforming growth factor beta (TGF-β), and epidermal growth factor are present. The injection of PRP into the affected tissue initiates the healing response necessary to reverse the degenerative process in the plantar fascia. The individual cytokines present in the platelet α-granules have been shown to enhance fibroblast migration and proliferation, up-regulate vascularization and increase collagen deposition in a variety of in vitro and in vivo settings.[17] The concentrated growth factors work in a synergetic manner to initiate a tendon healing response and this mechanism is likely to be active in chronic plantar fasciitis.[18]

ESWT has been in medical use since decades but its role for the management of chronic tendinopathies has been recently found and the evidence in support of its use in plantar fasciitis is growing.[9,10] The main mechanism of action active in this condition appears to be stimulation of neovascularization with subsequent soft tissue healing and pain relief.[9,10]

Both these modalities have shown promising results in many studies conducted to test their efficacy but there is no clear and hard evidence in the literature to support the use of PRP and ESWT for Plantar Fasciitis and no set guidelines are available for their routine use in clinical practice. With this in mind, this study was designed to evaluate as well as compare the efficacy of autologous PRP injection with ESWT in the management of recalcitrant cases of plantar fasciitis as per the defined methodology.

The PRP prepared in this study had a platelet amplification of approximately 3 times the baseline count. Previous studies have reported this amplification ranging from 2x (Omar et al.[16]) to 8x (Ragab et al.[19]). Regarding the technique of PRP production, varied methods have been used. Most authors including Wilson et al.,[20] Monto et al.,[21] Kumar et al.,[22] Kim et al.,[23] Ragab et al.[19] have used single spin technique while Martinelli et al.[24] and Aksahin et al.[25] used double spin method in their study. We have used a single spin method of PRP generation in our study. All studies mentioned above have used citrate dextrose solution as the anticoagulant and have not used any activator of PRP except Aksahin et al.[25] in which calcium has been used as an activator of PRP. We have also used the same anticoagulant for PRP preparation and have not used any activator. Buffering with sodium bicarbonate was done in two studies – Wilson et al.[20] and Kumar et al.,[22] while in all the other studies buffering has not been done. No buffering agent was used in our study. The volume of PRP injected ranged from 2.5 ml (Kumar et al.[22]) to 5 ml (Martinelli et al.[24] and Ragab et al.[19]). We injected 3 ml of PRP in each patient in the PRP group. All but two studies treated patients with only one injection of PRP. Kim et al.[23] used two injections, with a 2-week interval, while Martinelli et al.[24] injected each foot three times. We gave 3 injections of PRP with one month interval between each injection.

The mean baseline VAS score in our study in PRP Group was 7.07 which dropped to 2.21 at the end of 6 months. This result was similar to that reported by the study of Ragab et al.[19] The AOFAS score in our study in group-1 improved from 44.48 (baseline) to 81.79 (6 month) which is similar to the findings reported by Kumar et al.[22] Outcome assessment by Roles and Maudsley score also shows similar results in multiple studies.[22,24,25]

No study reported any complication following use of PRP.[26] We also found this procedure to be well tolerated by patients with no

complication reported. We did not utilize local anaesthetic, and the injections were performed by injecting directly into the area of maximal tenderness. Whilst we did not use ultrasound (USS) guidance for the injection, we accept arguably that this may allow for a more accurate placement of the PRP, and could be considered. This may be perceived as a shortcoming of the study, but a RCT by Kane et al.[27] showed no advantage of USG guidance over direct palpation guidance of the most tender area, when steroid was injected for plantar fasciitis.

In ESWT group of our study, ESWT was administered to patients using the Swiss DolorClast® device. Gerdesmeyer et al.[28] used the same device in their study in 2008 evaluating the role of ESWT in treatment of chronic recalcitrant plantar fasciitis and reported significant improvement in pain, function and quality of life.

Most studies including those by Gerdesmeyer et al.,[28] Rompe et al.,[10] Speed et al.[29] gave 3 sessions of ESWT to patients similar to our study. Ibrahim et al.[30] administered 2 sessions and Malay et al.,[31] 1 session of ESWT in their studies. All these studies included only those patients who had failed to improve with conservative treatment for a duration ranging from 3 to 12 months. In this study we have included patients who have already received some form of conservative treatment for atleast 3 months and who did not respond to the treatment. The total number of impulses administered ranged from 3800 (Malay et al.[31]) to 6300 (Rompe et al.[10]). We have administered total 6000 impulses (2000 impulses per session x 3) in our study. We have also not used any local anaesthesia prior to ESWT therapy in our study.

The results of our study were similar to another study in the Indian population by Krishnan et al.[32] However, a study by Speed et al.[29] found no significant improvement of symptoms with moderate dose ESWT in patients with Plantar Fasciitis. They reported that efficacy may be highly dependent upon machine types and treatment protocols.

Although the short-term beneficial effects of local steroid injection are well known, a meta-analysis by Yuan Xiong et al.[33] (2019) comparing Corticosteroid injection with Shockwave therapy found that both are effective in improving symptoms but VAS score improved better in Shockwave group highlighting that ESWT may be a better alternative for the management of chronic plantar fasciitis.

More recently, Soliman et al.[34] (2020) conducted a similar study comparing PRP vs ESWT for treatment of Plantar Fasciitis and found that Shockwave therapy improves function and pain earlier and more effective in patient with heel spur than PRP injection. Yalcin U[35] (2020) also compared PRP & ESWT in plantar fasciitis and reported significant improvements in VAS & Foot Function Index (FFI) in both groups, with greater improvement occurring in the PRP group.

The results of our study clearly show that improvement occurred in all parameters in both groups however, statistically significant improvements were observed only in the VAS score. Clinical improvements were seen in AOFAS score and the Heel Tenderness Index in both groups. These finding conclusively show that both modalities led to significant improvements in pain and functional status of patients. However, there are a few limitations of our study. Firstly, the diagnosis of plantar fasciitis was made purely on clinical grounds and no imaging modality was used for diagnosis, grading severity or to rule out plantar fascia tear. Secondly, the patients were followed up for a duration of 6 months and a review study must be done after a follow-up of 1–2 years to see if there was any recurrence/failure of treatment in the 2 groups.

5. Conclusion

At a follow-up duration of 6 months, our results were consistent with the previous studies which have suggested the efficacy of both local PRP injection and ESWT in treating chronic plantar fasciitis. Significant results were found only on VAS score for both groups (p-value <0.05). However, both modalities resulted in significant clinical improvement with no complications reported. Based on our results we cannot comment as to which of the two modalities is better as both modalities have shown good success rates without any complication reported in either of the two groups. Considering the ease of preparation and administration, lack of any adverse effects and cost effectiveness, we conclude that both autologous PRP and ESWT can become extremely useful modalities which can curtail the need for more invasive surgery in chronic cases of plantar fasciitis.

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Ethical board review statement

Each author certifies that his institution has approved the reporting of this case report, that all investigations were conducted in conformity with ethical principles of research, and that informed consent was obtained.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Research paper

Autologous PRP injection: A safe solution for plantar fasciitis☆

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ABSTRACT

Background: Plantar fasciitis is one of the most common causes of heel pain and in its severe forms it can lead to functional disability also. This study has been taken up to evaluate the role of Platelet Rich Plasma (PRP) in managing chronic severe plantar fasciitis when other techniques have failed. This article also focuses on the pathophysiology, diagnosis, other non-operative treatment modalities and surgical options earlier used for plantar fasciitis.

Methods: For 92 patients of plantar fasciitis, PRP was prepared by double spinning technique, and then immediately injection was given after dorsiflexion of the ankle and injecting from the medial aspect of the foot. It was done as a day care procedure and the patients were examined after 1 week, 4 weeks and 12 weeks after the procedure.

Results: After 12 weeks review, more than 60 patients showed great improvement in pain, with their VAS score of pain being below 7.

Conclusion: The article suggests good and effective use of PRP in treatment of plantar fasciitis, along with being a simple and safe procedure.

1. Introduction

The plantar fascia is a longitudinal bundle of fibrous bands beginning on the periosteum of the medial calcaneal tubercle, where it is thinner but in central portion it is thicker. It originates from the medial tubercle of the calcaneus and converges forming the arch of the foot and then moves across the deep transverse metatarsal ligaments to insert along the proximal end of phalanges. Its function is to support and cushion the foot during walking.[1] Chronic plantar fasciitis is a common problem (11%–15%) causing pain in the heel affecting mostly middle-aged people between 4th-6th decade.[2,3] There is no sex predilection but commonly affects athletics and over-weight people. Woods was the first to describe this syndrome in 1812, believing it to be one of the complications of tuberculosis.[4] As more of such cases were diagnosed over a period of time, this condition became associated with other chronic inflammatory syndromes and was referred to by different terms such as plantar fasciosis, jogger's heel, plantar fasciitis, heel (calcaneal) spur syndrome, and plantar fasciopathy.[5] Plantar fasciitis (PF) is most often diagnosed clearly on taking patient's history and performing physical examination. Patients complain of local point tenderness along the medial tuberosity of the calcaneum, pain on weight bearing and/or pain on taking first few steps. On examination it becomes clear that it is plantar fasciitis if on dorsiflexion of the patients' metatarsophalangeal joint, there is increase in pain. Other activities that stretches this fascia are walking barefoot without any arch support, climbing stairs, or toe walking. PF is thought to be a degenerative condition of tissue according to many studies rather than an inflammatory condition. Due to repetitive small tears/microtrauma to the fascia there occurs collagen denaturation. It has also been observed on histology that since healing does not occur due to continuous trauma the normal fascia and surrounding tissues are replaced by angiofibroblastic hyperplastic tissue and no inflammatory cell invasion is seen.[6] Treatment of plantar fasciitis ranges from conservative methods like rest, heel cord stretching, foot orthoses, silicone heel lifts, nonsteroidal anti-inflammatory drugs, eccentric exercise, night splints, and walking boots. The second line of treatment could be corticosteroid injections, botulinum toxin-A injections, extracorporeal shockwave therapy, surgical management where plantar fasciotomy with and without neurolysis of the calcaneal branches of the tibial nerve is done. But all these methods have failed to give long term relief and

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are associated with some complications.[7] In recent few years hence, use of PRP has proven to be a successful method to manage PF with promising long term results.

PRP is easily made with autologous whole blood sample through a centrifugation process. It is proven that when PRP is injected into an area of denatured tissue, the platelets release a multitude of growth factors which stimulates healing response.[8,9] The growth factors secreted are IGF-1, TGF-β, VEGF, PDGF and bFGF, which help in tendon and ligament healing and this is well documented.[10]

2. Material & methods

This prospective study for assessment of clinical effect of platelet rich plasma in PF. A total of 92 patients came to our department that were diagnosed to be suffering with plantar fasciitis. The patients presented with classical symptoms of heel pain that increased on dorsiflexion of metatarsophalangeal joint. Thus, diagnosis was made based on clinical presentation and examination. The patients in our study were between 35 years and 65 years of age. The ethical clearance was obtained from the ethical clearance committee. 20 ml of venous blood is withdrawn and divided into 4 tubes that are then put in the centrifugation machine. PRP was prepared by double spinning technique, first spin at 1200 rotation per minute (rpm) for 10 min and second spin at 2000 rpm with 10 min. Then immediately 2 ml PRP injection was given after dorsiflexion of the ankle and injecting from the medial aspect from the foot. All the aseptic precautions were taken before giving the injection. It was a day care procedure performed in the operation theatre, so patients were sent home after some time and were instructed to limit the use of that foot for atleast 24 h. No antibiotics or analgesics were given to the patient. A 10-mm visual analogue pain score (0, no pain; 10, worst pain possible) were used as outcome measures. The patients were examined after 1 week, 4 weeks and 12 weeks after the procedure.

3. Results

According to age distribution, 20 patients belonged to 30–40years age group, 38 patients between 41 and 50 years, 30 patients between 51 and 60 years and 4 patients between 61 and 70 years age [Table 1]. Gender wise distribution was 40 males and 52 females [Fig. 1]. Occupation wise, it was as follows that 22 were farmers, 33 were laborers, 20 patients were housewives, 5 were servants, 8 were shopkeepers and 4 were clerks [Table 2]. Of all patients included in the study few had other medical ailments like diabetes (10 patients) and hypertension (8 patients). No complications were observed in any of the patient treated with PRP. Patients with ankle arthritis were not included in the study. According to distribution of patients [Table 3] on VAS score (10 being severe pain and 0 as no pain), before injection 48 patients scored between 9 and 10, 32 patients 8–9, 10 patients 7–8 and 2 patients between 6 and 7. On 1st week follow up the graph gradually got reversed with

Table 1
Showing Age wise distribution in the patients with plantar fasciitis.

Age Distribution	Number of Patients
30–40 years	20
41–50 years	38
51–60 years	30
61–70 years	04

Legend 1 According to age distribution, 20 patients belonged to 30–40years age group, 38 patients between 41 and 50 years, 30 patients between 51 and 60 years and 4 patients between 61 and 70 years age.

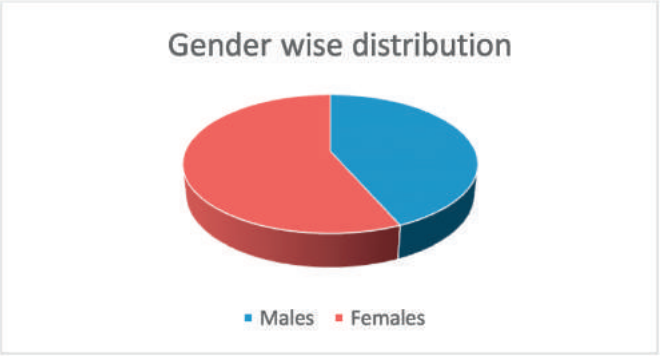

Fig. 1. Showing a graphical gender wise distribution, 40 males and 52 females in the patients with plantar fasciitis.

Table 2
Showing distribution of the patients according to the occupation.

Occupation	Number of Patients
Farmers	22
Laborers	33
Housewives	20
Servants	5
Shopkeepers	8
Clerks	4

Legend 3 Occupation wise, it was as follows that 22 were farmers, 33 were laborers, 20 patients were housewives,5 were servants, 8 were shopkeepers and 4 were clerks.

36 patients 9–10, 25 patients scored 8–9, 27 patients 7–8 and 4 patients had VAS score of 6–7. After final 12th week follow up the scores were like 10 patients between 9 and 10, 13 patients between 8 and 9, 39 patients had 7-8 score, and 30 patients scored 6–7 [Fig. 2].

4. Discussion

Plantar fasciitis is one of the most common cause of pain in the heel of the foot which restricts functions and can be difficult to treat if it becomes chronic. The chronic form of plantar fasciitis can lead to development of ankle stiffness and heel spurs. In this condition patient typically complains of sharp morning heel pain and “first-step” pain which improves with use over some time but can also worsen with excessive use.[11] In earlier days treatment of PF was done by orthosis, NSAID drugs, and steroid injection, but literature lacks clinical evidence and are also associated with complications. PRP has recently demonstrated its potential to manage chronic forms of PF that have not been cured by other conservative methods. PRP can be prepared by 3 different techniques like double spinning, buffy coat-based methods & soft single spin method. The first two methods yield L-PRP (higher concentration of platelets and leucocytes) in contrast to pure PRP obtained from the last method.[12] Our study has used the double spinning technique to prepare PRP. The concept behind using PRP is to increase regenerative abilities because of its high content of cytokines and cells, in hyperphysiologic doses. These promote faster cascade of healing process by promoting cellular chemotaxis, matrix synthesis, and proliferation.[13] In our study, patients were once injected by PRP, then their follow up was done after 1 week, 4 weeks and after 12 weeks. Barrett et al. applied a single injection of PRP in a pilot study of nine patients and reported 78% symptom resolution at short-term follow-up of two months.[14] In our study, patients who presented with severe pain (VAS score 9–10), there was improvement

Table 3
Showing VAS score of the patients before injection and at 1 week follow up and 12 weeks follow up.

VAS Score	Number of patients (Before Injection)	Number of patients (1 week follow up)	Number of Patients (12 week follow up)
9–10	48	36	10
8–9	32	25	13
7–8	10	27	39
6–7	02	04	30

Legend 4 According to distribution of patients on VAS score (10 being severe pain and 0 as no pain), before injection 48 patients scored between 9 and 10, 32 patients 8–9, 10 patients 7–8 and 2 patients between 6 and 7. On 1st week follow up the graph gradually got reversed with 36 patients 9–10, 25 patients scored 8–9, 27 patients 7–8 and 4 patients had VAS score of 6–7. After final 12th week follow up the scores were like 10 patients between 9 and 10, 13 patients between 8 and 9, 39 patients had 7-8 score, and 30 patients scored 6–7.

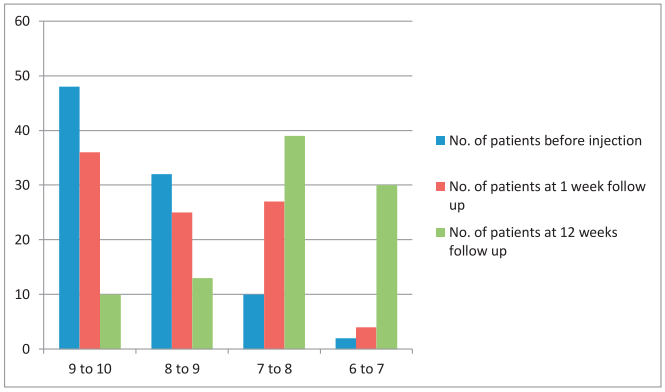

Fig. 2. Showing VAS score at interval before injection and at 1 week follow up and 12 weeks follow up.

in 79.2% patients after 12 weeks follow up. Steroid injections are considered one of the first-line treatments and have been found to produce satisfactory short-term results by blocking the inflammatory response and improving local edema, swelling, pain, and foot function. Unfortunately, steroid injections have been reported to be related to abscesses, osteomyelitis, fat pad atrophy, and plantar fascia tears.[15,16] Crawford et al. concluded that steroid injections can provide short term relief. However, a number of complications were noted including plantar fascial rupture, plantar fat pad atrophy, lateral plantar nerve injury secondary to injection, and calcaneal osteomyelitis and in iontophoresis, burning of the underlying skin.[17,18]

O'Malley and Vosseller[15] reviewed a series of 24 patients reporting success of using PRP in PF to be 66.6% after 6 months.[19]

5. Conclusion

The article suggests good and effective use of PRP in treatment of plantar fasciitis, along with being a simple and safe procedure. More studies are needed to be carried out to with larger sample sizes and single method of PRP preparation to help make this technique a gold standard for treating plantar fasciitis.

Authors contributions

"Sparsh Naik has seen the patient in the opd and has given the PRP injection and prepared the manuscript and has read and approved the final manuscript."

"Saumya Agarwal has helped with the introduction part and material and methods, read, arrange and approved the final manuscript."

"Shivank Prakash read and approved the final manuscript."

"Rohit Bhandari helped in making the discussion part of the manuscript."

"Prachi Agarwal helped with the statistical part of the manuscript."

Declaration of competing interest

None.

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Research paper

The results and safety of endoscopic plantar fascia release for treatment of chronic plantar fasciitis

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ABSTRACT

Background: A prospective study was conducted to evaluate the results of endoscopic plantar fascia release (EPFR) and its safety in treating patients with chronic plantar fasciitis.
Patients and methods: Thirty patients who had chronic plantar fasciitis for more than 6 months participated in this study from March 2015 to June 2018. Seventeen patients were females, and thirteen were males with an average age of 46 years (ranged between 35 and 52 years). All patients had a failed history of conservative treatment. They were treated with endoscopic plantar fascia release. If a heel spur existed, it was resected by an arthroscopic burr. Pain and functional limitations were evaluated with the American Orthopedic Foot and Ankle Society Scale (AOFAS) and Roles and Maudsley score.
Results: At the end of follow-up, the mean AOFAS scoring changed significantly from 67 points before surgery to 93 points ($P < .0001$) which was clinically significant. Sixteen (53.3%) patients had excellent results, 8 (26.6%) patients had good results, 4 (13.33%) patients had acceptable results, and 2 (6.66%) patients had poor results. Three cases complained of postoperative superficial infection at the medial portal. Two cases developed numbness and paraesthesia at the sole of the foot. Three patients had ongoing start-up pain that resolved within two months. The mean duration to full weight bearing after surgery was 40 days. All patients returned to full activities by a mean of 10 weeks.
Conclusion: Endoscopy offers the optimum solution for the resistant cases, but is not without complications. EPFR should be reserved only for severe cases after a trial period of conservative methods of treatment.

1. Introduction

Plantar fasciitis can be a painful and debilitating condition that often frustrates not only the patient but also the physician.[1] Patients with plantar fasciitis report sharp pain in the plantar aspect of the foot, in the medial portion of the heel.[2] Both sedentary patients and athletes suffer from it, with a higher frequency between the age of 40 and 60. After age 40 years, the fat pad begins to atrophy, with loss of water, collagen, and elastic tissue.[3] The total thickness and height of the fat pad decrease, resulting in diminished shock absorbency and decreased protection of the calcaneal tuberosity.[4]

More than 90% of cases improve with conservative treatment including non-steroidal anti-inflammatory drugs, stretching, night splint use, foot orthosis use, physical therapy, and Extracorporeal Shock Wave Therapy (ESWT). However, the remaining 10% of patients do not improve with conservative treatment and may be candidates for surgical treatment.[5]

Endoscopic plantar fascia release (EPFR) has been developed for the treatment of plantar fasciitis to reduce the incidence of surgical complications and shorten the duration to return to initial level of activities. Barrett and Day[5] initially developed EPFR for the treatment of chronic plantar fasciitis. Sahu[6] has reported that EPFR produced considerably better outcomes for patients complaining of plantar fasciitis, particularly those with mild or moderate symptoms. Different studies have documented that EPFR could be a successful minimally invasive technique for the treatment of persistent plantar fasciitis. However, EPFR is not without complications.[7,8]

The purpose of this study was to determine the clinical results and safety of EPFR as an advanced technique in the treatment of chronic plantar fasciitis.

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2. Materials and methods

In this prospective study a total of 30 patients who had chronic plantar fasciitis were treated by EPFR between March 2015 and June 2018. Seventeen patients were females and 13 were males with an average age of 46 years (ranged between 35 and 52 years). All patients who were included in the study had a failed history of conservative treatment in the form of non-steroidal anti-inflammatory drugs (NSAID), foot stretching exercises, local corticosteroid injection, night splint, heel cup, orthoses and/or shoe modifications. A written consent was taken from every patient before the start of the study.

Plantar fasciitis was diagnosed by history and physical examination. All patients characteristically had heel pain that was more extreme upon the first step in the morning. On physical examination, all patients had localized tenderness to palpation at the insertion of the plantar fascia over the medial side of the heel. Plain radiographic examination was performed for all patients to exclude other pathologies like stress fracture, subtalar arthritis, or intraosseous lesion. Preoperative Plain radiography showed a plantar calcaneal spur in 11 feet (Fig. 1).

The patients completed the background information and a history profile of the heel pain. The background information included age, gender, foot affected, duration of symptoms, and types of prior treatments. Demographics of subjects are shown in (Table 1).

2.1. Inclusion criteria

1 Patients who had heel pain lasting more than six months.
2 Patients who reported pain and tenderness over the medial side of the heel/foot.

2.2. Exclusion criteria

1 Patients younger than18 years.
2 Patients had plantar heel pain lasting more than 2 years.
3 A history of systemic disease.
4 A previous surgical release of plantar fascia.
5 Prior heel surgery.
6 Bilateral cases.

The pre-operative American Orthopedic Foot and Ankle Society (AOFAS) Scale[8] ranged between 52 and 73 with an average of 67. The pre-treatment duration of symptoms ranged between 7 and 20 months with an average of 13.9 months.

Table 1
Patient demographics.

Variable	Number
Patient	30
Male/Female	13/17
Foot affected	
Right – No. (%)	21 (70%)
Left – No. (%)	9 (30%)
Average age (years)	46
Pre-treatment duration (months)	13.97
Average AOFAS[a]	67

[a] American Orthopedic Foot and Ankle Society Scale.

2.3. Surgical technique

The procedure was performed under spinal anesthesia, with the patient placed in the supine position. Preoperative antibiotics were administered. A pneumatic tourniquet was applied to the upper thigh.

Endoscopic plantar fasciotomy was performed for all patients using medial and lateral portals. The medial portal was placed just anterior and inferior to the medial calcaneal tubercle (Fig. 2). The incision is made only in the skin, with blunt dissection; a blunt trochar was advanced across the inferior surface of the plantar fascia perpendicularly to the lateral aspect of the foot until tenting of the skin is noted which indicates the placement site of the lateral portal skin incision. The arthroscope was then introduced from medial portal for visualization of plantar fascia. Using a hook knife through the lateral portal and the slotted cannula, the medial half of the plantar fascia is divided from medial to lateral direction under direct visualization until the plantar fat tissue is exposed, which is the sign that the plantar fascia has been divided completely toward its superficial layer (Fig. 3). If a heel spur existed, it was resected by an arthroscopic burr. The pneumatic tourniquet was released and a compressive dressing was placed on the foot. Active range-of-motion exercises of the foot and ankle were performed one day after surgery. Partial weight bearing was permitted 5 days after surgery and gradually increased to full weight bearing in accordance with patient tolerance.

The follow-up period was 24–30 months with an average of 26 months. Evaluation and complete data were obtained from all patients. Patients were reviewed at 6, 12, and 24 weeks post-treatment and at 3 months interval until the end of the study. There were no patients lost to follow-up. The outcome measures were evaluated using the AOFAS and the criteria of Roles and Maudsley score.[9]

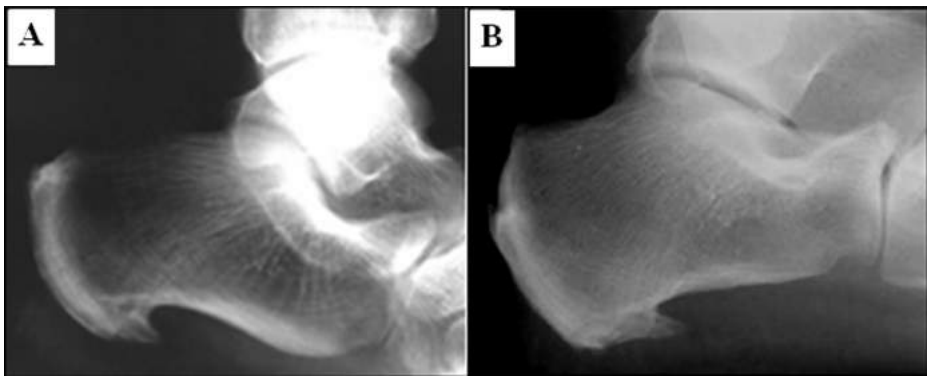

Fig. 1. (A & B) Preoperative X-rays showing calcaneal spurs.

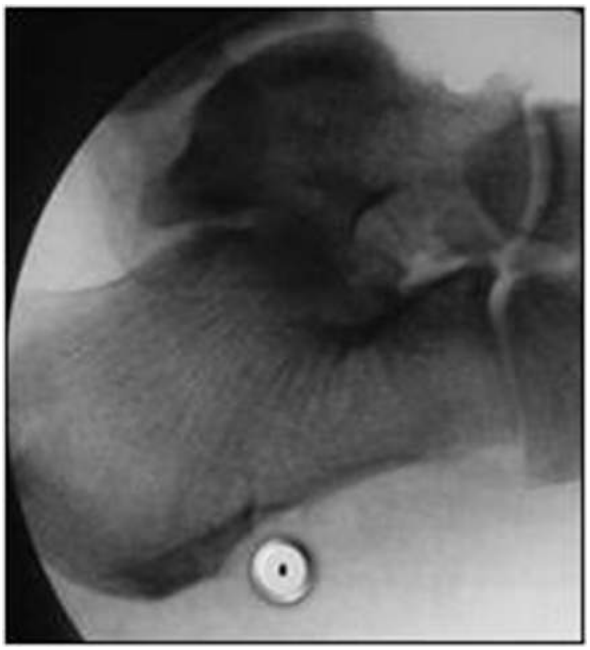

Fig. 2. A Fluoroscopic image confirming the calcaneal tuberosity and the origin of plantar fascia.

3. Results

The pre-operative AOFAS score was 67 points (ranged between 52 and 73) and changed significantly at the end of follow up to 93 points (ranged between 77 and 96) ($P < .0001$) which was clinically significant.

Regarding the pain score category of AOFAS, the mean score of pain improved from 17.3 points (range, 0–20 points) preoperatively to 35.5 points (range, 28–40 points) postoperatively which was clinically significant.

Regarding the patient satisfaction after treatment, 24 patients (80%) were satisfied, 4 patients (13.33%) were satisfied with reservation, and 2 patients (6.66%) were not satisfied.

According to the score of Roles and Maudsley as shown in (Table 2), 16 patients were excellent (53.3%), 8 were good (26.6%), 4 were acceptable (13.33%), and 2 cases were poor (6.66%).

The mean duration to full weight bearing after endoscopy was 40 days (range, 30–45 days). All the patients could return to complete activities by a mean of 10 weeks (range, 6–14 weeks).

Table 2
Results according to Roles and Maudsley score.

Result	EPF
Excellent	53.3%
Good	26.6%
Acceptable	13.33%
Poor	6.66%

Table 3
The overall results.

Variable	Number
Average Follow up (months)	26
Average AOFAS	93
Satified	80%
Satisfied with reservation	13.33%
Not Satisfied	6.66%

Results of patients are summarized in (Tables 3 and 4).

3.1. Complications

Three cases complained of postoperative superficial infection at the medial portal, which was significantly improved by antibiotics and daily dressings. Two cases had numbness and paraesthesia at the sole of the foot that resolved within 2 months after surgery. Three patients developed ongoing start-up pain that improved within two months.

