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ORIGINAL ARTICLE

Retrospective Study

Role of lateral soft tissues release in percutaneous hallux valgus correction: A medium term retrospective study

Fabio Zanchini, Ottorino Catani, Fabrizio Sergio, Alessia Boemio, Angelo Sieczak, Davide Piscopo, Salvatore Risitano, Gabriele Colò, Federico Fusini

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Abstract

BACKGROUND

In the field of minimally invasive surgery (MIS) for the treatment of hallux valgus (HV), different techniques have begun to emerge in the literature concerning the distal osteotomy of the first metatarsal bone, the synthesis or not of the metatarsal head, the possible association with lateral soft tissues release (LSTR) and osteotomy of the base of the first phalanx.

AIM
To evaluate the role of LSTR on percutaneous HV correction, evaluating functional and radiographical results.

METHODS
From January 2012 to May 2016 a total of 396 patients with mild to moderate symptomatic HV treated with the MIS technique were included in this retrospective study. The technique provides no internal fixation (WOS). Patients were divided into the LSTR group and no LSTR group (LSTR N). This surgical procedure (LSTR) was reserved for insufficient HV angle (HVA) correction during fluoroscopic control. Patients were evaluated at each follow-up by two other authors after appropriate training by senior authors (first practitioners). Clinical evaluation was performed before surgery, 6 mo after surgery, and 48 mo follow-up. American Orthopaedic Foot and Ankle Society (AOFAS) and visual analog scale (VAS) score was used to evaluate pain and function, and complications were recorded. In addition, the incidence of relapses and the degree of joint range of motion (ROM) with the association with the LSTR (capsule, adductor tendon, phalanx-sesamoid ligament, and the deep transverse metatarsal ligament) were evaluated. Radiological parameters included HVA and intermetatarsal angle (IMA). Patient satisfaction was assessed. Student *t*-test and Fisher exact test were used to assess statistical analysis.

RESULTS
From our study it is clear that no differences in term of HVA, VAS, IMA correction, rate of complications, and AOFAS score were found between groups, while a significant improvement of the same variables was found in each group between pre and postoperative values. A significant improvement in ROM at 6 mo (P = 0.018) and 48 mo (P = 0.02) of follow-up was found in LSTR N group. Complications were rare in both groups.

CONCLUSION
LSTR procedure on percutaneous HV correction seems to increase postoperative joint stiffness with a comparable incidence of relapse and a low incidence of complications.

Key Words: Hallux valgus; Percutaneous distal osteotomy; Lateral release; Minimally invasive surgery; Without ostheosynthesis; Range of motion

Core Tip: Our study evaluated a court of 396 patients treated with percutaneous technique, pain particular attention to the influence of the lateral soft tissues release (LSTR) on postoperative joint range of motion (ROM) and hallux valgus recurrence. A significant difference in ROM was recorded in the group where the LSTR was carried out, while there was no superior incidence of relapse between groups. ROM was revealed better at follow-up in LSTR not performed group. We believe these data represent an essential element to understanding the etiopathogenesis of complications. This data also enhances the validity of minimally invasive surgery with no osteosynthesis technique.

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INTRODUCTION

Hallux valgus (HV) is a common and progressive deformity of the forefoot with a multifactorial etiology[1]. This pathology most frequently affects women between the ages of 40 and 60. This deformity occurs in younger patients when there is a pathology that causes an overload on the first ray[2]. HV is defined by a variable as angular deviation of the first ray greater than 15° with a progressive abduction and pronation of the first phalanx and adduction, pronation and elevation of the first metatarsal. In literature are described wide variety of bony procedures, including osteotomies at the level of the head, midshaft, and base of the first metatarsal, as well as arthrodesis of the first metatarsal-cuneiform joint. The surgical treatments can be associated or not with lateral soft tissues release (LSTR)[3-5]. HV's surgical management is made difficult not only by the complexity of pathology, but also by the absence of a surgical gold standard[6].

At present, minimally invasive surgery (MIS) is performed with minimal skin incisions (1-3 mm), under intraoperative X-ray guidance, and with or without internal fixation[7]. There is some confusion in the terminology used when referring to MIS or percutaneous surgery. The term percutaneous, which means made through the skin, should be utilized when there is no internal fixation (K-wire or screw), and MIS should be reserved for procedures with minimal incision but with osteosynthesis[8].

This percutaneous management combines different procedures according to the complexity of the deformity to be corrected[9-12]. These procedures have become popular among foot surgeons, most arising from the traditional open distal metatarsal osteotomy. The advantages of percutaneous procedure are: 1-d hospitalization, and decrease postoperative morbidity and shorter rehabilitation times, in addition patients better accept this technique[7,13].

The choice to perform the percutaneous technique for the correction of HV rather than open surgery is not commonly accepted among orthopedic surgeons, despite the fact that this technique has been widely used for several years and its equal efficacy, and sometimes its superiority, compared to the open technique has been widely demonstrated in the literature. The main debate is whether or not internal fixation should be used[14].

The alignment of the first ray by medial rotation of the first metatarsal head and distal metatarsal articular angle (DMAA) correction is obtained by Reverdin-Isham percutaneous osteotomy an intra-articular medial closing wedge osteotomy of the distal metatarsal, associated with an Akin osteotomy[15], both performed without osteosynthesis[10,13,16-18]. Reverdin-Isham is not a complete osteotomy, as the first metatarsal lateral cortex is preserved; the closing wedge ensures contact of the metatarsal head with the metaphysis. A special post-surgical corrective bandage makes internal fixation unnecessary. Due to early weight bearing, that technique allows the osteotomy to heal with the toe in its proper position[19].

MIS was introduced first in Spain and then in Europe by de Prado *et al*[18] and Lucas y Hernandez *et al*[20]. However, to our knowledge, no previous study has evaluated the long-term results of this technique. Thus, this prospective study aimed to evaluate the radiographic and clinical outcomes of patients with mild-to-severe HV treated by MIS with Reverdin-Isham and Akin percutaneous osteotomy following exostectomy and LSTR. The study aims to evaluate the role of LSTR on percutaneous HV correction, evaluating functional and radiographical results.

MATERIALS AND METHODS

Patients selection

From January 2012 to May 2016, 396 consecutive Caucasian patients with symptomatic HV from mild to moderate were enrolled in this study. All parties have been informed and have given their consent to the publication of the data. Of these patients, 79% (355) were women, and 10.35% (41) were men. The age ranged from 28 to 82 years (mean age 64 years). The surgical procedures were performed by two surgeons Fabio Zanchini, MD, PhD, Professor and Ottorino Catani, the supporters of MIS in southern Italy, who followed the patients in the outpatient evaluation and diagnosed the study participants. The surgical technique, the inclusion and exclusion criteria, the postoperative course, and the rehabilitation protocol were the same for both groups. Patients were evaluated at each follow-up by two other authors after appropriate training by senior authors (first practitioners). Standard follow-up was each week for the first 42 d, then at 3, 6, 9, and 12 mo, and then yearly for at least 4 years.

The inclusion criteria were: Patients with mild to moderate painful HV after at least 6 mo of conservative treatment without acceptable results. Mild to moderate bunions have been included. This criterion was defined by the evaluation of the value of the intermetatarsal angle (IMA), described as mild (IMA from 10° to 13°), moderate (IMA from 14° to 20°), and severe (IMA > 20°). Patients with concurrent deformities in the lesser toe and metatarsalgia that required an accessory surgical time of finger correction and Distal Minimally Invasive Metatarsal Osteotomy (DMMO) of the II-III-IV metatarsal were also included. The presence of a previous correction of HV on the contralateral side or bilateral deformities were not considered an exclusion criterion. Patients who underwent previous HV correction surgery on the same side, with hallux rigidus, flat foot with joint laxity, rheumatoid arthritis, or other inflammatory conditions were excluded. Patients with diabetes, peripheral neuropathy, psychiatric and infectious diseases were excluded.

All procedures were performed under regional anesthesia with a sciatic blockage at the level of popliteal fossa using a nerve stimulator to inject 10 mL of mepivacaine hydrochloride at 1.5%, with ultrasound guidance. Of the 396 patients enrolled in the study, all subjects received the same surgical treatment, postoperative protocol and rehabilitation. From them, 209 (53%) underwent additional LSTR, defined as the transverse section of the adductor hallucis and lateral hemicapsulotomy. This surgical procedure was reserved for insufficient HV angle (HVA) correction during fluoroscopic control. The other 187 patients (47%) did not require additional surgical time.

Radiographic evaluation

Radiographic examination in anteroposterior and lateral weight-bearing projection was performed in all patients in the preoperative, immediate postoperative, and during 6 wk, 3, 6, and 9 mo follow-up, and then yearly. Each time, the following parameters were evaluated: HVA (normal value < 15°) and IMA (normal value < 10°). In addition, bone callus formation and the vanishing of transparency lines were screened to exclude consolidation delay or pseudoarthrosis. The lack of consolidation was defined as the persistence of the transparency lines and lack of bone callus formation after 9 mo from surgery. HVA values in the last follow-up > 15° were considered HV relapse.

Clinical evaluation

All patients were clinically evaluated with the same protocol in the preoperative and subsequent follow-up stages. The American Orthopaedic Foot and Ankle Society (AOFAS) scale was performed preoperatively, at 6 mo, and the last follow-up (4 years) for a maximum of 100 points divided into the following categories: Toe alignment (max 15 points), functional ability (max 45 points), and pain (max 40 points). Particular emphasis was given to the range of motion (ROM) evaluation by analyzing the global extension and flection of the metatarsophalangeal joint (MTPJ) and considering > 100° of motion the normal value, as described by Shereff *et al*[21] with the ideal value of 110°. The ROM evaluation was

performed preoperatively, at 6 mo, and then at the last follow-up.

Statistical analysis

Continuous data were reported as mean and standard deviation, while categorical data were reported as rate. The statistical analysis was performed using the student *t*-test, using appropriate software Sigmaplot (Systat software Inc., San Jose, A, United States). Data of AOFAS, visual analog scale (VAS), and ROM were compared between groups where LSTR was performed (LSTR Y) and LSTR not performed (LSTR N) through a 2-tailed Student *t*-test. At the same time, the rate of non-union, metatarsalgia, and complications were evaluated between groups with Fisher exact test. The *P*-value was set at $P < 0.05$.

Surgical technique

All patients were treated with the same surgical technique, with percutaneous correction of HV (ICD-9-CM 727.1; ICD-10 M20.1), except for the group of LSTR, where latera release of soft tissue was performed. Both group wee trated with WOS technique (Figure 1). In this technique, the percutaneous osteotomy with a 2.0 mm × 12.0 mm Shannon burr (cat. 256018, FH Orthopedics SAS, Heimsbrunn, France) were performed extracapsulary in the subcapital region, perpendicular to longitudinal axis. The head can be translated up to 90% of first ray shaft diameter to recentering the sesamoids. In case of high DMAA with a curved proximal phalanx, Akin osteotomy was performed with 2.0 mm × 12.0 mm Shannon Burr. The lateral release, when performed, was obtained using a Beaver 64 scalpel (Rüttgers, Solingen, Germany). The incision is made on the most lateral part of the dorsal aspect of the MTPJ of the great toe, lateral to the extensor tendons and the scapel blade is inserted parallel to the extensor tendons. The blade is introduced deeply, entering the joint between the proximal phalangeal and metatarsal articular surfaces, until it is noted to be rubbing on the cartilage. The scapel blade is then advanced deeper until it reaches the inferolateral aspect of the base of proximal phalanx of the great toe, which is the point of insertion of the adductor tendon of the great toe. The blade is rotated 90° to orient the cutting edge laterally, and it is moved laterally. At the same time the great toe is moved medially, tensing the adductor to facilitate section of the tendon, which can be confirmed on fluoroscopy. Lateral metatarsophalangeal capsulotomy is then performed, preserving the dorsal half to avoid excessive destabilization of the joint[22].

Postoperative care

All patients followed the same postoperative protocol and were followed in the same way standardized by the two surgeons. There were no changes in postoperative protocol between groups. Weightbearing was allowed 3 h after surgery with a flat sole and rigid shoe. The bandage was maintained for 5 wk (Figure 2A), with replacement every 7-14 d. Upon removal of the bandage, patients were instructed to wear an interdigital silicone separator for two months as a night bracer. Upon removal of the bandage was prescribed the same rehabilitation protocol to all patients (10 sessions of assisted mobilizations of the I M-F, step rehabilitation, active exercises, *etc*.).

RESULTS

Forty-one male patients and 355 females were included in the study. Two-hundred-nine patients were included in the LSTR Y group, while 187 patients were included in the LSTR N group, with a mean age of 64 ± 16.02 years and 63.85 ± 16.85 years, respectively. Results of preoperative, 6 mo, and last follow-up values of HVA, IMA, ROM, AOFAS, and VAS were reported in Table 1, while the clinical feature is reported as the last case (Figure 2B). Group comparison showed no difference in the preoperative value of HVA ($P = 0.523$), IMA ($P = 0.686$), ROM ($P = 0.596$), AOFAS ($P = 0.882$), and VAS ($P = 0.924$).

A significant difference was found in ROM between groups at 6 mo ($P = 0.018423$) and the last follow-up ($P = 0.02$). No differences were found in terms of HVA at 6 mo ($P = 0.593197$), and last follow-up ($P = 0.929243$) and IMA at 6 mo ($P = 0.750608$) and last follow-up ($P = 0.649461$), AOFAS at 6 mo ($P = 0.841372$) and last follow-up ($P = 0.737018$) and VAS at 6 mo ($P = 0.263118$) and the last follow-up ($P = 0.413075$). The rate of non-union showed no significant differences between groups ($P = 0.4541$); the same was found for metatarsalgia ($P = 0.5502$).

Complications and management

No thromboembolic complications, no cases of hallux varus due to hypercorrection, and no cases of avascular necrosis were reported. No nerve injury was observed in any of the patients. Complications were observed in 37 patients (about 9%); 21 in the LSTR Y group and 16 in the LSTR N group. The reported complications showed no significant differences in the two groups ($P = 0.73$).

Four patients developed a superficial infection at the medial access to exostosis, all resolved by general and local antibiotic therapy for 4 wk. One patient developed a deep infection which was also resolved by specific antibiotic administration after isolation of the bacterium. Seven patients submitted a consolidation delay. They were treated with pulsed electromagnetic fields (2 applications per day for 30 d) and administration of clodronic acid. Four reached healing and the complete regression of the symptomatology (pain and swelling of the MTPJ) after 12 mo from surgery. Two patients developed asymptomatic pseudoarthrosis: 1 required reintervention due to pain persistence. After 6 mo, the consolidation was achieved, with regression of the symptoms but subsequent development of joint stiffness.

In 9 patients, the medial margin of the cortical created impingement with soft tissues; two patients refused reintervention, while in 7 patients, the problem was solved with percutaneous removal of the bone prominence. Eleven patients reported HV recurrence with a mild HVA value lower than the preoperative values; in 5 patients, exostosis relapsed.

Table 1 The main clinical and radiological features of patients included in the study preoperatively, at 6 mo, and at the last follow-up

	Preop		6 mo		Last follow-up	
	Soft tissue release	No soft tissue release	Soft tissue release	No soft tissue release	Soft tissue release	No soft tissue release
HVA	22.4 ± 5.26	22.74 ± 5.5	11.11 ± 2.01	11.22 ± 1.86	12.06 ± 1.39	12.07 ± 1.32
IMA	12.6 ± 1	12.61 ± 0.98	8.14 ± 1.36	8.18 ± 1.33	8.930 ± 1.35	8.99 ± 1.34
ROM	101.94 ± 9.64	102.46 ± 9.9	104.47 ± 7.9	106.28 ± 7.24	104.70 ± 6.07	105.96 ± 6.4
AOFAS	68.08 ± 8.51	67.95 ± 8.17	88.95 ± 8	88.79 ± 8	90.58 ± 6.3	90.37 ± 6.41
VAS	4.41 ± 1.12	4.42 ± 1.14	1.28 ± 1.01	1.39 ± 0.99	0.93 ± 0.76	0.99 ± 0.74

HVA: Hallux valgus angle; IMA: Intermetatarsal angle; ROM: Range of motion; AOFAS: American Orthopaedic Foot and Ankle Society; VAS: Visual analog scale.

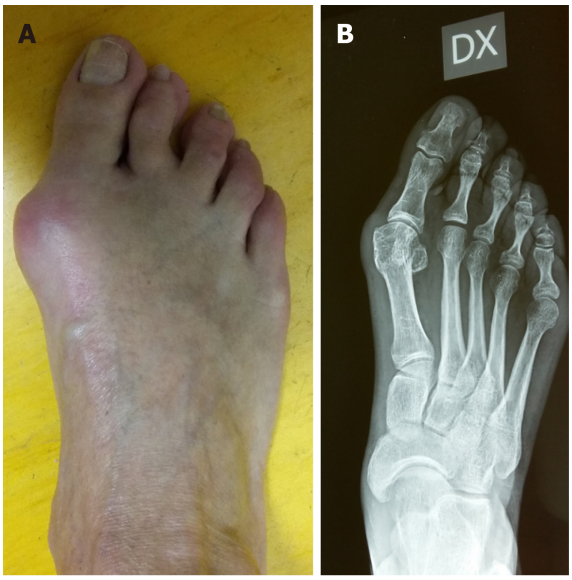

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Figure 1 Preoperative clinical and radiological features of a 42 years female patient with hallux valgus. A: Preoperative clinical; B: Radiological features.

There was no significant prevalence between treatment groups (P = 0.7628). Four of these patients underwent re-intervention and then declared satisfied with the result. In 8 patients, medial exostosis relapsed. Insufficient debris removal and/or exostectomy were found in all these patients. Seven of them underwent a subsequent reintervention with percutaneous exostectomy. Nineteen patients reported severe stiffness at 6 mo follow-up, with no differences between groups (P = 0.4817). A significant improvement in joint stiffness was reached in 8 patients who performed intense physiotherapy. After the revision of the preoperative X-ray, mild signs of joint degeneration were already highlighted in 85% of patients with residual joint stiffness. Eleven patients reported transfer metatarsalgia: 7 to medium-term follow-up and 4 to long-term follow-up. Four of these patients were treated with plantar orthoses with no more pain. Seven patients requested a re-intervention of percutaneous dorsalization osteotomy (DMMO) of the II-III-IV metatarsal head with symptomatology resolution. Two of them subsequently developed metatarsalgia II-V which was treated with orthoses.

DISCUSSION

Studies concerning percutaneous or MIS for treating HV have increased exponentially in recent years[23-25]. Growing scientific evidence demonstrates the percutaneous MIS technique's effectiveness in treating mild to moderate bunions. Compared with open techniques, the results overlap with fewer complications and greater patient satisfaction[26,27].

Our study evaluated a court of 396 patients treated with WOS technique as described by Lucattelli *et al*[22], pain particular attention to the influence of the LSTR on postoperative joint ROM and HV recurrence. A significant difference in ROM was recorded in the group where the LSTR was carried out, while there was no superior incidence of relapse between groups. Moreover, it must be noted that the starting ROM influences the postoperative ROM after surgery.

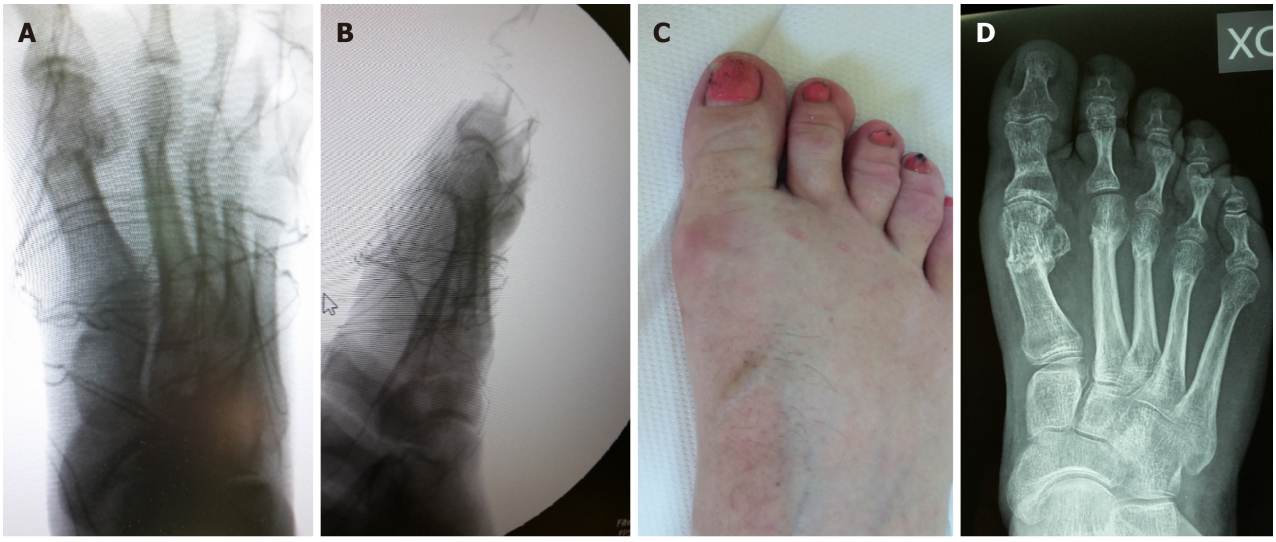

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Figure 2 Postoperative fluoroscopic picture of the patient treated with percutaneous hallux valgus correction without fixation (bandages) and follow-up. A: Postoperative fluoroscopic picture of the patient treated with percutaneous hallux valgus correction without fixation (bandages); B: Clinical and postoperative X-rays of the previous patients at 6 mo of follow-up.

According to the conclusions of the metanalysis of Izzo *et al*[28], we found no difference in AOFAS and recurrence rate between procedures, but ROM was revealed better at follow-up in LSTR N group, which was not directly investigated in the meta-analysis.

We believe these data represent an essential element to understanding the etiopathogenesis of complications. LSTR did not produce significant differences between the two groups regarding the increased incidence of relapses. This data also enhances the validity of MIS with no osteosynthesis technique. Being a step-by-step procedure, it allows us to reserve the LSTR as the last surgical gesture and carry it out exclusively when, from the intraoperative evaluation, sufficient metatarsal-phalangeal joint congruence has not been obtained[29].

The osteotomy practiced with a burr provided more significant shortening and joint decompression than the one performed with a blade[22,30]. We always associate Akin's osteotomy while keeping the medial cortical intact to balance the physiological loss of correction in post-op[31]. In agreement with Coughlin, the proper correction of DMMA allows the restoration of the balance of muscle forces at the level of the first ray in order to avoid adhesions and soft tissue retraction[1,32]. Our study reported better IMA correction than Reverdin and comparable results to Bauer *et al*[17] and Isham[19].

Our results demonstrated the reliability, durability, and lower incidence of complications of the technique than open techniques for HV correction[4,33]; we have recorded an incidence of complications of 9%, similar to other studies where the surgery was performed without fixation other than bandages[22,34-36] and fewer complications than studies with other MIS techniques[12,24].

According to Tournemine *et al*[37], we believe that the low incidence of this complication is due to our setting to practice DMMO in patients with particularly short metatarsals and patients with slightly and occasionally reported metatarsalgia[38,39]. Joint stiffness (global ROM < 95°) was recorded in 5.88% of patients treated without LSTR and 3.83% treated with LSTR, for a global rate of 4.8%. Some results could be justified by the lack of debris removal from the joint after exostectomy and partly by the lack of recognition of an initial hallux rigidus[40-42].

From the analysis of immediate postoperative radiography, we learned that the accurate removal of debris is a fundamental element, and two factors play a decisive role. The first is the image quality of the brightness amplifier during the intervention and the projection of the radiogram, which can be misinterpreted; and the second is the direct removal with the rasp towards the capsule to extract the fragments that often remain strictly attached to the capsule and are not easily removable even with saline solution irrigation[43]. To avoid the recurrence of exostoses we also recommend extending the exostectomy up to 2-3 mm beyond the profile of the medial cortex[25].

We reported a low percentage of pseudoarthrosis compared to those described in other different MIS techniques. In our view, it is one of the advantages of our technique. The removal of the exostosis makes it necessary for the axis correction with a lower head translation, which ensures more stability. Moreover, the osteotomy is performed intra-capsular and safely regarding bone consolidation[44,45]. The Bosch and SERI techniques needed a greater translation of the head, which is not modular. The infection rate is similar to other percutaneous studies, and it is lower than other studies analyzing treatment with K wire at a rate ranging from 0.8% to 8%[12,13,24,46].

As for most literature, no avascular necrosis was reported[47,48]. While even if rare, it was reported that an incidence of avascular necrosis ranges from 0.8% to 3.5%[49]. Low burr speed and continuous irrigation with saline solution are fundamental elements to avoid avascular necrosis and scrupulous respect for the osteotomy level[30]. We believe that the low incidence of transfer metatarsalgia is linked to our practice of DMMO (II-III-IV) in patients who report mild and occasional metatarsalgia, in particular in those in which a metatarsal formula with index minus is evidenced[30,50,51].

AOFAS score increased in both groups at 6 mo and last follow-up with increase in functional abilities and decrease in pain.

The study has several limitations; some are intrinsic to the study's retrospective nature, while others are intrinsic with the study design. The lack of randomization, priori sample size calculation, the lack of blindness, and the decision to perform soft tissue lateral release or not are the study's most critical limitations. The results of this study should be useful to surgeons treating these conditions. However, due to the lack of prospective studies in the literature regarding the LSTR procedure, we hope that our work will be a starting point for future prospective studies regarding this technique. We hope, in particular, that the aspect of joint stiffness will be deepened.

CONCLUSION

The percutaneous correction of HV is a reliable and safe procedure that significantly improves the AOFAS score and radiological angles, with a low risk of recurrence for the LSTR group. LSTR does not seem to affect pathology relapse, while the adequate correction of HVA remains the crucial factor. Early weight-bearing, minimal invasiveness, and the lack of internal fixation represent this technique's advantages. LSTR seems to increase postoperative joint stiffness with a comparable incidence of relapse and a low incidence of complications. This data also enhances the validity of MIS with no osteosynthesis technique. Being a step-by-step procedure, it allows us to reserve the LSTR as the last surgical gesture and carry it out exclusively when, from the intraoperative evaluation, sufficient metatarsal-phalangeal joint congruence has not been obtained.

ARTICLE HIGHLIGHTS

Research background

Several minimally invasive surgical techniques for the correction of hallux valgus (HV) have emerged in the literature. These techniques concern the distal osteotomy of the first metatarsal, the use or not of internal fixation, osteotomy of the base of the first phalanx (Akin osteotomy). All these techniques can be associated with the lateral release of soft tissues.

Research motivation

The lack of copious prospective studies regarding lateral soft tissues release (LSTR) procedure.

Research objectives

The object of this study is to evaluate the role of LSTR on percutaneous HV correction, evaluating functional and radiographical results.

Research methods

From January 2012 to May 2016, a total of 396 patients with mild to moderate symptomatic HV treated with the MIS technique were included in this retrospective study. The technique provides no internal fixation. Patients were divided into the LSTR group (LSTR Y) and no LSTR group (LSTR N). This surgical procedure (LSTR) was reserved for insufficient HV angle (HVA) correction during fluoroscopic control. Patients were evaluated at each follow-up by two other authors after appropriate training by senior authors (first practitioners).

Research results

We found a statistically significant difference in range of motion between the two groups (LSTR-N and LSTR-Y) at 6 mo ($P = 0.018423$) and the last follow-up ($P = 0.02$). There are no significant differences between groups for the other parameters assessed (HVA, intermetatarsal angle, American Orthopaedic Foot and Ankle Society, visual analog scale).

Research conclusions

LSTR does not seem to affect pathology relapse, while the adequate correction of HVA remains the crucial factor. LSTR seems to increase postoperative joint stiffness with a comparable incidence of relapse and a low incidence of complications.

Research perspectives

Because of the lack of copious prospective studies regarding LSTR procedure, we feel a more thorough literature review is presented with both prospective and retrospective analyses. The results of this study should be useful to surgeons treating this condition and can be used in the design of future investigations into the joint stiffness.

