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OPINION REVIEW

Revisiting Pauwels' classification of femoral neck fractures

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Abstract

Pauwels' femoral neck fracture classification is based on the biomechanical principle that shear stress and varus force increase along more vertically oriented fractures, resulting in higher risk of fracture displacement and ultimately nonunion. This principle continues to guide construct selection for femoral neck fracture internal fixation and is the foundation for treating non-union with valgus osteotomy. However, with poor inter- and intra-rater reliability, dated treatment recommendations, and unreliable prognostic value, the Pauwels classification cannot be directly applied in its entirety to the management of femoral neck fractures in modern practice.

Key Words: Pauwels; Fracture; Femoral neck; Internal fixation; Arthroplasty

Core Tip: Pauwels' classification of femoral neck fractures continues to guide construct selection for femoral neck fracture internal fixation and is the foundation for treating non-union with valgus osteotomy. However, with poor inter- and intra-rater reliability, dated treatment recommendations, and unreliable prognostic value, the Pauwels classification cannot be directly applied in its entirety to the management of femoral neck fractures in modern practice.

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INTRODUCTION

Femoral neck fractures are common, with an overall incidence of 146 per 100000 adults in 2013[1]. The increasing incidence with age is demonstrated by the occurrence of more than 800000 femoral neck fractures in patients older than 65 in the United States alone from 2003 to 2013[1]. The vast majority of femoral neck fractures are treated operatively, so there is morbidity and mortality associated with both the injury and its treatment[2]. Femoral neck fractures are costly not only to patients, but also the healthcare system at an estimated 17 to 20 billion dollars per year[3,4].

The first femoral neck fracture classification was described by Cooper[5] in 1823, who categorized these fractures by location into extracapsular or intracapsular variants. Later, in 1935, Pauwels[6] published his femoral neck fracture classification based on biomechanical principles. Fractures were categorized by orientation of the fracture line, across which compressive and shearing forces vary. Errors in interpretation of Pauwels' original manuscript, written in German, have caused confusion surrounding the fracture types in his classification system[7]. Meticulous analysis by several groups, as well as an English-language supplement published by Pauwels in 1976, provided subsequent clarification[7-9].

Pauwels devised his femoral neck fracture classification to: (1) Predict propensity for healing based on forces acting to displace the fracture; and (2) Identify the optimal treatment modality that neutralizes these forces. To achieve the above aims, Pauwels classified femoral neck fracture patterns as observed on anteroposterior (AP) plain films. The Pauwels classification predates modern hip fracture fixation devices and arthroplasty, which are understandably absent from the treatments recommended in the original manuscript. Both of these factors are barriers to the Pauwels classification fulfilling its purpose in current practice, as further discussed below.

CLASSIFICATION

Pauwels classified femoral neck fractures according to the degree of inclination of the fracture line measured from the horizontal on an AP radiograph (Table 1)[6-8]. The three types of femoral neck fractures according to Pauwels are: Type I, with fracture line inclination from 0° to 30°; Type II, with inclination of 30° to 50°; and Type III, with inclination of 50° and greater. Compressive forces predominate across horizontally oriented fractures with a low degree of inclination. Shear stresses and varus forces increase along more vertically oriented fractures with a high degree of inclination. As the distance between the fracture line and the center of the femoral head increases, so do these forces across the fracture.

The treatment and prognosis of femoral neck fractures according to Pauwels is determined by the biomechanical favorability at the fracture site for healing[6-8]. With low fracture line inclination there is compression at the fracture site, which promotes union. For this reason, Pauwels believed fractures with inclination angles less than 30° could be treated nonoperatively. Increasing fracture line inclination, accompanied by greater shear stress and varus force, results in higher risk of fracture displacement and ultimately nonunion. As a result, Pauwels recommended internal fixation for fractures with inclination angles of 30° to 50° and valgus osteotomy for fractures with inclination angles greater than 50°. These measures counteract and reverse, respectively, forces across steeply oriented fractures.

VALIDITY

Existing literature questions the validity of Pauwels' classification with regard to the description, treatment, and prognosis of femoral neck fractures. Several studies have found inter- and intra-observer reliability of the Pauwels classification to be worse than that of both AO and Garden classifications[10-12].

Nearly all femoral neck fractures, except for stress fractures involving the compression side, are currently treated operatively to allow early mobilization, improve healing, and prevent displacement[2]. Internal fixation or arthroplasty are the mainstays of treatment depending on patient age and physical demands[2,13]. However, Pauwels advised nonoperative management of Type I fractures in his classification scheme. Type III fractures are rarely treated with an acute valgus osteotomy as recommended by Pauwels. This procedure is now reserved for femoral neck fracture nonunion[14].

Table 1 Pauwels' classification of femoral neck fractures

	Inclination of fracture line from horizontal	Predominant force at fracture site	Treatment (original classification)	Treatment (modern)	Risk of nonunion
Type I	0-30	Compressive force	Nonoperative	Internal fixation *vs* arthroplasty	Low
Type II	30-50	Shearing stress	Internal fixation	Internal fixation *vs* arthroplasty	Medium
Type III	> 50	Significant shearing stress and varus force	Valgus osteotomy	Internal fixation *vs* arthroplasty	High

Pauwels believed that risk of displacement, and thus non-union, increased with femoral neck fracture line inclination. However, Parker and Dynan[15] found no relationship between Pauwels fracture type and rate of non-union. Calandruccio and Anderson[16] did not observe a higher rate of avascular necrosis with increasing Pauwels inclination angle. These findings are contrary to Pauwels' notion of more unfavorable biomechanics and healing potential at fracture sites with steeper inclination angles.

The failure to observe differences in union rate and avascular necrosis across Pauwels fracture types may be due to surgeon customization of fixation construct according to femoral neck fracture line inclination. In achieving desired union rates by appropriately counteracting fracture site shear stresses and varus forces, Pauwels' principles are validated. Multiple studies have highlighted the need for more robust fixation constructs to address the unfavorable biomechanics of Pauwels Type III fractures[13,17-20].

DISCUSSION

There are several factors that limit the applicability of the Pauwels classification. First, it may be difficult to accurately determine femoral neck fracture line inclination on immediate post-injury radiographs in which the lower extremity is often rotated, abducted, or adducted. In addition, the use of lateral radiographs for further fracture pattern evaluation is not described in Pauwels' classification. It has been suggested that inclination angle be measured on intraoperative post-reduction fluoroscopic imaging, but this diminishes the opportunity to utilize Pauwels' classification for preoperative planning[11]. Nonetheless, there are ways to consistently apply Pauwels' principles to fracture management. Femoral neck fracture line inclination can be determined using preoperative computed tomography images, ubiquitous in the workup of high energy trauma patients though not a part of Pauwels' original classification scheme.

Per Pauwels, a reference horizontal must be reliably established to measure fracture inclination but can only be arbitrarily assigned on potentially suboptimal radiographs. For this reason, Wang *et al*[21] proposed using the line perpendicular to the anatomic axis of the femur as an objective reference horizontal when measuring Pauwels' inclination angle.

Advances in fracture fixation and arthroplasty following publication of Pauwels' classification have rendered its treatment recommendations less applicable in certain circumstances. Pauwels suggested Type I fractures be treated nonoperatively, but it has since been established that nonoperative treatment of femoral neck fractures is associated with an unacceptably high mortality rate[22]. Valgus osteotomy is currently reserved for some femoral neck fracture non-unions, not Pauwels Type III fractures as originally described[13,14]. Pauwels' classification predates the advent of modern arthroplasty, so his treatment rubric does not address this modality. In older patients with displaced femoral neck fractures, fracture line inclination is less relevant as all such fractures are treated with arthroplasty[2,23]. However, the presence of a Pauwels Type III fracture in an older patient may have implications on femoral stem selection, specifically the need for a calcar replacing, fully porous coated, or distally fixed stem, if there is involvement of the lesser trochanter.

CONCLUSION

The Pauwels classification of femoral neck fractures is novel in its biomechanical basis. As a result, Pauwels contributed significantly to the evolution of our understanding and treatment of femoral neck fractures. The principles he described continue to guide construct selection for femoral neck fracture internal fixation and are the foundation for treating femoral neck fracture non-union with valgus osteotomy. However, with poor inter- and intra-rater reliability, dated treatment recommendations, and unreliable prognostic value, the Pauwels classification cannot be directly applied in its entirety to the management of femoral neck fractures in modern practice.

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ORIGINAL ARTICLE

Case Control Study

Paraspinal strength and electromyographic fatigue in patients with sub-acute back pain and controls: Reliability, clinical applicability and between-group differences

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Abstract

BACKGROUND

Paraspinal muscle strength and fatigue are considered important in low back pain (LBP) prevention and rehabilitation. High reliability of paraspinal strength and electromyographic (EMG)-fatigue parameters has not been universally reported. Moreover, the discriminative validity of these parameters requires further exploration, under the threat of potentially poor reliability of the methods examined.

AIM

To investigate the reliability and discriminative validity of paraspinal strength and EMG-related fatigue in subjects with recurrent LBP and healthy participants.

METHODS

Test-retest measurements were performed in 26 healthy and 66 LBP volunteers, for reliability. Paraspinal isometric maximal and mean strength were determined with a maximum voluntary isometric contraction (MVIC) protocol, performed in a custom-made device. For the fatigue test, participants performed a 60% MIVC level continuous isometric contraction of the paraspinals, in conjunction with EMG analysis from 4 muscle sites of the lumbar spine. Initial median frequency (IMF), the median frequency slope (MFslope), as well as the root mean square (RMS) slope EMG parameters were used as fatigue measures. Data were analysed with repeated measures ANOVA for test-retest differences. For reliability, the intraclass correlation coefficient ($ICC_{3,1}$), standard error of the measurement (SEM) and the smallest detectable difference (SDD) were reported. Group-related

differences for fatigue measures were analysed with a Multivariate Analysis of Covariance, with age, weight and strength as covariates.

RESULTS

Isometric strength presented statistically significant between-day differences ($P < 0.01$), however these did not exceed 10% (healthy: 7.2%/LBP-patients: 9.7%) and ICC reliability values were excellent, yet test-retest error was increased for the patient group (healthy: $ICC_{3,1}$: 0.92-0.96, SEM: 5.72-5.94 Hz, SDD: 18.51%-18.57%/LBP-patients: $ICC_{3,1}$: 0.91-0.96, SEM: 6.49-6.96, SDD: 30.75%-31.61%). For the frequency data, IMF reliability was excellent (healthy: $ICC_{3,1}$: 0.91-0.94, SEM: 3.45-7.27 Hz, SDD: 9.56%-20.14%/patients: $ICC_{3,1}$: 0.90-0.94, SEM: 6.41-7.59 Hz, SDD: 17.75%-21.02%) and of MF raw and normalised slopes was good (healthy: $ICC_{3,1}$: 0.78-0.82, SEM: 4.93-6.02 Hz, SDD: 13.66-16.67%/LBP-patients: $ICC_{3,1}$: 0.83-0.85, SEM: 6.75-7.47 Hz, SDD: 18.69%-20.69%). However, the reliability for RMS data presented unacceptably high SDD values and were not considered further. For discriminative validity, less MVIC and less steep MFslopes were registered for the patient group ($P < 0.01$).

CONCLUSION

Reliability and discriminative ability of paraspinal strength and EMG-related frequency parameters were demonstrated in healthy participants and patients with LBP.

Key Words: Low back pain; Power spectral analysis; Surface electromyography; Multifidus; Reliability

Core Tip: Patients with low back pain (LBP) frequently exhibit muscle strength and fatigue impairments. Sixty-six patients with sub-acute recurrent LBP, able to perform a short duration isometric maximal strength evaluation, followed by a brief submaximal endurance performance test of the paraspinals, demonstrated strength deficits, as well as electromyographic (EMG)-fatigue differences in relation to a group of healthy participants. Test-retest reliability examining the level of accuracy of strength and EMG-fatigue measures, and the discriminative validity of frequency data were also reported. There were no adverse effects of the methodology followed. Paraspinal muscle re-training to improve the identified deficits should be emphasised.

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INTRODUCTION

Low back pain (LBP) is drawing a lot of research effort worldwide, due to the disability and work loss associated with this health care condition[1]. For approximately 80% of LBP cases labeled as non-specific LBP a precise diagnosis cannot be established and only 15% of cases can be attributed to a specific pathology[1]. The "non-specific" category is the one that presents the greatest challenge, as it forms the largest group but also as there seems to be no apparent etiologic link between pain and structure[2].

Due to the episodic nature of LBP, the condition has been labelled as recurrent, if present on less than half the days (< 6 mo) in a 12-month period, occurring in multiple episodes over the year[3]. Around 2/3 of people who ever had back pain will have some recurrence each year[4]. The causes of recurrence are not clear and may vary for different populations, however both biomechanical and psychosocial factors have been proposed as contributors to LBP disability[1,5], with alterations in muscle structure

prior to study inclusion.

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and function being more evident in chronic LBP (CLBP) than in recurrent LBP (RLBP) [6,7].

The trunk muscle activity functional alterations already evident in people with RLBP even during periods of remission of symptoms compared to healthy controls, have been recently summarized as greater co-contraction, different redistribution of muscle activity, and delayed postural control of deeper trunk muscles[8]. Redistribution of the pattern of activity between different parts of the paraspinal muscles, synergistically contracting in response to the functional demands of spinal movement and stability, has also been described to vary between the upper and lower spinal segments in CLBP and healthy controls, rendering the lower spinal segments of patients with CLBP relatively unprotected upon sustained contractions, registering in parallel deficits in timed endurance[9]. Additionally, patients with RLBP compared to those with CLBP demonstrated a generalised lack of activation ability of the paraspinals while performing a low-load lumbar extension task, corresponding to a lower metabolic activity at both the erector spinae and multifidus and combined with less perceived exertion following completion of the task, possibly due to the lower activation levels of those muscles[6].

Considering the anti-gravity functional role of the paraspinals muscles, good paraspinal muscle endurance (fatigue-resistance), assessed with an isometric time to complete exhaustion test was found to prevent first-time occurrence of back pain in men only[10] and in both men and women, however only for subjects in the lowest performance tertile[11]. Measuring paraspinal fatigue to complete exhaustion possesses inherent limitations, as measurements can be affected by patients' psychology[12,13], depending on their willingness to perform a test that is physically demanding and potentially having a pain-provocation effect during its execution and afterwards.

Given the significant role of paraspinal muscle fatigue in LBP progression[14,15], alternative fatigue assessment techniques were required, to overcome validity issues in the determination of paraspinal endurance with the classic Sorensen test performed to complete exhaustion, especially in pain populations[16]. Significant metabolic processes within the muscle, associated with a decreasing pattern of motor unit firing frequencies can be detected with electromyographic (EMG) monitoring from the beginning of a contraction, much earlier than the time of mechanical inability to sustain the contraction, with accurate methods required to assess the pattern of these processes[17]. Therefore, brief paraspinal muscle testing, performed at set percentages of a maximum voluntary isometric contraction (MVIC), estimating the fatigue characteristics of contracting muscles from EMG-related parameters have been developed [18]. Indeed, EMG-fatigue data were more reliable under a task performed at a set percentage of an MVIC than a modified Sorensen test of 1 min duration, when directly compared in healthy participants[19].

Besides the brevity of the contractions required and the non-invasive nature of the surface EMG methods involved, it is of high importance to ascertain the reliability and validity level of the EMG-related spectrum and amplitude parameters of the paraspinal muscles, therefore providing an accessible monitoring method for clinicians [17]. However, the random nature of the EMG signal in general, as well as the EMG activity redistribution differences between healthy controls and patients with LBP[9], render these measurement properties difficult to achieve[20-22]. Additionally, the safety of paraspinal muscle maximal strength assessment in healthy and patient populations is important, due to the intense contractions involved. Due to the different physiological and structural changes identified between patients with recurrent and CLBP[6], between patients and healthy controls[9,23] and a possible role of paraspinal EMG-determined fatigue in the prediction of LBP development[15], the measurement of EMG-fatigue parameters of these muscles in different LBP patient subgroups and subjects without LBP requires systematic study.

The aims of this study were to investigate the reliability and discriminative validity of paraspinal strength and EMG-related endurance spectrum and amplitude parameters in subjects with RLBP at the sub-acute stage of symptoms in relation to healthy participants.

MATERIALS AND METHODS

Subjects

Adult subjects (> 18 years), without LBP (n = 26) and patients with LBP (n = 66), participated in this study, between January-September 2000. Subjects without LBP

were either students or University employees. Patients were recruited from the orthopaedic clinic of a local hospital and several local general practices. Patients were eligible for the study if they had a history of RLBP (repeated episodes of pain in past year collectively lasting for less than 6 mo)[24] of a nonspecific nature, defined as back pain complaints occurring without identifiable specific anatomical or neurophysiological causative factors[2]. To establish this, all patients included had a prior clinical examination by their physician, including a radiograph or a magnetic resonance imaging scan. Patients with previous spinal surgery, "red flags" (*i.e.*, serious spinal pathology or nerve root pain signs), signs and symptoms of instability (radiological diagnosis of spondylolysis or spondylolisthesis corresponding to a symptomatic spinal level; "catching," "locking," "giving way," or "a feeling of instability" in one or multiple directions of spinal movement)[25] were excluded. It was ensured that patients' symptoms were at a subacute stage, to avoid pain interference with testing. The anthropometric data of patients and healthy participants are presented in Table 1. Additionally, patients had to be medically fit (no cardiovascular, neurological or musculoskeletal inflammatory conditions), no pregnancy for female participants and willing to participate in the experimental procedures and be able to travel independently to the hospital. All subjects were employed at the time of study and were not involved in any current workers' compensation or litigation procedures.

The local National Health Service (NHS) Trust and University Ethical Committees granted ethical approval for all experiments. All research assessments were conducted in a local research centre. All subjects gave informed consent prior to their participation. All rights of participants were protected at all times, according to the declaration of Helsinki.

Apparatus and procedures for paraspinal strength measurement

Muscle strength was assessed in a custom-made isomyometer designed and manufactured by the Medical Physics Department (St Mary's Hospital, Central Manchester Healthcare Trust-CMHT). Its design was based on a very similar type of myometer developed in the Boston Neuromuscular Research Centre, the "Back Analysis System"[18,26]. Subjects were put in a standing position in the myometer, with appropriate stabilisation of the lower limbs. Subjects had to pull maximally backwards performing an isometric contraction of their paraspinal muscles and force was registered on an S-type load cell (250-kg Tedea Huntleigh, United Kingdom), positioned directly in front of their chest. A special built-in calibration system of the back myometer was also employed, in order to regularly test the transducer's linear response between 0-200 kg, with known weights (Medical Physics Dept). An inextensible strap made of nylon linked the transducer to the subjects. The strap was securely fixed on the subjects' back around the T6-T7 level, through a chest harness (Figure 1). In order to be able to comfortably generate paraspinal muscle strength, the hip, knees and ankle joints were placed in mid-range functional positions. The force transducer was interfaced to a computer and by means of a graphical programming analysis system (LabVIEW 5.0™, National Instruments, Texas, United States), its output was online displayed on a flat-screen computer monitor placed at participants eye-level for visual feedback purposes.

Paraspinal muscle MVIC was determined in the upright position, in the following manner: three or more MVIC attempts were requested until the efforts were within 5-10% of each other. The best effort was taken as the MVC. Contraction duration was kept as short as possible (3-5 s), to minimise any reduced motivation or pain arising from prolonged contractions. Rest intervals between repeat MVICs were set at 60-s[27,28].

Apparatus and procedures for EMG

A four-channel EMG recorder (MP100 WSW, BIOPAC Systems), was used to collect EMG signals from 2 different back muscles bilaterally, the erector spinae (L2/3) and multifidus (L4/5). EMG signals were high-pass and low-pass filtered at 8 and 500 Hz respectively, amplified (× 10, CMRR: 110 dB min, SNR: 65 dB min) and analogue-to-digital converted at a sampling rate of 1024 Hz. An additional sharp 50 Hz notch filter was applied for DC noise removal. The waveforms collected were online analysed by a graphical programming analysis system (LabVIEW™ 5.0) in order to continuously derive the median frequency (MF) of the power density spectrum every second, using a Fast Fourier Transform algorithm. Also, the root mean square (RMS) was calculated every second. A linear regression line was fitted through the MF and RMS 60-s history, to obtain a measure of the rate of MF decrease (Figure 2) and RMS increase.

Table 1 Anthropometric measures (mean ± SD) of participants

	Age (yr)	Height (cm)	Body mass (kg)	BMI (kg/m^2)
Healthy				
Male (n = 13)	27.0 ± 6.8[a]	178.4 ± 5.5	78.9 ± 8.7	24.7 ± 2.3
Female (n = 13)	24.6 ± 5.3[b]	163.0 ± 8.0	56.8 ± 5.7[b]	21.5 ± 3.5[b]
Total (n = 26)	25.8 ± 6.1[b]	170.7 ± 10.4	67.8 ± 13.4[b]	23.1 ± 3.3[b]
Patients				
Male (n = 34)	35.7 ± 10.2	177.5 ± 6.4	81.1 ± 10.6	25.7 ± 2.6
Female (n = 32)	39.2 ± 10.9	166.2 ± 5.8	74.5 ± 13.6	26.9 ± 4.4
Total (n = 66)	37.4 ± 10.6	172.1 ± 8.4	77.9 ± 12.5	26.3 ± 3.6

Significantly different to patients' corresponding data:
[a]P = 0.01.
[b]P < 0.01.
BMI: Body mass index.

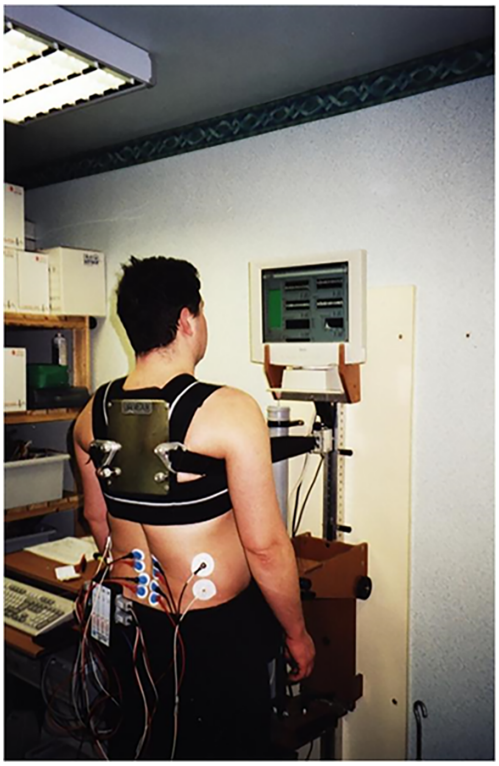

Figure 1 Performance of the 60-s isometric endurance test.

The bipolar electrode technique was utilised for the acquisition of the EMG signal. Appropriate skin preparation methods were used (light abrasion with fine sandpaper and wiping contact areas with cotton-wool soaked with surgical spirit) to reduce skin resistance to acceptable levels for recording, below 10 KOhms[19]. Four pairs of disposable pregelled surface electrodes (Ag/AgCl, Blue Sensor M-00-S, Medicotest, Ltd.) were applied in the direction of the muscle fibres, according to previous anatomic specifications[27,29]. As no significant differences have been identified between male and female subjects in the fibre orientation of both muscles[30], a uniform procedure was followed for electrode placement in both genders. The reference electrodes for each of the channels were placed on the skin surface, overlying an electrically unrelated tissue to the one the bipolar configuration was recording from [19]. Inter-electrode distance for the recording electrodes was set at 20 mm. The electrode location was reproduced in follow-up assessments by tracing their initial

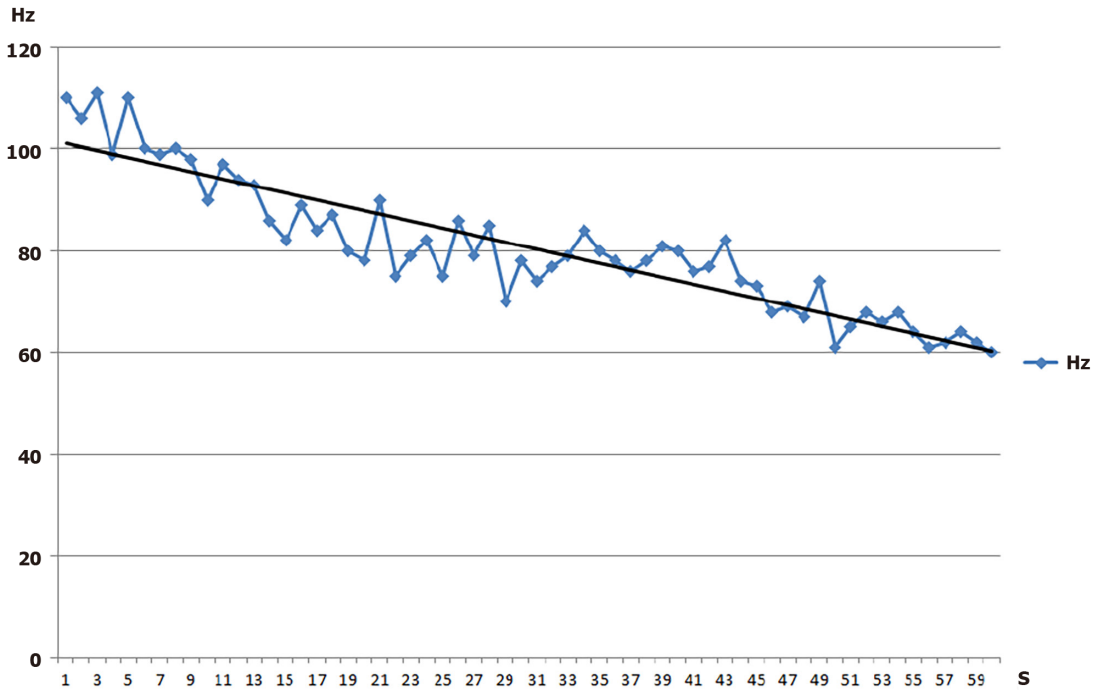

Figure 2 Schematic representation of the median frequency decrease with time. Hz: Hertz.

location onto a transparent A4 sheet, along with natural skin blemishes and distinctive marks, at the first assessment[19]. Skin impedance was checked right after the application of electrodes and was generally kept below 10 KOhms. In very few occasions appropriate skin impedance was not achieved and those electrodes had to be replaced and the skin preparation technique to be repeated.

Testing protocol and experimental design

The principal investigator conducted all experiments (test-retest reliability) in healthy participants and patients with LBP, to minimise any between-rater variance. Participants' paraspinal muscle strength and fatigue performance were assessed on two separate occasions, with a week's interval between measurements for normal subjects and a 3-5 d interval for patients. During the time interval between the 2 measurements, subjects were asked to maintain normal activities.

Muscle fatigue measurements followed the strength measurements on each of the 2 testing days. All subjects performed a 60% MVIC back muscle contraction in the isomyometer for 60 s, while EMG signal was acquired and online transformed to collect all EMG-fatigue related measurements for subsequent analysis.

Statistical analysis

Sample size was based on an a priori power calculation, estimating that at least 26 participants per group would be required to detect a 6.6%/min between-group difference in normalized MF slopes (MFslopes), at 80% power and a significance level of a = 0.05 (nQuery Advisor, v.3.0, Statistical Solutions, Saugus, MA, United States)[27].

The normality of distribution of all continuous variables was examined with the Kolmogorov-Smirnov test. Demographics were compared between-groups (independent samples *t*-test), to identify possible significant differences in factors known to affect the EMG-fatigue measures. Significant systematic between-sides differences were examined for the EMG-fatigue parameters (paired samples *t*-test).

For the reliability study, repeated measures ANOVA analysis was performed to detect any significant between-day systematic differences for each population separately. Test-retest reliability was established with 3 different measures, one of relative reliability, the intraclass correlation coefficient ($ICC_{3,1}$)[31] and two of absolute reliability, the standard error of measurement (SEM)[32,33] derived from the ANOVA error components and the smallest detectable difference (SDD)[33], to determine the magnitude of change that exceeds the threshold of measurement error at the 95% confidence level and is not to be attributed to test-retest error. The $ICC_{3,1}$ was chosen, as only one rater was involved in all measurements[31]. ICC values less than 0.50

indicate poor reliability, between 0.50 and 0.75 moderate, between 0.75 and 0.90 good and values greater than 0.90 excellent reliability[31]. The SEM is based only on the within-subject error/variability, it is a measure of the "precision" of measurement, expressed in the same units as the original measurement and can be directly compared against subjects' values. SDD is considered a "clinical applicability" index, derived from the SEM (SDD = 1.96√2SEM), expressed either in raw terms (actual units of measurement) or as a percentage of the parameter's grand mean. It is a useful index for diagnostic tests, indicating the level of change in a parameter attributed with 95% certainty to a true change in a subject's condition, instead of being caused by test-retest errors. A small SDD associated with repeated test application renders a measurement more responsive to change.

For paraspinal strength, two force variables were derived: mean strength (the mean of 3 MVICs within 5%-10% of each other) and maximum strength (the highest of the 3 MVICs) to establish whether any of the two presented an advantage over the other. If EMG-fatigue reliability indices were of good-excellent level, measures were averaged across bilateral muscles within a session, as this practice has been previously reported to increase the reliability of these measures further[34].

For discriminative validity, preliminary analysis was conducted (independent samples *t*-tests), to determine which of those EMG-fatigue variables that displayed good-excellent reliability also presented significant between-group differences. Subsequently, a one-way Multivariate Analysis of Covariance (MANCOVA) was conducted to determine whether the initially detected statistically significant between-group differences in EMG-fatigue parameters would remain significant, after controlling for factors that could have influenced in parallel the EMG-fatigue parameters. Such factors, according to previous studies, were age[35-38], participants' body mass[37] and the MVIC levels used for EMG-fatigue testing, with higher force levels resulting in higher fatigue rates[26] and were introduced as covariates. The assumptions required for conducting ANCOVA analysis were checked with relevant statistical procedures[39]. The statistical review of the study was performed by a biomedical statistician.

RESULTS

All data satisfied the normality of distribution criterion and were therefore summarised as means ± SD and analyzed with parametric statistics. The demographic characteristics of each group are presented in Table 1. Significant between-group differences were identified for age ($P < 0.001$), weight ($P = 0.002$) and body mass index ($P = 0.001$). Male and female participants were equally distributed in both groups, thus the effect of gender on EMG parameters was controlled.

Raw data from the two testing occasions are presented in Tables 2 and 3. For strength, the repeated measures ANOVA revealed statistically significant between-day differences in both groups, due to generally better performance on day 2 (Table 2). In clinical terms though, the mean % increase detected was rather insignificant (6.5%-7.2% for healthy and 9.4%-9.7% for patients). Relative reliability ICC indices were excellent for both mean and maximum MVIC, however the SDD was around 18.5% for healthy and 31.0%-31.5% for patients with LBP (Table 4).

For the EMG-fatigue measures (Table 3), only the L2/3 MFslope on the right side (raw) in healthy and L4/5 MFslope on the L side (normalized) in patients were significantly steeper on the second day. Data between sides were pooled, as no apparent R/L differences were present in general. EMG-fatigue reliability was similar in both populations (Table 5). The ICCs for the initial MF (IMF) data from individual channels and for the merged R/L values were excellent and the SDDs were between 9.5%-20.0% for healthy and 17.7%-21.0% for LBP patients. The ICCs for the raw and normalised MFslopes were good and the SDDs were between 13.7%-16.7% for healthy and 18.7%-20.7% for LBP patients. All 3 reliability indices (ICC, SEM, SDD) generally improved for the pooled data. However, the ICCs for the amplitude data (RMSslopes) were poor-moderate and the SDDs were between 41.1%-67.0% for healthy and 30.0%-40.1% for LBP patients, deemed as unacceptably high for clinical applications.

For the discriminative validity, no significant differences were identified for the IMF, therefore this parameter was not tested further, while all MFslopes presented significant between-group differences ($P < 0.001$). A one-way MANCOVA analysis determined that there was a statistically significant difference between the 2 groups of participants on the combined dependent variables, after controlling for age, weight and MVIC, $F(4,84) = 3.95$, $P = 0.006$, Wilks' Lambda = 0.835, partial $\eta^2 = 0.165$. Follow

Table 2 Maximum strength (mean ± SD) values in controls and patients

	Non-LBP (*n* = 26)			LBP (*n* = 66)		
MVIC (kg)	**Day 1 (practice)**	**Day 2**	***P* value**	**Day 1 (practice)**	**Day 2**	***P* value**
Maximum	85.8 ± 23.7	91.4 ± 26.7	0.005[b]	58.7 ± 24.8	63.5 ± 26.5	0.0005[b]
		Mean increase: 6.5%			Mean increase: 9.4%	
Mean	82.6 ± 22.7	88.5 ± 25.5	0.002[b]	56.0 ± 24.1	61.1 ± 26.0	0.0005[b]
		Mean increase: 7.2%			Mean increase: 9.7%	

[b]$P < 0.01$.

MVIC: Maximum/mean voluntary isometric contraction.

up univariate tests revealed that differences between healthy and participants with RLBP were highly significant ($P < 0.009$) for all the EMG-frequency slope data (raw MFslopes and normalised MFslopes), when controlling for age, weight and MVIC (Table 6). Assumptions for running a one-way MANCOVA were systematically checked prior to its conduct. Linear relationships between pairs of dependent variables and between pairs of dependent variables and covariates within each group of the independent variables were examined with scatterplot matrices. Homogeneity of regression slopes and homogeneity of variances and covariances were equal in all groups of the independent variable (Box's M Test of equality of covariance matrices, $P = 0.06$). Homogeneity of error variances of the dependent variables within each group were also equal (Levene's test of equality of error variances, $P > 0.05$). No significant univariate outliers were detected in the groups of independent variables for each of the dependent variables, by inspection of the standardised residuals.