4. Discussion

Plantar fasciitis is generally regarded as a self-limited condition; with more than 90% of cases respond to conservative treatment including nonsteroidal anti-inflammatory drugs, stretching, night splints, and foot orthosis. Other treatment modalities include Extracorporeal Shock Wave Therapy (ESWT), the injection of Botulinum toxin[10], Hyaluronic acid[11] or Platelet-Rich Plasma (PRP).[12] However, the remaining 5%–10% of patients do not improve with conservative treatment and may be candidates for surgical treatment.[5] Accordingly, some cases are resistant and may require more invasive maneuvers to be treated.

Plantar fasciotomy is the most frequent surgical method for plantar fasciitis. It is considered as the mainstay of surgical treatment.[6] Many procedures can be used to release the plantar fascia. These procedures comprise open fasciotomy, in-step plantar fasciotomy and minimally invasive fasciotomy which can be done

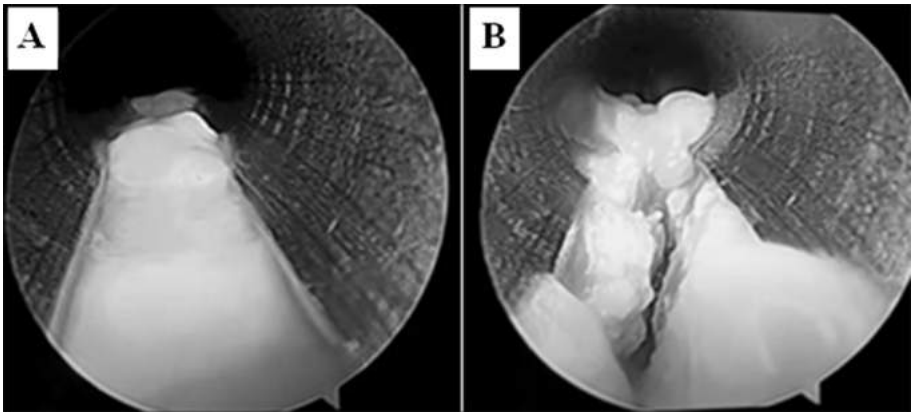

Fig. 3. Endoscopic view of plantar fascia. A: Before release. B: After the plantar fascia release.

Table 4
Outcomes at baseline and follow-up.

Case	Age	Sex	Foot affected	Duration of symptoms (month)	Prior treatment	Hospital stay (day)	Follow up (month)	Pre AOFAS (mean 67)	Post AOFAS (mean 93)
1	35	Female	Right	20	NSAID	3	24	70	96
2	44	Male	Left	16	Heel cup, NSAID	9	28	52	94
3	50	Female	Right	9	Heel cup	3	29	66	89
4	48	Female	Left	11	NSAID	8	24	70	96
5	44	Male	Right	22	NSAID	6	25	67	95
6	39	Female	Left	10	Night splint	5	24	70	77
7	50	Female	Right	13	Heel cup, NSAID	6	30	63	93
8	46	Male	Right	15	Night splint	6	28	59	93
9	44	Female	Right	16	NSAID	10	28	66	91
10	42	Female	Right	20	Local corticosteroid injection	7	26	70	93
11	45	Female	Right	16	Heel cup	10	24	73	92
12	42	Male	Left	7	Heel cup, NSAID	5	24	63	95
13	48	Female	Left	14	Orthosis	10	30	67	94
14	51	Male	Right	18	Heel cup	5	28	70	94
15	44	Male	Right	15	Heel cup	12	24	69	92
16	40	Female	Left	19	local corticosteroid injection	7	25	71	96
17	45	Female	Right	20	Heel cup	8	26	69	92
18	46	Female	Right	15	Heel cup	3	23	72	96
19	42	Male	Left	8	Heel cup, NSAID	11	26	68	95
20	47	Female	Right	9	Orthosis	5	26	67	91
21	50	Male	Left	20	Orthosis	8	24	70	88
22	51	Female	Left	13	Heel cup, NSAID	5	24	59	92
23	48	Female	Right	9	Heel cup	7	24	58	96
24	49	Male	Right	11	local corticosteroid injection	5	29	70	93
25	48	Male	Right	9	Night splint	10	24	69	95
26	49	Male	Right	12	Heel cup, NSAID	12	26	71	94
27	50	Male	Right	10	Shoe modifications	9	24	70	96
28	49	Female	Left	8	local corticosteroid injection	9	24	65	94
29	46	Male	Left	12	Shoe modifications	7	29	67	96
30	50	Female	Right	20	Night splint, NSAID	5	30	69	93

percutaneously or endoscopically.[6,12] Although open surgery is more frequent, there have been documented complications such as skin trouble, infection, nerve trouble, and constant pain accompanied by delayed recovery time.[13] However, endoscopic plantar fascia release (EPFR) is a viable alternative to the previously established open procedures.

EPFR is a minimally invasive procedure among many surgical alternatives for release of the fascia. It offers a possible greater working space and allows obvious visualization of the anatomy at the surgical site. This procedure was mainly performed to minimize the surgical complications and decrease the period to go back to the original level of activities.[14]

Barrett and Day[5] described a single-portal endoscopic procedure for plantar fasciitis in 1991. Thereafter many other authors conducted reports of endoscopic plantar fasciitis surgery. These studies showed satisfactory clinical outcomes with subjective satisfaction. O'Malley et al.,[15] reported on 20 cases treated with a 2-portal partial EPFR. The mean AOFAS score improved from 62 points to 80 points. Bazaz and Ferkel[16] documented that the mean AOFAS score improved from 66 points to 88 points.

Lui[7] reported a procedure of endoscopic release with a plantar and a dorsal portal to release the deep abductor hallucis fascia in order to decompress first branch of the lateral plantar nerve.

In a study including 17 patients who underwent uniport endoscopic release, Boyle and Slater[17] documented that 82.4% of cases had mild to no pain postoperatively. Likewise, Brekke and Green[18] reported a mean decrease in pain of 71.5% with a dual portal endoscopic procedure.

In the current study, 30 patients with chronic plantar fasciitis were treated by EPFR after failed conservative treatment. We performed total resection of the medial half of plantar fascia under direct vision. We did not need in any case to convert to open fasciotomy as the endoscopic technique was quite enough to release the medial half of plantar fascia. The post-operative clinical results were significantly improved in comparison with the pre-operative scores. The mean AOFAS score improved from 67 points to 93 points. The data of the present study indicated that 80% of patients were satisfied and reported complete relief of their pain and were able to return to full activity by a mean of 10 weeks.

Our outcomes are comparable to the study conducted by Fumito et al.,[19] who initially introduced the deep-fascial endoscopic approach to get a greater working space and a better view of the fascia. In their study, the mean AOFAS score improved from 64.2 points to 92.6 points. Our results are superior to the studies conducted by O'Malley et al.,[15] and Bazaz and Ferkel.[16] Our superior clinical outcomes may have been obtained due to the total resection of the medial half of plantar fascia under direct vision.

The heel spur commonly seen on x-rays with plantar fasciitis was considered as an incidental finding and thought to be a consequence of the plantar fasciitis and not the reason of heel pain and there was no significant pain reduction with calcaneal spur resection in patients with plantar fasciitis.[1,18–20] However, a previous article showed that there was a connective tissue richly supplied with blood vessels and nerves between the spurs and plantar fascia.[21] Accordingly, we believe that there is a possibility for the calcaneal spurs to lead to pain and they should be removed during the endoscopic fasciotomy procedure. In the current study calcaneal spur was removed in 11 (36.6%) cases. However, there were no statistical significant differences in the postoperative outcomes between them and the other cases.

Regarding the duration to getting back to athletic activities, Saxena[22] described the clinical outcomes of uniportal endoscopic plantar fasciotomy to treat 16 athletic patients. The mean period to return to activity was 2.7 months after surgery. In the study of Fumito et al.,[19] normal walking was established by all patients within a mean of 2 weeks after surgery, but the duration to full athletic activity was a mean of 10.9 weeks, similar to previous studies. In the current study the mean duration to full weight bearing after endoscopy was 40 days (range, 30–45 days). All patients could return to complete activities by a mean of 10 weeks (range, 6–14 weeks).

Several clinical trials documented that EPFR resulted in reduced post-operative morbidity and excellent pain relief. Patients' satisfaction ranges from 60% to 80%, whereas the complication rate after EPFR was relatively low.[14,23] Potential complications after EPFR included heel pain, lateral column pain, incisional pain, post-operative infection, calcaneal stress fractures, and nerve entrapment.[23] Longitudinal arch strain seems to happen in more than 50% of the chronic complications.[6]

In the current study, the release of the plantar fascia did not exceed the medial half and accordingly there was no cases of lateral column pain, which was in agreement with Brugh et al.,[24] who in a study on 50 feet reported that all patients who suffered from painful lateral column after the operation had a 60.6% mean percentage of released plantar fascia, while those that had no pain had only 48.7% of their fascia released. They documented that the greatest percentage of release should not exceed 50%.

In the current study, three cases complained of postoperative superficial infection at the medial portal, which was significantly improved by antibiotics and daily dressings. Two cases developed numbness and paraesthesia at the sole of the foot that improved within 2 months after surgery. Three patients had ongoing start-up pain that resolved within two months. All the complications were related to the invasive nature of the endoscopy and accordingly EPFR is recommended mainly for severe and resistant cases that were not cured with conservative or less invasive methods.

One of the limitations of this study is the small number of patients and short-term follow up. A long-term follow-up of more than 5 years is needed for adequate clarification. Another limitation of this study was that the analysis was not made dependent on a comparison with other methods of surgical techniques to release the plantar fascia.

The availability of multiple alternatives of EPFR like the use of different portals, calcaneal spur removal, calcaneal drilling, ultrasound-assisted, nerve decompression, and monopolar soft tissue electrode, proves that there is no gold standard technique for the operative treatment of recurrent plantar fasciitis.

Endoscopy is not without complications and the surgeon should be wise before performing an invasive maneuver that may not be totally safe, while he can get excellent results with a non invasive or less invasive maneuver with less morbidity. Other less invasive measures like PRP showed significantly better pain control and higher AOFAS scores at intermediate and long-term follow-up and could be tried before deciding the use of EPFR for chronic plantar fasciitis cases.[25]

5. Conclusions

Based on the results of this review, it should be noticed that EPFR cannot be considered as superior treatment than other less invasive, therapeutic methods, like ESWT or PRP.

The use of EPFR should be discussed on a case basis with each patient, while it could be only suggested as one of the various alternative options for the treatment of chronic, persistent plantar fasciitis.

Chronic persistent plantar fasciitis can be treated by the traditional conservative methods. However, other less invasive methods like PRP can be recommended in chronic resistant cases prior to endoscopic surgery. If all methods failed, EPFR would then offer the optimal treatment for the resistant cases.

Disclosure of interest

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Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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If I have not included an Acknowledgements, then that indicates that I have not received substantial contributions from non-authors.

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Research paper

A prospective observational study on the functional outcome of retrocalcaneal bursitis following arthroscopic management

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ABSTRACT

Introduction: Heel pain is a common foot and ankle complaint in the Orthopaedic OPD. Posterior heel pain occurs due to a handful of etiologies, more prominent of which is retrocalcaneal bursitis. Management of posterior heel pain in majority of the cases is non-operative. However, surgical intervention may be indicated if conservative therapies fail. This study aims at finding the functional outcome after arthroscopic management of retrocalcaneal bursitis.

Methodology: A total of 29 patients were recruited for the study after applying the selection criteria. Standard knee arthroscopy equipment and instruments were used with gravity assisted fluid system. After making medial and lateral portals, the inflamed bursa was debrided using a motorised shaver and an arthroscopic burr was used to resect the calcaneal prominence. A post-operative rehabilitation protocol was followed and the cases were followed up at regular intervals for a minimum of 12 months.

Results: After excluding losses to follow-up and post intervention exclusions, data of 23 patients were considered for statistical analysis. There was a consistent improvement in the variables of the AOFAS score at the follow up intervals. The total AOFAS score showed consistent improvement from a pre-operative mean score of 66.96 to a mean score of 88.44 at 03 months to maximal mean score of 96.00 at 6 months ($p < 0.001$). There were 02 minor complications in the form of hypoaesthesia in sural nerve distribution which were managed non-operatively. None of the cases required revision surgery.

Conclusion: Arthroscopic decompression is a feasible and efficient procedure for the treatment of retrocalcaneal disorders. The time to return to normal activity level is short. Sufficient exposure of the Achilles tendon and adequate removal of the calcaneal prominence and bursal tissue can be done effectively using an arthroscopic technique. It yields cosmetically better results with low incidence of complications.

Authors credit statement

Abhishek Kumar Mishra - Conceptualization; Investigation; Methodology; Resources, Chandermohan Singh - Project administration; Supervision; Resources, Vignesh S - Investigation; Data curation; Formal analysis; Roles/Writing - original draft; Writing – review & editing; Visualization

1. Introduction

Heel pain is one of the common reasons for attendance in the orthopaedic OPD. It is probably the second most common foot and ankle complaint after ankle sprain. It is estimated that heel pain accounts for about 1% of all visits to orthopaedic OPD.[1]

Pain at the posterior heel is most commonly caused by pathology at the calcaneal insertion site of the Achilles tendon or at its associated bursae. Two bursae are located just superior to the insertion of the Achilles tendon.[2] Anterior or deep to the tendon is the retrocalcaneal bursa, which is located between the Achilles tendon and the calcaneus. Posterior or superficial to the Achilles tendon is the subcutaneous calcaneal bursa, also called the Achilles

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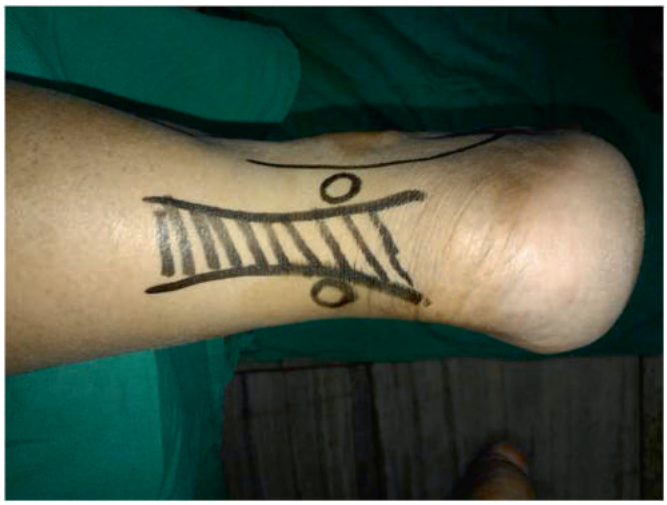

Fig. 1. Surface marking of portal positions including possible course of sural nerve.

bursa. This bursa is located between the skin and posterior aspect of the distal Achilles tendon. Inflammation of either or both of these bursae can cause pain at the posterior heel and ankle region.[3]

It is often difficult to differentiate Achilles tendinitis from retrocalcaneal bursitis. While retrocalcaneal bursitis causes tenderness just anterior to both medial and lateral edges of distal Achilles tendon, tenderness due to insertional tendinitis is more distal at the

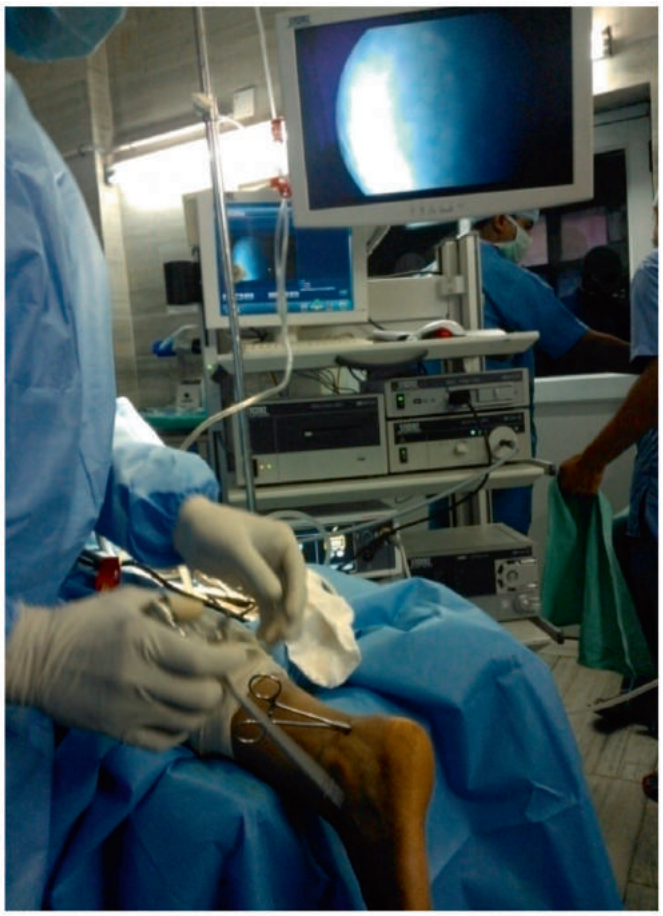

Fig. 2. Developing posterolateral portal.

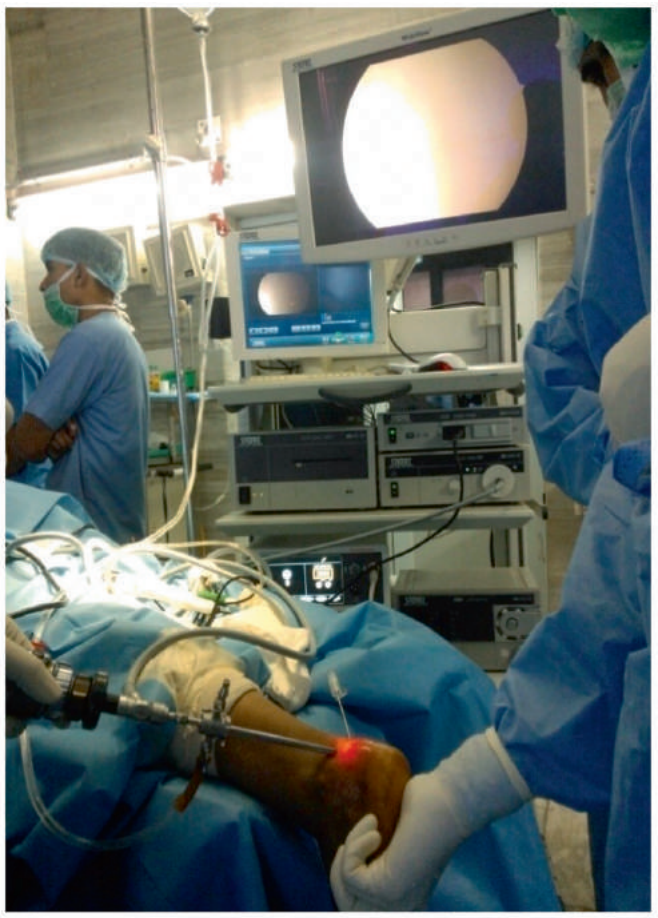

Fig. 3. Developing posteromedial portal.

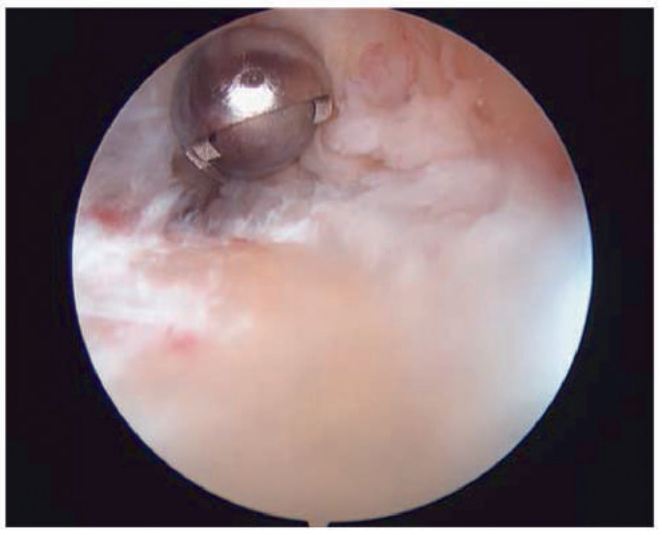

Fig. 4. A 4.0-mm arthroscopic shaver is indroduced into the medical portal, and the bursal tissue removed.

site of attachment to posterior calcaneus.[4]

Radiographs are usually the only diagnostic imaging modality required when evaluating posterior heel pain. A lateral radiograph will demonstrate calcification within the Achilles tendon insertion

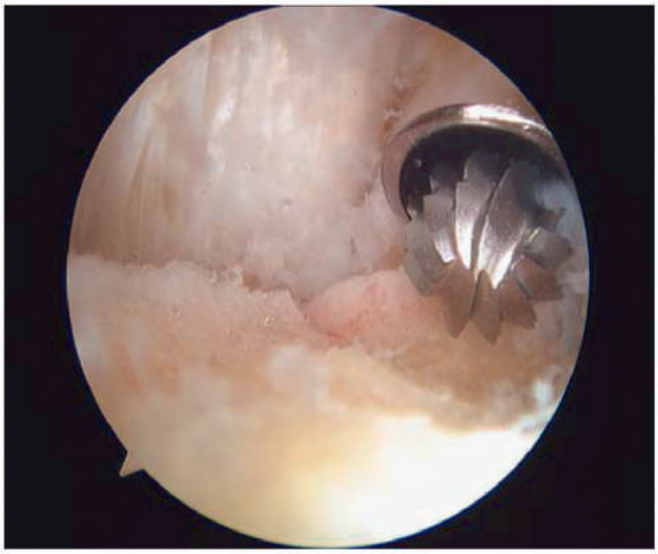

Fig. 5. Bony spur excision. The Achilles tendon fibres can be seen on the left passing distally to insert onto the middle third of the calcaneus.

and a prominent superior calcaneal prominence called as the Haglund deformity. Individuals with retrocalcaneal bursitis may have an absence of the normal radiolucency that is seen in the posteroinferior corner of the Kager fat pad, known as the retrocalcaneal recess or bursal wedge.[5] Magnetic resonance imaging (MRI) may demonstrate bursal inflammation, but this modality probably does not offer much more information than that can be found by careful physical examination. A review by Sayana MK et al. opines that an MRI or USG is not required for diagnosis of insertional Achilles tendinitis. However, they agree that an MRI is the most sensitive and reliable study in delineating the extent of intratendinous changes.[6] Ultrasonography may also be a potentially useful tool for diagnosing pathologies of the Achilles tendon.[7]

The majority of patients with retrocalcaneal bursitis respond to nonoperative treatment such as change of footwear, use of soft heel pads, moist heat, stretching exercises, local steroid injections, ultrasound therapy and extracorporeal shock wave therapy. In selected cases where conservative treatment fails, surgery may be indicated.[8] The traditional surgical management of retrocalcaneal bursitis consists of an open excision of the inflamed bursa, resection of the posterosuperior calcaneal tuberosity, and debridement of the Achilles tendinopathy if chronic degenerative changes are present and accessible.

In an effort to reduce the operative morbidity and recovery time endoscopic techniques have been described for management of this condition.[17] Minimally invasive surgeries may allow early postoperative recovery, minimal pain, and better cosmetic appearance. The technical feasibility of arthroscopic resection has been demonstrated by Roth et al.[9] in their cadaveric study.

The aim of this study is to assess the functional outcome of arthroscopic management of retrocalcaneal bursitis at a tertiary care orthopaedic centre.

2. Methodology

A prospective follow-up study was conducted on 29 patients with Retrocalcaneal bursitis with single intervention of arthroscopic surgery as described below. Sample size was calculated keeping the power of study at minimum of 80% and significance level at 5% and the sampling was done consecutively from the population who were already on conservative follow-up for heel pain from our OPD with study criteria applied. Patients in the age group Of 20–70 years with history of failed conservative treatment for 6 months or more were included in the study while patients with inflammatory arthropathy, previous hind foot surgery, bony deformity of ankle (except Haglund deformity), degenerative changes in Achilles tendon and malignancy were excluded from participation. Approval was obtained from the Institutional Ethical Comittee for the conduct of the study.

Informed consent was obtained from the participants. After

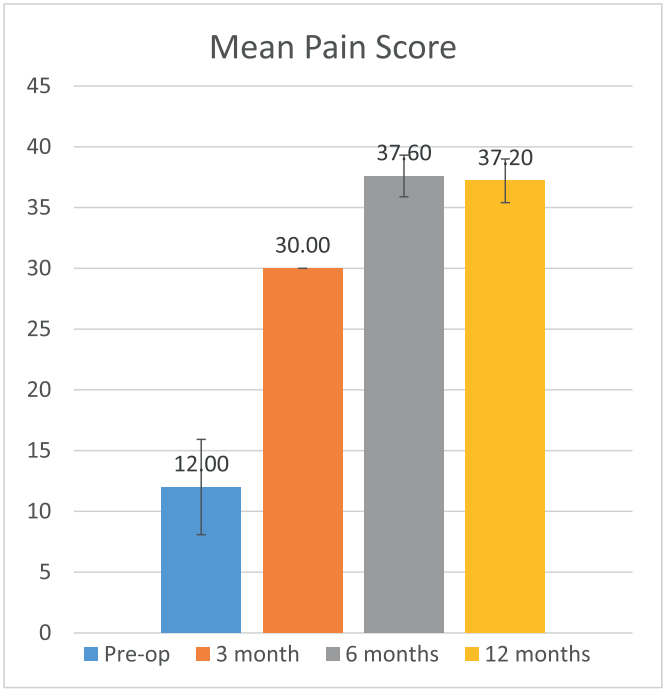

Fig. 6. Improvement in mean pain score over time.

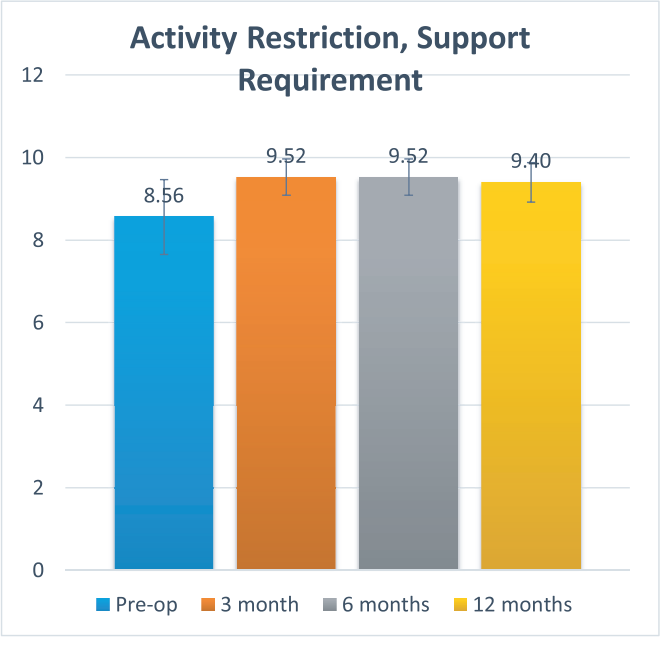

Fig. 7. Improvement in activity restriction and support requirement over time.

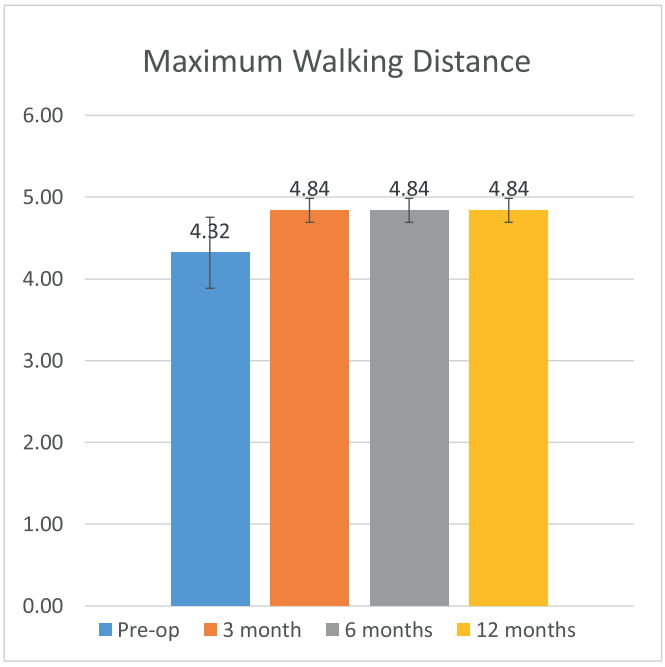

Fig. 8. Improvement in Maximum walking distance over time.

Fig. 9. Improvement in Walking Surface ability over time.

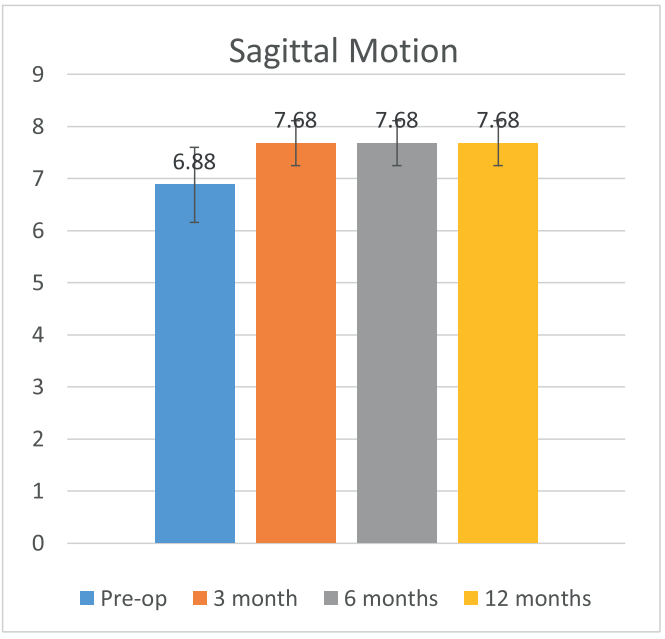

Fig. 10. Improvement in Sagittal plane motion over time.