FOOTNOTES

Author contributions: Zanchini F, Catani O, and Sergio F designed the research study and performed the research; Boemio A, Sieczak A,

and Piscopo D analyzed the data and wrote the manuscript; Colò G and Fusini F share co-last authorship, and they revised the text of the manuscript; and all authors have read and approve the final manuscript.

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REFERENCES

1 **Coughlin MJ**, Jones CP. Hallux valgus: demographics, etiology, and radiographic assessment. *Foot Ankle Int* 2007; **28**: 759-777 [PMID: 17666168 DOI: 10.3113/FAI.2007.0759]
2 **Castillo-López JM**, Munuera-Martínez PV, Algaba-Guisado C, Reina-Bueno M, Salti-Pozo N, Vargas-Macías A. Pathologic Disorders of the Foot in Professional Female Flamenco Dancers. *J Am Podiatr Med Assoc* 2016; **106**: 54-59 [PMID: 26895362 DOI: 10.7547/14-111]
3 **Stienstra JJ**, Lee JA, Nakadate DT. Large displacement distal chevron osteotomy for the correction of hallux valgus deformity. *J Foot Ankle Surg* 2002; **41**: 213-220 [PMID: 12194510 DOI: 10.1016/S1067-2516(02)80017-5]
4 **Baravarian B**, Briskin GB, Burns P. Lapidus bunionectomy: arthrodesis of the first metatarsocunieform joint. *Clin Podiatr Med Surg* 2004; **21**: 97-111, vi [PMID: 15012034 DOI: 10.1016/S0891-8422(03)00112-5]
5 **Biz C**, Corradin M, Petretta I, Aldegheri R. Endolog technique for correction of hallux valgus: a prospective study of 30 patients with 4-year follow-up. *J Orthop Surg Res* 2015; **10**: 102 [PMID: 26135394 DOI: 10.1186/s13018-015-0245-1]
6 **Trnka HJ**. Osteotomies for hallux valgus correction. *Foot Ankle Clin* 2005; **10**: 15-33 [PMID: 15831256 DOI: 10.1016/j.fcl.2004.10.002]
7 **Roukis TS**. Percutaneous and minimum incision metatarsal osteotomies: a systematic review. *J Foot Ankle Surg* 2009; **48**: 380-387 [PMID: 19423043 DOI: 10.1053/j.jfas.2009.01.007]
8 **Trnka HJ**. Percutaneous, MIS and open hallux valgus surgery. *EFORT Open Rev* 2021; **6**: 432-438 [PMID: 34267933 DOI: 10.1302/2058-5241.6.210029]
9 **Dennis NZ**, Das De S. Modified Mitchell's osteotomy for moderate to severe hallux valgus--an outcome study. *J Foot Ankle Surg* 2011; **50**: 50-54 [PMID: 21106414 DOI: 10.1053/j.jfas.2010.10.005]
10 **Magnan B**, Bortolazzi R, Samaila E, Pezzè L, Rossi N, Bartolozzi P. Percutaneous distal metatarsal osteotomy for correction of hallux valgus. Surgical technique. *J Bone Joint Surg Am* 2006; **88** Suppl 1 Pt 1: 135-148 [PMID: 16510807 DOI: 10.2106/JBJS.E.00897]
11 **Siclari A**, Decantis V. Arthroscopic lateral release and percutaneous distal osteotomy for hallux valgus: a preliminary report. *Foot Ankle Int* 2009; **30**: 675-679 [PMID: 19589315 DOI: 10.3113/FAI.2009.0675]
12 **Giannini S**, Faldini C, Nanni M, Di Martino A, Luciani D, Vannini F. A minimally invasive technique for surgical treatment of hallux valgus: simple, effective, rapid, inexpensive (SERI). *Int Orthop* 2013; **37**: 1805-1813 [PMID: 23820757 DOI: 10.1007/s00264-013-1980-8]
13 **Maffulli N**, Longo UG, Marinozzi A, Denaro V. Hallux valgus: effectiveness and safety of minimally invasive surgery. A systematic review. *Br Med Bull* 2011; **97**: 149-167 [PMID: 20710024 DOI: 10.1093/bmb/ldq027]
14 **Van Enoo RE**, Cane EM. Minimal incision surgery. A plastic technique or a cover-up? *Clin Podiatr Med Surg* 1986; **3**: 321-335 [PMID: 2938721]
15 **Redfern D**, Vernois J, Legré BP. Percutaneous Surgery of the Forefoot. *Clin Podiatr Med Surg* 2015; **32**: 291-332 [PMID: 26117570 DOI: 10.1016/j.cpm.2015.03.007]
16 **Laffenêtre O**, Millet-Barbé B, Darcel V, Lucas Y Hernandez J, Chauveaux D. Percutaneous bunionette correction: results of a 49-case retrospective study at a mean 34 months' follow-up. *Orthop Traumatol Surg Res* 2015; **101**: 179-184 [PMID: 25701161 DOI: 10.1016/j.otsr.2014.11.017]
17 **Bauer T**, de Lavigne C, Biau D, De Prado M, Isham S, Laffenétre O. Percutaneous hallux valgus surgery: a prospective multicenter study of 189 cases. *Orthop Clin North Am* 2009; **40**: 505-514, ix [PMID: 19773056 DOI: 10.1016/j.ocl.2009.05.002]
18 **de Prado M**, Ripoll PL, Vaquero J, Golanó P. Tratamiento quirúrgico percutáneo del hallux valgus mediante osteotomías múltiples. *Rev Esp Cir Ortop Traumatol* 2003; **47**: 406-416 [DOI: 10.1016/S1888-4415(03)76145-1]

19 **Isham SA**. The Reverdin-Isham procedure for the correction of hallux abducto valgus. A distal metatarsal osteotomy procedure. *Clin Podiatr Med Surg* 1991; **8**: 81-94 [PMID: 2015537 DOI: 10.1016/S0891-8422(23)00420-2]

20 **Lucas y Hernandez J**, Golanó P, Roshan-Zamir S, Darcel V, Chauveaux D, Laffenêtre O. Treatment of moderate hallux valgus by percutaneous, extra-articular reverse-L Chevron (PERC) osteotomy. *Bone Joint J* 2016; **98-B**: 365-373 [PMID: 26920962 DOI: 10.1302/0301-620X.98B3.35666]

21 **Shereff MJ**. Pathophysiology, anatomy, and biomechanics of hallux valgus. *Orthopedics* 1990; **13**: 939-945 [PMID: 2235742 DOI: 10.3928/0147-7447-19900901-06]

22 **Lucattelli G**, Catani O, Sergio F, Cipollaro L, Maffulli N. Preliminary Experience With a Minimally Invasive Technique for Hallux Valgus Correction With No Fixation. *Foot Ankle Int* 2020; **41**: 37-43 [PMID: 31437408 DOI: 10.1177/1071100719868725]

23 **Caravelli S**, Mosca M, Massimi S, Costa GG, Lo Presti M, Fuiano M, Grassi A, Zaffagnini S. Percutaneous treatment of hallux valgus: What's the evidence? A systematic review. *Musculoskelet Surg* 2018; **102**: 111-117 [PMID: 29081030 DOI: 10.1007/s12306-017-0512-x]

24 **Faldini C**, Nanni M, Traina F, Fabbri D, Borghi R, Giannini S. Surgical treatment of hallux valgus associated with flexible flatfoot during growing age. *Int Orthop* 2016; **40**: 737-743 [PMID: 26508497 DOI: 10.1007/s00264-015-3019-9]

25 **Catani O**, Fusini F, Zanchini F, Sergio F, Cautiero G, Villafañe JH, Langella F. Functional outcomes of percutaneous correction of hallux valgus in not symptomatic flatfoot: a case series study. *Acta Biomed* 2020; **91**: e2020065 [PMID: 32921761 DOI: 10.23750/abm.v91i3.8294]

26 **Pappas PG**, Kauffman CA, Andes DR, Clancy CJ, Marr KA, Ostrosky-Zeichner L, Reboli AC, Schuster MG, Vazquez JA, Walsh TJ, Zaoutis TE, Sobel JD. Clinical Practice Guideline for the Management of Candidiasis: 2016 Update by the Infectious Diseases Society of America. *Clin Infect Dis* 2016; **62**: e1-50 [PMID: 26679628 DOI: 10.1093/cid/civ933]

27 **Yassin M**, Bowirat A, Robinson D. Percutaneous surgery of the forefoot compared with open technique - Functional results, complications and patient satisfaction. *Foot Ankle Surg* 2020; **26**: 156-162 [PMID: 30737141 DOI: 10.1016/j.fas.2019.01.006]

28 **Izzo A**, Vallefuoco S, Basso MA, Ray R, Smeraglia F, Cozzolino A, Mariconda M, Bernasconi A. Role of lateral soft tissue release in percutaneous hallux valgus surgery: a systematic review and meta-analysis of the literature. *Arch Orthop Trauma Surg* 2023; **143**: 3997-4007 [PMID: 36352268 DOI: 10.1007/s00402-022-04693-x]

29 **Del Vecchio JJ**, Dalmau-Pastor M. Percutaneous Lateral Release in Hallux Valgus: Anatomic Basis and Indications. *Foot Ankle Clin* 2020; **25**: 373-383 [PMID: 32736735 DOI: 10.1016/j.fcl.2020.05.003]

30 **Fusini F**, Langella F, Catani O, Sergio F, Zanchini F. Mini-Invasive Treatment for Brachymetatarsia of the Fourth Ray in Females: Percutaneous Osteotomy With Mini-Burr and External Fixation-A Case Series. *J Foot Ankle Surg* 2017; **56**: 390-394 [PMID: 28089127 DOI: 10.1053/j.jfas.2016.10.015]

31 **Montiel V**, Yáñez Arauz JM, Suárez Á, Villas Tomé C, Alfonso Olmos-García M. Osteotomies of the second phalanx of the great toe: A clinical experience. *Foot (Edinb)* 2022; **53**: 101935 [PMID: 36037778 DOI: 10.1016/j.foot.2022.101935]

32 **Coughlin MJ**. Hallux valgus in men: effect of the distal metatarsal articular angle on hallux valgus correction. *Foot Ankle Int* 1997; **18**: 463-470 [PMID: 9278739 DOI: 10.1177/107110079701800802]

33 **Torrent J**, Baduell A, Vega J, Malagelada F, Luna R, Rabat E. Open vs Minimally Invasive Scarf Osteotomy for Hallux Valgus Correction: A Randomized Controlled Trial. *Foot Ankle Int* 2021; **42**: 982-993 [PMID: 34024185 DOI: 10.1177/10711007211003565]

34 **Baertich C**, Tablante AJC, Tablante EB, Lecoq M. Percutaneous, implantless basal closing wedge osteotomy for hallux valgus: Surgical technique and preliminary results in 114 patients. *Foot Ankle Surg* 2022; **28**: 1083-1088 [PMID: 35379571 DOI: 10.1016/j.fas.2022.03.005]

35 **Liszka H**, Gądek A. Percutaneous Transosseous Suture Fixation of the Akin Osteotomy and Minimally Invasive Chevron for Correction of Hallux Valgus. *Foot Ankle Int* 2020; **41**: 1079-1091 [PMID: 32659140 DOI: 10.1177/1071100720935036]

36 **Gutteck N**, Ulbricht M, Delank KS, Kielstein H, Schilde S. Minimally invasive hallux valgus correction with Internal Hallux Fixator® - A comparative cadaver study. *Foot Ankle Surg* 2022; **28**: 378-383 [PMID: 34275760 DOI: 10.1016/j.fas.2021.05.002]

37 **Tournemine S**, Calé F, Cazeau C, Bauer T, Stiglitz Y. Shortening effect influence of Distal Minimally Invasive Metatarsal Osteotomy in primary metatarsalgia. *Int Orthop* 2022; **46**: 983-988 [PMID: 34417638 DOI: 10.1007/s00264-021-05146-7]

38 **Samaila EM**, Ditta A, Negri S, Leigheb M, Colò G, Magnan B. Central metatarsal fractures: a review and current concepts. *Acta Biomed* 2020; **91**: 36-46 [PMID: 32555075 DOI: 10.23750/abm.v91i4-S.9724]

39 **Colò G**, Fusini F, Samaila EM, Rava A, Felli L, Alessio-Mazzola M, Magnan B. The efficacy of shoe modifications and foot orthoses in treating patients with hallux rigidus: a comprehensive review of literature. *Acta Biomed* 2020; **91**: e2020016 [PMID: 33559617 DOI: 10.23750/abm.v91i14-S.10969]

40 **Saur M**, Lucas Y Hernandes J, Barouk P, Bejarano-Pineda L, Maynou C, Laffenetre O. Average 4-Year Outcomes of Distal Oblique First Metatarsal Osteotomy for Stage 1 to 3 Hallux Rigidus. *Foot Ankle Int* 2022; **43**: 463-473 [PMID: 34747650 DOI: 10.1177/10711007211052298]

41 **Colò G**, Alessio-Mazzola M, Dagnino G, Felli L. Long-Term Results of Surgical Treatment of Valenti Procedures for Hallux Rigidus: A Minimum Ten-Year Follow-Up Retrospective Study. *J Foot Ankle Surg* 2019; **58**: 291-294 [PMID: 30850097 DOI: 10.1053/j.jfas.2018.08.055]

42 **Colò G**, Samaila EM, Magnan B, Felli L. Valenti resection arthroplasty for hallux rigidus: A systematic review. *Foot Ankle Surg* 2020; **26**: 838-844 [PMID: 31839478 DOI: 10.1016/j.fas.2019.11.009]

43 **Fusini F**, Alessandro M, Rava A, Kristijan Z, Felli L, Colò G. Aetiology, diagnosis, and treatment of brachymetatarsia: a narrative review. *Musculoskelet Surg* 2022; **106**: 99-109 [PMID: 34268706 DOI: 10.1007/s12306-021-00720-z]

44 **Martinelli N**, Cancilleri F, Marineo G, Marinozzi A, Longo UG, Denaro V. Pseudarthrosis after percutaneous distal osteotomy in hallux valgus surgery: a case report. *J Am Podiatr Med Assoc* 2012; **102**: 78-82 [PMID: 22232327 DOI: 10.7547/1020078]

45 **Ji L**, Wang K, Ding S, Sun C, Sun S, Zhang M. Minimally Invasive vs. Open Surgery for Hallux Valgus: A Meta-Analysis. *Front Surg* 2022; **9**: 843410 [PMID: 35388365 DOI: 10.3389/fsurg.2022.843410]

46 **Bösch P**, Wanke S, Legenstein R. Hallux valgus correction by the method of Bösch: a new technique with a seven-to-ten-year follow-up. *Foot Ankle Clin* 2000; **5**: 485-498, v [PMID: 11232393]

47 **Enan A**, Abo-Hegy M, Seif H. Early results of distal metatarsal osteotomy through minimally invasive approach for mild-to-moderate hallux valgus. *Acta Orthop Belg* 2010; **76**: 526-535 [PMID: 20973361]

48 **Magnan B**, Samaila E, Viola G, Bartolozzi P. Minimally invasive retrocapital osteotomy of the first metatarsal in hallux valgus deformity. *Oper Orthop Traumatol* 2008; **20**: 89-96 [PMID: 18338122 DOI: 10.1007/s00064-008-1231-0]

49 **Kadakia AR**, Smerek JP, Myerson MS. Radiographic results after percutaneous distal metatarsal osteotomy for correction of hallux valgus deformity. *Foot Ankle Int* 2007; **28**: 355-360 [PMID: 17371659 DOI: 10.3113/FAI.2007.0355]

50 **Arie EK**, Moreira NS, Freire GS, Dos Santos BS, Yi LC. Study of the metatarsal formula in patient with primary metatarsalgia. *Rev Bras Ortop* 2015; **50**: 438-444 [PMID: 26401502 DOI: 10.1016/j.rboe.2015.06.018]

51 **de Palma L**, Gigante A, Ventura A, Chillemi C. Regnauld procedure in the surgical treatment of metatarsalgia: interpretation of follow-up X-ray imaging. *J Foot Ankle Surg* 1997; **36**: 165-9; discussion 255 [PMID: 9232494 DOI: 10.1016/S1067-2516(97)80110-X]

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ORIGINAL ARTICLE

Observational Study

Comparison of clinical outcomes between total hip replacement and total knee replacement

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Abstract

BACKGROUND

Total hip replacements (THR) and total knee replacements (TKR) are effective treatments for severe osteoarthritis (OA). Some studies suggest clinical outcomes following THR are superior to TKR, the reason for which remains unknown. This study compares clinical outcomes between THR and TKR.

AIM

To compare the clinic outcomes of THR anad TKR using a comprehensive range of patient reported outcome measures (PROMs).

METHODS

A prospective longitudinal observational study of patients with OA undergoing THR and TKR were evaluated using a comprehensive range of generic and joint specific PROMs pre- and post-operatively.

RESULTS

A total of 131 patients were included in the study which comprised the THR group (68 patients) and the TKR group (63 patients). Both groups demonstrated significant post-operative improvements in all PROM scores ($P < 0.001$). There were no significant differences in post-operative PROM scores between the two groups: Hip and Knee Osteoarthritis Outcome scores ($P = 0.140$), Western Ontario and McMaster Universities Osteoarthritis Index pain ($P = 0.297$) stiffness ($P = 0.309$) and function ($P = 0.945$), Oxford Hip and Knee Score ($P = 0.076$), EuroQol-5D index ($P = 0.386$) and Short-Form 12-item survey physical component score ($P = 0.106$). Subgroup analyses showed no significant difference ($P > 0.05$) between cruciate retaining and posterior stabilised prostheses in the TKR group and no significant difference ($P > 0.05$) between cemented and uncemented fixation in the

THR group. Obese patients had poorer outcomes following TKR but did not significantly influence the outcome following THR.

CONCLUSION

Contrary to some literature, THR and TKR are equally efficacious in alleviating the pain and disability of OA when assessed using a comprehensive range of PROMs. The varying knee prosthesis types and hip fixation techniques did not significantly influence clinical outcome. Obesity had a greater influence on the outcome following TKR than that of THR.

Key Words: Obesity; Osteoarthritis; Patient reported outcome measures; Total hip arthroplasty; Total knee arthroplasty

Core Tip: Previous literature has suggested that the when comparing outcomes of total hip and knee replacements, on symptoms, function, and quality of life, as assessed by patient reported outcome measure (PROM) scores, total hip replacement have superior benefits to total knee replacements. This study has demonstrated, when a comprehensive range of PROM scores are used, both procedures are equivocally and very effective for the treatment of severe osteoarthritis. Sub-analysis in the study has confirmed that whilst obese patients have poorer outcomes, they can still greatly benefit from surgical intervention.

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INTRODUCTION

Osteoarthritis (OA) is a heterogenous disorder of joints which is characterised by degradation and loss of articular cartilage, osteophyte formation, subchondral remodelling and synovial inflammation which leads to symptoms of joint stiffness, instability, swelling, weakness and, most commonly, pain[1]. Globally, an estimated 240 million people globally suffer from the chronic sequelae of OA and is a leading cause of global disability[2,3]. Risk factors for OA include female gender[4], obesity[5], increasing age[6], and soft tissue trauma including meniscal tears[7]. As the United Kingdom population ages and becomes increasingly obese, rates of OA prevalence have increased from 8.2% to 10.7% in the past 20 years[4]. Over 90000 primary total knee replacements (TKR) and over 95000 primary total hip replacements (THR) were performed in 2019 in the United Kingdom[8].

First line conservative treatment of OA includes analgesia, physiotherapy, activity modification, viscosupplementation, orthotics, steroid injections, topical gels, *etc*[9]. When symptoms are refractory to a consented period of non-operative treatment, surgical intervention is indicated in patients considered anaesthetically fit to undergo the procedure[10]. TKR and THR are the most common surgical procedures for the management of end-stage OA[8]. The major aims of joint arthroplasties are to improve symptoms of pain and functionality whilst improving the biomechanical and kinematic milieu of the joint[11].

Primary TKRs involve replacing the articular surface of the femur and tibia using either a cruciate retaining (CR) or posterior stabilized (PS) prosthesis. Primary THRs involve reaming the articular surface of the acetabulum and also removing the head and proximal neck of the femur and implanting cup and stem prosthetic components into the acetabulum and femur respectively, using either a cemented or uncemented technique[12,13]. Alternatively, a hybrid approach of a cemented femoral stem and an uncemented acetabular component can be utilised.

Lower limb joint arthroplasty also aims to improve the individual's quality of life (QoL). Patient reported outcome measures (PROMs) are validated instruments which assess the symptoms, function and wellbeing of patients from their own perspective[14]. These offer a more detailed analysis than overall satisfaction rates. Published satisfaction rates following TKR average 81%[15] and range from 75% to 92%[16] whereas slightly higher rates, 86% to 95%, are reported following total hip arthroplasty[17]. A few studies have compared TKR and THR using PROMs to identify which is associated with the greatest improvement in clinical outcomes[18-20]. These studies suggest THRs are associated with superior outcomes however they are limited by a lack of variety of PROM instruments.

Wylde *et al*[18] compared the midterm clinical outcomes for TKR and THR procedures between 5 and 8 years post-operatively using the Oxford Knee Scores (OKS) and Oxford Hip Scores (OHS) respectively for 1725 patients. This showed clinical outcomes following THR were statistically superior to those following TKR. However, the use of only a single PROM score, despite the vast cohort size, provides a weak comparison of the two surgical procedures. Equipoise remains over the clinical outcomes following TKR and THR in this cohort when using additional PROM instruments, particularly joint-specific PROMs that do not consider comorbidities.

Current literature provides clear justification comparing TKR and THR using a more extensive selection of PROM instruments than previous studies which will help to identify if results remain similar under a more scrutinous comparison. Previous research has suggested that an increased body mass index (BMI) is associated with worse post-operative functional scores and increased complications following TKR than patients of normal BMI[21]. Similarly, clinical outcomes following THRs were worse for obese and morbidly obese patients than those who were non-obese[22]. Furthermore, increasing levels of obesity have been shown to increase total stress and stress distribution in hip implants [23]. The impact of obesity using PROMs following TKR and THR also requires further investigation. The aim of this study was to quantitatively evaluate patients with OA of the hip and knee before and after joint replacement surgery using validated PROMs and to compare the clinical outcomes between THR and TKR.

MATERIALS AND METHODS

This was a prospective longitudinal observational study of adult patients with advanced hip and knee OA, that was refractory to initial conservative treatment, who underwent elective primary THR and primary TKR, respectively, by a single consultant orthopaedic surgeon between August 2015 and March 2019. All patients included in this study completed PROM forms at their initial outpatient clinic consultation and also 12 mo following their surgery at their final post-operative follow-up clinic appointment. This study was exempt from institutional review board and ethics committee approval as it was a pragmatic study evaluating the existing clinical practice of the senior author. This observational study constituted part of the second author's Masters dissertation.

All TKR's were implanted *via* a standard medial para-patellar approach using Palacos + Gentamycin PMMA cement (Heraus Medical Gmbh, Hanau, Germany). The TKR prosthesis used for the TKR group was Genesis II (Smith & Nephew Inc., Memphis, Tennessee, United States) for both the CR and PS implants and all patients also had patella resurfacing (round resurfacing onlay patella). All THR's were implanted *via* standard posterior approach using Palacos + Gentamycin PMMA cement (Heraus Medical Gmbh, Hanau, Germany) for the cemented hip components. The cemented THR prosthesis used was the cemented Exeter V40 femoral stem (Stryker Corp., Michigan, United States) and the cemented Exeter X3 RimFit acetabular cup (Stryker Corp., Michigan, United States). The uncemented THR prosthesis used was the uncemented anthology femoral stem (Smith & Nephew Inc., Memphis, Tennessee, United States) and the uncemented R3 acetabular cup (Smith & Nephew Inc., Memphis, Tennessee, United States). The hybrid THR used the cemented Exeter V40 femoral stem along with the uncemented R3 acetabular cup. Generic PROM scores for all patients included: (1) EuroQol-5D index (EQ-5D)[24-27]; (2) Short Form 12-item Survey (SF-12)[28]; and (3) Self-assessment Co-Morbidity Questionnaire (SCQ)[29]. Knee specific PROM scores for TKR patients included: (1) Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)[30,31]; (2) Knee Osteoarthritis Outcome Score (KOOS)[32,33]; and (3) OKS [34,35]. Hip specific PROM scores for THR patients included: (1) WOMAC[30,31]; (2) Hip Osteoarthritis Outcome Score (HOOS)[36,37]; and (3) OHS[35,38].

All data was scored and analysed according to the instructions in the original publications for each PROM, and any missing data was handled in line with the current literature. The OKS and the OHS were calculated using the updated standardised scoring system; 0 to 48 as described by Murray *et al*[35].

Statistical analysis

An a priori power calculation for this study was derived from previously published literature of the WOMAC score[39] with a minimal clinically important change of 10 and a standard deviation of 15. The sample sizes were based on a conventional type I error of 5% and a type II error rate of 10% (*i.e.*, 90% power). The calculation revealed that a sample size of approximately 49 subjects per group was required for a clinically relevant between group mean difference. Plotted histograms with fitted curve lines, box-plots, normal Q-Q plots and the Shapiro-Wilk statistic were used to test normality of data distribution. Almost all the continuous variables in the study displayed a skewed distribution and therefore the relevant non-parametric statistical tests were used for the data analysis. The Mann-Whitney *U* test was used for the between group statistical analyses and the Wilcoxon Signed Rank test was used for the within group analyses. The Kruskal-Wallis *H* test was used for the three-group hip prosthesis data analysis and the BMI analysis. The level of statistical significance was set at $P < 0.05$. Statistical analysis was performed using SPSS for Windows version 26.0 (IBM Corp., Armonk, New York). The power calculation was performed using Minitab statistical software version 18 (Minitab LLC, State College, Pennsylvania).

RESULTS

Patient demographics

A total of 131 patients were included in the study which constituted the TKR group ($n = 63$) and the THR group ($n = 68$). Table 1 shows their demographics, which overall, where very similar between the two groups. On average both groups were approximately 70 years old, overweight to obese, predominantly female and had undergone unilateral joint replacements. Both groups had similar American Society of Anaesthesiologist Physical Classification System classifications and SCQ scores.

Table 1 Patient demographics

	Total knee replacement (*n* = 63)	Total hip replacement (*n* = 68)
Age (yr), mean ± SD	72.1 ± 8.3	68.7 ± 9.4
Gender (male:female)	22:41	27:41
Laterality (left:right:bilateral)	27:34:2	27:41:0
Height (m), mean ± SD	1.62 ± 0.09	1.66 ± 0.10
Weight (kg), mean ± SD	80.2 ± 15.1	82.6 ± 16.7
BMI (kg/m^2), mean ± SD	30.4 ± 4.2	30.0 ± 5.5
ASA median (range)	2 (1-3)	2 (1-3)
SCQ median (range)	4 (0-15)	5 (0-18)

BMI: Body mass index; ASA: American Society of Anaesthesiologist Physical Classification System; SCQ: Self-Assessed Co-Morbidity Questionnaire.

TKR vs THR

Tables 2 and 3 (within-group analyses) show that all PROM scores significantly improved post-operatively as compared to their pre-operative results for both TKR and THR, respectively, with the only exception being the SF-12 MCS sub-score for THR (Table 3). Table 4 (between-group analysis) show no statistically significant differences in any of the PROM analyses between the two groups pre-operatively (with the only exception being KOOS/HOOS sports and recreation) or post-operatively.

TKR prostheses type

Of the 63 TKR patients, 36 had CR TKRs and 27 had PS TKRs. When comparing CR to PS TKRs there were no statistically significant differences in PROM scores between the two implants, neither pre-operatively nor post-operatively as shown in Table 5.

THR prosthesis type

Of the 68 THR patients, 36 had cemented THRs, 28 had uncemented THRs, 4 had hybrid THRs. The comparisons of pre-operative and post-operative PROM score are shown in Table 6. As the sample size of the hybrid group was small, no upper bound interquartile range value was produced during statistical analysis, thus only the lower quartile value is given. The different types of fixations showed no statistically significant differences pre-operatively or postoperatively. The difference in HOOS symptoms score did generate a *P*-value of 0.046 however given the borderline statistical significance and being the only identified difference between any of the THR subgroups, it is likely to reflect a type I statistical error.