DISCUSSION

Back pain is a very prevalent musculoskeletal pathology of recurrent nature[4], and has been associated with a variety of possible causative factors[5]. 'Previous LBP' significantly contributes to the condition's recurrence, having an odds ratio between 1.5-4.5[5]. However, many of the remaining physical impairments from 'previous LBP' episodes that possibly contribute to symptoms' recurrence remain speculative, as in their majority these are not apparent with radiological methods or are masked during clinical assessment by co-existing pain, disability or psychological parameters[1]. Thus LBP is labelled in many instances as 'non-specific'[2].

Nearly all (14/15) clinical guidelines on the effective management of non-specific LBP in primary care recommend the use of exercise, among other treatment options [40]. The type of exercise should be adapted according to the specific requirements of each LBP stage, however endurance re-training of the trunk muscles is well-placed within the 'muscle re-education' algorithm proposed[41]. Periods of pain remission between recurrences should be viewed as opportune timeframes to assess and functionally re-train the neuromuscular and anatomical deficits of trunk muscles, than being periods of rest that progressively lead to deconditioning of the neuromuscular system[8].

Under this framework, the present study aimed to assess the reliability of MVIC and of EMG time-dependent frequency and amplitude parameters of the paraspinals during an isometric fatigue test at 60% MVIC level, in patients with RLBP and healthy controls. Group-related performance differences were also examined.

Paraspinal strength

Many factors need to be carefully considered in a maximal performance test such as the assessment of isometric strength. The upright position of the subjects was selected, as it has been successfully used before in multiple studies of different research centres [23,42,43], without any known contra-indications reported in the literature (safety of test ensured). Also, the intention was to avoid any lifting-type strength assessment activities where the trunk is in forward flexion[44]. Trunk forward flexion may have been the position that some of the LBP participants had "injured" themselves in the past and also it is not a comfortable position for many LBP patients[25], so on these grounds it was avoided. Additionally, no significant benefit over the upright position

Table 3 Mean ± SD values on 2 separate days for initial median frequency, median frequency-slope and root mean square for the isometric endurance test in both groups

	Healthy (*n* = 26)			LBP (*n* = 66)		
Parameter	**Day 1**	**Day 2**	***P* value**	**Day 1**	**Day 2**	***P* value**
IMF (Hz)						
L2/3 R	60.3 ± 10.9	61.0 ± 11.1	0.48	66.5 ± 17.6	66.1 ± 15.8	0.82
L2/3 L	58.2 ± 9.0	59.1 ± 12.3	0.52	63.5 ± 17.2	61.9 ± 13.2	0.18
L4/5 R	89.3 ± 20.3	91.0 ± 16.4	0.49	83.2 ± 24.3	83.0 ± 21.3	0.89
L4/5 L	90.9 ± 20.1	92.3 ± 17.3	0.59	82.7 ± 26.0	83.5 ± 20.8	0.59
L2/3	59.24 ± 9.7	60.1 ± 11.4	0.44	65.0 ± 16.4	64.0 ± 13.8	0.39
L4/5	90.1 ± 19.4	91.6 ± 15.9	0.49	82.9 ± 24.3	83.2 ± 20.0	0.83
MF slopes (raw, Hz/s)						
L2/3 R	-0.30 ± 0.14	-0.35 ± 0.12	0.02[a]	-0.12 ± 0.16	-0.12 ± 0.17	0.77
L2/3 L	-0.30 ± 0.11	-0.31 ± 0.10	0.52	-0.10 ± 0.18	-0.11 ± 0.14	0.41
L4/5 R	-0.48 ± 0.16	-0.54 ± 0.22	0.19	-0.23 ± 0.25	-0.22 ± 0.20	0.62
L4/5 L	-0.56 ± 0.21	-0.61 ± 0.19	0.19	-0.21 ± 0.25	-0.23 ± 0.25	0.53
L2/3	-0.30 ± 0.11	-0.33 ± 0.10	0.08	-0.11 ± 0.16	-0.11 ± 0.15	0.51
L4/5	-0.52 ± 0.17	-0.57 ± 0.19	0.13	-0.22 ± 0.23	-0.22 ± 0.20	0.84
MF slopes (normalised, %/min)						
L2/3 R	-28.8 ± 11.5	-31.5 ± 9.0	0.14	-9.0 ± 15.2	-9.9 ± 15.8	0.55
L2/3 L	-29.9 ± 9.3	-29.8 ± 8.4	0.95	-8.1 ± 15.9	-10.5 ± 14.8	0.11
L4/5 R	-34.0 ± 11.3	-34.2 ± 11.9	0.90	-15.0 ± 15.7	-15.0 ± 12.0	0.98
L4/5 L	-36.4 ± 10.7	-37.7 ± 10.4	0.58	-13.2 ± 14.0	-17.1 ± 13.3	0.01[a]
L2/3	-29.3 ± 9.8	-30.6 ± 7.9	0.39	-8.6 ± 14.8	-10.2 ± 14.5	0.21
L4/5	-35.2 ± 9.6	-36.0 ± 10.2	0.67	-14.1 ± 13.7	-16.1 ± 11.7	0.10
RMS slopes (normalised, %/min)						
L2/3 R	43.4 ± 45.0	37.4 ± 35.2	0.35	10.4 ± 21.4	11.3 ± 18.5	0.72
L2/3 L	27.4 ± 30.8	29.0 ± 28.3	0.73	11.3 ± 17.3	13.9 ± 22.8	0.17
L4-5 R	42.6 ± 35.9	32.7 ± 29.2	0.19	14.3 ± 21.2	12.6 ± 22.2	0.43
L4/5 L	37.1 ± 36.2	38.4 ± 34.1	0.85	10.3 ± 19.3	13.9 ± 21.2	0.07

[a]$P < 0.05$.

Hz: Hertz; IMF: Initial median frequency; MF: Median frequency; RMS: Root mean square.

in EMG-fatigue reliability has been demonstrated with the latter type of experiment [44]. Confirming previous observations, MVIC measurement with the methods used was not associated with any new low back injuries. Only slight discomfort was reported by some participants from the patient group during the performance of the MVICs and for a short period (around 10 min) afterwards.

Similar trends with other strength experiments[43] were observed for the non-LBP as well as the RLBP population used for the paraspinal strength repeated measures, reflecting a learning effect between the 2 measurement sessions. Both groups of participants generally demonstrated increased strength output on the second testing occasion. However, due to the standardised methodology employed[28], the average increase was kept below 10% (between 6.5%-9.7%), a value clinically rather insignificant. Indeed, a similar previous study that conducted 3 measurement sessions, reported no further improvement in isometric MVIC after the second session[34]. In view of this learning effect though, for the discriminative validity analysis, only data from the second testing occasion were utilised.

Table 4 Maximum strength reliability indices in controls and patients

	Controls (*n* = 26)			Patients (*n* = 66)		
Parameter	**$ICC_{3,1}$**	**SEM**	**SDD%**	**$ICC_{3,1}$**	**SEM**	**SDD%**
MVIC (kg)						
Maximum	0.92 (0.83-0.97)	5.94	18.57	0.91 (0.86-0.94)	6.96	31.61
Mean	0.96 (0.90-0.98)	5.72	18.51	0.96 (0.93-0.97)	6.49	30.75

ICC: Intraclass correlation coefficient; SEM: Standard error of the measurement; SDD: Smallest detectable difference; MVIC: Maximum/mean voluntary isometric contraction.

EMG-Fatigue: initial values and time dependent changes

This reliability study in the patient group was the largest so far in the literature[20]. Results clearly indicate that the technique employed for healthy participants and patients, considering the relative (ICCs) and absolute reliability indices (SEMs/SDDs) together[32,33], demonstrated good-excellent reliability for all the frequency-related parameters and that clinical differences can be reliably detected for values of EMG-fatigue MFslopes that exceed 18.7%-20.7%/min of initial values. Averaging data between sides, as previously suggested[34], increased reliability and decreased measurement error even further. The general trend in participants of this study was that no between-sides imbalances were present. It has to be emphasized, though, that the method of averaging data between-sides renders the technique insensitive in detecting between-sides differences present in some individuals.

Conversely, amplitude related RMS slopes presented with poor-moderate test-retest reliability and were not processed further. It might have been that these indices were either more sensitive to the differences in MVIC levels between-sessions or that they present more variability in day-to-day testing, due to load sharing phenomena present in sustained contractions[9]. However, as a general trend, it can be attested that RMS increases were lower in general for the patients with RLBP than the healthy participants (Table 3), denoting a lower activation of those muscles in RLBP, similar to other studies[6,41].

Similar findings for poor reliability in RMS amplitude slopes have been previously reported for isometric fatigue testing at 60% MVIC level[19,44], however for MFslopes variable reliability levels have been reported[20-22,34].

EMG-frequency parameters group-related performance differences

For discriminative validity, a one-way MANCOVA determined that there was a statistically significant difference between the 2 groups of participants regarding the EMG-frequency raw or normalised MFslopes from both upper and lower muscle sites, after controlling for age, weight and MVIC. Interestingly, while the EMG time-dependent frequency parameters presented highly significant differences between the two groups, less decline in MFslopes was demonstrated in patients with RLBP.

The rate of decrease in MF, as expressed by the least squares linear regression from the beginning to the end of a sustained contraction (MFslope) has been initially proposed to be mainly related to the endurance capacity of a muscle (Figure 2), with steeper slopes indicating greater muscle fatigue almost invariably present in patients with CLBP[18,45,46]. The rate of fatigue with this type of experiment depends on the level of sub-maximal contraction it is performed, in this instance at 60% MVIC level. Therefore, if patients under-perform during MVIC generation, they will be performing the fatigue test under a lower load level. Thus, in this study, the MVIC was introduced as a covariate in the ANCOVA analysis, to statistically control against this eventuality.

The paraspinals are a characteristic example of a multi-layer multiple muscle system, synergistically activated to perform a variety of tasks under different conditions[8,9] in combination with muscles from adjacent body parts[47]. The initial distribution of activation in their various parts and the progressive re-distribution of activation during sustained activities[6,9], is organised and continuously monitored by the central nervous system (CNS). However, various factors relative to cognitive[12,48] or physiologically-controlled peripheral requirements like inter-individual characteristics[37], task biomechanical demands[19,49], the presence of atrophy related mainly to ongoing disability[7] or pain frequency characteristics (recurrent or continuous)[6] can lead to either steeper MFslopes (in case of selective atrophy of type II fibres[50] or a 'confronter' type of patient with LBP[48]) or less steep MFslopes (due to generalised

Table 5 Reliability of initial median frequency, median frequency-slope and root mean square for the isometric endurance test in both groups

	Controls (n = 26)			Patients (n = 66)		
Parameter	**$ICC_{3,1}$**	**SEM**	**SDD**	**$ICC_{3,1}$**	**SEM**	**SDD**
IMF (Hz)						
L2/3 R	0.91 (0.80-0.96)	3.32	9.19	0.80 (0.69-0.87)	7.56	20.95
L2/3 L	0.82 (0.63-0.92)	4.57	12.66	0.80 (0.69-0.87)	6.88	19.06
L4/5 R	0.82 (0.61-0.92)	7.99	22.13	0.82 (0.73-0.89)	9.64	26.70
L4/5 L	0.81 (0.60-0.91)	8.31	23.02	0.86 (0.79-0.92)	8.61	23.85
L 2/3	0.94 (0.87-0.98)	3.45	9.56	0.90 (0.84-0.94)	6.41	17.75
L 4/5	0.91 (0.79-0.96)	7.27	20.14	0.94 (0.90-0.96)	7.59	21.02
MF slopes (raw, Hz/s)						
L2/3 R	0.61 (0.27-0.81)	0.07	0.19	0.75 (0.62-0.84)	0.08	0.22
L2/3 L	0.67 (0.36-0.85)	0.06	0.17	0.66 (0.50-0.78)	0.09	0.25
L4/5 R	0.52 (0.14-0.77)	0.13	0.36	0.73 (0.60-0.83)	0.12	0.33
L4/5 L	0.55 (0.18-0.78)	0.13	0.36	0.62 (0.45-0.75)	0.15	0.41
L 2/3	0.77 (0.46-0.90)	0.06	0.17	0.86 (0.77-0.91)	0.08	0.22
L 4/5	0.73 (0.35-0.89)	0.11	0.30	0.88 (0.80-0.92)	0.10	0.28
MF slopes (normalised, %/min)						
L2/3 R	0.67 (0.36-0.85)	5.79	16.03	0.69 (0.55-0.80)	8.59	23.79
L2/3 L	0.65 (0.33-0.84)	5.36	14.85	0.69 (0.54-0.80)	8.44	23.38
L4/5 R	0.64 (0.31-0.83)	7.11	19.69	0.62 (0.45-0.75)	8.59	23.79
L4/5 L	0.50 (0.11-0.75)	7.60	21.05	0.57 (0.38-0.71)	8.66	23.99
L 2/3	0.82 (0.57-0.92)	4.93	13.66	0.85 (0.75-0.91)	7.47	20.69
L 4/5	0.78 (0.49-0.91)	6.02	16.67	0.83 (0.73-0.90)	6.75	18.69
RMS slopes (normalised, %/min)						
L2/3 R	0.73 (0.46-0.88)	21.00	58.17	0.48 (0.27-0.65)	14.48	40.11
L2/3 L	0.76 (0.51-0.89)	14.83	41.08	0.71 (0.56-0.81)	10.83	30.00
L4/5 R	0.44 (0.04-0.72)	24.07	66.67	0.73 (0.60-0.83)	11.26	31.19
L4/5 L	0.54 (0.17-0.78)	24.20	67.03	0.61 (0.44-0.74)	12.44	34.46

Hz: Hertz; ICC: Intraclass correlation coefficient; SEM: Standard error of the measurement; SDD: Smallest detectable difference; IMF: Initial median frequency; MF: Median frequency; RMS: Root mean square.

inhibition[6,51], redistribution of muscle activity phenomena[23,28] or 'avoider' type of patient with LBP[48]), or even a mixed picture[38,42] compared to healthy participants.

EMG signal estimating the rate of muscle fatigue, through analysis of the frequency and time domain of the signal is rather complex, affected by the anatomical and physiological properties of muscles[6], the control scheme of the CNS[9] and the characteristics of the equipment used to collect the signal[26]. EMG fatigue measures, collected at a certain level of maintained contraction according to the methodology of the experiment conducted, are considered relatively independent of subjects' volitional effort, as the firing frequency of motor units cannot be perceived nor regulated[18].

However, it can also be logically derived that non-volitional alterations in the organization of the motor commands controlled by the CNS[52], can influence the manifestations of EMG-fatigue time-dependent indices[23,42]. A point to consider in the interpretation of paraspinal muscle behaviour under maximal (strength) or prolonged (fatigue-related) contractions is the present and past history of LBP episodes. If patients are in an acute or even at a sub-acute remission stage of symp-

Table 6 Adjusted between-group median frequency-slope differences in the isometric endurance test at 60% of maximum voluntary isometric contraction

	Healthy (*n* = 26)		LBP (*n* = 66)		Mean difference	*P* value
Parameter	Mean	SE	Mean	SE		
MF slopes (raw, Hz/s)						
L2/3	-0.25	0.03	-0.14	0.02	0.12	0.002[b]
L4/5	-0.44	0.05	-0.26	0.02	0.18	0.002[b]
MF slopes (normalised, %/min)						
L2/3	-22.4	2.9	-13.0	1.4	9.4	0.009[b]
L4/5	-29.4	2.5	-18.4	1.2	11.0	0.000[b]

[b]$P < 0.01$.

Hz: Hertz; LBP: Low back pain; MF: Median frequency.

toms, local muscle pain inhibition phenomena and redistribution of myoelectric activity are favoured[53]. Recent results show that paraspinal muscles in patients with recurrent or with non-continuous CLBP are not yet infiltrated by fat when compared to patients with continuous CLBP; however, patients with RLBP demonstrate lowered activation ability of the paraspinal muscles in general, compared to patients with CLBP[6]. Our results of decreased MVIC and less time-dependent MFslope decline in both muscle sites (corresponding to iliocostalis and multifidus) in patients with RLBP compared to healthy controls concur with this finding, although derived with different methodology (testing position) and outcomes (strength and EMG-fatigue measures). However, three studies with similar methodology to ours confirm our findings[23,42,54], another two studies that reported 'mixed' findings partly confirm our findings, as some participants demonstrated steeper and some less steep MFslopes in relation to healthy counterparts[48,55] and another one registered similar although not statistically significant trends[28]. Indeed, in one of the former three studies that clearly demonstrated between-group differences it was stated that "unexpectedly, healthy men showed higher fatigability than back pain patients", a result attributed to the smaller absolute load that patients performed the fatigue test[54]. However, the ANCOVA analysis has shown that the MFslope differences in the current study remained highly significant even after controlling for the MVIC values between-groups also, therefore the hypothesis of transient muscle inhibition is favoured. Indeed, given the recurrent nature of LBP in the patients recruited in this study, it is possible that the less steep slopes obtained both at higher (L2/3) and lower (L4/5) segments are due to generalised muscle decreased activation/partial inhibition of normal activity for a given level of contraction, rather than atrophy of type II fibers, more apparent in patients with non-specific CLBP[7].

Additionally, two studies on the redistribution of paraspinal muscle activity under sustained contractions offer complementary support to the findings of this study. The first showed that in healthy participants there was an increase in paraspinal level of contraction at lower spinal segments, whereas patients with CLBP did not demonstrate such shift[56]. In the second, patients with RLBP demonstrated a shift of activity from lower to higher spinal levels in relation to healthy controls and that the extent of this redistribution of activity correlated with lower endurance times[9]. The finding of redistribution of activity between upper and lower segments, at least between the ones (L2/3 *vs* L4/5) examined herein, is not supported by this study, as similarly less MFslope decline was demonstrated in higher and lower spinal segments. Possible differences in the task employed or as a large array of electrodes was not used in our study could have accounted for the differences between the results of our study and this latter study. The fact remains that in both of those studies a lower activation in lower spinal segments has been supported, a finding concordant with our study for the L4/5 spinal level. A previous study had even documented a shift of muscle activity towards the gluteals in relation to that of lower spinal segments in patients with CLBP relative to controls[47].

Another issue to consider is the direction of a 'desired improvement' in the patient group which is a debatable point, as the MFslopes in this group were significantly less steep than in the healthy participants ($P < 0.002$) across all muscle sites monitored, even after controlling for age, weight and different MVIC levels between the groups

(Table 6). Indeed, opposite changes in MF slopes post rehabilitation have been reported, possibly reflecting better activation of paraspinal muscles post-rehabilitation [51]. Pain-related muscle inhibition phenomena and different load-sharing patterns in the back muscles of patients, which may be a possible CNS strategy (non-volitional) to distribute the load "evenly" between all muscle groups involved in the contraction[23, 42,48,54,55] may potentially limit the applicability of the frequency spectrum EMG indices as endurance indicators. Alternatively, they may expand the definition of power spectrum frequency parameters, as indicators of neural motor control strategies [42].

Limitations-Future directions

A single rater experienced in the measurement methods employed was only involved in all measurements, to eliminate any between-rater error. Also, due to the variability of the EMG signal, only isometric examination methods of the paraspinal muscles were employed. However, the test-retest reliability, clinical applicability and discriminative validity of the methods involved was thoroughly examined in an adequate sample of healthy volunteers and in patients with recurrent non-specific LBP at a sub-acute stage of symptoms. An a priori sample size calculation was also performed to ensure sufficient power of the study based on expected between-group differences. Future studies could further examine the inter-rater reliability of the techniques already presented or expand the testing methods to either examine different exercise tasks (intermittent isometric contractions, different MVIC levels, dynamic contractions), including additional muscle groups (abdominals, gluteals) and patients with LBP with a range of neuromuscular deconditioning, disability and cognitive characteristics that affect functional performance.

CONCLUSION

Reliability, clinical applicability and discriminative ability of paraspinal strength and EMG-related frequency parameters were demonstrated in healthy participants and patients with non-specific recurrent sub-acute LBP. The EMG-related amplitude parameters did not present adequate reliability and the IMF parameter did not present significant differences between the groups examined. Further examination of those methods is endorsed.

ARTICLE HIGHLIGHTS

Research background

A significant predictor of low back pain (LBP) recurrence is 'previous LBP'. Partly, this may be due to persisting neuromuscular system activation deficits linked to strength deficits, as well as endurance deficits in patients with recurrent LBP (RLBP) even during periods of symptoms remission. LBP management clinical guidelines propose muscle re-conditioning as a prerequisite for successful management of recurrences.

Research motivation

Paraspinal muscle strength and endurance deficits require reliable monitoring. To overcome patient motivation or cognitive-related concerns affecting maximal strength testing, as well as endurance testing with prolonged contractions to complete exhaustion, alternative methods have been proposed in patients with RLBP, in order to establish the contribution of those parameters in neuromuscular deconditioning, to limit further recurrences.

Research objectives

As electromyographic (EMG)-based frequency and amplitude domain time dependent alterations, linked to the endurance characteristics of the muscles monitored have not been universally obtained for the paraspinals, a primary objective of this study was to determine the reliability of those measures. The reliability level of maximal paraspinal muscle strength performance was also examined. Furthermore, the discriminative validity of paraspinals muscle strength and time-dependent EMG frequency and amplitude domain alterations was tested.

Research methods

A custom-made isomyometer was utilised to initially assess the maximum voluntary isometric contraction (MVIC) of the paraspinals in the upright trunk position. Subsequently, short duration (60-s) isometric contractions at a submaximal level of contraction (60% of MVIC) were employed, to determine the EMG-time dependent frequency [initial median frequency (IMF) and median frequency (MF) slopes] and amplitude changes [root mean square (RMS) slopes] of the paraspinal muscles with recording electrodes placed at 4 muscle sites (L2/3 and L4/5, bilaterally). The most reliable parameters were used further to test the between populations discriminative ability of the method.

Research results

For both groups, MVIC presented excellent intraclass correlation coefficient (ICC) reliability values, although statistically significant between-day increases ($P < 0.01$) were recorded, within a margin of 10%; test-retest error was increased for patients compared to healthy participants. The EMG reliability of the frequency parameters was good (MF slopes) to excellent (IMF), however for the amplitude parameter (RMS slope) it was poor, for both groups. Statistically significant less MVIC and less steep MF slopes were registered for the patient group. These findings confirm previous research in the field, however in a larger population of participants with a history of RLBP and a sufficiently large comparison group of healthy participants.

Research conclusions

Although EMG time-dependent frequency parameters presented highly significant differences between the two groups, these were in the opposite than the expected direction. The validity of this finding is enhanced for two reasons; the between-group differences in MF slopes remained after statistically controlling for possible confounders and these differences were confirmed at all muscle sites monitored. Apparently, alterations in the organization of the motor commands in patients with RLBP can additionally influence the manifestations of EMG-related time-dependent indices. Therefore, the alterations in the EMG-frequency spectrum under sustained contractions cannot only be considered as indicators of peripheral fatigue or peripheral muscle atrophy.

Research perspectives

This methodology of EMG-related alterations followed in the current experiment is reliable. The validity of the between-group differences obtained between patients with RLBP and healthy participants requires further study. In order to explain the significance of the current findings, the history of LBP has to be taken into consideration. Therefore, results from patients with varying amounts of LBP-related disability and disease duration are required, in conjunction with detailed imaging methods of peripheral muscle state and recording of the different patterns of activation utilised under controlled experimental conditions or less controlled functional tasks. Furthermore, the effect of exercise on EMG-related frequency parameters and whether the alterations registered post-exercise in the frequency domain correspond to less LBP recurrences requires examination from a clinical viewpoint.

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ORIGINAL ARTICLE

Retrospective Cohort Study

Preseason elimination impact on anterior cruciate ligament injury in the National Football League

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Abstract

BACKGROUND

Anterior cruciate ligament (ACL) injuries represent detrimental injuries in the National Football League (NFL). A significant portion of these injuries often occur in preseason exhibitions. The Coronavirus disease 2019 pandemic presented a unique disruption to preseason NFL football with the cancelation of all preseason games.

AIM

To compare the incidence of ACL tears through the first eight weeks of the NFL season in 2020 to the mean incidence over the previous 5 seasons (2015-2019) and determine if there was any change in incidence with the elimination of the preseason.

METHODS

NFL players who suffered ACL tears during the preseason and first eight weeks of the NFL season from 2015-2020 were identified. The number of ACL injuries for the 2015-2019 seasons was compared to the 2020 season for four different timeframes. For each analysis, the cumulative number of ACL injuries to that time point was used to calculate the percent difference for descriptive analysis. Additionally, the number of teams with at least one player suffering an ACL tear were identified and compared using Chi-Squared testing. Finally, a cumulative relative risk was calculated for each week played.

RESULTS

There were 14 ACL tears through the first four games of the 2020 season, a 118.8% (14 *vs* 6.4) increase in comparison to the 5-year average over the first 4 regular season weeks of 2015-2019. However, when accounting for injuries occurring during the preseason from 2015-2019, there were 18.6% (14 *vs* 17.2) fewer total ACL injuries through regular season week 4 with no significant difference in

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percentage of teams impacted when these preseason injuries were accounted for P = 0.394. Results were similar (19 *vs* 17.2) over 8 total games played (whether regular season or preseason), and over 8 regular season games (P = 0.196, P = 0.600).

CONCLUSION
The elimination of the NFL preseason resulted in a higher rate of injuries during the first 4 games of the regular season. However, these increases are offset by the injuries typically sustained during the preseason. This suggests there may be front-loading of injuries over the course of an NFL season, such that players may be more prone to injury when the intensity of play suddenly increases, whether in the preseason or regular season.

Key Words: Anterior cruciate ligament; National football league; Player safety; Ligamentous injury; Preseason; COVID-19

Core Tip: The coronavirus disease 2019 pandemic presented a unique disruption to preseason National Football League (NFL) football with the cancelation of all preseason games. This study compared the incidence of anterior cruciate ligament (ACL) tears through the first eight weeks of the NFL season in 2020 to the mean incidence over the previous 5 seasons and found that there was indeed an increase in ACL tears through the first four games of the 2020 season with no significant difference when accounting for the preseason. This suggests that there may be front-loading of injuries over the course of an NFL season. In summary, this study suggests that if preseason games are eliminated, players can expect similar rates of ACL tears overall when compared to conventional seasons, but with more ACL tears in the first four weeks of the regular season.

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INTRODUCTION

Anterior cruciate ligament (ACL) injuries are among the most common knee injuries in American football players, and their incidence increases with increased level of competition. In one survey, 14.2% of retired National Football League (NFL) players reported a history of ACL injury[1]. Because of the high incidence of ACL injuries and their potential to end players' seasons or careers, extensive research has been conducted to identify risk factors that may contribute to ACL injury and modifications to improve player safety. One of these modifiable risk factors may be preseason training.

Over the last decade, NFL and National Football League Players Association have disputed the importance and number of preseason games necessary before the NFL season. Since 1978, NFL teams participated in a 4-game stretch of weekly exhibition games to prepare for the upcoming season. However, in 2020 the coronavirus disease 2019 (COVID-19) pandemic presented a unique disruption to this sequence, with all preseason games cancelled prior to the beginning of the season.

ACL tears are catastrophic and common injuries in football, with athletes estimated to have a ten times higher risk of rupture in participation when compared to other sports[2]. A recent systematic review reported the overall return to play rate in NFL athletes after an ACL tear at only 67.2%, with significant variability depending on the position and experience of the athlete[3-5]. Additionally, of players able to return, the financial impact of these injuries on player earning potentials is well documented, with salary losses of roughly $2 million per year after injury[6].

The purpose of this study was to compare the incidence of ACL tears through the first eight games played of the NFL season in 2020 to the mean incidence over the previous 5 seasons (2015-2019) and determine if there was any change in incidence with the elimination of the preseason.

MATERIALS AND METHODS

NFL players who suffered ACL tears during preseason games and first eight regular season games played of the NFL season for the years 2015-2020 were identified and confirmed using reports from official NFL team websites. Only injuries occurring during regular and preseason games were included. Injuries occurring in organized team activities, practices, or individual training sessions were not included in the analysis, as regimens and activities of individual players and teams inherently vary considerably. The five-year total and yearly mean number of ACL injuries were calculated for the 2015-2019 seasons and compared to the 2020 season for four different timeframes.

First, the first four regular season games of the 2020 season were compared to the first four regular season games of 2015-2019 season, excluding any preseason injuries. Second, the first four regular season games for the 2020 season were compared to first four regular season games played of the 2015-2019 season, including injuries sustained in the four preseason games accrued in 2015-219. Third, the first 8 regular season games played for the 2020 season were compared to the first eighth regular season games played of the 2015-2019 season, including injuries sustained in the four preseason games. Lastly, the cumulative number of injuries through 8 wk of any gameplay were compared, and a relative risk was calculated for player injuries per game played by each week. In other words, the first 4 preseason games of 2015-2019 were analyzed in combination with the first 4 games of their respective regular seasons and compared to the first 8 regular season games of 2020.

For each analysis, the cumulative number of ACL injuries to that time point was used to calculate the percent difference for a descriptive analysis. Additionally, the number of teams with at least one player suffering an ACL tear were identified and compared using Chi-Squared testing. All collected data was then analyzed using IBM SPSS Statistics Version 25 (Armonk, NY, United States). P values < 0.05 were considered statistically significant.

RESULTS

Comparison of first four regular season games

There was a total of 14 ACL tears through the first four games of the 2020 season, a 118.8% increase in comparison to the 5-year average over the first 4 wk of the 2015-2019 seasons (Table 1 and Figure 1A). More teams (11) were impacted with an ACL tear in 2020 during the first 4 wk of the season than any season from 2015-2019. Chi squared testing demonstrated a significant difference in rates of teams impacted (Table 1; P = 0.039) in 2020 compared to 2015-2019.

Comparison through the first four regular season games, including preseason

When accounting for injuries occurring during the preseason from 2015-2019, there were 18.6% fewer total ACL injuries through regular season week 4 (Table 1 and Figure 1B). There was no significant difference in percentage of teams impacted when these preseason injuries were accounted for (Table 1; P = 0.394).

Comparison through the first eight regular season games, including preseason

Repeat analysis through 8 wk comparing the 2020 season to the 2015-2019 averages including the preseason demonstrated similar results to week 4 analysis, with overall tears down 16.7% with no significant difference in the number of teams affected (Table 1; P = 0.196).

Comparison of the first eight games played

When comparing an equivalent number of games, regardless of regular or preseason designation, there was a 10.5% increase in ACL tear occurrence in the 2020 season (Table 1 and Figure 1C), but no significant difference in the number of teams impacted (Table 1; P = 0.600), or injury rate at any timepoint through eight weeks (Table 2).

Table 1 Cumulative anterior cruciate ligament tear count

Season	Total ACL tears	Percent difference	Teams impacted	*P* value[1]
Through four regular season games, excluding preseason				
2020	14	+118.8%	**11**	**0.039**
2015-2019 average	6.4		**5.8**	
Through four regular season games, including preseason injuries				
2020	14	-18.6%	11	0.394
2015-2019 average	17.2		13.6	
Through eight regular season games, including preseason injuries				
2020	19	-16.7%	12	0.196
2015-2019 average	22.8		16.0	
Through eight games played, regular or preseason				
2020	19	+10.5%	12	0.600
2015-2019 average	17.2		13.6	

[1]*P* value calculated using Chi-squared analysis. Bold indicated statistical significance.
ACL: Anterior cruciate ligament.

Table 2 Week by week comparison of cumulative anterior cruciate ligament tear rate for the first 8 games played

	Year	Total injuries	Total games	Rate	RR	95%CI	*P* value
Game 1	2020	3	16	0.188	1.071	0.348-3.302	0.904
	2015-2019	14	80	0.175			
Game 2	2020	10	32	0.313	1.724	0.937-3.174	0.08
	2015-2019	29	160	0.181			
Game 3	2020	13	48	0.271	1.477	0.865-2.524	0.153
	2015-2019	44	240	0.183			
Game 4	2020	14	63	0.222	1.317	0.781-2.22	0.301
	2015-2019	54	320	0.169			
Game 5	2020	15	77	0.195	1.237	0.745-2.055	0.412
	2015-2019	63	400	0.158			
Game 6	2020	17	91	0.187	1.338	0.826-2.169	0.237
	2015-2019	67	480	0.140			
Game 7	2020	19	105	0.181	1.333	0.844-2.107	0.218
	2015-2019	76	560	0.136			
Game 8	2020	19	119	0.160	1.181	0.748-1.864	0.476
	2015-2019	86	636	0.135			

RR: Relative risk; CI: Confidence interval.