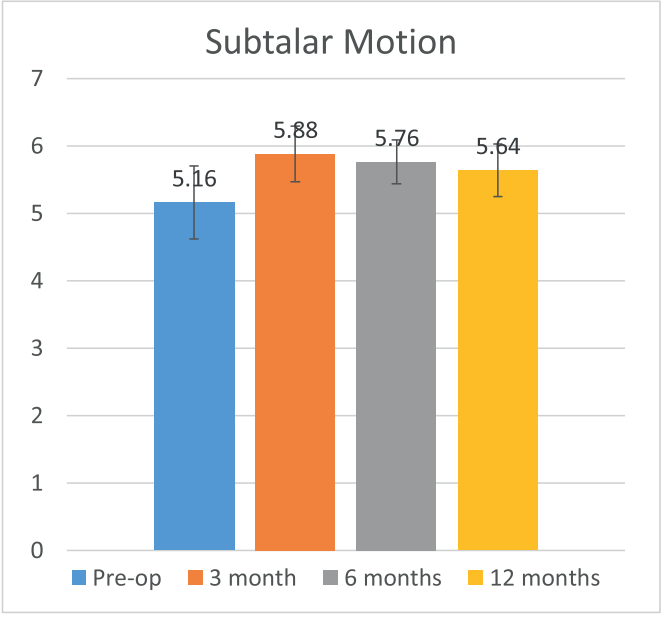

Fig. 11. Improvement in Subtalar Motion over time.

thorough history and clinical examination, patients were evaluated with an X-ray of the foot and heel, and ultrasound of the heel to screen for degenerative changes of the tendo-achilles. In cases where it was difficult to distinguish whether symptoms were caused by retrocalcaneal bursitis or insertional Achilles tendinopathy, an MRI was used to differentiate. All the patients recruited for the study had a trial of conservative management prior to study and have documented failure to improve.

The goal of the surgical treatment was to remove the calcaneal prominence and to decompress the inflamed bursa and surrounding soft tissues.

After spinal anaesthesia, patient is positioned prone. Cleaning, draping and surface marking was done including possible course of sural nerve (Fig. 1). Posterolateral viewing portal (Fig. 2) and posteromedial portal (Fig. 3) for instrumentation were made. Standard telescope of 4 mm diameter with 30° viewing angle was used. Gravity assisted fluid system with 3 L NS used. Debridement carried out using motorised shaver, arthroscopic burr and RF ablation probe as required.

After removal of inflamed bursal tissue (Fig. 4), the posterosuperior calcaneal prominence is resected using either an arthroscopic shaver or a 4.0-mm arthroscopic burr (Fig. 5) moving from posterior to anterior direction, avoiding injury to the tendon at all times. The resection is carried out both medially and laterally into the sulcus of the calcaneus and down to the attachment of the Achilles tendon.

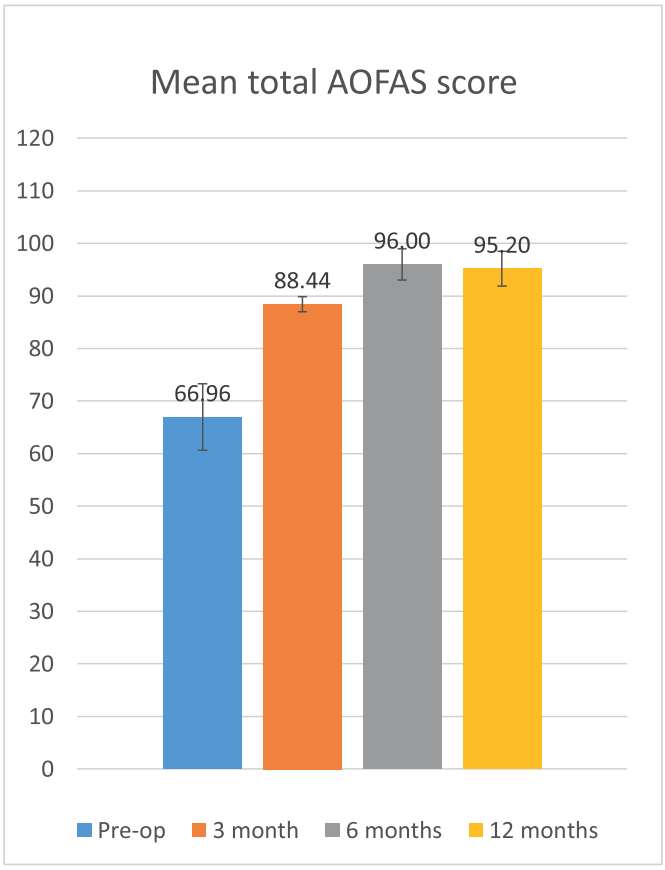

Fig. 12. Improvement in Total AOFAS Score over time.

If the Achilles tendon was found to be damaged or diseased it is debrided at this time. An arthroscopic probe is inserted into the retrocalcaneal space to confirm attachment of the Achilles tendon. The foot is then plantarflexed and dorsiflexed to verify any areas of impingement. The retrocalcaneal space is irrigated with saline. The portal sites are then closed with nonabsorbable sutures, compression dressing is applied and the foot is splinted in slight equinus.

Postoperatively, the patients were advised not to bear weight for 14 days. They were prescribed limb elevation, local ice application and NSAIDs for pain relief. They were allowed to bear weight as tolerated with an ankle brace for another 2–3 weeks. At 4 weeks normal walking was resumed, and normal shoe wear permitted at the discretion of the patient. For those patients who underwent debridement of the Achilles tendon, the time to full weight bearing was delayed by three months which is the normally expected time for tendon healing. Followup was continued for a period of 12 months at regular intervals. Radiographs were obtained during the postoperative visits for evaluation of completeness of resection of the bony deformity initially and subsequent post operative radiographs were looked for re-appearance of radiolucency in the Kager fat pad region. Functional outcome was evaluated using the American Orthopaedic Foot and Ankle score (AOFAS) at three, six and twelve months and compared to pre-operative scores. A study by Talal Ibrahim et al. shows that AOFAS provides quality-of-life information that conveys acceptable validity regarding conditions affecting the foot and ankle.[10] Paired *t*-test was applied to compare mean values at different time points. Frequency table were generated for categorical and nominal data. SPSS version 18.0 was used to analyse the data.

3. Results

A total of 29 patients were recruited for the study out of which 25 were available for follow-up at the conclusion of the study. 04 were lost to follow-up. The data from 02 patients were omitted from the statistical analysis as they were found to have one of the exclusion criteria, namely, Achilles tendinopathy, during intra-operative evaluation. The following parameters were recorded for analysis of the remaining 23 patients.

Around 78% of the study population belonged to the age bracket of 30–60 years. 60% (n = 14) were males. The left heel was involved in 34% (n = 8) of the patients and the right heel in 26% (n = 6) whereas 40% (n = 9) of the patients had a bilateral involvement.

3.1. AOFAS variable evaluation

3.1.1. Pain score: (total score 40)

The study participants showed consistent and significant improvement in pain score by 6 months compared to the preoperative score. The maximum improvement was obtained by 6 months and was statistically significant ($p < 0.001$, mean difference of 25.60) and clinically significant since majority of patients attained the maximum score of 40 and therefore had excellent outcomes. The pain score after 6 months has plateaued until 12 months with insignificant variation. Fig. 6 shows the variation in mean pain score over time.

3.1.2. Function: (total score 50)

Functional status has been subdivided into the following heads.

3.2. Activity restriction and support requirement

Scored ranging from 10 for no limitation and no support requirement to 0 for severe limitation and use of assistive device for activity of daily living. There was a significant improvement in mean scores from 8.56 preoperatively to 9.52 at 6 months ($p < 0{,}001$, mean difference of 0.96) and plateaued thereafter with a mean of 9.4 at 12 month postoperatively as shown in Fig. 7.

3.2.1. Maximum walking distance: blocks (1 block = 0.08 km)

Maximum walking distance with best score of 5 and worst score of 1 also showed significant improvement postoperatively at 3 months ($p < 0.01$, mean difference of 0.52) and plateaued thereafter as shown in Fig. 8.

3.3. Walking surface

Walking surface was scored 5 when there is no difficulty in walking on any surface and 0 for severe difficulty on uneven terrain, stairs, incline and ladders. As such this variable was not compromised significantly in study group peoperatively and a slight positive move in score was noted which was not significant ($p = 0.16$) as shown in Fig. 9.

3.4. Gait abnormality

There was no significant gait abnormality in study group and so no significant difference could be noted postoperatively.

3.5. Saggital plane motion

Flexion and extension improved after intervention with more gain in dorsiflexion in post op period. The score improved from 6.88 preoperatively to 7.68 at 3 months ($p = 0.02$, mean difference of 0.80) and plateaued thereafter as shown in Fig. 10.

Table 1
Comparison of functional outcomes from literature with outcomes from our study.

	Ortmann FW et all	Jerosch J et all	Dijk CN et all	Kondreddi V et all	Our study
Excellent	26	41	15	16	21
Good	3	34	04	06	02
Fair	–	03	01	03	00
Poor	1	03	00	00	00
Total	30	81	20	25	23

3.6. Subtalar motion

Movement at subtalar joint also significantly improved from preoperative mean value of 5.16–5.88 at 3 month of surgery ($p = 0.03$, mean difference of 0.72) and plateaued thereafter with insignificant variations till 12 months as shown in Fig. 11.

Since there was no ankle instability in preoperative period this variable remained same. Presence of malalignment or any kind of deformity was an exclusion criteria of study so no change is observed in this variable.

3.7. Total score

Total score showed significant improvement at each review points when compared to the preoperative mean score of 66.96. The mean score shows significant improvement at 3 months ($p < 0.001$, mean difference in 21.48). There was a significant improvement from 3 months to 6 months mean score ($p < 0.001$, mean difference is 7.56) Thereafter, the total score has plateaued with insignificant variation ($p = 0.08$, mean difference is 0.80) as shown in Fig. 12.

4. Discussion

Our data suggests that the outcome following arthroscopic management of retrocalcaneal bursitis is comparable to studies in the existing literature. The complications associated with surgery has been minimal in the form of only two patient developing hypoaesthesia in sural nerve distribution which responded to neurotropic medication and obsevation. None of the patients needed revision surgery.

The time taken by the patients for return to most of the normal activities after surgery has been eight to twelve weeks in our study. AOFAS scoring system was used for preoperative and postoperative assessment as the same scoring system has been used widely by different studies in the existing literature. Leitze Z et al.,[11] Kondreddi V et al.[12] and Tahir Ogut et al.[13] have used the same scoring system for assessing functional outcome.

AOFAS scoring system (ankle-hindfoot-scale- 100 total score) consist of assessment in three major heads namely pain (40 points), function (total 50 points divided into various subheads) and alignment (10 points).

Pain improved significantly after intervention as evidenced by improvement in pain score. Other components of AOFAS scoring systems which showed improvement were activity limitation and support requirement, maximum walking distance, walking surface and sagittal motion. No change were observed in their individual scores of rest of the components such as alignment since they were not altered pre-operatively.

Similar to our study, other studies in literature document very low incidence of complications.[11–13] Leitze Z et al.[11] conducted a comparative study between open and arthroscopic method of retrocalcaneal bursitis and noted complication rates of open procedure vs arthroscopic were as follows: rate of infection - 12% vs 3%, rate of altered sensation - 18% vs 10%, rate of scar tenderness - 18% vs 7%. Ortmann et al.[14] conducted study on 32 heals managed by arthroscopic surgery and the complications encountered were 01 major and 01 minor. Major being Achilles tendon rupture 03 weeks after surgery and the minor being residual pain and swelling that required reoperations through an open procedure. However, there were no wound healing complications or infections. Dijk CN et al.[15] conducted study on 20 patients in which there were no surgical or post surgical complications.

Since there is no available data on Minimum Clinically Important Difference (MCID) of AOFAS score specific to retrocalcaneal bursitis or hindfoot conditions in general, the MCID of the score for other foot and ankle conditions was taken as a surrogate for analysis of clinical outcomes and grading purpose. The study by Hiok et al. shows the MCID for good outcome was 30.2 and for fair outcome it was 7.9 for AOFAS score used in Hallux Valgus surgery.[16] Based on Hiok et al. study, an arbitrary classification was used for our study purpose to document outcomes in ordinal form. An AOFAS total score difference of more than 30 with improvement in pain score by more than 20 points and cases were total score or pain score reached maximum possible in the scale i.e., 100 and 40 respectively was considered excellent outcome, whereas total score improvement in range 20–30 with pain score improvement in range 15–20 was considered good outcome, whereas total score improvement in range 10–20 and pain score improvement in range 10–15 was considered fair outcome and finally a total score and pain score improvement less than 10 was considered as poor outcome.

Comparitive outcomes of our study with results of other similar studies in literature is shown in Table 1.

5. Conclusion

Our study was a prospective observational study on the outcome of retrocalcaneal bursitis following arthroscopic management.

Our data suggests that the outcome following arthroscopic management of retrocalcaneal bursitis is good and is comparable to outcomes from studies in the existing literature. Also the complications associated with arthroscopic surgery in our study had been minimal and managed with non-operative means. None of the patients needed revision surgery.

Arthroscopic decompression is a feasible and efficient procedure for the treatment of retrocalcaneal disorders. The time to return to normal activity level is short (most of the score subheads reached maximal improvement by 3 months). Sufficient exposure of the Achilles tendon and removal of the calcaneal prominence and bursal tissue can be done effectively using an arthroscopic technique. It yields cosmetically better results with low incidence of complications.

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An improved method for processing chondroprogenitor pellets following chondrogenic differentiation for histology and immunohistochemical staining using agarose

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ABSTRACT

Purpose: In-vitro models of cartilage regeneration based on pellet cultures have been widely used to evaluate chondrogenic potential of the cell of interest and predict probable in-vivo behavior. However, pellet processing is a major challenge during handling (due to small size and possible damage to structural contour following sectioning and staining). The present study aimed to utilize human articular cartilage derived chondroprogenitors to assess if agarose-encapsulation of pellets prior to paraffin processing enable easier handling without affecting tissue morphology, glycosaminoglycan staining and immunohistochemical analysis of Collagen type II protein.

Methods: Passage 3 chondroprogenitors (n = 3) were evaluated for MSC markers using flow cytometry and subjected to chondrogenic differentiation as pellets cultures. Post-differentiation, the pellets were subjected to either: a) paraffin embedding, b) agarose encapsulation followed by paraffin embedding or c) agarose encapsulation followed by cryosectioning. All sections were subjected to histological staining for glycosaminoglycan uptake: Alcian blue, Safranin O (Bern score) and Toluidine blue with immunohistochemical processing for collagen type II protein deposition.

Results: With respect to staining and structural integrity, comparable uptake was seen in both paraffin sections and agarose embedded sections while the latter exhibited notably uniform pellets with distinct marginal demarcation. Although plain paraffin and agarose encapsulated sections demonstrated equivalent staining as represented by comparable Bern scores, glycosaminoglycan uptake, and Collagen type II deposition, cryosections exhibited significantly poor staining properties.

Conclusion: Agarose encapsulation of differentiated pellets prior to routine paraffin embedding, eases handling difficulties whilst maintaining structural integrity with optimal staining outcomes.

1. Introduction

The relative avascular and aneural architecture of the articular cartilage limits its self-healing capacity following injury or degeneration.[1] The articular cartilage is primarily composed of extracellular matrix which includes proteoglycans and collagen type II interspersed with a sparse distribution of chondrocytes and chondroprogenitors.[2] Current therapeutic strategies for cartilage repair include pharmacological therapies, surgical interventions, and cell-based therapies.[3] Among the various cell types used, mesenchymal stem cells (MSCs) have shown promising results and have been used to create experimental models to further understand cartilage pathologies and evaluate its potential treatment.[4]

In order to enable multipotency of MSCs, multiple cell culture methods using these cells include monolayer, pellet, micro mass and bio scaffold culture systems.[5] For chondrogenesis, high density

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cell culture systems (pellet/micro mass) provide a three-dimensional microenvironment that permits interaction between cells, mimicking precartilage condensation, a phenomenon observed during embryonic development.[6] Pellet and micro mass cultures are widely used methods in cartilage research to evaluate chondrogenic potential of MSCs and understand signaling pathways involved.[7,8] In order to form the aggregates, MSCs are added at a high concentration ($\simeq 2.5 \times 10^5$ to 1×10^6) to either polypropylene tubes followed by centrifugation to generate a pellet or left undisturbed in low adhesion round bottom plates to form a micro mass. Though high-density cell culture environment displays superiority to two-dimensional cultures (dedifferentiation and lower chondrogenesis), histological processing of pellets requires careful handling and can be a strenuous task.[9] The primary obstacles encountered include loss of pellet during histological processing and construct instability, leading to loss of spherical cell contour during sectioning, thereby rendering the process both time-consuming and inconvenient.

Automation in histopathology has eased histopathological processing, enabling faster and standardized work system. However, some areas within this process are still dependent on manual performance and capability of handling staff. One such procedure is paraffin embedding of pellets, which requires specific expertise for tissue sectioning. Pre-embedding techniques have been used for handling various small tissue samples and one of the most commonly used media is agar.[10–12] Agarose, a transparent marine-based polysaccharide has been used as an embedding material for histopathological processing of small tissues and also as a microcapsule in various cell culture systems.[13,14] Their temperature sensitive water-soluble property enables easy embedding of tissue whilst not adhering to tissue material.

Articular cartilage derived chondroprogenitors have been classified as MSCs fulfilling the minimal criteria of International Society of Cellular Therapy 2006, namely displaying adherence to plastic, positive expression of CD105, CD73, CD90, negative expression of CD45, CD34 with positive trilineage potential into adipogenic, osteogenic and chondrogenic lineages.[15,16] The recent discovery of these progenitors has garnered much interest in the field of cartilage tissue engineering and regeneration, due to their inherent chondrogenic properties and lower inclination to hypertrophy.[17]

In this study, isolated chondroprogenitors were characterized, and centrifuged to form standard pellets which were further subjected to chondrogenic differentiation. Our primary objective was to assess if agarose-encapsulated pellets prior to paraffin processing would enable easier handling without affecting tissue morphology, glycosaminoglycan staining and immunohistochemical analysis of Collagen type II protein using standard laboratory protocols. Our control included routinely used paraffin embedding and processing. Furthermore, we wanted to evaluate if agarose-encapsulated pellets could be subjected for cryosectioning and staining.

2. Methods and materials

2.1. Study design

The study protocol involving procurement of human knee joint samples was approved by the Institutional Review board and carried out as per the guidelines laid down by the Institutional Ethics Committee. Human articular cartilage was harvested from three non-diseased knee joints (mean age: 22±4yrs). Prior to all sample collection written informed consent was obtained. Our inclusion criteria of non-diseased joints were post-trauma subjects requiring above-knee amputation as a part of their treatment and causes such as tumors, infection and inflammation of the knee were excluded.

Enzymatically digested and released cartilage cells were subjected to fibronectin adhesion assay to obtain chondroprogenitors. They were further culture expanded to passage 3 and characterized using fluorescence assisted cell sorting (FACS) for positive and negative MSC markers. The cells were pelleted at concentration of 0.5×10^6 and subjected to chondrogenic differentiation for a minimum period of 21 days. Following this, the pellets were fixed and subjected to either one of the following: a) paraffin embedding, b) agarose encapsulation followed by paraffin processing or c) agarose encapsulation followed by cryosectioning. All the sections were subjected to histological staining for a) proteoglycan/glycosaminoglycan uptake: Alcian blue, Safranin O, Toluidine blue, b) total collagen: Picrosirius red, c) immunohistochemical processing for collagen type II protein and d) Hematoxylin & Eosin (Fig. 1). Subjective comparison was performed assessing stain uptake, maintenance of structural contour integrity and ease of processing. In addition, Safranin O-stained slides were subjected to the Bern score, a visual histological grading system based on uniformity and intensity of stain, cell morphology, intracellular distance and amount of accumulated matrix,[18] by two blinded individual observers.

2.2. Isolation and culture of chondroprogenitors

Cartilage shavings (1 mm^3) were subjected to sequential enzymatic digestion using 12IU pronase for 3hrs (Mat no: 10165913103, Roche, Switzerland), followed by 100IU collagenase type II for 12hrs to obtain individual chondrocytes. The harvested cells were subjected to fibronectin differential adhesion (Cat no: F1141, Sigma Aldrich, US), for 20 min in Glutamax-F12 containing 10% fetal calf serum (FCS) at a concentration of 4000 cells/well. Post incubation non-adherent cells and medium were removed and replaced with stromal growth media [Glutamax-F12 containing 0.1 mM ascorbic acid (Sigma), L-glutamine 2.5 mM/L (Sigma) and antibiotics. Adherent cells were maintained for 10–12 days to obtain clusters of >32 cells (chondroprogenitor clones), following which they were isolated and re-plated (1 clone/5 cm^2). Further expansion of chondroprogenitors to passage 3 was done as per protocol described by Nelson et al.[19] For expansion in addition to the aforementioned medium, human recombinant transforming growth factor beta2 (TGFβ2) 1 ng/ml (Cat no: 4343-5 Biovision, San Francisco, US) and fibroblastic growth factor FGF2 5 ng/ml (Cat no: 4037, Biovision, San Francisco, US) were added. The stromal medium was changed once every three days.

2.3. Phenotyping: FACS

Chondroprogenitors were characterized by FACS. The studied antibodies against human surface antigen were a) positive MSC markers: CD105-FITC, CD73-PE, CD90-PE, and b) negative MSC markers: CD34-PE, CD45-FITC (Table S1). The staining protocol followed manufacturers guidelines received with the individual antibodies. Isotype controls were run for the specific CD markers. BD FACS Celesta flow cytometer was used for data acquisition. Gating and analysis were done using BD FACS Diva v 5.0.2 software. FACS results are reported as Mean ± Standard deviation.

2.4. Chondrogenic differentiation

Harvested passage 3 chondroprogenitors at concentration of 0.5×10^6 cells were added to 2 ml microcentrifuge tubes, centrifuged at 400 g for 10min and left undisturbed for a period of 48 h. The formed pellets were subjected to chondrogenic differentiation using HiChondroXLTM (AL523, Himedia, India) and StemPro

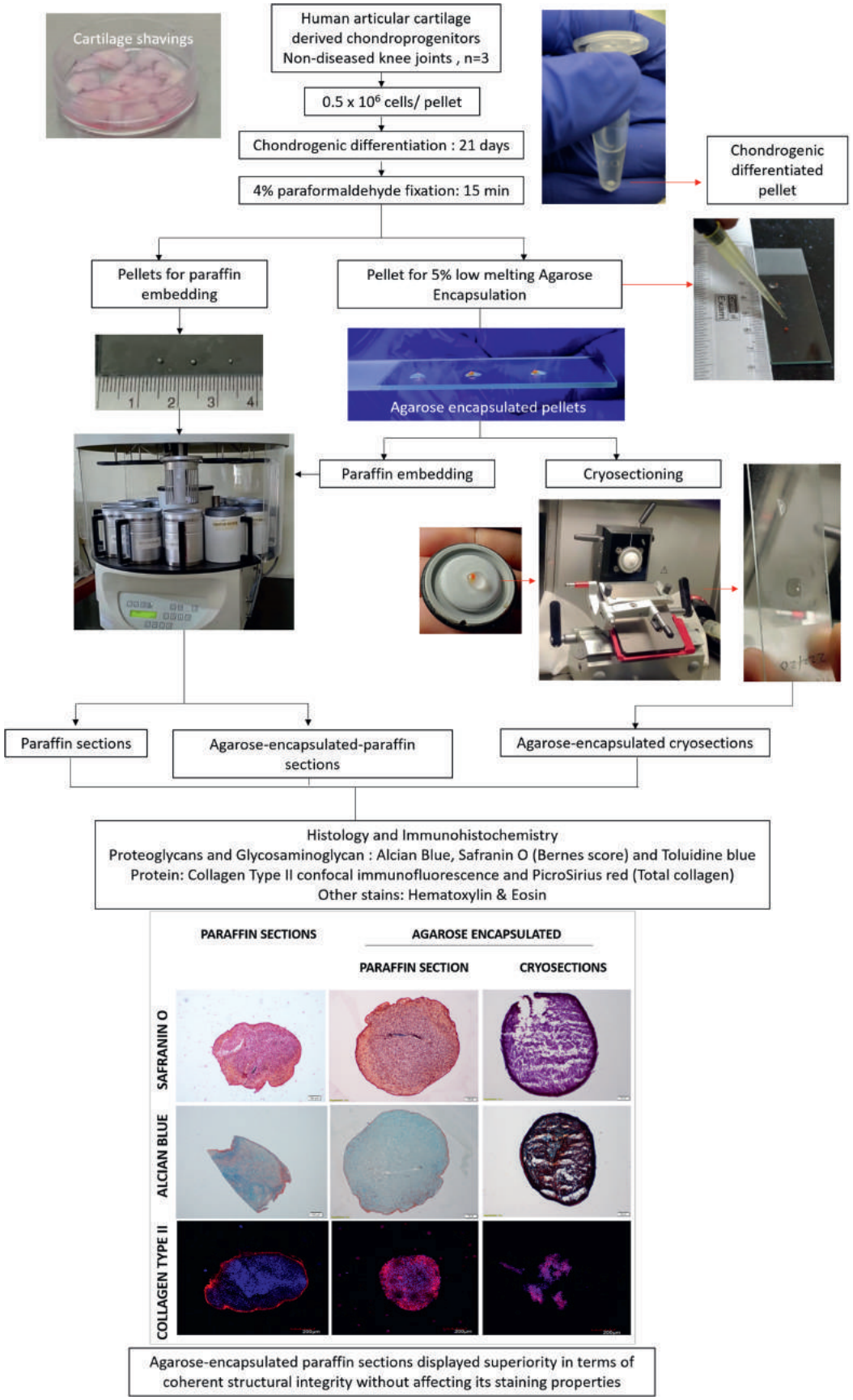

Fig. 1. Graphical abstract outlining the three groups used for comparison namely a) paraffin embedding, b) agarose-encapsulation followed by paraffin processing or c) agarose-encapsulation followed by cryosectioning. Samples were taken from three donors in each group. The isolated chondroprogenitors were subjected to chondrogenic differentiation in a pellet system followed by confirmatory staining for glycosaminoglycans (Safranin O and Alcian Blue), immunofluorescence for Collagen Type II and other stains (Toluidine blue, PicroSirius red and Hematoxylin & Eosin). Agarose-encapsulated paraffin sections displayed superiority in terms of coherent structural integrity without affecting its staining properties when compared to paraffin section. Cryosections of agarose-encapsulated pellets displayed poor uptake and fragmentation of sections.

chondrogenesis differentiation kits (A1007101, ThermoFischer Scientific) in accordance with the manufacturer's protocol. The medium was changed once every 3 days for a minimum period of 21 days.

2.5. Pellet processing

The pellets were washed in phosphate buffered solution and subjected to short fixation using 4% paraformaldehyde for 15 min. Following this they were subjected to either one of the following: a) paraffin embedding, b) agarose encapsulation followed by paraffin processing or c) agarose encapsulation followed by cryosectioning. The pellets were collected using a wide bore pipette tip and placed on clean glass slides. In order to ease identification of pellets during processing, a minimal amount of mercurochrome was applied.

2.6. Paraffin embedding

The pellets were carefully transferred from the slide to a tissue paper, which was folded and placed into a labelled plastic tissue cassette.

2.6.1. Agarose encapsulation

Freshly prepared 5% solution of low melting agarose (A9414, Sigma) using PBS solution was placed at 60 °C to maintain their liquified state. In order to encapsulate the pellet, 10 μl of agarose solution was pipetted directly on to the pellet center and placed on ice for 5 min to hasten solidification. The encapsulated pellets were either subjected to paraffin embedding as mentioned above or cryosectioning.

2.6.2. Paraffin processing

Standard tissue processing protocol was followed. In brief, cassettes were subjected to dehydration sequence in series of ethanol solution of increasing concentration (70%–100%) for 10 min each. Next, in order to ensure ethanol clearing, multiple changes with xylene were performed. This was followed by wax infiltration and paraffin embedding into mold cassettes. 4 μm sections were taken with the help of microtome on poly-L lysine (PLL) coated slides.

2.6.3. Cryosection

Agarose-encapsulated pellets were placed on precooled chucks and covered with optimal cutting temperature (OCT) embedding gel. 4 μm tissue section were taken on PLL slides and immediately stored at −20 °C.

2.7. Staining

2.7.1. Alcian Blue staining

Alcian staining was conducted according to routine protocols. In brief, sections were washed and stained with Alcian Blue pH:2.5 (Cat no: J60122, Alfa Aesar, US) for 15 min and counterstained with neutral red for 1 min.

2.7.2. Safranin O fast green staining

The sections were stained with Wiegert's Iron Hematoxylin working for 10 min, washed, and dipped in 1% acid alcohol followed by 0.01% fast green solution for 3 min. After draining the slides 1% acetic acid was added for 30 s and 0.1% Safranin O for 5 min. This was followed by dehydration with series of graded alcohol and clearing in xylene.

2.7.3. Toluidine blue staining

The sections were stained with 0.1% Toluidine blue (C·I No-52040 Qualigens) solution for 5 min, washed, and dipped in 95% alcohol. This was followed by dehydration with series of graded alcohol and clearing in xylene.

2.7.4. Picrosirius red staining

The sections were hydrated, stained with 0.1% Picro-sirius red (C·I.35,782) for 1 h and counter stained with Hematoxylin for 7 min. The sections were washed and mounted prior to imaging.

2.8. Other stains

2.8.1. Hematoxylin & Eosin staining

The sections were hydrated and treated with Hematoxylin for 8 min, washed and dipped in 1% acid alcohol and lithium carbonate for bluing. This was followed by staining with Eosin for 1min, dehydration, clearing and mounting.