Obesity

Comparisons of pre-operative and post-operative PROM scores of the TKR group and the THR group by BMI classification are shown in Tables 7 and 8 respectively. In the TKR group (Table 7) there were no significant differences between BMI classifications pre-operatively. However, higher BMI classifications (more obese patients) scored significantly worse following TKR in the KOOS Pain (P = 0.046), KOOS QoL (P = 0.032) and WOMAC pain (P = 0.045) sub-scores. Overall, there were no statistically significant differences pre- or post-operatively in the THR group (Table 8) pertaining to BMI classifications with the only exception being patients with a higher BMI had poorer OHS pre-operatively, however this was of borderline statistical significance (P = 0.046).

DISCUSSION

This study showed that both primary THR and primary TKR significantly improved patient reported outcomes following surgery in patients with advanced hip and knee OA. Overall, there was no significant difference in PROM scores post-operatively between the two procedures and are therefore considered to be equally efficacious in this regard. A large effect size, and of strong statistical significance was seen as found in recent United Kingdom studies[40].

The TKR group and THR group had similar baseline demographics in terms of age and gender as well as general health pertaining to anthropometric measures and prevalence of medical comorbidities, thereby allowing for a valid direct comparison of their PROM scores. The between-group pre-operative comparison of outcome scores showed no significant differences, reflecting the impact of pain, function, and QoL of severe hip and knee OA can be equally debilitating. The post-operative scores also showed no significant differences between the two groups suggesting that two procedures are equally effective at improving pain, function, and QoL. This is contrary to the findings of other studies[18-20] whereby THR outcomes have been shown to be superior to TKR outcomes. Bachmeier *et al*[19] found superior WOMAC and Medical Outcomes Study Short Form-36 (MOS SF-36) scores in the THR group. The conclusion of that

Table 2 Comparison of pre-operative and post-operative patient reported outcome measure scores: Total knee replacement

	Pre-operative (*n* = 63), median (IQR)	Post-operative (*n* = 63), median (IQR)	*P* value[1]	*Z* value
KOOS pain	36 (25-44)	92 (77 – 98)	< 0.001[a]	-6.617
KOOS symptoms	36 (21-46)	89 (82 – 93)	< 0.001[a]	-6.842
KOOS ADL	38 (31-44)	88 (78-97)	< 0.001[a]	-6.902
KOOS Sport/Rec	5 (0-25)	70 (50-86)	< 0.001[a]	-4.571
KOOS QoL	13 (6-25)	75 (56-93)	< 0.001[a]	-6.457
Overall KOOS	28.9 (18.2-37.9)	80.7 (64.5-89.4)	< 0.001[a]	-5.160
WOMAC pain	40 (30-50)	90 (80-100)	< 0.001[a]	-6.575
WOMAC stiffness	25 (25-37.5)	75 (63-100)	< 0.001[a]	-6.708
WOMAC function	38.2 (30.9-44.1)	91.2 (77.9-97.1)	< 0.001[a]	-6.625
Oxford knee score	15 (11-19)	40 (33-43)	< 0.001[a]	-6.618
EQ-5D index	0.345 (0.211-0.548)	0.821 (0.703-1)	< 0.001[a]	-6.237
EQ-5D VAS	65 (50-80)	83 (71-95)	< 0.001[a]	-5.323
SF-12 PCS	27.6 (23.2-32.1)	43.8 (33.0-50.4)	< 0.001[a]	-5.333
SF-12 MCS	47.0 (39.3-56.5)	58.6 (51.5-61.3)	< 0.001[a]	-3.832

[1]Wilcoxon Signed Rank test.

[a]Statistically significant $P < 0.05$.

IQR: Interquartile range; KOOS: Knee Osteoarthritis Outcome Score; ADL: Activities of daily living; Sport/Rec: Sports and recreation; QoL: Quality of life; WOMAC: Western Ontario and McMaster Universities Osteoarthritis Index; EQ-5D: EuroQol-5D index; VAS: Visual Analogue Scale; SF-12: Short form 12 item survey; PCS: Physical component summary; MCS: Mental component summary.

study is limited, as it had approximately 50% dropout rate at 12 mo, the use of only a small range of PROM scores and was conducted 22 years ago where much has changed in the field of arthroplasty surgery. Choi *et al*[20] also found superior clinical outcomes for THR at 2 years using WOMAC and SF-12 scores. That study was limited by its unequal demographics between the two cohorts as the TKR group were older, more overweight and contained a much higher proportion of females. Additionally, only one disease specific (WOMAC) and one generic (SF-12) PROM score was assessed. The WOMAC score uses generic joint-related questions to compare clinical outcomes but are not joint specific [30]. The MOS SF-36 and SF-12 are generic health PROM scores, therefore co-factors such as medical comorbidities[41] may confound the overall end results as unhealthier patients will have worse scores irrespective of the clinical outcomes of their osteoarthritic joints post-operatively. Additionally, the THR group in one study were significantly older, more overweight and had a higher proportion of females, than the TKR group[20]. Wylde *et al*[18] compared only the Oxford Hip and Knee Scores but were able to demonstrate greater improvements in the THR group at 5-8 years despite a response rate of 72%.

This study explored the differences in PROM scores between CR and PS TKR implants. These procedures have their respective advantages and can impact post-operative clinical outcomes differently. The implant utilised is dependent upon patient eligibility as well as surgeon training and experience[42]. In principle, a CR TKR retains the posterior cruciate ligament (PCL) which preserves the femoral rollback mechanism thereby improving stability and proprioception which provides a more natural gait than a PS prosthesis[43,44]. PS TKRs involve replacing the PCL by inserting an articulating femoral cam and tibial spine mechanism[45] which is considered to be more mechanically stable with improved knee flexion[46]. CR TKR may be contra-indicated in the presence of a degenerated, deficient or chronically ruptured PCL, a PCL with poor elasticity, significant coronal and sagittal knee malalignment or in patients with a history of knee trauma where soft tissue balancing may prove difficult[42]. This study demonstrated there are no significant differences in post-operative PROM scores between the two implants. This confirms previous findings of no differences in PROMS between these types of knee arthroplasty[47,48].

THR techniques involve cemented, uncemented or a hybrid approach. Each has benefits depending on patient eligibility. Cementing is associated with improved overall survival and all-cause revision rates compared to uncemented and hybrid fixations[49] and has less complications in elderly patients with low bone density[50]. However, uncemented fixation may have superior survivorship than cemented fixations in younger patients, and overall, uncemented fixation is slightly more commonly practiced than cemented in England and Wales[51]. Uncemented fixation removes the risk of cement fragmentation and subsequent implant loosening requiring revision, and importantly prevents the possibility of bone cement implantation syndrome which can cause cardiovascular collapse and can be fatal[52]. Hybrid THR avoids the complication of acetabular cement fragmentation whilst retaining the aforementioned advantages of a cemented femoral stem[53]. There is little evidence demonstrating superior overall outcomes of hybrid THRs to other fixations[54].

Table 3 Comparison of pre-operative and post-operative patient reported outcome measure scores: Total hip replacement

	Pre-operative (*n* = 68), median (IQR)	Post-operative (*n* = 68), median (IQR)	*P* value[1]	*Z* value
HOOS pain	33 (25-40)	92 (77-98)	< 0.001[a]	-4.868
HOOS symptoms	38 (30-49)	89 (82-93)	< 0.001[a]	-4.909
HOOS ADL	37 (26-43)	88 (78-97)	< 0.001[a]	-4.841
HOOS Sport/Rec	19 (6-31)	70 (50-86)	< 0.001[a]	-4.788
HOOS QoL	19 (6-31)	75 (56-93)	< 0.001[a]	-4.663
Overall HOOS	28.9 (18.2-37.9)	80.7 (64.5-89.4)	< 0.001[a]	-4.681
WOMAC pain	40 (30-49)	95 (85-100)	< 0.001[a]	-4.932
WOMAC stiffness	25 (25-50)	88 (75-100)	< 0.001[a]	-4.760
WOMAC function	36.8 (28.3-44.1)	91.9 (75.7-98.5)	< 0.001[a]	-4.864
Oxford hip score	14 (10-20)	42 (35-47)	< 0.001[a]	-4.912
EQ-5D index	0.335 (0.169-0.533)	0.857 (0.643-1)	< 0.001[a]	-4.918
EQ-5D VAS	65 (50-80)	90 (79-95)	< 0.001[a]	-4.357
SF-12 PCS	24.8 (21.7-29.3)	50.6 (36.5-55.0)	< 0.001[a]	-4.623
SF-12 MCS	49.6 (39.9-58.3)	57.8 (55.4-59.8)	0.076	-1.776

[1]Wilcoxon Signed Rank test.

[a]Statistically significant $P < 0.05$.

IQR: Interquartile range; KOOS: Knee Osteoarthritis Outcome Score; ADL: Activities of daily living; Sport/Rec: Sports and recreation; QoL: Quality of life; WOMAC: Western Ontario and McMaster Universities Osteoarthritis Index; EQ-5D: EuroQol-5D index; VAS: Visual Analogue Scale; SF-12: Short form 12 item survey; PCS: Physical component summary; MCS: Mental component summary.

This study showed none of the implantation techniques demonstrated superior or inferior PROM scores as compared to each other. This is contrary to some previous evidence that uncemented THRs have better EQ-5D scores and pain relief [55,56].

This study has demonstrated hip and knee arthroplasty remain highly effective treatments for severe OA and greatly improve pain, function, and QoL regardless of the surgical method used. Results suggest that all prostheses for TKR and fixations for THR in this study, considering patient eligibility, remain as effective options for treating hip and knee OA to provide good clinical outcomes.

Obesity was associated with higher pain and poorer QoL following TKR as shown by the KOOS and WOMAC scores respectively in the present study. Obesity has previously been associated with a higher rate of post-operative complications including pain, superficial wound infections, deep joint infections, deep vein thrombosis, mechanical failure and dislocations as well as worse clinical outcomes such as more chronic pain, more disability and a higher risk of revision[57-59]. This study confirmed these findings as demonstrated by worse post-operative scores in KOOS pain, KOOS QoL, and WOMAC pain instruments for overweight and obese patients following TKR.

Si *et al*[21] found poorer post-operative clinical outcomes following TKR in obese patients using the Knee Society Score only, and Deakin *et al*[22] demonstrated obesity to be associated with worse clinical outcomes following both TKR and THR using the OKS and OHS respectively. These studies found significant differences between those considered: Not obese (BMI < 30), obese (BMI 30-40) and morbidly obese (> 40). In the present study, weight categories of normal (BMI < 25), overweight (BMI 25-30), obese (BMI > 30) and morbidly obese (BMI > 40) were used, thereby not conflating 'normal' and 'overweight' patients. Obese patients with hip OA had worse symptoms pre-operatively according to only one instrument (OHS) however this difference was not significant post-operatively. Conversely, in the TKR group, worse post-operative outcomes where demonstrated in obese patients for KOOS pain, KOOS QoL and WOMAC pain subscores.

For obese patients, pre-operative weight loss is routinely advocated as part of their conservative management. Overall, this study demonstrates good outcomes, as shown by improvements across multiple PROM scores, can be achieved in obese patients. Patients that are categorised as overweight or obese should not be denied arthroplasty based on BMI alone as obese patients obtained improved clinical outcomes and alleviation of their OA symptoms, however, caution should be exercised in the morbidly obese category of patients. The loss of functionality, associated with OA, may be a factor in patients being unable to lose weight through regular exercise. However, weight loss is primarily driven by diet, much more so than exercise, although the two combined approaches yield the best results. Therefore, it reasonable to consider total joint replacement if similar outcomes to patients of normal BMI are attainable. Furthermore, the previous studies measure one disease specific PROM each, the present study adds a more extensive insight into the impact of obesity on post-operative outcomes.

Table 4 Comparison of pre-operative and post-operative patient reported outcome measure scores: Total knee replacement *vs* total hip replacement

		TKR (*n* = 63), median (IQR)	THR (*n* = 68), median (IQR)	*P* value[1]	*Z* value	*U* value
KOOS/HOOS pain	Pre-operative	36 (25-44)	33 (25-40)	0.597	-0.528	1755
	Post-operative	92 (77-98)	95 (84-100)	0.208	-0.370	1206
KOOS/HOOS symptoms	Pre-operative	36 (21-46)	38 (30-49)	0.415	-0.415	1729
	Post-operative	89 (82-93)	90 (80-100)	0.629	-0.483	1189
KOOS/HOOS ADL	Pre-operative	38 (31-44)	37 (26-43)	0.298	-1.040	1656
	Post-operative	88 (78-97)	91 (76-98)	0.711	-0.370	1206
KOOS/HOOS Sport/Rec	Pre-operative	5 (0-25)	19 (6-31)	0.030[a]	-2.164	1001
	Post-operative	70 (50-86)	75 (56-100)	0.158	-0.141	738
KOOS/HOOS QoL	Pre-operative	13 (6-25)	19 (6-31)	0.106	-1.616	1519
	Post-operative	75 (56-93)	84 (58-94)	0.499	-0.676	1030
KOOS/HOOS overall	Pre-operative	28.9 (18.2-37.9)	28.0 (21.0-37.6)	0.833	-0.211	1267
	Post-operative	80.7 (64.5-89.4)	88.8 (72.9-95.5)	0.140	-1.476	713
WOMAC pain	Pre-operative	40 (30-50)	40 (30-49)	0.984	-0.02	1886
	Post-operative	90 (80-100)	95 (85-100)	0.297	-1.04	1020
WOMAC stiffness	Pre-operative	25 (25-37.5)	25 (25-50)	0.583	-0.55	1786
	Post-operative	75 (63-100)	88 (75-100)	0.309	-1.02	1114
WOMAC function	Pre-operative	38.2 (30.9-44.1)	36.8 (28.3-44.1)	0.639	-0.47	1798
	Post-operative	91.2 (77.9-97.1)	91.9 (75.7-98.5)	0.945	-0.07	1151
OKS/OHS	Pre-operative	15 (11-19)	14 (10-20)	0.859	-0.177	1826
	Post-operative	40 (33-43)	42 (35-47)	0.076	-1.775	932
EQ-5D index	Pre-operative	0.345 (0.211-0.548)	0.335 (0.169-0.533)	0.719	-0.36	1761
	Post-operative	0.821 (0.703-1)	0.857 (0.643-1)	0.386	-0.87	988
EQ-5D VAS	Pre-operative	65 (50-80)	65 (50-80)	0.308	-1.02	1579
	Post-operative	83 (71-95)	90 (79-95)	0.374	-0.89	1019
SF-12 PCS	Pre-operative	27.6 (23.2-32.1)	24.8 (21.7-29.3)	0.073	-1.79	1308
	Post-operative	43.8 (33.0-50.4)	50.6 (36.5-55.0)	0.106	-1.62	690
SF-12 MCS	Pre-operative	47.0 (39.3-56.5)	49.6 (39.9-58.3)	0.777	-0.28	1574
	Post-operative	58.6 (51.5-61.3)	57.8 (55.4-59.8)	0.438	-0.78	784

[1]Mann-Whitney *U* test.

[a]Statistically significant $P < 0.05$.

IQR: Interquartile range; TKR: Total knee replacement; THR: Total hip replacement; KOOS: Knee Osteoarthritis Outcome Score; HOOS: Hip Osteoarthritis Outcome Score; ADL: Activities of daily living; Sport/Rec: Sports and recreation; QoL: Quality of life; OKS: Oxford Knee Score; OHS: Oxford Hip Score; WOMAC: Western Ontario and McMaster Universities Osteoarthritis Index; EQ-5D: EuroQol-5D index; VAS: Visual Analogue Scale; SF-12: Short form 12 item survey; PCS: Physical component summary; MCS: Mental component summary.

A strength of this study is its comparison of multiple disease specific PROMs and (KOOS, HOOS, WOMAC, OKS and OHS) as well as generic PROMs (EQ-5D scores and SF-12). The use of this variety of scores can provide a more holistic and detailed assessment of clinical outcomes than that available in the current literature. Appropriate power calculations prove this study is adequately powered and less likely to produce a type-II statistical error. An additional strength of this study is that the hip and knee OA cohorts had similar demographics and severity of OA disease, allowing for direct comparison of improvements between the two arthroplasty procedures.

There are some potential limitations of this study. The relative impact of arthroplasty on hip and knee OA were compared directly using HOOS and KOOS in Table 4, despite them being separate instruments. Whilst different, they are comprised of the same metrics and sub-scores which enable direct comparisons. This method has previously been used

Table 5 Comparison of pre-operative and post-operative total knee replacement patient reported outcome measure scores: Cruciate retaining *vs* posterior stabilised implants

		Cruciate retaining (*n* = 36), median (IQR)	Posterior stabilised (*n* = 27), median (IQR)	*P* value[1]	*Z* value	*U* value
KOOS pain	Pre-operative	36 (23-44)	36 (25-42)	0.568	-0.57	445.0
	Post-operative	89 (69-100)	94 (83-97)	0.271	-1.10	348.5
KOOS symptoms	Pre-operative	36 (26-53)	32 (21-43)	0.181	-1.34	390.0
	Post-operative	86 (80-89)	89 (86-93)	0.074	-1.79	358.5
KOOS ADL	Pre-operative	39 (31-46)	38 (29-44)	0.950	-0.06	481.5
	Post-operative	88 (75-96)	94 (82-97)	0.292	-1.05	410.5
KOOS Sport/Rec	Pre-operative	5 (0-29)	5 (0-25)	0.721	-0.36	277.0
	Post-operative	70 (50-85)	70 (60-95)	0.671	-0.43	237.5
KOOS QoL	Pre-operative	6 (2-25)	13 (6-27)	0.408	-0.83	411.0
	Post-operative	75 (56-81)	75 (61-94)	0.557	-0.59	354.5
Overall KOOS	Pre-operative	29. 8 (20.8-36.5)	27.2 (16.8-38.5)	0.880	-0.15	286.5
	Post-operative	81.3 (64.0-88.8)	80.7 (75.3-90.8)	0.730	-0.35	232.0
WOMAC pain	Pre-operative	40 (30-50)	35 (30-50)	0.867	-0.17	474.0
	Post-operative	90 (75-100)	95 (85-100)	0.376	-0.88	363.0
WOMAC stiffness	Pre-operative	25 (25-47)	25 (25-38)	0.930	-0.09	480.0
	Post-operative	75 (63-88)	75 (75-100)	0.112	-1.59	374.5
WOMAC function	Pre-operative	39.0 (30.9-45.2)	38.2 (29.4-44.1)	0.851	-0.19	472.5
	Post-operative	88.2 (73.5-97.1)	94.1 (82.4-97.0)	0.286	-1.07	350.5
Oxford knee score	Pre-operative	14 (11-21)	15 (12-18)	0.760	-0.31	451.0
	Post-operative	41 (33-43)	40 (34-44)	0.794	-0.26	408.0
EQ-5D index	Pre-operative	0.322 (0.217-0.530)	0.392 (0.181-0.568)	0.747	-0.32	428.0
	Post-operative	0.795 (0.679-1)	0.829 (0.714-1)	0.885	-0.15	368.5
EQ-5D VAS	Pre-operative	65 (50-80)	80 (53-83)	0.180	-1.34	348.5
	Post-operative	85 (79-95)	80 (70-86)	0.151	-1.44	346.5
SF-12 PCS	Pre-operative	28.1 (23.2-31.6)	25.7 (23.4-32.5)	0.653	-0.45	379.5
	Post-operative	43.8 (34.9-52.2)	44.6 (28.3-50.9)	0.572	-0.57	248.5
SF-12 MCS	Pre-operative	44.0 (38.7-53.9)	49.7 (41.6-57.1)	0.294	-1.05	341.5
	Post-operative	57.5 (49.9-60.6)	59.4 (51.4-61.6)	0.306	-1.02	227.0

[1]Mann-Whitney *U* test.

IQR: Interquartile range; KOOS: Knee Osteoarthritis Outcome Score; ADL: Activities of daily living; Sport/Rec: Sports and recreation; QoL: Quality of life; WOMAC: Western Ontario and McMaster Universities Osteoarthritis Index; EQ-5D: EuroQol-5D index; VAS: Visual Analogue Scale; SF-12: Short Form 12 item survey; PCS: Physical component summary; MCS: Mental component summary.

[18] for comparing OHS against OKS, as was the case in the present study too. PROMS provide clinicians and researchers with a tool to translate a qualitative description of patient's symptoms into quantitative measures that can be used to tailor an individual's management or assess and compare treatment methods in broader populations. However, PROM questionnaires are subject to missing data and errors due to patient factors such as willingness to complete all the questionnaires and comprehension of the wording of the individual items within each instrument. Inherently, studies using PROMs carry the potential for bias from these factors. Missing data was handled using established methods accordingly[30,60]. This study was conducted using data from a single surgeon at a single centre which may limit the generalisability of the findings but had the advantage of ensuring uniform procedures so that all other factors of the patient's care remained consistent. Longer term follow-up of clinical outcomes after surgery would also be advantageous to evaluate if the parity of results persisted in the long-term too.

Table 6 Comparison of pre-operative and post-operative total hip replacement patient reported outcome measure scores: Cemented, uncemented and hybrid fixations

		Cemented (*n* = 36), median (IQR)	Uncemented (*n* = 28), median (IQR)	Hybrid (*n* = 4), median (IQR)	*P* value[1]	*H* value
HOOS pain	Pre-operative	35 (22.4-44.6)	31 (25-38)	40 (33-X)	0.512	1.338
	Post-operative	95 (70-100)	98 (93-100)	89 (83- X)	0.332	2.205
HOOS symptoms	Pre-operative	40 (30-50)	35 (29-45)	35 (15-X)	0.544	1.216
	Post-operative	85 (75-90)	95 (85-100)	73 (65-X)	0.046[a]	6.614
HOOS ADL	Pre-operative	37 (25-43)	35 (28-44)	40 (35-X)	0.808	0.425
	Post-operative	91 (68-96)	98 (84-100)	80 (66-X)	0.176	3.479
HOOS Sport/Rec	Pre-operative	16 (5-27)	25 (6-43)	25 (19-X)	0.611	0.986
	Post-operative	75 (48-95)	94 (75-100)	59 (50-X)	0.111	4.405
HOOS QoL	Pre-operative	19 (6-31)	19 (13-38)	31 (25-X)	0.401	1.827
	Post-operative	75 (50-94)	88 (69-100)	56 (50-X)	0.259	2.703
Overall HOOS	Pre-operative	26.1 (19.7-40.0)	29.7 (21.5-40.3)	35.9 (25.3-X)	0.812	0.418
	Post-operative	88.4 (64.8-92.2)	95.0 (79.0-98.8)	71.4 (65.2-X)	0.130	4.086
WOMAC pain	Pre-operative	45 (25-55)	35 (30-40)	40 (35-X)	0.497	1.398
	Post-operative	95 (65-100)	95 (90-100)	90 (80-X)	0.764	0.538
WOMAC stiffness	Pre-operative	25 (25-50)	25 (25-38)	25 (25-X)	0.964	0.074
	Post-operative	88 (75-88)	88 (75-100)	69 (63-X)	0.170	3.540
WOMAC function	Pre-operative	39.7 (26.5-50.0)	34.6 (29.0-44.1)	39.7 (35.3-X)	0.790	0.472
	Post-operative	91.2 (67.7-95.6)	98.5 (83.8-100)	80.1 (66.2-X)	0.190	3.317
Oxford hip score	Pre-operative	14 (10-19)	14 (11-22)	19 (17-X)	0.238	2.872
	Post-operative	41 (33-46)	44 (39-47)	38 (34-X)	0.347	2.118
EQ-5D index	Pre-operative	0.375 (0.155-0.533)	0.314 (0.217-0.535)	0.604 (0.482-X)	0.128	4.106
	Post-operative	0.836 (0.592-1)	1 (0.747-1)	0.790 (0.580-X)	0.529	1.274
EQ-5D VAS	Pre-operative	65 (50-80)	65 (39-80)	60 (60-X)	0.938	0.127
	Post-operative	90 (70-95)	90 (80-98)	80 (65-X)	0.779	0.499
SF-12 PCS	Pre-operative	25.0 (21.1-27.3)	25.3 (21.9-31.1)	24.7 (20.4-X)	0.597	1.030
	Post-operative	50.6 (32.3-54.8)	53.4 (43.3-55.8)	42.9 (36.4-X)	0.447	1.610
SF-12 MCS	Pre-operative	49.5 (41.1-58.2)	50.6 (38.7-58.6)	50.7 (34.4-X)	0.980	0.040
	Post-operative	56.6 (53.7-59.8)	59.2 (57.3-60.8)	47.1 (36.1-X)	0.128	4.104

[1]Kruskal Wallis *H* test.

[a]Statistically significant $P < 0.05$.

IQR: Interquartile range; HOOS: Hip Osteoarthritis Outcome Score; ADL: Activities of daily living; Sport/Rec: Sports and recreation; QoL: Quality of life; WOMAC: Western Ontario and McMaster Universities Osteoarthritis Index; EQ-5D: EuroQol-5D index; VAS: Visual Analogue Scale; SF-12: Short Form 12 item survey; PCS: Physical component summary; MCS: Mental component summary.

CONCLUSION

THR and TKR are greatly effective at improving pain, function, and QoL in patients with severe OA. The clinical outcome of both procedures was found to be equally efficacious in this regard post-operatively. No significant difference was found in the outcome between CR and PS TKR implants, nor was a significant difference found between cemented and uncemented THRs. Obesity had a greater influence on the outcome following TKR than that of THR.

Table 7 Pre-operative and post-operative impact of body mass index category on patient reported outcome measure scores: Total knee replacements

		Normal (*n* = 8), median (IQR)	Overweight (*n* = 24), median (IQR)	Obese (*n* = 31), median (IQR)	*P* value[1]	*H* value
KOOS pain	Pre-operative	41 (22-51)	38 (26-49)	33 (22-42)	0.230	2.936
	Post-operative	97 (95-100)	92 (73-97)	88 (72-98)	0.046[a]	6.160
KOOS symptoms	Pre-operative	32 (23-62)	38 (21-56)	32 (22-43)	0.701	0.712
	Post-operative	91 (86-95)	89 (86-93)	86 (79-93)	0.129	4.098
KOOS ADL	Pre-operative	40 (25-53)	38 (34-45)	40 (26-43)	0.466	1.527
	Post-operative	96 (89-99)	91 (78-97)	87 (76-96)	0.214	3.079
KOOS Sport/Rec	Pre-operative	5 (0-63)	8 (0-25)	5 (0-20)	0.621	0.952
	Post-operative	75 (60-100)	73 (51-84)	65 (45-88)	0.582	1.083
KOOS QoL	Pre-operative	19 (0-44)	19 (6-31)	6 (6-19)	0.302	2.394
	Post-operative	91 (75-99)	75 (63-100)	63 (47-81)	0.032[a]	6.881
Overall KOOS	Pre-operative	36.5 (12.1-51.1)	32.2 (20.8-43.8)	26.6 (16.7-33.7)	0.354	2.075
	Post-operative	87 (80-97)	81.3 (67.2-92.0)	79.9 (64.1-84.8)	0.208	3.139
WOMAC pain	Pre-operative	45 (25-54)	40 (30-50)	35 (25-50)	0.332	2.206
	Post-operative	100 (95-100)	90 (75-99)	90 (79-100)	0.045[a]	6.186
WOMAC stiffness	Pre-operative	38 (6-59)	25 (25-47)	25 (25-38)	0.704	0.702
	Post-operative	100 (75-100)	75 (63-100)	75 (63-88)	0.084	4.960
WOMAC function	Pre-operative	39.7 (25.0-53.3)	38.2 (34.1-45.2)	39.7 (26.5-44.1)	0.521	1.302
	Post-operative	97.1 (93.0-100)	91.2 (78.3-97.1)	86.0 (75.7-97.1)	0.125	4.154
Oxford knee score	Pre-operative	17 (11-23)	15 (11-19)	14 (11-19)	0.566	1.137
	Post-operative	39 (38-40)	42 (33-45)	39 (33-43)	0.559	1.165
EQ-5D index	Pre-operative	0.502 (0.107-0.630)	0.304 (0.215-0.479)	0.356 (0.206-0.535)	0.606	1.002
	Post-operative	0.837 (0.821-1)	0.837 (0.735-1)	0.767 (0.633-0.939)	0.260	2.696
EQ-5D VAS	Pre-operative	80 (65-80)	80 (50-90)	60 (50-70)	0.139	3.940
	Post-operative	80 (74-85)	85 (70-95)	85 (70-90)	0.652	0.856
SF-12 PCS	Pre-operative	29.6 (24.8-36.4)	28.2 (23.9-37.8)	27.2 (21.6-29.9)	0.257	2.714
	Post-operative	49.0 (44.0-51.7)	46.9 (30.1-53.3)	38.5 (32.5-49.6)	0.379	1.942
SF-12 MCS	Pre-operative	48.2 (38.1-54.6)	50.1 (40.0-59.6)	45.0 (38.6-54.1)	0.692	0.737
	Post-operative	58.6 (53.4-60.6)	59.3 (44.2-62.3)	57.8 (51.2-60.5)	0.897	0.208

[1]Kruskal Wallis *H* test.
[a]Statistically significant $P < 0.05$.
KOOS: Knee Osteoarthritis Outcome Score; ADL: Activities of daily livin; Sport/Rec: Sports and recreation; QoL: Quality of life; WOMAC: Western Ontario and McMaster Universities Osteoarthritis Index; EQ-5D: EuroQol-5D index; VAS: Visual Analogue Scale; SF-12: Short Form 12 item survey; PCS: Physical component summary; MCS: Mental component summary.