DISCUSSION

The results of this study demonstrate that without participation in preseason games, NFL players sustain ACL injuries at a higher rate during the early portion of the regular season. However, when accounting for injuries sustained in preseason, the differences quickly equilibrate and there is no difference in the total number of ACL injuries, or the ACL injuries per game played. Additionally, the injury rate per game

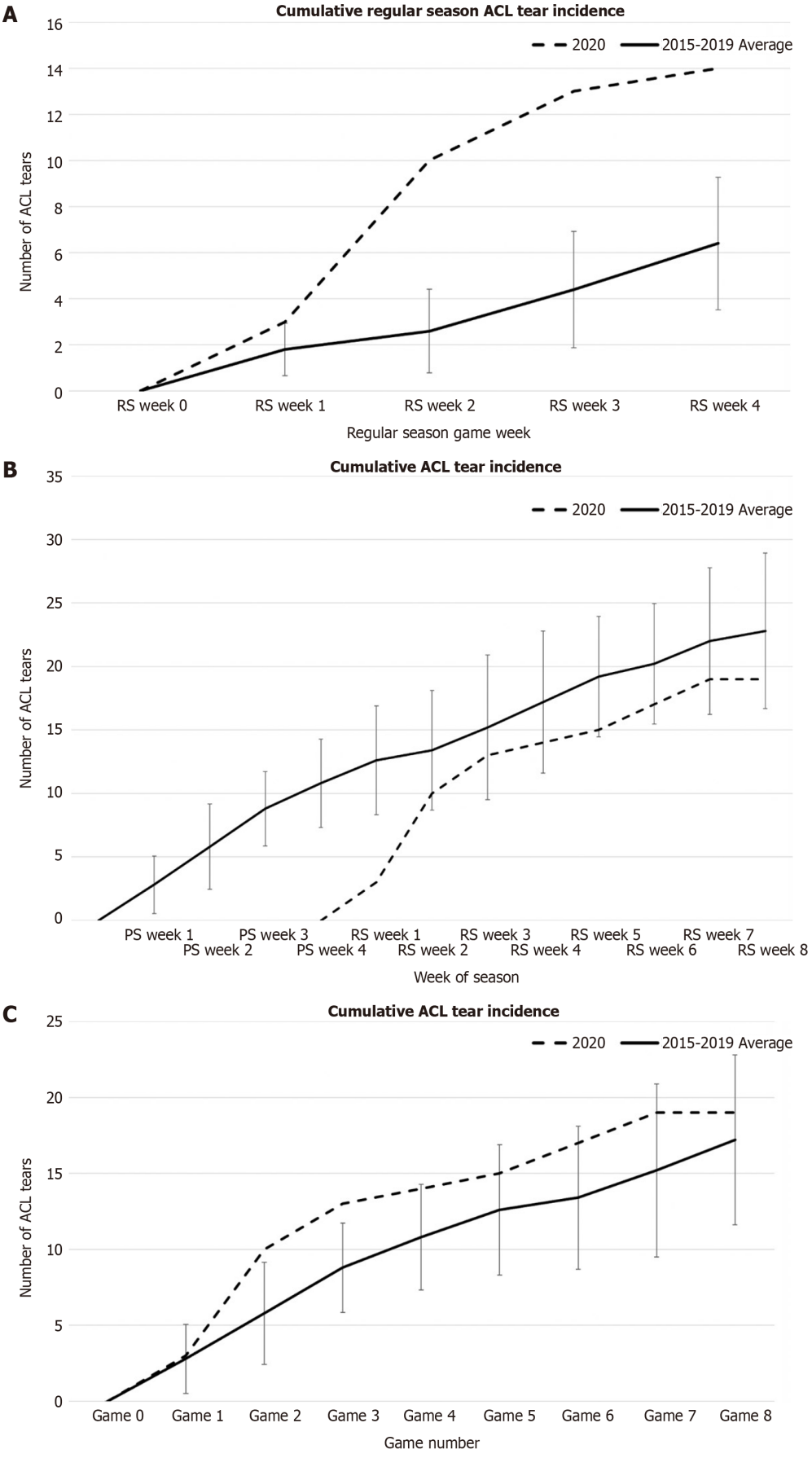

Figure 1 Cumulative plot comparing the number of anterior cruciate ligament tears. A: In the first four regular season (RS) games of the 2020 season to the 2015-2019 RS; B: In the 2020 season to the 2015-2019 average for the preseason (PS) and first 8 wk of the RS. C: In the 2020 season to the 2015-2019 average over the first 8 games played (PS or RS) in each group. Error bars designate the CI above and below the mean. ACL: Anterior cruciate ligament; RS:

Regular season; PS: Preseason.

played is not statistically different between seasons with and without a preseason.

Recent studies of rugby, Australian rules football, and European soccer teams showed that increased participation in preseason training sessions was associated with a lower in-season injury burden[7-9]. One study of European soccer teams found that every 10 additional preseason training sessions that team members participated in was associated with significantly fewer in-season layoff days due to injury and significantly fewer severe in-season injuries[9]. This highlights the potential benefits of increased preseason training in reducing in-season injury burden. With no preseason games in the 2020 season, NFL players participated in less preseason training. This was associated with an increased risk of injury during their early regular season games compared to a traditional year. However, when comparing the first games played of the 2020 season *vs* the preseason games in prior seasons, there is no significant difference in total number of injuries or injury rate.

The above information suggests that the elimination of preseason and pre-season training would increase the incidence of ACL injury, which is consistent with the results of our study. Additionally, some studies suggest that targeted training and warm-up exercises can reduce the incidence and risk of ACL injuries[10,11]. One study of American National Collegiate Athletic Association soccer by Silvers-Granelli *et al* [10] demonstrated that the FIFA 11+ injury prevention program, a 15-20 min dynamic warm-up program performed before training and games, resulted in a 4.25-fold reduction in the likelihood of ACL injury. This highlights the importance of warm-up training directly before vigorous training or exercise. Currently, the NFL does not have a standardized warm-up program, and there have been little to no studies on the impact of warm-up training in the NFL. Thus, the implementation of a similar program into NFL preseason training, regular season training, and NFL games should be explored in future studies, as it may help reduce the incidence of ACL injury.

Another study by Li *et al*[12] investigated the relationship between soft tissue injury and training load in American football. Player training load was measured using wearable global position system devices outfitted to record acceleration in various axes. They found that a sudden increase in training load was associated with more soft tissue injuries, including ankle ligamentous injury, knee ligamentous injury, hamstring strain and other muscle strain. They concluded that soft tissue injuries during the regular season occurred most often during weeks with increased training loads, as compared to the training load over the month prior to injury[12]. These findings are consistent with the results demonstrated in our study, as a large workload increase in 2020 relative to limited offseason participation may have predisposed NFL athletes to early-season injury. The results of our study show a significant increase in the number of teams with ACL tears in the first four weeks of the 2020 season, as compared to the average number of teams with ACL tears from the first four regular season weeks of the 2015 through 2019 seasons (Table 2). Seeing as regular season games are often played with greater intensity due to the increased level of competition[12], it is likely that NFL players in the first four weeks of the 2020 season experienced increased physical demands, or in the words of Li *et al*[12], "training loads", as compared to the weeks leading up to the regular season since there were no preseason games. This sudden increase in physical demand may contribute to the increased ACL tears in the first four weeks of the 2020 regular season in comparison to the recent historic average.

However, it is notable that when including ACL injuries from the preseason and the first four weeks of the regular season in 2015 to 2019 in comparison to injuries in the first four weeks of the 2020 season, there was no significant increase in teams impacted by ACL injury through the first four or eight regular season games of the season. Thus, this higher susceptibility to ACL injury due to increased training demand may simply occur in the preseason instead of the regular season historically. In fact, when including preseason games, descriptive reports in this study demonstrated an 18.6% decrease in ACL injuries in the first four weeks of the 2020 season in comparison to 2015-2019 and a 16.7% decrease through the first eight weeks. Results remained inconclusive when looking at injury incidence over an equivalent timespan, with a 10.5% increase in 2020 ACL tear frequency compared to the running average of the preceding 5 NFL seasons with no significant difference in the number of teams impacted. This highlights that there may be front-loading of injuries, such that players may be more prone to injury when the intensity of play suddenly increases, whether that is in the preseason or regular season. This is further supported in our chronologic analysis, which demonstrated no change in the relative risk at any timepoint in the

first 8 games of NFL play, regardless of if they were preseason or regular season games. Thus, players are likely at increased risk of injury when they engage in full contact play, whether it is in the preseason or regular season. Steiner *et al*[13] found that full contact preseason practice and scrimmages correlated with a significant increase in practice injuries among college football players, as compared to non-contact practice. This was true of in-season full contact practices and scrimmages as well. This is substantiated by the fact that the majority of ACL injuries in American football are from contact[1].

The major limitation of the current study is that it is observational and retrospective. While this data shows an interesting association between the number of ACL injuries, as well as number of teams with ACL injuries with and without a preseason, we cannot draw conclusions on the causative effect of a preseason since many factors affect a player's risk for ACL injury. These include external factors, such as playing surface and cleat design, as well as internal factors, such as previous injury, age, body composition, knee alignment, intercondylar notch width, muscle flexibility, foot biomechanics, and movement patterns[14-17]. This study also did not account for injuries that occurred during practices, off-season training, and organized team activities, though these occur at much lower rates than in-game injuries. Additionally, we only have one season of data in which no preseason games were played. Finally, there are additional variables that complicate the 2020 season, including multiple players opting out of the season entirely, other players missing time due to COVID-19 protocols, and game scheduling delays as a result of COVID-19.

CONCLUSION

While the COVID-19 pandemic is first and foremost a calamity, it has provided a unique opportunity to examine the rates of ACL injuries in the NFL with a complete elimination of the preseason. The results of this study suggest that if preseason games are eliminated, players can expect similar rates of ACL tears overall when compared to conventional seasons, but with more ACL tears in the first four weeks of the regular season.

ARTICLE HIGHLIGHTS

Research background

In 2020, the National Football League (NFL) preseason was eliminated due to the coronavirus disease 2019 pandemic. The purpose of this study was to determine if this unique elimination of the preseason resulted in a change in incidence of anterior cruciate ligament (ACL) tears.

Research motivation

Prior to the pandemic, there had been many discussions regarding the need of the NFL preseason, with the main concern being player safety. Our goal was to obtain relevant data on the impact of the preseason on ACL injuries that can be used for future discussions around that topic.

Research objectives

The main objective of this study was to compare the incidence of ACL tears through the first eight weeks of the 2020 NFL season to the mean incidence over the previous 5 seasons (2015-2019) and determine if there was any change in incidence in 2020. Though this objective was realized, this data can be strengthened if future studies are performed for a greater number of NFL seasons, as we were only able to obtain 5 years of data for this study.

Research methods

NFL players who sustained ACL tears during the preseason and first eight weeks of the NFL season from 2015-2020 were identified using online publicly available data. The number of ACL injuries for the 2015-2019 seasons was compared to the 2020 season.

Research results

A 118.8% increase in ACL tears was noted through the first four games of the 2020 season in comparison to the previous 5-year average over the first four regular season weeks of 2015-2019. However, when accounting for injuries occurring during the preseason from 2015-2019, there were 18.6% fewer ACL injuries through regular season week 4.

Research conclusions

There may be front-loading of injuries over the course of an NFL season, such that players may be more prone to injury when the intensity of play suddenly increases, whether in the preseason or regular season. This study also suggests that although the elimination of the preseason results in similar rates of ACL tears overall, it is correlated with increased ACL tears in the first four weeks of the regular season.

Research perspectives

Future research should be performed comparing the 2020 NFL season with a greater number of NFL seasons, as further data is needed to obtain more definitive results. Additionally, warm-up training has not been studied extensively in American football and is certainly a topic that should be studied for ACL injury prevention.

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Retrospective Study

Risk of methicillin-resistant staphylococcus aureus prosthetic joint infection in elective total hip and knee arthroplasty following eradication therapy

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Abstract

BACKGROUND

Prosthetic joint infection (PJI) is a devastating complication requiring prolonged treatment and multiple operations, leading to significant morbidity for the patient. Patients are routinely tested for methicillin-resistant staphylococcus aureus (MRSA) colonisation. MRSA positive patients are given eradication therapy. We hypothesise that patients who are MRSA positive pre-operatively, have increased risk of developing PJI.

AIM

To identify deep wound infection (PJI) rates in patients who are colonised MRSA positive compared with those who are not colonised; and long term clinical and radiological outcomes.

METHODS

All patients who underwent total hip and knee replacements (THR/TKR) between December 2009 and December 2019 were identified. Patients who were also identified as being MRSA positive at pre-operative assessment were then selected. Confirmation of prescribing eradication treatment was recorded. Patient records, including consultation letters, operation notes and microbiology results were reviewed retrospectively. Comparison of outcomes for each MRSA positive patient was made with 2 MRSA negative patients undergoing the same operation of a similar age by the same consultant.

RESULTS

Screening identified 42 knee and 32 hip arthroplasty patients as MRSA positive, 84 MRSA negative knee and 64 hip patients were reviewed. Patients were matched with medical co-morbidities in each group. Mean follow up was 5 years. PJI was identified in 4/32 (12.5%) of THR MRSA positive and 3/42 (7%) of TKR

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patients. All patients had PJI within one year of surgery.

CONCLUSION

MRSA positive patients are given eradication therapy routinely. However, no confirmation of eradication is sought. Patients who have MRSA colonisation pre-operatively, in our study had a significantly increased risk of PJI, when compared to negative patients. We would recommend establishing true eradication after treatment prior to arthroplasty.

Key Words: Hip; Knee; Prosthetic joint infection

Core Tip: Retesting to ascertain true eradication of methicillin-resistant staphylococcus aureus (MRSA) prior to arthroplasty is essential. Without this, eradication treatment success remains undetermined with the resultant increased incidence of MRSA prosthetic joint infection and associated morbidity and mortality with revision surgery.

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INTRODUCTION

Total joint arthroplasty (TJA) of the hip and knee are the two most commonly performed orthopaedic procedures. Due to an aging population, the numbers of patients undergoing TJA is increasing yearly as shown in the National Joint Registry reports[1]. Prosthetic joint infection (PJI) after TJA is reported in 1%-2% of patients[2]. Revision arthroplasty has significantly higher complication rates with infection rates reported over 20%. PJI has increased morbidity and mortality for patients and increased associated healthcare costs due to treatment, length of stay and readmission [2]. PJI was defined by adaptation of the Musculoskeletal Infection Society criteria a described by Parvizi *et al*[3] Major and minor criteria were used[3]. In our institution inflammatory markers are taken (C-reactive protein and erythrocyte sedimentation rate) and aspiration of the joint are routinely performed and observation for a sinus tract. We do not perform synovial tests or alpha-defensin.

Depending on microbial virulence, PJI can manifest either early (within the first few weeks after implantation) or with a delay (typically within 3 mo and 3 years). Early infections manifest with clear local and systemic signs of inflammation and are predominately high virulence organisms (*e.g.* Staphylococcus aureus, enterococcus and streptococcus). Delayed infections usually present insidiously with symptoms to suggest failing implants such as joint pain and loosening. Low virulence organisms often responsible such as coagulase negative staphylococci or cutibacterium species[4].

All prosthetic joints remain susceptible to haematogenous seeding from a distant primary focus during their entire indwelling time[2]. High vascularity of periprosthetic tissue exposes the prosthesis to the highest risk of haematogenous infection in the first years after implantation. Patients often present with acute onset of clinical symptoms after a painless post-operative period[5]. The risk after bacteraemia with S. aureus is reported up to 34%[6]. The most commonly isolated organism in PJI after TJA is staphylococcus aureus. Present in the anterior nares, 25%-30% of the population are colonized at any given time. Carriers are at higher risk for surgical site infection (SSI) after invasive medical or surgical procedures. It has been demonstrated in the literature that carriers are 2 to 9 times higher to have a SSI[7]. Strains of methicillin-resistant staphylococcus aureus (MRSA) are much lower, 1% of the population with a higher preponderance for the elderly, immune-compromised or those with multiple co-morbidities. It has been shown that 85% of SSIs can be traced to endogenous colonisation of the patient[7].

The centers of disease control recognised nasal colonisation as a risk factor for SSI [8]. As a result there has been a focus on pre-operative screening and decolonisation prior to the patient undergoing surgery. Most strategies to decrease the incidence of SSIs have focused on timely antibiotic administration, optimising patients co-morbidities and nutrition, minimising surgical wound contamination in the operating theatre by using isolation suits and reduced personnel in the theatre suite.

The purpose of this study are to (1) Identify deep wound infection (PJI) rates in patients who are colonised MRSA positive compared with those who are not colonised; and (2) Long term clinical and radiological outcomes.

Ethical approval was not required for this study.

MATERIALS AND METHODS

This study is a retrospective analysis of elective primary total hip and total knee arthroplasty procedures done at our institution from December 2009 to December 2019. Patients were identified from a prospectively collected database and cross-referenced with the hospital database using procedural codes. The policy at our institution is to screen for MRSA using (culture) swabs in surgical pre-operative assessment when the patient is listed for elective surgery. Those patients identified as colonised with MRSA are contacted and instructed to undergo self-administered standard protocol decolonisation eradication therapy. This consists of prontoderm® nasal spray (Braun) and octenisan® antimicrobial wash (Schulke) to be used 5 d prior to and finishing on the morning of surgery. The patients are not retested following treatment.

The microbiology data of all these patients was reviewed, which confirmed the preoperatively diagnosed MRSA colonised patients. Detailed review of the medical records of these patients was undertaken to determine risk factors, eradication prophylaxis and perioperative antibiotics and outcomes.

Indication for surgery, operating consultant, co-morbities, age and complications including infection and revision were recorded for all patients. A control group was generated using patients undergoing the same elective arthroplasty procedure by the same consultant, within a 6 mo time period. Patients were matched on a 2 to 1 basis of MRSA negative to positive by comparable age (within 5 years) and same co-morbidities to make the groups representative of each other rather than using all the arthroplasty patients. To reduce selection bias, patients in the non-MRSA cohort were selected by operative date closest to the operative date of the MRSA positive patient, surgeon and co-morbidities selected.

Antibiotic prophylaxis for primary arthroplasty patients is teicoplanin 1.2 g intravenous on induction if the patient had tested positive for MRSA colonisation. Standard protocol is a stat dose of cefuroxime 1.5 g intravenous on induction and no further antibiotics.

At pre-operative assessment patients have a health screen, observation parameters are taken and blood tests are performed to identify any abnormalities that require addressing prior to surgery and an electrocardiogram is performed. Patients provide a urine sample for analysis at pre-operative assessment and are treated if required.

Patient outcomes are recorded for SSI, organisms, complications, revision procedures undertaken and eventual outcome.

RESULTS

Between January 2009 and December 2019, 3166 total knee arthroplasty and 2738 hip athroplasty procedures were performed.

For the purpose of this study, we used matched analysis with a ratio of 2 MRSA negative patients to 1 colonised MRSA positive patient.

The total number of MRSA negative patients was 3124 total knee replacements (TKRs) and 2706 total hip replacements (THRs). Combining positive MRSA colonised and negative patients, MRSA colonisation was observed in 74 patients (32 hip, 42 knee) with a colonisation rate of 1.25%.

All 74 patients were issued with decolonisation treatment to be utilised for the 5 d prior to surgery; however, no patients were retested prior to their surgery.

There were 42 MRSA colonised positive TKR patients matched based on surgeon, age, co-morbidities with 84 MRSA negative patients. The average age was 69.3 years (range 54-83). The average follow up was 4.78 years (range 1-10). Table 1 outlines the

Table 1 Total knee replacement–demographics

	MRSA negative	MRSA positive
Mean age (yr)	70.2	69.3
Follow up (yr)	4.88	4.78
Total no. Patients	84	42
Male, *n* (%)	38	19
Female, *n* (%)	46	23

MRSA: Methicillin-resistant staphylococcus aureus.

demographics of this group.

Our cohort of colonised patients self-administered their decolonisation therapy and all lived at home. In the MRSA colonised positive TKR group, 7 patients were diabetic, 21 patients had pre-existing cardiac disease and were on anticoagulation, 12 patients had chronic respiratory conditions, 10 has inflammatory conditions (on steroids/methotrexate) and 2 patients had a malignancy.

Of 3 out of 42 TKR patients developed MRSA PJI requiring revision surgery within 1 year of their index procedure, giving an incidence of 7%. 2 out of 3 patients underwent two-stage revision and 1 patient underwent debridement, antibiotics and implant retention (DAIR). Mean follow up from revision surgery is 4 years and all patients are clinically and radiologically infection free. Patient one was diabetic and had renal disease, patient two was diabetic and had respiratory disease and malignancy and patient three was on steroid for inflammatory disease and had pre-existing ischaemic heart disease and used anticoagulation.

The MRSA negative TKR control group, which consisted of 84 patients, matched by surgeon and comorbidities as described above had an average age of 70.2 years (range 50-82). Follow up average 4.8 years (range 1-10). Of the 84 patients there was 1 patient with diagnosed with an e. coli PJI requiring a DAIR. This patient had chronic kidney disease. The patient is clinically and radiologically infection free at 6 years. The incidence of PJI was 1.2%.

There were 32 MRSA positive THR patients matched based on surgeon, age, co-morbidities with 64 MRSA negative patients. The average age was 67.6 (range 54-94). The average follow up was 5.1 years (range 1-10 years). Table 2 outlines the demographics of this group.

In the MRSA positive THR group, 4 patients were diabetic, 12 had cardiac conditions and were on anticoagulation, 7 had chronic respiratory conditions, 2 had inflammatory conditions (on steroids/methotrexate) and 4 had malignancy.

Out of the 32 patients, 4 developed MRSA PJI requiring revision surgery within 1 year of their index procedure giving an incidence of 12.5%. Three patients underwent two-stage revision and 1 underwent single stage with prolonged antibiotics. Patient one had diabetes and was on steroid, patient two had chronic kidney disease and ischemic heart disease and used anticoagulation, patient three had malignancy and was on steroid and patient four was diabetic with chronic renal disease and respiratory disease. Mean follow up from revision surgery is 5 years and all patients are infection free clinically and radiologically.

The MRSA negative THR control group, which consisted of 64 patients, matched by surgeon and co-morbidities as described above had an average age of 67.8 years (range 50-94). Follow up average 6 years (range 1-10 years). Of the 64 patients, there have been no incidences of PJI during this follow up period.

The results of the incidence of PJI are summarised in Table 3.

All PJI s were methicillin resistant, there were no methicillin sensitive staphylococcus organisms.

DISCUSSION

This study demonstrates a higher incidence of methicillin resistant staphylococcus aureus infection in patients who have been previously colonised in elective hip and knee arthroplasty. The results of this study show that at our institution there is a 1.25% MRSA colonisation rate in patients undergoing total hip and knee arthroplasty. This is

Table 2 Total hip replacement-demographics

	MRSA negative	MRSA positive
Mean age (yr)	67.8	67.7
Follow up (yr)	6	5.1
Total no. Patients	64	32
Male, *n* (%)	16	9
Female, *n* (%)	48	23

MRSA: Methicillin-resistant staphylococcus aureus.

Table 3 The results of the incidence of prosthetic joint infection

	MRSA negative	MRSA positive
Total knee replacement	1/84 (1.2%)	3/ 42 (7%)
Total hip replacement	0/64	4/32 (12.5%)

MRSA: Methicillin-resistant staphylococcus aureus.

comparable with studies in the literature demonstrating rates by Tandon *et al*[8] of 1.3%.

PJI after THR and TKR are associated with substantial patient morbidity and economic burden to the healthcare system. Many approaches and resources have focused on infection reduction methods. A targeted strategy is to identify patients who are MRSA positive and attempt to decolonise them, as MRSA is a risk factor for PJI. There are limited data on the success of decolonisation protocols and their subsequent effect on PJI. A 69% reduction in the prevalence of PJI has been demonstrated with screening and eradication[9,10].

Kim *et al*[11] include the single largest cohort of orthopaedic patients[11]. They found a decrease in surgical site and PJI in their treatment group with compared with historical controls and MRSA negative patients.

Literature has shown mixed results on the role of decolonisation of MRSA carriers and is effect on carrier rates and PJI in elective orthopaedic surgery. This in part depends on whether patients comply with treatment.

Shukla *et al*[12] identified 2.5 times higher risk than the normal population of developing postoperative MRSA SSI and PJI in carriers in an orthopaedic trauma unit [12].

In a prospective observational study of elective hip and knee replacements, One study showed no postoperative cases of staphylococcus aureus SSI at 1 year follow up in the group who had screening and successful decolonisation treatment. 3.5% infection rate was noted in the concurrent control group[12]. This is in keeping with the results we obtained suggesting retesting and further eradication treatment contributes towards the prevention of PJI.

A weakness of this study is that it is a retrospective analysis. A weakness of our protocol is that patients are issued the treatment and it is used up to and finishing on the day of surgery however, there is no assurance that the patients comply. There is no re-test to ensure eradication of MRSA and no opportunity for further eradication treatment if the patient is still positive.

Kim *et al*[11] have shown that there is 22% treatment failure rate with MRSA decolonisation nasal and soap treatment. They hypothesise that the factors associated with treatment failure are non-compliance and the presence of resistant organisms. This supports the need for screening post treatment to ensure eradication and address any modifiable risk factors for PJI. This also has an impact on consent and quantifying risk for patients.

The balance is in favour of screening, eradication therapy and re-screening to reduce the risk of PJI, which is a costly complication following elective surgery. The financial implications of treating MRSA PJI are immense. Current revision practice is changing in the United Kingdom[13]. Pathways for centralisation and regionalisation of revision services are being created. Nathwani[14] studied the impact on separate elements

–hospital, patient and society[14]. Bozic and Ries[15] showed that costs associated with revision arthroplasty due to infection are 2.8 times higher than aseptic revision and 4.8 times higher than primary arthroplasty[15]. Revisions due to infection were associated with 3 times the number of repeat hospitalisations and outpatient visits and nearly 4 times the number of operations with approximately 22 d in hospital when compared with aseptic revisions. Given the current protocol–12.5% of THR and 7% of TKRs becomes infected with MRSA, which generates complications and carries with it the financial implications.

Screening for MRSA is inexpensive (500 rupees for a screening test). Although this study did not investigate the cost analysis of MRSA PJI, VandenBergh *et al*[16] determined the cost-effectiveness of perioperative mupirocin (Bactroban; GlaxoSmithKline, Middlesex, United Kingdom) in cardiothoracic surgery[16]. They suggested that due to the immense cost of a PJI, an effective intervention with a relatively cheap agent like mupirocin is likely to be cost-effective as a risk reduction of 1% would be cost-effective already. Also the side effect profile of mupirocin is negligible. This has to be balanced with the risk of recurrence and resistance to standard treatment, which is a recognised complication[16,17]. Young and Winston[18] estimated the cost effectiveness of a screen and treat strategy. Based on a carriage rate of 31% and a risk reduction of 48%, a saving of approximately $1.5 million *per* 10000 patients screened was predicted. In the United States of America for example where 30 million surgical procedures are performed annually, extrapolation results in a saving of $4.5 billion (£3.5 billion). This would reduce the revision burden in the healthcare economy and also patient morbidity.

We acknowledge that this is a retrospective study and therefore has limitations however we aimed to reduce bias by using continuous patients in the non-MRSA group to match the MRSA positive patients by demographic and co-morbidities.

CONCLUSION

In conclusion, our retrospective study has demonstrated that there is a significantly higher risk of MRSA PJI in patients who have had MRSA colonisation undergoing total hip and knee replacements. We advocate rescreening of patients and further eradication treatment. If the patient fails to respond and remains MRSA positive then this can form the basis of discussion during the consent process for joint arthroplasty. Screening and treatment for MRSA is cheap and effective when used which in comparison to the morbidity and cost associated with MRSA PJI.

ARTICLE HIGHLIGHTS

Research background

Difference in screening between two hospital trust which were merging.

Research motivation

Developing a uniform policy for screening and managing methicillin-resistant staphylococcus aureus (MRSA) prosthetic joint infection (PJI).

Research objectives

Eradication therapy is not universally effective. The reasons for this are multifactorial including dose strength and compliance.

Research methods

All patients who underwent total hip and knee arthroplasty between December 2009 and December 2019 were identified. Patients who were also identified as positive for MRSA in the preoperative evaluation. After recording the confirmation of the eradication treatment prescription, all the processes were reviewed retrospectively. The results of each MRSA-positive patient were compared with the results of two MRSA-negative patients who had the same consultant, were of the same age, and had the same surgery.

Research results

Screening identified 42 knee and 32 hip arthroplasty patients as MRSA positive, 84

MRSA negative knee and 64 hip patients were reviewed. Patients were matched with medical co-morbidities in each group. Mean follow up was 5 years. PJI was identified in 4/32 (12.5%) of total hip replacements MRSA positive and 3/42 (7%) of total knee replacements patients. All patients had PJI within one year of surgery.

Research conclusions

MRSA positive patients are given eradication therapy routinely. However, no confirmation of eradication is sought. Patients who have MRSA colonisation pre-operatively, in our study had a significantly increased risk of PJI, when compared to negative patients. We would recommend establishing true eradication after treatment prior to arthroplasty.

Research perspectives

Further research needs to be performed into eradication therapy and strategy and also for those patients who do not respond to eradication therapy.

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ORIGINAL ARTICLE

Retrospective Study

Reliability of a simple fluoroscopic image to assess leg length discrepancy during direct anterior approach total hip arthroplasty

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Abstract

BACKGROUND

Direct anterior approach (DAA) total hip arthroplasty (THA) in a supine position provides a unique opportunity to assess leg length discrepancy (LLD) intra-operatively with fluoroscopy. Reported fluoroscopic techniques are useful but are generally complicated or costly. Despite the use of multiple techniques for leg length assessment, LLD continues to be a major post-operative source of patient dissatisfaction further emphasizing the importance of near-anatomic restoration. The utility of an alternative direct measurement of LLD on an intra-operative fluoroscopic pelvic image during DAA THA has not been reported.

AIM

To determine the reliability of a novel simple intra-operative measurement of LLD using a parallel line technique on a single fluoroscopic digital image of the pelvis.

METHODS

One hundred and seventy-one patients who underwent DAA THA were included for analysis. Intra-operative fluoroscopic and post-operative anterior-posterior radiographs were imported to TraumaCad and calibrated for LLD measurement. LLD was measured on each image using the right-left hip differences in lesser trochanter to pelvic reference line distances. Pelvic reference points included the teardrops and ischia. Fluoroscopic LLD was compared to the gold-standard measurement of LLD measured on a post-operative radiograph.

RESULTS

Mean absolute difference in teardrop referenced LLD between fluoroscopic and post-operative radiographs was 2.17 mm and based on the ischia mean absolute difference was 2.63 mm. Linear regression of fluoroscopic and post-operative

disclose.

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radiograph LLD based on teardrop and ischia LLD found r^2 values of 0.57 and 0.84, respectively. Mean absolute difference between fluoroscopic and post-operative x-ray LLD was within 5 mm in 95% of cases regardless of pelvic reference.

CONCLUSION

This study demonstrates that a single fluoroscopic view obtained during DAA THA for leg length assessment is clinically useful.

Key Words: Leg-length discrepancy; Total hip arthroplasty; Intra-operative fluoroscopy; Direct anterior approach; Limb asymmetry

Core Tip: The direct anterior approach (DAA) for total hip arthroplasty (THA) has grown in popularity among Orthopaedic Surgeons in recent years. Despite the growth in this approach for THA, leg length discrepancy continues to be a major source of post-arthroplasty dissatisfaction in patients. Here we demonstrate that a single intra-operative fluoroscopic image for leg length assessment has clinical significance among patients undergoing DAA THA.

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INTRODUCTION

Leg length discrepancy (LLD) is a significant source of patient dissatisfaction after total hip arthroplasty (THA). An error in achieving acceptable leg length may manifest as discomfort, nerve palsy, pelvic obliquity, compensatory lumbar scoliosis, or result in need for revision surgery[1-4]. To minimize LLD after THA, multiple techniques have been developed for intra-operative assessment of leg length. In a survey conducted by the British Hip Society, surgeons reported utilizing a median of five techniques during THA to estimate LLD[5].

The direct anterior approach (DAA) for THA with a patient in a supine position has recently grown in popularity and presents an opportunity to use fluoroscopy intra-operatively to assess component position, size, femoral offset and LLD. Use of a specialized traction table facilitates this procedure but may also increase reliance on fluoroscopically based assessment of LLD[6,7]. Reported techniques to assess LLD intra-operatively with fluoroscopy during DAA THA include printed or virtual image overlays, concurrent imaging of a radio-opaque linear marker, and computer assisted image analysis techniques to correct for image distortion[5,8]. These previously reported fluoroscopic techniques can add time, complexity, radiation exposure, or significant cost to the procedure.

The aim of this study is to determine the reliability of an alternative novel simple intra-operative measurement of LLD using a parallel line technique on a single fluoroscopic digital image of the pelvis during DAA THA.

MATERIALS AND METHODS

Subjects

A retrospective study was performed of DAA THA's performed by two fellowship trained adult reconstruction surgeons between January 1, 2019 and December 31, 2019. Over this period, 182 patients were identified as eligible for inclusion in this study. Eligibility criteria included THA done by DAA on a Hana table, an adequate quality

appropriate intra-operative fluoroscopic image saved, and a standard post-operative pelvic radiograph available. The fluoroscopic image had to be a centered view of the pelvis such that both lesser trochanters were visible with all final THA components in place including the final femoral head. This study was approved by our institutional review board.

LLD Intra-operative measurement

During each DAA THA, LLD was assessed after trial components were in place using a single view of the pelvis obtained with an 18-inch OEC image intensifier (GE Healthcare). The image was typically performed with each leg externally rotated 20 degrees to display the profiles of the lesser trochanters. Once an adequately centered image of the pelvis was obtained, a line was drawn between the radiographic teardrops utilizing the OEC digital measurement tool. Then a second line was drawn through the prominence of the lesser trochanters. The two lines were then visually inspected to determine how near they were to parallel. Adjustments to trial components were made as necessary and fluoroscopic measurements repeated until satisfactory leg length was achieved. Other factors considered in determining leg length included soft tissue tension determined with a "shuck test" and correlation of intra-operative images with the pre-operative template. After the final components were placed, a centered fluoroscopic view of the pelvis was saved. This was the same view of the pelvis used to assess leg length during component trialing. Finally, after surgical closure, an anterior-posterior (AP) pelvis radiograph was obtained in the OR with the patient supine on a hospital bed.