2.9. Immunofluorescence (IF) staining

a) IF for paraffin sections and agarose-encapsulated-paraffin sections

Slides were kept at 65 °C for overnight incubation. Following treatment with xylene, the pellets were hydrated with descending grades of alcohol (100%–70%). The sections were washed with PBS and 0.1% PBST (0.1% TritonX100). For antigen retrieval treatment with 1 mg/ml pronase and 5 mg/ml hyaluronidase was performed at 37 °C for 30 min each. Following protein block [1% bovine serum albumin (BSA) and 6% FCS: 30 min], primary mouse monoclonal Anti-Collagen type II antibody [DSHB Hybridoma Product II-II6B3] at a concentration of 5 μg/ml was added (2% BSA in PBS) and incubated overnight at 4 °C. Next day, the slides were washed and treated with protein block solution (0.5% BSA and 3% FBS) for 5 min prior to secondary antibody IgG (H + L) highly cross-adsorbed Goat anti-Mouse, Alexa Fluor® 594, Invitrogen™ (Catalogue no: A11032, 1:100 dilution) for 30 min. Counterstaining was done with 10 μg/ml DAPI (Sigma) for 5 min and mounted with 90% glycerol.

b) IF for agarose-encapsulated cryosections

Slides were air dried for 30 min and treated with ice cold methanol for 10min. The slides were hydrated with descending grades of alcohol (100%–70%) and washed with PBS and 0.1% PBST (0.1% TritonX100). For antigen retrieval treatment with 1 mg/ml pronase and 5 mg/ml hyaluronidase was performed at 37 °C for 10 min each. Following protein block [1% bovine serum albumin (BSA) and 6% FCS: 10 min], primary mouse monoclonal Anti-Collagen type II antibody [DSHB Hybridoma Product II-II6B3] at a concentration of 5 μg/ml was added and incubated at 30min. The slides were washed and treated with protein block solution (0.5% BSA and 3% FBS) for 5 min prior to secondary antibody IgG (H + L) highly cross-adsorbed Goat anti-Mouse, Alexa Fluor® 594, Invitrogen™ (Catalogue no: A11032, 1:100 dilution) for 30 min. Counterstaining was done with 10 μg/ml DAPI (Sigma) for 5 min and mounted with 90% glycerol. All processed slides were imaged using FV1000 model Olympus laser scanning confocal microscopy.

2.10. Statistical analysis

One-way ANOVA with post hoc Bonferroni correction was applied to compare the Bern score between the groups. FACS data is presented as mean ± standard deviation. A P value of <0.05 was considered to be significant. Microsoft Excel, and IGOR Pro-Version 5.0.4.8 (Wave metrics Inc.) were used for analysis and graphical representation.

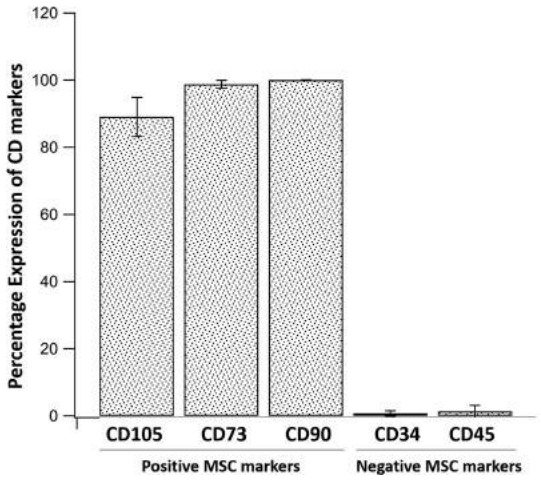

Fig. 2. Percentage expression of CD105, CD73, CD90, CD34 and CD45 of passage 3 chondroprogenitors. Data expressed as mean ± SD; n = 3. CD: Cluster of differentiation.

3. Results

3.1. Culture and FACS

Chondroprogenitors were isolated from three donors and subsequently culture expanded to passage 3. Following fibronectin adhesion assay, chondroprogenitors displayed clonality, achieving a population doubling of 5 by day 10. The polyclonal cultures showed favorable expansion in monolayer cultures. Analysis of FACS performed at P3 revealed high expression of CD105, CD73 and CD90 (positive MSC markers) and minimal expression of CD34, CD45 (Figs. 2 and 3).

3.2. Confirmatory staining following chondrogenic differentiation

Both paraffin and agarose-encapsulated-paraffin sections showed comparable glycosaminoglycan deposition as evidenced by Safranin O, Alcian blue, Toluidine blue, PicroSirius red (total collagen) (Fig. 4) and collagen type II uptake (Fig. 5, Fig. S1). With regard to handling the pellet during processing and sectioning, the agarose-encapsulated pellets were much easier in terms of cassette transfers and recovery for sectioning. Cryosections of agarose-encapsulated pellets displayed poor uptake of sulphated glycans with clumping of cells and fragmentation of sections. The Bern score of Safranin O fast green sections showed significantly higher

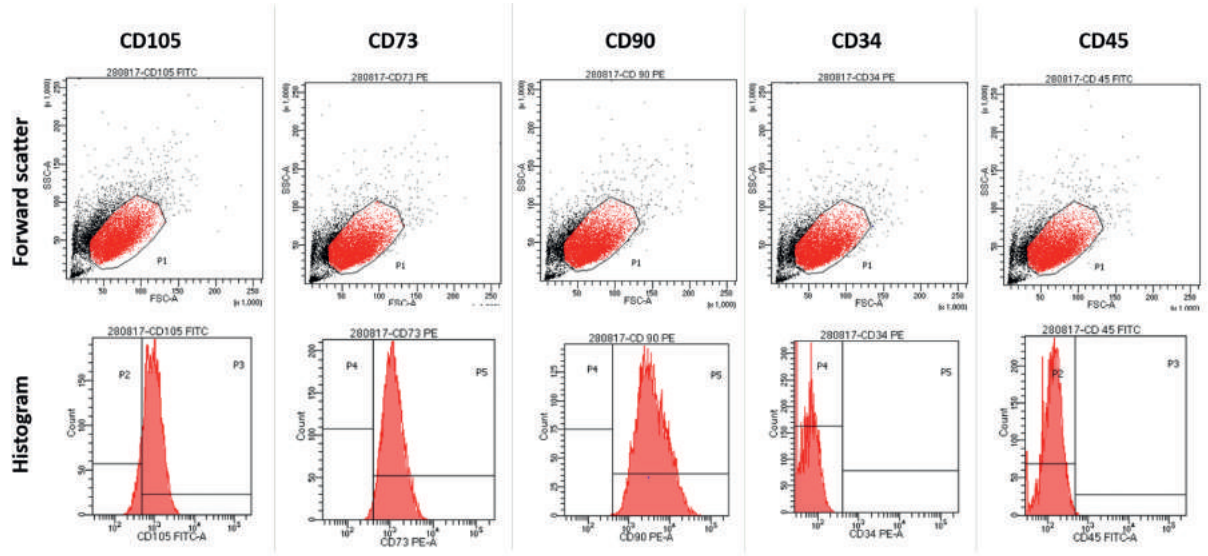

Fig. 3. Representative FACS graphs for the corresponding antibodies. Upper panel: Forward scatter-size plot, lower panel: histogram. CD: Cluster of differentiation.

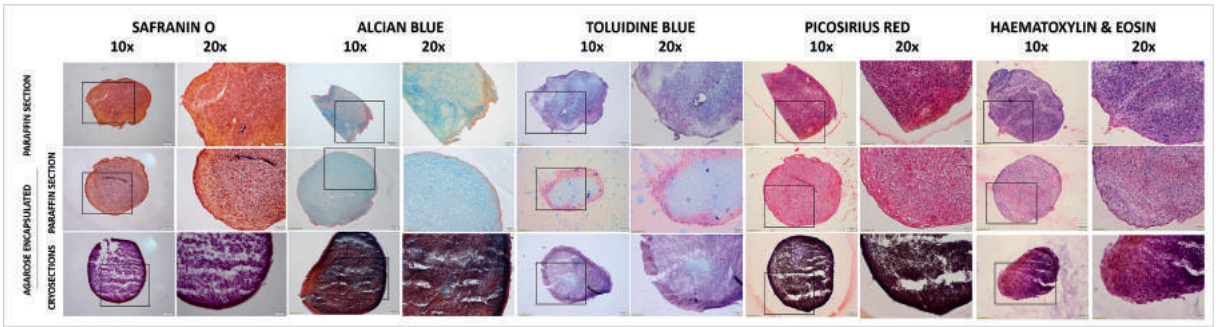

Fig. 4. Representative microscopic images of differentiated chondroprogenitor pellets subjected to Safranin O, Alcian Blue, Toluidine blue, PicroSirius red and Hematoxylin & Eosin staining following either a) paraffin embedding, b) agarose-encapsulation-paraffin processing or c) agarose-encapsulation cryosectioning. Magnification: 100X and 200X.

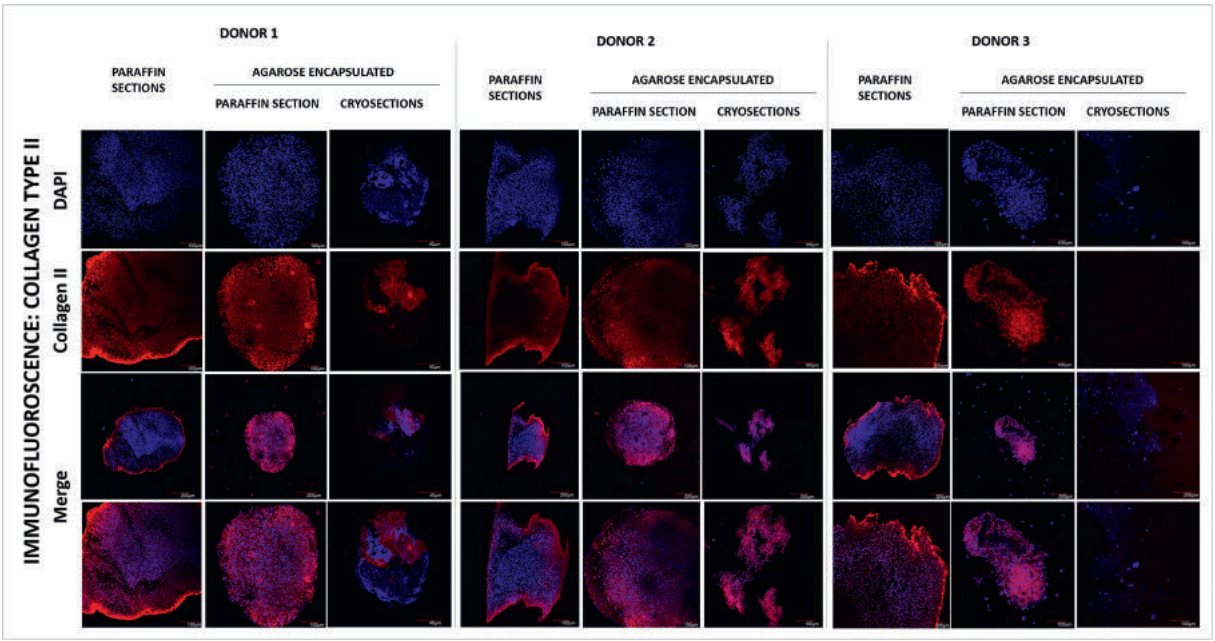

Fig. 5. Confocal images of Collagen II protein, indirectly labelled with secondary Alex Fluor 594 antibodies (red channel) and cell nuclei labelled with DAPI (blue channel). Study arm include pellets following either a) paraffin embedding, b) agarose-encapsulation-paraffin processing or c) agarose-encapsulation cryosectioning, n = 3. Magnification: Scale bar.

values in the paraffin section (5.7 ± 0.9) and agarose-encapsulated-paraffin section (6 ± 0.4) groups when compared to the cryosections (2.1 ± 0.2, $p < 0.01$) (Table 1). Regarding structural integrity of the sections, agarose encapsulation yielded the best morphology of the three groups.

4. Discussion

With regard to cell-based therapy utilization for cartilage repair and regeneration, histochemical analysis following three-dimensional pellet culture of the cell of interest, provides valuable information on cell-to-cell interaction and probable in-vivo behavior. Commonly used assessment parameters for comparison of pellet cultures include histological staining for glycosaminoglycans and immunohistochemical analysis for collagen type II content on intact pellets, among others. Common obstacles encountered include pellet handling/loss prior to paraffin embedding, shear-stress during sectioning leading to distorted contour and sub-optimal staining. Agarose encapsulation has been utilized for processing small sized tissue samples to overcome hurdles as mentioned before with no effect on staining properties. This is due to its neutral nature, high transparency, minimal adherence to tissue sample with easy detachability and scaffolding action which helps maintain morphological integrity of the processed sample.

Since there are no reports examining the effect of agarose encapsulation on pellet cultures being used for assessing

Table 1
Breakdown of Bern scoring by individual blinded observers for evaluation of Safranin O cartilaginous pellet. P: Peripheral area of pellet and C: Central area of pellet.

BERN SCORE: FOR THE EVALUATION OF SAFRANIN O–FAST GREEN STAINED CARTILAGINOUS PELLET CULTURES AND ENGINEERED TISSUE SECTIONS (MINIMUM SCORE: 0; MAXIMUM SCORE: 9)[18]						
Scoring categories: scores	Blinded observer 1			Blinded observer 2		
Uniformity and darkness of Safranin O–fast green stain	Paraffin	Agarose encapsulated		Paraffin	Agarose encapsulated	
a) No stain: 0		Paraffin	Cryosection		Paraffin	Cryosection
b)Weak staining of poorly formed matrix: 1	P:2, C:1	P:2, C:1	P:1, C:0	P:2, C:1	P:1, C:0	P:0, C:0
c)Moderately even staining: 2	P:2, C:1	P:2, C:1	P:1, C:0	P:2, C:1	P:1, C:0	P:0, C:0
d) Even dark stain: 3	P:3, C:1	P:2, C:1	P:1, C:0	P:2, C:1	P:1, C:0	P:0, C:0
Distance between cells/amount of matrix accumulated a) High cell densities with no matrix in	P:3, C:1	P:2, C:2	P:1, C:0	P:2, C:0	P:1, C:0	P:0, C:0
between (no spacing between cells): 0	P:2, C:1	P:3, C:2	P:1, C:0	P:2, C:0	P:2, C:0	P:0, C:0
	P:3, C:2	P:3, C:2	P:1, C:0	P:2, C:0	P:2, C:0	P:0, C:0
b) High cell densities with little matrix in between (cells <1 cell-size apart):1						
c) Moderate cell density with matrix (cells approx. 1cell-size apart): 2						
Low cell density with moderate distance between cells (>1 cell) and an extensive matrix: 3						
Cell morphologies represented a) Condensed/necrotic/pycnotic bodies: 0	P:3, C:3	P:3, C:3	P:1, C:1	P:3, C:3	P:3, C:3	P:3, C:3
	P:3, C:3	P:3, C:3	P:1, C:1	P:3, C:3	P:3, C:3	P:3, C:3
b) Spindle/fibrous: 1	P:3, C:3	P:3, C:3	P:1, C:0	P:3, C:3	P:3, C:3	P:3, C:3
c) Mixed spindle/fibrous with rounded chondrogenic morphology: 2						
d) Majority rounded/chondrogenic: 3						
Grade= Sum*Percentage of area represented	6.35 ± 1.26	7.2 ± 0.35	1.13 ± 0.46	5.1 ± 0.61	4.8 ± 0.52	3
Combined Scores	**Paraffin section: 5.7 ± 0.9**					
	Agarose encapsulated paraffin sections: 6 ± 0.4					
	Agarose encapsulated cryosections: 2.1 ± 0.2					

chondrogenic differentiation, this study involved comparison of agarose encapsulated pellets (followed by routine paraffin embedding) with those following standard processing techniques. Additionally, agarose-encapsulated pellets were subjected to cryosectioning and evaluated. It was observed that encapsulated pellets were much easier to handle and identify prior to and during sectioning. With respect to staining and structural integrity, comparable uptake was seen in both paraffin sections and agarose embedded sections while the latter exhibited notably uniform pellets with distinct marginal demarcation. Although paraffin sections and agarose encapsulated sections demonstrated equivalent staining as represented by comparable Bern scores (Safranin O), Alcian Blue uptake and Collagen type II deposition, the cryosections exhibited significantly poor staining properties. Moreover, the friable nature of the cryosection caused handling difficulties prior to processing and marked fragmentation of the pellet.

This is the first study to evaluate addition of agarose encapsulation prior to routine processing of chondrogenically differentiated progenitor pellets, with results pointing to ease in handling and reduced structural distortion. A noteworthy observation to optimize agarose encapsulation and subsequent processing is to trim excess scaffold to ensure uniform embedding and retention of a thin agarose margin. This quick, cost effective technique can be included as a component of routine processing of pellets to obtain optimal results during histological processing and analysis, thereby yielding vital information, applicable for translational research in cartilage tissue engineering.

Credit author statement

Soosai Manickam Amirtham: design of study, data curation and analysis, validation of data, writing, final approval of the manuscript. Upasana Kachroo, design of study, data curation and analysis, validation of data, writing, final approval of the manuscript. Deepak Vinod Francis: formal analysis, validation of data, writing, final approval of manuscript. Kawin Padmaja, formal analysis, validation of data, Writing, Final approval of manuscript. Elizabeth Vinod: design of study, data curation and analysis, validation of data, writing, acquisition of funds, final approval of the manuscript.

Declaration of competing interest

The author(s) declare(s) that there is no conflict of interest.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jajs.2021.05.005.

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Research paper

The contact pressure of ultra-high-molecular-weight polyethylene cables is twice as high as that of titanium cables

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ABSTRACT

Background: Metal cables exhibit favorable clinical performance because of their high fixing force. Cables composed of ultra-high-molecular-weight polyethylene (UHMWPE) are relatively new and were first used for trauma around 2010; only a few cases involving the use of UHMWPE cables have been reported. Surgeons need to know whether the fixing force of UHMWPE cables is higher or lower than that of metal cables. This study aims to compare the fixing forces of UHMWPE cables and a titanium cable using the contact pressure as an index.
Method: We studied UHMWPE cables with widths of 3 mm and 5 mm and a titanium cable. A thin pressure sensor was set on the femoral diaphysis, and the cables were wrapped on simulated tissues and tightened with clamping forces based on the indication values displayed on the tensioner of each cable. During osteosynthesis, tissues can remain unremoved depending on the fracture site and procedure. *Sus scrofa* domesticus thigh tissues with thicknesses of 2 mm and 5 mm were prepared for simulating tissues, and the contact pressures in cases with and without tissues were compared.
Results: When no tissues were remained, the contact pressure of the titanium cable with a clamping force of 50 kgf was equal to that of the UHMWPE cables with a clamping force of 30 kgf. When tissues were remained, the contact pressure of the titanium cable with a clamping force of 50 kgf was twice as high as that of the UHMWPE cables with a clamping force of 30 kgf.
Conclusion: It was revealed that the contact pressure of UHMWPE cables clamped with the maximum force was twice as high as that of metal cables. This result is expected to contribute toward the selection of cables according to a desired clamping force.

1. Introduction

Internal fixation during osteosynthesis is expected to provide the local fixation of fracture sites and is also required to maintain natural musculoskeletal mobility. Cerclage cables used for internal fixation must meet these apparently contradictory conditions. Cerclage cables are an important auxiliary means for fixation and are widely used for subtrochanteric fractures, fractures around implants, and other orthopedic disorders.[1–6] The medical materials approved and sold are mainly pure titanium, titanium alloy, titanium-niobium alloy, stainless steel, cobalt-chromium alloy, polyethylene-telephthalate, and ultra-high-molecular-weight polyethylene (UHMWPE), which are roughly classified as metal and resin materials.

Because the clamping technique used varies among the materials, they are selected based on the preference of surgeons and correspond to the merits and demerits for patients. Metal cables have been a mainstream tool for osteosynthesis, and many biomechanical studies on metal cables have been reported.[7–9] The merit of metal cables is that sufficient pressure can be loaded onto the fractured part.[10] However, cases involving delayed union when

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using a metal cable have been reported.[11,12] There exists a lack of consensus regarding the use and benefits of metal cables among orthopedic and trauma surgeons.

In recent years, UHMWPE cables have drawn attention because they are easier to handle and more flexible than metal cables. UHMWPE cables are superior to metal cables because they do not evoke metal-induced inflammation. UHMWPE cables are non-stretchable and undergo negligible local stress concentration because their wide surface is used for fixation.[13] In addition, UHMWPE cables have the properties of being non-absorbent and radiolucent (causing no metal artifacts) and are easy to temporarily fix and retighten. Although studies on animals have confirmed the safety of these cables,[14] only a few comparisons of the clamping forces of UHMWPE cables and metal cables have been reported.

It is necessary for surgeons to know whether the clamping force of UHMWPE cables is higher or lower than that of metal cables. Tensioners dedicated to each cable have a clamping-force indicator. Surgeons perform clamping based on this indicator. However, as the clamping mechanism varies depending on the cable, the same indication value can correspond to different clamping forces. Therefore, this report is expected to help surgeons select the indication values displayed on tensioners. This study aims to compare the fixing forces of UHMWPE cables and a titanium cable using the contact pressure as an index. When a cable is clamped, the surrounding tissues are removed with forceps but can still remain unremoved. In this study, simulated tissues were used, and the contact pressure at the femoral diaphysis was measured based on the assumption of a fracture of the distal stem. Thus far, biomechanical studies have not reported the results of contact pressure measurements with tissues.

2. Materials and methods

This study did not involve humans and did not require IRB approval. UHMWPE cables (NESPLON® cable system, Alfresa Pharma Corporation, Japan) with widths of 3 and 5 mm and a titanium cable with a diameter of 1.8 mm (AI wiring system, Aimedic MMT Co., Ltd., Japan) were used. A femur simulating the human anatomical shape (Sawbones #3403, Pacific Research Laboratories, Inc., WA, USA) was used to tighten the femoral diaphysis with each cable. During osteosynthesis, the tissue may remain dependent on the fracture region and surgical procedure. To simulate tissue, the femoral regions of *Sus scrofa* domesticus with thicknesses of 2 and 5 mm were prepared. Furthermore, the cases with and without tissue were compared.

A thin pressure sensor of the contact pressure distribution measurement system (I-SCAN, NITTA Corporation, Japan) was set on the femoral diaphysis, which was wrapped on the tissue and tightened using the tensioner of each cable (Fig. 1). The system detects contact pressures of 0.1 MPa–5.0 MPa with a conductive ink set at the sensor site, which is 50 mm in length, 50 mm in width, and 0.1 mm in thickness. When pressure is applied to the sensing points, the electrical resistance changes; it is converted from analog to digital and input into a personal computer.

The UHMWPE cable was fastened using a knot and retightening with a tightening gun. The UHMWPE cables were gradually tightened with forces of 10, 20, and 30 kgf and fastened with a maximum value of the clamping force indicator of 30 kgf. A state with the tightening gun removed is regarded as released, based on the assumption of being indwelled in the body, in clinical cases.

The titanium cable was pulled left and right using a cable tensioner and fastened by crushing the sleeve using a crimper. The clamping force indicator values for the cable tensioner of the titanium cable were 10, 20, 30, 40, and 50 kgf. To align the conditions with those when clamping the UHMWPE cables, the titanium cable

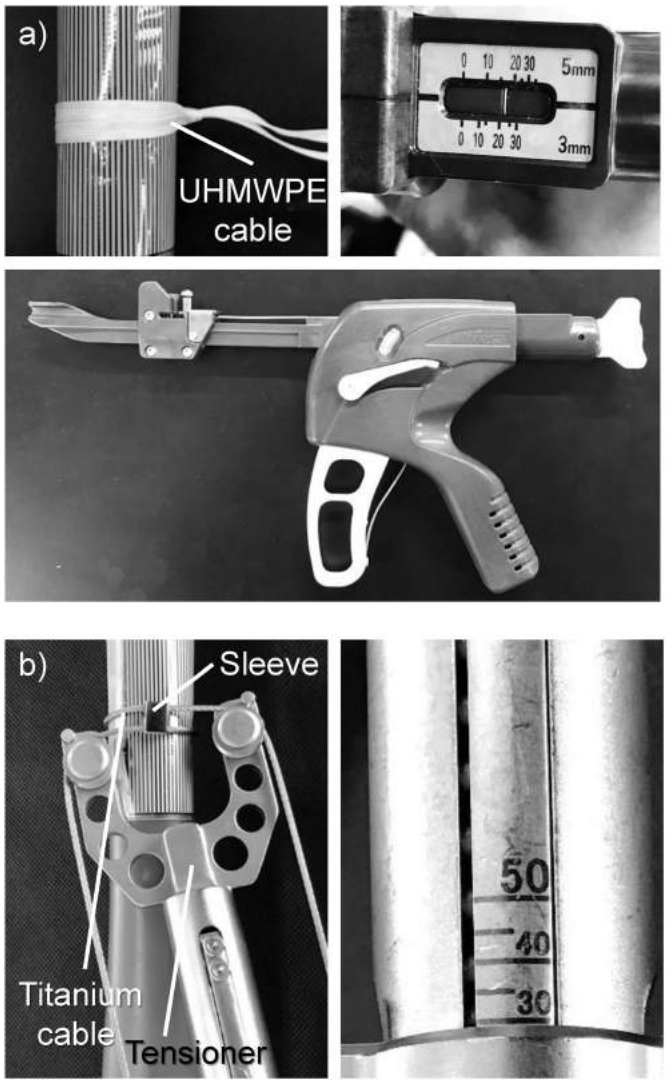

Fig. 1. Cables and their fixations. a) An UHMWPE cable (Right), the clamping force indicator (Left), and the tensioner (Bottom). b) A titanium cable and tensioners (Right) and the clamping force indicator (Left).

was gradually tightened with forces of 10, 20, and 30 kgf; fastened with a maximum value of the clamping force indicator, 50 kgf; and then released (Fig. 2).

The contact detection pressure and contact detection cell count were displayed from the acquired contact pressure distribution, and the contact area was calculated from the sensor area. Because the contact pressure in the sleeve and knot increased for each cable, the clamping region was excluded from data processing.

3. Results

The contact pressure of the UHMWPE cables, which had widths of 3 mm and 5 mm and were clamped with different forces, increased as the clamping force increased (Fig. 3). It was revealed that, as the tissue was thicker, the contact pressure of the titanium cable did not increase with the indication value of clamping force displayed on the fastener and that linearity could not be maintained. It was clarified that, when tissues were remained, the contact pressure of the titanium cable with a clamping force of 50 kgf was as high as or lower than that of the UHMWPE cables

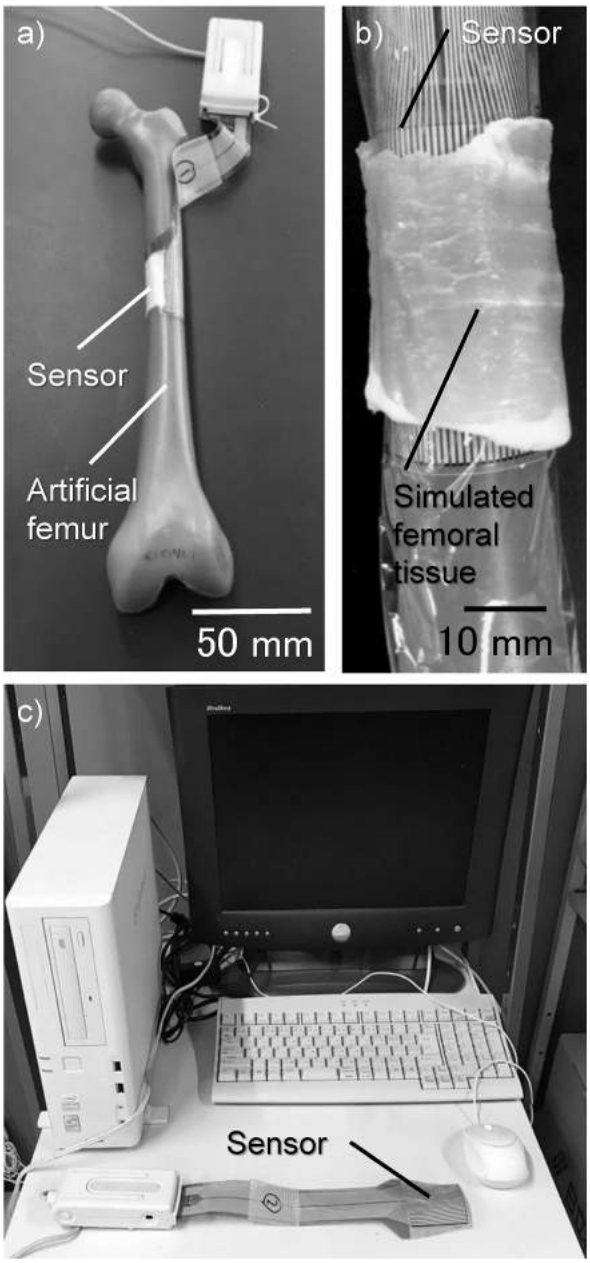

Fig. 2. Materials and systems. a) A sensor sheet on an artificial femur without tissue. b) Simulated femoral tissue wrapped around an artificial femoral diaphysis. c) Pressure distribution analysis system.