Table 8 Pre-operative and post-operative impact of body mass index category on patient reported outcome measure scores: Total hip replacements

		Normal (*n* = 14), median (IQR)	Overweight (*n* = 16), median (IQR)	Obese (*n* = 34), median (IQR)	Morbidly obese (*n* = 4), median (IQR)	*P* value[1]	*H* value
HOOS pain	Pre-operative	38 (23-43)	35 (29-44)	30 (25-39)	22.5 (15-X)	0.405	2.917
	Post-operative	99 (65-100)	99 (86-100)	93 (73-97)	97 (97-97)	0.310	3.582

HOOS symptoms	Pre-operative	40 (28-53)	38 (25-53)	40 (30-49)	35 (25-X)	0.720	1.339
	Post-operative	90 (63-100)	98 (69-100)	85 (78-90)	85 (85-85)	0.718	1.349
HOOS ADL	Pre-operative	39 (23-48)	38 (32-42)	33 (27-43)	18 (18-X)	0.277	3.860
	Post-operative	92 (67-99)	98 (73-100)	84 (63-96)	94 (94-94)	0.294	3.712
HOOS Sport/Rec	Pre-operative	28 (20-31)	25 (19-44)	6 (0-25)	13 (6-X)	0.088	6.536
	Post-operative	88 (75-100)	91 (55-100)	63 (34-91)	75 (75-75)	0.252	4.090
HOOS QoL	Pre-operative	25 (6-41)	25 (19-31)	19 (13-25)	13 (0-X)	0.486	2.443
	Post-operative	88 (58-100)	81 (53-98)	69 (38-90)	94 (94-94)	0.376	3.106
Overall HOOS	Pre-operative	35.9 (29.9-41.7)	36.0 (24.8-38.5)	25.7 (20.7-33.3)	25.0 (12.8-X)	0.267	3.950
	Post-operative	91.2 (88.8-100)	95.1 (68.3-98.6)	79.0 (60.4-90.0)	89.0 (89.0-89.0)	0.256	4.047
WOMAC pain	Pre-operative	40 (33-63)	38 (31-53)	38 (30-45)	25 (15-X)	0.445	2.673
	Post-operative	100 (68.8-100)	100 (85-100)	90 (75-98)	95 (95-95)	0.332	3.417
WOMAC stiffness	Pre-operative	38 (19-50)	38 (25-50)	25 (25-38)	25 (13-X)	0.377	3.099
	Post-operative	94 (56-100)	94 (66-100)	75 (75-88)	75 (75-75)	0.483	2.459
WOMAC function	Pre-operative	39.7 (30.1-54.4)	39.7 (32.0-43.8)	33.1 (26.8-44.1)	17.6 (17.6-X)	0.267	3.951
	Post-operative	91.9 (69.1-99.3)	98.5 (73.2-99.6)	83.8 (63.2-95.6)	94.1 (94.1-94.1)	0.313	3.562
Oxford hip score	Pre-operative	23 (12-29)	18 (13-22)	13 (10-19)	7 (5-X)	0.046[a]	8.001
	Post-operative	44 (35-47.75)	44 (36-48)	39 (31-45)	47 (47-47)	0.275	3.882
EQ-5D index	Pre-operative	0.527 (0.059-0.699)	0.481 (0.235-0.568)	0.289 (0.210-0.420)	0.169 (-0.199-X)	0.305	3.624
	Post-operative	1 (0.659-1)	1 (0.685-1)	0.750 (0.639-0.892)	1 (1-1)	0.158	5.198
EQ-5D VAS	Pre-operative	60 (40-80)	80 (60-85)	65 (40-74)	65 (40-X)	0.250	4.105
	Post-operative	93 (60-100)	94 (71-100)	80 (75-84)	90 (90-90)	0.106	6.114
SF-12 PCS	Pre-operative	31.8 (19.7-37.1)	26.8 (22.5-37.9)	24.1 (21.4-27.6)	25.0 (21.7-X)	0.370	3.144
	Post-operative	54.8 (40.5-56.0)	49.3 (36.4-55.3)	43.9 (28.0-54.8)	49.3 (49.3-49.3)	0.590	1.914
SF-12 MCS	Pre-operative	59.5 (51.2-63.1)	53.5 (39.9-61.7)	47.4 (40.1-52.7)	32.3 (16.7-X)	0.075	6.919
	Post-operative	57.5 (55.9-59.8	59.8 (55.7-60.8)	57.7 (50.2-59.8)	60.8 (60.8-60.8)	0.334	3.396

[1]Kruskal Wallis *H* test.

[a]Statistically significant $P < 0.05$.

IQR: Interquartile range; HOOS: Hip Osteoarthritis Outcome Score; ADL: Activities of daily living; Sport/Rec: Sports and recreation; QoL: Quality of life; WOMAC: Western Ontario and McMaster Universities Osteoarthritis Index; EQ-5D: EuroQol-5D index; VAS: Visual Analogue Scale; SF-12: Short Form 12 item survey; PCS: Physical component summary; MCS: Mental component summary.

ARTICLE HIGHLIGHTS

Research background

Patient report outcome measures (PROMs) quantitatively assess patient's symptoms, function and quality of life (QoL). It is known severe osteoarthritis (OA) can be alleviated by joint replacement. To what extent these procedures improve symptoms, function, and QoL can vary depending on the joint, type of procedure, and patient co-factors. Additionally, it is important to maintain a contemporary assessment of the impacts of current surgical practice. The significance of this study is it is the first study of its type to assess the impact of total hip replacements (THR) and total knee replacements (TKR) using a large range of PROMS, in a modern cohort, which also provides sub-analysis on the impact of implant type and obesity.

Research motivation

Previous literature on the impact of THR and TKR is either out-of-date or very narrow in it's scope. As an orthopedic surgeon, it is important to predict the impact of these procedures, in order to tailor management for each patient. Therefore, knowing the impact of modern arthroplasty on symptoms, function, and QoL should be explored and available in the literature. Additionally, factors such as obesity can significantly deter surgeons from offering surgery to patients due to known peri-operative risks without fully appreciating the long term benefits patients can achieve. It is therefore our motivation to explore if THR and TKR can offer good outcomes to patients and begin to explore which

patient, implant and operative factors can lead to the best outcomes or pose particular risks. Future research can use the approach of this study identify which of the factors should be considered when counseling patients with severe OA.

Research objectives

The primary objective of this study was to explore patient reported outcome measures in patients before and after total hip and knee replacement procedures. This was achieved with a sufficiently powered study to detect statistical and clinic significance, and comparison of the two groups was also achieved. Future research can monitor the impact of these procedures as surgical technology continues to improve. Additionally, further research can proceed determine which other factors impact patient outcomes following joint arthroplasty.

Research methods

This study is a pragmatic clinic study of real time clinical practice. The PROMs used in this study are routinely collected in clinical practice and some contribute to data collected by the United Kingdom National Joint Registry. The range of PROMs, although used in a different context, have been utilised in the MD thesis of the senior author. These studies shared similar methodologies to the studies cited. The value of using a range PROMs could be incorporated into national joint registries to allow for research which is highly powered and diverse in its assessment of outcomes.

Research results

This study contributes to the modern literature by demonstrating that hip and knee arthroplasty are equally effective at treating the symptoms of severe OA, and equally successful at improving patient function and QoL. This study reflects more recent clinical practice, more comparable clinical cohorts and a broader range of PROMS than the current literature offers. These results can be built upon to establish which other factors impact patient outcomes following joint arthroplasty.

Research conclusions

This study proposes the theory that hip and knee OA can be equally symptomatic in severity, and limiting in QoL and function to patients. Furthermore, arthoplasty is equally effecting at improving these outcomes, regardless of the method used (cruciate retaining *vs* posterior stabilized, cemented *vs* uncemented). This study compares established outcome measures for established surgical procedures. Whilst no new or novel methodology is proposed, a comprehensive assessment has been demonstrated for the first time in the literature.

Research perspectives

Broadly speaking, research should aim to establish which patient, operative and implant factors can be optimised in order to produce the best outcomes, and mitigate risk, for patient undergoing joint arthroplasty for OA.

FOOTNOTES

Author contributions: Green A, Walsh A, and Al-Dadah O contributed to the conception of the study design, data collection and analysis, and all have proofread the manuscript in its final form.

Institutional review board statement: This was a prospective longitudinal observational study which did not require IRB/ethics committee approval but was registered with the local hospital trust.

Informed consent statement: This study was an observational study using existing data from routine clinical care. Therefore, separate consent forms were not required.

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REFERENCES

1 **Hunter DJ**, Bierma-Zeinstra S. Osteoarthritis. *Lancet* 2019; **393**: 1745-1759 [PMID: 31034380 DOI: 10.1016/S0140-6736(19)30417-9]
2 **Global Burden of Disease Study 2013 Collaborators**. Global, regional, and national incidence, prevalence, and years lived with disability for 301 acute and chronic diseases and injuries in 188 countries, 1990-2013: a systematic analysis for the Global Burden of Disease Study 2013. *Lancet* 2015; **386**: 743-800 [PMID: 26063472 DOI: 10.1016/S0140-6736(15)60692-4]
3 **Cross M**, Smith E, Hoy D, Nolte S, Ackerman I, Fransen M, Bridgett L, Williams S, Guillemin F, Hill CL, Laslett LL, Jones G, Cicuttini F, Osborne R, Vos T, Buchbinder R, Woolf A, March L. The global burden of hip and knee osteoarthritis: estimates from the global burden of disease 2010 study. *Ann Rheum Dis* 2014; **73**: 1323-1330 [PMID: 24553908 DOI: 10.1136/annrheumdis-2013-204763]
4 **Swain S**, Sarmanova A, Mallen C, Kuo CF, Coupland C, Doherty M, Zhang W. Trends in incidence and prevalence of osteoarthritis in the United Kingdom: findings from the Clinical Practice Research Datalink (CPRD). *Osteoarthritis Cartilage* 2020; **28**: 792-801 [PMID: 32184134 DOI: 10.1016/j.joca.2020.03.004]
5 **Conde J**, Scotece M, Gómez R, Lopez V, Gómez-Reino JJ, Gualillo O. Adipokines and osteoarthritis: novel molecules involved in the pathogenesis and progression of disease. *Arthritis* 2011; **2011**: 203901 [PMID: 22046513 DOI: 10.1155/2011/203901]
6 **Shane Anderson A**, Loeser RF. Why is osteoarthritis an age-related disease? *Best Pract Res Clin Rheumatol* 2010; **24**: 15-26 [PMID: 20129196 DOI: 10.1016/j.berh.2009.08.006]
7 **Englund M**, Guermazi A, Roemer FW, Aliabadi P, Yang M, Lewis CE, Torner J, Nevitt MC, Sack B, Felson DT. Meniscal tear in knees without surgery and the development of radiographic osteoarthritis among middle-aged and elderly persons: The Multicenter Osteoarthritis Study. *Arthritis Rheum* 2009; **60**: 831-839 [PMID: 19248082 DOI: 10.1002/art.24383]
8 The National Joint Registry 19th Annual Report 2022 [Internet]. London: National Joint Registry; 2022 Oct- [PMID: 36516281]
9 **Lim WB**, Al-Dadah O. Conservative treatment of knee osteoarthritis: A review of the literature. *World J Orthop* 2022; **13**: 212-229 [PMID: 35317254 DOI: 10.5312/wjo.v13.i3.212]
10 **Dreinhöfer KE**, Dieppe P, Stürmer T, Gröber-Grätz D, Flören M, Günther KP, Puhl W, Brenner H. Indications for total hip replacement: comparison of assessments of orthopaedic surgeons and referring physicians. *Ann Rheum Dis* 2006; **65**: 1346-1350 [PMID: 16439438 DOI: 10.1136/ard.2005.047811]
11 **Price AJ**, Alvand A, Troelsen A, Katz JN, Hooper G, Gray A, Carr A, Beard D. Knee replacement. *Lancet* 2018; **392**: 1672-1682 [PMID: 30496082 DOI: 10.1016/S0140-6736(18)32344-4]
12 **Petis S**, Howard JL, Lanting BL, Vasarhelyi EM. Surgical approach in primary total hip arthroplasty: anatomy, technique and clinical outcomes. *Can J Surg* 2015; **58**: 128-139 [PMID: 25799249 DOI: 10.1503/cjs.007214]
13 **Hu CY**, Yoon TR. Recent updates for biomaterials used in total hip arthroplasty. *Biomater Res* 2018; **22**: 33 [PMID: 30534414 DOI: 10.1186/s40824-018-0144-8]
14 **Dawson J**, Doll H, Fitzpatrick R, Jenkinson C, Carr AJ. The routine use of patient reported outcome measures in healthcare settings. *BMJ* 2010; **340**: c186 [PMID: 20083546 DOI: 10.1136/bmj.c186]
15 **Bourne RB**, Chesworth BM, Davis AM, Mahomed NN, Charron KD. Patient satisfaction after total knee arthroplasty: who is satisfied and who is not? *Clin Orthop Relat Res* 2010; **468**: 57-63 [PMID: 19844772 DOI: 10.1007/s11999-009-1119-9]
16 **Choi YJ**, Ra HJ. Patient Satisfaction after Total Knee Arthroplasty. *Knee Surg Relat Res* 2016; **28**: 1-15 [PMID: 26955608 DOI: 10.5792/ksrr.2016.28.1.1]
17 **Hamilton DF**, Lane JV, Gaston P, Patton JT, Macdonald D, Simpson AH, Howie CR. What determines patient satisfaction with surgery? A prospective cohort study of 4709 patients following total joint replacement. *BMJ Open* 2013; **3** [PMID: 23575998 DOI: 10.1136/bmjopen-2012-002525]
18 **Wylde V**, Blom AW, Whitehouse SL, Taylor AH, Pattison GT, Bannister GC. Patient-reported outcomes after total hip and knee arthroplasty: comparison of midterm results. *J Arthroplasty* 2009; **24**: 210-216 [PMID: 18534427 DOI: 10.1016/j.arth.2007.12.001]
19 **Bachmeier CJ**, March LM, Cross MJ, Lapsley HM, Tribe KL, Courtenay BG, Brooks PM; Arthritis Cost and Outcome Project Group. A comparison of outcomes in osteoarthritis patients undergoing total hip and knee replacement surgery. *Osteoarthritis Cartilage* 2001; **9**: 137-146 [PMID: 11330253 DOI: 10.1053/joca.2000.0369]
20 **Choi JK**, Geller JA, Yoon RS, Wang W, Macaulay W. Comparison of total hip and knee arthroplasty cohorts and short-term outcomes from a single-center joint registry. *J Arthroplasty* 2012; **27**: 837-841 [PMID: 22386606 DOI: 10.1016/j.arth.2012.01.016]
21 **Si HB**, Zeng Y, Shen B, Yang J, Zhou ZK, Kang PD, Pei FX. The influence of body mass index on the outcomes of primary total knee arthroplasty. *Knee Surg Sports Traumatol Arthrosc* 2015; **23**: 1824-1832 [PMID: 25217315 DOI: 10.1007/s00167-014-3301-1]
22 **Deakin AH**, Iyayi-Igbinovia A, Love GJ. A comparison of outcomes in morbidly obese, obese and non-obese patients undergoing primary total knee and total hip arthroplasty. *Surgeon* 2018; **16**: 40-45 [PMID: 28139371 DOI: 10.1016/j.surge.2016.10.005]
23 **Ammarullah MI**, Santoso G, Sugiharto S, Supriyono T, Kurdi O, Tauviqirrahman M, Winarni TI, Jamari J. Tresca stress study of CoCrMo-on-CoCrMo bearings based on body mass index using 2D computational model. *J Tribol* 2022; **33**: 31-38
24 **EuroQol Group**. EuroQol--a new facility for the measurement of health-related quality of life. *Health Policy* 1990; **16**: 199-208 [PMID: 10109801 DOI: 10.1016/0168-8510(90)90421-9]
25 **Brooks R**. EuroQol: the current state of play. *Health Policy* 1996; **37**: 53-72 [PMID: 10158943 DOI: 10.1016/0168-8510(96)00822-6]
26 **Bilbao A**, García-Pérez L, Arenaza JC, García I, Ariza-Cardiel G, Trujillo-Martín E, Forjaz MJ, Martín-Fernández J. Psychometric properties of the EQ-5D-5L in patients with hip or knee osteoarthritis: reliability, validity and responsiveness. *Qual Life Res* 2018; **27**: 2897-2908 [PMID: 29978346 DOI: 10.1007/s11136-018-1929-x]
27 **Greiner W**, Weijnen T, Nieuwenhuizen M, Oppe S, Badia X, Busschbach J, Buxton M, Dolan P, Kind P, Krabbe P, Ohinmaa A, Parkin D, Roset M, Sintonen H, Tsuchiya A, de Charro F. A single European currency for EQ-5D health states. Results from a six-country study. *Eur J Health Econ* 2003; **4**: 222-231 [PMID: 15609189 DOI: 10.1007/s10198-003-0182-5]

28 **Ware J Jr**, Kosinski M, Keller SD. A 12-Item Short-Form Health Survey: construction of scales and preliminary tests of reliability and validity. *Med Care* 1996; **34**: 220-233 [PMID: 8628042 DOI: 10.1097/00005650-199603000-00003]

29 **Sangha O**, Stucki G, Liang MH, Fossel AH, Katz JN. The Self-Administered Comorbidity Questionnaire: a new method to assess comorbidity for clinical and health services research. *Arthritis Rheum* 2003; **49**: 156-163 [PMID: 12687505 DOI: 10.1002/art.10993]

30 **Bellamy N**, Buchanan WW, Goldsmith CH, Campbell J, Stitt LW. Validation study of WOMAC: a health status instrument for measuring clinically important patient relevant outcomes to antirheumatic drug therapy in patients with osteoarthritis of the hip or knee. *J Rheumatol* 1988; **15**: 1833-1840 [PMID: 3068365]

31 **Bellamy N BW**, Goldsmith CH, Campbell J; Stitt L Validation study of WOMAC: a health status instrument for measuring clinically important patient relevant outcomes following total hip or knee arthroplasty in osteoarthritis. J Orthop Rheumatol. 1988; 1: 95-108

32 **Roos EM**, Lohmander LS. The Knee injury and Osteoarthritis Outcome Score (KOOS): from joint injury to osteoarthritis. *Health Qual Life Outcomes* 2003; **1**: 64 [PMID: 14613558 DOI: 10.1186/1477-7525-1-64]

33 **Roos EM**, Roos HP, Lohmander LS, Ekdahl C, Beynnon BD. Knee Injury and Osteoarthritis Outcome Score (KOOS)--development of a self-administered outcome measure. *J Orthop Sports Phys Ther* 1998; **28**: 88-96 [PMID: 9699158 DOI: 10.2519/jospt.1998.28.2.88]

34 **Dawson J**, Fitzpatrick R, Murray D, Carr A. Questionnaire on the perceptions of patients about total knee replacement. *J Bone Joint Surg Br* 1998; **80**: 63-69 [PMID: 9460955 DOI: 10.1302/0301-620X.80B1.7859]

35 **Murray DW**, Fitzpatrick R, Rogers K, Pandit H, Beard DJ, Carr AJ, Dawson J. The use of the Oxford hip and knee scores. *J Bone Joint Surg Br* 2007; **89**: 1010-1014 [PMID: 17785736 DOI: 10.1302/0301-620X.89B8.19424]

36 **Klässbo M**, Larsson E, Mannevik E. Hip disability and osteoarthritis outcome score. An extension of the Western Ontario and McMaster Universities Osteoarthritis Index. *Scand J Rheumatol* 2003; **32**: 46-51 [PMID: 12635946 DOI: 10.1080/03009740310000409]

37 **Nilsdotter AK**, Lohmander LS, Klässbo M, Roos EM. Hip disability and osteoarthritis outcome score (HOOS)--validity and responsiveness in total hip replacement. *BMC Musculoskelet Disord* 2003; **4**: 10 [PMID: 12777182 DOI: 10.1186/1471-2474-4-10]

38 **Dawson J**, Fitzpatrick R, Carr A, Murray D. Questionnaire on the perceptions of patients about total hip replacement. *J Bone Joint Surg Br* 1996; **78**: 185-190 [PMID: 8666621 DOI: 10.1302/0301-620X.78B2.0780185]

39 **Ehrich EW**, Davies GM, Watson DJ, Bolognese JA, Seidenberg BC, Bellamy N. Minimal perceptible clinical improvement with the Western Ontario and McMaster Universities osteoarthritis index questionnaire and global assessments in patients with osteoarthritis. *J Rheumatol* 2000; **27**: 2635-2641 [PMID: 11093446]

40 **Sabah SA**, Knight R, Alvand A, Beard DJ, Price AJ. Early patient-reported outcomes from primary hip and knee arthroplasty have improved over the past seven years : an analysis of the NHS PROMs dataset. *Bone Joint J* 2022; **104-B**: 687-695 [PMID: 35638211 DOI: 10.1302/0301-620X.104B6.BJJ-2021-1577.R1]

41 **Ware JE Jr**, Sherbourne CD. The MOS 36-item short-form health survey (SF-36). I. Conceptual framework and item selection. *Med Care* 1992; **30**: 473-483 [PMID: 1593914 DOI: 10.1097/00005650-199206000-00002]

42 **Song SJ**, Park CH, Bae DK. What to Know for Selecting Cruciate-Retaining or Posterior-Stabilized Total Knee Arthroplasty. *Clin Orthop Surg* 2019; **11**: 142-150 [PMID: 31156764 DOI: 10.4055/cios.2019.11.2.142]

43 **Harato K**, Bourne RB, Victor J, Snyder M, Hart J, Ries MD. Midterm comparison of posterior cruciate-retaining versus -substituting total knee arthroplasty using the Genesis II prosthesis. A multicenter prospective randomized clinical trial. *Knee* 2008; **15**: 217-221 [PMID: 18325770 DOI: 10.1016/j.knee.2007.12.007]

44 **Sorger JI**, Federle D, Kirk PG, Grood E, Cochran J, Levy M. The posterior cruciate ligament in total knee arthroplasty. *J Arthroplasty* 1997; **12**: 869-879 [PMID: 9458252 DOI: 10.1016/S0883-5403(97)90156-X]

45 **Scuderi GR**, Pagnano MW. Review Article: The rationale for posterior cruciate substituting total knee arthroplasty. *J Orthop Surg (Hong Kong)* 2001; **9**: 81-88 [PMID: 12118138 DOI: 10.1177/230949900100900217]

46 **Luo SX**, Zhao JM, Su W, Li XF, Dong GF. Posterior cruciate substituting versus posterior cruciate retaining total knee arthroplasty prostheses: a meta-analysis. *Knee* 2012; **19**: 246-252 [PMID: 22300844 DOI: 10.1016/j.knee.2011.12.005]

47 **Mayne A**, Harshavardhan HP, Johnston LR, Wang W, Jariwala A. Cruciate Retaining compared with Posterior Stabilised Nexgen total knee arthroplasty: results at 10 years in a matched cohort. *Ann R Coll Surg Engl* 2017; **99**: 602-606 [PMID: 28653546 DOI: 10.1308/rcsann.2017.0086]

48 **Dowsey MM**, Gould DJ, Spelman T, Pandy MG, Choong PF. A Randomized Controlled Trial Comparing a Medial Stabilized Total Knee Prosthesis to a Cruciate Retaining and Posterior Stabilized Design: A Report of the Clinical and Functional Outcomes Following Total Knee Replacement. *J Arthroplasty* 2020; **35**: 1583-1590.e2 [PMID: 32139194 DOI: 10.1016/j.arth.2020.01.085]

49 **Maggs J**, Wilson M. The Relative Merits of Cemented and Uncemented Prostheses in Total Hip Arthroplasty. *Indian J Orthop* 2017; **51**: 377-385 [PMID: 28790466 DOI: 10.4103/ortho.IJOrtho_405_16]

50 **Mears SC**. Management of Severe Osteoporosis in Primary Total Hip Arthroplasty. *Curr Transl Geriatr Exp Gerontol Rep* 2013; **2**: 99-104 [DOI: 10.1007/s13670-013-0044-7]

51 The National Joint Registry 17th Annual Report 2020 [Internet]. London: National Joint Registry; 2020 Sep- [PMID: 33439585]

52 **Donaldson AJ**, Thomson HE, Harper NJ, Kenny NW. Bone cement implantation syndrome. *Br J Anaesth* 2009; **102**: 12-22 [PMID: 19059919 DOI: 10.1093/bja/aen328]

53 **Phedy P**, Ismail HD, Hoo C, Djaja YP. Total hip replacement: A meta-analysis to evaluate survival of cemented, cementless and hybrid implants. *World J Orthop* 2017; **8**: 192-207 [PMID: 28251071 DOI: 10.5312/wjo.v8.i2.192]

54 **Horne G**, Culliford N, Adams K, Devane P. Hybrid total hip replacement: outcome after a mean follow up of 10 years. *ANZ J Surg* 2007; **77**: 638-641 [PMID: 17635275 DOI: 10.1111/j.1445-2197.2007.04177.x]

55 **Rolfson O**, Donahue GS, Hallsten M, Garellick G, Kärrholm J, Nemes S. Patient-reported outcomes in cemented and uncemented total hip replacements. *Hip Int* 2016; **26**: 451-457 [PMID: 27229164 DOI: 10.5301/hipint.5000371]

56 **Kuijpers MFL**, Van Steenbergen LN, Schreurs BW, Hannink G. Patient-reported outcome of 95% of young patients improves after primary total hip arthroplasty: identification of 3 recovery trajectories in 3,207 patients younger than 55 years from the Dutch Arthroplasty Register. *Acta Orthop* 2022; **93**: 560-567 [PMID: 35727110 DOI: 10.2340/17453674.2022.3140]

57 **Pozzobon D**, Ferreira PH, Blyth FM, Machado GC, Ferreira ML. Can obesity and physical activity predict outcomes of elective knee or hip surgery due to osteoarthritis? A meta-analysis of cohort studies. *BMJ Open* 2018; **8**: e017689 [PMID: 29487072 DOI: 10.1136/bmjopen-2017-017689]

58 **Cushnaghan J**, Bennett J, Reading I, Croft P, Byng P, Cox K, Dieppe P, Coggon D, Cooper C. Long-term outcome following total knee arthroplasty: a controlled longitudinal study. *Ann Rheum Dis* 2009; **68**: 642-647 [PMID: 18664545 DOI: 10.1136/ard.2008.093229]

59 **Christensen TC**, Wagner ER, Harmsen WS, Schleck CD, Berry DJ. Effect of Physical Parameters on Outcomes of Total Knee Arthroplasty. *J Bone Joint Surg Am* 2018; **100**: 1829-1837 [PMID: 30399077 DOI: 10.2106/JBJS.18.00248]

60 **Perneger TV**, Burnand B. A simple imputation algorithm reduced missing data in SF-12 health surveys. *J Clin Epidemiol* 2005; **58**: 142-149 [PMID: 15680747 DOI: 10.1016/j.jclinepi.2004.06.005]

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ORIGINAL ARTICLE

Observational Study

Importance of computed tomography in posterior malleolar fractures: Added information to preoperative X-ray studies

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Abstract

BACKGROUND

Ankle fractures are common lesions of the lower limbs. Approximately 40% of ankle fractures affect the posterior malleolus (PM). Historically, PM osteosynthesis was recommended when PM size in X-ray images was greater than 25% of the joint. Currently, computed tomography (CT) has been gaining traction in the preoperative evaluation of ankle fractures.