LLD Measurement technique

Fluoroscopic and AP radiographs each with the final components in position were imported to TraumaCad for analysis by two independent observers (Nelms NJ and Caus S). Fluoroscopic and AP radiographs were calibrated manually to adjust for image magnification by matching the circular shape of the THA femoral head to the surgical component size in millimeters as recorded in the subject's operative note. The digital leg length comparison tool within TraumaCad was utilized to measure LLD based on teardrop and ischial pelvic reference lines (Figures 1 and 2). From each reference line a perpendicular distance was measured to the medial prominence of the right and left lesser trochanters. The left hip distance was subtracted from the right hip on both the fluoroscopic and x-ray images so that a positive or negative value represented which leg was longer. A positive value indicated a longer right leg, conversely a negative value indicated a shorter right leg. This was important to be able to define the relative LLD by side in case fluoroscopy and x-ray conflicted as to which leg was longer.

After all measurements were independently completed by two observers, cases with an inter-observer disagreement in LLD measurement of greater than 5 mm in either the intra-operative fluoroscopic images or anterior posterior radiographs were flagged for repeat measurement[8]. Repeat measurements were again performed independently to determine if the two observers could agree within 5 mm on LLD measurement. Of the initial 182 cases there were 25 cases for which two observers could not agree within 5 mm on LLD and a second independent measurement was completed. Of these 25 cases, the observers were unable to agree within 5 mm on the measured LLD in 11 cases. These 11 cases were removed from further analysis because the measurement inconsistency was attributed to poor image quality or difficult to define radiographic landmarks. This left a final count of 171 subjects for statistical analysis.

Statistical methods

The mean, standard deviation, and maximum LLD measured on x-ray and intra-operative fluoroscopy with teardrop and ischium references were calculated (n = 171). The difference in x-ray and fluoroscopic LLD was calculated by subtraction and the absolute value taken. The mean absolute difference in x-ray and fluoroscopic LLD measurements were compared between the teardrop and ischial reference points using a paired t-test. Linear regression was performed to determine the relationship between LLD measured with fluoroscopy *vs* x-ray for both teardrop and ischial references.

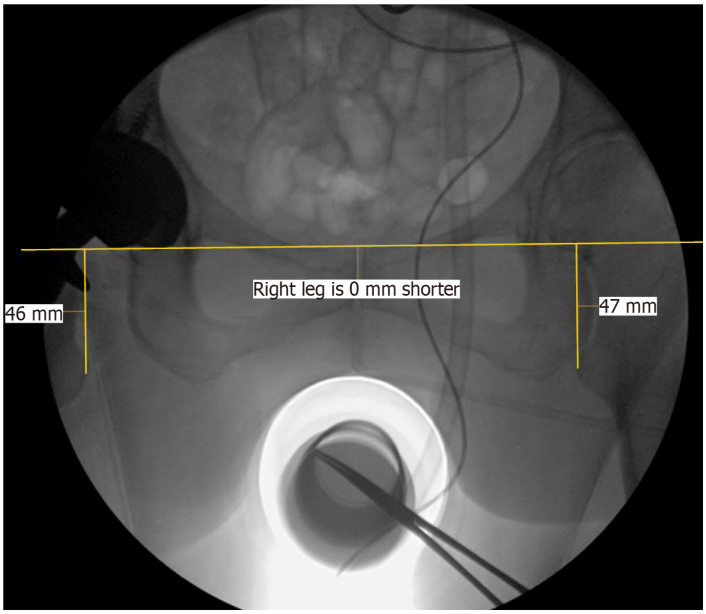

Figure 1 Intra-operative fluoroscopy image capture. Representative image of observer obtained leg length discrepancy measurements on a saved intra-operative fluoroscopic view of the pelvis. Image capture was performed by the OEC image intensifier intra-operatively as described. Shown is a line drawn through bilateral radiographic teardrops with perpendicular lines to the medial prominence of bilateral lesser trochanters.

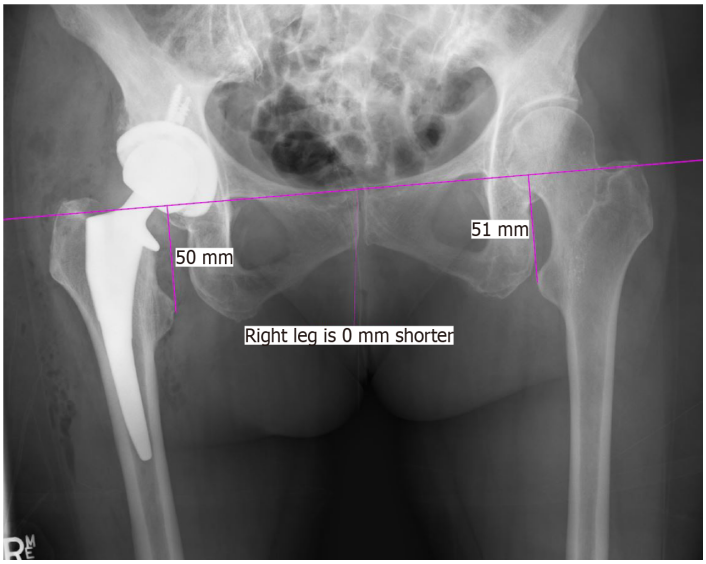

Figure 2 Post-operative x-ray image capture. Representative image of observer obtained leg length discrepancy measurements on a corresponding post-operative anterior-posterior x-ray of the pelvis. Single line drawn through bilateral radiographic teardrops with perpendicular lines to the medial prominence of bilateral lesser trochanters.

RESULTS

Overall mean LLD measured by the teardrops with fluoroscopy was 2.89 mm (SD = 2.07) and by x-ray 2.45 mm (SD = 2.11). Mean LLD measured by the ischia with fluoroscopy was 3.93 mm (SD = 2.95) and by x-ray 3.27 mm (SD = 3.01) (Table 1). Measurements with both teardrop and ischial landmarks demonstrated a statistically significant difference between the mean observed LLD with fluoroscopy compared with the gold standard x-ray (P = 0.007, P < 0.001). This difference included a bias toward overestimation of LLD by fluoroscopy especially when using an ischial pelvic reference.

Based on the teardrops, the mean absolute difference in LLD between fluoroscopic and x-ray was 2.17 mm (SD = 1.7). Referencing the ischia, the mean absolute difference in fluoroscopic and x-ray LLD was 2.63 mm (SD = 1.64) (Table 2). There was a statistically significant difference between the ischial and teardrop reference measurements

Table 1 Comparison of fluoroscopic and x-ray leg length discrepancy

	Fluoroscopic				X-ray				
	Mean	SD	Min	Max	Mean	SD	Min	Max	*P* value
LLD by Teardrops	2.89	2.07	0.0	11.0	2.45	2.11	0.0	12.5	0.007
LLD by Ischiums	3.93	2.95	0.0	16.0	3.27	3.01	0.0	15.5	< 0.001

Summary descriptive statistics including mean, SD, minimum and maximum values for leg length discrepancy as obtained by two independent observers. LLD: Leg length discrepancy.

Table 2 Absolute difference in leg length discrepancy

	Teardrop				Ischium				
	Mean	SD	Min	Max	Mean	SD	Min	Max	*P* value
Fluoro-x-ray difference	2.17	1.7	0.0	9.50	2.63	1.64	0.0	9.5	< 0.001

Absolute difference in mean leg length discrepancy between fluoroscopy and x-ray obtained measurements using radiographic teardrop or ischium reference points. All measurements were obtained by two independent observers.

of LLD, with a larger discrepancy between x-ray and fluoroscopic LLD observed using the ischial reference points ($P < 0.001$).

Linear regression of fluoroscopic and x-ray measurements based on the teardrops and ischia found r^2 values of 0.57 and 0.84, respectively (Figure 3). Despite the observed statistical differences, the absolute difference in LLD between fluoroscopic and x-ray measurements with either landmark was within 5 mm in 95% of cases. In only 1.8% of cases were both teardrop and ischial referenced fluoroscopic LLD measurements greater than 5 mm different from the gold standard x-ray LLD. Furthermore, we achieved a LLD of < 5 mm in 88.9% of patients and of < 10 mm in 98.8% of patients as assessed on a gold-standard post-operative x-ray of the pelvis.

DISCUSSION

Direct measurement of LLD on a single fluoroscopic view of the pelvis during DAA THA provided a clinically reasonable estimation of LLD in most of our cases. Using the teardrops for pelvic reference resulted in the closest association between intra-operative fluoroscopic and post-operative x-ray LLD. Although an ischial reference had a stronger linear correlation for LLD than the teardrops, there was a greater systematic overestimation of LLD when measuring from the ischia with fluoroscopy. Nonetheless, the difference between fluoroscopic and x-ray assessment of LLD using either teardrop or ischial landmarks was typically relatively small from a clinical standpoint. The fluoroscopic measurements with either pelvic landmark were in agreement with post-operative x-ray LLD measurements by a margin of 5 mm in 95% of cases. This degree of accuracy is useful because up to a 5 mm LLD is widely considered clinically insignificant and even up to and slightly beyond 10 mm may not be clinically meaningful[8-11]. For comparison, this simple technique appears more accurate than intra-operative x-ray assessment of LLD with patients in a lateral position. One study found that taking an x-ray with a patient in a lateral position resulted in 20% of cases displaying an intra-operative LLD measurement more than 5 mm different from that measured on a post-operative supine AP pelvis x-ray[12]. It also remains unclear as to the amount of post-operative LLD that can be tolerated without impacting patient function or satisfaction post-operatively[11,13]. Some studies have shown no clinically significant detrimental outcomes in LLDs approaching or even greater than 10 mm, while others have reported significantly worse OHS scores in patients able to perceive any LLD post-operatively[14,15]. Despite evidence that some LLD can be well tolerated after THA, restoration of near anatomic leg length is an important goal. Minimizing LLD after THA is critical because patient perceived post-operative LLD can result in post-operative joint pain, early revision arthroplasty or litigation[16].

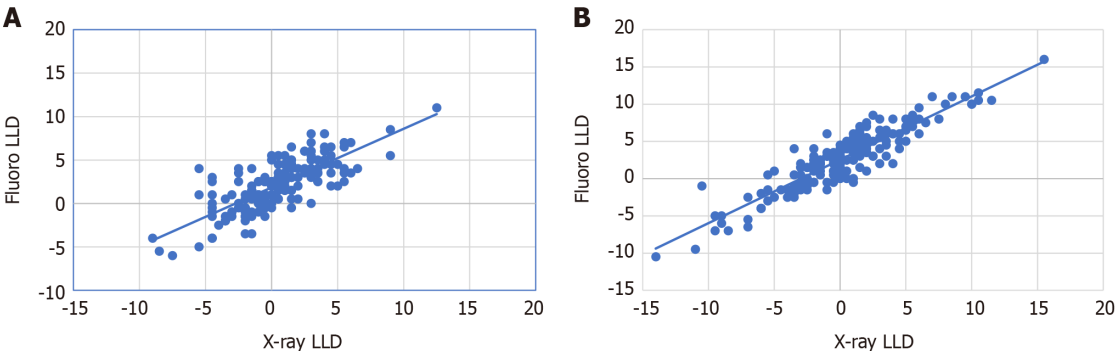

Figure 3 Measured leg length discrepancy. A: Measured leg length discrepancy based on teardrop reference point. Comparison showing mean x-ray leg length discrepancy (LLD) and fluoroscopic LLD using radiographic teardrop reference points as measured by two independent observers. Corresponding linear regression r^2 value of 0.56; B: Measured leg length discrepancy (LLD) based on ischium reference point. Comparison showing mean x-ray and fluoroscopic LLD using ischium references points as measured by two independent observers. Corresponding linear regression r^2 value of 0.87. LLD: Leg length discrepancy.

While there is growing clinical evidence in support of a DAA for THA, there is not a gold-standard technique for intra-operative LLD assessment[1,7,13,17]. Previously reported fluoroscopic techniques can add time, complexity, or cost[18-21]. One common technique is overlaying traced printed fluoroscopic images of the contralateral hip, or of the operative hip taken at the start of the procedure, with an image of the operative hip with trial implants in place. This relies heavily on accurate tracing and the surgeon may risk breaching sterility to draw on the images themselves. Also access to a fluoroscopic printer and the cost of printing supplies may prevent this from being universally available to surgeons. Another simple technique is to lay a transverse metal rod over the patient while images are taken until the rod is positioned in a way to estimate a relative LLD. Unfortunately, this usually requires multiple fluoroscopic images to achieve appropriate position of the rod. More specialized computer assisted techniques can partially automate LLD comparisons by allowing virtual image overlays, image stitching, and image correction for distortion. All of these commercial products based on advanced technology add cost.

The benefits of fluoroscopy during DAA THA are technique dependent, but fluoroscopy can provide an intra-operative assessment of leg length, offset, component size, and implant position[22-25]. Interestingly, Bingham *et al*[26] found no significant difference in post-operative LLD with or without use of intra-operative fluoroscopy when DAA THA was performed by very experienced surgeons with specific techniques which differ from ours. They achieved an impressive mean post-operative LLD of only 1.1 mm with fluoroscopy and 0.8 mm without. However, all DAA THA's performed in that study without fluoroscopy were performed on a standard operating table with both legs draped to allow direct visual comparison of LLD. Potential benefits of DAA THA on a specialized traction table include improved surgical exposure and access for intra-operative fluoroscopy. Fluoroscopic assessment of LLD is particularly helpful when a specialized traction table is used for DAA THA because the patient's feet are placed in traction boots which prevents direct clinical comparison of LLD. Even the two most commonly used intra-operative fluoroscopic measurement techniques to minimize image distortion may not result in anatomic leg length restoration. Austin *et al*[8] reported an average LLD measured on final post-operative x-rays relative to the teardrops of 4.8 mm using fluoroscopic tracing and 4.4 mm using a transverse metal rod technique[8]. These values are similar but surprisingly greater than our comparable average post-operative LLD of 2.45 mm LLD on post-operative x-rays. Austin *et al*[8] also reported that of the two fluoroscopic techniques, even the most accurate resulted in a final LLD of < 5 mm in only 59.6% of patients but of < 10 mm in 95.3%, which contrasts with our rates of 88.9% and 98.8%, respectively.

We found the assessment of LLD on a single fluoroscopic view of the pelvis to be a useful and simple technique of moderate accuracy. We suspect that by drawing lines through the teardrops or ischiums and comparing this to a line through the lesser trochanters is effective because image distortion is partially cancelled by such effects on both lines. In our clinical practice, we have achieved success by combining this parallel line fluoroscopic estimation of LLD with careful pre-operative templating and assessment of THA tension with a "shuck test" using a bone hook to feel the force necessary to distract the hip. We believe it is important to have more than one technique to estimate LLD intra-operatively. This study shows the clinical usefulness of fluoroscopy during THA on a traction table using a very simple technique.

Our study does have several limitations. In 6% of cases, our independent observers could not agree within 5 mm on the LLD measurements. This demonstrates some subjectivity in identifying radiographic landmarks despite efforts to establish consistency in these measurements between observers prior to beginning this study. We believe it was reasonable to exclude these cases so that the effects of subjective image interpretation can be diminished. We acknowledge that any measurement of LLD based on imaging of the pelvis alone may not represent discrepancy in overall leg lengths. True leg length comparison requires clinical evaluation or long leg x-rays, each of which also have their own intrinsic inaccuracies. Even so we demonstrate that combining this fluoroscopic technique with careful pre-operative templating and assessment of joint laxity resulted in minimal average post-operative LLD apparent on x-ray. And this demonstrates that the effects of intra-operative fluoroscopic image distortion do not preclude the clinical usefulness of this simple technique. Our findings are in contrast to the degree of fluoroscopic distortion observed by Carlson *et al*[27]. This could be because there was less electromagnetic interference in our operating suites or the use of a different model of C-arm.

CONCLUSION

An intra-operative estimation of LLD of moderate accuracy can be achieved during DAA THA by assessment of a simple AP fluoroscopic image. Assessment of LLD with this technique is achieved by comparing how parallel a digital line drawn through the radiographic teardrops is to a line drawn between corresponding points on the lesser trochanters.

ARTICLE HIGHLIGHTS

Research background

The direct anterior approach (DAA) in total hip arthroplasty (THA) with a patient in the supine position has gained popularity in recent years and provides an opportunity for intra-operative fluoroscopy for assessment of leg length discrepancy (LLD), as well as other intra-operative parameters of interest to Orthopaedic surgeons. LLD remains a significant source of patient dissatisfaction post-arthroplasty and we recognize an opportunity to evaluate the reliability of a novel simple parallel line technique on a single intra-operative fluoroscopic image.

Research motivation

The increase in popularity of the DAA THA combined with the opportunity to utilize intra-operative fluoroscopy has made surgeons wonder about the reliability of fluoroscopy in the clinical setting. We aimed to provide an assessment of this based on a simple parallel line technique on a single intra-operative fluoroscopic image of the pelvis once final arthroplasty components had been positioned.

Research objectives

The primary objective of this study was to understand the accuracy and reliability of a novel simple intra-operative fluoroscopy LLD assessment technique as compared to the standard post-operative x-ray.

Research methods

171 intra-operative fluoroscopic and anterior-posterior (AP) radiographs with final components in position were imported to TraumaCad for observer LLD analysis. LLD measurements were taken on each image utilizing right-left hip differences in lesser trochanters to two separate pelvic reference points. These were either the radiographic teardrops or ischia. Fluoroscopic LLD measurements were compared to the standard measurement of LLD on a post-operative AP radiograph.

Research results

Mean absolute difference between fluoroscopic and post-operative x-ray LLD was within 5 mm in 95% of cases regardless of pelvic reference point. Utilizing the simple parallel line technique on a single fluoroscopic image of the pelvis we achieved an LLD of < 5 mm in 88.9% of subjects and of < 10 mm in 98.8% of subjects as measured

on the gold-standard post-operative x-ray.

Research conclusions

We demonstrate moderate accuracy in estimation of LLD intra-operatively by assessment of a simple AP fluoroscopic image, specifically with a novel simple parallel line technique. This technique is performed by visually comparing how parallel a digital line drawn trough the radiographic teardrops is to a line drawn between corresponding points on the lesser trochanters. We acknowledge the importance of continuing to have more than one technique intra-operatively to most accurately estimate LLD.

Research perspectives

Our study adds to a body of research investigating the clinical usefulness of intra-operative fluoroscopy in the DAA THA, specifically we demonstrate that this technique has clinical benefit in our cohort of patients. Not only do we hope this adds to the body of research and clinical understanding of fluoroscopy, but also hope it can be utilized as an additional reliable technique for assessment of intra-operative LLD.

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ORIGINAL ARTICLE

Retrospective Study

Anthropometric method for estimating component sizes in total hip arthroplasty

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Abstract

BACKGROUND

Preoperative templating is essential in total hip arthroplasty (THA) as it not only helps to facilitate the correct implant type and size but also determines the post-operative biomechanics. Templating is also increasingly important from a medico-legal perspective and recommended in the British Orthopaedic Association Guide to Good Practice. Although templating has become increasingly digitised, there are no simple anthropometric models to predict implant sizes in the absence of digital methods.

AIM

To assess the accuracy of using an easily obtainable measurement (shoe size) to predict component sizes in THA compared with digital templating.

METHODS

Digital radiographs from a cohort of 102 patients (40 male, 62 female) who had undergone uncemented or hybrid THA at a single centre were retrospectively templated to desired cup and stem sizes using TraumaCad®. We compared the

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templated size to the actual size of the implant and assessed if there was any correlation with the patient's shoe size.

RESULTS

Statistically significant positive correlations were observed between: shoe size and templated cup size ($\rho = 0.92$, $P < 0.001$); shoe size with implanted cup size ($\rho = 0.71$, $P < 0.001$); shoe size and templated stem size ($\rho = 0.87$, $P < 0.001$); and shoe size with implanted stem size ($\rho = 0.57$, $P < 0.001$). Templated and implanted acetabular cup sizes were positively correlated ($\rho = 0.76$, $P < 0.001$) and were exact in 43.1% cases; 80.4% of implanted cup sizes were within 1 size (+/- 2 mm) of the template and 100% within 2 sizes (+/- 4 mm). Positive correlation was also demonstrated between templated and implanted femoral stem sizes ($\rho = 0.69$, $P < 0.001$) and were exact in 52.6% cases; 92.6% were within 1 size of the template and 98% within 2 sizes.

CONCLUSION

This study has shown there to be a significant positive correlation between shoe size and templated size. Anthropometric measurements are easily obtainable and can be used to predict uncemented component sizes in the absence of digital methods.

Key Words: Anthropometric; Digital templating; Hip; Preoperative planning; Total hip arthroplasty

Core Tip: Templating for component size in total hip arthroplasty is becoming increasingly digitised, which can be limited by cost and availability of software. There are no anthropometric models to predict component sizes in the absence of digital methods. We demonstrated significant positive correlations between a patient's shoe size and both their templated and implanted component sizes. Shoe size can reliably predict implant sizes in uncemented hip arthroplasty. In addition to helping the surgeon make a rapid estimation of implant size; this simple system can also assist purchasing departments to plan preoperative stock requirements without specialised software.

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INTRODUCTION

Accurate preoperative templating is an essential step in total hip arthroplasty (THA) and is recommended by the British Orthopaedic Association's Best Practice for Hip Arthroplasty[1]. Templating has proven to be effective in selecting the correct implant size, optimisation of biomechanics such as leg length discrepancy, centre of rotation and alignment. Furthermore, preoperative planning has been well documented to improve component stability, reduce the operative time and minimise wear due to implant malposition[2].

Alongside the widespread introduction of digital radiography throughout the United Kingdom, preoperative templating of THA has become increasingly digitised with several software products currently on the market. However these software packages may not be universally available and are dependent on the user's training and level of surgical experience[3]. Digital templating and computer-navigated surgery have been used to improve the quality and outcomes of THA however these methods can be expensive and may not be a feasible option for some departments.

Preoperative estimations of implant sizes may be useful for resource-scarce departments as it allows for better organisation of hospital funds by reducing the number of excess implants "on the shelf"[4]. Shoe size is an easily obtainable and cost-free anthropomorphic measurement, which is a reliable reflection of foot length, overall longitudinal growth and stature[5,6]. We propose preoperative shoe size as a simple measurement tool for predicting component sizes for primary uncemented THA. The aim of this study is to determine the accuracy of using this measurement as an estimator for acetabular cup and femoral stem sizes when compared with digitally templated sizes for the same hip.

MATERIALS AND METHODS

Patients

A retrospective, single-centre cohort study was performed for patients who had received primary uncemented or hybrid THA for osteoarthritis between October 2015 and October 2016. Patients were excluded if they had a body mass index (BMI) greater than 35; had undergone previous foot and ankle surgery; diagnosed with foot or ankle disease; noted a change in shoe size during adulthood or if they required a complex primary arthroplasty. Cemented components of hybrid THA were also excluded. A total of 102 acetabular cups and 95 femoral stems from 102 consecutive patients were included in the final analysis, comprising of 40 men and 62 women. The mean age of the study group was 69.9 ± 10.9 years (range 33-90) and mean BMI 32 ± 3.6 (range 20.2-39.0). All THAs were performed by a single surgeon and using a posterior approach to the hip. The uncemented components implanted were the POLAR R3 cup and POLARSTEM stem (Smith & Nephew, Memphis, TN, United States). Implant sizes were recorded along with the corresponding patient's standard United Kingdom shoe size at the time of surgery. Shoe sizes ranged from 3 to 11. Institutional Review Board approval was not required in accordance with the United Kingdom National Research Ethics Service guidance on the use of anonymised data collected retrospectively as part of routine clinical care.

Radiographs and templating

Preoperative anteroposterior (AP) digital pelvic radiographs were obtained for all patients using a standard protocol (Figure 1) with the feet internally rotated at 15 and the X-ray beam centered on the superior margin of the symphysis pubis[7]. All patient identifiers were removed from radiographs and replaced by unique sequential numbers before being imported into TraumaCad® (Brainlab, United States) for calibration and templating. Each component was digitally templated to a desired size in a manner as described by Bono[8], by two orthopaedic surgeons who were familiar with the software (Figure 2). A third examiner (senior surgeon) reviewed all size discrepancies and a final decision was achieved by consensus. All examiners were blinded to the actual size of the implanted components.

Statistical analysis

The Spearman's rank correlation coefficient (ρ) was used to assess the correlation between the patient's shoe size with: (1) Templated component size; and (2) Implanted component size; and if there was any difference between templated and implanted sizes. A P value of < 0.05 was considered to be statistically significant. Statistical analysis was performed with SPSS v22.0 (IBM, Armonk, NY, United States). By analyzing any observed relationships we intended to produce a table for estimating the component size from the patient's shoe size.

RESULTS

Statistically significant positive correlations were observed between: shoe size and templated cup size ($\rho = 0.92$, $P < 0.001$); shoe size with implanted cup size ($\rho = 0.71$, $P < 0.001$); shoe size and templated stem size ($\rho = 0.87$, $P < 0.001$); and shoe size with implanted stem size ($\rho = 0.57$, $P < 0.001$). Correlation coefficients based on gender subgroups are presented in Table 1. Templated and implanted acetabular cup sizes were exact in 43.1% cases, 80.4% of implanted cup sizes were within 1 size (+/- 2 mm) of the template and 100% were within 2 sizes (+/- 4 mm). Templated and implanted femoral stem sizes were exact in 52.6% cases, 92.6% were within 1 size of the template

Table 1 Subgroup correlation coefficients (Spearman's rank)

	Overall	*P* value	Male	*P* value	Female	*P* value
Shoe/templated cup	0.923	< 0.001[a]	0.782	< 0.001[a]	0.828	< 0.001[a]
Shoe/implanted cup	0.712	< 0.001[a]	0.007	0.964	0.527	< 0.001[a]
Shoe/templated stem	0.872	< 0.001[a]	0.835	< 0.001[a]	0.786	< 0.001[a]
Shoe/implanted stem	0.570	< 0.001[a]	0.137	0.400	0.647	< 0.001[a]

[a]$P < 0.05$ was selected to indicate statistical significance.

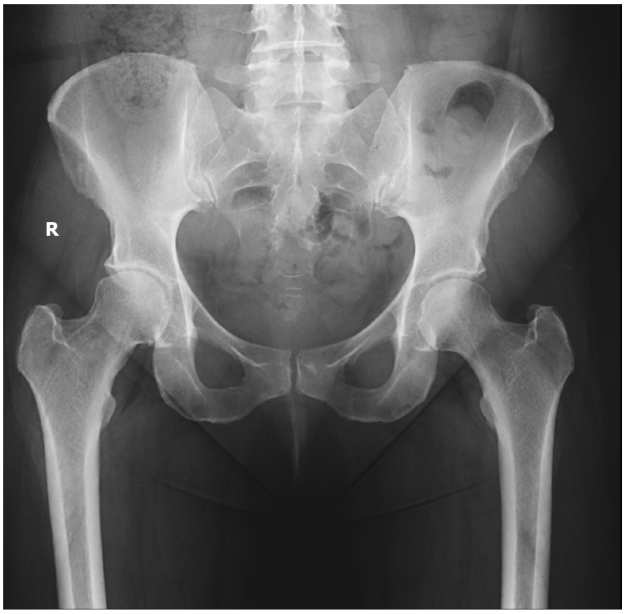

Figure 1 Standardised anteroposterior pelvic radiograph. A preoperative radiograph of a patient with a degenerative right hip was obtained in the standardised protocol with the feet internally rotated at 15 and with the X-ray beam centered on the superior margin of the symphysis pubis.

and 98% were within 2 sizes. Statistically significant positive correlations were observed between implanted cups ($\rho = 0.76$, $P < 0.001$) and stems ($\rho = 0.69$, $P < 0.001$) from their templated sizes. Predicted component sizes from shoe size, adjusted for sex, are presented in Table 2.

DISCUSSION

Templating is an important step prior to performing a total hip replacement, as there has shown to be a greater risk of prosthesis failure if components are inadequately sized[9]. Accurate templating should form part of the routine preoperative assessment and is not only recommended by the British Orthopaedic Association Guide to Best Practice[1] but is also associated with reduced operative time and fewer complications [10]. Preoperative planning encourages surgical precision by accounting for femoral offset restoration, leg length correction and implant alignment[2]. Analogue templating using manufacturer acetates has become incompatible since the widespread introduction of digital radiography throughout all acute hospitals in the United Kingdom. As a result templating has become digitised and allows the user to accurately calibrate the magnification and sizing of the radiograph. Predicting implant sizes can enable orthopaedic purchasing departments to procure accurate stock volumes. This is an important factor when considering the cost and shelf life of expensive implants.

Recent studies have proposed the use of 3D computed tomography (CT) and magnetic resonance imaging with reports of up to 100% predictive accuracy for templating cup size and orientation when compared with 2D templating from digital radiographs[11,12]. However, Westacott *et al*[13] further observed that CT scans are

Table 2 Quick reference table

United Kingdom shoe size: Male	**6**	**7**	**8**	**9**	**10**	**11**	**12**
Predicted cup size	51	52	53	54	54	55	56
Predicted stem size	2	2 - 3	3	4	4	5	6
United Kingdom shoe size: Female	**3**	**4**	**5**	**6**	**7**	**8**	**9**
Predicted cup size	46	48	49	50	51	52	53
Predicted stem size	0	0-1	1-2	2	2-3	3	3-4

Quick reference conversion table for predicted cup and stem sizes from United Kingdom shoe sizes by male and female subgroups.

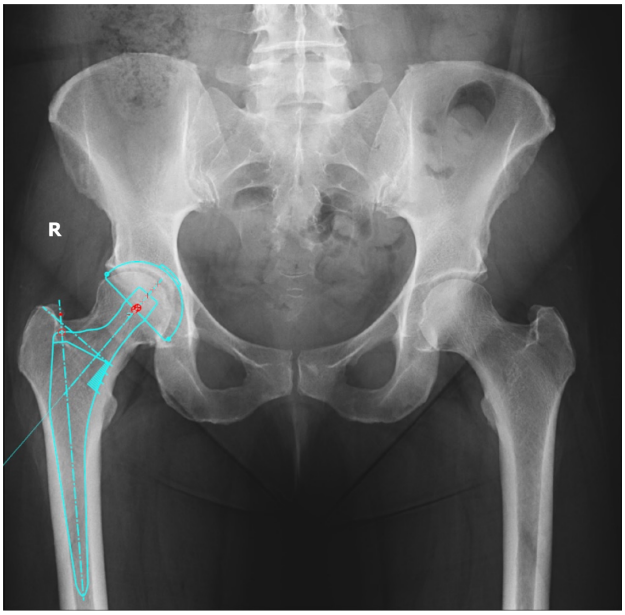

Figure 2 Digital templating using TraumaCAD®. Acetabular and femoral components of an uncemented total hip arthroplasty are digitally templated to a desired size from a standardised and calibrated pelvic radiograph.

performed with the subject supine and therefore do not represent the functional position of the pelvis when the subject is standing. Consequently the pelvic obliquity due to tilt and leg length discrepancy will change the abduction angle and version when standing and may not provide the optimum functional position of the implants. Nonetheless, templating software is expensive and may not be readily available in all orthopaedic departments due to local hardware, software and financial constraints. Surgeons may also wish to avoid the additional radiation risk and cost burden associated with routine preoperative CT scanning for all their patients.

The precision of digital templating is dependent on the quality, rotation and magnification of radiographs. Various methods have been developed, notably the KingMark®, in an effort to calibrate digital radiographs for accurate templating[14]. For patients with advanced degenerative arthritis it may not be possible to obtain a good quality radiograph. In such cases the templating can be performed on the contralateral hip though in patients with bilateral deformities, this process becomes less reliable. Templating relies on the subjective decision of the examiner and can be affected by their level of surgical experience and familiarity with templating software. As a result there are varying degrees of intraobserver reliability reported in the literature[11,15].

Similar to our study findings, the difference in sizes between predicted and implanted uncemented prostheses are well documented in THA, as these implants require an element of under-reaming for press-fit fixation[16]. Consequently, surgeons may opt for a smaller than templated prosthesis size to avoid intraoperative fracture if they feel that stability has been achieved. Furthermore, some hip systems such as the POLARSTEM are designed to be impacted into a compacted cancellous bone bed for fixation. As a result post-operative radiographs may reveal an approximately 1 mm

radiolucent line between the stem and the inner cortex, which represents this cancellous layer[17].

In this study we chose shoe size as a non-invasive, fast and harm-free measurement as a predictor for stature[6]. Recent studies have also demonstrated a significant positive correlation between shoe size and component size in total knee arthroplasty with up to 80% predictive accuracy[18,19]. To date, a similar correlation has not been described for THA in the current literature. Unlike height or weight, foot length does not change significantly during adulthood[20]. Collective evidence from forensic literature advocates that shoe size can reliably predict both skeletal foot size and the overall height of the individual[5,6]. The standard United Kingdom shoe size arises from the longitudinal length of the 'last', which is the physical template over which a shoe is manufactured[19]. As each person determines which shoe size provides the best fit it therefore follows that the individual knows his or her size accurately. In the outpatient setting shoe size is a readily obtainable value and doesn't require additional measurement aids such as for height or weight, which may not be easily available. We further propose a simple conversion table to enable the surgeon to make a quick estimation for the required component sizes from both male or female shoe sizes (Table 2).

We acknowledge several limitations in our study. Our modest sample size was comparable to those in mentioned in the literature though it was not large enough to calculate predictive rules pairing unique shoe sizes to their exact component sizes. This study investigated United Kingdom shoe sizes and therefore the relationships described may not translate to some countries. Patients with a history of foot and ankle surgery were excluded from this report as the dimensions of the foot may change in adulthood secondary to deformity such as hallux valgus. However, Sawalha *et al*[19], in their series of 93 knee replacements did not see any change in accuracy of predicting component size from shoe size when patients with foot pathology or history of foot surgery were included. This would indicate that shoe size is a reliable predictor of component size in all patients irrespective of foot pathology. Our sample size excluded cemented implants, which may limit the broader application of our reported results to cemented hip systems. Finally, the authors appreciate the increasing worldwide use of templating software and computer navigated arthroplasty surgery. However like many other departments, templating software licences are often limited to the operating theatre suites and may not readily be available in the outpatient setting when consulting patients. The proposed advantage of an anthropometric predictive model allows for easy, rapid component size estimation in the absence of computer software and may have a role in allowing purchasing departments to procure accurate stock levels well in advance of planned arthroplasty procedures.