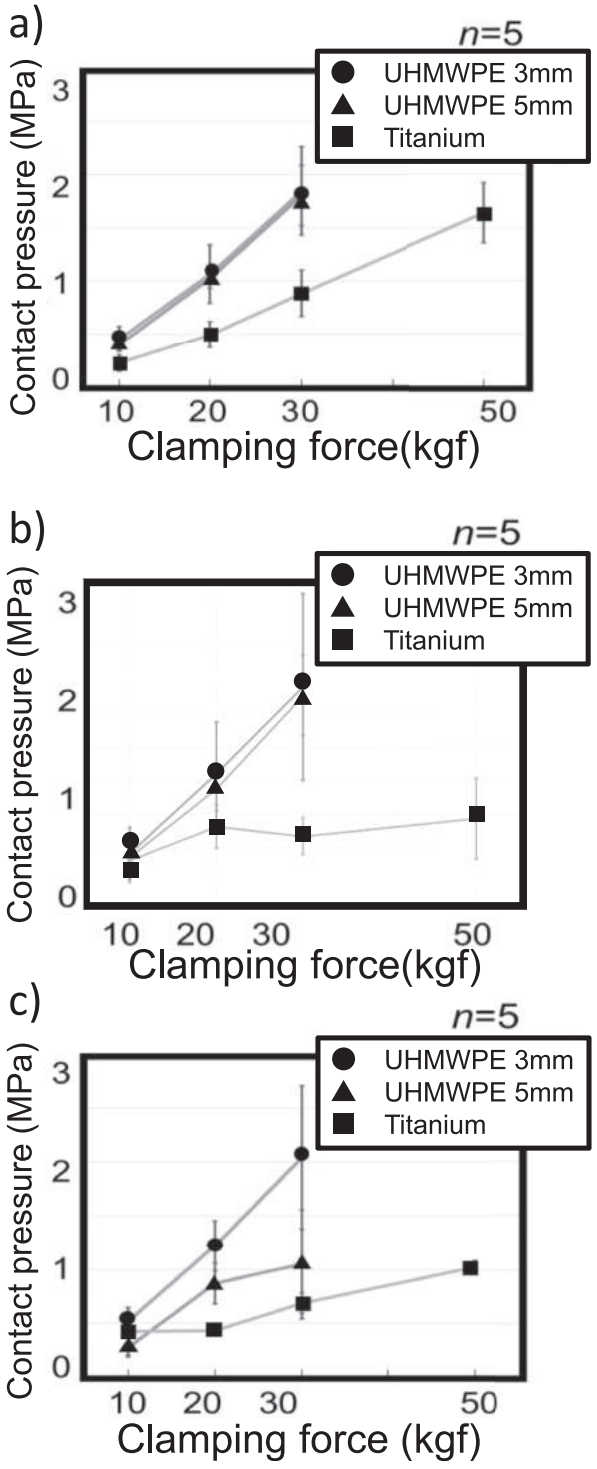

Fig. 3. Contact pressure at each clamping force. a) Without tissue. b) Tissue 2-mm thick. c) Tissue 5-mm thick.

with a clamping force of 20 kgf. When no tissues were remained, the contact pressure of the titanium cable with a clamping force of 50 kgf was equal to that of the UHMWPE cables with a clamping force of 30 kgf. It was confirmed that, with a significance level of 5%, no significant difference was noted in the contact pressures after release between the titanium cable and the UHMWPE cables, although they had different maximum clamping forces of 50 kgf and 30 kgf, respectively.

The contact pressure distributions of the UHMWPE cables showed that the UHMWPE cable with a width of 5 mm had a larger contact area than the UHMWPE cable with a width of 3 mm (Fig. 4). It was revealed that the number of contact sites increased with an increase in the clamping force, independent of the presence or thickness of tissues, and that the UHMWPE cables with a clamping force of 30 kgf had a large contact area. The contact pressure distribution of the titanium cable showed that the contact area increased with an increase in the clamping force, independent of the presence or thickness of the tissues (Fig. 5). The titanium cable exhibited a smaller contact area than the UHMWPE cables. With a significance level of 5%, a significant difference was noted in the contact areas after release between the titanium cable and the

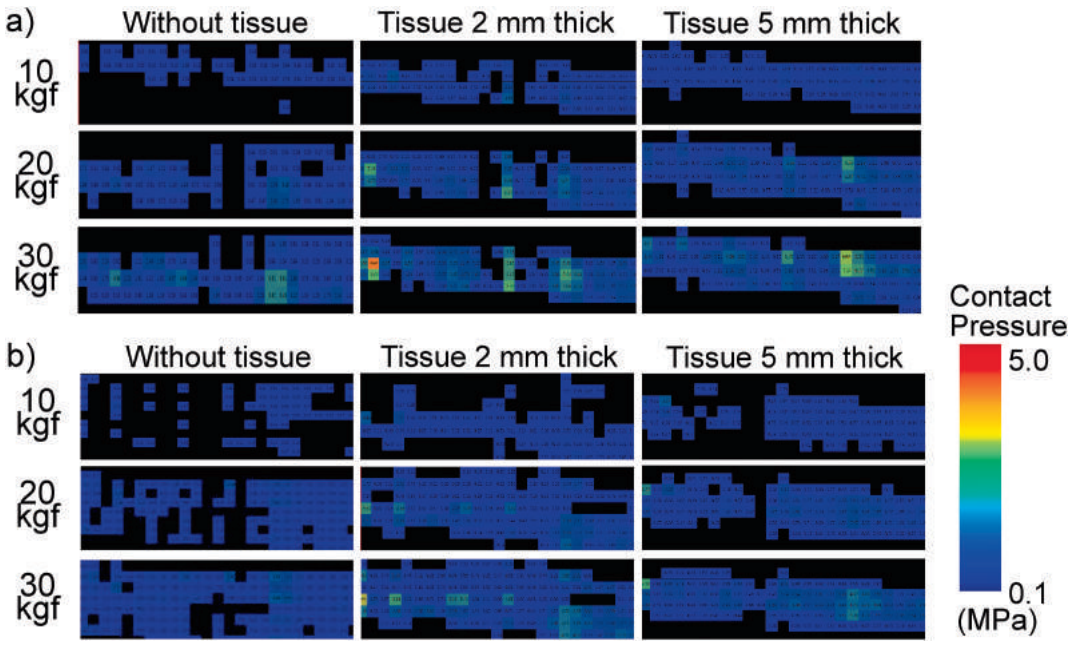

Fig. 4. Pressure distribution of UHMWPE cables. Top of the vertical direction is the proximal femur direction. Bottom of the vertical direction is the distal femur direction. Horizontal axis is the circumferential direction of the femur. a) 3-mm wide. b) 5-mm wide.

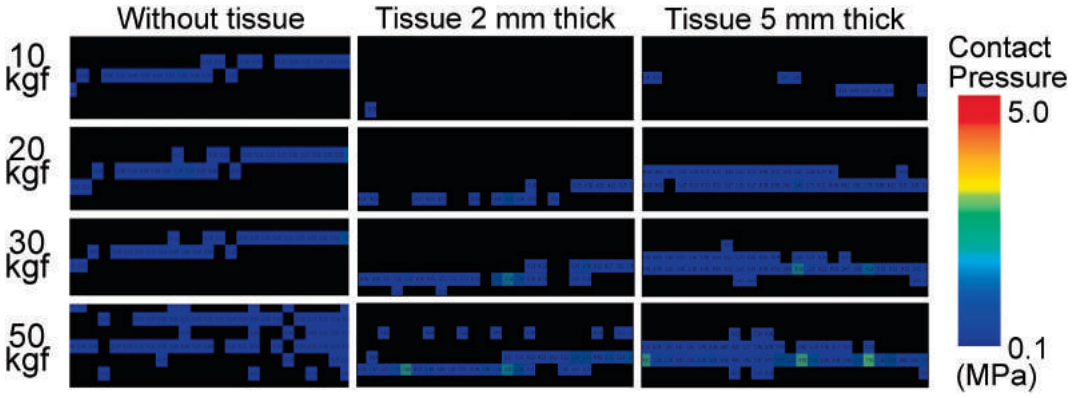

Fig. 5. Pressure distribution of a titanium cable. Top of the vertical direction is the proximal femur direction. Bottom of the vertical direction is the distal femur direction. Horizontal axis is the circumferential direction of the femur.

UHMWPE cables with widths of 3 mm and 5 mm, under all the conditions considered (Fig. 6). The titanium cable showed a smaller contact area than the UHMWPE cables with widths of 3 mm and 5 mm, independent of the tissue thickness.

4. Discussion

Biomechanical studies have reported that metal cables have a high fixing force.[15] It is important for surgeons to know whether the fixing force of UHMWPE cables is higher or lower than that of metal cables. UHMWPE cables are relatively new and were first used for trauma around 2010; only a few cases involving the use of UHMWPE cables have been reported5. The results of this study are expected to help in selecting indication values displayed on tightening guns.

Surgeons frequently clamp a UHMWPE cable with a force of 30 kgf in order to affix the cable. The clamping of UHMWPE cables with a force of 30 kgf corresponds to clamping with a contact pressure of 2 MPa, which is three times that of metal cables depending on the thickness of tissues. A pressure of 2 MPa is equivalent to 15,000 mmHg, which is high for living bodies. It is feared that clamping UHMWPE cables with a force of 30 kgf may cause blood circulation disorders9. The clamping of UHMWPE cables with a force of 20 kgf will provide the same fixing force as the clamping of titanium cables with 50 kgf, provided as much tissue as possible is removed using forceps.

Titanium cables have a higher maximum indication value at 50 kgf than UHMWPE cables. Titanium cables have a smaller diameter (1.8 mm) and thus should show a higher indication value than UHMWPE cables. The low contact pressure of the titanium cable was attributed to the loss of clamping force caused by the sleeve rotation after release. Many cases of a decrease in clamping force owing to sleeve rotation have been reported.[7,16] In theory, UHMWPE cables with a width of 3 mm should have a higher contact pressure than UHMWPE cables with a width of 5 mm. As the UHMWPE cable with a width of 3 mm had a higher contact pressure

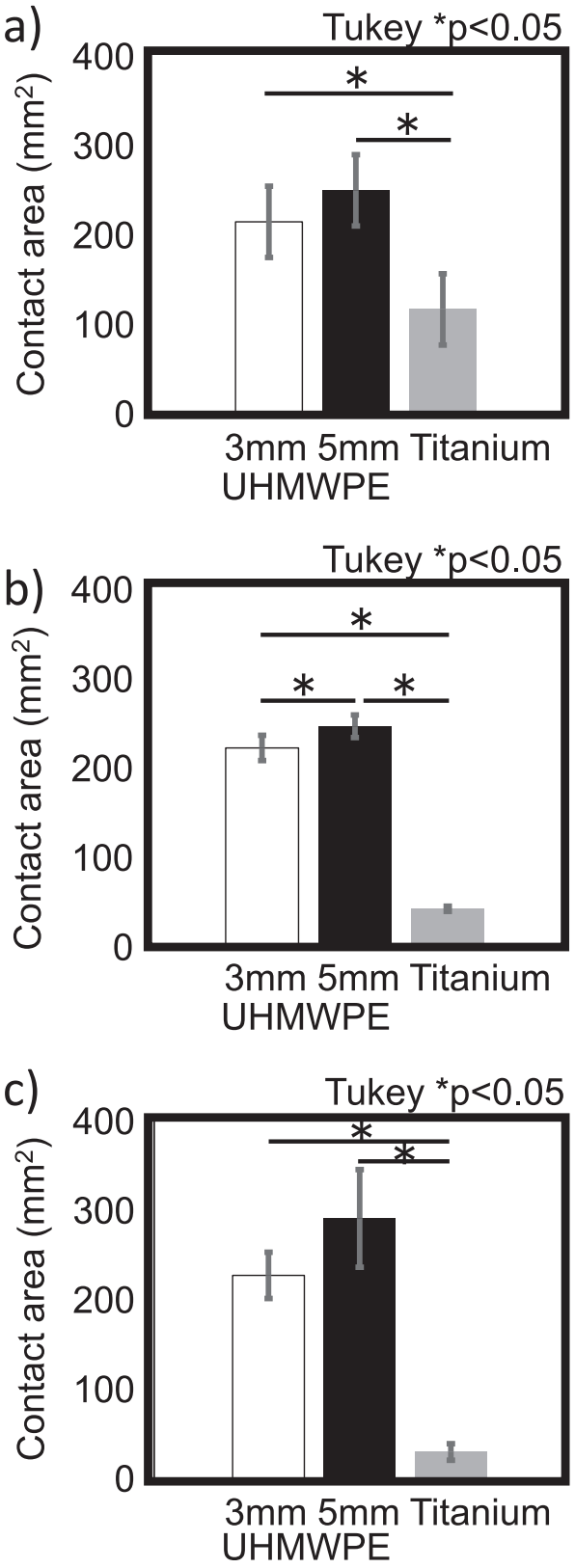

Fig. 6. Contact area after release of cables. a) Without tissue. b) Tissue 2-mm thick. c) Tissue 5-mm thick.

than the UHMWPE cable with a width of 5 mm, although no significant difference was noted, and the result was judged to be valid. As there is no difference in contact pressures when using UHMWPE cables with widths of 3 mm and 5 mm, operators can select UHMWPE cables based on their preferences.

Regarding limitations, linea aspera was excluded from the target of data processing because it overlapped with the clamping region; however, as linea aspera shows a characteristic shape in the femoral diaphysis, the inclusion of this region in the target area would have clarified more anatomical characteristics of the contact pressure distribution. The simulated femur was a model with the linea aspera shaped as an almost smooth circle. However, if a cadaver with marked linea aspera is used, the characteristics of the diaphysis may be reflected in the data. The area simply reflected the width and diameter of the cable, whereas it might be difficult to compare the contact pressure because the clamping force after release differed and the clamping system was also different.

5. Conclusions

When no tissues were used, the contact pressure of the titanium cable clamped with a force of 50 kgf was equal to that of UHMWPE cables clamped with a force of 30 kgf. When tissues are used, the contact pressure of UHMWPE cables clamped with the maximum force is twice as high as that of metal cables, and this solid fixation is maintained even after release. As there is no major difference in the contact pressures when using UHMWPE cables with widths of 3 mm and 5 mm, operators can select UHMWPE cables based on their preferences.

Declaration of competing interest

This study was funded by Alfresa Pharma Corporation (Osaka, Japan). The study sponsors did not have any involvement in the study design or collection, analyzing, or interpretation of data; in the writing of the manuscript; or in the decision to submit the manuscript for publication.

The contact pressure of ultra-high-molecular-weight polyethylene cables is twice as high as that of titanium cables

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Research paper

Comparison of combined adductor canal block with peri-hamstring infiltration versus adductor canal block for postoperative analgesia in arthroscopic anterior cruciate ligament reconstruction surgery

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ABSTRACT

Background: Pain after anterior cruciate ligament reconstruction (ACLR) can be attributed to both arthroscopic surgery and graft - donor site. Conventionally used techniques of peripheral nerve blockade may not provide complete analgesia to graft - donor site. Moreover, femoral nerve blockade is known to cause quadriceps strength deficit. The purpose of this study was to evaluate whether addition of peri-hamstring infiltration to adductor canal block can lead to better analgesia after surgery than block alone.
Methods: 60 ASA grade I & II patients scheduled for anterior cruciate ligament reconstruction surgery using ipsilateral hamstring autograft under subarachnoid block were randomly distributed into 2 groups to receive postoperatively either adductor canal block alone (group A) or peri-hamstring infiltration along with adductor canal block (group AH). Adductor canal block was given in both the groups using 15 ml of 0.5% ropivacaine with 1:200000 adrenaline. Patients in Group AH received additional 20 ml 0.5% ropivacaine with 1:200000 adrenaline at hamstring donor site. Postoperative pain on Visual Analogue Score (VAS) at various time intervals, time to first rescue analgesic requirement, cumulative analgesic requirement over 24 h, quadriceps strength, adverse effects and patient satisfaction were recorded.
Results: Statistically significant difference in mean VAS score (resting & dynamic) was observed in both the groups at 8 and 12 h (p value < 0.001). Time to first rescue analgesic was longer in group AH (11.47 ± 2.92hrs) compared to group A (8.13 ± 1.28hrs). Cumulative ketorolac requirement was lower in group AH (34 ± 18.86 mg) in contrast to group A (49 ± 20.06 mg). Quadriceps strength was comparable in both the groups and no major complications were observed in either group. However, patient satisfaction measured by Numeric Rating Scale (NRS) was much better in group AH.
Conclusion: Peri-Hamstring infiltration of local anaesthetic along with adductor canal block is better than adductor canal block alone at allaying postoperative pain due to hamstring autograft.

1. Introduction

Anterior cruciate ligament (ACL) injury is the commonest athletic injury.[1] ACL reconstruction, performed on outpatient basis is second most common orthopedic surgery performed.[2] ACL reconstruction (ACLR) is generally performed on ambulatory basis using ipsilateral hamstring - gracillis/patellar tendon graft. Postoperatively pain from the donor-site and anterior knee due to surgery can lead to decreased range of motion, poor rehabilitation and recovery with delayed discharge. This postoperative pain, if not treated adequately may lead to chronic pain.[3] Hence, effective pain management is crucial for success of such fast-track surgeries to optimize functional recovery and improved patient satisfaction.[4]

Till date, numerous analgesic techniques have been investigated for ACLR such as parenteral opioids, peripheral nerve blocks as single injection or continuous catheter technique, peri-articular and intra articular local instillation of analgesia (LIA).[5,6,7] Consensus regarding any gold standard modality is still lacking.[8] Opioids lead to many side effects (nausea,

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vomiting,dizziness,vertigo) which may cause delayed discharge after outpatient surgery.

Femoral nerve block has been a well documented analgesic modality for postoperative analgesia after ACLR since many years. However, it is frequently associated with quadriceps strength deficit causing delayed mobilization.[9]

Adductor canal block (ACB), has been evaluated as an attractive alternative analgesic technique for knee surgeries.[10] It is predominantly a sensory block of saphenous nerve, and preserves quadriceps muscle strength, which helps protect against falls and facilitates early mobilization.[11] Hamstring -gracillis tendon is taken as a graft for ACLR. Adductor canal blockade does not provide analgesia for this graft-donor site.[12] Sciatic nerve blockade is another option for postoperative analgesia of hamstrings and posterior thigh after ACLR surgery. Sciatic nerve block is cumbersome to perform, requires expertise and is too invasive for an outpatient surgery.

Hamstring donor site injection involving deposition of local anaesthetic around hamstring tendon using sleeve of arthroscopic shaver blade constitutes a simple and useful treatment option. Perihamstring LIA has been reported to be more effective than placebo or femoral nerve block.[13] However, its role in combination with adductor canal block for postoperative analgesia in patients undergoing ACLR with ipsilateral hamstring autograft has not been investigated till date.We hypothesized that adductor canal block combined with hamstring donor site block would be more effective than adductor canal block alone with regard to post operative analgesia, especially of the donor site after ACLR surgery with ipsilateral hamstring autograft.

Therefore, we conducted this prospective randomized study comparing combined adductor canal block and hamstring donor site block versus adductor canal block alone to assess the quality of postoperative analgesia provided by both the techniques. The primary outcome criteria was post operative pain assessment on visual analogue scale at 8 h while secondary outcomes included time for rescue analgesia, cumulative analgesia required over 24 h, complications associated with the procedures, quadriceps muscle power post surgery and patient satisfaction in terms of pain relief.

2. Methods

The proposed study was conducted, in Sports Injury Centre of a tertiary care Hospital and a Teaching Institute after obtaining clearance from the hospital ethics committee over three months period (Dec 2019–Feb 2020). Sixty patients of either sex in the age group 18–60 yr belonging to American Socitey of Anesthesiologists (ASA) grades I and II scheduled for unilateral ACLR surgery using hamstring graft under subarachnoid block (SAB), were included after taking informed consent from all the participants. Patients with history of allergy to local anaesthetics, cardiopulmonary disorder, coagulopathy or on anticoagulant therapy, with local site infection, body mass index (BMI) > 30 kg/m^2 and unable to understand visual analogue scale (VAS) were excluded from the study.

Participants were randomly allocated into 2 groups with 30 patients in each group according to computer generated block randomization technique. In this technique, patients were randomized in a series of blocks of ten. Label 'A' represented group receiving Adductor Canal block and the label 'AH' represented group receiving Adductor Canal with perihamstring infiltration group. A randomly generated sequence of 10 treatment allocations (5 each of A and AH) were concealed within sequentially numbered sealed 10 opaque envelopes. Once a patient consented to enter a trial, an envelope was opened and the patient was then offered the allocated group.

Group A (n= 30): Patients received adductor canal block postoperatively with 15 ml 0.5% ropivacaine with 1:200000 adrenaline.

Group AH (n=30): Patient received adductor canal block postoperatively with 15 ml 0.5% ropivacaine with 1:200000 adrenaline along with local instillation of 20 ml 0.5% ropivacaine with 1:200000 adrenaline in hamstring donor site.

All patients underwent detailed pre-anaesthetic check-up and were kept fasting overnight. Patients were explained about the advantages and side effects of both the techniques and were explained about the use of visual analogue scale (0–10). All Patients were given Tab Alprazolam 0.5 mg, at night and 2 hours prior to surgery.

After shifting to operating room, standard monitors including ECG, non invasive blood pressure (NIBP), pulse oximeter (SpO_2) were attached and baseline parameters [Heart rate, BP, SpO_2, respiratory rate] were noted in all patients. Under all aseptic precaution, Subarachnoid block (SAB) was given in lateral position at L3-L4 intervertebral space. 2.2 ml of 0.5% bupivacaine (H) was given after confirming free flow of cerebrospinal fluid. Adequacy and level of block was confirmed. Oxygen was given by Venturi mask at 6l/min. Vitals were monitored throughout the surgery.

After completion of surgery, ACB was performed in both treatment groups: Group A and AH under ultrasound guidance using a high frequency linear probe (6–13 MHZ Imagic agile, Peachtree, Georgia 38 mm). Patient was placed in supine position with operated limb externally rotated and with slight flexion at knee. Under aseptic precautions, probe was placed transversely on medial aspect of midthigh; midway between ASIS and base of patella. Sartorius muscle, femoral artery and femoral vein were identified to localize adductor canal. The saphenous nerve was identified as hyperechoic structure lateral to femoral artery. A 5 mm 22g G B Braun needle was inserted in plane from lateral to medial direction, thereafter, 15 ml 0.5% ropivacaine with 1:200000 adrenaline was injected in close proximity to saphenous nerve just lateral to femoral artery after negative aspiration and excluding pain or resistance on injection. In addition in Group AH, 15 ml of 0.5% ropivacaine with 1:200000 adrenaline was injected by a surgeon at the end of surgical procedure with knee in 45° flexion. The injection was performed using arthroscopic sleeve just before deflation of tourniquet. A 20 ml syringe loaded with study drug was attached to sleeve and assembly was guided carefully towards the pes anserinus into the donor site wound. Local anaesthetic was injected through sleeve as a single bolus. Sartorius fascia and skin closure were done in standard fashion to prevent leakage of anaesthetic solution. The donor site infiltration as well as adductor canal block were performed by experienced persons.

Postoperative pain (at rest) and dynamic pain score during 45° active knee flexion were evaluated at 0, 2, 4, 8, 12, 24 hours from the completion of surgery using a Visual Analogue Scale (VAS) scoring from zero (no pain) to 10 (worst pain).[14] The anaesthesiologist who assessed the patients was blinded to the group allocation. Rescue analgesia in the form of injection Ketorolac 30 mg intravenously (I.V.) was administered on demand or if VAS score was $\geq$4 upto maximum of three doses 8 hours apart and its time was noted. Tramadol 50 mg IV was given in case of inadequate relief of pain after injection ketorolac. Time for rescue analgesia was defined as the time from completion of hamstring block and adductor canal block till requirement of first rescue analgesia demanded by the patient. Total amount of analgesia required over 24 hours was noted. Quadriceps muscle strength was determined at similar time points by asking patient to perform straight leg rise against gravity and was graded as: Grade 0 - complete motor paralysis, Grade 1-motor weakness, Grade 2- normal muscle power.[12] Site of predominant pain (donor site or port site) was determined. Complications & side effects related to block procedures and analgesic

drugs (vascular puncture/nausea/vomiting/sedation) were noted. Patient satisfaction was rated by the patient at the end of 24 hours on an 11-point Numeric Rating Scale (NRS: 0–10; 0 = extremely satisfied and 10 = totally dissatisfied).[15] Patient satisfaction was regarded excellent if the NRS was between 0 and 2; good (3–5); fair (6–8) and poor (9–10).

2.1. Statistical analysis

Sample size was calculated on the basis of a pilot study done in 10 patients. The mean VAS difference between adductor canal block and adductor canal block with hamstring infiltration was observed to be 15 mm with S.D of 20 mm at 8 hours postoperatively. Taking these values as reference, the minimum required sample size with 80% power of study and 5% level of significance was 28 patients in each study group. So total sample size taken was 60 (30 patients per group). The data entry was done in the Microsoft EXCEL spreadsheet and the final analysis was done with the use of Statistical Package for Social Sciences (SPSS) software version 21.0. Categorical variables were expressed as number and percentage (%) while presentation of continuous variables was done as mean ± SD and median values. The comparison of the variables which were quantitative in nature (age, BMI, duration of surgery, tourniquet time, number of times rescue analgesia was required and mean time for first rescue analgesia) were analyzed using Unpaired t-test/ Mann-Whitney test. VAS score was analyzed using Independent t-test. Among the qualitative variables, ASA grade and gender were analyzed using Chi-Square test while site, quadriceps strength, side effects and patient satisfaction were analyzed using Fisher's exact test. For statistical significance, p value of less than 0.05 was considered as significant.

3. Results

Total 66 patients scheduled to undergo ACLR under spinal anesthesia were considered for eligibility. After screening for exclusion criteria, 60 participants were included and were randomly divided into 2 treatment groups of 30 each (Fig. 1). No difference was observed between the groups regarding demographic profile such as age, gender, BMI and ASA grades(Table 1). Both the groups were comparable with respect to duration of surgery (p- 0.375) and tourniquet time (p-0.453).

Resting mean VAS score in postoperative period was comparable in both groups at 0, 2, 4 and 24 h (p = 1, 1, 0.163, 0.758 respectively). At 8 h, mean VAS score was higher in group A (5.3 ± 0.95) in comparison to group AH (3.07 ± 1.48) (p value < 0.001) while at 12 h, score was less for group A (2.9 ± 1.47) compared to group AH (4.6 ± 1.61) (p = < 0.001). Similar trend was observed for dynamic VAS score at same time intervals. (P value = 1, 0.738, 0.650, 0.344 at 0, 2, 4 and 24 h). At 8 h mean dynamic VAS score was higher for group A (5.87 ± 1.07) than for group AH (3.5 ± 1.59) (p < 0.001). However, at 12 h, mean dynamic VAS score was 3.33 ± 1.63 for group A and 5.27 ± 1.82 for group AH (P = 0.001).(Fig. 2).

Regarding the pain at port-site versus graft-donor site, results were found to be statistically significant in both groups. (p = 0.0001). In group A, 73.33% patient had pain at both port and donor site while 26.67% had only port site pain. In group AH 23.33% had pain at both donor and port site and 76.67% had only port site pain(Fig. 3).

Mean time after block, when first rescue analgesia was demanded by patients was 8.13 ± 1.28 h in group A and 11.47 ± 2.92 h in group AH. The result is statistically significant between the groups. (p= <0.001). None of the patient required secondary rescue analgesic. Mean frequency of rescue analgesia

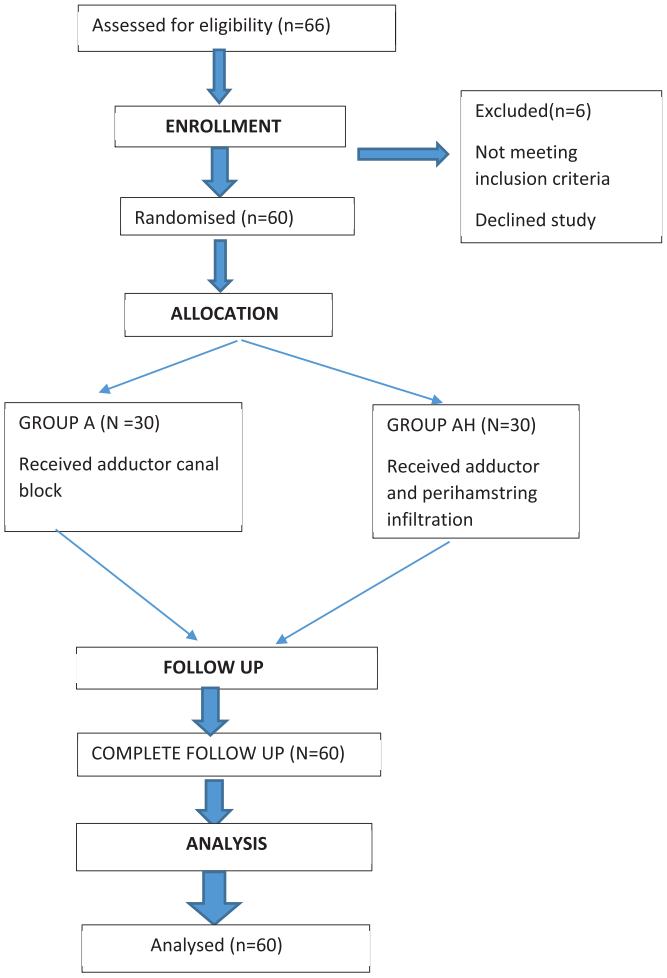

Fig. 1. Consort diagram.

demanded by patients in group A was 1.63 ± 0.67 and for group AH was 1.13 ± 0.63. The results were statistically significant between the groups (p = 0.004). Mean cumulative requirement of rescue analgesia dose in group A was 49 ± 20.06 mg and for group AH was 34 ± 18.86 mg showing statistically significant difference between the groups (p = 0.004). (Table 2).

No statistically significant difference in quadriceps strength assessment was observed at any time point after SAB in both groups and almost all patients could perform straight leg raising test with normal power at 8 h. No major complications of blocks or side effects of analgesic drug were seen. Only one patient (3.33%) had vascular puncture during ACB in group AH and only two patients (6.66%) experienced nausea in group A.

Overall patient satisfaction was significantly different between the groups. In group AH, 25 (83.3%) patients had excellent satisfaction (NRS < 2) compared only 6 (20%) patients in group A. Good satisfaction (NRS 3–5) was observed in 21 (70%) patients in group A and 5 (16.67%) patients in group AH. Fair satisfaction (NRS 6–8) was observed in 3 (10%) patients in group A (Table 3). None of the patients experienced poor satisfaction.