AIM

To elucidate the similarity in dimensions and to correlate PM size in X-ray images with the articular surface of the affected tibial plafond in the axial view on CT (AXCT) of a PM fracture.

METHODS

Eighty-one patients (mean age: 39.4 ± 13.5 years) were evaluated (54.3% were male). Two independent examiners measured PM size in profile X-ray images (PMXR) and sagittal CT (SAGCT) slices. The correlation of the measurements between the examiners and the difference in the PM fragment sizes between the two images were compared. Next, the PM size in PMXR was compared with the surface of the tibial plafond involved in the fracture in AXCT according to the Haraguchi classification.

RESULTS

The correlation rates between the examiners were 0.93 and 0.94 for PMXR and

SAGCT, respectively ($P < 0.001$). Fragments were 2.12% larger in SAGCT than in PMXR ($P = 0.018$). In PMXR, there were 56 cases < 25% and 25 cases ≥ 25%. When PMXR was < 25%, AXCT corresponded to 10.13% of the tibial plafond. When PMXR was ≥ 25%, AXCT was 24.52% ($P < 0.001$). According to the Haraguchi classification, fracture types I and II had similar PMXR measurements that were greater than those of type III. When analyzing AXCT, a significant difference was found between the three types, with II > I > III ($P < 0.001$).

CONCLUSION

PM fractures show different sizes using X-ray or CT images. CT showed a larger PM in the sagittal plane and allowed the visualization of the real dimensions of the tibial plafond surface.

Key Words: Ankle fracture; Posterior malleolar fracture; Computed tomography; X-ray; Posterior malleolus fracture; Trimalleolar facture

Core Tip: The study showed fractures of the posterior malleolus (PM) were different sizes on X-ray and computed tomography (CT) images. It is possible to see that some PM patterns considered small on radiographs affected a significant joint area when CT scans were performed. CT scans also showed that the actual size of the PM fragment was larger than that seen on radiographs.

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INTRODUCTION

Ankle malleolar fractures are the most common fractures among those involving load-bearing joints[1]. Approximately 40% of ankle fractures are trimalleolar fractures[2], which affect the posterior edge of the tibia in addition to the lateral and medial malleoli, more specifically the portion known as Volkmann's triangle or posterior malleolus (PM)[3]. Fractures involving the PM cause more incongruity, joint instability, and worse results than unimalleolar or bimalleolar fractures of the ankle[4-7].

Since the article by Nelson and Jensen[7] in 1940, the internal fixation of the PM has been recommended in ankle fractures, considering a size of one-third of the fragment relative to the articular surface of the tibia in lateral X-ray images. Other authors have stipulated a value of 25% of the articular surface as the determinant for the fixation of the posterior fragment to thereby restore ankle congruity[8-10]. PM fixation is currently controversial[11-14], and variable clinical results have been obtained in the treatment of trimalleolar fractures[15]. The classic recommendation to fix PM fractures with a radiological size ≥ 25% theoretically improves articular congruence and reduces the risk of post-traumatic arthritis[16,17]. On the other hand, some authors report fixing PM fractures of various sizes, including small fragments (< 25%), under the justification of providing more stability to the ankle joint and better functional results[18,19].

When diagnosing a PM in lateral ankle X-ray images, its visualization is frequently impaired by overlapping bone images, plaster immobilizations, or external fixators[20]. Moreover, measuring the size of a posterior fracture can be difficult, resulting in the underestimation of the size of the PM, which leads to an inaccurate interpretation, which in turn interferes with the treatment[20-22]. Thus, computed tomography (CT) is increasingly recommended in the treatment of ankle fractures, especially when the PM is affected[14,23]. CT allows a better interpretation of all joint fragments, particularly regarding PM morphology and size, and it also aids in preoperative planning[24,25]. Different PM fracture patterns are observed in CT studies, depending on the size of the bone fragment, its anatomical location, bone impaction, and the fragment's relationship with other malleoli and the syndesmosis[15,23]. Specific PM classifications have been created, with associated recommendations for the best treatment for each type of fracture[2,26-28].

However, there is no clear relationship between the size of the PM in X-ray images and its actual size in CT slices or between the articular surface of the affected tibia and the fracture. Thus, the aim of the present study was to analyze PM size in X-ray and CT studies and to relate the size of the fragment obtained from X-ray images to the articular area of the tibial plafond.

MATERIALS AND METHODS

Over a 5-year period from 2016 to 2021, 370 patients diagnosed with an ankle fracture were treated at our hospital (a level 1 trauma center). Of these fractures, 144 involved the PM. The study included patients aged 18 years or older with an

ankle fracture or fracture-dislocation involving the PM [AO Foundation/Orthopedic Trauma Association (AO/OTA) classification 44-A3, 44-B3, and 44-C1/2]. Cases of tibial plafond fractures, cases of ankle fractures associated with other hindfoot fractures, and cases with incomplete data in the medical records, such as absence of appropriate X-ray and CT images, were excluded. A total of 81 patients met the study's inclusion criteria. The study was approved by our Institutional Ethics Committee. The fractures were categorized according to the AO/OTA classification, and the Haraguchi CT classification was used specifically for the PM[26].

The Enterprise Imaging XERO Viewer software (Agfa HealthCare, Mortsel, Belgium) version 8.1.2 was used to select and analyze X-ray images, and the RadiAnt DICOM Viewer software (Medixant, Poznań, Poland) version 2.3 was used to analyze CT images. The PM fragments were measured on lateral X-ray images (PMXR) by two independent examiners (herein named X and Y), based on the relationship between fracture size and total articular surface (Figure 1). In sagittal CT (SAGCT) slices, the image with the largest PM was selected, and the latter was measured by the two examiners (X and Y). Similarly, to PMXR, PM size in SAGCT was measured using the proportion between the size of the fracture fragment and the total length of the joint (Figure 2). A second CT image was used in the axial plane to determine the size of the affected articular area in the tibial plafond. A point 5 mm above the highest point of the tibial articular surface was marked on the sagittal plane, and the corresponding axial (AXCT) slice was selected. The total tibial and PM areas were measured using the RadiAnt DICOM Viewer 2.3 software, and the fragment size relative to the total tibial plafond area on the AXCT was calculated (Figure 3).

Fractures were categorized into two groups based on the PMXR measurement: (1) PM < 25% of the joint; and (2) PM ≥ 25% of the joint. This cutoff value was used due to the consensus in the literature. Based on these groups, PM size was compared between PMXR and SAGCT, and the mean value of the examiners' measurements was considered. A second evaluation was performed to determine the difference in PM size based on a classification of the fractures into smaller PMXR intervals, namely < 15%, 15%–19.9%, 20%–24.9%, 25%–29.9%, and ≥ 30% of the articular surface. For AXCT, the size of the affected articular surface was measured in both groups (A and B), and the size of the PM and the involvement of the articular surface were compared in the respective morphological categories using the classification proposed by Haraguchi *et al*[26].

The statistical analysis was performed using the SPSS Statistics software for Mac (IBM Corporation, Armonk, NY, United States), version 23, considering the mean of the values obtained by the examiners in PMXR and SAGCT. Data normality was tested for the quantitative variables using the Kolmogorov–Smirnov test. Interobserver reliability was assessed using the Kappa method for the qualitative variables and Pearson's correlation for the quantitative variables. For direct comparison between X-ray and CT, the paired-sample *t*-test or the Wilcoxon, Mann–Whitney, and Kruskal–Wallis tests were used, depending on data normality, type of variable, and number of groups. The significance level was $P < 0.05$, with a 95% confidence interval.

RESULTS

A total of 81 patients participated in the study, of whom 44 were male (54.3%) and 37 were female (45.6%), with a mean age of 39.4 years (± 13.5). One ankle fracture (1.2%) was type A in the AO/OTA classification, 51 (62.9%) were type B, and 29 (35.8%) were type C. It was observed that the PM presented more than one fracture line in 22 cases (27.2%), which is described in the literature as a chondral or intercalary fragment at the center of the fracture, between the metaphysis and the posterior tibial cortex[29,30] (Table 1).

The PMXR sizes measured by examiners X and Y were 21.15% and 20.46%, respectively, with a mean of 20.81% and Pearson's correlation index of 0.93 ($P < 0.001$). With regard to SAGCT, the values obtained were 23.45% and 22.39%, with a mean of 22.92% and Pearson's index of 0.94 ($P < 0.001$). This interobserver correlation was excellent both for PMXR and SAGCT (Table 2). Thus, regardless of the measured image, a good interobserver evaluation was obtained with the proposed measurement method. A significant difference was found in mean size between the images, with PM size in SAGCT being 2.12% (95% confidence interval: 0.3–3.8) greater than in X-ray images ($P = 0.018$).

When the sample was divided into two groups according to PMXR size, groups A (< 25%) and B (≥ 25%) had 56 and 25 patients, or 69.13% and 30.86% of the sample, respectively. When analyzing the AXCT of all fractures, the PM affected a mean 14.57% of the tibial plafond, but there was a difference between the groups, with 10.13% and 24.52% of the tibial plafond affected in group A (< 25%) and in group B (≥ 25%), respectively, ($P < 0.001$) (Table 3). The subdivision into the < 15.0%, 15.0%–19.9%, 20.0%–24.9%, 25.0%–29.9%, and ≥ 30.0% intervals and their respective AXCTs (Table 3) was performed to evaluate the gradual increase in the affected articular surface according to PMXR size. There were differences among all the evaluated subgroups, namely a gradual surface increase with the increase in PMXR; only the 20.0%–24.9% interval showed no statistical significance relative to the previous subgroup.

According to the Haraguchi classification, 29 fractures (35.8%) were type I, 33 (40.7%) were type II, and 19 (23.4%) were type III. In group A there were 21, 16, and 19 type I, type II, and type III fractures, respectively, whereas in group B there were 8 and 17 type I and type II fractures, respectively. The analysis of PM size in the X-ray images showed that type I and type II fractures had similar PMXR size (21.6% and 24.8%) and that both were larger than type III (small shell-shaped) fractures ($P < 0.001$).

In the overall evaluation of the articular surface, differences were found in AXCT among all Haraguchi CT categories, with PM fragments with mean values of 12.24%, 22.80%, and 3.84% of the tibial plafond surface, respectively, resulting in II > I > III ($P < 0.001$) (Table 4 and Figure 4). Differences in the articular surface of the tibial plafond (AXCT) for the Haraguchi subtypes were found in both groups, with $P < 0.001$ in group A and $P = 0.002$ in group B (Table 5 and Figure 5).

Table 1 Demographic and lesion characteristics, *n* = 81

Characteristic	Subcategory	*n* (%)
Age[a]		39.48 (± 13.59)
Sex	Male	44 (54.32)
	Female	37 (45.67)
Diagnosis	Fracture	42 (51.85)
	Fracture + dislocation	39 (48.14)
AO/OTA 44	A	1 (1.23)
	B	51 (62.96)
	C	29 (35.80)
Haraguchi	1	29 (35.80)
	2	33 (40.74)
	3	19 (23.45)
Intermediate fragment	Yes	22 (27.16)
	No	59 (72.83)

[a]Mean (standard deviation). AO/OTA: AO Foundation/Orthopedic Trauma Association.

Table 2 Interobserver reliability of posterior malleolus size measurements

	Examiner X	Examiner Y	Pearson's	*P* value
X-ray measurement				
Absolute size of the tibia	5.28 (± 0.83)	5.09 (± 0.82)	0.88	< 0.001
Absolute size of the PM	1.43 (± 0.75)	1.32 (± 0.69)	0.92	< 0.001
MP size (PMXR)[a]	21.15 (± 10.20)	20.46 (± 9.66)	0.93	< 0.001
Mean PM size[a]	20.81 (± 9.70)		-	-
CT measurement				
Absolute size of the tibia	3.23 (± 0.65)	3.13 (± 0.62)	0.95	< 0.001
Absolute size of the PM	0.97 (± 0.38)	0.88 (± 0.37)	0.89	< 0.001
PM size (SAGCT)	23.45 (± 9.51)	22.39 (± 9.96)	0.94	< 0.001
Mean PM size	22.92 (± 9.60)			
Interobserver agreement				
PM < 25% in X-ray images	56	58	0.88	< 0.001
PM ≥ 25% in X-ray images[b]	25	23		
PM < 25% in CT[b]	51	56	0.76	< 0.001
PM ≥ 25% in CT[b]	30	25		

[a]Percentage.
[b]Cases (absolute frequency). CT: Computed tomography; PM: Posterior malleolus; PMXR: Profile X-ray images of the posterior malleolus; SAGCT: Sagittal computed tomography images of the posterior malleolus.

DISCUSSION

Historically, X-ray has been the most widely used imaging technique in the diagnosis of malleolar fractures and consequently of PM fractures. The indication for PM fixation is mostly associated with its size relative to the joint, although no consensus has emerged to date on the smallest articular fragment size that requires surgery[8,30,31].

Table 3 Analysis of the articular surface of the ankle affected by the posterior malleolar fracture in axial computed tomography slices

Grouping according to PMXR < 25% and ≥ 25% (cases)	All cases	Group A, < 25%	Group B, ≥ 25%	*P* value	
	14.57% (81) (± 9.84)	10.13% (56) (± 6.71)	24.52% (25) (± 8.40)	< 0.001	
Subdivision of PMXR, %	< 14.9	15.0-19.9	20.0-24.9	25.0-29.9	≥ 30.0
Affected articular surface % (cases)	7.65 (26) (± 6.92)	11.03[a] (18) (± 5.57)	14.31 (11) (± 6.34)	20.79[a] (14) (± 4.19)	27.87[a] (12) (± 10.78)

[a]Statistically significant ($P < 0.05$) when compared to the previous group. PMXR: Profile X-ray images of the posterior malleolus.

Table 4 Relationship between the size of the posterior malleolus and the affected articular surface according to the Haraguchi classification

Classification	Haraguchi			
	I	II	III	*P* value
Cases (%)	29 (35.8)	33 (40.7)	19 (23.4)	N/A
X-ray				
PM size % (PMXR)	21.66[a] (± 9.91)	24.84[a] (± 9.03)	12.45 (± 4.17)	< 0.001
CT				
Articular surface of the tibial plafond % (AXCT)	12.24 (± 5.47)	22.80 (± 8.28)	3.84 (± 2.78)	< 0.001

[a]There was a statistically significant difference only when compared to Haraguchi III. There was no significant difference between Haraguchi I and II; there was a statistically significant difference when all categories were compared. The $P < 0.001$ value was found when comparing the three groups and indicates a significant statistical difference. AXCT: Axial computed tomography slice of the posterior malleolus; CT: Computed tomography; N/A: Not applicable; PM: Posterior malleolus; PMXR: Profile X-ray images of the posterior malleolus.

Table 5 Articular surface of the posterior malleolus in axial computed tomography slices according to the Haraguchi classification

Haraguchi (*n*)	Size of the posterior malleolus, by X-ray	
	< 25%, *n* = 56	≥ 25%, *n* = 25
I (29)	10.84% (± 3.74)[a]	15.29% (± 7.62)[b]
II (33)	17.99% (± 5.79)[a]	27.33% (± 7.81)[b]
III (19)	3.84% (± 2.78)[a]	-

[a]$P < 0.001$.
[b]$P = 0.002$.

The fact that there are different forms of measuring PM size should be considered. In addition, factors, such as image quality, immobilizations, and fixations, can interfere with PM measurement[20]. Several X-ray parameters have been studied to interpret ankle fractures, and PM size has good interexaminer reproducibility[21]. There is controversy regarding the best way of measuring PM size in lateral X-ray images; moreover, interobserver agreement shows variable results[22]. Currently, many authors consider CT essential for an adequate understanding of PM fractures due to the limitations of X-ray images and because CT aids in surgical planning by providing information on PM size and morphology and on its relationship with other malleoli and with the syndesmosis[20-22,32,33].

In the present study, considering only the X-ray images, the interobserver correlation for PM size was 0.93 ($P < 0.001$), which is excellent and higher than that obtained by Meijer *et al*[22] in an analysis with a larger number of examiners. This result suggests that good quality preoperative X-rays are fundamental for the adequate interpretation of the PM findings. A correlation of 0.94 ($P < 0.001$) was also achieved in the measurement performed in sagittal CT, which showed that an accurate measurement of the PM can be achieved using a simple method, regardless of the complementary exam that is used.

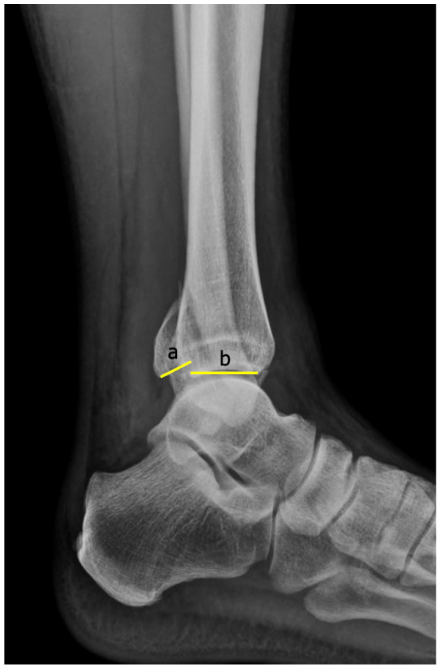

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Figure 1 Measurement of the size of a posterior malleolus fracture fragment in a profile X-ray image. The proportion between the fracture and the total articular surface, *i.e.* the a/(a + b) ratio, was evaluated.

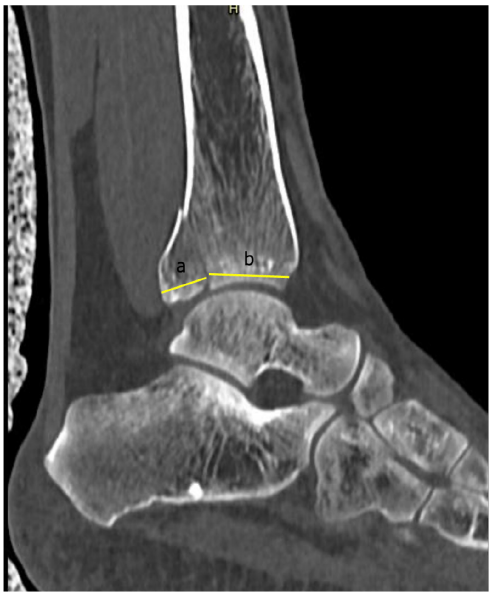

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Figure 2 Measurement of a posterior malleolus fracture fragment in a sagittal tomography slice R. Similarly to what was completed for X-ray images, the proportion between the fracture and the total articular surface, *i.e.* the a/(a + b) ratio, was evaluated.

Most patients (56; 69.1%) had PM < 25% in PMXR. Therefore, if only the PM size was considered, the choice would be not to fix that fragment[13,16,34]. Stringfellow *et al*[35] compared X-ray and CT images and found that CT slices showed a larger PM than X-ray images in 92% of the cases. This result is similar to that obtained in the present study, in which the mean PM was found to be 2.12% larger (P = 0.018) in CT images. Thus, considering only the 25% cutoff value in PMXR as an indication for PM fixation, patients with fractures considered to be borderline, with PMXR values close to 25%, would probably fail to have the posterior fragment treated adequately if the diagnosis were based solely on X-ray images. For this reason, in recent decades, several authors started recommending the fixation of fragments < 25% because they feared that X-ray images could underestimate PM size when compared to CT[10,21].

Another concern is that X-ray images may not be adequate for the visualization of small osteochondral fragments and articular surface impaction[23,29,30,36]. The present case series supports this concern, as an osteochondral or intermediate fragment was found in 27.1% of CT images. Similarly, Büchler *et al*[21] reported that 23% of osteochondral

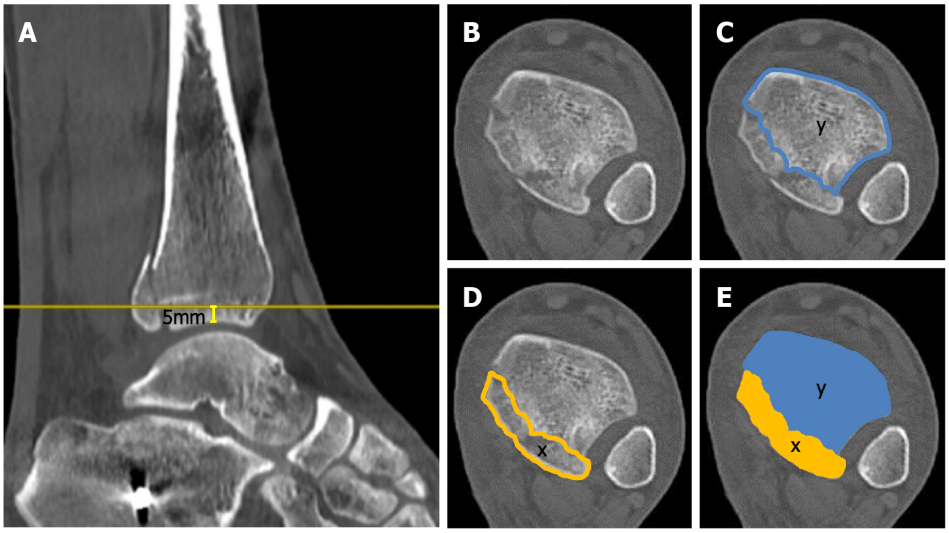

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Figure 3 Axial computed tomography scan posterior malleolus measure. A: The sagittal plane; B: The corresponding axial slice was selected 5 mm above the highest point of the tibial articular surface; C: In the axial image, the tibial articular surface; D: The area corresponding to the posterior malleolus fracture was measured; E: Thus, the x/(x + y) ratio was used to obtain the percentage of the tibial plafond surface (axial view) involved in the posterior malleolus.

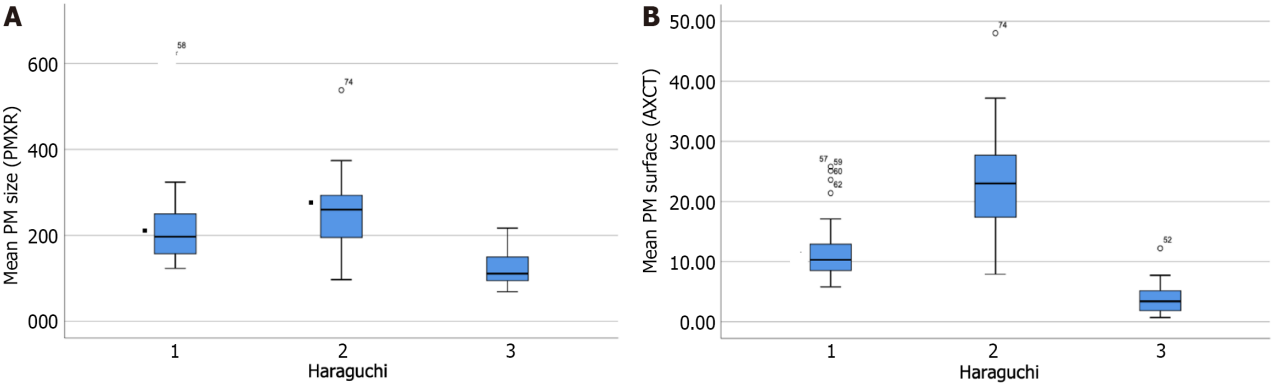

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Figure 4 Comparative size of posterior malleolus on X-rays and axial computed tomography scan according to the Haraguchi classification. A: The percent size of the posterior malleolus measured in profile X-ray images according to Haraguchi classification; B: The percent size of the posterior malleolus measured in axial tomography images according to the Haraguchi classification. A statistically significant difference was found only when compared to Haraguchi 3. No difference was found between Haraguchi 1 and 2 ($P < 0.001$). PMXR: Posterior malleolus size in profile X-ray images; AXCT: Axial computed tomography slice of the posterior malleolus.

fractures were not identified in X-ray images but were present in sagittal CT slices, thus suggesting that X-ray images have low sensitivity for diagnosing intermediate PM fragments, which could be a further hindrance for articular reduction[21,23,30].

By correlating X-ray images with axial CT slices, it is possible to determine the size of the articular surface affected by the PM fragment. In an initial evaluation considering groups < 25% and ≥ 25%, a significant difference in the percentage of affected articular surface was found: 10.13% *vs* 24.52% ($P < 0.001$). Previous studies have proposed random predetermined PM size intervals to evaluate the clinical results, articular congruity, and post-traumatic arthritis[35]. Similarly, by determining smaller PM intervals for X-ray images (< 15.0%, 15.0%-19.9%, 20.0%-24.9%, 25.0%-29.9%, and ≥ 30.0%), it was possible to evaluate the gradual increase in the percentage of affected articular surface in each interval relative to the previous interval. It should be noted that fragments in intervals 15.0%-19.9% and 20.0%-24.9% may have a similar articular surface. These results indicate that fragments considered small in X-ray images represent a relatively larger articular surface.

When the fractures were grouped according to their CT classification, type I and type II fractures had a similar size in X-ray images and could only be differentiated from type III (small shell) fractures; however, axial CT showed the difference between the articular surfaces of each CT type, as shown by the descriptive study of Haraguchi *et al*[26]. All the different CT types of fractures also showed differences in the size of the axial surface between groups A and B. We emphasize that the articular surfaces of the tibial plafond in type II fractures in group A and type I fractures in group B were of similar size (Figure 5). This means that although type II fragments in group A were deemed small in X-ray

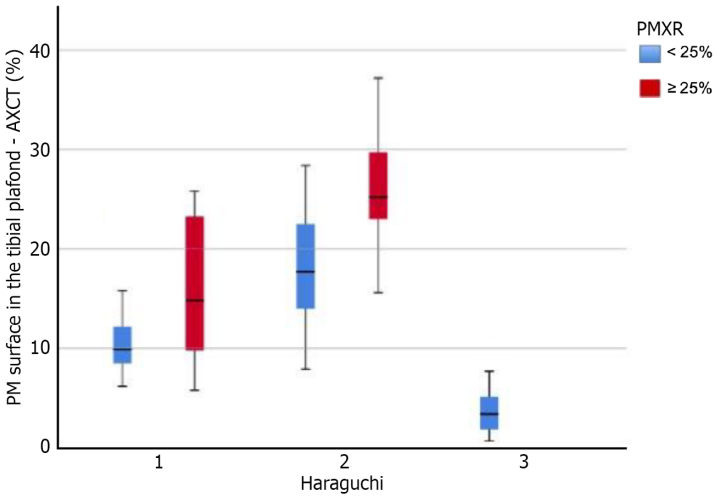

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Figure 5 The distribution of the percent area of the tibial plafond of the posterior malleolus fracture according to the various Haraguchi classification types. Blue: Group A; Red: Group B; PMXR: Posterior malleolus size in profile X-ray images; AXCT: Axial computed tomography slice of the posterior malleolus; PM: Posterior malleolus.

images (< 25%), the articular involvement was similar to that of a large fragment, such as one from group B. This information can only be obtained from the CT evaluation. Thus, the exclusive use of X-ray images for preoperative planning is associated with the risk of PMs with a larger area than expected being treated inadequately, which can interfere with the patient's postoperative results.

The present study achieved a relevant sample, considering other studies on the same subject[26-28], and the study variables showed excellent correlation and interobserver agreement according to Landis and Koch[37], who demonstrated the applicability of the measuring method. However, the present study also had some limitations. The distribution of PM fractures among the three CT categories was satisfactory. However, there was a significant sample loss, and the distribution was based solely on 2D CT images, when some studies also used 3D images to evaluate PM[22, 33]. Finally, the present findings add new information to the topic of articular involvement in PM fractures, which will hopefully aid the analysis of the clinical results of patients with PM fractures in future studies.