CONCLUSION

In conclusion, our study shows there to be a strong positive correlation between shoe size and templated component sizes in primary uncemented THA. This relationship may allow surgeons to confidently predict component sizes in the absence of digital templating.

ARTICLE HIGHLIGHTS

Research background

Preoperative templating is an essential in total hip arthroplasty (THA) as the correct size and orientation of components play a key role in the success of the prosthesis. Templating is becoming digitised yet many orthopaedic departments lack access to software due to cost and resources.

Research motivation

Available evidence surrounding the correlation between a patient's shoe size and knee arthroplasty component sizes suggests reliable positive correlations. Our motivation for this study was to assess if there was a reliable anthropometric method to predict THA component sizes from shoe size in the absence of digital methods.

Research objectives

We aim to determine the accuracy of using an easily obtainable measurement (shoe

size) to predict component sizes in THA when compared with the digitally templated sizes of the same hip.

Research methods

We performed a retrospective review of 102 patients (40 male, 62 female) who had undergone elective uncemented or hybrid THA at our single centre. Standardised digital pelvic radiographs were retrospectively templated to desired cup and stem sizes using TraumaCad®. We then compared the templated size to the actual size of the implant that the patient received and assessed if there was any correlation with the patient's shoe size.

Research results

Statistically significant positive correlations were observed between patient shoe size: templated cup and implanted cup size; templated stem and implanted stem size. Positive correlations were also demonstrated between templated and implanted acetabular cup sizes, and templated and implanted stem sizes.

Research conclusions

Our study has shown there to be strong positive correlations between shoe size and templated component sizes in primary uncemented THA. Shoe size is an easily obtainable measurement and can allow surgeons to confidently predict component sizes in the absence of digital templating.

Research perspectives

Future research should evaluate the clinical significance of these findings with cemented hip systems.

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ORIGINAL ARTICLE

Retrospective Study

Treatment of knee osteochondritis dissecans with autologous tendon transplantation: Clinical and radiological results

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Author contributions: Ayas MS, Turhan AU, Açıl S, Gül O, Öner K and Okutan AE designed the research study; Ayas MS, Turhan AU, Açıl S, Gül O, Öner K and Okutan AE performed the research, analyzed the data and wrote the manuscript; All authors have read and approve the final manuscript.

Institutional review board statement: This study was approved by the institutional review board of our hospital.

Informed consent statement: Patients were not required to give informed consent to the study because the analysis used anonymous clinical data that were obtained after each patient agreed to treatment by written consent.

Conflict-of-interest statement: The authors declare that there are no conflicts of interest.

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Abstract

BACKGROUND

Defect treatment with tendon autograft in osteochondral lesions has been published in the literature with an experimental study in dogs. To demonstrate that it is possible to treat knee osteochondral lesions with the technique of autologous tendon transplantation.

AIM

To evaluate the clinical and radiological results of patients with knee osteochondral lesions who were treated with autologous tendon transplantation.

METHODS

Twenty patients (22 knees) with osteochondritis dissecans (OCD) lesions involving the knee were treated with autologous tendon transplantation between 2005-2018. All lesions were International Cartilage Repair Society grade IV. All patients were evaluated clinically at final follow-up with knee injury and osteoarthritis outcome score (KOOS); and radiologically with magnetic resonance observation and cartilage repair tissue (MOCART) and Kellgren-Lawrence (KL) classification.

for data sharing.

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L-Editor: A
P-Editor: Wang LYT

RESULTS
A total of 20 patients (22 knees) with a mean age of 25.5± 6.8 years were included. The average defect size was 4.2 ± 2.1 cm^2, and the average defect depth was 0.9 ± 0.4 cm. Total KOOS score was preoperatively 29.4 ± 5.5 and was later found to be 81.5 ± 5.9 after an average of 68.7 ± 37.7 mo follow-up. The mean MOCART score was 56.2 ± 10.7. Preoperatively, all of the patients had KL grades of 0–1; during the follow-up period, 80% of the patients showed no radiological progress of osteoarthritis. Patients with less than 4 cm^2 lesion had statistically significantly better overall KOOS than patients whose more than 4 cm^2 lesion, particularly in sport and quality of life subscales.

CONCLUSION
The autologous tendon transplantation is a single-step, safe, simple, cost-effective method for the treatment of knee OCD with satisfactory clinical and radiological outcomes, particularly in patients with less than 4 cm^2 lesion.

Key Words: Osteochondritis dissecans; Knee; Tendon; Transplantation; Autologous; Peroneus

Core Tip: Defect treatment with tendon autograft in osteochondral lesions has been published in the literature with an experimental study in dogs. However, to date, only one case in the capitellum of the elbow has been scientifically published in humans. This retrospective study shows that knee osteochondral lesions are possible with tendon autograft transplantation technique.

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INTRODUCTION

Knee osteochondritis dissecans (OCD) is a common pathology affecting the articular cartilage and resulting in the delamination of subchondral bone[1,2]. The exact causes are unknown, however, biological (ischemia, osteonecrosis) and mechanical factors (trauma, overuse) has been proposed[3,4]. The OCD can cause a very wide range of clinical presentation from completely asymptomatic to functional impairment. If left untreated, these lesions may lead to the development of osteoarthritis[5].

The management of OCD in young patients who may not be good candidates for arthroplasty remains a challenge for the knee surgeons. Many treatments have been proposed including fragment fixation, microfracture, osteochondral autograft /allograft transplantation, matrix-induced chondrogenesis, and autologous chondrocyte implantation, depending on the size and depth of lesion[6,7]. The purpose of any surgical interventions is to re-establish the joint surface, provide the joint congruency, relieve the symptoms and decrease the risk of degenerative osteoarthritis. The numerous number of treatment options reveals the challenge of the management of knee OCD. However, the real challenge being to choose the 'most rational' of several alternative options which potentially differing in their outcomes.

Osteochondral autograft transplantation and mosaicplasty are common surgical procedures for treating symptomatic International Cartilage Repair Society (ICRS) grade 3 or 4 defects smaller than 3 cm^2[8]. These techniques has several advanteges including resurface the defect with normal cartilage and replace concurrently the subchondral bone. But, the donor site morbidity is a major disadvantage. Furthermore, obtaining a congruent surface with donor grafts requires technically challenging skill [9]. To address these problems, we have proposed a new graft source, the peroneus longus tendon, hypotesizing that the tendon autograft with elastic structure can enable

easly joint congruence and with solid structure can provide early weight-bearing. Encouraged by the success of tendon autograft in a dog model[10], the technique was applied in a series of 20 patients with a OCD.

The purpose of this study is to retrospectively evaluate the clinical and radiological results of autologous tendon transplantation using the peroneus longus tendon in patients with ICRS grade 3 or 4 defects.

MATERIALS AND METHODS

This study was approved by the institutional review board of our hospital. Patients were retrospectively followed up for a minimum of 2 years and data were evaluated retrospectively. Twenty-two consecutive knees (20 patients, 2 bilateral) who underwent autologous tendon transplantation for knee OCD were enrolled from 2005 to 2018. The inclusion criteria for the treatment were (1) Patients with osteochondral defects graded IV on ICRS (International Cartilage Repair Society) classification; (2) Patients with a OCD lesions located at the femoral condyles, sized more than 2 cm^2, causing knee symptoms (pain, swelling or locking) and lesions were not suitable for fixation; and (3) Patients who failed a conservative treatment at least 6-mo period. The exclusion criteria were (1) Kellgren and Lawrence grade ≥ 2 osteoarthritis; (2) Osteonecrosis and infammatory arthropathy; (3) Meniscal deficiency or ligament instability; (4) Patients with other general medical conditions (*e.g.*, diabetes mellitus or rheumatoid arthritis); (5) Multiple and recent intra-articular injections with steroids; (6) Deformity or OA at ipsilateral and contralateral hip or ankle joints; and (7) Possible non-compliance to the proposed rehabilitation protocol.

Preoperatively, all patients underwent a thorough physical examination, including knee passive and active range of motion, ligamentous stability and knee specific tests. Standard radiography were acquired in every patient to evaluate the osteochondral lesions and knee osteoarthritis. The magnetic resonance images (MRI) were obtained routinely to evaluate the size and depth of the OCD lesion. Patients were assessed with Knee Injury and Osteoarthritis Outcome Score (KOOS) before the operation and at the final follow-up. The radiological outcomes were assessed with magnetic resonance observation of cartilage repair tissue (MOCART) score and with Kellgren-Lawrence (KL) classification.

The osteochondral defect repair was radiologically evaluated by MRI using the Magnetic Resonance Observation of Cartilage Repair Tissue (MOCART). Images were evaluated according to defect filling, integration into the border region, surface of the repair tissue, structure of the repair tissue, signal intensity of the repair tissue, subchondral lamina status, integrity of the subchondral bone, and joint adhesion and infusion[11]. Integrity assessment of the subchondral bone could not be made because the defect area was restored with autologous tendon in the treatment procedure. Therefore, the score ranged from 0 (worst result) to 90 (best possible result).

MRI was performed on a 1.5 Tesla system (Avanto; Siemens Medical Solution, Erlangen, Germany) using ankle coil. The following sequences with axial, coronal and sagittal plains were used: T1-weighted turbo spin echo (T1W TSE) [TR/TE = 777/12 ms, matrix = 320 x 224, field of view (FOV) = 16 cm, excitations = 1, slice thickness = 3 mm, spacing = 0.6 mm], fat saturated proton density weighted turbo spin echo (PDW TSE FS) (TR/TE = 3330/47 ms, matrix = 320 x 224, FOV = 16 cm, excitations = 1, slice thickness = 4 mm, spacing = 1.2 mm), and fat saturated T2-weighted turbo spin echo (T2 TSE FS) (TR/TE = 5200/75 ms, matrix = 208 x 256, FOV = 16 cm, excitations = 1, slice thickness = 4 mm, spacing = 1.2 mm).

KOOS is a specific questionnaire form about the knee containing 42 questions in 5 individual subheadings. These 5 subgroups are: pain, symptoms, activities of daily living, sports and quality of life. KOOS is a recommended scoring system in cartilage repair patients and is a reliable test being used in patients after their surgical treatments of focal cartilage lesions in recent years[12].

Surgical technique

All procedures were performed in a supine position under general or spinal anesthesia and a thigh tourniquet was applied. A diagnostic arthroscopy was performed, intraarticular conditions were evaluated, associated meniscal injuries were treated and any loose bodies were removed. A mini-arthrotomy was used, depending on the size and site of the lesion. The osteochondral lesion was removed and debrided until viable bleeding bone was reached. The subchondral bone was drilled at 2-4 mm intervals with 1 mm thick K-wire. Following this, a longitudinal posterolateral mini-incision

was opened over the peroneus longus tendon, 10 cm proximal to the lateral malleolus on the ipsilateral side. A split portion of tendon was harvested from the peroneus longus. The graft was folded back on itself and held with absorbable suture, creating a "ball" and then fixed into the defect with suture anchor (Figure 1). The spherical congruency of the joint was checked. Finally, a cylindrical cast or orthosis was applied at 15 degrees of knee flexion.

Post-operative follow-up; Immediate isometric quadriceps exercise was started postoperatively. All patients were mobilized with weight-bearing on postoperative day 1. At the end of the 4th week, cylindrical cast was removed and active and passive knee joint movements were prescribed. All patients followed the same rehabilitation protocol for 6 mo, respectively, based on current knowledge of the graft healing biology: protect the transplant from excessive loads and shearing forces, gain full extension and gradual recovery of knee flexion, progressive recovery in daily functional activities, increase the strength of the quadriceps and hamstrings, recovery of full range of motion, further increase in strength of quadriceps and flexors muscles, further increase in functional activities level, prepare athlete for a return to team and competition with good recovery of the aerobic endurance, maintain a good quality of life, avoiding excess of body fat and preventing risk of reinjury.

All patients were followed up in the outpatient clinic at the 2nd week, 4th week, 8th week, 12th week, 6th month, at the end of 1 year and at the last clinical follow-up. Clinical follow-ups; It was performed together with a surgeon and a physiotherapist in the surgical team, and the data were documented at each clinical control.

All patients were evaluated radiologically with MRI at the end of the first year and at the last follow-up. Radiological evaluations were evaluated by 2 independent radiologists in consensus.

Statistical analysis

The statistical analysis was performed using SPSS Version 22.0 statistical analysis software. Percentage, rate, average and SD were used as descriptive statistics. The compliance of the quantitative data with normal distribution was evaluated using the Kolmogorov–Smirnov test. The parametric data were compared using the Student *t*-test and the nonparametric data were compared using the Mann-Whitney *U* test. *P* value less than 0.05 was considered to be statistically significant.

RESULTS

Twenty-two knees of 20 patients underwent autologous tendon transplantation who had knee OCD were included in the study. The mean patient age was 25.5 ± 6.8 years (range, 19-42 years) and the follow-up period was 68.7± 37.7 mo (range, 30-182 mo). Detailed patients demographics are shown in Table 1.

Preoperatively, the average KOOS score was 32.2 ± 5.8 for pain, 28.2 ± 6.4 for symotom, 44.5 ± 8.1 for activity of daily living, 22.4 ± 4.6 for sport, and 24.5 ± 5.8 for quality of life. Postoperatively, the average KOOS score was 91.3 ± 4.2 for pain, 89.1 ± 7.2 for symptom, 85.1 ± 6.8 for activity of daily living, 74.5 ± 7.2 for sport, and 72.4 ± 8.1 for quality of life. Preoperative total KOOS score was 29.4 ± 5.5 (range, 21.4-40.5). KOOS total score was found to be increased to 81.5 ± 5.9 (range, 74.2-92.7). All parameters of the KOOS score improved significantly ($P < 0.001$) (Table 2).

The mean MOCART score was found 56.2 ± 10.7 (range, 40-75) at last follow-up. There was no significant correlation between the total MOCART and KOOS scores. Preoperatively, all of the patients had Kellgren–Lawrence grades of 0–1; during the follow-up period, 80% ($n = 16$) of the patients no showed radiographical progression of osteoarthritis (Figure 2). Patients with less than 4 cm^2 lesion had statistically significantly better overall KOOS ($P < 0.01$) than patients whose more than 4 cm^2 lesion. In terms of the KOOS subscales, however, this was true only with sport ($P = 0.01$) and quality of life ($P = 0.02$). There were no statistically significant differences in the subscales pain, symptoms and activity of daily living (Figure 3).

Second-look arthroscopy was performed during contralateral knee operation to the patients who was operated from both knees at one year intervals. Second look arthroscopy view at 1-year follow-up of ICRS grade 4 of medial femoral condyle showing filling of the defect with a well-integrated, smooth surfaced and stable regenerated cartilage. The graft adaptation and incorporation were assessed to be excellent (Figure 4).

Peroneus longus tendons were used as autologous grafts in all patients. No complications developed in any patient regarding donor site. In the graft donor site, no patient

Table 1 Demographic characteristics of patients

Age at time of surgery, yr, mean ± SD (range)	25.5 ± 6.8 (19-42)
Sex, M/F, *n* (%)	15 (75%)/5 (25%)
BMI, kg/cm^2, mean ± SD (range)	27.1 ± 3.5 (21.6-32.4)
Side, R/L, *n* (%)	13 (59.9%)/9 (40.1%)
Location, MFC/LFC, *n* (%)	18 (81.8%)/4 (18.2%)
Size, cm^2, mean ± SD (range)	4.2 ± 2.1 (2.1-9.0)
Depth, cm, mean ± SD (range)	0.9 ± 0.4 (0.4-1.7)
Follow-up duration, mo, mean ± SD (range)	68.7 ± 37.7 (30-182)

BMI: Body mass index; F: Female; L: left; LFC: Lateral femoral condyle; M: Male; MFC: Medial femoral condyle; R: Right; SD: Standard deviation.

Table 2 Clinical and radiological results of patients

	Preoperative, mean ± SD (range)	At final follow-up, mean ± SD (range)	*P* value
Total KOOS score	29.4± 5.5 (21.4-40.5)	81.5 ± 5.9 (74.2-92.7)	< 0.01
Pain	32.2 ± 5.8	91.3 ± 4.2	< 0.01
Symptoms	28.2 ± 6.4	89.1 ± 7.2	< 0.01
ADL	44.5 ± 8.1	85.1 ± 6.8	< 0.01
Sport	22.4 ± 4.6	74.5 ± 7.2	< 0.01
QOL	24.5 ± 5.8	72.4 ± 8.1	< 0.01
MOCART score	NM	56.2 ± 10.7 (40-75)	NM
Kellgren-Lawrence grade	0.4 ± 0.1 (0-1)	0.6 ± 0.1 (0-1)	NS

ADL: Activity of daily living; QOL: Quality of life; KOOS: Knee injury and osteoarthritis outcome score; MOCART: Magnetic resonance observation of cartilage repair tissue score; NM: Not measured; NS: Not significant; SD: Standard deviation.

reported a neurological symptom. Hypertorphic scar tissue did not occur in any of the patients in the donor site. At the end of the 6th month, all patients returned to their daily work and daily activities without any restrictions.

DISCUSSION

The most important finding of the present study is that all of the patients treated with autologous tendon transplantation had "excellent and good" clinical and radiological outcomes with minimum 2 years follow-up. All parameters of the KOOS score improved significantly ($P < 0.001$). Patients with less than 4 cm^2 lesion had statistically significantly better overall KOOS ($P < 0.01$) than patients whose more than 4 cm^2 lesion.

The main aim in the treatment of osteochondral defect is to restore joint integrity by creating a tissue that is the same or similar to the biomechanical properties of the articular cartilage. This is the basic logic of this method. The reason we think of using tendons in the treatment of OCD is that the tendon has a viscoelastic and anisotropic structure that has main tasks of carrying energy from muscle to bone and storing energy with its highly organized hierarchy[13-15]. Tendons have been proven to increase their amounts of proteoglycan and glycosaminoglycan present in the matrix under compression conditions, and can resist compressive loads thanks to these two substances[13,15,16]. Another feature of the tendons is that they can change their structures and compositions in case of mechanical load changes. Cells in the tendon are responsible for adaptive changes and can alter gene expression, protein synthesis and cell phenotype against mechanical load. In addition, the extracellular matrix of the

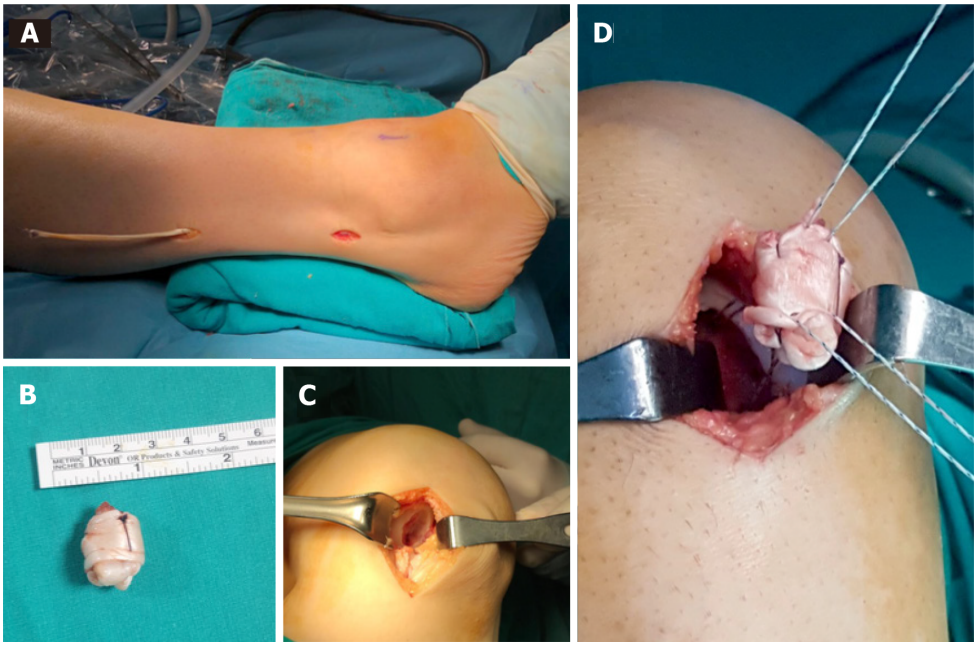

Figure 1 The technique of harvesting the autologous peroneal tendon from the donor area and placing it in the prepared osteochondral lesion area of the knee. A: Two mini incisions were made in the ipsilateal leg to harvest a split portion of the peroneus longus tendon; B: Intaoperative image showing the rolled peroneus longus tendon with absorbable suture; C: Osteochondral defect was prepared for transplantation; D: The rolled tendon autograft was transplanted into the osteochondral defect space and fixed with suture anchor.

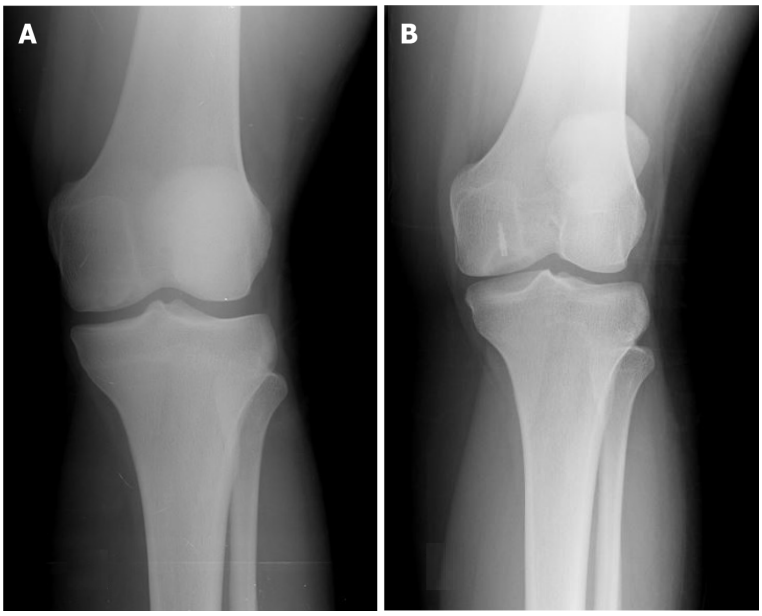

Figure 2 Radiographic images of a patient treated with the Autologous Tendon Transplantation technique. A: Anteroposterior radiograph of the knee of a 24-year old female with a symptomatic lesion of the medial femoral condyle (4.6 cm^2 size and 1.4 cm depth); B: Anteroposterior radiograph of the knee 6 years after autologous tendon transplantation with suture anchor show congruency of the articular surface of the medial femoral condyle. There are no arthritic changes. The patient is asymptomatic, free from pain and has no limitation of movement.

tendon acts as a scaffold, allowing cell adhesion, development, and differentiation[16, 17]. Joint compliance is easily provided by the elastic structure of the tendon, hence solid structure forms a load carrying surface; thus, the pain is eliminated, joint functions are preserved and degeneration is stopped. The results of this technique we have described show that we have achieved this.

The technique we have described is actually a tissue-based cartilage repair technique. Therefore, it can be compared with osteochondral autograft or allograft repair techniques, which are tissue-based repair techniques. The most important advantage of the osteochondral autograft technique is that the graft is autograft and it

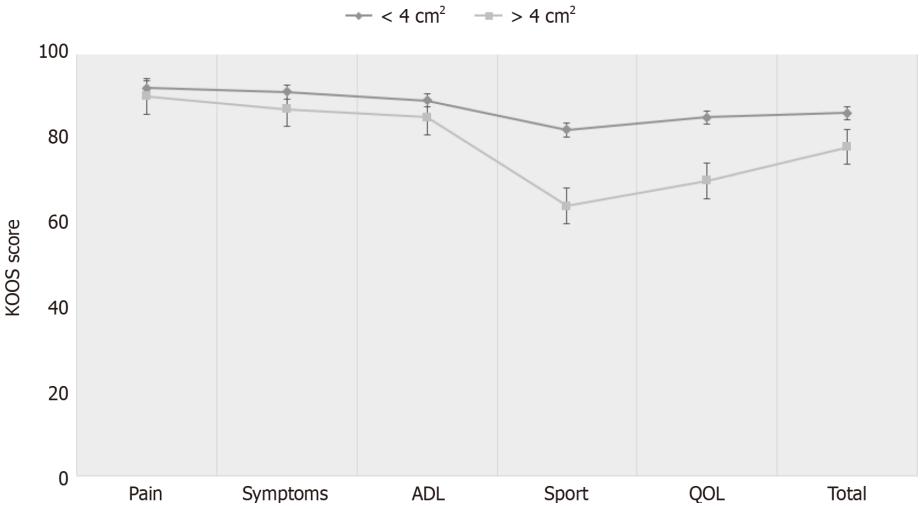

Figure 3 Knee injury and osteoarthritis outcome scores for different defect size. Patients with less than 4 cm^2 lesion had statistically significantly better overall knee injury and osteoarthritis outcome score than patients whose more than 4 cm^2 lesion, particularly in sport and quality of life subscales. KOOS: Knee injury and osteoarthritis outcome score; ADL: Activity of daily living; QOL: Quality of life.

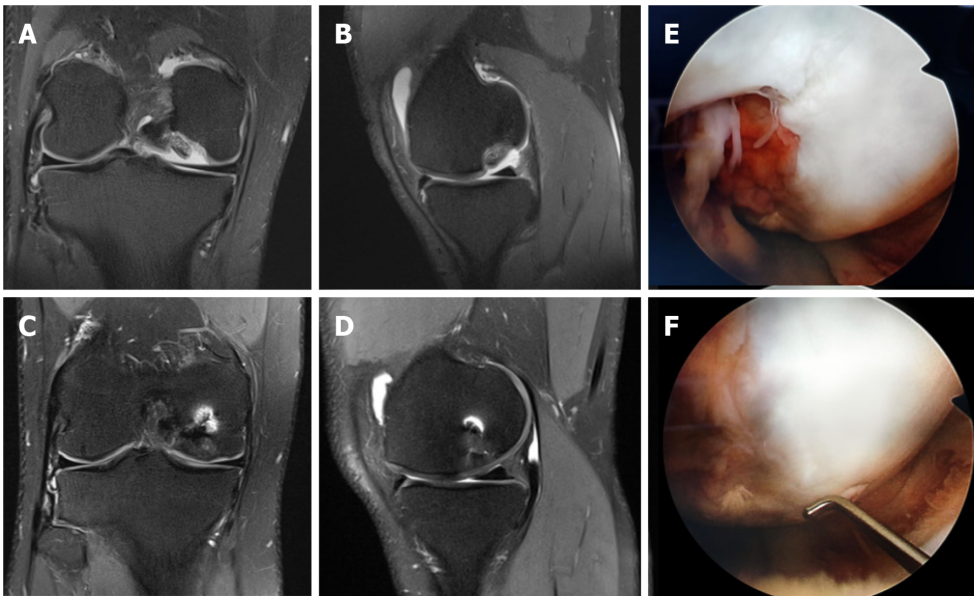

Figure 4 Magnetic resonance images and intraoperative images of a patient treated with the Autologous Tendon Transplantation technique. A, B: Coronal and Sagittal T2 section magnetic resonance images (MRI) of a grade 4 osteochondral lesion involving articular surface of medial femoral condyle (3.4 cm^2 size and 0.5 cm depth) in 24-year old male; C, D: 1-year follow-up coronal and sagittal T2 section MRI showing complete filling of the defect and establishment of smooth articular surface; E, F: Second look arthroscopy view at 1-year follow-up of grade 4 osteochondral lesion of medial femoral condyle showing filling of the defect with a well-integrated, smooth surfaced and stable regenerated cartilage.

enables the subchondral tissue to be restored[18]. But it has potential disadvantages such as donor site morbidity and poor joint compliance. In addition, the larger the defect area is, the higher the risk of complications are[19]. The osteochondral autograft technique may exhibit mismatch in connection geometry at the recipient site. In addition, the need for multiple grafts in large lesions complicates the provision of joint geometry and increases donor site morbidity. This can cause premature degeneration of the graft and joint, synovitis, and pain[20-23].

Another tissue-based cartilage repair technique is osteochondral allografts. These allografts have been used for many years in orthopedic surgery to reconstruct osteochondral defects[24]. It has also become an option in the treatment of cartilage abnormalities affecting subchondral bones, such as osteochondritis dissecans[25]. Osteochondral allograft is a highly beneficial procedure especially in the treatment of large lesions that are between the sizes 2-20 cm^2 and in the treatment of a failed OCD [26-29]. Even if successful results have been reported in previous studies, the most

important disadvantage of osteochondral allografts are their shorter storage life. Williams *et al*[30] in their study; reported that fresh human osteochondral allograft tissue that was kept for more than fourteen days, preserves its glycosaminoglycan content and biomechanical properties, yet it significantly loses its chondrocyte viability, viable cell density and metabolic activity. Other disadvantages of this method are the difficulty of accessibility to the graft, immunogenicity and graft rejection, the risk of disease transmission such as HIV and Hepatitis, disjointedness in joint geometry and collapse problems[25,31]. With the autograft we used, the disadvantages of osteochondral allografts are avoided.

The most important limitation of this study is the small number of patients. Even if we compare the study with previous studies, the absence of a control group is another limitation. Cartilage evaluation was evaluated with standart (1.5 Tesla system (Avanto; Siemens Medical Solution, Erlangen, Germany) MRI. Another shortcoming is that we did not perform imaging with gadolinium-enriched MRI.

CONCLUSION

This technique allows to avoid many of the disadvantages of other techniques. Important advantages; It is done in one step, it is an autograft, it does not require additional cost and it is easy to apply. Since it is an autograft, there is no risk of tissue rejection and contagious infection. Similar clinical and radiological results were obtained when compared to other treatment modalities. The autologous tendon transplantation is a single-step, safe, simple, cost-effective method for the treatment of knee OCD with satisfactory clinical and radiological outcomes, particularly in patients with less than 4 cm^2 lesion.

ARTICLE HIGHLIGHTS

Research background

This research was initiated by being inspired by the article titled "Treatment of osteochondral defects with tendon autografts in a dog knee model" made in 1999 and the articles titled "Tendon regeneration: an anatomical and histological study in sheep" published in 2004.

Research motivation

Our teacher Ahmet Uğur Turhan's interest in joint surgery and his publications in 1999-2004 inspired him.

Research objectives

In order to protect the knee joint, the authors share the new technique with the world, and share the results with the world and to inspire new publications.

Research methods

A report of multiple patients with the same treatment, but no control group or comparison group.

Research results

All parameters of the knee injury and osteoarthritis outcome score (KOOS) score improved significantly in all patients. Patients with lesions less than 4 cm^2 had a significantly better overall KOOS than patients with lesions greater than 4 cm^2.

Research conclusions

Autologous tendon transplantation has satisfactory clinical and radiological results in patients with osteochondral lesions of the knee.

Research perspectives

The autologous tendon transplantation is a single-step, safe, simple, cost-effective method for the treatment of knee osteochondritis dissecans with satisfactory.

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ORIGINAL ARTICLE

Clinical Trials Study

Direct anterior approach *vs* Hardinge in obese and nonobese osteoarthritic patients: A randomized controlled trial

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Institutional review board statement: The Scientific Research Council of the "KAT" General Hospital of Attica, Athens, Greece approved the study's protocol (ref: No8/19-03-2019).

Clinical trial registration statement: The study has been registered at www.isrctn.com following identification number:

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Abstract

BACKGROUND

The increased prevalence of obesity has resulted in orthopedic surgeons being likely to face many patients with a high body mass index (BMI) who warrant total hip arthroplasties (THAs) over the coming years. Studies' findings considered the postoperative clinical, and functional outcomes in these patients are controversial, and selecting the most appropriate surgical approach remains debatable.

AIM

To compare pain-levels, functionality, and quality-of-life in obese and nonobese osteoarthritic patients who have undergone primary total hip arthroplasty through either direct-anterior-approach (DAA) or Hardinge-approach.

METHODS

One hundred and twenty participants (> 50 years) were divided into four groups according to the surgical approach (DAA or Hardinge) and patients' BMI (nonobese < 30 kg/m^2 *vs* obese ≥ 30 kg/m^2). Outcomes were measured preoperatively and postoperatively (6th and 12th week). Pain was measured with Face Pain Scale-Revised (FPS-R). Functionality was measured with Timed Up & Go (TUG) test and Modified Harris Hip Score-Greek version (MHHS-Gr). Quality-of-life was evaluated with the 12-item-International Hip Outcome Tool-Greek version (iHOT12-Gr) (Clinical Trial Identifier: ISRCTN15066737).

ISRCTN15066737 https://doi.org/10.1186/ISRCTN15066737.

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

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RESULTS

DAA *vs* Hardinge: (week 6) DAA-patients showed 12.2% less pain, more functionality (14.8% shorter TUG-performance time, 21.5% higher MHHS-Gr), and 38.16% better quality-of-life (iHOT12-Gr) compared to Hardinge-patients (all *P* values < 0.001). These differences were further increased on week 12 (all *P* values ≤ 0.05)]. DAA-obese *vs* Hardinge–obese: (week 6) DAA-obese patients had less pain, shorter TUG-performance time, better MHHS-Gr and iHOT12-Gr scores than Hardinge-obese (all *P* values < 0.01). (Week 12) Only the TUG-performance time of DAA-obese was significantly shortened (22.57%, *P* < 0.001). DAA-nonobese *vs* DAA-obese: no statistically significant differences were observed comparing the 6th and 12th weeks' outcomes.