4. Discussion

Main findings of this study confirm our hypothesis that combination of ACB with peri-hamstring infiltration is significantly better than ACB alone regarding the efficacy of postoperative pain

Table 1
Demographic parameters.

PARAMETERS	GROUP A	GROUP AH	pVALUE
AGE (Yr) (mean±sd)	28.43 ± 6.42	28.43 ± 7.66	0.411
Sex(M:F) n(%)	25:5(83.33:16.67)	24:6(80:20)	0.787
BMI(Kg/m^2) (mean±sd)	26 ± 2.02	26.01 ± 1.81	0.927
ASA Grade(I:II) n(%)	23:7 (76.66:23.34)	24:6 (80: 20)	0.942
Duration of surgery(hr) (mean±sd)	1.55 ± 0.35	1.34 ± 0.26	0.375
Tourniquet time(min) (mean±sd)	69.97 ± 16.88	70 ± 6.31	0.453

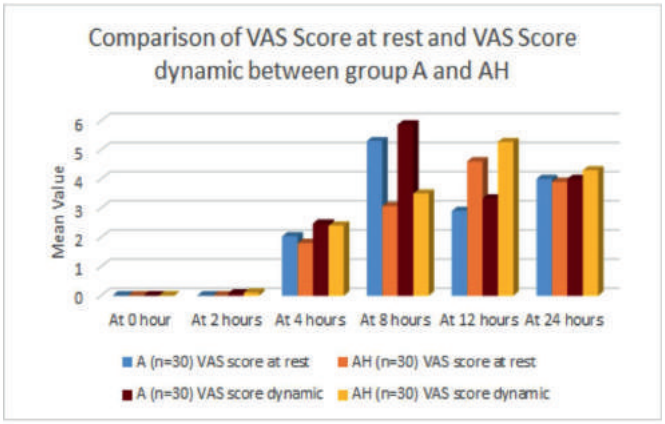

Fig. 2. Graph showing VAS scores at rest & dynamic (on knee flexion) at various postoperative intervals.

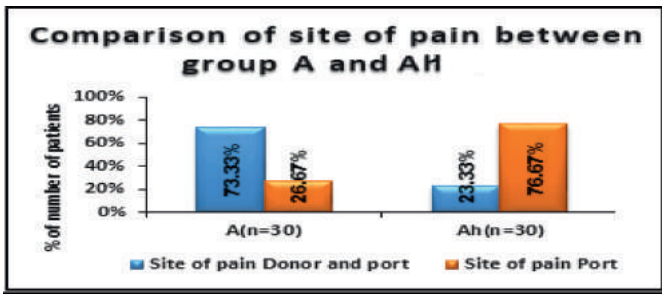

Fig. 3. Graph showing comparison of site of pain between the 2 groups.

relief and consumption of cumulative analgesic requirement over 24 h period. First analgesic requirement was significantly delayed with combined technique compared to ACB alone. The combination technique is safe and effective modality to provide postoperative pain relief after arthroscopic hamstring -autograft ACLR surgery.

Effective pain control after ACLR is important to allow early mobilization and full regain of knee extension to avoid flexion contractures. No single method of postoperative pain control is sufficient, multimodal approach is, therefore, advisable. Regional anaesthetic techniques are becoming increasingly popular. Femoral and adductor canal block are frequently used peripheral nerve blocks in literature. Recently, concern has been raised regarding the

Table 3
Patient satisfaction by Numeric Rating Scale (NRS).

Patient satisfaction	A (n = 30)	Ah (n = 30)
Excellent n(%)	6 (20%)	25 (83.33%)
Good n(%)	21 (70%)	5 (16.67%)
Fair n(%)	3 (10%)	0 (0%)
Poor n(%)	0 (%)	0 (0%)
Total n(%)	30 (100%)	30 (100%)

risk of persistent motor impairment after FNB for ACLR.[16] Predominantly being a sensory block of saphenous nerve, ACB at mid thigh level is an upcoming alternative. Several studies have concluded ACB superior to FNB in terms of early ambulation by preserving quadriceps muscle strength.[10] Perihamstring local instillation of anaesthetic agent (LIA) with FNB has been reported to be more effective than femoral nerve block alone.[17] However, role of LIA in combination with adductor canal blockade and its comparison with ACB in ACLR surgery has not been investigated till date.

Analgesic efficacy of ACB in knee arthroscopic surgeries is well established.[10] Pain after ACLR using hamstring autograft may arise in anatomical areas innervated by sciatic and obturator nerves.[18-] Neither FNB nor ACB may provide sufficient analgesia to this component of pain[19] Instillation of LA to hamstring donor site is a recently described simple and useful treatment option to provide almost complete knee analgesia after this surgery.[20]

In our study, highest value of mean VAS (rest & dynamic) was observed at 8 h (5.3 ± 0.95) in group A and at 12 h (3.07 ± 1.48) in group AH after the block. This resulted into an early requirement of first rescue analgesia and consequently less VAS score at 12 h in group A. Mean VAS at 0, 2, 4 and 24 h was insignificant between the groups due to residual effect of SAB till 4 h. At 24 h, effect of all the blocks had worn off. Our results are in accordance with a multicenter trial conducted by Bavrel et al.[21] where authors evaluated different anaesthetic and analgesic techniques used for ACLR surgery with different types of autografts. Patient group with periarticular LIA at hamstring graft site had lowest VAS scores on day 1 and 3 postoperatively and was concluded to be most effective analgesic modality. The result of this finding was attributed to the diffusion of LA around saphenous nerve over a prolonged period of time. We also observed prolonged analgesia with combination technique compared to adductor canal alone and study was concluded at 24 h. Longer duration of analgesia in their study could be due to difference in anaesthetic and analgesic techniques used.

Similar to our study, Bushnell BD et al.[17] reported lower VAS

Table 2
Pain related outcomes.

PARAMETERS	GROUP A	GROUP AH	Pvalue
Time for 1st rescue analgesia(hrs) (mean±sd)	8.13 ± 1.28	11.47 ± 2.92	<0.001
Frequency of rescue analgesia required(mean±sd)	1.63 ± 0.67	1.13 ± 0.63	<0.001
Cumulative analgesia(mg) (mean±sd)	49 ± 20.06	34 ± 18.86	<0.001

scores in patient receiving FNB with hamstring donor site block compared to patient receiving FNB alone in 27 patients undergoing ACLR under general anesthesia (GA). They concluded their study after 2 h of patient's arrival in PACU. Since half-life of Bupivacaine is approximately 3.5 h, effect on VAS was expected to be prolonged but not monitored in the study.

Our results are also similar to a study conducted by Fauno et al.[13] in 45 patients scheduled for ACLR under GA. Hamstring block was given using 20 ml 0.25%bupivacaine. Authors observed significantly lower mean VAS score in intervention group every hour upto 6 h compared to placebo. Study was concluded thereafter.

However, our study results are in contrast to the study performed by Ritwick et al.[22] who compared saphenous nerve block (SNB) with and without LIA in ACLR using 15 ml 0.5% ropivacaine. No statistically significant difference in VAS score was observed in both the groups at 0, 8 and 24 h. SNB with LIA group had significantly lower VAS at 4 h post surgery as compared to LIA alone (1.9 vs 3.0, $p = 0.037$) Reason for such contrast could be due to ACB performed preoperatively in this study whereas we performed it postoperatively.

Sonney-Cottet B et al.[20] conducted a study in 158 patients undergoing ACLR surgery with hamstring graft under GA. 20 ml 0.75% Ropivacaine was instilled around hamstring in one group (HDS) while the other group received same volume intra-articular (IA). Unlike our results,authors documented clinically insignificant difference in mean VAS score in PACU and at 24 h. Difference in results could be due to larger volume of drug used by us.

Similarly, our results differ from a study conducted by Kevin Stebler et al.[23] where analgesic efficacy of ACB was compared to LIA in 104 subjects using 0.5% Ropivacaine. No significant difference was found in resting and dynamic pain scores measured at 2, 24 and 48 h after ACLR between the groups. Reason for contrasting result could be due to assessment of VAS scores after 24 h when the effect of ACB had already worn off as mean duration of action of ropivacaine lasts approximately for 8 h only. Moreover, no adjuncts were added to local anaesthetic as done in our study. Also, we used dual technique of ACB and LIA in one group.

In agreement to the results of previous trial, in our study, only 7 patients (23.33%) complained of pain at graft harvest site in group AH compared to 22 (73.33%) in group A due to prolonged effect of Ropivacaine with adrenaline.[13,17,21] First rescue analgesic requirement was delayed in AH group (11.47 ± 2.92 h) due to dual block in comparison to group ACB alone. (8.13 ± 1.28 h). Unlike other trials, effect of ACB and LIA were prolonged in our study due to more volume and addition of adrenaline as an adjuvant which prolongs the action of Ropivacaine by reducing its maximum plasma concentration due to local vasoconstriction caused at the site of injection, delaying systemic absorption,[24] hence, prolonging duration of analgesia provided by the block. Our results were different from previous researchers due to the difference in their study design.

Higher cumulative analgesia was required in group A (49 ± 20.06 mg) compared to group AH (34 ± 18.86 mg) over 24 h period proving superiority of combination technique. Our findings are consistent with Fauno P et al.[13] where they observed less opioid requirement upto 6 h in hamstring group. Beveral et al.[21] also documented least (14%) morphine requirement in hamstring site LIA group. On the contrary, Cottet BS et al.[20] and Stebler K[23] reported no difference in total analgesia consumed between the groups. Difference in their results could be due to less volume of LA used without adjuvant and at different location.

Our maximum patients (93.33%) regained motor strength at 4 h postoperatively after wearing off of the spinal blockade. Duration of analgesia lasted for 8 and 12 h in group A and AH respectively indicating no effect of ACB or LIA on quadriceps strength. Previous researchers have also reported similar findings.[10,23]

No major side effects or complications related to procedure were recorded. Two patient had nausea in group A (6.66%) and one patient (3.33%) had vascular puncture in group AH similar to results reported by other authors demonstrating safety of both the techniques. [10],17,20,[21].

Clinically significant difference in patient satisfaction was observed between the two groups at 24 h due to longer duration of analgesia provided by combination technique secondary to more volume of LA and addition of adjuvant unlike others.[23]

4.1. Limitations

Baseline VAS score was not noted in our study which could be a possible confounding factor. The adductor canal block was given by an experienced anaesthesiologist in all the patients and the result may vary with the beginners performing the blocks.

5. Conclusion

Combination of Adductor canal block and perihamstring infiltration is significantly better as compared to adductor canal block alone in terms of reduced postoperative VAS scores for pain and cumulative analgesic requirement over 24 hour period in patients undergoing arthroscopic anterior cruciate ligament reconstruction surgery using hamstring autograft.

Credit roles

Dr. Suman Saini: Conceptualization, Methodology, Investigation, writing: Writing – original draft and review & editing, Formal analysis, Validation, Visualization, Supervision & project administration, Dr. Neha Khattar: Conceptualization, Methodology, Investigation, writing: Writing – original draft. Dr. Divya Gautam: writing: Writing – original draft & review & editing. Dr. Nidhi Agrawal: Conceptualization, Methodology, Investigation, writing: review & editing, Formal analysis, Validation, Visualization, Supervision & project administration, Dr. Anju Gupta: Conceptualization, Methodology, investigation.

Declaration of competing interest

None.

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Research paper

The test-retest reliability, concurrent validity and minimal detectable change of the 3-m backward walking test in patients with total hip arthroplasty

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ABSTRACT

Purpose: To determine the test–retest reliability, concurrent validity and minimal detectable change of the 3-m backward walking test (3MBWT) in patients with Total Hip Arthroplasty (THA).
Methods: A total of 29 patients after unilateral primary THA were enrolled in the study. All evaluations were carried out by the same physiotherapist. The test-retest reliability of the 3MBWT was assessed at an hour interval and analyzed by the Intraclass correlation coefficient (ICC). In the concurrent validity analysis, the Spearman correlation coefficient between 3MBWT and Harris Hip Score (HHS) was calculated. In addition, the standard error of measurement (SEM_{95}) and Minimal Detectable Change (MDC_{95}) values were also calculated.
Results: The mean age of the patients was 75.6 ± 10.0 years. The mean time of the second test was 2.41 s better than the first assessment. The ICC score of 3MBWT was 0.983. Test-retest reliability was excellent. SEM_{95} and MDC_{95} values were 1.56 and 4.33, respectively. Both test and retest evaluations of the 3MBWT were correlated with the HHS ($p < 0.01$). The degree of correlations was moderate.
Conclusion: The 3MBWT is a valid and reliable test in patients with primary unilateral THA. The MDC value of 3MBWT provides essential information to clinicians about patients' clinical progression.

1. Introduction

Total hip arthroplasty (THA) is one of the most frequent arthroplasty procedures in orthopaedics which is used to reduce pain, increase the functional activity level and balance in patients with primary hip osteoarthritis.[1,2] Patients with hip osteoarthritis have difficulty maintaining their postural stability and balance.[3,4] With the reconstruction of the hip joint, excision of the joint capsule, acetabular labrum, muscle, tendon and ligaments is performed. These changes negatively affect the function of proprioceptive mechanoreceptors in many muscles, tendons, controlling the movement and maintaining balance.[4,5] Patients with THA have decreased hip and knee muscle strength (hip abductor, extensor, flexor and adductor) and postural sway and consequently loss of balance.[6] Decreased balance and muscle strength are important risk factors that causing falls before and after THA.[7] Studies report that approximately 40% of patients falling after surgery and about 50% of patients before THA.[8,9] Falls are considered as the most common cause of injury among the elderly population. The use of assistive devices, muscle weaknesses, visual and hearing impairments, chronic diseases and gait-balance disorders are risk factors for falling.[10] Performance assessment methods are important for clinicians to determine the prognosis and the healing of patients after joint arthroplasty.[11] Physical performance-based assessments are used to evaluate the function of patients. These tests are used in the observation of the patient's adequacy level and change in functionality, and the patient is evaluated by doing that functional activity in person.[12] General performance tests are single standing, timed sitting tests and walking tests, which are tests related to balance and fall parameters. These tests are primarily those that evaluate walking forward, turning back and taking steps.[11]

One of the performance tests, the 3-m backward test (3MBWT)

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is a difficult test and is used to evaluate proprioception, neuromuscular control, protective reactions, fall risk, and balance.[13] However, backward walking is clearly more difficult. Patients need more neuromuscular control, proprioception, and protective reflexes. Researchers have newly demonstrated that backward walking is more sensitive at identifying age-related changes in mobility and balance compared with forward walking.[14,15] The 3MBWT is proved to be reliable in patients with THA.[11] Depending on the effect of walking patterns after total hip arthroplasty, reductions in 3 m walk back walking performance may occur. Therefore, it is important to measure 3MBWT safely in patients with THA. In this way, the applicability of the test in the clinic can be ensured. In the literature, the validity and test-retest reliability of the 3MBWT has been shown in orthopedic and neurological patients, while there is no study in patients with THA.[11,16] Therefore, our study provides psychometric properties of a clinical test of the 3MBWT in THA. Specifically, we aimed to determine test-retest reliability, concurrent validity, and minimal detectable change of the 3MBWT in patients with THA.

2. Material and methods

2.1. Subjects and clinical setting

A cross-sectional prospective study was carried out with 29 unilateral primary THA patients who were followed up in Adana City Training and Research Hospital, Home Health Care Services. Our study was conducted with a "test-retest" design, and the psychometric properties of the "3-m backward walk test" were examined in patients who were determined by using the convenience sample. In order to simulate the functional gait of patients in normal daily life, evaluations were carried out only in the home setting of individuals who have the proper room or corridor width and length for this test. It is also aimed to prevent the effects of fatigue or anxiety which could be seen in the clinical settings and to be performed in a quiet natural environment that reflects the real-life better.[17] In addition, it may be effective to use this method in order to enable patients to evaluate remotely, because, in some special circumstances, it may not be possible for the patient to go to the clinic.[18] In this environment, there were no sills or obstacles that could negatively affect walking. Corridors without materials that could also hinder walking such as carpets and rugs were selected. The floor was flat, bowless, hardwood, or concrete. The participants were tested in casual wear. The stopwatch recorded the number of seconds and tenths of a second of the test.

The inclusion criteria were; (1) **operated for THA at least ≥6 months ago**, (2) ≥18 years. The exclusion criteria of the study were; (1) other surgical operations of the lower extremities including revision THA, (2) had bilateral THA, (3) patients with cognitive illness or disorder and who cannot understand verbal instructions of the test, (4) neurological conditions that may affect musculoskeletal mobility (e.g., hemiplegia) or other serious orthopedic conditions that may affect gait (e.g., fracture), (5) body mass index (BMI) ≥40 kg/cm2, (6) patients who do not give consent to participate in the study.

The sample size required to analyze the test-retest reliability of the 3MBWT was calculated using the G*power 3.1.9 software with an effect size f = 0.5, alpha level = 0.05 and power = 0.80.[19,20] Accordingly, 29 patients were sufficient to calculate statistical analysis. The study was carried out in accordance with the ethical principles and the Helsinki Declaration. Informed consent of the patients was obtained. The study protocol was approved by the ethics committee of Ege University (No:20-6T/3).

2.2. Procedures

The sociodemographic and clinical characteristics (e.g., gender, age, affected hip) were recorded, which may affect patients' walking ability. The functional status and symptoms of the patients were evaluated with the Harris Hip Score.[21] The 3-m backward walk test (3MBWT) was performed twice with an interval of an hour on the same day.[13]

All evaluations were carried out by the same physiotherapist who has more than 7 years of experience and is also experienced in performing orthopaedics performance tests. It was preferred to collect data with a single evaluator in order to avoid the inter-rater variability error rate between the evaluations. In this way, each evaluation parameter obtained from each patient provided the highest consistency of the data.[22] The patient was measured at one time for both test and retest. Allowing 3 trials for 3MBWT and using the average value of these trials was not preferred due to factors such as learning and fatigue effects.[23] Before starting the data collection process, the tester was given practical information on the application of a newly developed performance test, "3MBWT". After this training session, the physiotherapist performed this test with the pilot application in two patients and practiced. The current time was not reported until both testing and retesting was completed or during any test. The therapist who administered the test by standing and walking about a half meter behind the patient in order not to direct the patient's walking speed and ensure safety. During the test, the physiotherapist directed the patient with only verbal instructions. Patients were allowed to use assistive devices. Between the test and retest, patients were not allowed to drink or eat anything, except water. In the 3MBWT test, the protocol was followed as described by Carter et al.[13] Patients were asked to walk comfortably but as quickly as possible during the test. While it is not allowed to reach a high speed or running that would disrupt safety, the verbal cues given were not intended to encourage the patient. Test setting (room or corridor) marked with 3 m straight and colored non-elastic tape. Before the test, the patient was given a verbal and practical explanation about the test, and the therapist applied it once and explained it in detail. Warm-up trials were not permitted to avoid fatigue and learning effects.[23] Patients were allowed to look behind whenever they wanted or had difficulty. Between the test and retest, patients waited in sitting to prevent the effect of fatigue. The details of the 3MBWT and other measurements are given below.

2.3. Harris Hip Score (HHS)

HHS is the most frequently used tool for the evaluation of postoperative patients in hip osteoarthritis. It is a comprehensive and multidimensional tool evaluating pain, deformity, contracture, functional, and daily life activities. It is scored out of 100. A high score indicates the good clinical condition. It has been shown to be reliable in THA and its Turkish version has been validated.[21]

2.4. 3-Meter backwards walk test (3MBWT)

The course was determined with a flat and colored tape by measuring a distance of 3 m. In addition, a 90-degree perpendicular horizontal start and end line were added to the beginning and end of this straight line. The patients were asked to locate their heels at the level of the horizontal band at the starting line. Patients were allowed to look back. The test was performed once and the time was recorded with a stopwatch. Participants instructed to walk comfortably, safely, but as quickly as possible and stop at the finish line.[13]

2.5. Statistical analysis

All statistical analysis was calculated by using SPSS for Windows v25.0 software (SPSS Inc, Chicago, IL, USA). For quantitative variables, mean and standard deviation (SD) were presented. Percent (%) were reported for qualitative variables. The confidence interval of 95% was accepted. Shapiro-Wilk and Kolmogorov–Smirnov tests were used to determine the normal distribution of data. The test-retest reliability of the 3MBWT was analyzed by using the Shrout and Fleiss Type (2,1) intraclass correlation coefficients (ICC) model. Since all evaluations are made by a single evaluator (physiotherapist), a two-way random-effect model single-measure reliability analysis was used.[24] ICC is classified as good (0.60–0.80) and excellent (0.80–1.0), considering internationally accepted guidelines.[24]

The minimum detectable change (MDC_{95}) was calculated to demonstrate the minimum size of change that reflects the clinically significant change rather than the possible evaluation errors. The MDC was calculated based on the standard error of measurement (SEM) conforming to the following formula: $MDC_{95} = 1.96*SEM*\sqrt{2}$. Standard error measurement (SEM) was calculated to ensure the accuracy of the evaluation method with the following formula: $SEM = SD*\sqrt{(1\text{-}ICC)}$.[25] SEM and MDC were calculated for 3MBWT.

The concurrent validity was analyzed using the Spearman correlation coefficient (r). The 3MBWT was compared with HHS. The correlation coefficient between the scores was interpreted strong if the coefficient was $\geq$0.5; moderate if the value was between 0.5 and 0.35; and poor if the value was $\leq$0.35.[26]

3. Results

A total of 29 patients (75.6 ± 10.0 years) were included in the study, 17 women (58.6%), 12 men (41.4%). The characteristics of the patients are presented in Table 1. The majority of patients (%55.2) were not using assistive devices. **The average time duration of the evaluation was 14.72 ± 14.14 months.**

The absolute values of the clinical measurements were presented in Table 2. The mean time of the second test was 2.41 s better than the first assessment. None of the test trials were disqualified from statistical analysis. Test-retest reliability and concurrent validity analysis results of 3MBWT are given in Table 3 and Table 4, respectively. The ICC score of 3MBWT was 0.983. Test-retest reliability was excellent. SEM_{95} and MDC_{95} values were 1.56 and 4.33, respectively. Both test and retest evaluations of the 3MBWT were correlated with the HHS ($p < 0.01$). The degree of correlations was moderate.

Table 1
The characteristics of the patients.

n:29	Total
Age (years, mean ± SD)	75.6 ± 10.0
BMI (kg/m,^{2} mean ± SD)	27.4 ± 3.6
Duration after THA surgery (months, mean ± SD)	14.72 ± 14.14
Gender (n, %)	
Women	17 (58.6)
Men	12 (41.4)
The operated side (n, %)	
Right	16 (55.2)
Left	13 (44.8)
Walking aid (n, %)	
Yes	13 (55.2)
No	16 (44.8)

SD: standard deviation, n: number of patients, THA: Total hip arthroplasty.

Table 2
Absolute values (mean, standard deviation, min-max) of the assessments.

n:29	**Mean ± SD**	**Range**
HHS	64.31 ± 13.46	(38.15–93)
3MBWT		
Test	26.68 ± 12.88	(6–51)
Retest	24.27 ± 12.27	(5–45)

SD: standard deviation, n: number of patients, 3MBWT: 3-meter backward walk test, HHS: Harris Hip Score.

Table 3
Test-retest reliability of the 3MBWT

n: 29	Difference (Mean ± SD)	ICC (95% CI)	SEM_{95}	MDC_{95}
3MBWT	2.41 ± 2.33	0.983 (0.96–0.99)	1.56	4.33

n: number of patients, ICC: Intra-class correlation coefficient, CI: Confidence interval, α: Cronbach's alpha, SEM: Standard error of measurement; MDC: Minimal detectable change, 3MBWT: 3-m backward walk test.

Table 4
Correlation between HHS and 3MBWT

n: 29	3MBWT (test)	3MBWT (retest)
HHS	−0.488*	−0.486*

**: $p < 0.01$, n: number of patients, 3MBWT: 3-m backward walk test, HHS: Harris Hip Score.

4. Discussion

In the present study, we aimed to investigate test-retest reliability, concurrent validity, and minimal detectable change of 3MBWT. To the best of our knowledge, this is the first study to examine the test-retest reliability and other psychometric properties of 3MBWT in patients with total hip arthroplasty. According to the results of our study, 3MBWT was found reliable and valid. The SEM and MDC values of the test were revealed and it was provided to guide clinicians in terms of showing how effective the clinical status changes are.

By demonstrating the concurrent validity and the test-retest reliability of 3MBWT, a specific performance-based objective assessment was provided for the evaluation of symptoms (balance and fall-related signs) in patients with THA. In this test, given that it is more difficult to walk backward, it will be possible to specifically assess neuromuscular control, proprioception, and protective reflexes against falling, more effectively.[11] Parameters such as muscle strength, balance, falling and walking are important in terms of showing the functional and performance level of the patient after total hip arthroplasty.[27,28] The 3MBWT allows clinicians to show the degree of effectiveness of these parameters simultaneously in patients with THA. For this reason, we think that the 3MBWT should be extensively used because it has an easy and short-term evaluation feature in patients with THA.

Another feature of this test is that it requires more skills and is more difficult than other tests.[13] Although the patient is allowed to perform look back while walking backward in order to provide balance, it enables the proprioceptive sense to be evaluated more effectively by reducing the visual feedback. In particular, considering that the mean age of our patients is high (75.6 ± 10.0), the frequency of using assistive devices is high rated (55.2%), the evaluation of the proprioception during walking will also be essential in terms of providing walking training by emphasizing the proprioception, more comprehensibly. Compared to the Timed Up and Go Test (TUG) test, which is one of the most frequently used performance tests, this test only performs backward walking and a

more homogeneous evaluation by performing backward walking without any other task.[29] Considering that our patients are elderly individuals who receive treatment within the home care services and have no access to the hospital, it is important to evaluate these tests in the patient's home environment. Fatigue and anxiety frequency may be higher in elderly patients during the hospital admission process. Assessment results may be more effective at home if the patient has adequate settings in their home. Because the elderly individuals in this case group generally need to resident care, also they spend most of their time at home because of sociocultural lifestyles.

In the postoperative period of THA patients, objective functional performance measurements are frequently used to assess the physical function of the patients. Assessment tools used in clinical studies and trials should be valid, reliable and responsive. In addition, it is important to present reference values in order to observe the minimum significant clinical change in patients' clinical status.[11] All these psychometric properties need to be revealed before using these tests.

After total hip arthroplasty, the rate of functional status healing observed in the post-operative period increases up to 26 weeks and then shows a slower progression. For this reason, the patients included in our study were at least 6 months after surgery.[30] In our study, test-retest reliability was evaluated by intraclass correlation coefficient (ICC = 0.983, 95%CI = 0.96–0.99). The reliability was excellent. The psychometric analysis of the 3MBWT was performed in older individuals, patients with total knee arthroplasty, Parkinson's disease, and stroke in previous studies.[11,13,16,31] 3MBWT was found reliable in all studies. Reliability analysis was analyzed with ICC only in the study of patients with total knee arthroplasty (ICC = 0.942).[11]

We performed the HSS score to provide the concurrent validity of the 3MBWT. The mean of the HSS score was (64.31 ± 13.46). The functional status of the patients was poor. Considering the fact that our patients are individuals who receive home care and in very old age (75.6 ± 10.0), the results of the HSS was acceptably normal. 3MBWT was correlated with HHS ($r_{test} = -0.488$, $p < 0.01$, $r_{retest} = -0.486$, $p < 0.01$). According to these correlation results, there was a moderate correlation, validity was found to be within the acceptable limits. Since HHS is known to be an observational and objective assessment tool filled by a clinician that evaluates many objective situations such as pain and physical performance, comparing with 3MBWT was appropriate. In the development study conducted with elderly individuals and also reliability study with Parkinson's disease, validity of the 3MBWT was examined by comparing with TUG. Both studies were reported that 3MBWT was valid.[13,31] In the study conducted with individuals with total knee arthroplasty, HHS was used only to observe the functional status of patients.[11]

MDC and SEM values were made with the formula specified in the method. These evaluations are of great importance for clinicians. Because in order for the evaluation scores of this test to be useful, the MDC value must be determined. In this study, SEM and MDC were found 1.56 and 4.33, respectively. SEM was used to identify the possible error associated with the patient's score, while MDC was used to interpret the clinical significance of the score obtained. Physiotherapists should expect to be higher than 4.33 to see that rehabilitation programs are effective. In this way, 3MBWT will be able to reveal the more precise and real change.

5. Conclusions

Test-retest reliability of the 3MBWT is excellent and concurrent validity is moderate for patients with unilateral primary THA. 3MBWT is a practical, simple to use. The clinician can evaluate the THA patients quickly and without loss of time. The absence of cost is a great advantage and could be applied at home. The MDC value of 3MBWT provides essential information to the clinicians in observation of patients' clinical progression.

Credit author statement

Fatih Özden: Conceptualization, Investigation, Methodology, Writing- Original draft preparation. Gökhan Coşkun: Investigation, Writing- Reviewing and Editing. Serkan Bakırhan: Writing- Original draft preparation, Writing- Reviewing and Editing.

Ethical approval

The study was carried out in accordance with the ethical principles and the Helsinki Declaration. Informed consent of the patients was obtained. The study protocol was approved by the ethics committee of Ege University (No:20-6T/3).

Declaration of competing interest

The authors report no conflicts of interest and certify that no funding has been received for this study and/or preparation of this manuscript.