CONCLUSION

The size of PM fractures varies when evaluated by X-ray and CT. CT studies show a larger PM in the sagittal plane compared to PMXR images, and they also allow the identification of the presence of intermediate or chondral fracture fragments. Preoperative CT makes it possible to determine the real size of the articular surface of the tibial plafond, which can be underestimated if only X-ray is used.

ARTICLE HIGHLIGHTS

Research background

For many decades when a posterior malleolus (PM) fracture was diagnosed, the size of the fragment on radiographs was always taken into consideration at the time of treatment. Therefore, fixation of the PM was recommended when greater than 25% of the tibial joint surface was involved.

Research motivation

This study aimed to see the real size of the PM fragment in ankle fractures and determine whether an X-ray image would be sufficient to show the real size of the fracture. It is also unknown if there is any correlation between PM size on X-rays and computed tomography (CT) scans.

Research objectives

To compare the PM size of the X-rays with the sagittal CT scans to see if they are similar and to evaluate the PM size compared with the axial CT scan and the articular surface of the tibial plafond involved in the ankle fracture.

Research methods

Two foot and ankle specialists compared measurements of PM size on radiographs with CT scans. The PM size on the

sagittal images and the joint surface area of the tibial plafond on the axial images were compared.

Research results

We found that PM fragments were 2.12% larger in sagittal CT than in X-rays. When analyzing axial CT scans, a significant difference was found between the three types of Haraguchi fractures.

Research conclusions

PM fractures showed different sizes using X-ray or CT images. CT showed a larger PM in the sagittal plane and allowed the visualization of the real dimensions of the tibial plafond surface.

Research perspectives

This study showed that CT is better to understand the size of the PM. Even small PM fractures on X-rays can affect a large portion of the articular surface. It would be recommended not to underestimate small PM fractures and always perform preoperative CT evaluation.

FOOTNOTES

Author contributions: De Marchi Neto N, Christian RW and Severino NR contributed to conceptualization; De Marchi Neto N and Nesello PFT contributed to methodology; De Marchi Neto N and Nesello PFT contributed to formal analysis and investigation; De Marchi Neto N and Nesello PFT contributed original draft preparation and figures; Bergamasco JMP and Costa MT contributed reviewing and editing; Christian RW and Severino NR contributed to supervision.

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REFERENCES

1 **Palmanovich E**, Brin YS, Laver L, Kish B, Nyska M, Hetsroni I. The effect of minimally displaced posterior malleolar fractures on decision making in minimally displaced lateral malleolus fractures. *Int Orthop* 2014; **38**: 1051-1056 [PMID: 24346511 DOI: 10.1007/s00264-013-2224-7]
2 **Klammer G**, Kadakia AR, Joos DA, Seybold JD, Espinosa N. Posterior pilon fractures: a retrospective case series and proposed classification system. *Foot Ankle Int* 2013; **34**: 189-199 [PMID: 23413057 DOI: 10.1177/1071100712469334]
3 Volkmann R. Report on the disease cases treated at the halle surgical clinic in the year of 1873. *Beitr Chir* 1875; 104-109. In German
4 **Jaskulka RA**, Ittner G, Schedl R. Fractures of the posterior tibial margin: their role in the prognosis of malleolar fractures. *J Trauma* 1989; **29**: 1565-1570 [PMID: 2585569 DOI: 10.1097/00005373-198911000-00018]
5 **Irwin TA**, Lien J, Kadakia AR. Posterior malleolus fracture. *J Am Acad Orthop Surg* 2013; **21**: 32-40 [PMID: 23281469 DOI: 10.5435/JAAOS-21-01-32]
6 **Danford NC**, Hellwinkel JE, Nocek MJ, Boddapati V, Greisberg JK, Trofa DP. Fractures of the posterior malleolus: a systematic review and analysis of patient-reported outcome scale selection. *Eur J Orthop Surg Traumatol* 2023; **33**: 1125-1131 [PMID: 35430691 DOI:

10.1007/s00590-022-03261-8]
7 **Nelson M**, Jensen N. The treatment of trimalleolar fractures of the ankle. *Surg Gynecol Obstet* 1940; **71**: 509-514
8 **Heim D**, Niederhauser K, Simbrey N. The Volkmann dogma: a retrospective, long-term, single-center study. *Eur J Trauma Emerg Surg* 2010; **36**: 515-519 [PMID: 26816305 DOI: 10.1007/s00068-010-0061-6]
9 **Evers J**, Barz L, Wähnert D, Grüneweller N, Raschke MJ, Ochman S. Size matters: The influence of the posterior fragment on patient outcomes in trimalleolar ankle fractures. *Injury* 2015; **46** Suppl 4: S109-S113 [PMID: 26542855 DOI: 10.1016/S0020-1383(15)30028-0]
10 **Langenhuijsen JF**, Heetveld MJ, Ultee JM, Steller EP, Butzelaar RM. Results of ankle fractures with involvement of the posterior tibial margin. *J Trauma* 2002; **53**: 55-60 [PMID: 12131390 DOI: 10.1097/00005373-200207000-00012]
11 **Bartoníček J**, Rammelt S, Tuček M. Posterior Malleolar Fractures: Changing Concepts and Recent Developments. *Foot Ankle Clin* 2017; **22**: 125-145 [PMID: 28167058 DOI: 10.1016/j.fcl.2016.09.009]
12 **Carr D**, Vannabouathong C, Petrisor BA, Parekh SG, Bhandari M. Posterior-Based Approaches to Open Reduction Internal Fixation of Bimalleolar and Trimalleolar Fractures: A Systematic Review and Meta-analysis. *J Foot Ankle Surg* 2020; **59**: 373-378 [PMID: 32131005 DOI: 10.1053/j.jfas.2019.09.004]
13 **De Vries JS**, Wijgman AJ, Sierevelt IN, Schaap GR. Long-term results of ankle fractures with a posterior malleolar fragment. *J Foot Ankle Surg* 2005; **44**: 211-217 [PMID: 15940600 DOI: 10.1053/j.jfas.2005.02.002]
14 **Bergman C**, Morin M, Lawson K. Anatomy, Classification, and Management of Ankle Fractures Involving the Posterior Malleolar Fragment: A Literature Review. *Foot Ankle Orthop* 2019; **4**: 2473011419887724 [PMID: 35097350 DOI: 10.1177/2473011419887724]
15 **Neumann AP**, Rammelt S. Ankle fractures involving the posterior malleolus: patient characteristics and 7-year results in 100 cases. *Arch Orthop Trauma Surg* 2022; **142**: 1823-1834 [PMID: 33835195 DOI: 10.1007/s00402-021-03875-3]
16 **McDaniel WJ**, Wilson FC. Trimalleolar fractures of the ankle. An end result study. *Clin Orthop Relat Res* 1977; 37-45 [DOI: 10.1097/00003086-197701000-00006]
17 **Verhage SM**, Krijnen P, Schipper IB, Hoogendoorn JM. Persistent postoperative step-off of the posterior malleolus leads to higher incidence of post-traumatic osteoarthritis in trimalleolar fractures. *Arch Orthop Trauma Surg* 2019; **139**: 323-329 [PMID: 30430238 DOI: 10.1007/s00402-018-3056-0]
18 **Mason LW**, Marlow WJ, Widnall J, Molloy AP. Pathoanatomy and Associated Injuries of Posterior Malleolus Fracture of the Ankle. *Foot Ankle Int* 2017; **38**: 1229-1235 [PMID: 28758439 DOI: 10.1177/1071100717719533]
19 **Evers J**, Fischer M, Raschke M, Riesenbeck O, Milstrey A, Gehweiler D, Gueorguiev B, Ochman S. Leave it or fix it? How fixation of a small posterior malleolar fragment neutralizes rotational forces in trimalleolar fractures. *Arch Orthop Trauma Surg* 2022; **142**: 1031-1037 [PMID: 33507380 DOI: 10.1007/s00402-021-03772-9]
20 **Ferries JS**, DeCoster TA, Firoozbakhsh KK, Garcia JF, Miller RA. Plain radiographic interpretation in trimalleolar ankle fractures poorly assesses posterior fragment size. *J Orthop Trauma* 1994; **8**: 328-331 [PMID: 7965295 DOI: 10.1097/00005131-199408000-00009]
21 **Büchler L**, Tannast M, Bonel HM, Weber M. Reliability of radiologic assessment of the fracture anatomy at the posterior tibial plafond in malleolar fractures. *J Orthop Trauma* 2009; **23**: 208-212 [PMID: 19516096 DOI: 10.1097/BOT.0b013e31819b0b23]
22 **Meijer DT**, Doornberg JN, Sierevelt IN, Mallee WH, van Dijk CN, Kerkhoffs GM, Stufkens SA; Ankle Platform Study Collaborative – Science of Variation Group; Ankle Platform Study Collaborative - Science of Variation Group. Guesstimation of posterior malleolar fractures on lateral plain radiographs. *Injury* 2015; **46**: 2024-2029 [PMID: 26253385 DOI: 10.1016/j.injury.2015.07.019]
23 **Seo J**, Yang KH, Shim DW, Cho H, Park YC. Marginal impaction associated with posterior malleolar fracture in rotational ankle injury. *Injury* 2022; **53**: 756-761 [PMID: 34924191 DOI: 10.1016/j.injury.2021.12.013]
24 **Kumar A**, Mishra P, Tandon A, Arora R, Chadha M. Effect of CT on Management Plan in Malleolar Ankle Fractures. *Foot Ankle Int* 2018; **39**: 59-66 [PMID: 29232164 DOI: 10.1177/1071100717732746]
25 **Bouche PA**, Gaujac N, Corsia S, Leclerc P, Anract P, Auberger G. Ankle CT scan allows better management of posterior malleolus fractures than X-rays. *Eur J Orthop Surg Traumatol* 2022; **32**: 1301-1309 [PMID: 34468840 DOI: 10.1007/s00590-021-03104-y]
26 **Haraguchi N**, Haruyama H, Toga H, Kato F. Pathoanatomy of posterior malleolar fractures of the ankle. *J Bone Joint Surg Am* 2006; **88**: 1085-1092 [PMID: 16651584 DOI: 10.2106/JBJS.E.00856]
27 **Bartoníček J**, Rammelt S, Kostlivý K, Vaněček V, Klika D, Trešl I. Anatomy and classification of the posterior tibial fragment in ankle fractures. *Arch Orthop Trauma Surg* 2015; **135**: 505-516 [PMID: 25708027 DOI: 10.1007/s00402-015-2171-4]
28 **Mason LW**, Kaye A, Widnall J, Redfern J, Molloy A. Posterior Malleolar Ankle Fractures: An Effort at Improving Outcomes. *JB JS Open Access* 2019; **4**: e0058 [PMID: 31334465 DOI: 10.2106/JBJS.OA.18.00058]
29 **Sultan F**, Zheng X, Pan Z, Zheng Q, Li H, Wang J. Characteristics of intercalary fragment in posterior malleolus fractures. *Foot Ankle Surg* 2020; **26**: 289-294 [PMID: 31027877 DOI: 10.1016/j.fas.2019.03.011]
30 **Bartoníček J**, Rammelt S, Tuček M, Naňka O. Posterior malleolar fractures of the ankle. *Eur J Trauma Emerg Surg* 2015; **41**: 587-600 [PMID: 26253884 DOI: 10.1007/s00068-015-0560-6]
31 **White TO**. In defence of the posterior malleolus. *Bone Joint J* 2018; **100-B**: 566-569 [PMID: 29701100 DOI: 10.1302/0301-620X.100B5.BJJ-2017-1440.R1]
32 **Donohoe S**, Alluri RK, Hill JR, Fleming M, Tan E, Marecek G. Impact of Computed Tomography on Operative Planning for Ankle Fractures Involving the Posterior Malleolus. *Foot Ankle Int* 2017; **38**: 1337-1342 [PMID: 28954524 DOI: 10.1177/1071100717731568]
33 **Zhang K**, Jia X, Qiang M, Chen S, Wang S, Wang D, Chen Y. Quantitative Evaluation of Articular Involvement of Posterior Malleolus Associated with Operative Indication: A Comparative Study of Six Methods Based on Radiography and CT. *Biomed Res Int* 2020; **2020**: 6745626 [PMID: 31998795 DOI: 10.1155/2020/6745626]
34 **Tejwani NC**, Pahk B, Egol KA. Effect of posterior malleolus fracture on outcome after unstable ankle fracture. *J Trauma* 2010; **69**: 666-669 [PMID: 20838137 DOI: 10.1097/TA.0b013e3181e4f81e]
35 **Stringfellow TD**, Walters ST, Nash W, Ahluwalia R; Posterior Malleolus Study Group. Management of posterior malleolus fractures: A multicentre cohort study in the United Kingdom. *Foot Ankle Surg* 2021; **27**: 629-635 [PMID: 32878722 DOI: 10.1016/j.fas.2020.08.003]
36 **Alluri RK**, Hill JR, Donohoe S, Fleming M, Tan E, Marecek G. Radiographic Detection of Marginal Impaction in Supination-Adduction Ankle Fractures. *Foot Ankle Int* 2017; **38**: 1005-1010 [PMID: 28617051 DOI: 10.1177/1071100717709565]
37 **Landis JR**, Koch GG. An application of hierarchical kappa-type statistics in the assessment of majority agreement among multiple observers. *Biometrics* 1977; **33**: 363-374 [PMID: 884196 DOI: 10.2307/2529786]

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ORIGINAL ARTICLE

Randomized Controlled Trial

Efficacy and safety of thermobalancing therapy with Dr Allen's Device for chronic low back pain: A randomised controlled trial

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Abstract

BACKGROUND

Lumbar disc herniation and non-specific low back pain are common conditions that seriously affect patients' health-related quality of life (HRQoL). Although empirical evidence has demonstrated that novel Thermobalancing therapy and Dr Allen's Device can relieve chronic low back pain, there have been no randomised controlled trials for these indications.

AIM

To evaluate the efficacy of Dr Allen's Device in lumbar disc herniation (LDH) and non-specific low back pain (NSLBP).

METHODS

A randomised clinical trial was conducted investigating 55 patients with chronic low back pain due to LDH (n = 28) or NSLBP (n = 27), out of which 15 were randomly assigned to the control group and 40 were assigned to the treatment

group. The intervention was treatment with Dr Allen's Device for 3 mo. Changes in HRQoL were assessed using the Numerical Pain Rating Scale and the Japanese Orthopedic Association Back Pain Questionnaire.

RESULTS

Thermobalancing therapy with Dr Allen's Device showed a significant reduction in pain in the treatment group ($P < 0.001$), with no recorded adverse effects. Both pain assessment scales showed a significant improvement in patients' perception of pain indicating improvement in HRQoL.

CONCLUSION

The out-of-hospital use of Thermobalancing therapy with Dr Allen's Device for Low Back Treatment relieves chronic low back pain significantly and without adverse effects, improves the level of activity and HRQoL among patients with LDH and NSLBP. This study demonstrates the importance of this safe first-line therapy that can be used for effective at-home management of chronic low back pain.

Key Words: Chronic low back pain; Lumbar disc herniation; Non-specific low back pain; Thermobalancing therapy; Dr Allen's Device; Numerical pain rating scale

Core Tip: This prospective randomised controlled trial assessed the efficacy and safety of novel Thermobalancing therapy and wearable Dr Allen's Device for chronic low back pain. Patients with non-specific low back pain and lumbar disc herniation were assessed by the Numerical Pain Rating Scale, and the Japanese Orthopedic Association Back Pain Evaluation Questionnaire. Research results showed a significant reduction in pain and the improvement in patients' health-related quality of life in the treatment group. No adverse effects were observed. Therefore, Thermobalancing therapy with Dr Allen's Device can be recommended for the at-home management of chronic low back pain.

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INTRODUCTION

Non-specific low back pain (NSLBP) is the leading cause of disability worldwide[1]. Of the numerous causes of low back pain, lumbar disc herniation (LDH) is a major contributor accounting for around 9% of chronic low back pain (CLBP) in the population[2]. The main symptom of LDH and NSLBP is chronic pain in the lower spine area that can impact the quality of life and heavily burden individuals, their families, and society[3].

Common treatments for NSLBP and LDH include pain management with acetaminophen, nonsteroidal anti-inflammatory drugs (NSAIDs), opioids and anticonvulsants, steroid injections, and spinal surgeries. Oral medications for pain control can be effective but they only provide short term symptomatic relief and are not without adverse effects. NSAIDs, acetaminophen and anticonvulsants can cause serious side effects and can lead to health problems, such as gastrointestinal complications and cardiovascular events[4,5]. Opioid use in people with chronic pain can cause constipation, nausea, itching, dizziness and can even result in opioid dependence. Opioid overdose is becoming a major public health problem[6,7]. Epidural "around the spinal cord" steroid injections aimed at relieving low back pain can lead to irreversible complications and should therefore be used as the last resort[8]. Lower back surgeries may provide pain relief more rapidly than conservative therapy but carry more risk and the outcomes at one year are similar using both these modalities. Moreover, surgery can still be an option after conservative therapy[9].

The above adverse effects of the available treatment options for low back pain limit their use and highlight the need for a conservative, safe and effective mode of treatment.

Over the last decade, Thermobalancing therapy and non-invasive Dr Allen's Devices were used in patients for effective and safe out-of-hospital management of chronic diseases affecting different organs. This novel treatment was patented as "Therapeutic device and method"[10].

The use of Thermobalancing therapy with Dr Allen's Device as a monotherapy in men over 55 years of age with benign prostatic hyperplasia (BPH) showed improvement of clinical symptoms, including lower urinary tract symptoms[11,12]. Evidence also suggests that Thermobalancing therapy is effective in the treatment of chronic prostatitis/chronic pelvic pain syndrome[13] and kidney stone disease (KSD) without renal colic[14].

Although empirical evidence has also demonstrated that this novel treatment option can relieve chronic low back pain in cases of lumbar disc herniation and non-specific causes, there have been no randomised control trials for these indications.

This is the first clinical study that attempts to demonstrate the effectiveness and safety of Dr Allen's Device for Low Back Treatment in patients with chronic low back pain due to LDH or NSLBP, as well as the ability of this therapy to improve health-related quality of life (HRQoL).

MATERIALS AND METHODS

Study design and participants

Our study was a prospective, randomised, interventional, parallel group study conducted to demonstrate the efficacy of Dr Allen's Device for low back treatment in the management of chronic low back pain. The trial was registered at the Iranian Registry of Clinical Trials. The study was conducted in accordance with the Declaration of Helsinki. It was approved by the Ethics Review Committee.

Patients aged 18-60 years having low back pain for at least 12 wk were recruited at a hospital and an outpatient clinic for the trial after initial radiological evaluation. For every patient with LDH, one patient with NSLBP was recruited to maintain a 1:1 ratio of the conditions. Participants were excluded if they had severe co-morbidities, such as cancer, heart failure or infection.

A total of 55 male and female patients with low back pain met the eligibility criteria and were recruited for the study. The patients were then randomised into treatment and control groups. This resulted in two groups: A treatment group of 40 patients with chronic low back pain, consisting of 20 patients with NSLBP and 20 patients with LDH, and a control group of 15 patients consisting of 7 patients with NSLBP and 8 patients with LDH. Randomisation was performed using simple randomisation procedures and computer-generated random numbers. No blinding was done due to the nature of the intervention.

Patient satisfaction was considered an adequate representation of treatment efficacy and was assessed at the beginning of the study and after treatment using two well-established self-administered questionnaires: Numerical Pain Rating Scale (NPRS)[15] and The Japanese Orthopedic Association Back Pain Evaluation Questionnaire (JOABPEQ)[16]. The NPRS scores were obtained at the beginning of the study and after 1 and 3 mo of using Dr Allen's Device for low back treatment, and the JOABPEQ scores were obtained at the beginning and end of therapy.

Randomisation

A total of 55 patients with chronic low back pain were recruited for the clinical trial after receiving a detailed explanation of the clinical trial and the possible benefits of thermobalancing therapy, and after giving informed consent. They were divided into two groups, those with LDH and those with NSLBP, based on their aetiology identified by radiological imaging. The ratio of patients in these groups was 1:1 as an equal number of patients with LDH (n = 28) and NSLBP (n = 27) were recruited. Although NSLBP is more common on average in the general population, the type of pain in LDH tends to be more severe, and such patients present more frequently to the hospital compared to patients with NSLBP.

Each group (LDH, NSLBP) was randomised separately using a 3:1 ratio for ethical reasons as the control group was not going to receive the intervention. It was decided that a larger treatment group would allow for a better understanding of adverse effects if any. Patients with LDH were randomised into a treatment group of 20 patients and a control group of 8 patients and patients with NSLBP were randomised into a treatment group of 20 patients and a control group of 7 patients. The final treatment group consisted of 40 patients and the control group consisted of 15 patients.

Intervention

The intervention was Thermobalancing therapy with Dr Allen's Device for Low Back Pain Treatment used as a monotherapy for a 3-mo period. The patients in the treatment group used Dr Allen's Device for low back pain treatment as a monotherapy for 3 mo. Patients in the control group did not receive any intervention.

Dr Allen's Device for Low Back Pain Treatment

Dr Allen's Device is a Class I medical device and registered with the British Medicines and Healthcare Products Regulatory Agency (MHRA). Thermobalancing therapy with Dr Allen's Device can be used as an out-of-hospital treatment by patients at home. Dr Allen's Device applies a thermoelement, made from a special wax-based material, topically to the skin or worn over close-fitting underwear over the affected organs. In people with lower back pain, the thermoelement is applied to the back over the sore area (Figure 1). This thermoelement accumulates the naturally emitted body heat, warms up, directs heat to the region of pain, and maintains the optimal level of heat in the region of pain over time. Wearing and using Dr Allen's Device for Low Back Pain Treatment is comfortable.

Outcomes

The NPRS and the JOABPEQ were used to assess the effectiveness of treatment. The NPRS is an 11-point pain rating scale that can be used to estimate the degree of pain experienced by the patient. The scale ranges from 0 (no pain) to 10 (worst imaginable pain)[17]. A study about the responsiveness of NPRS has found that a 2-point improvement represents meaningful change[18].

The JOABPEQ has 25 questions which evaluate 5 functional domains with scores ranging from 0-100. According to a study, a 20 point improvement in the functional domains of JOABPEQ represents meaningful change[19].

In our study, the change in the NPRS score and the functional domains of JOABPEQ assessed before the intervention and during the follow up period was considered as the primary endpoint.

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Figure 1 Dr Allen's Device for Low Back Pain Treatment applied to the affected lower back area.

Sample size estimation

Sample size was calculated using G*Power software. A total of 54 participants (40 participants in treatment group and 14 participants in control group) were required to conduct a two tailed study with a type I error of 5% and a power of 80%. We had 15 patients in the control group.

Statistical analysis

The collected data was organised in Microsoft Excel and statistical analysis of the results was performed using the Data Analysis module of Microsoft Excel 2010. Paired sample t-tests were used for the comparison of parametric data. The non-parametric data was assessed using the Mann-Whitney U test. A P value < 0.05 was considered statistically significant.

RESULTS

A total of 55 patients with chronic low back pain either due to NSLBP (n = 27) or LDH (n = 28) identified by radiological assessment participated in the study. After randomisation, the treatment group consisted of 40 patients, 20 with LDH and 20 with NSLBP, and the control group consisted of 15 patients, 8 with LDH and 7 with NSLBP, as shown in the patient allocation flow diagram (Figure 2).

Mean age of the patients was 41.07 ± 8.05 years. The overall male to female ratio was 29:26. Correlation analysis between demographic variables and the NPRS and JOABPEQ scores and patient characteristics are detailed in Table 1. Pearson's product-moment correlation was used for continuous variables and point-biserial correlation was used for dichotomous variables.

For initial evaluation, patients were presented with the NPRS scale and the JOABPEQ. Instructions about how to answer the questions were provided and the clinicians ensured that the patients understood the questions adequately in order to obtain the most accurate responses. Details of low back pain intensity experienced by the patients was obtained using the NPRS scale as answers to four questions, namely, "How would you rate your pain RIGHT NOW", "USUAL level of pain during the last week", "BEST level of pain during the last week" and "WORST level of pain during the last week". The patients scored the intensity of their pain from 0 to 10.

The JOABPEQ questionnaire required answers to 25 separate questions which were then evaluated to scores ranging from 0 to 100 for five different functional domains.

The NPRS scale was presented to the patients again at the end of one month, and the NPRS scale and the JOABPEQ were presented to the patients again at the end of three months of treatment and their responses were compared with the initial assessment.

A 2-point improvement in the different parameters of the NPRS scale was considered significant. Out of the 40 patients in the treatment group, 82.5%, 77.5%, 75% and 75% showed significant improvement in the "How would you rate your pain RIGHT NOW", "USUAL level of pain during the last week", "BEST level of pain during the last week" and the "WORST level of pain during the last week" scores respectively. A total of 7 patients had unchanged scores and 2 patients experienced increased pain intensity.

In the control group, none of the patients showed any significant improvement. Out of the 15 patients in the control group, 26.67%, 40%, 40% and 13.3% showed significant increase in the "How would you rate your pain RIGHT NOW", "USUAL level of pain during the last week", "BEST level of pain during the last week" and "WORST level of pain during the last week" scores indicating increase in pain intensity. Scores remained unchanged in 12 patients.

On statistical analysis, the comparison of the mean initial and final pain scores in the treatment group was found to be statistically significant across all the parameters of the NPRS scale, while no statistically significant change was observed in the control group. The comparison is presented in Figure 3 and in Table 2.

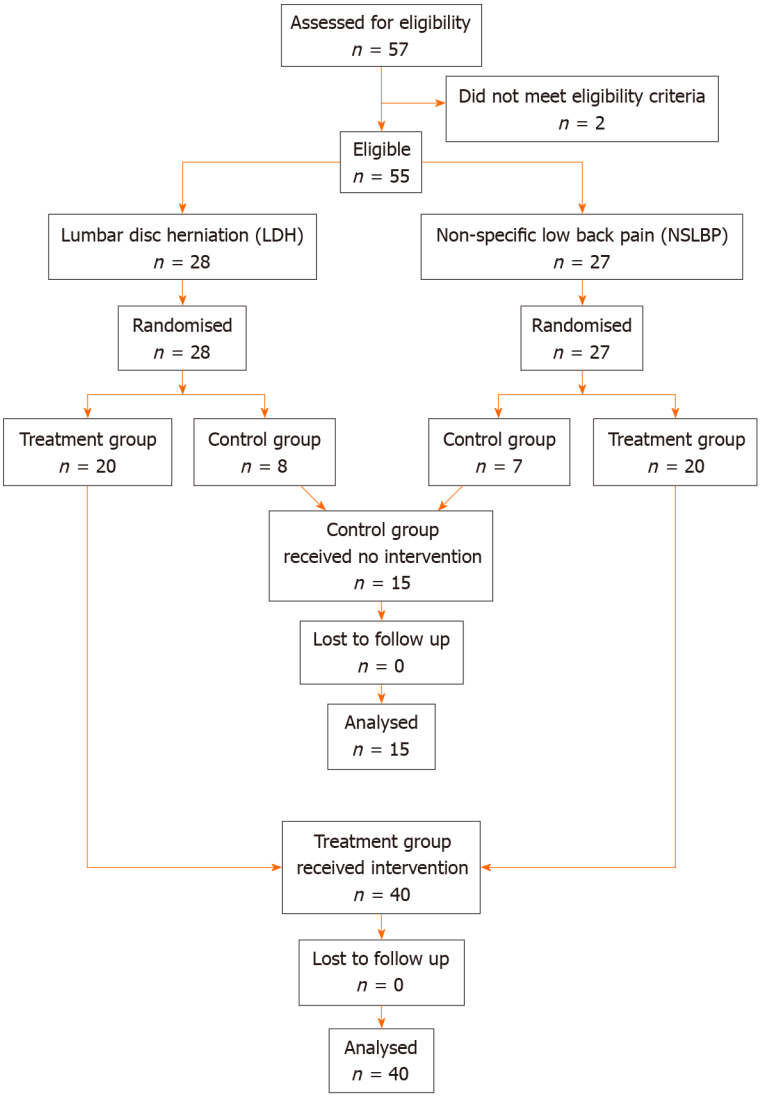

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Figure 2 Patient allocation flow diagram.