CONCLUSION

DAA-groups reported less pain, more functionality and better quality-of-life, compared to the Hardinge-groups. The DAA benefited obese and nonobese patients, similarly yet faster, suggesting that it should be the more preferred choice for obese patients, instead of Hardinge. However, more comparative studies with more extended follow-up periods are needed to confirm our results and better evaluate all patients' long-term outcomes.

Key Words: Total hip arthroplasty; Osteoarthritis; Obesity; Pain; Functional ability; Quality-of-life

Core Tip: The selection of the best total hip arthroplasties (THA)-surgical approach for obese hip osteoarthritis patients is a matter of debate. In the present study, both obese and nonobese patients of direct anterior approach (DAA) groups reached equivalent pain-levels, functionality, and quality-of-life. Moreover, the comparison between obese patients showed that DAA leads faster to better functional ability and quality-of-life than the Hardinge approach. These findings suggested that DAA is a better suited THA surgical approach than Hardinge for patients with increased body mass index.

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INTRODUCTION

In recent years, there has been a growing interest in minimally invasive surgical techniques that are used for the performance of total hip arthroplasty (THA). The advantages of these techniques include lesser soft tissue trauma, lesser amount of blood loss, minor postoperative pain, shorter hospital stay, better aesthetic appearance of the incision and a faster recovery time[1-3]. Over the past decade, the direct anterior approach (DAA) has sparked scientific interest due to its soft-tissue-preserving nature (intermuscular and internerval technique), coupled with the relatively lower risk of dislocation[4]. The DAA approach can be performed through a vertical or a horizontal (bikini) incision[5].

On the other hand, THA is an effective treatment for most patients who suffer from pain and decreased functionality due to end-stage symptomatic hip osteoarthritis (OA) [6]. Epidemiological studies report that hip OA occurs in 88 out of 100000 people, and the reported prevalence was 0.9 and 1.6 per 1000 yearly, in both men and women, respectively[7]. Within the Greek population, 0.9 per 1000 people develop osteoarthritis of the hip and the incidence of the disease is 1.5 per 1000 in women and 0.3 per 1000 in men[8]. The main risk factors for developing hip OA are advanced age, family history of OA, previous hip injury, hip dysplasia and obesity. Specifically, obesity is a high-ranking risk factor for osteoarthritis development, as its effect increases the joint

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reaction forces and alters gait biomechanics by creating abnormal loadings[9]. Additionally, the increased accumulation of body fat and adipokines contributes to low-grade systemic inflammation that adversely affects the cartilage's normal biology [10]. In the literature, it has been reported that obesity is significantly associated with a greater need for joint replacement and that compared to patients with normal body mass index (BMI), obese patients may require a THA up to ten years earlier[9].

Several studies have indicated that obesity is associated with both a higher complication rate after THA and poorer clinical functional outcomes[11-13]. Other studies have shown that obese patients do not differ from nonobese in terms of postoperative outcomes[14-16]. The data are considered controversial and further studies need to be performed on obese patients, especially comparative evaluations that compare minimally invasive techniques such as DAA with classical surgical techniques, such as the Hardinge approach (HA). The Hardinge was chosen because, compared to other classical surgical approaches used in obese patients, it offers better access to the hip joint and achieves a lower rate of dislocation by preserving the joint's posterior stabilizer muscles[17].

This trial aims to compare DAA and Hardinge in hip OA patients who have undergone primary THA, with regards to postoperative pain levels, functional status, and quality-of-life. In addition, it was investigated whether these parameters differ between obese and nonobese patients.

MATERIALS AND METHODS

Study design

The present study was a prospective, four-group randomised controlled trial (Clinical Trial Identifier: ISRCTN15066737) conducted according to the ethical principles stated in the Declaration of Helsinki and its later amendments[18]. The Scientific Research Council of the "KAT" General Hospital of Attica, Athens, Greece approved the study's protocol (ref: No8/19-03-2019). The study conformed to the "Consolidated Standards of Reporting Trials" (CONSORT) 2010 Statement checklist of information to include when reporting a randomised trial[19].

Sample size estimation

It was estimated that a sample size of 120 patients was required in order to have a 90% probability of demonstrating a –between surgical approaches- difference of 10% change from baseline to 6th week (DAA: -50% ± 12% *vs* Harginge: 40% ± 12%) in TUG test performance time, with a significance of < 5% (Two-tailed test).

Participants

Participants were selected from patients who have chosen to be operated by either of the two chief orthopedic surgeons/co-researchers of the present trial. One of the head-orthopedic surgeons (GM) performs primary THA using DAA technique -through a single vertical incision-[20], whilst the other (SP) prefers the Hardinge[21]. Surgical approach and BMI were used as factors in the randomisation process, while the randomisation list was formed on the basis of these factors. An independent clinician was responsible for the random allocation sequence and assigned participants to groups. Specifically, participants were divided into four groups (30 patients per group) according to both the surgical approach used and their body mass index (BMI), as follow: (1) DAA-nonobese group: patients with BMI ≥ 20 kg/m^2 and < 30 kg/m^2, who underwent THA through DAA; (2) DAA-obese group: Patients with BMI ≥ 30 kg/m^2, who underwent THA through DAA; (3) Harginge-nonobese group: patients with BMI ≥ 20 kg/m^2 and < 30 kg/m^2, who underwent THA through Harginge; and (4) Harginge-obese group: patients with BMI ≥ 30 kg/m^2, who underwent THA through Harginge.

To be eligible for randomization, patients had to meet the following inclusion criteria: Symptomatic hip OA, age > 50 years, and to be ambulatory before surgery. Patients were excluded if they had dementia, chronic respiratory disease, chronic renal failure, heart failure or neurological disorder. In addition, after discharge, patients would also be excluded if they discontinued the postoperative physiotherapy before the 6th week's measurement. No patient or clinician was blinded to the group allocation.

An uncemented prosthesis was used in all patients. Physiotherapy intervention was started on the first postoperative day and lasted for 6 wk, firstly on an in-patient basis, and following hospital discharge, home-based. One physiotherapist was responsible

for carrying out the physiotherapy during hospitalization and at home, evaluating the progress according to the protocol and ensuring the patient's compliance adherence to it, on all groups.

Procedures

Outcome measures were obtained at three different time points: prior to surgery (baseline), at the end of the 6th week, and at the end of the 12th week, postoperatively. Pain-levels were measured with the Face Pain Scale – Revised (FPS-R)[22,23]. Functional ability was evaluated with the objective physical performance measure Timed Up & Go (TUG) test[24], and with the reliable and validated Greek version of the Modified Harris Hip Score (MHHS-Gr)[25]. Quality-of-life was measured with the reliable and validated Greek version of the International Hip Outcome Tool -12 items (iHOT12-Gr)[26]. One examiner carried out the measurements of all outcomes, and he did not involve in any other part of the study.

Outcome Measures

FPS-R: The FPS-R is a patient-reported instrument frequently used to measure pain intensity. It includes six facial expressions covering the entire range of pain levels in an ascending -regarding discomfort levels- order[22]. Patients describe their pain according to one of the six facial expressions that correspond to their pain and enabling them to translate their subjective experience of pain into a quantitative, numeric measure[23].

TUG test: The TUG test was used to assess participants' functionality. This test was introduced in 1991 as a modification of the "Get-Up and Go" test[24]. It is a simple, easy, and thus widespread clinical tool for measuring the lower limbs' functionality and mobility[27]. The TUG test measures the time (in seconds) taken by a participant to stand up from an armed chair with a seat height of 46 cm, walk for 3 m, turn around a cone and return to sit on that very same chair. A shorter performance time represents better functionality[24,27]. Participants were asked to perform the test as quickly as they could while still feeling safe, and were allowed to use the walking aid on which they depended on at the time of measurement. The participants performed the test twice, with a 5-minute resting interval in between. The shorter of the two performance times was then recorded.

MHHS: The MHHS is a patient-reported questionnaire that includes assessments based on pain and on function[25]. One item evaluates the pain (0-44 points), while 7 items evaluate the patient's functionality (0-47 points). The total points form a scale from 0 to 91. A multiplier of 1.1 provides a total score of 100 (best possible outcome) [28].

iHOT12: The iHOT12 questionnaire includes 12 questions on the patient's symptoms, functional and sports limitations as well as social, emotional, and occupational limitations[26]. The patient is asked to consider the problems arising from their hip disorders and quantify their quality-of-life level on a 100 mm horizontal line (visual analogue scale) by marking it with a slash. Each question has equal value, giving a mean score from 0-100. A score of 100 indicates excellent quality-of-life (full function and no symptoms), whereas zero signifies the worst quality-of-life (maximum limitations and extreme symptoms)[29].

Statistical analysis

Data was expressed as mean ± SD or mean ± SE (for two way ANOVA analysis results) for continuous variables and as percentages for categorical data. The Kolmogorov—Smirnov test was utilized for normality analysis of the continuous variables.

The two-way ANOVA model was used to examine the interaction between the "Surgical Approach" factor (DAA & Hardinge) and "BMI" factor (< 30 kg/m^2 and ≥ 30 kg/m^2). In the case that there was no statistically significant interaction, we compared the factor "Surgical Approach" regardless of "BMI" factor and the factor "BMI" regardless of "Surgical Approach" factor.

Due to we have found significant interaction, we created a new factor categorising the combination of the existing categories of "Surgical Approach" with "BMI" factors (DAA-nonobese, DAA-obese, Hardinge-nonobese, Hardinge-obese). The analysis of variables was performed using the "One way ANOVA model". Pairwise comparisons were performed using the Bonferroni test.

All tests were two-sided and statistical significance was set at $P < 0.05$. All analyses were carried out using the statistical package SPSS v21.00 (IBM Corporation, Somers, NY, United States).

RESULTS

Descriptive and clinical data

Patient recruitment lasted from January 2018 to March 2020, by which time the required number of participants had been reached. The recruitment procedure is depicted in the flow diagram in Figure 1. Eight patients (one from DAA-nonobese group, two from DAA-obese group, two from Hardinge–nonobese group and four from Hardinge-obese group) were lost to follow up due to wound healing problems. Finally, data from 120 patients (30 patients per group) were analysed (Figure 1). There is homogeneity between compared groups for all demographic and clinical characteristics apart from weight ($P < 0.001$) and BMI ($P < 0.001$), as expected (Table 1). At baseline, there is a statistically significant difference between compared groups in relation of variables, FPS-R ($P = 0.045$), TUG ($P = 0.033$), MHSS-Gr ($P < 0.001$); except iHOT12-Gr ($P = 0.100$) (Table 1); hence, the percentage (%) of changes of all variables/outcome scores in between groups - from baseline to 6th and 12th week- were presented.

The comparison of all variables/outcomes' scores during the observation period per group, showed that its absolute values were statistically significant different ($P < 0.001$) (Table 2). Patients of all groups benefited from the THA regarding the pain's level, functionality and quality-of-life.

The exploration of interaction between "BMI" and "Surgical Approach" factors revealed statistically significant difference in pain-levels (FPS-R) at 12th week [$F(1.116) = 4.11$, $P = 0.045$] (Table 3). Exploring the data to illustrate the source of that interaction, we also compared the percentage of change of the other variables/outcome measures (TUG, MHHS-Gr, iHOT112-Gr) from baseline to 6th and 12th week: a) across the two surgical approaches by BMI-level, and b) across BMI-level per surgical approach, adjusting significance cut-off points for multiple comparison.

Comparative results

DAA *vs* Hardinge regardless of BMI: At the 6th postoperative week's measurements, DAA patients reported 12.2 % lesser pain (FPS-R), more functional ability (14.8% faster TUG test performance time and 21.5% higher MHHS-Gr score), and 38.2% better quality-of-life (iHOT12-Gr) compared to Hardinge patients, with statistically significant differences (all P values <0.001) (Table 4). At 12th postoperative week's measurements these differences of both DAA groups' outcomes were further increased [FPS-R: 9.9% ($P < 0.001$), TUG test: 21.2 % ($P < 0.001$), MHHS-Gr: 22.5% ($P = 0.05$), and iHOT12-Gr: 40.5% ($P < 0.001$)] (Table 4). The DAA resulted in less postoperative pain, and offered faster and increased functional ability and better quality-of-life compared to the Hardinge.

DAA-nonobese *vs* Hardinge-nonobese: At the measurement of the 6th postoperative week, the DAA-nonobese group had better % percentage of change in all outcomes: [FPS-R: 14.8% ($P < 0.001$), TUG test: 13.5 % ($P < 0.001$), MHHS-Gr: 16.5% ($P = 0.026$), and iHOT12-Gr: 44.9% ($P < 0.001$)] in comparison to the Hardinge –nonobese (Table 4). At the 12th postoperative week's measurements the DAA-nonobese FPS-R was lowered by 14.0% ($P < 0.001$), the TUG test performance time was shortened by 19.8 % ($P < 0.001$), and iHOT12-Gr got higher by 41.7% ($P = 0.048$), than Hardinge –nonobese. Although the DAA-nonobese group MHHS-Gr was higher by 11.5%, no statistically significant difference was revealed ($P = 0.777$) (Table 4). The DAA leads faster to better functional ability and quality-of-life compared to the Hardinge, in nonobese patients.

DAA-obese *vs* Hardinge-obese: At the 6th postoperative week's measurements DAA-obese patients had a greater % percentage of change of all outcomes [FPS-R: 9.7% ($P = 0.002$), TUG test performance time: 16.0% ($P < 0.001$), MHHS-Gr: 26.6% ($P = 0.012$), and iHOT12-Gr: 31.4% ($P = 0.031$) compared to Hardinge-obese patients (Table 4). At the 12th postoperative week's measurements, the only statistically significant difference was revealed at TUG test performance time of DAA-obese: 22.6% ($P < 0.001$), while the differences of the FPS-R, MHHS-Gr and iHOT-Gr were not statistically significant (Table 4). Regarding obese patients, DAA leads faster to better functional ability and quality-of-life compared to the Hardinge; at 12 wk the statistically significant

Table 1 Demographic characteristics and clinical measurements of the study sample (*n* = 120)

Characteristics and Clinical Measurements	DAA–nonobese (*n* = 30)	DAA–obese (*n* = 30)	Hardinge–nonobese (*n* = 30)	Hardinge–obese (*n* = 30)	*P* value
Age (yr)[1]	66.40 ± 7.31	63.73 ± 6.96	69.00 ± 9.00	63.73 ± 6.96	0.102
Height (m)[1]	1.65 ± 0.09	1.64 ± 0.10	1.62 ± 0.08	1.64 ± 0.09	0.442
Weight (kg)[1]	73.10 ± 10.95	92.63 ± 14.14[a,b]	66.30 ± 8.10	93.93 ± 16.09[a,b]	< 0.001
Body mass index (kg/m^2)[1]	26.61 ± 2.16	34.27 ± 4.12[a,b]	25.30 ± 2.03	34.73 ± 4.57[a,b]	< 0.001
Dominant lower limb, *n* (%)					
Right	24 (80.0)	25 (83.3)	27 (90.0)	25 (83.3)	0.756
Left	6 (20.0)	5 (16.7)	3 (10.0)	5 (16.7)	
Affected hip, *n* (%)					
Right	15 (50.0)	18 (60.0)	14 (46.7)	18 (60.0)	0.442
Left	15 (50.0)	12 (40.0)	16 (53.3)	12 (40.0)	
Walking aid, *n* (%)					
No	25 (83.3)	22 (73.3)	24 (80)	19 (63.3)	0.292
Yes	5 (16.7)	8 (26.7)	6 (20.0)	11 (36.7)	
Kellgren & Lawrence classification, *n* (%)					
Grade 3	21 (70.0)	19 (63.3)	20 (66.7)	19 (63.3)	0.939
Grade 4	9 (30.0)	11 (36.7)	10 (33.3)	11 (36.7)	
Face Pain Scale-Revised[1] (10 = worst pain)	6.47 ± 1.55[a]	6.87 ± 1.80	7.13 ± 1.36	7.60 ± 1.52	0.045
Timed Up and Go test (s)[1]	16.09 ± 3.07[a]	16.07 ± 5.56[a]	17.12 ± 5.22	19.32 ± 4.99	0.033
Modified Harris Hip Score – Greek version[1] (100 = max best score)	41.00 ± 6.55	33.94 ± 9.62[b]	38.53 ± 8.15	31.66 ± 11.14[b]	< 0.001
International Hip Outcome Tool (12 items) – Greek version[1] (100 = max best score)	31.43 ± 9.04	31.52 ± 8.26	28.28 ± 9.24	26.39 ± 10.00	0.100

[1]The values are expressed as mean ± SD.
[a]$P < 0.005$ *vs* DAA-nonodese.
[b]$P < 0.005$ *vs* Hardinge –nonobese. DAA: Direct anterior approach.

differences between groups were narrowed.

Nonobese *vs* obese regardless of surgical approach: At the 6th postoperative week's measurements obese patients reported higher MHHS-Gr (16.8%) with statistically significant difference ($P = 0.001$) than nonobese. No statistically significant differences were revealed regarding the other outcomes (Table 5). At the 12th postoperative week's measurements obese patients' MHHS-Gr score was further increased (37.5%, $P = 0.001$), but still no statistically significant differences were revealed regarding the other outcomes (Table 5). Overall, regardless of the surgical approach, the only statistically significant difference between obese and nonobese patients was revealed in the self-reported functional ability as expressed by the MHHS-Gr questionnaire.

DAA-nonobese *vs* DAA-obese: At the 6th postoperative weeks' measure-ments, no statistically significant differences were observed in the comparison of postoperative outcomes (Table 5). Likewise, no statistically significant differences were observed in comparing postoperative outcomes at the 12th postoperative weeks' measurements (Table 5). The DAA similarly benefited both obese and nonobese patients.

Hardinge-nonobese *vs* Hardinge-obese: At the 6th postoperative weeks' measure-ments, no statistically significant differences were observed between Hardinge-nonobese and Hardinge-obese groups (Table 5). At the 12th postoperative weeks' measurements, only the TUG test performance time of Hardinge-nonobese patients was significantly shorter (5.5%, $P = 0.001$) compared to Hardinge-obese patients (Table 5). Overall, Hardinge-nonobese reached in higher functionality, as expressed by

Table 2 Comparison of outcomes' scores during the observation period per group

Groups	Preoperative measurement	6th postoperative week	12th postoperative week	*P* value
Face Pain Scale-Revised (min 0 - max 10)				
DAA-nonobese	6.46 ± 1.55	1.97 ± 0.72	0.13 ± 0.35	F(2.58) = 563.8, $P < 0.001$
DAA-obese	6.87 ± 1.79	1.93 ± 0.69	0.30 ± 0.53	F(2.58) = 293.1, $P < 0.001$
Hardinge-nonobese	7.13 ± 1.36	3.20 ± 0.80	1.17 ± 0.70	F(2.58) = 830.9, $P < 0.001$
Hardinge-obese	7.60 ± 1.52	3.00 ± 0.69	1.00 ± 0.69	F(2.58) = 673.7, $P < 0.001$
Timed Up and Go Test (second)				
DAA-nonobese	16.09 ± 3.07	11.22 ± 2.29	7.81 ± 1.74	F(2.58) = 399.81, $P < 0.001$
DAA-obese	16.07 ± 5.56	10.95 ± 2.52	8.02 ± 2.32	F(2.58) = 89.55, $P < 0.001$
Hardinge-nonobese	17.12 ± 5.21	14.17 ± 3.69	11.62 ± 3.00	F(2.58) = 122.04, $P < 0.001$
Hardinge-obese	19.32 ± 5.00	16.60 ± 4.14	14.33 ± 3.84	F(2.58) = 289.56, $P < 0.001$
Modified Harris Hip Score – Greek version (min 0 – max 100)				
DAA-nonobese	41.00 ± 6.54	70.75 ± 8.20	92.41 ± 3.83	F(2.58) = 1148.1, $P < 0.001$
DAA-obese	33.94 ± 9.62	63.98 ± 10.86	87.83 ± 6.29	F(2.58) = 893.7, $p<0.001$
Hardinge-nonobese	38.53 ± 8.15	60.68 ± 10.68	82.17 ± 9.00	F(2.58) = 1291.8, $P < 0.001$
Hardinge-obese	32.07 ± 10.41	53.82 ± 15.00	74.38 ± 11.78	F(2.58) = 1066.6, $P < 0.001$
International Hip Outcome Tool (12 items) – Greek Version (min 0 – max 100)				
DAA-nonobese	31.43 ± 9.04	67.00 ± 10.05	86.18 ± 10.00	F(2.58) = 703.53, $P < 0.001$
DAA-obese	31.52 ± 8.25	66.06 ± 12.95	88.43 ± 7.77	F(2.58) = 740.71, $P < 0.001$
Hardinge-nonobese	28.28 ± 9.24	50.39 ± 15.72	67.96 ± 14.77	F(2.58) = 411.82, $P < 0.001$
Hardinge-obese	26.39 ± 10.00	47.21 ± 16.88	63.46 ± 16.21	F(2.58) = 351.81, $P < 0.001$

All values are presented as mean ± SD; All time points are statistically significant different between them, $P < 0.001$. DAA: Direct anterior approach.

Table 3 Interaction between "body mass index" and "surgical approach" factors

Outcomes/Variables	6th postoperative week	12th postoperative week
Face Pain Scale-Revised	F(1.116) = 1.96, $P = 0.164$	F(1.116) = 4.11, $P = 0.045$
Timed Up and Go Test	F(1.116) = 0.97, $P = 0.328$	F(1.116) = 0.79, $P = 0.376$
Modified Harris Hip Score – Greek version	F(1.116) = 1.01, $P = 0.316$	F(1.116) = 0.93, $P = 0.337$
International Hip Outcome Tool (12 items) – Greek Version	F(1.116) = 0.80, $P = 0.373$	F(1.116) = 0.11, $P = 0.917$

Significant $P < 0.05$.

TUG test, than Hardinge-obese patients.

DISCUSSION

In the present study, the effect of two different THA surgical approaches (DAA *vs* Hardinge) on postoperative pain levels, functionality and quality-of-life in both obese and nonobese hip OA patients was explored. Our results showed that the DAA resulted in less postoperative pain, and offered faster achieved and increased functional ability and better quality-of-life compared to the Hardinge. In addition, the measured outcomes of the aforementioned parameters did not differ between obese and nonobese DAA patients; DAA similarly benefited both obese and nonobese patients.

Table 4 The % percentage changes of outcome scores, between surgical approaches, according and regardless of body mass index, compared to corresponding baseline measurements

		Nonobese (BMI < 30 kg/m^2)			Obese (BMI ≥ 30 kg/m^2)			Comparison between surgical approaches regardless of BMI		
Outcomes/ variables	**Postope-rative measure-ments**	**DAA[1]**	**Hard-inge[1]**	***P* value[3]**	**DAA[1]**	**Hard-inge[1]**	***P* value[3]**	**DAA[2]**	**Hardinge[2]**	***P* value[3]**
Face Pain Scale - Revised (%)	6th week	-70.1 ± 6.7	-55.3 ± 7.3	< 0.001	-70.0 ± 15.8	-60.3 ± 6.9	0.002	-70.0 ± 1.3	-57.8 ± 1.3	< 0.001
	12th week	-98.4 ± 4.1	-84.4 ± 8.2	< 0.001	-93.3 ± 18.7	-87.5 ± 8.3	0.429	-95.8 ± 1.4	-86.0 ± 1.4	< 0.001
Timed Up and Go Test (%)	6th week	-30.1 ± 6.5	-16.5 ± 4.8	< 0.001	-29.9 ± 10.9	-13.9 ± 2.9	< 0.001	-30.0 ± 0.9	-15.2 ± 0.9	< 0.001
	12th week	-51.2 ± 6.4	-31.4 ± 5.9	< 0.001	-48.5 ± 14.4	-25.9 ± 3.9	< 0.001	-49.9 ± 1.1	-28.7 ± 1.1	< 0.001
Modified Harris Hip Score – Greek version (%)	6th week	76.2 ± 27.4	59.6 ± 13.9	0.026	97.9 ± 38.5	71.4 ± 23.6	0.012	87.0 ± 3.5	65.5 ± 3.5	< 0.001
	12th week	132.9 ± 50.4	121.4 ± 43.2	0.777	181.4 ± 89.6	147.8 ± 56.4	0.317	157.1 ± 8.1	134.6 ± 8.1	0.050
International Hip Outcome Tool (12 items) – Greek version (%)	6th week	124.4 ± 51.6	79.5 ± 22.9	< 0.001	115.7 ± 39.4	84.3 ± 46.0	0.031	120.1 ± 5.3	81.9 ± 5.3	< 0.001
	12th week	192.0 ± 76.1	150.3 ± 43.7	0.048	195.4 ± 64.2	156.1 ± 67.5	0.077	193.7 ± 8.3	153.2 ± 8.3	< 0.001

[1]The values are presented as mean ± SD.

[2]The values are presented as mean ± SE (%).

[3]*P* value$_{\text{Bonferroni correction}}$. BMI: Body mass index; DAA: Direct anterior approach.

The selection of the best surgical approach for THA remains a matter of debate. While Hardinge is widely used, mainly due to its reduced dislocation rate[17], DAA is gaining popularity as its intermuscular pathway preserves soft tissues, ensuring an excellent functional outcome and reduced postoperative pain[4]. Our results are in line with other studies which suggest that DAA is more beneficial to the patients in terms of postoperative pain relief and faster recovery, than Hardinge[30]. A recent meta-analysis has concluded that, in comparison to the lateral approach, the anterior approach is correlated with reduced pain at 6 wk postoperatively, increased walking velocity, stride length and step length, while no difference was found in the Harris Hip Score and the rate of complications[31]. In the present study, we found that DAA was associated with higher pain relief, enhanced functional outcomes and quality-of-life at the 6th week, while these outcomes increased even more at 12th week.

Several studies have shown that obese patients do not differ from the nonobese ones in terms of postoperative outcomes[14-16]. Similarly, in the present study, both obese and nonobese patients of DAA groups reached equivalent pain-levels, functionality and quality-of-life, suggesting that BMI is indeed not a factor that will influence the postoperative outcomes of DAA. However, this was not observed in Hardinge-groups. Although at 6th weeks' measurements, no statistically significant differences were observed between Hardinge-nonobese and Hardinge-obese groups, at 12th week, Hardinge-nonobese presented significantly improved TUG test performance time in comparison to Hardinge-obese patients. This could be explained by the fact that, preoperatively, Hardinge-nonobese had no-significant shorter TUG test performance time than Hardinge-obese (Table 1), which became significant after the THA.

The comparison between obese patients showed that, DAA leads faster to better functional ability and quality-of-life compared to the Hardinge. At 12th postoperative week's measurements, the only statistically significant difference was revealed at TUG test performance time of DAA-obese group. This is not surprising since it is well known that the hip abductor strength improved at 3 mo following THA performed by a conventional approach, such as Hardinge[32], while the hip abductor strength was linear associated with TUG test[33].

In the present study, most cases with wound healing problems were reported in Hardinge-obese patients (four out of 35 patients, 11.4%), as shown in our flow diagram. This rate was lower than the rates reported in the literature, for obese

Table 5 The % percentage changes of outcome scores, between body mass index groups, according and regardless of surgical approach, compared to corresponding baseline measurements

Outcomes/ variables	Postope-rative measure-ments	DAA			Hardinge approach			Comparison between BMI groups regardless of surgical approach		
		Nonobese	Obese[1]	*P* value[3]	Nono-bese[1]	Obese[1]	*P* value	Nono-bese[2]	Obese[1]	*P* value[3]
Face Pain Scale - Revised (%)	6th week	-70.1 ± 6.7	-70.0 ± 15.8	1.000	-55.3 ± 7.3	-60.3 ± 6.9	0.304	-62.7 ± 01.3	-65.1 ± 1.3	0.178
	12th week	-98.4 ± 4.1	-93.3 ± 18.7	0.468	-84.4 ± 8.2	-87.5 ± 8.3	0.451	-91.4 ± 1.4	-90.4 ± 1.4	0.631
Timed Up and Go Test (%)	6th week	-30.1 ± 6.5	-29.9 ± 10.9	1.000	-16.5 ± 4.8	-13.9 ± 2.9	0.102	-23.3 ± 0.9	-21.9 ± 0.9	0.278
	12th week	-51.2 ± 6.4	-48.5 ± 14.4	0.783	-31.4 ± 5.9	-25.9 ± 3.9	0.001	-41.3 ± 1.1	-37.2 ± 1.1	0.010
Modified Harris Hip Score – Greek version (%)	6th week	76.1 ± 27.4	97.9 ± 38.5	0.068	59.6 ± 13.9	71.4 ± 23.6	0.102	67.9 ± 3.5	84.6 ± 3.5	0.001
	12th week	132.9 ± 50.4	181.4 ± 89.6	0.061	121.4 ± 43.2	147.8 ± 56.4	0.186	127.1 ± 8.1	164.6 ± 8.1	0.001
International Hip Outcome Tool (12 items) – Greek version (%)	6th week	124.4 ± 51.6	115.7 ± 39.4	0.841	79.5 ± 22.9	84.3 ± 46.0	0.957	102.0 ± 5.3	100.0 ± 5.3	0.793
	12th week	192.0 ± 76.1	195.4 ± 64.2	1.000	150.3 ± 43.7	156.1 ± 67.5	1.000	171.1 ± 8.3	175.7 ± 8.3	0.697

[1]The values are presented as mean ± SD.
[2]The values are presented as mean ± SE (%).
[3]*P* value$_{\text{Bonferroni correction}}$. BMI: Body mass index; DAA: Direct anterior approach.

patients, on other classical surgical approaches, ranging from 14.5% to 22%[34,35]. Regarding DAA, one incidence in nonobese and two incidences in obese participants were found (3.5 % and 5.7%, respectively). The study's results are within the rates reported in the literature: for DAA-nonobese ranging between 0.8% and 3%, while for DAA-obese patients ranging from 4.46% to 10.0%[36-38]. It is worth to be noted that the horizontal (bikini) incision was shown to facilitate even more wound healing in obese patients. In the retrospective comparative study by Manrique *et al*[39], involving obese patients (BMI > 30 kg/m^2) it was reported that patients with horizontal incision had significant lower rates of wound healing problems compared to patients with vertical incision (0.00% *vs* 16.6%, $P = 0.04$)[39]. Nevertheless, the current evidence is limited, and further trials are warranted to identify differences between the two DAA skin incisions regarding wound healing in obese patients.

While the risks associated with THA in obese patients are well documented [11,34], the present study results show that DAA would be a preferable THA approach for obese patients. Since it is a minimally invasive surgical technique that provides the most direct access to the hip joint, DAA can be safely performed, by an experienced surgeon and under certain precautions, without an increased and adverse risk for obese patients[4,40].

Strengths and limitations

The present study was a four-group randomised controlled trial. All patients underwent uncemented THA, and the same physiotherapist was responsible for the physiotherapy intervention in all four groups. After discharge, the supervision and guidance from the physiotherapist, during in-home sessions, helped ensure patient adherence to protocol and thus, the study's dropout rate was minimal. Moreover, all measurements were made by the same examiner, who was not involved in any other part of the study. These factors added strength and statistical power to the results of this study.

On the other hand, there are important limitations that ought to be mentioned. Patients were followed up until the 12th postoperative week; it is, therefore, unclear whether the observed postoperative differences between DAA and Hardinge will be maintained over time, even though several studies consistently showed better outcomes with DAA during functional rehabilitation within one year of surgery[41-

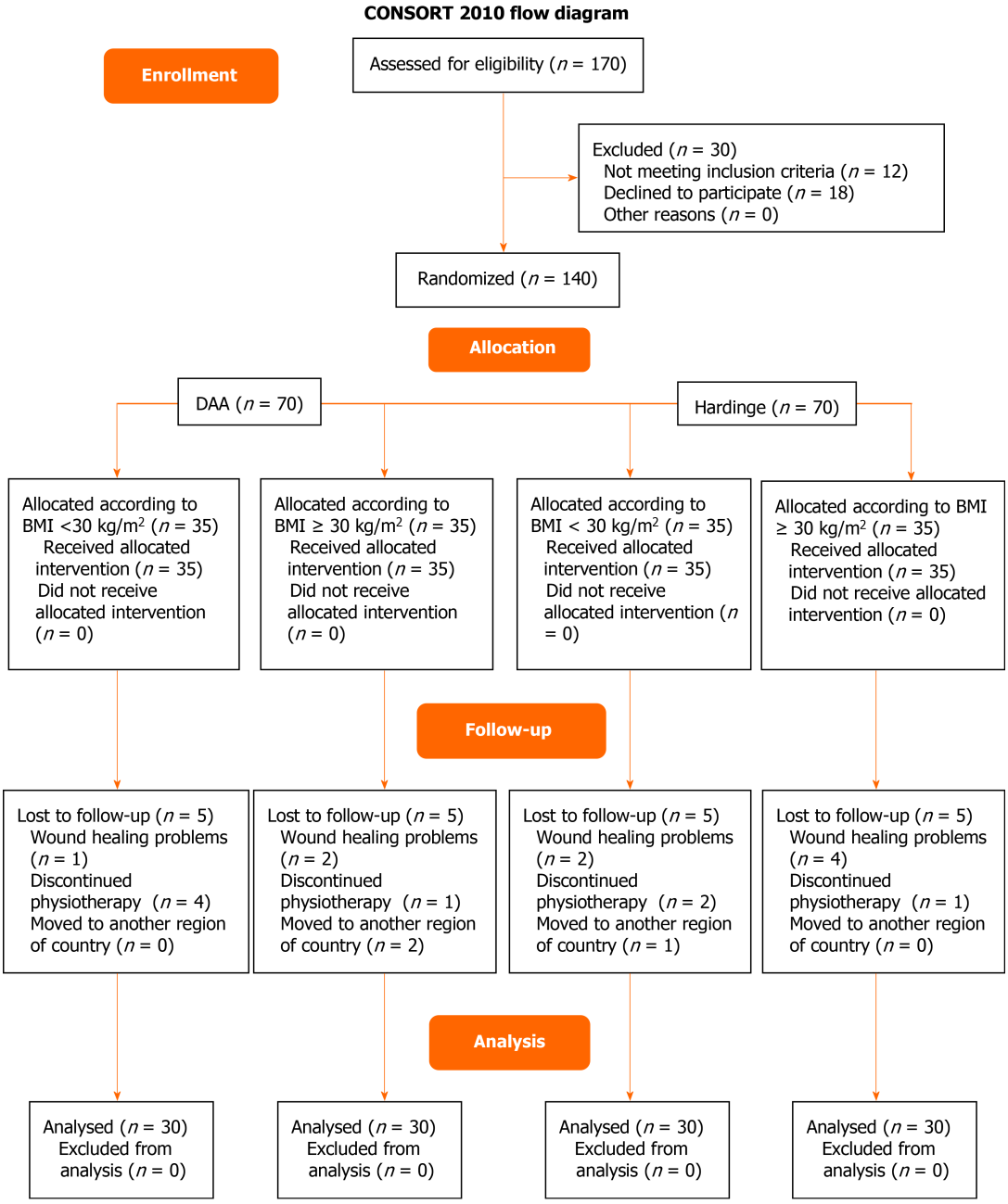

Figure 1 The flow diagram of the study. DAA: Direct anterior approach.