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Retrieval analysis of the PRECICE OPTY-LINE magnetically controlled realignment nail: A report of two cases

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ABSTRACT

Purpose: The OPTY-LINE extendable nail is a magnetically-controlled, intra-medullary realignment device that is specifically designed for open-wedge high tibial osteotomy (HTO). The aim of this study was to perform a comprehensive retrieval analysis of OPTY-LINE nails and assess them for any signs of damage, corrosion and wear.
Patients and methods: Two routinely explanted OPTY-LINE nails were initially radiographed and force tested before mechanical section and disassembly. Macroscopic and microscopic inspection was performed and specific areas of the nails were identified for profilometry and scanning electron microscopy.
Results: Radiographs did not show any evidence of implant failure. Force testing resulted in no force output from one nail, while the second nail generated a maximum force of 706 N. Macroscopic inspection revealed wear patterns consistent with off-axis loading. Energy Dispersive X-Ray Spectrometry did not identify physiologic fluid ingress, however, O-Ring seal wear and moisture within the mechanism was concerning. Black debris was embedded within the O-Ring grooves of both nails.
Conclusion: This retrieval study is the first to evaluate the performance of the OPTY-LINE nail. Signs of off-axis wear and corrosion were identified and we support current recommendations for routine implant removal within one year. This study will inform and guide further retrieval analyses of the OPTY-LINE nail.

1. Introduction

High tibial osteotomy (HTO) is a common treatment for unicompartmental osteoarthritis with varus deformity in young, active patients.[1] It is a realignment procedure that aims to shift the weight-bearing axis, thereby unloading articular cartilage and redistributing mechanical forces over the relatively intact lateral compartment. Numerous studies have shown that accuracy of correction relative to pre-operative planning is the most important predictor of success,[2] yet in spite of this, alignment correction in HTO is highly variable.[3]

The technique of distraction osteogenesis is therefore attractive and several authors advocate the use of dynamic external fixation, especially for large corrections or those with a significant intra-articular deformity.[4,5] Bone graft is not required and alignment correction can be fine-tuned in the post-operative setting. Distraction osteogenesis is well-established in the field of limb-lengthening, where intra-medullary magnetic nails have eliminated many of the drawbacks of traditional external fixators, such as pin-site infections, tethering of skin and muscles as well as the daily burden of frame-wear.[6]

With internal lengthening options, the most commonly implanted device worldwide is the PRECICE nail (NuVasive Specialized Orthopedics, San Diego, California, USA) with over 10,000 implantations to date (company data, August 2019).[7] The device consists of two telescoping titanium tubes housing a rare earth magnetic metal spindle used to drive a 3-stage, 1:64 reduction planetary gearbox. The drive-pin rotates a leadscrew, with the

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List of abbreviations

DLO	Double Level Osteotomy
EDX	Energy-Dispersive X-Ray
ERC	External Remote Control
HTO	High Tibial Osteotomy
MAGEC	MAGnetic Expansion Control
MCGR	Magnetically Controlled Growth Rods
MPTA	Medial Proximal Tibial Angle
PTFE	Polytetrafluoroethylene
SEM	Scanning Electron Microscopy
SLO	Single Level Osteotomy

overall effect of extending or contracting the telescopic component. With a stroke capacity ranging from 5 cm to 8 cm, internal mechanism torque is achieved through the use of an External Remote Control (ERC). The ERC contains two large magnets that produce a controllable rotating flux experienced by the internal magnet (Fig. 1).[6]

Since its initial FDA approval in 2011, the PRECICE nail has undergone a number of design iterations.[8] P1 describes the initial nail design and an early modification to casing size. With P2, the original modular system of outer shell welds was exchanged for a monobloc design due to evidence of fracturing. This also allowed for a larger extending bar diameter and coincided with a corrugated anti-rotation female aperture design. P2.1 represents the most recent version where the anti-rotation 'crown' was internalized in response to failure reports at the tip of the nail.[6] A labelled radiograph is shown in Fig. 2.

The OPTY-LINE system is a novel version of this device designed specifically for medial-open wedge HTO.[9] The nail is inserted into the proximal tibia after a standard osteotomy is performed and following a latent period of several days, the osteotomy is gradually opened in increments of 0.5 mm–1 mm per day. Once the desired correction is achieved (which may include reversal in direction if there has been a small over-correction), the distraction is concluded (Fig. 3). NuVasive recommends elective removal of all its lengthening nails approximately one year post-operatively, provided solid union has occurred.

The aim of this study was to perform the first comprehensive retrieval and sectioning analysis of explanted OPTY-LINE nails, examining characteristics such as device wear, corrosion, residual functionality and loading limits. As this is the first-of-a-kind study, inspiration for device sectioning and internal component analyses was drawn from retrieval studies of alternative, and often similar, orthopaedic devices.

2. Materials and methods

2.1. Patient and nail details

Retrieval analysis was undertaken on two OPTY-LINE nails from two patients. The nails were assigned unique identifiers of N001 and N002. Details of the patients and the retrieved nails are shown in Table 1. Each patient underwent a medial open-wedge HTO using the OPTY-LINE nail. In one case, this was a single-level osteotomy. In the second, a double-level osteotomy was performed and the patient underwent concomitant lateral closing-wedge distal femoral osteotomy with a TomoFix plate (DePuy Synthes, Zuchwil, Switzerland). Each patient achieved their planned alignment correction with no implant failures. Solid union was achieved in both knees and there were no complications.

2.2. Plain radiographs

Each device was radiographed for signs of internal mechanism failure. Subcomponent identification was facilitated by an in-depth review of patents surrounding the device. This was performed using Google Patents database search function and returned three patents with detailed engineering drawings (Appendix A).

2.3. Force testing

As force testing of this device has not previously been described, two of the authors (RJJ and TJ) designed a novel testing protocol involving a force-testing rig provided by NuVasive (Fig. 4). The rig consisted of a digital linear force gauge (DFE II Series, Ametek®, New York, USA) fixed to a spring-piston setup. A bespoke locating block (Appendix B) was manufactured to secure the nail in place and provide a location for the ERC. Each nail was secured to the rig with a 5 N pre-load and the ERC placed on top of the locating block. The nail was then allowed to distract to its maximum length or until an indication was given that maximum load was reached.

2.4. Mechanical sectioning and disassembly

Mechanical sectioning and subsequent disassembly of each device was performed using a high-speed, cutting tool (Dremel, Racine, Wisconsin, USA). Guided by the radiographic images, incomplete circumferential cuts were made to the shell until the casing was thin enough to snap, thereby minimizing internal contamination with titanium debris. Extracted subcomponents were stored separately to avoid cross-contamination.

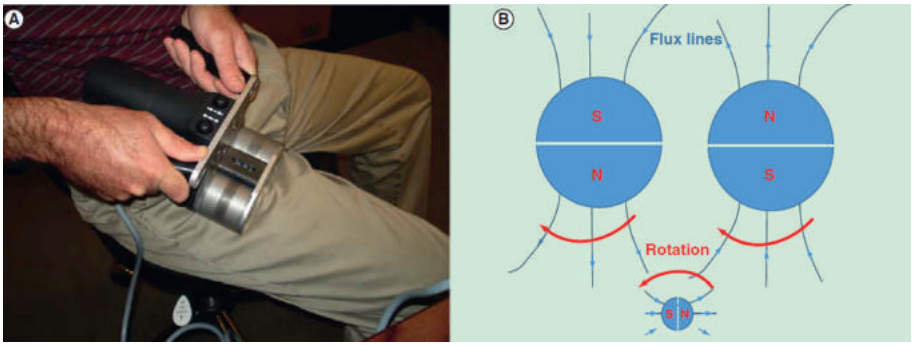


Fig. 1. A. Photograph of an external remote control (ERC) device. B. Illustration of how rotation of the two external remote control magnets (big circles) cause the nail magnet (small circle) to rotate through their magnetic fields. Courtesy of Paley D. PRECICE intramedullary limb lengthening systems. *Expert Rev Med Devices*. May 2015; 12(3):231-49.

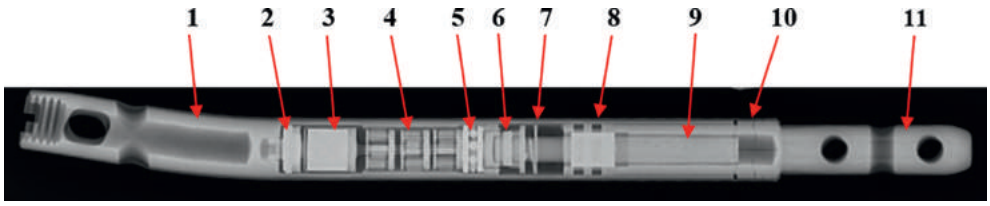


Fig. 2. Lateral radiograph of explanted OPTY-LINE nail
1. Titanium Alloy (Ti_6Al_4V) Case ('Female Component')
2. Radial Bearing
3. Rare Earth Magnet
4. 3-Stage Planetary Gear System
5. Axial Bearing
6. Drive Pin
7. Split Washer
8. Double O-Ring Seals
9. Leadscrew
10. Anti-Rotation Device
11. Extending Bar.

2.5. Macroscopic inspection

Following decontamination with soap and water using non-abrasive sponging, each nail was visually inspected for any signs of damage or obvious surface wear. All findings were photographed and areas of interest noted for further inspection. Much of this inspection took place during the initial force testing and disassembly phase.

2.6. Microscopic inspection

Areas previously identified during macroscopic inspection were fully dimensioned using either digital calipers (Mitutoyo, Huddersfield, UK) or a CNC Quick Scope Vision Measuring System (Mitutoyo, Huddersfield, UK).

2.7. Scanning electron microscopy (SEM)

SEM was performed using an ATM3030 Tabletop Scanning Electron Microscope (Hitachi, Tokyo, Japan) to further characterize and assess any surface wear. Using the energy-dispersive X-Ray (EDX) capabilities of this microscope, identification and quantification of elements from targeted sample areas was performed to assess for fluid ingress and corrosion. All samples were stored using individual sample tubes for SEM stubs (Agar Scientific, Essex, UK).

2.8. Wear

Characterization and measurement of surfaces was performed using an optical profilometer (InfiniteFocusSL, Alicona, Austria). The surface damage present on the extending bar component was quantified by two methods. Firstly, the technique outlined by Foong et al.[8] was used to gain a relative value for wear using the following measure:

$$\text{Wear} = \frac{\text{Area of Valleys of a trace from visibly worn region}}{\text{Area of Valleys of a trace from visibly unworn region}}$$

The 'Area of Valleys' is also known as the 'Oil Retention Volume', which is calculated from the bearing area of a curved surface as follows:

$$\text{Area of Valleys} = 0.5 * \text{Rvk} * (1 - \text{Rmr2})$$

where, *Rvk* is the reduced valley height parameter and *Rmr2* is the peak material ratio parameter. Therefore, our final equation for wear was as follows:

$$\text{Wear} = \frac{0.5 * \text{Rvk} * (1 - \text{Rmr2}) \text{ of the worn surface}}{0.5 * \text{Rvk} * (1 - \text{Rmr2}) \text{ of the unworn surface}}$$

Secondly, an estimate of the minimum wear volume was made using the volume measurement module of MeasureSuite (Alicona, Austria). A scan of the main wear scar was obtained, which then had its form converted from a cylindrical to a planar dataset. With the volume measurement mode set to Cutting Plane, the height of the plane was adjusted until only the wear scar was measured, giving the core volume of the wear scar (Fig. 5).

3. Results

3.1. Plain radiographs

Plain radiographs revealed that both nails had an intact internal mechanism with no evidence of drive-pin fracture.

3.2. Force testing

Field application to N001 with an ERC was attempted for a total of 5 min but failed to produce distraction. Attempts to manually apply a field with a ring magnet were unsuccessful, so force testing on N001 was discontinued at this point.

Field application to N002 with an ERC resulted in an immediate increase in force, with a gradual increase to a maximum of 706 N. At this point, there was an audible 'click' and the force gauge readout simultaneously decreased to 665 N.

3.3. Mechanical sectioning and disassembly

The mechanical sectioning and disassembly process is detailed in Appendix C.

3.4. Macroscopic inspection

Proximal to distal macroscopic inspection, sequenced as in Fig. 2, is displayed in Table 2 and Appendix E.

3.5. Microscopic inspection

Dimensioning and standard microscopy of each component was performed. The principal finding was that the closest matching

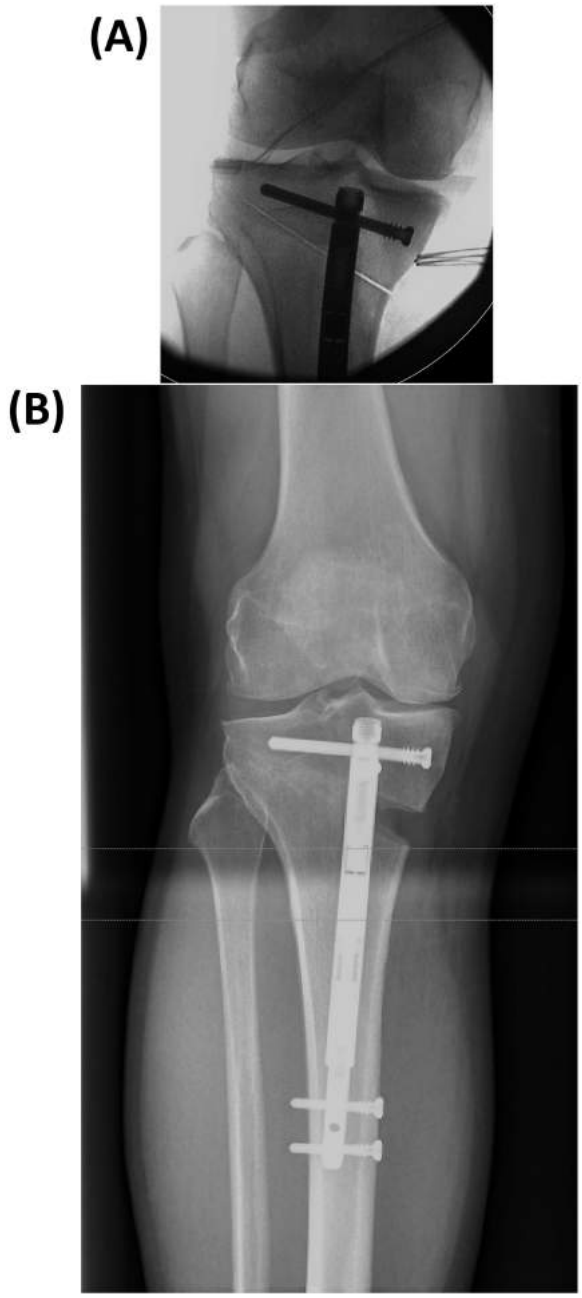


Fig. 3. A. Fluoroscopy showing the osteotomy immediately after the procedure. B. Radiograph at ten weeks following distraction.

commercial designation for the axial bearing was the BA 3 (thrust ball bearings, single direction) manufactured by SKF (Svenska Kullagerfabriken, Gothenburg, Sweden) with a basic static load rating of 720 N.[10]

3.6. Scanning electron microscopy

SEM of the O-Rings revealed minimal signs of surface damage (Fig. 6A) as well as the presence of metallic particles embedded in the surface (Fig. 6B), consistent with the gross metallic contamination noted at macroscopic inspection.

EDX testing for fluid ingress beyond the O-Rings did not reveal sodium, potassium or calcium peaks as would be expected to be seen with ingress of physiologic fluids beyond the O-Ring gaskets. A high fluorine detection peak was noted.

3.7. Wear

The longitudinal damage running the full length of each extending bar was identified as fretting corrosion, a wear process occurring at the contact area between two materials under load and subject to slight relative movement[11] (Fig. 7).

Extending bar surface damage near the O-Ring groove was also identified as fretting corrosion (Fig. 8) and was found to have a higher surface roughness on both nails (N001, Ra 1.4 μm; N002, Ra 0.7 μm) compared to the visibly un-worn side of the same bar (Ra 0.4 μm). Unit-less wear quantification of this scar, according to Foong et al.'s[8] method, was 1.029 and 2.527 for N001 and N002, respectively. Wear volume according to our second method was 0.00038 mm^3 and 0.00900 mm^3 for N001 and N002, respectively.

4. Discussion

PRECICE nails have been shown in numerous studies to be an effective method of distraction osteogenesis, making limb lengthening easier and more comfortable for patients with limb length discrepancy.[12,13] Performance reports of the OPTY-LINE system have also provided early promising results. In comparison studies with a conventional HTO group, surgical accuracy was higher and gap healing appeared faster in patients managed with the OPTY-LINE nail.[9,14]

Similar technology has been used in magnetically controlled growth rods (MCGR) to treat early onset scoliosis and the MAGEC system of MCGRs shares the same manufacturer (NuVasive Specialized Orthopedics, San Diego, California, USA), as well as a similar mechanism, as the PRECICE nail. Concern has been raised, however, regarding the use of MAGEC rods due to the risk of implant failure.[15,16] High rates of failure and significant tissue metallosis have been associated with locking pin fracture, O-Ring seal failure and metal wear debris, leading to the issue of a Field Safety Notice (FSN) for the MAGEC system by NuVasive in 2019.[17] Off-axis loading has been identified as a fundamental mechanism of failure and the consequent metallosis – both local and potentially systemic - is a major cause for concern.[18] Subsequent to this, NuVasive issued a FSN in January 2021, this time for the PRECICE family of devices while they address (i) the unknown long-term biological safety profile and (ii) the use of these devices in children.[19]

To the best of our knowledge, this is the first comprehensive retrieval analysis of the OPTY-LINE nail and is the first study to force test explanted PRECICE nail devices.

The peak force obtained by nail N002 was found to be 706 N. This force is transmitted through the drive-pin and modelling the pin as a simple beam in a three-point bend test reveals that the force required to break the pin could be as low as 660 N. This is concerning as if early union occurs, the nail could potentially exert enough force to damage or fracture the pin. However, the legitimacy of this model is questionable and further studies are required to understand the force vector orientations. The force applied by the ERC in our study is a tensile force, whereas in-vivo forces are likely compressive. Although the peak force obtained is less than the force generated in single-legged stance by a 73.4 kg patient (720 N), this is not representative of how distraction is clinically performed.

An optimal disassembly protocol was not established in this study and many of the internal components were not accessible without damaging and potentially contaminating the components.

Table 1
Demographics of implants and patients.

Nail Details		
Study Nail Reference	N001	N002
Device (Design)	PRECICE OPTY-LINE (P2.1)	PRECICE OPTY-LINE (P2.1)
Model Number	HTO10.7–20A155	HTO10.7–20A155
Correction Time (days)	69	89
Implantation Time (months)	16.5	13.1
Patient Details		
Age (years)	63	31
BMI (kg/m^2)	28.9	29.8
Gender	Female	Male
Indication for Osteotomy	Genu Varum	Idiopathic
SLO or DLO	DLO	SLO
Pre-Operative MPTA (°)	80.9	85.3
[a]Post-Operative MPTA (°)	91.8	93.6

SLO, Single Level Osteotomy; DLO, Double Level Osteotomy; MPTA, Medial Proximal Tibial angle.
[a] At 12-month follow-up.

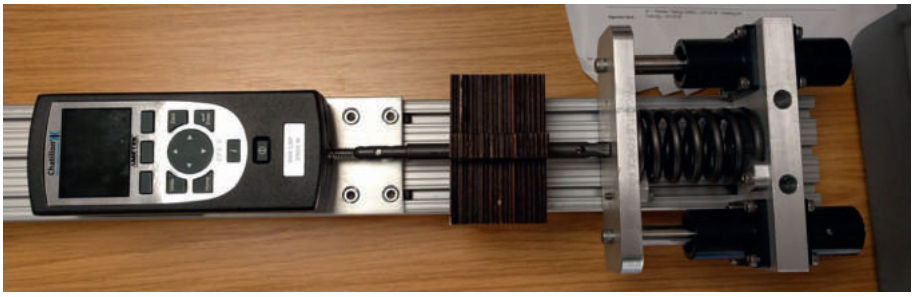


Fig. 4. Customized force testing rig with OPTY-LINE nail and bespoke locating block.

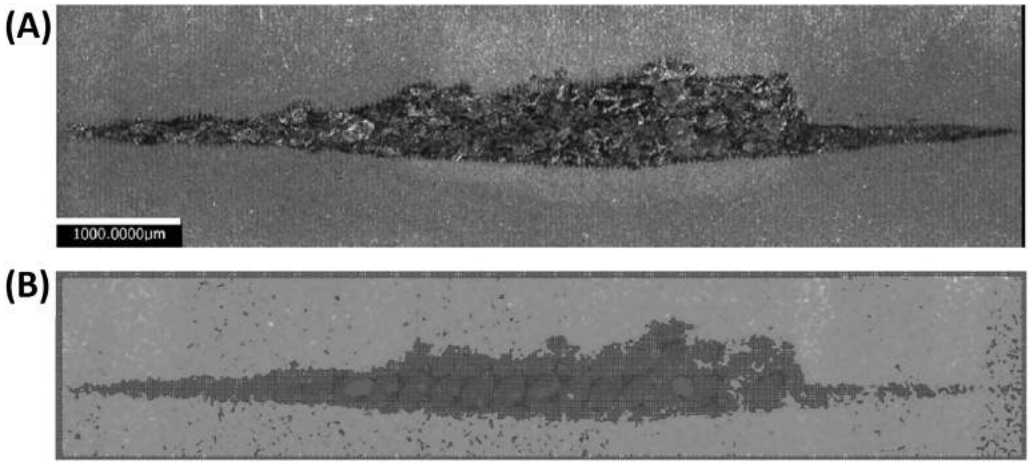


Fig. 5. A. Scan of main wear scar on the extending bar of nail N002. B. Diagram of cutting plane above wear scar scan showing area for volume measurement.

Ideally, two longitudinal cuts without internal contamination would allow for complete in-situ analysis of all components. Future cut recommendations are shown in Appendix D.

The measured material volume loss in our study was infinitesimally small, measuring only 0.00038 mm^3 and 0.00900 mm^3 for nail N001 and N002, respectively. Extending bar longitudinal wear, identified as fretting corrosion, was seen in an identical fashion to previous PRECICE nail retrieval studies[8,20] and an additional main wear scar, identified as fretting corrosion, was also present on each bar. The wear marks did not lie in the same longitudinal line, but were separated by approximately 20° of the bar's circumference. The cause of this separation is unknown, but the presence of damage on only one side of the bar is indicative of off-axis loading. Off-axis loading occurs when the mechanical axis of the limb (in any plane) differs to the longitudinal axis of the implant, in particular the extending bar axis. This is evidenced by the 'coup' actuator-on-bar wear at the female aperture in combination with the 180°, proximal, internal 'contrecoup' actuator-on-bar wear identified at the level of the O-Rings (Fig. 9). In a large multi-centre study by Joyce et al.,[21] off-axis loading was also identified as a cause of wear, corrosion, metallosis and failure in the MAGEC system of MCGRs. However, unlike the MAGEC system, the cause of off-axis

Table 2
Macroscopic inspection summary.

No.	Component	N001	N002	*Figure
1	Casing	Signs of retrieval damage Deposits found around radial bearing seat	Signs of retrieval damage	
2	Radial Bearing	Intact and smooth running	Not assessed	E1
3	Magnet	Intact with small deformation on gear	Intact on radiograph	
4	Gearing System	Seized. Internal gears would not separate from sun gear	Intact on radiograph	
5	Axial Bearing	Lower race fractured Internal race discoloration	Intact on radiograph	E2
6	Drive Pin	Black debris observed Corner fracturing with visible material loss Support area surface damage	Intact on radiograph	E3
7	Split Washer	Intact	Intact on radiograph	
8	O-Rings	Gaskets intact Debris embedded in both grooves, internal and external to the rings	Gaskets intact Debris embedded in both grooves, internal and external to the rings	E4
9	Leadscrew	No surface damage Moisture present Smooth meshing action with extending bar	No surface damage Moisture present Smooth meshing action with extending bar	E5
10	Anti-Rotation Device	Loaded with black metallic debris	Loaded with black metallic debris	E6
11	Extending Bar	Surface damage in two locations One side was polished near the O-rings Longitudinal damage along entire bar length	Surface damage in two locations One side was polished near the O-rings Longitudinal damage along entire bar length	E7

* Figures available in Appendix E.

loading in this instance is likely due to the design of the nail itself, rather than the force regime it is subjected to. The distal bend of the nail alone is enough to cause off-axis loading.

EDX analysis for physiologic fluid ingress beyond the O-Ring gaskets was reassuringly negative. However, given the eccentric wear of the O-Rings, the presence of metal debris in the O-Ring grooves and the SEM results, together with the presence of moisture beyond the O-Rings, concern remains for potential internal corrosion and subsequent egress of metal ions. The most interesting peak that was detected in all EDX samples was fluorine. This occurred with mass percentages as high as 57% and is thought to relate to a fluorinated lubricant such as polytetrafluoroethylene (PTFE).

Three other retrieval studies of the PRECICE system have been performed. Foong et al.[8] examined eleven consecutively explanted PRECICE nails used for femoral distraction (five P1, three P2 and three P2.1 designs) while Panagiotopoulou et el.[20] describe a retrieval analysis of twelve PRECICE femoral nails and three

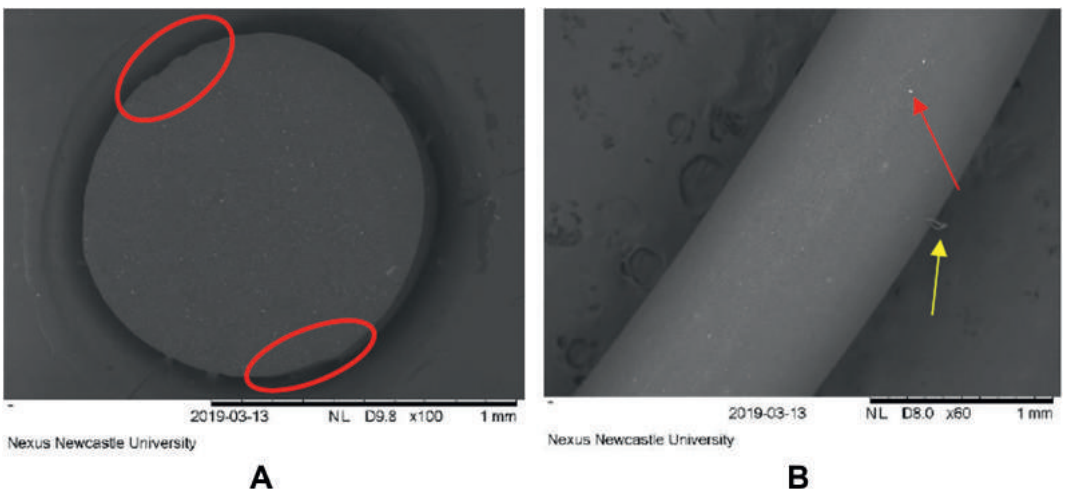


Fig. 6. SEM Images of N001 O-Ring sample. A. Sectioned end view. The red ellipses mark two areas where some material has been removed on either side of the ring. B. Side view. The red arrow indicates light metallic particles embedded in the surface. The yellow arrow shows some tissue lint.

Fig. 7. Alicona image of extending bar longitudinal damage. Both fretting and pitting corrosion are present on this view.

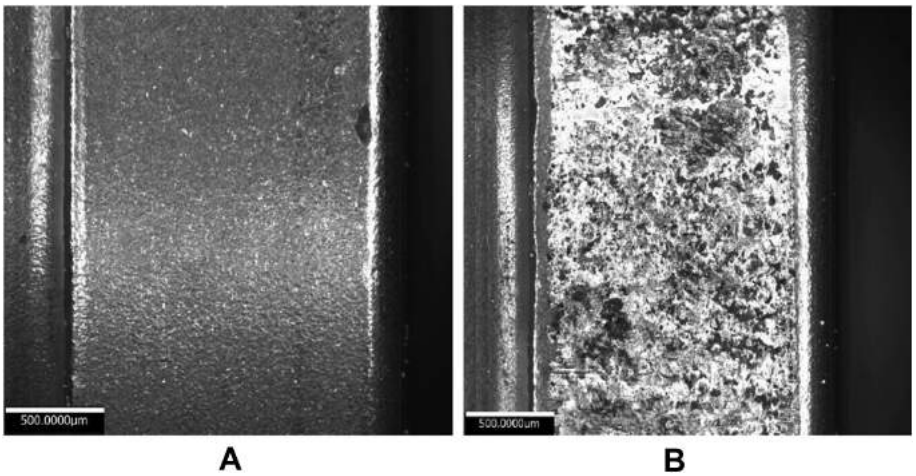


Fig. 8. Extending Bar Pitting Corrosion
A. Alicona image of extending bar reference surface. B. Alicona image of extending bar pitting corrosion.

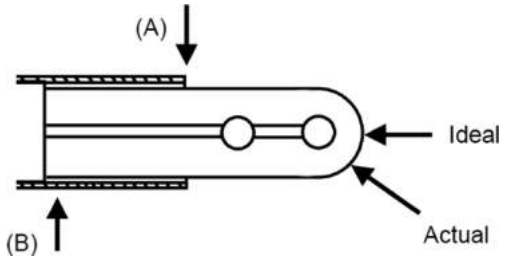


Fig. 9. Schematic diagram of the proposed mechanism by which surface damage was caused to the extending bar. A and B represent reaction forces.

PRECICE tibial nails (six P1, four P2 and five P2.1 designs). In both studies, all nails demonstrated design-specific surface damage to the telescopic component. Macroscopic inspection revealed regularly-spaced notches along the extending bar, likely reflecting the regularity in the frequency and degree of lengthening. This is consistent with the off-axis loading and actuator-on-bar wear seen in our study. Moreover, as the bending moment increased with implant distraction, the marks on the extending bar closer to the actuator became deeper and broader. No hardware complications were found in the nails examined by Foong et al. but Panagiotopoulou et el. noted two actuator pin fractures, both in P1 nail designs. In both studies, wear and internal corrosion were observed to decrease as the designs were changed, suggesting that the design modifications have had an effect in improving overall implant performance. However, following sectioning, Panagiotopoulou et el. noted black debris in all implants and there was evidence of physiologic substances within the latest design nails.