The scores of the five domains of JOABPEQ evaluated at the beginning of the study were compared with those evaluated at the end of 3 months. In the treatment group, all 40 patients showed an improvement indicated by an increase in 20 points in the low back pain domain. A 72.5% improvement was observed in the lumbar function domain and 10% of the patients showed worsening. Walking ability was improved in 75% of the patients and worsened in 10% of the patients. Social life function was improved in 75% of the patients of the treatment group and worsened in 5%. Mental health was improved in 77.5% of patients, with no patients showing worsening.

In the control group, a very small proportion of patients, i.e., 13.3%, 6.7%, 20% and 6.7% of the 15 patients experienced an improvement in low back pain, lumbar function, walking ability and social life domains respectively. No improvement was observed in the mental health domain. Most patients experienced low scores across all domains.

A comparison of the mean difference between the scores of the five functional domains before and after thermobalancing therapy showed a statistically significant improvement across all domains in the treatment group. No significant improvement was observed in the control group, but a statistically significant worsening of lumbar function and mental health were seen further emphasising the need for effective treatment. This data is presented in Figure 4 and in Table 3.

The changes in the NPRS and the JOABPEQ scores before and after Thermobalancing therapy with Dr Allen's Device show significant improvement in pain perception in all patients in the treatment group.

Harms

The use of Dr Allen's Device for low back pain treatment did not cause any adverse events in the participating individuals. This observation confirms that thermobalancing therapy and Dr Allen's Device are safe.

Table 1 Patient characteristics and correlation analysis

Characteristic	Treatment group	Correlation coefficient (r)	Control group	Correlation coefficient (r)
Number of patients (*n*)	40		15	
Age (mean ± SD)	42.2 ± 8.49	-0.1124[a]; 0.099[b]	38.06 ± 5.98	0.4919[a]; 0.045[b]
Gender (M:F)	18:22	0.2353[a]; -0.08[b]	11:4	0.1183[a]; -0.34[b]
NSLBP:LDH	1:1	-0.131[a]; 0.126[b]	7:8	0.1396[a]; 0.172[b]
NPRS – how would you rate your pain right now?	6.48 ± 1.63		8.07 ± 1.16	
JOABPEQ – low back pain	8.9 ± 14.38		10.40 ± 12.66	

[a]Correlation analysis with initial NPRS (How would you rate your pain right now?) score.
[b]Correlation analysis with initial JOABPEQ (Low back pain) score.
NSLBP: Non-specific low back pain; LDH: Lumbar disc herniation; NPRS: Numerical Pain Rating Scale; JOABPEQ: The Japanese Orthopedic Association Back Pain Evaluation Questionnaire.

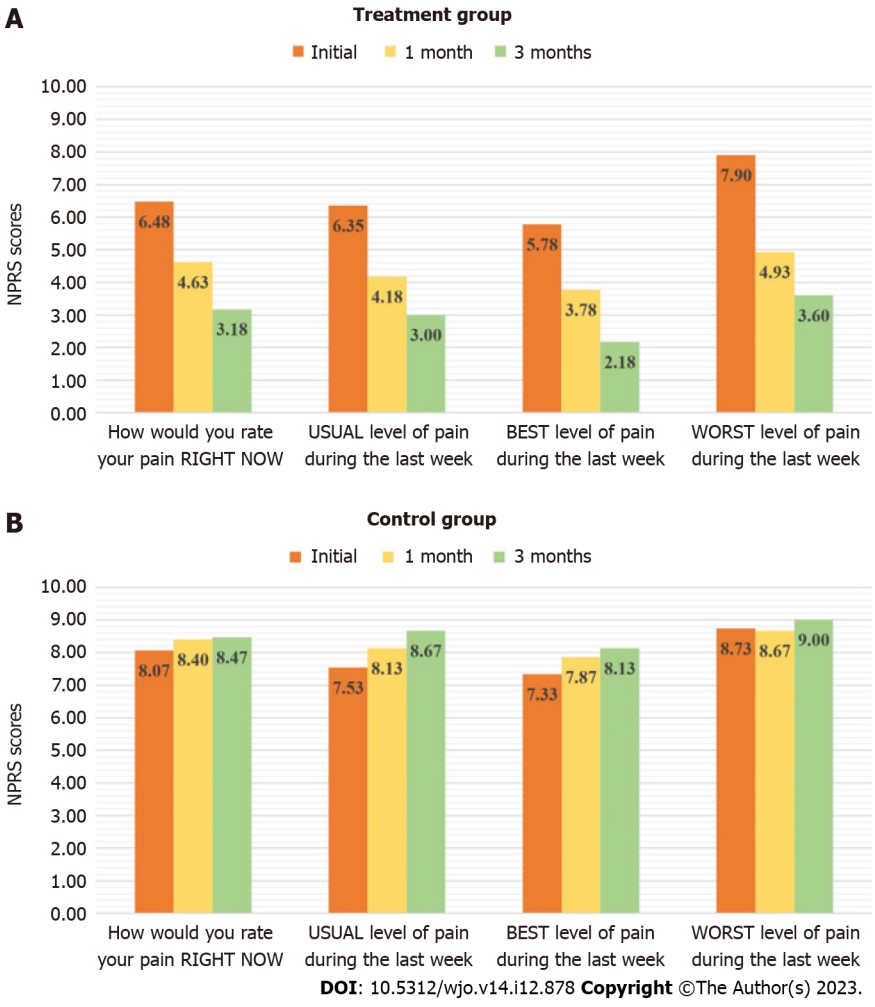

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Figure 3 The comparison of mean Numerical Pain Rating Scale (NPRS) scores in the treatment and control groups at initial evaluation and at 1 and 3 mo. A: Treatment group; B: Control group.

DISCUSSION

The aim of this study was to determine the effect of Thermobalancing therapy on CLBP, defined as pain that continues for 12 wk or longer, and to assess the general improvement in the HRQoL in male and female patients when used as monotherapy compared with patients who received no treatment. The objective of this study was not to compare one treatment with another but to show the efficacy of the prolonged use of the intervention on the treatment group and, as

Table 2 Comparison of Numerical Pain Rating Scale scores before and after Thermobalancing therapy with Dr Allen's Device

	NPRS parameters	Initial (mean ± SD)	1 mo (mean ± SD)	3 mo (mean ± SD)	*P* value (0-3 mo)
Treatment group	How would you rate your pain RIGHT NOW	6.48 ± 1.63	4.63 ± 1.00	3.18 ± 1.87	**< 0.001**
	P value	**< 0.001**[a]	**< 0.001**[b]		
	USUAL level of pain during the last week	6.35 ± 1.23	4.18 ± 0.96	3.0 ± 1.43	**< 0.001**
	P value	**< 0.001**[a]	**< 0.001**[b]		
	BEST level of pain during the last week	5.78 ± 1.25	3.78 ± 0.97	2.18 ± 1.62	**< 0.001**
	P value	**< 0.001**[a]	**< 0.001**[b]		
	WORST level of pain during the last week	7.9 ± 1.50	4.93 ± 1.10	3.6 ± 2.01	**< 0.001**
	P value	**< 0.001**[a]	**< 0.001**[b]		
Control group	How would you rate your pain RIGHT NOW	8.07 ± 1.16	8.4 ± 0.63	8.47 ± 0.64	> 0.05
	P value	> 0.05[a]	> 0.05[b]		
	USUAL level of pain during the last week	7.53 ± 0.92	8.13 ± 0.52	8.67 ± 0.49	> 0.05
	P value	> 0.05[a]	> 0.05[b]		
	BEST level of pain during the last week	7.33 ± 0.98	7.87 ± 0.64	8.13 ± 0.74	> 0.05
	P value	> 0.05[a]	> 0.05[b]		
	WORST level of pain during the last week	8.73 ± 1.10	8.67 ± 0.49	9.00 ± 0.38	> 0.05
	P value	> 0.05[a]	> 0.05[b]		

[a]*P* value comparing NPRS score at 0 and 1 mo.
[b]*P* value comparing NPRS score at 1 and 3 mo.
NPRS: Numerical Pain Rating Scale; SD: Standard deviation.

expected, the final data showed a significant improvement in pain in the treatment group and no change in the control group indicating that the intervention was efficacious.

A difference in baseline NPRS scores of the treatment and control groups was observed. This can be attributed to the difference in the sizes of the treatment (n = 40) and control (n = 15) groups. Since this difference in baseline values occurred despite efficient randomisation, we consider the data valid.

The results of our study show that Thermobalancing therapy is safe and reduces the intensity of back pain, consequently improving the level of activity among patients with LDH and NSLBP. The results showed that there was significant difference in the improvement of daily activities between the treatment and control groups with the treatment group showing a striking functional improvement. However, the difference in effectiveness between the NSLBP treatment group and the LDH treatment group was not significant, implying that Dr Allen's Device was equally effective in improving the symptoms and functional activity in chronic low back pain due to lumbar disc herniation or other non-specific causes.

These findings allow to suggest that Dr Allen's Device can be used as the first-line therapy for chronic low back pain.

Low back pain can occur due to a variety of causes, and, in most instances, the cause is multifactorial. The pain can be caused due to a pathology in either the soft tissues, the vertebrae, the joints, intervertebral discs, or neurovascular structures. The numerous treatment modalities available for low back pain include conservative treatments like self-care, psychological care, physical rehabilitation and symptomatic care, and surgical procedures in refractory cases where the pain is not amenable to any conservative option. But most treatment modalities are singular in their effectiveness and, therefore, are not effective when more than one cause of the pain concurrently exist[20].

Dr Allen's Device for low back treatment is a novel, conservative option in the treatment of chronic pain in the lower spine. It is easy to use with no identified adverse effects in the short or long term. It is a comfortable, wearable device which allows long term patient compliance. As observed in our study, thermobalancing therapy and Dr Allen's Device provide pain relief in chronic low back pain due to intervertebral disc related causes as well as other causes, thereby making it a holistic treatment option for this condition.

Low back pain is more common in females than in males and its prevalence increases with age. A study evaluated physical and mental health indicators to assess the quality of life in patients with low back pain and found that irrespective of sociodemographic conditions, and the presence of other comorbidities or causes of chronic pain, low back pain can significantly lower quality of life[21].

The NPRS scale and the JOABPEQ are indicators of pain intensity and quality of life respectively. Both these indicators have been found to be reliable, responsive, and valid as indicators of pain and functional abilities. The combined use of NPRS scale and JOABPEQ as done in our study have been found to be the most appropriate tools to assess pain as well as

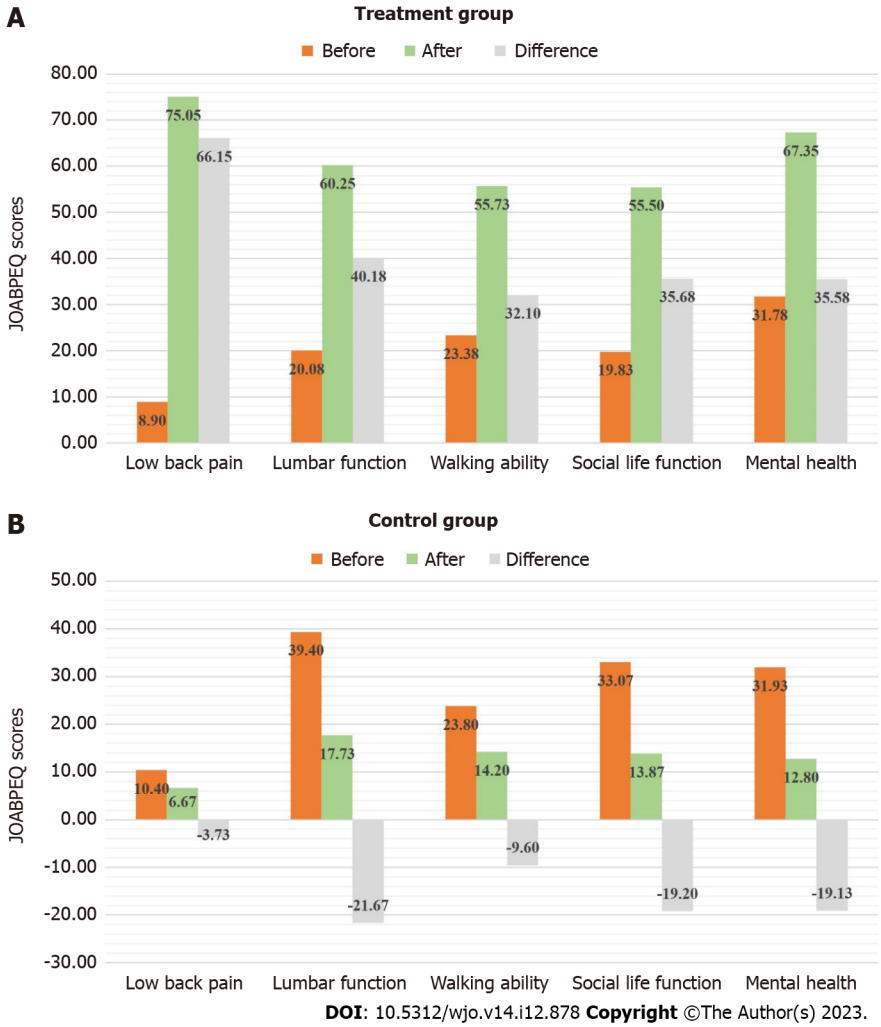

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Figure 4 The comparison of mean Japanese Orthopedic Association Back Pain Evaluation Questionnaire (JOABPEQ) functional domains at initial and final evaluations at 3 mo, and their difference. A: Treatment group; B: Control group.

quality of life in patients with low back pain[22].

The strengths of our study are the combined use of a pain intensity scale and a quality-of-life questionnaire enabling us to better understand the benefits of Thermobalancing therapy on individual well-being.

Back pain is associated with physical, psychological, emotional, social changes, and even inappropriate exercise[23,24]. However, a survey found no significant association between LBP and psychological stress[25]. Health systems must prioritise policies that empower doctors and consumers to make informed choices, encourage clinicians to provide appropriate care to those who need it most and provide financial support for evidence-based non-pharmacological treatment[26].

Dr Allen's Device is a valuable medical innovation for the at-home use[27]. Its patented design accumulates the naturally emitted body heat and spreads it to the affected organs and areas of the body to which it is applied[28]. This out-of-hospital treatment targets the cause of pain at the capillary level. It improves blood circulation locally, that reduces inflammation and pressure in the affected tissue and, consequently, relieves chronic pain and other clinical symptoms[29, 30].

Limitations

The limitation of our study is the lack of an alternative treatment mode in the control group to compare the efficacy of Thermobalancing therapy with available first line treatment modalities for low back pain. In line with previous clinical trials on this treatment modality for other chronic diseases, such as chronic prostatitis, BPH and KSD, blinding was not performed due to the impracticality of a placebo group using such a wearable medical device for a long duration.

CONCLUSION

This research confirms that the use of non-invasive Dr Allen's Device gradually relieves chronic low back pain and improves the level of activity in patients with LDH or NSLBP. The study highlights the importance of this novel out-of-

Table 3 Comparison of the Japanese Orthopedic Association Back Pain Evaluation Questionnaire (JOABPEQ) functional domains before and after Thermobalancing therapy with Dr Allen's Device

	JOABPEQ functional domains	Initial evaluation	Final evaluation	Difference	*P* value
Treatment group	Low back pain	8.9 ± 14.38	75.05 ± 20.97	66.15	**< 0.001**
	Lumbar function	20.08 ± 18.24	60.25 ± 18.38	40.17	**< 0.001**
	Walking ability	23.38 ± 19.09	55.73 ± 21.07	32.35	**< 0.001**
	Social life function	19.83 ± 14.02	55.50 ± 17.37	35.67	**< 0.001**
	Mental health	31.78 ± 20.85	67.35 ± 13.83	35.57	**< 0.001**
Control group	Low back pain	10.40 ± 12.66	6.67 ± 13.13	-3.73	0.29
	Lumbar function	39.40 ± 25.57	17.73 ± 14.69	-21.67	**0.01**
	Walking ability	23.80 ± 30.96	14.20 ± 16.01	-9.6	0.69
	Social life function	33.07 ± 24.10	13.87 ± 9.24	-19.2	**0.01**
	Mental health	31.93 ± 19.76	12.80 ± 6.83	-19.13	**< 0.001**

JOABPEQ: The Japanese Orthopedic Association Back Pain Evaluation Questionnaire.

hospital treatment option as all participants in the treatment group experienced a significant improvement in their health-related quality of life as a result of using Dr Allen's Device at home during a 3-mo period and reported no side effects or complications. Overall, the study demonstrates high efficacy and safety of thermobalancing therapy and Dr Allen's Device for low back treatment in male and female patients with chronic low back pain. Thus, this wearable medical device can be used as the first-line therapy for chronic pain in the lower spine, and for effective at-home management of low back pain due to LDH and other non-specific causes.

ARTICLE HIGHLIGHTS

Research background

Chronic low back pain (CLBP) is a highly prevalent cause of disability worldwide. Of the numerous causes of low back pain, lumbar disc herniation (LDH) is a major contributor accounting for around 9% of CLBP in the population. The main symptom of LDH is chronic pain in the lower spine area that can impact the quality of life and heavily burden individuals, their families, and society. Standard treatments include pain management with acetaminophen, nonsteroidal anti-inflammatory drugs (NSAIDs), opioids and anticonvulsants, steroid injections, and spinal surgeries.

Research motivation

Multiple adverse effects of the standard treatment options for low back pain limit their use and highlight the pressing need for a new conservative, safe and effective mode of treatment.

Research objectives

This is the first clinical study that attempts to demonstrate the efficacy and safety of Dr Allen's Device for Low Back Pain Treatment in patients with chronic low back pain due to lumbar disc herniation (LDH) or non-specific low back pain (NSLBP), as well as the ability of this therapy to improve health-related quality of life.

Research methods

A total of 55 patients with chronic low back pain were recruited and randomised for the clinical trial. Thermobalancing therapy with Dr Allen's Device for Low Back Pain Treatment was used as a monotherapy for a 3-month period. The Numerical Pain Rating Scale (NPRS) and the Japanese Orthopedic Association Back Pain Evaluation Questionnaire (JOABPEQ) were used to assess the effectiveness of treatment. The effect on chronic low back pain was assessed as the primary health outcome.

Research results

The study showed that most patients in the treatment group experienced a significant pain reduction in the low back area, an improvement in the lumbar function, walking ability, social life, and mental health, with no patients showing worsening of these parameters. It was confirmed that the treatment with Dr Allen's Device was effective and safe in patients with non-specific low back pain and lumbar disc herniation.

Research conclusions

Thermobalancing therapy with Dr Allen's Device can be recommended for an effective at-home management of chronic low back pain.

Research perspectives

The results suggest that this treatment may also be effective and safe for other types of chronic back pain and further research in this direction is needed.

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FOOTNOTES

Author contributions: Allen S, Rashid A, Adjani A and Akram M designed the research study; Akram M, Khan FS and Khalil MT performed the research; Sherwani R contributed as statistician; Allen S, Rashid A, Adjani A and Akram M analysed the data and wrote the manuscript; All authors have read and approved the final manuscript.

Institutional review board statement: This study was performed in line with the principles of the Declaration of Helsinki. The study was reviewed and approved by the Ethics Review Committee of the Government College University Faisalabad (Approval No. GCUF/ERC/111).

Clinical trial registration statement: This study is registered at https://www.irct.ir/trial/69235. The IRCT registration number is: IRCT20211022052833N2.

Informed consent statement: All study participants provided informed written consent prior to study enrolment.

Conflict-of-interest statement: All the authors report no relevant conflicts of interest for this article.

Data sharing statement: The datasets used and/or analysed during the current study and the full trial protocol are available from the corresponding author upon reasonable request.

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REFERENCES

1 **Gianola S**, Bargeri S, Del Castillo G, Corbetta D, Turolla A, Andreano A, Moja L, Castellini G. Effectiveness of treatments for acute and subacute mechanical non-specific low back pain: a systematic review with network meta-analysis. *Br J Sports Med* 2022; **56**: 41-50 [PMID: 33849907 DOI: 10.1136/bjsports-2020-103596]

2 **Hoy D**, March L, Brooks P, Blyth F, Woolf A, Bain C, Williams G, Smith E, Vos T, Barendregt J, Murray C, Burstein R, Buchbinder R. The global burden of low back pain: estimates from the Global Burden of Disease 2010 study. *Ann Rheum Dis* 2014; **73**: 968-974 [PMID: 24665116 DOI: 10.1136/annrheumdis-2013-204428]

3 **Grabovac I**, Dorner TE. Association between low back pain and various everyday performances: Activities of daily living, ability to work and sexual function. *Wien Klin Wochenschr* 2019; **131**: 541-549 [PMID: 31493101 DOI: 10.1007/s00508-019-01542-7]

4 **Wehling M**. Non-steroidal anti-inflammatory drug use in chronic pain conditions with special emphasis on the elderly and patients with relevant comorbidities: management and mitigation of risks and adverse effects. *Eur J Clin Pharmacol* 2014; **70**: 1159-1172 [PMID: 25163793 DOI: 10.1007/s00228-014-1734-6]

5 **Enthoven WT**, Roelofs PD, Deyo RA, van Tulder MW, Koes BW. Non-steroidal anti-inflammatory drugs for chronic low back pain. *Cochrane Database Syst Rev* 2016; **2**: CD012087 [PMID: 26863524 DOI: 10.1002/14651858.CD012087]

6 **Deyo RA**, Von Korff M, Duhrkoop D. Opioids for low back pain. *BMJ* 2015; **350**: g6380 [PMID: 25561513 DOI: 10.1136/bmj.g6380]

7 **Abdel Shaheed C**, Maher CG, Williams KA, Day R, McLachlan AJ. Efficacy, Tolerability, and Dose-Dependent Effects of Opioid Analgesics for Low Back Pain: A Systematic Review and Meta-analysis. *JAMA Intern Med* 2016; **176**: 958-968 [PMID: 27213267 DOI: 10.1001/jamainternmed.2016.1251]

8 **Suri P**, Pashova H, Heagerty PJ, Jarvik JG, Turner JA, Comstock BA, Bauer Z, Annaswamy TM, Nedeljkovic SS, Wasan AD, Friedly JL. Short-term improvements in disability mediate patient satisfaction after epidural corticosteroid injections for symptomatic lumbar spinal stenosis. *Spine (Phila Pa 1976)* 2015; **40**: 1363-1370 [PMID: 26010037 DOI: 10.1097/BRS.0000000000001000]

9 **Deyo RA**, Mirza SK. CLINICAL PRACTICE. Herniated Lumbar Intervertebral Disk. *N Engl J Med* 2016; **374**: 1763-1772 [PMID: 27144851 DOI: 10.1056/NEJMcp1512658]

10 **Allen S**, Adjani A. Therapeutic Device and Method, United States Patent and Trademark Office. U.S. Patent No: US9408744B2, 9 August 2016. (accessed June 11, 2023). Available from: https://www.google.com/patents/US9408744

11 **Allen S**, Aghajanyan IG. Benign Prostatic Hyperplasia Treatment with New Physiotherapeutic Device. *Urol J* 2015; **12**: 2371-2376 [PMID: 26571324]

12 **Allen S**, Aghajanyan IG. Thermobalancing conservative treatment for moderate-to-low-degree lower urinary tract symptoms (LUTS) secondary to prostate enlargement. *Cogent Medicine* 2016; **3**: 1 [DOI: 10.1080/2331205X.2016.1195067]

13 **Allen S**, Aghajanyan IG. Effect of thermobalancing therapy on chronic prostatitis and chronic pelvic pain syndrome. *J Clin Urol* 2017; **10**: 347-354

14 **Allen S**, Adjani A. Benign Prostatic Hyperplasia and Kidney Stone Disease Thermobalancing Therapy with Dr Allen's Device: Key to Successful Ageing Without Medications, Surgery, and Risky Exposure to Coronavirus Infection. *Nephro-Urol Mon* 2021; **13**: e110771 [DOI: 10.5812/numonthly.110771]

15 **Suzuki H**, Aono S, Inoue S, Imajo Y, Nishida N, Funaba M, Harada H, Mori A, Matsumoto M, Higuchi F, Nakagawa S, Tahara S, Ikeda S, Izumi H, Taguchi T, Ushida T, Sakai T. Clinically significant changes in pain along the Pain Intensity Numerical Rating Scale in patients with chronic low back pain. *PLoS One* 2020; **15**: e0229228 [PMID: 32126108 DOI: 10.1371/journal.pone.0229228]

16 **Hashizume H**, Konno S, Takeshita K, Fukui M, Takahashi K, Chiba K, Miyamoto M, Matsumoto M, Kasai Y, Kanamori M, Matsunaga S, Hosono N, Kanchiku T, Taneichi H, Tanaka N, Kanayama M, Shimizu T, Kawakami M. Japanese orthopaedic association back pain evaluation questionnaire (JOABPEQ) as an outcome measure for patients with low back pain: reference values in healthy volunteers. *J Orthop Sci* 2015; **20**: 264-280 [PMID: 25687654 DOI: 10.1007/s00776-014-0693-1]

17 **Jensen MP**, Turner JA, Romano JM, Fisher LD. Comparative reliability and validity of chronic pain intensity measures. *Pain* 1999; **83**: 157-162 [PMID: 10534586 DOI: 10.1016/s0304-3959(99)00101-3]

18 **Childs JD**, Piva SR, Fritz JM. Responsiveness of the numeric pain rating scale in patients with low back pain. *Spine (Phila Pa 1976)* 2005; **30**: 1331-1334 [PMID: 15928561 DOI: 10.1097/01.brs.0000164099.92112.29]

19 **Fukui M**, Chiba K, Kawakami M, Kikuchi S, Konno S, Miyamoto M, Seichi A, Shimamura T, Shirado O, Taguchi T, Takahashi K, Takeshita K, Tani T, Toyama Y, Yonenobu K, Wada E, Tanaka T, Hirota Y; Subcommittee of the Clinical Outcome Committee of the Japanese Orthopaedic Association on Low Back Pain and Cervical Myelopathy Evaluation. JOA Back Pain Evaluation Questionnaire (JOABPEQ)/JOA Cervical Myelopathy Evaluation Questionnaire (JOACMEQ). The report on the development of revised versions. April 16, 2007. The Subcommittee of the Clinical Outcome Committee of the Japanese Orthopaedic Association on Low Back Pain and Cervical Myelopathy Evaluation. *J Orthop Sci* 2009; **14**: 348-365 [PMID: 19499305 DOI: 10.1007/s00776-009-1337-8]

20 **Knezevic NN**, Candido KD, Vlaeyen JWS, Van Zundert J, Cohen SP. Low back pain. *Lancet* 2021; **398**: 78-92 [PMID: 34115979 DOI: 10.1016/S0140-6736(21)00733-9]

21 **Husky MM**, Ferdous Farin F, Compagnone P, Fermanian C, Kovess-Masfety V. Chronic back pain and its association with quality of life in a large French population survey. *Health Qual Life Outcomes* 2018; **16**: 195 [PMID: 30257670 DOI: 10.1186/s12955-018-1018-4]

22 **Yao M**, Xu BP, Li ZJ, Zhu S, Tian ZR, Li DH, Cen J, Cheng SD, Wang YJ, Guo YM, Cui XJ. A comparison between the low back pain scales for patients with lumbar disc herniation: validity, reliability, and responsiveness. *Health Qual Life Outcomes* 2020; **18**: 175 [PMID: 32522196 DOI: 10.1186/s12955-020-01403-2]

23 **Ouchi K**, Watanabe M, Tomiyama C, Nikaido T, Oh Z, Hirano T, Akazawa K, Mandai N. Emotional Effects on Factors Associated with Chronic Low Back Pain. *J Pain Res* 2019; **12**: 3343-3353 [PMID: 31908519 DOI: 10.2147/JPR.S223190]

24 **Chan CW**, Mok NW, Yeung EW. Aerobic exercise training in addition to conventional physiotherapy for chronic low back pain: a randomized controlled trial. *Arch Phys Med Rehabil* 2011; **92**: 1681-1685 [PMID: 21839983 DOI: 10.1016/j.apmr.2011.05.003]

25 **Alturkistani LH**, Hendi OM, Bajaber AS, Alhamoud MA, Althobaiti SS, Alharthi TA, Atallah AA. Prevalence of Lower Back Pain and its Relation to Stress Among Medical Students in Taif University, Saudi Arabia. *Int J Prev Med* 2020; **11**: 35 [PMID: 32363022 DOI: 10.4103/ijpvm.IJPVM_264_19]

26 **Traeger AC**, Buchbinder R, Elshaug AG, Croft PR, Maher CG. Care for low back pain: can health systems deliver? *Bull World Health Organ* 2019; **97**: 423-433 [PMID: 31210680 DOI: 10.2471/BLT.18.226050]

27 **Adjani A**, Allen S. The at-home delivery of treatment for benign prostate enlargement and chronic prostatitis enabled by Dr Allen's Device is a valuable healthcare innovation during a pandemic. *Medico Research Chronicles* 2021; **8**: 334-344 [DOI: 10.26838/MEDRECH.2021.8.4.542]

28 **Allen S**. Innovative Thermobalancing therapy and Dr Allen's Device for the first time employ body energy to treat chronic prostatic diseases effectively. *Int J Qual Innovation* 2020; **6** [DOI: 10.1186/s40887-020-00035-0]

29 **Allen S**. The Vascular Factor Plays the Main Role in the Cause of Pain in Men with Chronic Prostatitis and Chronic Pelvic Pain Syndrome: The Results of Clinical Trial on Thermobalancing Therapy. *Diseases* 2017; **5** [PMID: 29117111 DOI: 10.3390/diseases5040025]

30 **Allen S**, Aghajanyan I. Use of thermobalancing therapy in ageing male with benign prostatic hyperplasia with a focus on etiology and pathophysiology. *Aging Male* 2017; **20**: 28-32 [PMID: 27960590 DOI: 10.1080/13685538.2016.1247151]

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CASE REPORT

Unicompartimental knee arthroplasty metallosis treated with uni-on-uni revision: A case report

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Abstract

BACKGROUND

Metallosis is the result of metallic wear debris in the soft tissues and is associated to both local and systemic inflammatory response. Metallosis has been reported after total hip and total knee arthroplasty (TKA), but rarely after a unicompartimental knee arthroplasty (UKA). In the context of UKA metallosis, surgeons often opt for revision using a TKA. However, in this paper, the authors successfully treated UKA revising the metal back only.