44]. However, the fact that DAA allowed our patients to achieve a more rapid recovery than Hardinge concluded to their postoperative rehabilitation being less costly, since their independency was faster obtained, regardless of BMI. Another limitation is that DAA and Hardinge were performed by two different orthopaedic surgeons, a fact that may predispose biased conclusions. Even though our results are indicative, further research is needed to produce safer results regarding the impact of obesity in pain, functional outcomes, and quality-of-life after THA in between different approaches, which is ultimately more appropriate for obese hip OA patients.

CONCLUSION

In conclusion, the patients of our study reported less pain, more functionality and quality-of-life improvements, more so after THA with DAA, compared to the Hardinge. Moreover, DAA exhibits equivalent postoperative outcomes in obese and nonobese patients, suggesting a better-suited THA surgical approach for patients with increased BMI. Understanding the postoperative changes in pain's level, functional

outcomes and quality-of-life in both obese and nonobese patients, as reported in the current study, will be helpful for both the patients and the surgeons regarding the decision-making process for the more appropriate THA surgical technique.

ARTICLE HIGHLIGHTS

Research background

Total hip arthroplasty (THA) is an effective treatment for most patients who suffer from pain and decreased functional ability due to hip osteoarthritis (OA). The main risk factors for developing hip OA are advanced age, family history of OA, previous hip injury, hip dysplasia, and obesity. The increased prevalence of obesity has resulted in orthopedic surgeons being likely to face many patients with a high body mass index (BMI) who warrant THAs over the coming years. On the other hand, there has been growing interest in the direct anterior approach (DAA) in recent years because of its soft-tissue–preserving nature. Total hip arthroplasty (THA) is an effective treatment for most patients who suffer from pain and decreased functional ability due to hip osteoarthritis (OA). The main risk factors for developing hip OA are advanced age, family history of OA, previous hip injury, hip dysplasia, and obesity. The increased prevalence of obesity has resulted in orthopedic surgeons being likely to face many patients with a high body mass index (BMI) who warrant THAs over the coming years. On the other hand, there has been growing interest in the direct anterior approach (DAA) in recent years because of its soft-tissue–preserving nature.

Research motivation

In the literature, it has been reported that obesity is significantly associated with a greater need for joint replacement and that compared to patients with normal body mass index (BMI), obese patients may require a THA up to ten years earlier. Some studies indicate that obesity is associated with poorer clinical, functional outcomes, while others have shown that obese patients do not differ from the nonobese in this respect. The data are considered controversial, and further studies need to be performed on obese patients, especially comparative evaluations that compare minimally invasive techniques such as DAA with classical surgical techniques, such as the Hardinge approach. Compared to other classical surgical approaches used in obese patients, the Hardinge was chosen because it offers better access to the hip joint and achieves a lower dislocation rate by preserving its posterior stabilizer muscles.

Research objectives

We aimed to compare DAA and Hardinge in hip OA patients who have undergone primary THA regarding postoperative pain levels, functional status, and quality-of-life. In addition, it was investigated whether these parameters differ between obese and nonobese patients.

Research methods

The present study was a prospective, four-group randomized controlled trial (Clinical Trial Identifier: ISRCTN15066737). One hundred twenty participants were divided into four groups (30 patients per group) according to both the surgical approach used and their body mass index (BMI) as follow: DAA-nonobese group (BMI < 30 kg/m^2), DAA-obese group (BMI ≥ 30 kg/m^2), Harginge-nonobese group (BMI < 30 kg/m^2) and Harginge-obese group (BMI ≥ 30 kg/m^2). Measurements were carried out prior to surgery (baseline) and postoperatively (at the end of the 6th week and 12th week). Pain levels were measured with the Face Pain Scale – Revised (FPS-R). Functional ability was evaluated with the Timed Up & Go (TUG) test and the Greek version of the Modified Harris Hip Score (MHHS-Gr). Quality-of-life was measured with the Greek version of the International Hip Outcome Tool -12 items (iHOT12-Gr).

Research results

DAA *vs* Hardinge regardless of BMI: The DAA resulted in less postoperative pain and offered faster and increased functional ability and better quality-of-life than the Hardinge. DAA-nonobese *vs* Hardinge-nonobese: The DAA leads faster to better functional ability and quality-of-life compared to the Hardinge in nonobese patients. DAA-obese *vs* Hardinge-obese: DAA leads faster to better functional ability and quality-of-life of obese patients than the Hardinge; at 12 wk, statistically significant differences between groups were narrowed. Nonobese *vs* obese regardless of surgical

approach: the only statistically significant difference between obese and nonobese patients was revealed in the self-reported functional ability. DAA-nonobese *vs* DAA-obese: no statistically significant differences were observed in comparing postoperative outcomes. The DAA similarly benefited both obese and nonobese patients. Hardinge-nonobese *vs* Hardinge-obese: Hardinge-nonobese reached higher functionality than Hardinge-obese patients.

Research conclusions

DAA patients reported less pain, more functionality, and quality-of-life improvements compared to the Hardinge. Moreover, DAA exhibits equivalent postoperative outcomes in obese and nonobese patients, suggesting a better-suited THA surgical approach for patients with increased BMI.

Research perspectives

Further research based on well-designed studies with longer follow-up and larger samples need to be performed to elucidate the efficacy of DAA on functionality and quality of life of hip OA obese patients.

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ORIGINAL ARTICLE

Observational Study

Work-related musculoskeletal injuries among upper extremity surgeons: A web-based survey

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Informed consent statement: This study didn't require consent forms from the participants and filling up the survey was considered a consent from the participating surgeons.

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Abstract

BACKGROUND

Work-related injuries have gained recent attention, especially in the orthopaedic literature. As upper extremity orthopaedic surgical tasks require repetitive and constant maneuvers, these surgeons can be at increased risk of acquiring work-related musculoskeletal (MSK) disorders during their years in practice.

AIM

To assess the prevalence, characteristics and impact of MSK disorders among upper extremity orthopaedic surgeons.

METHODS

A modified version of the physical discomfort survey was sent to surgeons who were members of the American Shoulder and Elbow Surgeons and the Canadian shoulder and elbow society *via* e-mail. The collected data were analyzed using descriptive statistics, one-way analysis of variance, and Fisher's exact test. *P* values of < 0.05 were considered statistically significant.

RESULTS

Of the 142 respondents, 90.8% were males and the majority were younger than 55 years old (65.5%). A work-related MSK injury was reported by 89.4% of respondents, of which the most common diagnoses were low back pain (26.1%) and lateral elbow epicondylitis (18.3%). Among those that reported an injury, 82.7% required treatment and 26% required time off work as a direct result of their injury. The need to undergo treatment due to the injury was associated with increased number of injuries ($P < 0.01$). Moreover, surgeons were more likely to require time off work when they had been in practice for > 21 years ($P < 0.05$).

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CONCLUSION

A high proportion of surgeons in our survey reported MSK injuries, with more than one quarter of surgeons reported requiring time off work due to an MSK injury. The high incidence of these disorders may place a financial and psychological burden on surgeons and affect their ability to provide patient care. Awareness of operative ergonomics, irrespective of surgical specialty may help to decrease or possibly prevent the occurrence of these disorders.

Key Words: Upper; Extremity; Surgeon; Prevalence; Musculoskeletal; Disorders

Core Tip: A high proportion of surgeons in our survey reported MSK injuries, with more than one quarter of surgeons reported requiring time off work due to an MSK injury. Awareness of operative ergonomics, irrespective of surgical specialty may help to decrease or possibly prevent the occurrence of these disorders.

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INTRODUCTION

Healthcare professionals are exposed daily to occupational hazards in their work environment, which can be chemical, radiation, psychological or musculoskeletal (MSK)[1-3]. The latter has gained increased attention in the medical literature due to its high prevalence in physicians, especially surgeons, in addition to its significant impact both physically and psychologically on the physician and thus health care system in general[4-6].

While all surgeons have been found to have an increased risk of sustaining work related MSK disorders, recent studies have shown that the orthopaedic surgeon is at an even increased risk[2,6-8]. Repetitive and constantly forceful surgical tasks have been identified as the major contributing factor to their increased prevalence in orthopaedic surgeons. In addition, these MSK disorders can involve multiple regions, including the lower back and both upper and lower extremities.

Improving operative room setup and ergonomics, in addition to implementing safe workplace recommendations can lead to a decrease in the incidence of these injuries[9-11]. Multiple hurdles have been identified that prevent specific ergonomic setups or hinder executing work space recommendations, which may contribute to the lack of decline of these MSK disorders in the healthcare profession population[12-13].

We performed a study to investigate the prevalence and characteristics of MSK disorders among upper extremity orthopaedic surgeons. In addition, we assessed for any associated risk factors and explored the impact of these injuries on the upper extremity surgeon's practice.

MATERIALS AND METHODS

A modified version of the physical discomfort survey was sent to surgeons who were members of the American Shoulder and Elbow Surgeons and the Canadian shoulder and elbow society *via* e-mail. The initial email was sent in June 2016, followed by a reminder email in December 2016, and survey collection was ended in June 2017.

The survey contained questions related to the surgeons demographics (*e.g.*, age, gender, hand-dominance, type of practice, number of years in practice and annual caseload), which were divided into groups guided by previously published similar studies. Also, the survey contained questions exploring work related MSK injuries, these were divided into anatomical regions, including neck, shoulder, elbow/forearm,

Table 1 Demographics of surveyed upper extremity surgeons

	Number	Percentage (%)
Total respondents	142	100
Sex		
Male	129	90.8
Female	13	9.2
Hand dominance		
Right	122	85.9
Left	20	14.1

wrist/hand, hip, knee, foot and ankle, low back. In addition, participants were asked about both treatments required and time off work required due to the reported injuries, if any.

The collected data were analyzed using descriptive statistics, one-way analysis of variance, and Fisher's exact test. P values of < 0.05 were considered statistically significant.

RESULTS

One hundred and forty-two surgeons responded to the survey, with a respondent rate of 12.5%. Of the 142 respondents, 90.8% were males and 9.2% were females (Table 1). Hand dominance was right in 122 and left in 20 respondents (Table 1). More than 60% of the respondents were younger than 55 years old (Figure 1). The majority of responding surgeons were within their first 20 years of practice (Figure 2). We found that above half of the respondents were in academic practice, 23.2% in community practice, 18.3% in private practice.

Work-related MSK injuries were reported by 89.4% of respondents (Table 2), of which the most common diagnoses were low back pain (26%), lateral elbow epicondylitis (18%), and neck pain (15.5%) (Figure 3). We found no association between the number of work-related injuries incurred and age, type of practice nor years in practice.

Of the surgeons that reported an injury, 82.7% required treatment, with 65.7% requiring medical treatment, 20% requiring surgical treatment and 14.3% requiring both (Table 3). The need to undergo treatment due to the injury was associated with increased number of injuries ($P < 0.01$). Age and number of years in practice were not associated with the requirement of treatment for sustained injuries. More than a quarter of the surgeons required time off work as a direct result of their injury, which was associated with being in practice for > 21 years ($P < 0.05$), but not with the surgeon's age (Table 2).

DISCUSSION

A number of studies in the current literature have assessed the prevalence of work-related hazards, both on a general healthcare worker scale and specific medical and surgical specialties[1,2,14,15]. Our current study explored the prevalence of MSK injuries in the orthopaedic upper extremity surgeon population, who share with other orthopaedic surgeons' exposure to forceful and repetitive operative task that put this cohort at an increased risk for sustaining these injuries during their career.

More than 89% of our studied cohort reported a work related MSK injury at some time in their career, with spine and elbow injuries being the most common. This prevalence was found to be higher than the findings in previously published studies in other orthopaedic specialties, as in a study of 183 arthroplasty surgeons, 66% reported a work-related MSK injury[14]. Similarly, in the orthopaedic trauma surgeon and pediatric orthopaedic surgeon cohorts the prevalence was 66% and 67%, respectively [6,7]. Concerning the most commonly reported regions, cervical and lumbar spine disease and rotator cuff pathology were identified as the most common work-related musculoskeletal disorders in a recent meta-analysis of 5828 physicians[4]. In the

Table 2 Percentage of surveyed upper extremity surgeons with disorders and their requirement of time off work according to sex, age, hand dominance, type of practice, number of institutes, years in practice and annual caseload

	Number of respondents (%)	Number of respondents with injuries (%)	Number of injured requiring time off work (%)
Age (yr)			
≤ 45	38.7	81.8	14.5
46-55	26.8	92.1	34.2
56-65	26.1	70.3	29.7
> 65	8.4	91.7	8.3
Sex			
Male	90.8	92.2	24
Female	9.2	61.5	15.4
Hand dominance			
Right	85.9	88.5	26.2
Left	14.1	95	5
Type of practice			
Academic	50.7	88.9	23.6
Community	23.2	87.9	21.2
Private	18.3	88.5	26.9
Other	7.8	100	18.2
Number of institutes			
1	92.3	88.5	23.7
> 1	7.7	100	18.2
Year in practice			
≤ 10	26.7	78.9	15.8
11-20	35.2	90	26
21-30	21.2	100	30
> 30	16.9	91.7	20.8
Annual caseload			
≤ 250	15.5	90.9	18.2
251-500	64.1	87.9	22
501-750	16.9	91.7	33.3
> 750	3.5	100	20

orthopaedic literature, low back and elbow injuries (especially lateral epicondylitis) were the most common regions involved in the majority of these studies, similar to our findings[6,7]. This may be attributed to the sometime long operative procedures associated with a standing posture, in addition to the frequent pronation/supination movements required during these procedures.

Interestingly, we found no association between the age nor number of years in practice and the risk for sustaining a work-related MSK injury. This is in agreement with the study by Alqahtani *et al*[14] on 183 arthroplasty surgeons, that also found no association. In contrast, a study on the orthopaedic trauma surgeon population identified an association between the number of MSK disorders and the surgeons age and number of years in practice. Alzahrani *et al*[6,7]. also found the same association in a study of 402 pediatric orthopaedic surgeons, where increasing age, working in more than one institute and being in practice more than 21 years was associated with increased number of work-related MSK injuries.

Table 3 Percentage of surveyed upper extremity surgeons with diagnosed disorders per region and number of respondents requiring treatment, requiring surgical treatment and requiring time-off work due to their musculoskeletal disorders

Region	Percentage of respondents with injuries	Percentage of injured respondents requiring treatment	Percentage of treated respondents requiring surgical treatment	Percentage of treated respondents requiring time-off work
Neck	32.3	17.7	5.9	4.4
Shoulder	36.0	22.8	6.6	7.4
Elbow	27.2	14.0	2.2	1.5
Forearm, wrist and hand	32.3	13.2	4.4	3.7
Hip and thigh	6.8	3.0	3.0	2.3
Knee and lower leg	15.9	9.1	6.1	4.6
Foot and ankle	10.6	4.6	0	0
Lower back	43.9	26.5	3.0	5.3

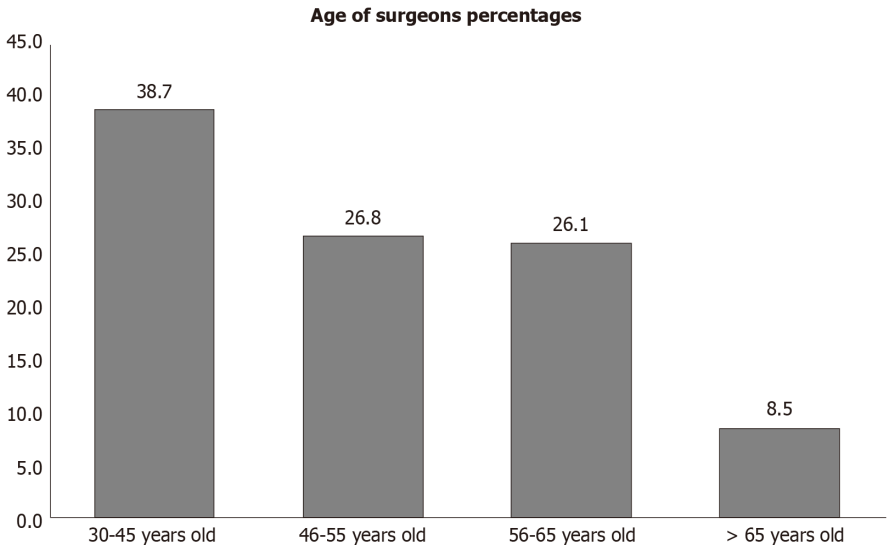

Figure 1 Surgeon age distribution.

Our current study and previously published literature indicate that the risk of work-related musculoskeletal disorders is high, especially in orthopaedic surgeons. Specific attention should be directed towards improving operative room ergonomics and surgeon education on the adequate and safe postures and movements while in the operating room[10,16]. In addition, utilizing instruments that decrease the requirement of repetitive forceful movements in the operating room (*e.g.*, power for inserting screws) may help protect these surgeons during their long career[13].

Our study has some limitations, including recall bias of these reported injuries. In addition, similar to previously used surveys which include self-reported measures, our current survey has not had its reliability and validity established. Also, due to the low response rate, selection bias may also be another limitation. But we believe that this sample size is truly representative of the population in study as the sample size is similar to a number of previously published similar studies.

CONCLUSION

MSK injuries were reported by a high proportion of our surveyed cohort of upper extremity surgeons, with more than a quarter of them requiring time off work. As these injuries may place a psychological burden on the surgeon and affect the

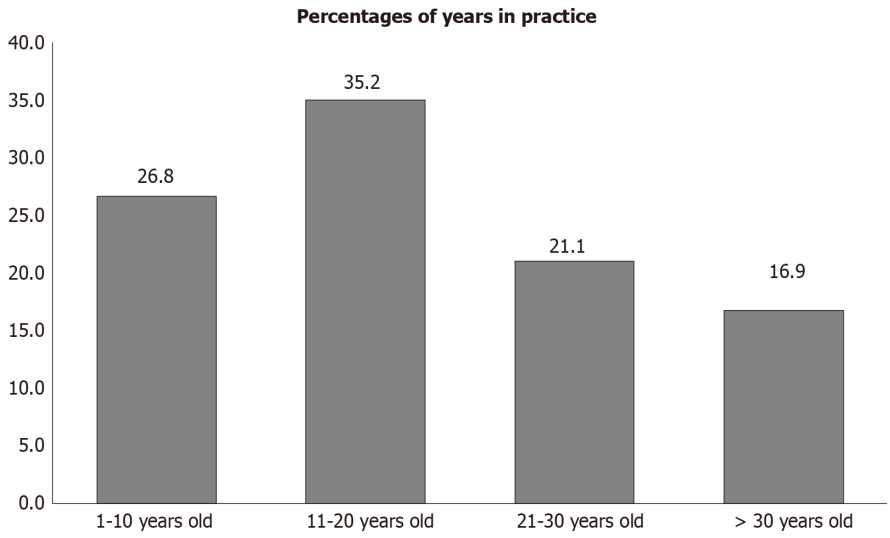

Figure 2 Surgeons years in practice among survey participants.

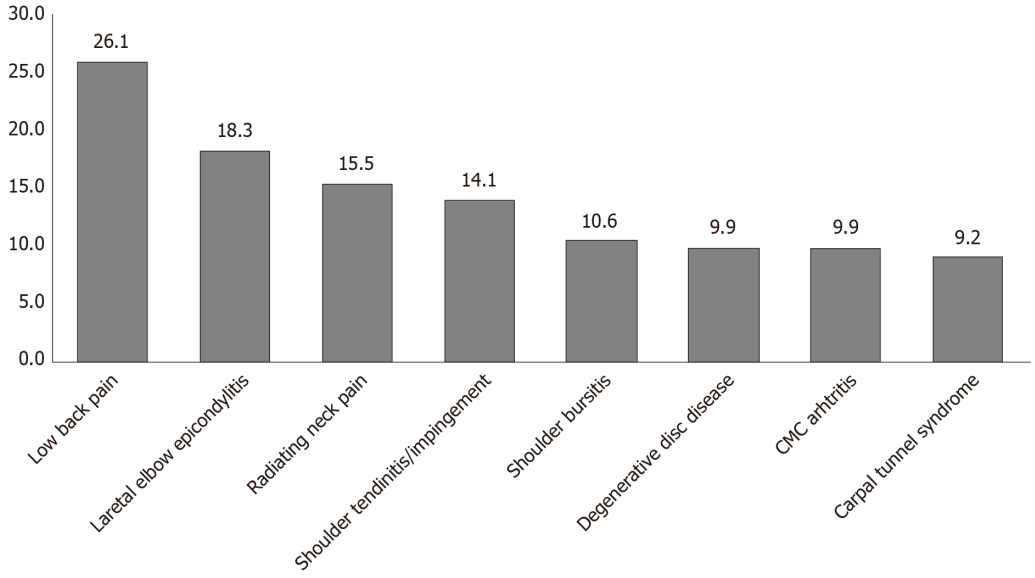

Figure 3 Musculoskeletal disorders and complaints among survey participants.

healthcare system, specific attention should be directed towards improving ergonomics and safety in the operative room to help decrease the high prevalence of these injuries in the future.

ARTICLE HIGHLIGHTS

Research background

Upper extremity orthopaedic surgical tasks require repetitive and constant maneuvers, which can put them at increased risk of acquiring work-related musculoskeletal disorders during their years in practice.

Research motivation

As these injuries may place a psychological burden on the surgeon and affect the healthcare system, attention should be directed at studying their prevalence and associated factors.

Research objectives
To assess the prevalence, characteristics and impact of musculoskeletal disorders among upper extremity orthopaedic surgeons.

Research methods
A modified version of the physical discomfort survey was sent to surgeons who were members of the American Shoulder and Elbow Surgeons and the Canadian shoulder and elbow society *via* e-mail. The collected data were analyzed using descriptive statistics, one-way analysis of variance, and Fisher's exact test. *P* values of <0.05 were considered statistically significant.

Research results
A work-related musculoskeletal injury was reported by 89.4% of respondents, of which the most common diagnoses were low back pain and lateral elbow epicondylitis.

Research conclusions
Musculoskeletal injuries were reported by a high proportion of our surveyed cohort of upper extremity surgeons, with more than a quarter of them requiring time off work.

Research perspectives
Specific attention should be directed towards improving ergonomics and safety in the operative room to help decrease the high prevalence of these injuries in the future.

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EVIDENCE-BASED MEDICINE

Implementation science for the adductor canal block: A new and adaptable methodology process

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Abstract

BACKGROUND

Following the successful Perioperative Surgical Home (PSH) practice for total knee arthroplasty (TKA) at our institution, the need for continuous improvement was realized, including the deimplementation of antiquated PSH elements and introduction of new practices.

AIM

To investigate the transition from femoral nerve blocks (FNB) to adductor canal nerve blocks (ACB) during TKA.

METHODS

Our 13-month study from June 2016 to 2017 was divided into four periods: a three-month baseline (103 patients), a one-month pilot (47 patients), a three-month implementation and hardwiring period (100 patients), and a six-month evaluation period (185 patients). In total, 435 subjects were reviewed. Data within 30 postoperative days were extracted from electronic medical records, such as physical therapy results and administration of oral morphine equivalents (OME).

RESULTS

Our institution reduced FNB application (64% to 3%) and increased ACB

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utilization (36% to 97%) at 10 mo. Patients in the ACB group were found to have increased ambulation on the day of surgery (4.1 *vs* 2.0 m) and lower incidence of falls (0 *vs* 1%) and buckling (5% *vs* 27%) compared with FNB patients ($P < 0.05$). While ACB patients (13.9) reported lower OME than FNB patients (15.9), the difference ($P = 0.087$) did not fall below our designated statistical threshold of P value < 0.05.

CONCLUSION
By demonstrating closure of the "knowledge to action gap" within 6 mo, our institution's findings demonstrate evidence in the value of implementation science. Physician education, technical support, and performance monitoring were deemed key facilitators of our program's success. Expanded patient populations and additional orthopedic procedures are recommended for future study.

Key Words: Total knee arthroplasty; Femoral nerve block; Adductor canal block; Physical therapy; Oral morphine equivalent; Action-related information gap

Core Tip: This study showed improved immediate postoperative outcomes of total knee arthroplasty patients through effective anesthetic management, specifically in regard to increased mobility (4.1 *vs* 2.0 m) and decreased oral morphine equivalents (13.9 *vs* 15.9) by employing adductor canal block instead of femoral nerve block. Our data supports the value of implementation science to generate institutional change though the application of guidelines from the modified Consolidated Framework for Implementation Research. It is proposed that the key enablers of implementation success, and in our case achieved a "knowledge to action" gap closure in 6 mo, are physician education, technical support, and performance monitoring.

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INTRODUCTION

The "knowledge to action gap" is notoriously large in clinical medicine and translation implementation can take up to 17 years[1]. The apparent disconnect, deemed the "second translational gap," is one of the most daunting tasks facing the global healthcare system as declared by the World Health Organization (WHO)[2-3]. Although the Enhanced Recovery Program (ERP), Perioperative Surgical Home (PSH) and the WHO's Surgical Safety Checklist (SSC) program have achieved remarkable success in the perioperative setting, these programs have varied significantly in their clinical effectiveness at the institutional level, often due to the uneven implementation effectiveness.

Historically, there are delays in two factors which enable success: the foundation of strong clinical evidence and a sound implementation process. The latter is challenging to achieve with consistency at an institutional level. In 2016, we previously reported the success of PSH practice for ambulatory total knee arthroplasty (TKA) at our institution's pilot program[4]. Within approximately 24 mo, we spread the practice through our 21 hospitals and surgical centers guided by the Consolidated Framework for Implementation Research (CFIR)[5]. By employing CFIR principles, we achieved both clinical and implementation effectiveness in all our facilities, which led to significant reductions in length of stay (LOS) for all TKA patients regardless of where they received the care in our system.

The need for continuous improvement was made aware at our institution, including the removal of antiquated PSH elements and the introduction of new practices. Specifically, the substitution of the routine femoral nerve block (FNB) for the adductor canal block (ACB) was deemed important due to demonstrated improvements in postoperative quadriceps strength, patient mobility, and knee recovery in TKA patients[6]. While ACB practice was not novel, its strategy for effective and rapid implementation was of utmost interest, particularly to investigate how change management could be translated to other interventions.

The primary three goals of our study were to investigate the role of implementation guidelines adapted from the Consolidated Framework for Implementation Research (CFIR) to phase-out the routine FNB and phase-in the alternative ACB[7]. to assess our institution's implementation process measured through utilization rates by neuraxial anesthesia type; to compare perioperative outcomes between FNB and ACB patient. By using CFIR guidelines,[7]. we deimplemented the routine FNB and implemented the abductor ACB as the new standard at our institution. We report here the principle, process and effectiveness of such an implementation method.

MATERIALS AND METHODS

Objective

To evaluate the step-by-step implementation and deimplementation roadmap depicted in Figure 1. Specific implementation factors at our institution were part of an overall change management plan adopted from the Consolidated Framework for Implementation Research[7].

Setting, design and sample size

A baseline period (103 patients) was established from June to August 2016. Following a one-month pilot (47 patients) in September 2016 during which those trained in the ACB educated the providers in the team. Patients were informed of the change if they had received the FNB for their previous procedure. The dosage and technicality of the blocks were standardized and disseminated at the beginning of the pilot and reminders were given at each phase.

A three-month implementation and hardwiring period (100 patients) from October to December 2016 was executed for the replacement of FNB for ACB. From January to June 2017, there was a six-month evaluation period (185 patients). During the evaluation period, the dataset was analyzed to determine providers for whom there remained obstacles to implementation; these barriers were addressed biweekly and resolved. In total, 435 TKA patients were reviewed over 13 mo from June 2016 to June 2017.

Methods for data collection and distribution

Data on patient demographics (*e.g.*, sex, age, BMI, ASA status), anesthesia and analgesia (*e.g.*, OME), intraoperative data (*e.g.*, length of operation, estimated blood loss, site infection, transfusion), and perioperative outcomes (*e.g.*, pain scores, distance traveled, buckling, LOS, 30 d readmission, MI or stroke, UTI, and fall) were collected and reviewed. Data was collected prospectively; however, it was retrospectively analyzed as a cohort over time. Reports were generated to evaluate progress initially biweekly and then monthly and during each phase until full implementation. Oral morphine equivalents (OME) were determined based on the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) equianalgesic calculator as an average over 24 h after surgery. Analysis was conducted in imperial units and then converted to International System of Units (SI) equivalents (*e.g.*, feet to meters).

Data Analysis

Statistical analysis was performed to compare between ACB and FNB groups using JMP® Pro, Version 13 (SAS Institute Inc., Cary, NC, 1989-2020) at a P value < 0.05. Continuous variables were summarized using descriptive statistics, such as mean, median, and range, and evaluated using two-tailed Student's t-test. Proportions were calculated for ordinal variables and compared using Pearson chi-squared test. Outliers were removed as defined as three times outside 10% tail quantile.

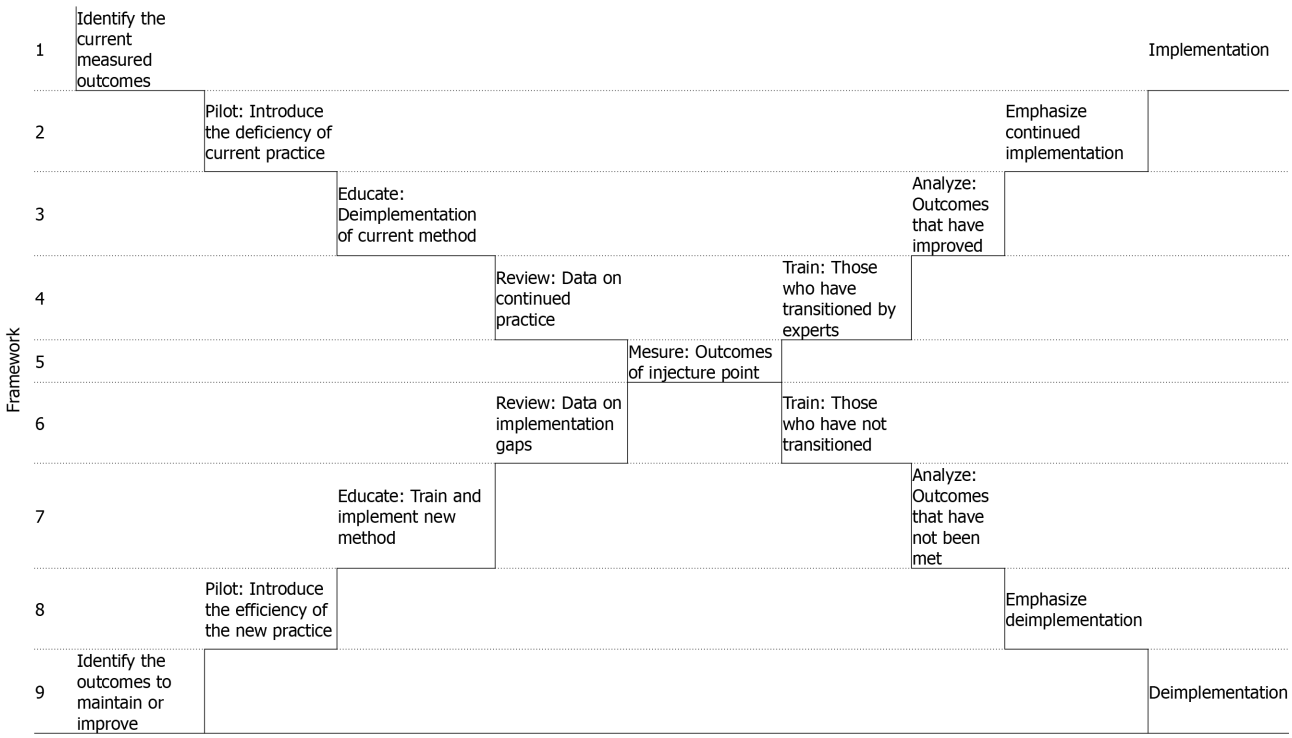

Figure 1 Nine steps involved in inverse pathways to implementation and deimplementation.

RESULTS

Overall, study population characteristics shown in Table 1 were similar to our reported baseline. Figure 2 illustrates the phase-out of the FNB and phase-in of the ACB over the 13-month study period. The preference for ACB *vs* FNB as peripheral nerve block improved after the pilot from October 2016 (36% *vs* 64%) to post-implementation in June 2017 (97% *vs* 3%).