Eltayeby et el.[7] introduced the concept of the "Sleeper" nail, describing a theoretical off-label lengthening process whereby dormant PRECICE nails remain in-situ and kinetically inactive for one year between osteotomy and lengthening stages. With "functional" defined as the ability to lengthen 5 mm short of the nail's full stroke capacity and retract back to 35 mm, they found that 84% of explanted nails performed successfully. Almost 50% of the fully deployed nails in the study failed the test, leading the authors to conclude that in some cases, fully deploying the nail may cause internal mechanism damage. Analysis of wear, corrosion or mechanical sectioning was not performed in this study.

This study was limited to two explanted devices and force testing was successfully completed on only one nail. Retrieval analysis of many more devices is required before firm conclusions can be drawn. Nonetheless, the OPTY-LINE system is a novel device for high tibial osteotomy and warrants early and robust analysis.

5. Conclusion

The PRECICE OPTY-LINE nail appears to be a well-performing device but caution is urged when it comes to the mechanical design considering the force testing results in this study. Off-axis loading is proposed to be the main mechanism of damage to the extending bar. This is the first report of evaluation of the OPTY-LINE nail and we feel our study provides good evidence to support and guide further retrieval analyses.

Funding

There is no funding source.

Ethical approval

The project was exempt from IRB review as it does not meet the criteria for human subjects research. All patients consented to implant removal and subsequent implant analysis.

Authors' contribution

SPR and JMB performed a literature review and drafted the manuscript. MJD is the senior surgeon who performed both cases. RJJ and TJJ performed the retrieval analysis of the explanted nails. All authors read and approved the final manuscript.

Declaration of competing interest

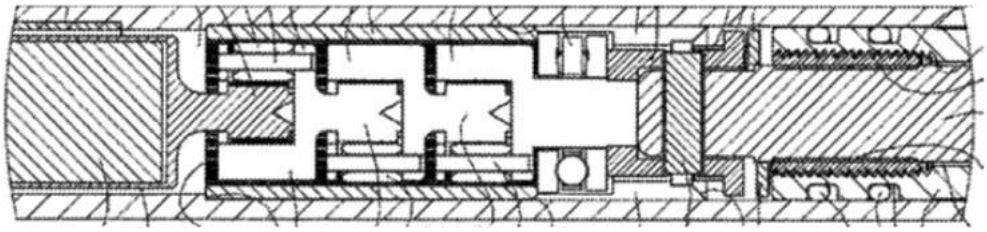
Matt J Dawson previously received historic consultancy remuneration and has received research support (in the form of medical devices and a research grant) from NuVasive Specialized Orthopedics, ending in 2018. The other authors have no financial conflict of interest to declare.

Acknowledgements

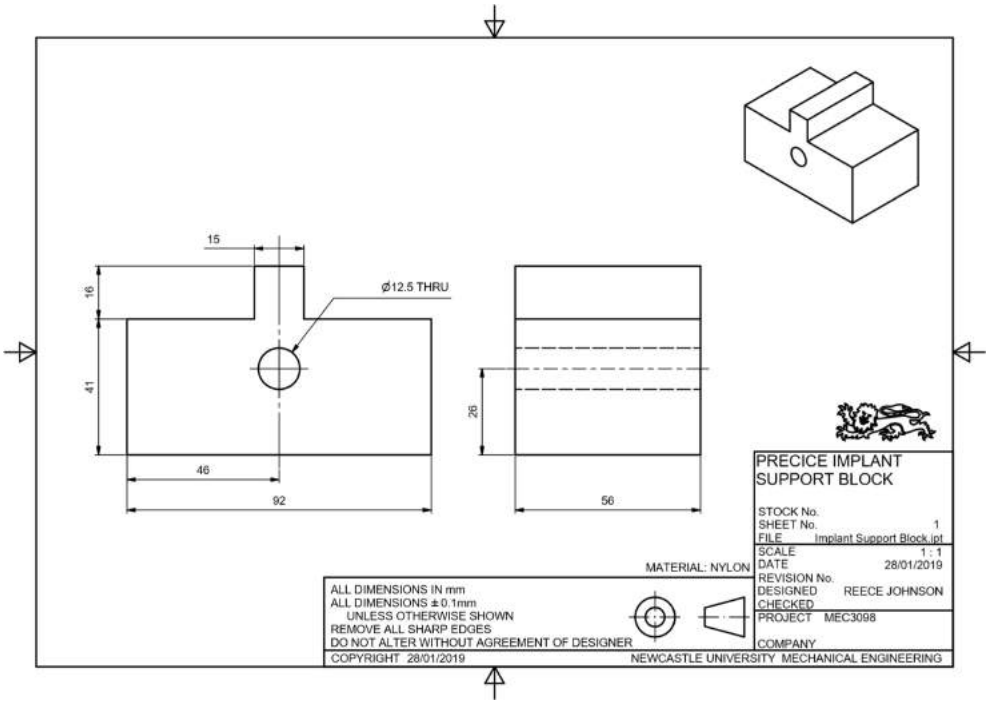
Dr. Simon Smith assisted with the mechanical sectioning and disassembly of the nails.

Mr. Michael Foster assisted with the laboratory work during this study.

Appendix A. Example of patent cross-sectional diagram (NuVasive, 2015)



Appendix B. Engineering drawing of bespoke locating block for force testing rig. The External Remote Control is placed on top of the locating block



Appendix C. Mechanical sectioning and disassembly

C.1. Nail N001 Summary

Fig. C1 shows the cut locations used to open N001 during the sectioning process. Without any published sectioning protocols to follow, cuts were made to avoid any internal components. Cut 1 was made to disable the effects of the anti-rotation device and allow the extending bar to be unscrewed from the leadscrew. Cut 2 was made to provide access to the gearing system but was unsuccessful, so two further cuts were made directly above internal components. Following all four cuts, access was gained to the internal mechanism assembly (Fig. C2). The gearing system seized which prevented any further disassembly. The outer casing was cut away (Fig. C3) to expose the drive-pin and separate the leadscrew. Overall, access was gained to every component, excluding the gears.

C.2. Nail N002 Summary

Based on findings from nail N001, nail N002 was only cut in one location (Fig. C4). This was believed to be the optimal cutting

location as the axial bearing, drive-pin and first planetary gear stage are linked together as one sub-assembly. Patent information suggested that this sub-assembly was interference-fitted (*NuVasive 2015*) into the casing, so it was thought that cutting here would weaken the fit and allow all components to slide out. This single cut had the same effect as cut 1 on nail N001 and enabled the extending bar to be unscrewed from the remaining device (Fig. C5). However, despite attempts at extraction with a bespoke slide-hammer, the components proximal to the cut remained firmly inside the casing.

Appendix C Figures

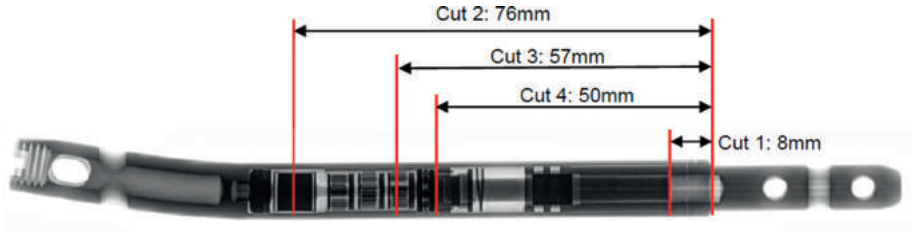


Fig. C1. Dimensioned nail radiograph demonstrating the locations of the cuts made to nail N001.

Fig. C2. Component sub-assembly from nail N001.

Fig. C3. Component sub-assembly from nail N001 post-cutting.

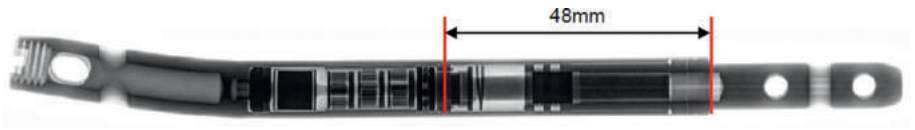
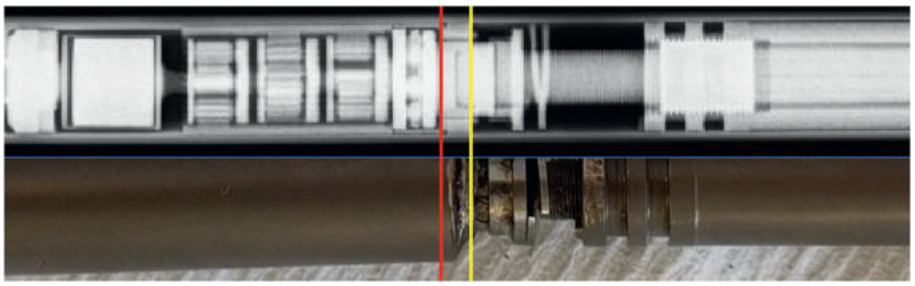


Fig. C4. Dimensioned nail radiograph demonstrating the location of the cut made to nail N002.

Fig. C5. Final disassembly of nail N002.

Appendix D. Side-by-side comparison of a radiograph to nail N002 in its final study condition. The red line shows the recommended next cut location for nail N002 and the yellow line indicates an additional cut to make if the device is new



Appendix E. Macroscopic inspection figures

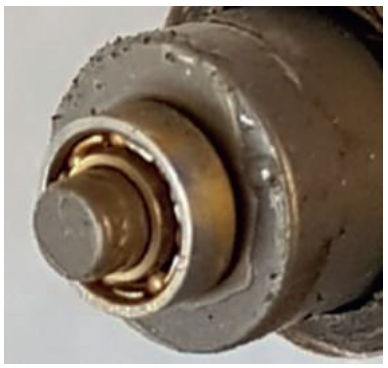


Fig. E1. Radial bearing on magnet shaft.

Fig. E2. Axial bearing race, fractured into three pieces, showing discolored raceway.

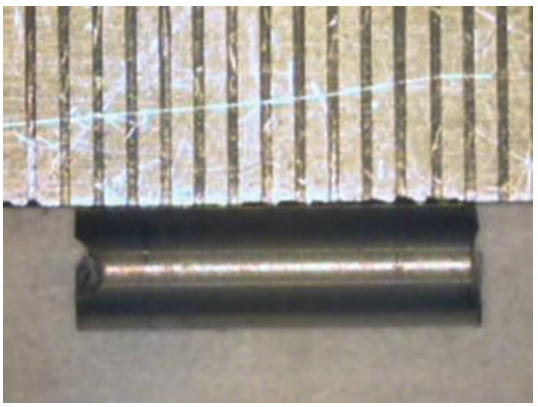


Fig. E3. Drive-pin next to a 0.5 mm scale, showing fractured corners and marked surfaces.

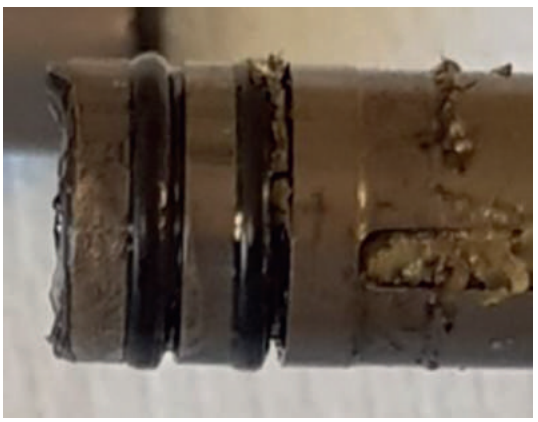


Fig. E4. O-Rings with debris inside the grooves.

Fig. E5. Leadscrew plan view showing moisture.

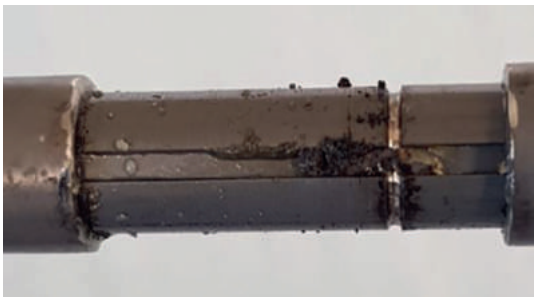


Fig. E6. Anti-rotation grooves of extending bar showing black debris and signs of moisture.

Fig. E7. Extending bar showing debris and longitudinal surface damage.

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Case report

Organized prepatellar hematoma associated with severe varicose veins and revisiting prepatellar anatomy and hematomas

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ABSTRACT

Background: While haemorrhagic bursitis and Morel Lavallee lesions occur in the prepatellar region, hematoma secondary to ruptured superficial vein, mimicking the above lesions, has not been reported. It is important to be aware of this entity as it would need further evaluation and surgical management.
Case report: We report a rare case of prepatellar hematoma of Right knee following a fall in a 72-year-old lady associated with severe varicose veins in both lower limbs, treated by evacuation and suction drain and followed by reinforcement sutures three days after the evacuation. There was no recurrence after the procedure. We discuss the MRI findings of our case, revisit the anatomy related to the prepatellar bursa, the differential diagnosis for a prepatellar hematoma, how to differentiate this lesion from others and their treatment options.
Conclusion: A detailed assessment of the patient is necessary to identify varicose veins in such cases which need surgical treatment to prevent recurrences or persistent ooze.

1. Background

Prepatellar hematoma is a relatively rare occurrence. Common causes include trauma, anticoagulation, Morel Lavallee lesion and coagulation disorders. It is important to differentiate between haemorrhagic bursitis and a superficial hematoma. Severe varicose veins lead to distended subcutaneous veins which have the potential to rupture following an injury. The difference between hematomas following other causes and that after rupture of distended veins is that the primary cause, which is varicosity, must be treated and a ruptured vein identified to prevent potential recurrences or persistent oozing. We report a rare case of prepatellar hematoma associated with varicose veins in a 72-year-old lady, successfully treated by evacuation and suction drain. We discuss the anatomy related to prepatellar bursitis and the approach to differentiate between the causes of hematomas in this region. Such a case has not been reported in the literature before.

2. Case report

A 72-year-old lady presented with swollen Right lower limb and painful swelling of Right knee since 20 days. This was preceded by a fall onto her knee from standing position, directly impacting the front of the knee. There were no other injuries. She was treated by a local physician with analgesics. The pain decreased initially, but the swelling in front of the knee did not subside. She progressively developed swelling of the whole lower limb which started seven days prior to the presentation to us. She is a known epileptic for which she was on oral Phenytoin and had a history of distended veins since few years in both lower limbs without any history of ulcers or bleeding episodes from lower limbs. She does not suffer from coagulopathy and was not on any anticoagulants or anti-inflammatories.

On examination, she was apyrexial, and the right lower limb was swollen and oedematous, with hyperpigmentation of both feet extending proximally to just above the ankle. She had severe tortuous varicose veins in both lower limbs. All distal pulses were palpable, and there was no evidence of compartment syndrome or neurological deficit.

There was a prepatellar swelling measuring 10 cms × 6 cms in

Abbreviations: MRI, Magnetic Resonance Imaging; ML, Morelle Lavallee Lesion.
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the subcutaneous plane, mobile over the underlying patella. It was firm and tender to palpation. There was no evidence of effusion or instability of the knee. Flexion of the knee was restricted to 45° due to pain.

Radiograph of the knee showed soft tissue swelling superfcial to the patella but no evidence of fracture. MRI of the knee revealed an organized hematoma in the prepatellar region, in the subcutaneous plane [Fig. 1]. There was a pad of fat between the swelling and the underlying patella, as shown in [Fig. 2]. Doppler ultrasound of deep veins was done to rule out DVT. Doppler ultrasound findings of the superficial veins is depicted in [Fig. 3]. A cardiac assessment revealed the patient had severe tricuspid regurgitation and mild Pulmonary Arterial Hypertension.

Under local anaesthesia, a transverse incision was made close to the equator of the swelling near the inferior pole of the patella and dark clotted blood evacuated from the swelling. There were no active bleeders or oozing at the end of the procedure. A suction drain was placed and removed after 24 hours. Reinforcement sutures were applied on day three postoperatively, as she had persistent oozing from her wound. The limb was immobilized in a static knee brace until suture removal. The oozing stopped after the second suturing and wound healed without any recurrence of swelling at six weeks follow up. She was referred to a vascular surgeon who advised surgical treatment for her varicose veins on the affected side.

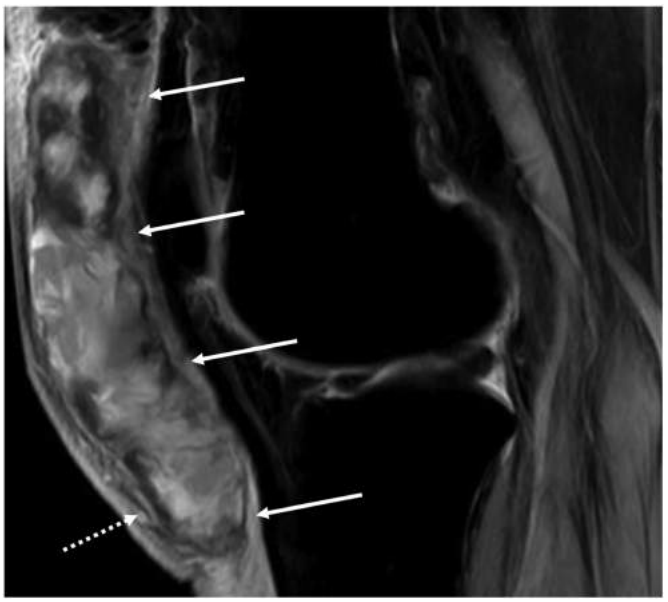

Fig. 2. Shows a sagittal section of hematoma. Solid arrows indicate layer of fat deep to the hematoma and superficial to the patellar tendon and patella. Dotted arrow points to one of the subcutaneous veins to indicate plane of the veins.

3. Discussion

Dye et al.,[1] in their cadaver dissections, described three layers and three bursae in the prepatellar region. The three layers are the superficial transverse fascial layer, intermediate oblique aponeurotic layer and the deep longitudinal rectus femoris tendon. The three bursae associated are:

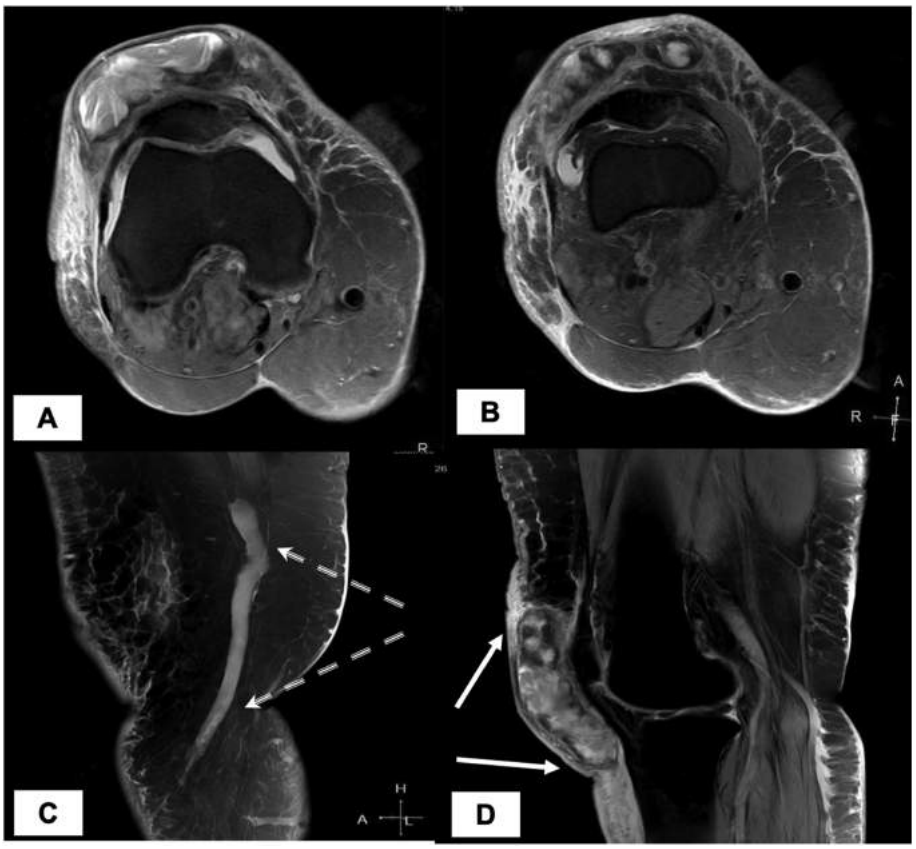

Fig. 1. Shows MRI films PD fat sat images of the knee A: shows transverse section showing hematoma superficial to the patella. B: shows transverse section proximal to the knee joint line and presence of pad of fat between the patella and the lesion. C: shows distended tortuous varicose vein. D: shows a sagittal section arrows indicating extent of the lesion.

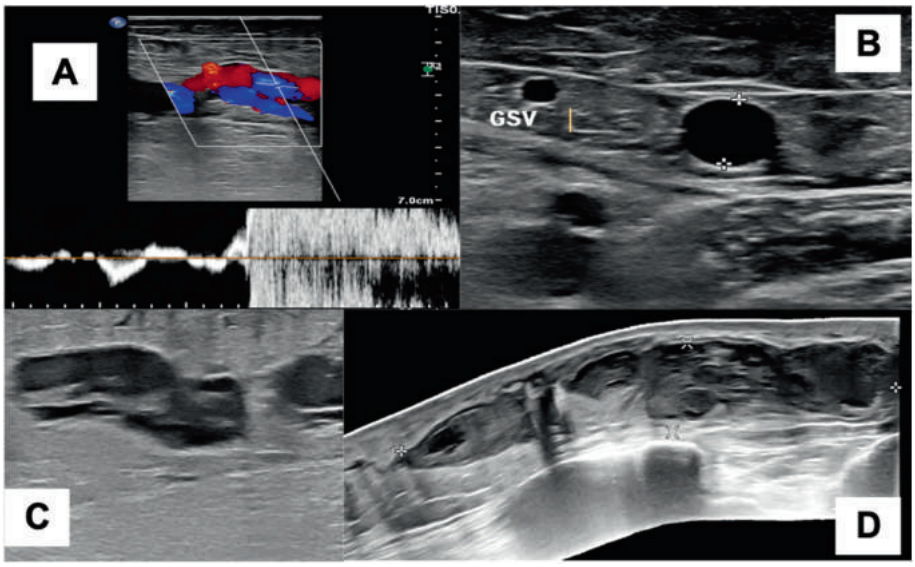

Fig. 3. Grey scale and doppler ultrasound images of right lower limb A: shows pulse doppler study showing significant grade III reflux at saphenofemoral junction. B: shows transverse grey scale image of dilated great saphenous vein with caliber of 9mm. C: shows tortuous varicosity along great saphenous vein territory. D: shows panoramic longitudinal image indicating extent of the prepatellar lesion with presence of pad of fat between the patella and lesion. Few smaller varicosity tributaries were noted adjacent to the hematoma.

(i) subcutaneous-between subcutaneous fat and the superficial transverse fascial layer,
(ii) subfascial – between the fascia and aponeurosis and
(iii) sub aponeurotic – between aponeurosis and tendon.

Similar findings were supported by an MRI and sonography guided bursography study by Aguiar et al.[2] All three bursae occur deep to the subcutaneous fat layer.

It is important to find the plane of the hematoma in order to know the aetiolsogy. Differential diagnosis would be a haemorrhagic prepatellar bursitis, Morel Lavallee (ML) Lesion in the prepatellar region, fat necrosis, coagulopathy related hematoma and a hematoma secondary to a ruptured varicose vein. The exact cause would be difficult to find unless an MRI scan was taken. While the treatment of all these lesions is the same, namely evacuation of hematoma, finding the cause would prevent a potential recurrence and would point to the need for further surgery to address the cause.

In the case of Morel Lavallee lesion, shearing of the skin and subcutaneous fat on the underlying fascia causes rupture of vessels crossing these planes, creating a hematoma superficial to the bursal plane.[3] The hematoma consists of a combination of venous and/or arterial blood depending on which vessel is ruptured. Mechanism of injury usually is a force tangential to fascial planes, causing shearing injury to vessels crossing the planes. A decreased cutaneous sensation is frequently reported due to shear injury to the cutaneous nerves. Vanhegan[4] reported an incidence of 15.7% of ML lesions around the knee. ML lesions have been classified by Mellado and Bencardino[5] into six types based on the location and the time since development and all of them occur between the fascial plane and the subcutaneous fat. Use of synthetic glue has been found to be effective in closing the lesion after drainage.[6]

Haemorrhagic bursitis occurs deep to the subcutaneous fat in the bursal planes as described above and hence will be seen superficial to the patella and deep to subcutaneous fat. It will be surrounded by a capsule, and the swelling will be limited to the anatomical planes and span of the bursa. It cannot extend to areas where the bursa is not expected to be present unless the bursa ruptures or the capsule stretches. The typical size of the bursa is expected to be around 40mm in the coronal plane anterior to the patella with a 7–8mm medial or lateral extension beyond patellar borders.[2] The fluid, in this case, will be a combination of blood and inflammatory fluid.

A ruptured varicose vein, which is the cause in this case report, will be seen within the subcutaneous fat as superficial veins are located within the subcutaneous fat as shown in the figure. As the hematoma expands, a pad of fat is maintained between the patella, prepatellar bursae and the hematoma.

We believe that in our case, the hematoma occurred secondary to rupture of a distended subcutaneous vein. We acknowledge the fact that this aetiology cannot be documented directly. It can be derived indirectly from the fact that since subcutaneous tissue contains veins as evident in Fig. 2, distended superficial veins secondary to varicosities in the lower limb and rupture of one of these could be the reason for the hematoma collection.

The hematoma in our case occurred within the subcutaneous fat clearly depicted in figures with a pad of fat between the swelling and the patella.

4. Conclusion

There are two key messages that we would like to identify with this case. 1. To differentiate between aetiologies of a prepatellar hematoma and 2. To emphasise the fact that hematomas secondary to varicosities would require additional surgeries to control ooze and to treat the varicosities to prevent potential recurrences.

Declaration of competing interest

No conflict of interest declared for all authors.

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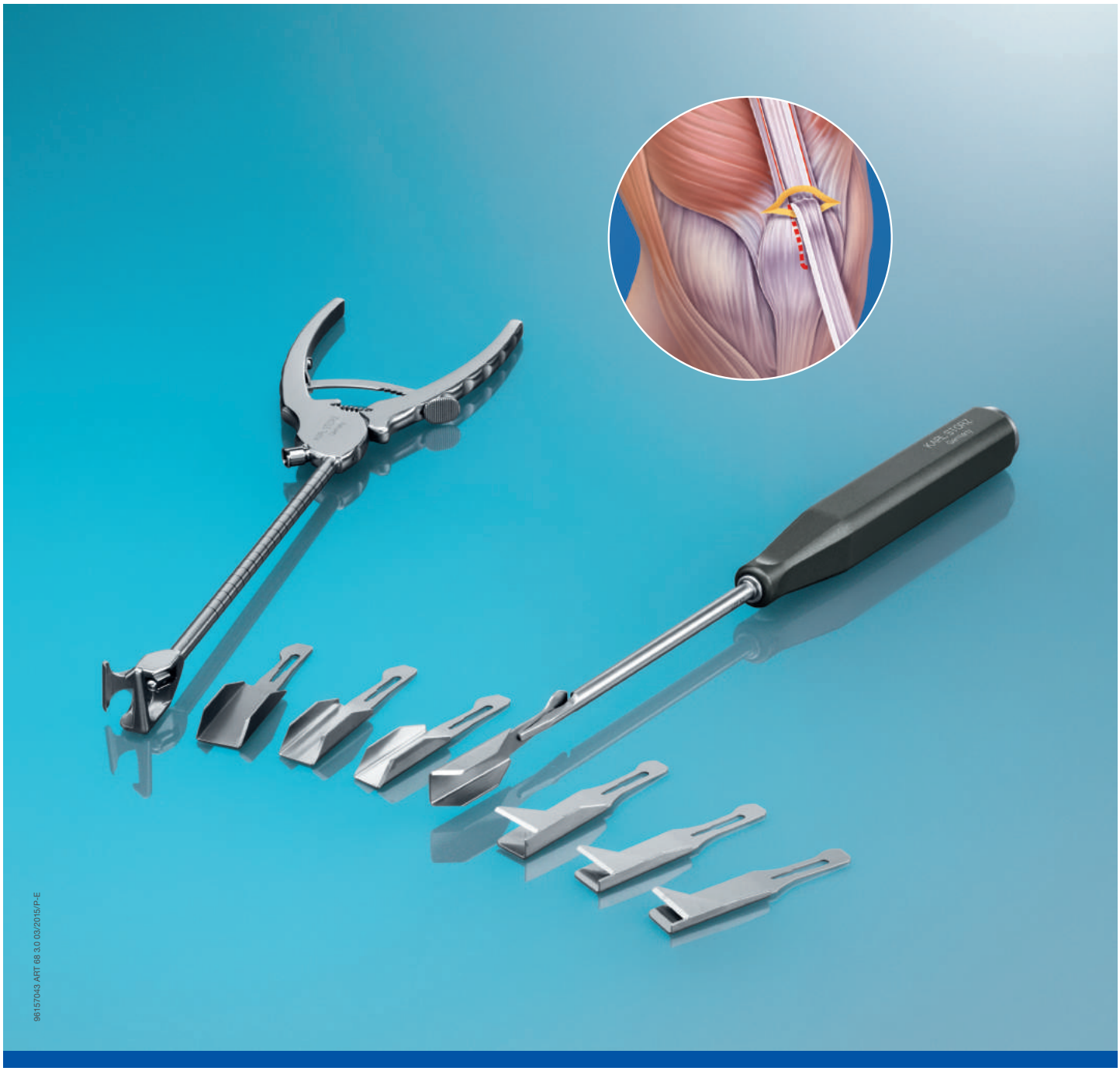

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