CASE SUMMARY

Prior to treat our patient we conducted a literature research through which we identified eleven cases of metallosis after UKA, ten (90.9%) were treated revising using though a TKA. Only one case was managed through a uni-on-uni revision, reporting high knee function. Our patient complained worsening pain and function after a snap occurred at 16 mo after UKA implantation. At 18 mo following surgical debridment and uni-on-uni revision surgery, our patient exhibited a relevant improvement in Oxford Knee Score and a reduction of metal ion levels in the blood.

CONCLUSION

Our study highlights that in case of metallosis after UKA, the treatment may be based on surgical debridement and just revising the mobilized components.

Key Words: Metallosis; Unicompartimental knee arthroplasty; Revision; Uni-on-uni revision; case report; Review; Case report

Core Tip: Metallosis is a rare but serious complication of unicompartimental knee arthroplasty. It is generally treated through surgical debridment and revision to a total knee arthroplasty. However, in case of absence of critical signs of implant malpositioning, soft tissue impairment or bone loss, it could be successfully resolved through surgical debridment and uni-on-uni revision.

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INTRODUCTION

Metallosis is a condition in which prosthetic metallic wear produces debris that could be observed in soft tissues, causing both local and systemic inflammation, and could be associated to malignant tumors and systemic toxicity[1,2]. Metallosis had been associated mainly with total hip arthroplasty (THA)[3]. In fact, it could be observed in 2%-5% of metal-on-metal THA implants, yet it was also described in the context of total knee arthroplasty (TKA) and less frequently unicompartimental knee arthroplasty (UKA)[4]. Metallosis treatment contemplates wide surgical debridement and revision surgery. Nevertheless, the authors noticed that the revision seems to differ from the damage entity. The rare cases of metallosis after an UKA are generally treated through a revision with TKA[5-15]. In this article, we review the literature and introduce a case of 77 years old man presenting an UKA metallosis treated with debridement and UKA tibial metalback revision.

CASE PRESENTATION

Chief complaints

This article reports the case of a 77 years old patient with a metallosis after a UKA.

History of present illness

13-mo before, the patient perceived a "snap", that was initially conservatively treated, considering the complete and painless range of motion documented during outpatient evaluation.

History of past illness

Sixteen months prior to the metallosis diagnosis, the patient underwent to a medial UKA for unicompartimental knee osteoarthritis.

Personal and family history

The patient had no other relevant co-morbidities.

Physical examination

In the three months after the "snap," the patient started to report a constant worsening of knee pain and a substantial reduction of joint function [oxford knee score (OKS) of 27/48].

Laboratory examinations

Baseline blood ion levels were in line with a diagnosis of metallosis (Chrome 1.26 μg/L, Cobalt 3.94 μg/L).

Imaging examinations

The imaging performed at that time confirmed tibial implant loosening (Figure 1) and revision surgery was necessary after excluding infection[16-18].

Multidisciplinary expert consultation

Prior to treat the patient, the research team decided to evaluate all the possible procedures. Therefore, a literature research was conducted through PubMed by two independent reviewers (Braile A and Conza G) using the following terms in their various combinations "Unicompartmental knee arthroplasty," "metallosis," "liner dislocation", "fixed-bearing", "mobile-bearing". Studies compatible with our criteria were included and controversies between the two reviewers were analyzed by a third author for the inclusion decision (Salini V).

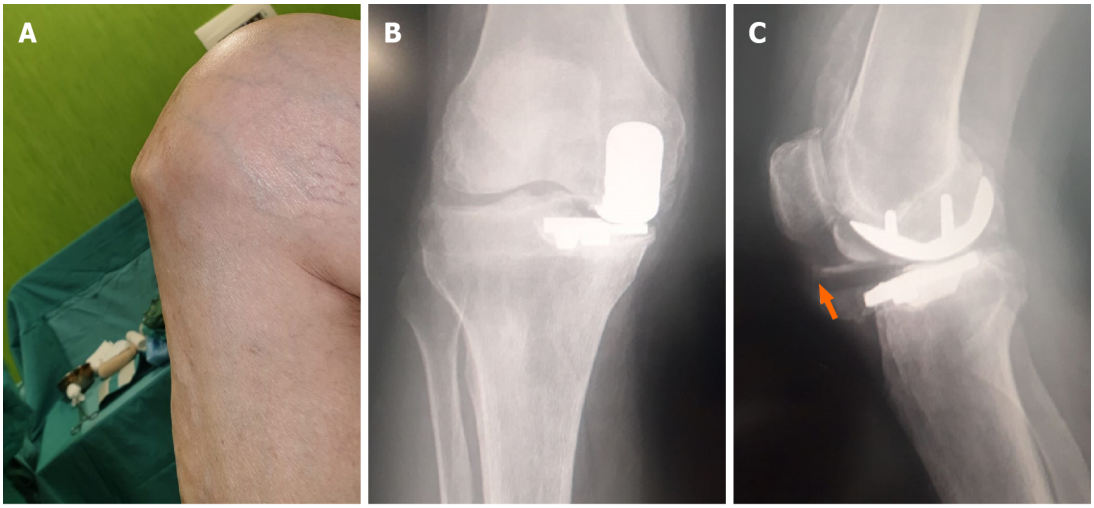

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Figure 1 Patient's preoperative evaluation. A: Clinics; B: Radiographs; C: Liner dislocation is indicated with white arrow.

The literature search was conducted only in PubMed given that 90% of high-quality studies can be retrieved from this database, as reported by Rollin *et al*[19]. Therefore, to summarize the knowledge around a specific topic, PubMed research should be considered cost-effective as practitioners are able to easily retrieve most of the literature by using it[19, 20]. All articles on metallosis after UKA in English, Spanish and Italian languages were included and analyzed in the present review. Articles with incomplete follow-up were excluded. The references cited in the included articles were also reviewed to identify further relevant studies. Data from each retrieved study were collected using a pre-arranged form. Out of 45 records identified, 20 presented criteria for further review. Eleven articles were then excluded after abstract review because did not meet the inclusion criteria. One further article was included after reviewing references cited in the included articles. Therefore, 10 articles, including 11 patients were retrieved and analyzed in the present study (Figure 2).

Patient age averaged 66.4 years (54-76 years), metallosis occurred at a mean time of 42.58 mo from the UKA. Out of 11 patients, 9 (81.8%) were treated through revision TKA. Two cases necessitated a second revision TKA at a mean of 39 mo. The functional outcome improved in all eleven cases (Table 1).

FINAL DIAGNOSIS

Intraoperatively, signs of soft tissue metallosis were evident (Figure 3). Following soft-tissue debridement and specimen collection, a component stability test confirmed isolated loosening of the tibial implant. Surgical specimen and baseline blood ion levels confirmed metallosis (Chrome 1.26 μg/L, Cobalt 3.94 μg/L).

TREATMENT

The mobilized tibial component was revised using a larger Genus UNI Alderortho implant (Cormano, Italy).

OUTCOME AND FOLLOW-UP

We assessed the patient functional status through OKS and blood ion levels as previously recommended[21,22]. The patient presented a normal postoperative course. Complete range of motion, OKS score improvement (40/48), and good knee alignment were reported at 18 mo (Figure 4), while normalization of Ion blood levels (Chrome 0.95 μg/L, Cobalt 1.06 μg/L) were documented at 30 d after the uni-on-uni revision (Table 2).

DISCUSSION

Although UKA is an effective bone-preserving surgical option for unicompartmental symptomatic knee osteoarthritis in young and middle-aged patients[23], several complications may arise after its implantation. Due to the increasing number of arthroplasties performed yearly, optimizing the complication management is necessary.

In our case, we attributed metallosis and implant failure due to the progressive subclinical spinout of the polyethylene liner in an undersized tibial component which led to a posterior overload on the tibial implant. The surgeons performed

Table 1 Litterature review

Article info					Studied population									Outcomes					
N.	Ref.	Year	Journal	Type	Population (n.)	Sex	Age (yr)	Implant type	Months elapsed between implantation and bearing dislocation	Metal ions (Cr/Cb)	Type of precedure	Function pre-op	Knee ROM pre-op	Metal ions (Cr/Cb) last follow-up	Function last follow-up	Knee ROM last follow-up	General complications	Infection	Fracture	Implant loosening (yes /months)
1	Sanchis-Alfonso *et al*[5]	2007	*KSSTA*	Case report	1	M	54	Fixed bearing		NA	Revision with TKA			NA						
2	Apostolopoulos *et al*[6]	2014	*J Long Term Eff Med Implants*	Case report	1	M	67	Mobile bearing	54	NA				NA			None	No	No	Yes /54
3	Vecchini *et al* [10]	2019	*Acta Biomed*	Case report	1	M	71	NA		NA	Revision with TKA		10-110	NA		0-130	None	No	No	
4	Greco *et al*[11]	2018	*The knee*	Case report	1	M	72	Fixed bearing		NA	Revision with TKA			NA			None	No	No	
5	Rajgopal *et al* [13]	2018	*Arthroplast today*	Case report	1	M	58	NA	24	NA	Revision with TKA	KSS 48 OKS 19 UCLA 3	0-100	NA	KSS 82 OKS 40 UCLA 7		None	No	No	Yes /24
6	Vajapey *et al*[8]	2021	*Arthroplasty*	Case series	2	F	76	NA	60	NA	Revision with TKA		30-120	NA			None	No	No	
7	Kiran *et al*[14]	2021	*JBJS Case connector*	Case report	1	M	61	Fixed bearing	60	NA	Revision with TKA		NA	NA	OKS 39		None	None	None	
8	Foran *et al*[9]	2013	*Clin Orthop Relat Res*	Case series	1	NA	NA	NA	56	NA	Revision with TKA			NA						
9	Luyet *et al*[12]	2015	*Acta Ortop. Belg.*	Case report	1	F	67	NA	1,5	NA	Revision with UKA	ksk 59 KSF 60	0-90	NA	Ksk 87 KSF 90	0-110		No	No	
10	Pescador *et al* [15]	2016	*Reumatol Clin.*	Case report	1	F	72	NA		NA	Revision with TKA			NA						
TOT.					11	6 M /4 F	Mean: 66, 4	3 Fixed /1 Mobile	Mean: 42, 58		9 TKA /1 UKA									

NA: Not available; TKA: Total knee arthroplasty; UKA: Unicompartmental knee artrhoplasthy; KSS: Knee society score; UCLA: UCLA activity scale; OKS: Oxford knee score; KSF: Knee society function score.

Table 2 Illustrating oxford knee score and blood ion levels before and after revision surgery

	Pre-revision	Last follow-up
OKS	27	40
Chrome (μg/L)	126	106
Cobalt (μg/L)	334	95

OKS: Oxford knee score.

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Figure 2 Summary of article inclusion process.

UKA revision with a new UKA larger tibial implant against general recommendations because no tibial slope or coronal malalignment were present[24-27].

Very few cases of UKA revision with a new UKA implant were described in the available literature. Luyet *et al*[12] in a case of anterior dislocation of the polyethylene liner at 6 wk, presenting as a painful and swollen knee[13] furtherly complicated by metallosis decided to treat it through a uni-on-uni revision. Following the surgery, the patient presented good clinical and radiological outcomes in a 2 year follow-up[12]. Good clinical outcomes were reported after a Uni-on-uni revision also in an another a recent review about metallosis after knee replacement[4]. Epinette *et al*[27] in a retrospective study of 36 UKA-to-UKA revision surgery described this treatment as a reliable option, with lower morbidity and better functional outcomes compared with UKA-to-TKA revision. The authors suggested to reserve in patients with limited bone defects and no extension of the lesions[27].

Our review is limited by several factors including low patient number, the absence of a statistical analysis related to the nature of the review, and lack of literature on UKA metallosis. However, to the best of our knowledge, this is the first study reporting bloodstream ion changes while confirming clinical improvement following uni-on-uni revision in case of UKA metallosis. However, we believe that further analysis is necessary to confirm successful uni-on-uni revisions in case of metallosis.

CONCLUSION

In conclusion, we suggest that aseptic UKA metallosis without critical signs of malpositioning, soft tissue impairment or bone loss could be treated with surgical debridement and unicompartimental knee revision arthroplasty. This kind of approach could lead to a significant improvement of functional outcomes, and blood ion levels.

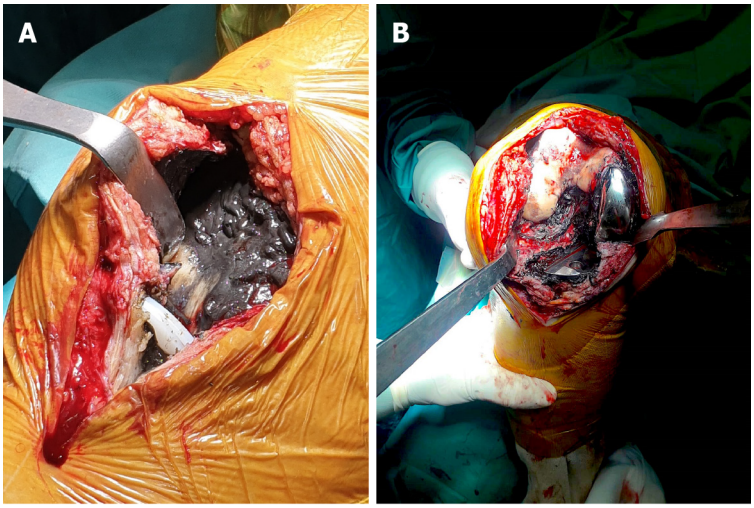

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Figure 3 Intraoperative photographs documenting peri-prosthetic soft tissue metallosis. A: Note the luxated bearing; B: Note the metal back debris.

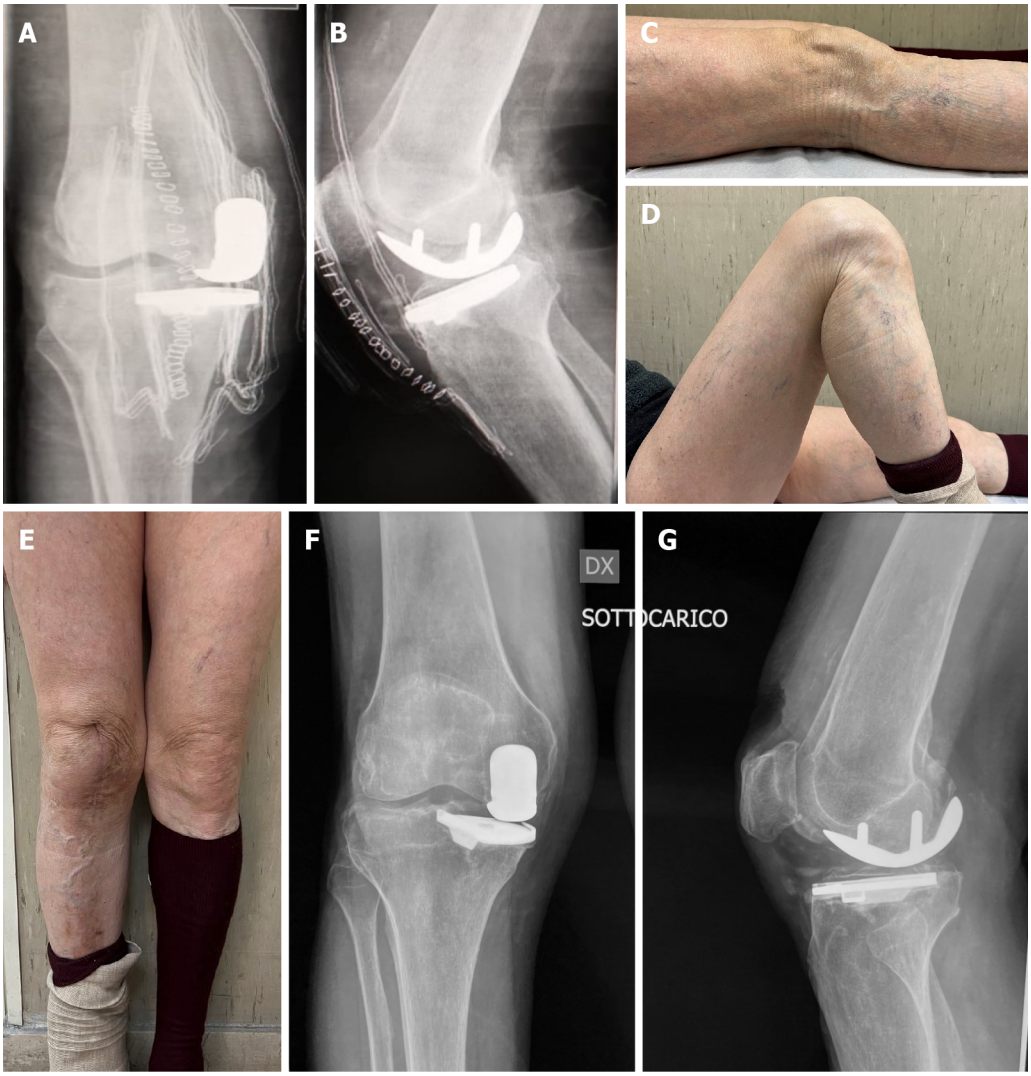

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Figure 4 Postoperative history. A and B: Postoperative X-rays; C-E: Clinical evaluation documenting range of motion at final follow-up; F and G: Radiographies documenting implant alignment at final follow-up.

FOOTNOTES

Author contributions: Braile A, Conza G and Salini V performed material preparation and data collection; Placella G, Toro G, Salini V performed data analysis and interpretation; Abu Mukh A and De Cicco A written the first draft of the manuscript; Placella G and Toro G revised the paper and wrote the final version of the manuscript; Toro G and Salini V supervised the entire study; all authors commented on previous versions of the manuscript; all authors read and approved the final manuscript; all authors contributed to the study conception and design.

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REFERENCES

1 **Toro G**, De Cicco A, Braile A, Landi G, Schiavone Panni A. New insights on metal allergy in total joint arthroplasty. *J Biol Regul Homeost Agents* 2020; **34**: 125-130. IORS Special Issue on Orthopedics [PMID: 33739017]
2 **Pesce V**, Maccagnano G, Vicenti G, Notarnicola A, Lovreglio P, Soleo L, Pantalone A, Salini V, Moretti B. First case report of vanadium metallosis after ceramic-on-ceramic total hip arthroplasty. *J Biol Regul Homeost Agents* 2013; **27**: 1063-1068 [PMID: 24382188]
3 **Goderecci R**, Fidanza A, Necozione S, Francione V, Indelli PF, Calvisi V. Ultrasound-based decision making following metal-on-metal hip arthroplasty. *J Clin Orthop Trauma* 2020; **11**: 79-84 [PMID: 32001990 DOI: 10.1016/j.jcot.2019.04.009]
4 **Sahan I**, Anagnostakos K. Metallosis after knee replacement: a review. *Arch Orthop Trauma Surg* 2020; **140**: 1791-1808 [PMID: 32715399 DOI: 10.1007/s00402-020-03560-x]
5 **Sanchis-Alfonso V**. Severe metallosis after unicompartmental knee arthroplasty. *Knee Surg Sports Traumatol Arthrosc* 2007; **15**: 361-364 [PMID: 17028866 DOI: 10.1007/s00167-006-0207-6]
6 **Apostolopoulos AP**, Katsougrakis I, Fanous R, Harrison A, Saavedra E. Severe metallosis following polyethylene dislocation in a mobile-bearing medial unicompartmental knee replacement. *J Long Term Eff Med Implants* 2014; **24**: 147-150 [PMID: 25272213 DOI: 10.1615/jlongtermeffmedimplants.2014010563]
7 **Fujii T**, Matsui Y, Noboru M, Inagaki Y, Kadoya Y, Tanaka Y. Meniscal Bearing Dislocation of Unicompartmental Knee Arthroplasty with Faint Symptom. *Case Rep Orthop* 2015; **2015**: 217842 [PMID: 26137336 DOI: 10.1155/2015/217842]
8 **Vajapey SP**, Alvarez PM, Chonko D. Bearing failure in a mobile bearing unicompartmental knee arthroplasty: an uncommon presentation of an implant-specific complication. *Arthroplasty* 2021; **3**: 16 [PMID: 35236477 DOI: 10.1186/s42836-021-00073-9]
9 **Foran JR**, Brown NM, Della Valle CJ, Berger RA, Galante JO. Long-term survivorship and failure modes of unicompartmental knee arthroplasty. *Clin Orthop Relat Res* 2013; **471**: 102-108 [PMID: 22895691 DOI: 10.1007/s11999-012-2517-y]
10 **Vecchini E**, Ditta A, Gelmini M, Maluta T, Valentini R, Ricci M, Magnan B. Rupture of the femoral component and severe metallosis of the knee 10 years after unicompartmental knee arthroplasty (UKA): a case report. *Acta Biomed* 2019; **90**: 198-202 [PMID: 30715025 DOI: 10.23750/abm.v90i1-S.8082]
11 **Greco N**, Berend K. Polyethylene liner dislocation of fixed-bearing medial oxinium unicompartmental arthroplasty with severe metallosis. *Knee* 2018; **25**: 341-345 [PMID: 29525546 DOI: 10.1016/j.knee.2018.01.004]
12 **Luyet A**, Fischer JF, Jolles BM, Lunebourg A. Unexpected wear of an unicompartimental knee arthroplasty in oxidized zirconium. *Acta Orthop Belg* 2015; **81**: 790-795 [PMID: 26790806]
13 **Rajgopal A**, Panda I, Tyagi VC. Early failure with massive metallosis and posteromedial wear following atraumatic anterior cruciate ligament rupture after medial unicompartmental knee arthroplasty. *Arthroplast Today* 2018; **4**: 15-19 [PMID: 29560389 DOI: 10.1016/j.artd.2017.09.007]
14 **Kiran M**, Kho J, Hepburn E, Chakraverty J, Davies H. Chronic Wear-Induced Bearing Dislocation in a Fixed-Bearing Unicompartmental Knee Arthroplasty: A Case Report. *JBJS Case Connect* 2021; **11** [PMID: 34491688 DOI: 10.2106/JBJS.CC.21.00364]
15 **Pescador D**, Calero-Paniagua I, Sánchez-González MD, Montilla C. Metallosis as a cause of pain and inflammation in a patient with a knee replacement: A case description. *Reumatol Clin* 2016; **12**: 112-113 [PMID: 26099454 DOI: 10.1016/j.reuma.2015.04.005]
16 **Toro G**, Braile A, Zappulo E, Panni AS, Indelli PF. Does D-Dimer really help in the diagnosis of chronic periprosthetic joint infections (PJI)? A case-control study. *Journal of Arthroscopy and Joint Surgery* 2020; **7**: 189-193 [DOI: 10.1016/j.jajs.2020.08.006]

17 **Panni AS**, Ascione F, Rossini M, Braile A, Corona K, Vasso M, Hirschmann MT. Tibial internal rotation negatively affects clinical outcomes in total knee arthroplasty: a systematic review. *Knee Surg Sports Traumatol Arthrosc* 2018; **26**: 1636-1644 [PMID: 29247357 DOI: 10.1007/s00167-017-4823-0]

18 **Vasso M**, Braile A, Ascione F, Toro G, De Cicco A, Lepore F, Schiavone Panni A. Two-stage reimplantation in periprosthetic knee infection. *Eur Rev Med Pharmacol Sci* 2019; **23**: 51-58 [PMID: 30977871 DOI: 10.26355/eurrev_201904_17474]

19 **Rollin L**, Darmoni S, Caillard JF, Gehanno JF. Searching for high-quality articles about intervention studies in occupational health--what is really missed when using only the Medline database? *Scand J Work Environ Health* 2010; **36**: 484-487 [PMID: 20740265 DOI: 10.5271/sjweh.3082]

20 **Pillastrini P**, Vanti C, Curti S, Mattioli S, Ferrari S, Violante FS, Guccione A. Using PubMed search strings for efficient retrieval of manual therapy research literature. *J Manipulative Physiol Ther* 2015; **38**: 159-166 [PMID: 25499192 DOI: 10.1016/j.jmpt.2014.11.005]

21 **Swiatkowska I**, Martin N, Hart AJ. Blood titanium level as a biomarker of orthopaedic implant wear. *J Trace Elem Med Biol* 2019; **53**: 120-128 [PMID: 30910194 DOI: 10.1016/j.jtemb.2019.02.013]

22 Cobalt Blood Level. Science Direct Topics. Available from: https://www.sciencedirect.com/topics/nursing-and-health-professions/cobalt-blood-level

23 **Johal S**, Nakano N, Baxter M, Hujazi I, Pandit H, Khanduja V. Unicompartmental Knee Arthroplasty: The Past, Current Controversies, and Future Perspectives. *J Knee Surg* 2018; **31**: 992-998 [PMID: 29514367 DOI: 10.1055/s-0038-1625961]

24 **Hernigou P**, Deschamps G. Posterior slope of the tibial implant and the outcome of unicompartmental knee arthroplasty. *J Bone Joint Surg Am* 2004; **86**: 506-511 [PMID: 14996875 DOI: 10.2106/00004623-200403000-00007]

25 **Crawford DA**, Berend KR, Lombardi AV. Management of the Failed Medial Unicompartmental Knee Arthroplasty. *J Am Acad Orthop Surg* 2018; **26**: e426-e433 [PMID: 30113345 DOI: 10.5435/JAAOS-D-17-00107]

26 **Lombardi AV Jr**, Kolich MT, Berend KR, Morris MJ, Crawford DA, Adams JB. Revision of Unicompartmental Knee Arthroplasty to Total Knee Arthroplasty: Is It as Good as a Primary Result? *J Arthroplasty* 2018; **33**: S105-S108 [PMID: 29691172 DOI: 10.1016/j.arth.2018.03.023]

27 **Epinette JA**, Leyder M, Saragaglia D, Pasquier G, Deschamps G; Société Française de la Hanche et du Genou. Is unicompartmental-to-unicompartmental revision knee arthroplasty a reliable option? Case-control study. *Orthop Traumatol Surg Res* 2014; **100**: 141-145 [PMID: 24373806 DOI: 10.1016/j.otsr.2013.10.013]

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