Table 2 demonstrates a summary of patient outcomes between the two groups. While FNB cases utilized lower amounts of local anesthetic (mg), ACB cases were shown to have lower estimated blood loss (mL), fall rates, and incidence of buckling during physical therapy. While the ACB group (13.9) reported lower OME *vs* FNB group (15.9), the difference did not meet our statistical threshold of $P < 0.05$ ($P = 0.087$). On the day of surgery, ACB patients were observed to have an increased mean distance traveled during mobilization compared with FNB patients (4.1 *vs* 2.0 m) as demonstrated in Figure 3.

DISCUSSION

While the average duration to translate new practice into routine adoption is 17 years, only half of evidence-based changes end up reaching broad medical usage[8-9]. In 2012, the replacement of low-value care, defined as inefficient or unwarranted health care practices, received widespread recognition by the American Board of Internal Medicine Foundation through its Choosing Wisely (CW) initiative[10-13]. Although CW campaigns gained initial enthusiasm, promising recommendations often stood in isolation, which resulted in poor adoption rates and lacked the capacity for sustained change[14-17]. The reasons for delayed or missed uptake of evidence-based practices include inadequate resources for mobilizing change, competing demands of providers, and dissonance between operational and research priorities[18]. In addition, the context of current practices, including both the barriers and facilitators of change, is an overlooked, yet imperative, consideration for successful deimplementation[19]. Thus, there is the need to develop targeted strategies to increase the proliferation of evidence-based practices, chiefly by learning through case studies in hospital systems [20].

As of today, implementation science remains an overlooked opportunity for accelerating patient care and improving clinical outcomes. Annually, there are nearly

Table 1 Population description

Demographics	Results
Total, *n*	435
Anesthesia, *n* (%)	
Spinal	368 (85)
General	67 (15)
Spinal converted to General	8 (2)
Sex, *n* (%)	
Male	148 (34)
Female	287 (66)
Age, Mean, Median [Range]	72.3, 71 [65.0-91.0]
Age Group, *n* (%)	
65 to 75	329 (76)
76 to 85	93 (21)
86 to 91	13 (3)
ASA status, *n* (%)	
I or II	283 (65)
III, IV, or V	152 (35)

ASA status: American Society of Anesthesiologists Physical Status Classification System.

seven million complications and one million deaths shortly after surgery, despite the fact that the perioperative patient care accounts for more than 60% of hospital expenditure[2]. Moreover, it has been shown that roughly half of adverse outcomes are potentially avoidable[21]. In spite of many established clinical pathways and strategies that have been tailored to minimize negative impacts, the clinical outcomes have been staggering not due to lack of evidence and knowledge, but because of lack of implementation framework and strategies to sustain the effect of positive changes.

By applying the principle of implementation science, we replaced the femoral nerve block for TKA with the abductor canal block within 13 mo in our established PSH pathway. The learning for the new technique was rapid, the group adoption and transition of the practice was immediate, and consolidation of learning and practice was persistent. We found that ACB patients had increased ambulation and decreased falls and buckling compared with FNB patients, thereby validating an institutional practice change to enhance short-term patient outcomes after surgery. Our findings on improvement mobility are consistent with explanations that ACB may help assist in speedier knee recovery and maintenance of quadriceps strength[6]. We demonstrate that significant healthcare performance improvement can be achieved through the synergistic effect of evidence-based practice and evidence-based implementation science. Furthermore, successful implementation can be achieved through the simultaneous deimplementation of old practices within established PSH pathways.

Past research suggests that ERP initiatives are facilitated by successful pilot programs that generate preliminary evidence and demonstrate local effectiveness for further implementation[22-23]. As defined by Proctor et. al, our institution achieved high penetration, or diffusion rate of intervention, and sustainability, or continued use of intended practice, in the replacement of ACB for FNB during our 13-month study period[24]. Furthermore, it has been suggested that increasing ERP visibility, such as advertising pilot start dates, are beneficial to the implementation process[25,26]. In our case, much attention was focused around our program's launch, as evidenced by the spike in ACB uptake (72%) during the September 2016 pilot. Although there was a subsequent dip in the following two months (36% and 44%), the steady adoption and study's inverse relationship between ACB implementation and FNB deimplementation indicate strong adherence to our program's intended outcome.

Comprehensive transition packages are recommended for dissemination across other regions[13,27]. The Institute for Healthcare Improvement (IHI) advocates that

Table 2 Summary of patient outcomes

Variable	Adductor	Femoral	*P* value
Demographics			
Number of patients	289 (66%)	146 (34%)	-
Sex			0.57
Male	101 (35%)	47 (32%)	-
Female	188 (65%)	99 (68%)	-
Age	72.3, 71 [65-91]	72.3, 71 [65-91]	0.90
BMI in kg/m^2	31.2, 31.0 [19.3-50.0]	30.8, 29.8 [21.0-51.1]	0.55
ASA status			0.52
I or II	185 (64%)	98 (67%)	-
III, IV, or V	104 (36%)	48 (33%)	-
Intraoperative data			
Anesthesia			0.067
Spinal	246 (85%)	114 (78%)	-
General	38 (13%)	29 (20%)	-
Spinal converted to General	5 (2%)	3 (2%)	-
Length of operation in min	122.7, 118 [83-235]	121.7, 107 [83-199]	0.64
Estimated blood loss in mL	57.6, 45 [20-200]	68.2, 75 [20-200]	0.0031[b]
Local anesthetic in mg	94.2, 100 [11.3-225]	89.4, 93.8 [11.3-150]	0.036[a]
Site infection or redness	2 (1%)	1 (1%)	0.99
Transfusion	1 (0%)	1 (1%)	0.62
Day of surgery outcomes			
Pain score from 0 to 10	1.9, 1.7 [0-6.6]	2.0, 1.7 [0-6.1]	0.59
OME	13.9, 12.8 [0-66]	15.9, 15 [0-50]	0.087
Distance traveled in meters	4.1, 1.5 [0-45.7]	2.0, 0.3 [0-30.5]	0.0004[b]
Buckling	14 (5%)	40 (27%)	< 0.0001[b]
Physical therapy complication	7 (2%)	2 (1%)	0.47
Postoperative outcomes			
Length of stay in days	1.9, 1.4 [1.1-8.4]	2.1, 2.1 [1.1-6.2]	0.091
30 d readmission	8 (3%)	7 (5%)	0.27
MI and stroke	0 (0%)	0 (0%)	-
UTI	1 (0%)	1 (1%)	0.69
Fall	0 (0%)	2 (1%)	0.046[a]

[a]$P < 0.05$;
[b]$P < 0.01$. Continuous variables represented as mean, median [range] and evaluated using two-tailed Student's *t*-test. Ordinal variables represented as *n* (%) and evaluated using Pearson chi-squared test. Outliers for length of operation, estimated blood loss, OME, and distance traveled were removed as defined as three times the interquartile range outside 0.1 tail quantile. BMI: Body mass index; ASA status: American Society of Anesthesiologists Physical Status Classification System; OME: Oral morphine equivalents based on Hospital Consumer Assessment of Healthcare Providers and Systems equianalgesic calculator; MI: Myocardial infarction; UTI: Urinary tract infection.

"care bundles" provide solid evidence for change in practice, limited debate over efficacy, and robust acceptance[28]. Gilhooly *et al*[29] categorized compliance to practice changes into three levels: high (70%-100%), medium (40%-69%), and low (0%-39%). Specifically, while high and medium compliance groups leveraged interdisciplinary teams, champion networks, and structured audits and feedback loops, low compliance groups employed less interactive strategies, such as posters and screen

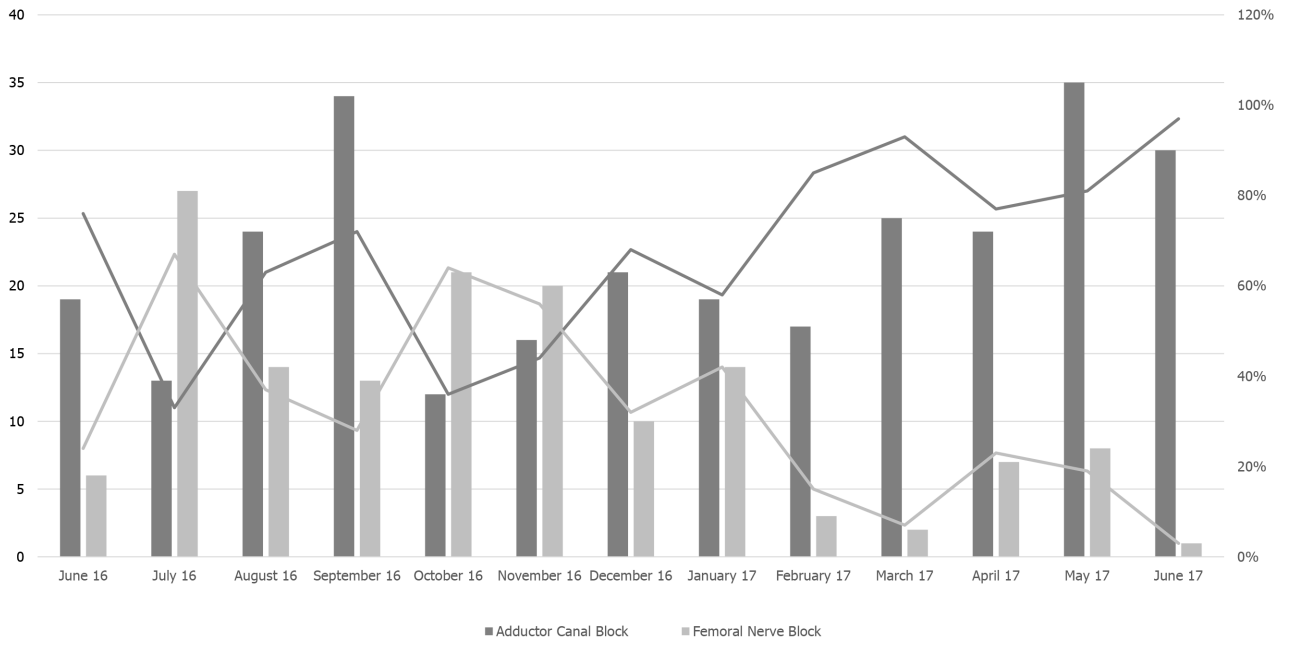

Figure 2 Utilization rates of adductor *vs* femoral canal block over our 13 mo study period demonstrate successful implementation and deimplementation adherence.

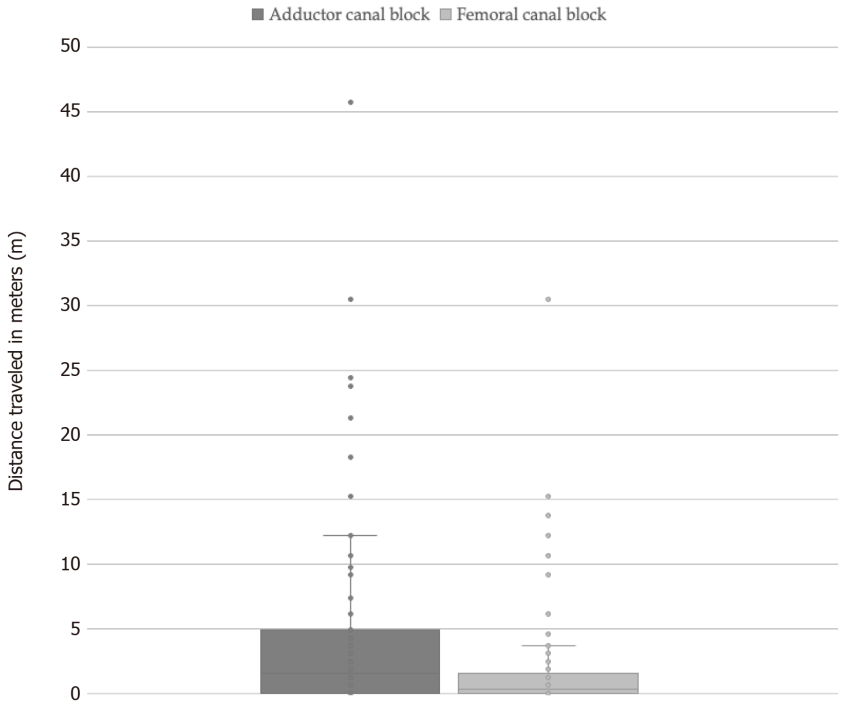

Figure 3 Patients receiving adductor canal block achieved a greater distance traveled in meters on postoperative day 0 compared to femoral canal block patients.

saver reminders[29]. Our institution serves as another case study of how high engagement strategies, including one-on-one coaching and timely program evaluations, helped a large provider team realize 97% ACB utilization rate by our study's endpoint.

It is often discussed that the primary end goal of implementation science is to achieve "sustainability", in which new knowledge and reformed practices are embedded in routine care[30]. As Rapport *et al*[30] propose in their "diffusion-dissemination-implementation" continuum, the concept of sustainability, along with adoption, is only one of five critical stages in the feedback loop that ensure sound

implementation. With the goal for implementation science to seek long-term impact, purposeful language (*i.e.*, terminology that can be refined and fit future needs) and shared agendas with the greater hospital organization help support sustainable change [30]. In our case, we ensured that our program's messaging mirrored our group's strategic initiatives, as well as the broader transformational goals of our hospital management organization. In building the case for practice change, it has been recommended that pre-implementation data includes, at a minimum, one year of prior data to support the endorsement of senior leaders and assignment of resources and capital[31]. While post-implementation cost savings analysis can facilitate future programs, there may be incalculable benefits, such as expanded experiential learning opportunities for residents and encouragement in critical thinking and evaluation of therapeutic interventions[31].

There are limitations to our study. By prescribing exclusion criteria to patients under 65 years old, our findings on ACB mobility benefits and lower incidence of falls and buckling may be narrowed to the older patient and more representative of the demographics of our specific medical center. In a previous analysis of data on 9580 total hip and knee patients across 11 of our region's medical centers, it was found that 40% of patients were under 65 years old[32]. Future studies should explore younger patient populations and various demographics. Furthermore, there was variability in how the estimated distance traveled during postoperative physical therapy was recorded. For example, while some providers noted mobility progress in imperial units (*e.g.*, "80 feet"), others included more qualitative measurements (*e.g.*, "2 sidesteps") which needed to be normalized in our database by adopting consistent assumptions (*i.e.*, 1 sidestep = 1 foot). There is an opportunity for standardization in approach for tracking key physical therapy metrics as we continue to build our dataset across our regional network. In the future, there is value for implementation strategies to include cost to benefit analyses on the allocated change management resources (*e.g.*, training, dedicated staff, campaign awareness) and perioperative patient outcomes to quantify the financial impact of such programs.

CONCLUSION

In this study, we closed the "knowledge to action gap" within 6 mo, proving the implementation effectiveness of the Consolidated Framework for Implementation Research and implementation science in our setting. The inverse relationship between the adoption of ACB utilization and phasing out of FCB suggests the benefits of implementation science guided by a roadmap of physician education, technical support, and performance monitoring. Moreover, our study demonstrates evidence that transition to ACB as the choice regional anesthesia technique during TKA may improve patient mobility and physical therapy outcomes following surgery. There is an opportunity to bridge our growing knowledge in improving perioperative techniques with an effective implementation framework. Next steps including expanded patient populations, additional medical centers, and other orthopedic procedures are warranted.

ARTICLE HIGHLIGHTS

Research background

In 2016, we employed Perioperative Surgical Home (PSH) practice change for ambulatory total knee arthroplasty (TKA) resulting in reduced length of stay in our system. Nevertheless, we acknowledged the need for continuous improvement and implementation of new practices to optimize short-term outcomes in our TKA patient population.

Research motivation

We employed a new look at implementation science to remove outdated PSH elements and adopt modified consolidated framework for implementation research (mCFIR) practices. Our motivation was to investigate the transition from femoral nerve blocks (FNB) to adductor canal nerve blocks (ACB) and how learnings on change management could be applied to other surgical areas.

Research objectives

To execute our institution's implementation process during the phase-out of FNB and phase-in of ACB during TKA. While the rationale for ACB practice was not novel, we focused on identifying the enablers of success practice change.

Research methods

We tracked our institution's implementation progress through utilization rates by neuraxial anesthesia type. Goals of enhancing patient care were validated through the comparison of perioperative outcomes between FNB and ACB patients.

Research results

Application of the mCFIR was shown to be successful in implementing institutional practice change for ACB during TKA within 6 mo. Increased patient mobility and improved physical therapy outcomes were demonstrated in ACB *vs* FNB patients.

Research conclusions

Our institution's successful phase-out of FNB and phase-in of ACB within 6 mo demonstrates the valuable role of implementation science. Effective physician education with technical support and metrics evaluation are critical methods to achieve swift practice change.

Research perspectives

Future research should be focused on younger patient populations and different orthopedic procedures.

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SYSTEMATIC REVIEWS

Femoral lengthening in young patients: An evidence-based comparison between motorized lengthening nails and external fixation

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Abstract

BACKGROUND

Femoral lengthening is a procedure of great importance in the treatment of congenital and acquired limb deficiencies. Technological advances have led to the latest designs of fully implantable motorized intramedullary lengthening nails. The use of these nails has increased over the last few years.

AIM

To review and critically appraise the literature comparing the outcome of femoral lengthening in children using intramedullary motorized lengthening nails to external fixation.

METHODS

Electronic databases (MEDLINE, CINAHL, EMBASE, Cochrane) were systematically searched in November 2019 for studies comparing the outcome of femoral lengthening in children using magnetic lengthening nails and external fixation. The outcomes included amount of gained length, healing index, complications and patient reported outcomes.

RESULTS

Checklist.

Of the 452 identified studies, only two (retrospective and non-randomized) met the inclusion criteria. A total of 91 femora were included. In both studies, the age of patients treated with nails ranged from 15 to 21 years compared to 9 to 15 years for patients in the external fixation group. Both devices achieved the target length. Prevalence of adverse events was less in the nail (60%-73%) than in the external fixation (81%-100%) group. None of the studies presented patient reported outcomes.

CONCLUSION

The clinical effectiveness of motorized nails is equivalent or superior to external fixation for femoral lengthening in young patients. The available literature is limited and does not provide evidence on patient quality of life or cost effectiveness of the interventions.

Key Words: Lengthening nails; Motorized nails; Distraction ostepgenesis; Lengthening

Core Tip: Femoral lengthening in young patients using motorized lengthening nails has gained recent popularity. This study reviewed the literature comparing the outcomes of femoral lengthening using motorized lengthening nails and external fixators in this age group. The advantages and complications of each treatment option were discussed.

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INTRODUCTION

Limb length discrepancy (LLD) is a common finding in multiple congenital and acquired disorders. LLD may lead to significant consequences such as changes in gait biomechanics, back pain, lower limb osteoarthritis, psychological problems, and poor function and lifestyle. It is accepted that LLD below 2 cm can be treated with appropriate orthotics. LLD of 2 to 5 cm can be managed with growth modification (epiphysiodesis) of the longer side. For a LLD greater than 5 cm, limb lengthening is indicated[1].

Gavrill Ilizarov introduced the concept of distraction osteogenesis (DO) and circular external fixators for management of trauma and deformities[2]. For decades, the Ilizarov technique was the most effective method of limb lengthening. It is cheap, reproducible and allows correction of angular deformities and spanning of joints if required[3]. However, external fixation significantly limits the patient's activities and life style and has a high risk of complications[4]. The preference of external fixation for bone lengthening has started to decline since the introduction of motorized lengthening nails.

Lengthening nails are intramedullary telescopic devices that securely fix within the intramedullary canal and telescope to produce the desired length (Figure 1). The older designs of lengthening nails relied on a ratchet mechanism that was activated by rotating the leg to produce lengthening[2]. Recent designs of lengthening nails provide distraction by activation of a motor inside the nail with external remote control (ERC) applied externally to the limb. Motorized nails include the PRECICE nail (PRECICE lengthening nail: Nuvasive, CA, United States) and Fitbone nail [FITBONE Telescope Active Actuator (TAA) nail: Wittenstein Intens, Igersheim, Germany].

The initial designs of lengthening nails were associated with failure of the telescoping mechanism[5]. The newer generation of motorized lengthening nails have improved results[6-9]. Lengthening nails were reported to offer more active post-operative life styles, fewer post-operative infections and less metal work failures compared to earlier designs and external fixation[10]. Motorized lengthening nails

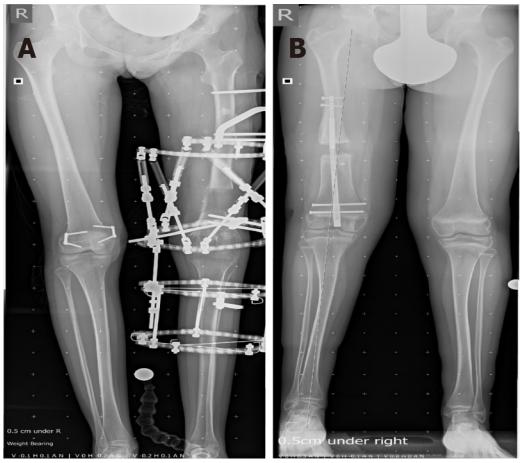

Figure 1 Left femoral lengthening with external fixation (A) and right femoral lengthening with magnetic lengthening nail (B).

have been used initially for femoral lengthening, however their applications have increased to include other long bones such as tibia[7] and humerus[11].

The average cost of the motorized nail implants is £12000-£13000 (€14000–€15000/$15000-$16000) while the average cost of external fixators varies from £3000 to £9000 (€3500–€10500/$3500-$11500)[12].

Within the limited resources available to the National Health Service (NHS) and the United Kingdom being a welfare state, increasing emphasis has been placed on cost-effectiveness. The assessment of health-related quality of life (HR-QoL) and cost utility analysis have become the foundation of economic evaluation of health technologies and gained importance in supporting the decision for allocation of NHS resources.

The recent shift to use motorized nails for bone lengthening in children despite the significant difference in implant costs compared to traditional treatment with external fixation necessitated this systematic review. This review is focused on femoral lengthening only because the initial lengthening nails were designed for femoral lengthening and the femur is the most frequently lengthened bone with motorized nails.

We present a systematic review of the studies comparing femoral lengthening in children using motorized nails to external fixation. We aimed to identify the most clinical and economic effective technique of femoral lengthening in children.

MATERIALS AND METHODS

Review question

Is the extra cost of the motorized intramedullary nails compared to external fixation in children justified?

This question can be divided to the following questions: (1) What is the clinical effectiveness of motorized lengthening nails in comparison to external fixation for femoral lengthening in children? (2) Is there a difference in the HR-QoL between the two techniques? and (3) What is the cost effectiveness of the two techniques?

Methods

Eligibility criteria: All studies, irrespective of design, that compared the outcomes of both techniques for femoral lengthening in children (less than 18 years old). All indications for femoral lengthening were included. Use of a motorized lengthening nail was the intervention and any type of external fixation was considered the comparator. The outcomes included clinical, radiological and HR-QoL.

Literature search strategy: Literature search on Healthcare Database Advanced Search (HDAS) was conducted on Medline and EMBASE databases. The HDAS search was supplemented with a complementary search on PubMed (NCBI) database. Medical subject heading (MeSH) was identified from the available studies and searched separately. References and citations from the identified studies were screened to identify further eligible papers. Terms "limb lengthening", "bone lengthening", "distraction osteogenesis', "external fixation", Ilizarov", intramedullary nails",

"lengthening nails", "magnetic nails", "quality of life", "cost-benefit analysis"," Health care cost" and "quality adjusted life years" were used for the HDAS search, A thesaurus was used to further identify the MeSH on different databases. Different results were combined with "and' or "or" where applicable. The reference lists of all relevant articles were screened to find other potentially relevant articles. Titles, abstracts and when relevant the full texts of the relevant studies were reviewed. Only studies published in English were retrieved. No time limit was selected.

Data extraction: Study design, methodology, country, number and age of participants, type of intervention and outcome of treatment (clinical, radiological, and quality of life) were recorded.

Quality assessment of eligible papers was performed using the Critical Appraisal Skills Program (CASP) checklist.

Data synthesis: Given the small number of papers retrieved, we provide a narrative summary of findings and a description of their strengths and limitations rather than calculating summary scores/statistical analysis.

RESULTS

A total of 452 studies were identified (Figure 2). After screening the titles and abstracts of these studies, 98 were considered potentially eligible for inclusion. Of these, 30 were excluded because the full texts were not available. Of the remaining 62, 60 were excluded, either because they were not comparative studies (58) or were not in children[2]. Therefore, there were only two studies which met our inclusion criteria.

Study design and patient population

Both were non-randomized retrospective studies. Szymczuk *et al*[13] compared the PRECICE nail in 30 femora to 32 cases of femoral lengthening using the LRS (Limb Reconstruction System Orthofix, McKinney, TX, United States) monolateral external fixator. The average ages were 15.4 and 9.4 years for the nail and external fixator groups respectively. Black *et al*[14] compared the outcome of femoral lengthening using the retrograde Fitbone nail in 15 femora with the outcome of lengthening using circular fixators in 14 femora. The average ages were 15 and 18 years for the nail and external fixator groups respectively.

Outcomes

Both studies evaluated the outcome based on average length achieved, and complications. Szymczuk *et al*[13] also reviewed range of movement (ROM) and healing index (HI). None of the studies reported children's quality of life or cost of treatment.

Gain in length and HI

Szymczuk *et al*[13] reported an average length gain of 4.8 cm (range 3.4 to 6.2 cm) with the PRECICE nail and 5.6 cm (range 3.9 to 7.3 cm) with the LRS external fixator. In their study, 26 patients (87%) in the nail and 28 patients (88%) in the fixator group achieved the target length of 4 cm. The healing index (HI) was 34.3 d/cm and 29.3 d/cm for nails and fixators respectively. Length of hospitalisation was not recorded.

Black *et al*[14] reported an average length gain of 4.8cm (range 1 to 7.4 cm) and 4.4 cm (range 1.5 to 7 cm) with the external fixator and motorized nails respectively. In Black's study, 10 patients (71%) in the external fixator group and 11 (73%) patients in the nail achieved the target length of 4 cm. There was no report on HI, however the time to full weight bearing was 7.7 mo with nails and 8.8 mo with external fixators. Length of hospitalisation was 7 and 9.5 d with nails and fixators respectively.

Complications

Szymczuk *et al*[13] reported complications in 18 (60%) of the nails compared to 26 (81%) in the fixator group ($P < 0.001$). The average complication per lengthening session was 1.0 with nails and 1.8 with external fixators.

By comparison, Black *et al*[14] reported complications in 10 (73%) of the nails compared to all 15 (100%) in the circular fixator group. Minor complications such as pin site infections and minimal joint contractures were seen in 5 (33%) of the nail group compared to 12 (79%) in the circular frame group. There was no statistical difference between the rate of types II and IIIA complications between the two groups.

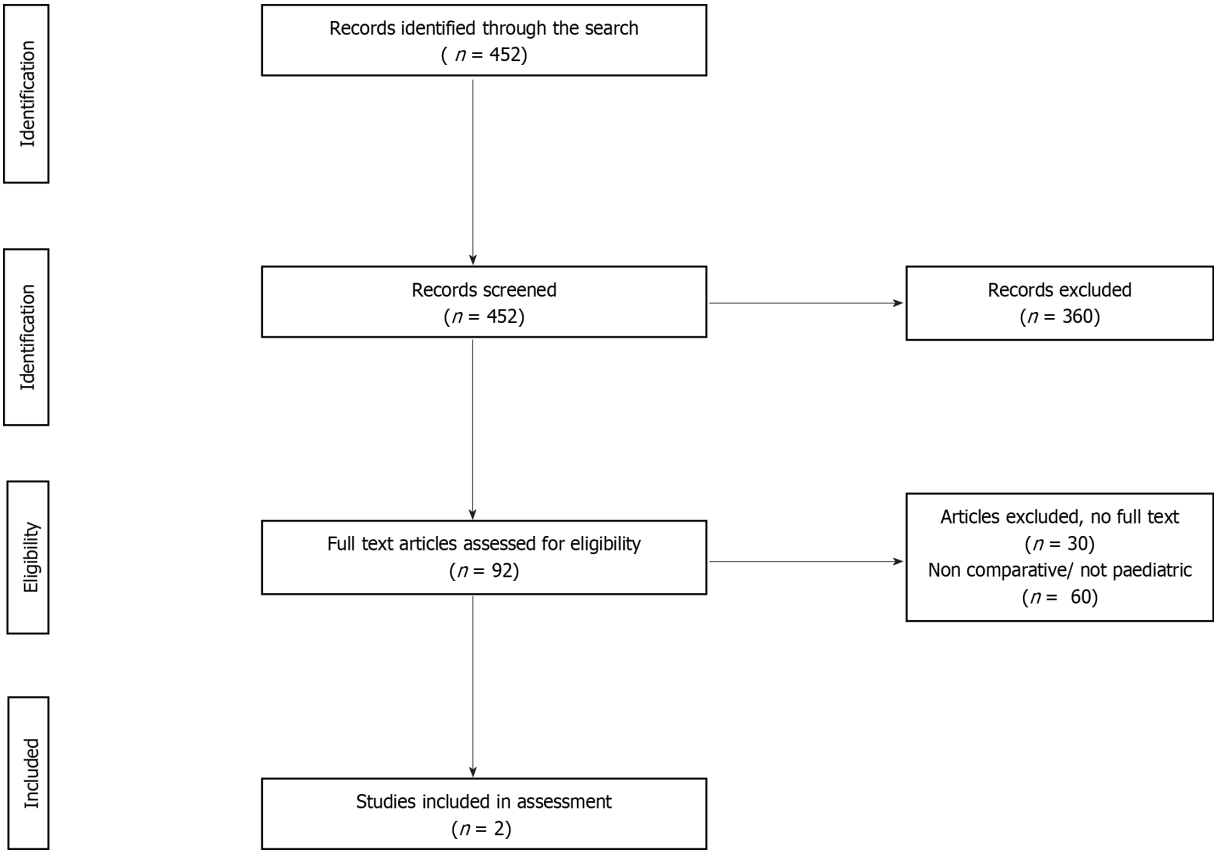

Figure 2 PRISMA flow diagram for the systematic review.

Serious complications such as joint dislocations were less common with the nails, 3 (20%) compared to 5 (36%). In the circular fixator group, there was no statistical difference between the two groups for moderate complications such as delayed union. The average complication per lengthening was 1.2 with nails and 2.6 with external fixators. Characteristics of the publications are summarized in Table 1. Results are summarized in Table 2.

Quality of papers: This is summarized in Table 3.

DISCUSSION

The presented literature review identified a lack of comparative studies in children. Two studies combined adults and children in the same group but did not present the data in such a way as to allow extraction of the pediatric data[15,16]. There is no evidence of QOL comparison between these interventions. No cost analysis was presented to support the use of lengthening nails. All these findings mandate further research to cover these points.

The current knowledge in respect to the research questions are summarized as follow: What is the clinical effectiveness of motorized lengthening nails in comparison with external fixation for femoral lengthening in children?

Both motorized nails and external fixators can effectively achieve the target femoral length. Range of motion of the knee was better preserved during the course of lengthening with nails, however there was no significant difference at the final follow up visit[13]. The overall gained length was greater with external fixators compared to motorized nails; 4.8 *vs* 4.4 cm[14] and 5.6 *vs* 4.8 cm[13] respectively. Black *et al*[14] reported a shorter time to union (by 1.1 mo) with motorized nails although Szymczuk *et al*[13] reported a shorter healing index (by 5 d/cm) with the LRS external fixator. Complication rates were lower with lengthening nails however knee subluxation was specifically reported with the nails due to the inability of the technology to span the knee. For this reason a recommendation to reconstruct knee ligaments at preparatory surgery prior to lengthening with nails was suggested[13]. However, the long-term outcome and cost effectiveness of ligament reconstructions prior to lengthening are

Table 1 Characteristics of the included publications

Ref.	Study design	Patient characteristics	Intervention	Comparator	Clinical outcomes
Black *et al* [14]	Comparative non-randomized retrospective	(1) Congenital short femur; (2) Skeletally mature children; (3) *n* = 29 (15 in FITBONE group and 14 in circular external fixation group); and (4) Age (mean): 18.2 yr in FITBONE and 15.8 yr in circular fixators	Motorized lengthening nails (FITBONE)	Circular external fixator	Length achieved, complications rates
Szymczuk *et al*[13]	Comparative non-randomized retrospective	(1) Congenital short femur; (2) *n* = 62 (30 in PRECICE group and 32 in LRS group); and (3) Age (mean): 15.4 yr in PRECICE and 9.4 yr in LRS	Magnetic lengthening nails (PRECICE)	LRS external fixator	ROM, length achieved HI and complication rates

not yet clear.

External fixation devices are very versatile, they can be applied in young children with short or deformed femora[2]. External fixators are relatively cheap compared to motorized intramedullary nails, however there were many reported adverse events related to external fixators. Pin site infection, pain, stiffness, fracture, injury to nerves or vessels and psychological problems were frequently reported with external fixation [17]. On the other hand, intramedullary nails can only be used in relatively longer femora with appropriate width of the medullary canal. The presence of an open distal femoral physis in skeletally immature children is generally a contraindication for retrograde nails however, if the femoral canal is wide enough and the femur had normal proximal anatomy a trochanteric entry nail can be used safely[18].

Laubscher *et al*[15], reported better clinical outcomes and less complications with magnetic nails compared to monolateral fixator for femoral lengthening. This study included paediatric and adult age groups. According to this study 100% of the nail and 68% of the fixator participants chose to have same treatment again. Horn *et al*[16], compared the outcome of femoral lengthening with motorized nails to external fixation in age and sex matched patients. The mean age of patients was 27 years. HI and knee ROM were better with lengthening nails, while complications were more frequent with external fixators. Morrison *et al*[19], compared the outcome of humeral lengthening with lengthening nails in 6 patients to external fixations in 7 patients. Lengthening nails patients had less complications compared to external fixators. Lengthening nails were reported to be safe, well tolerated, and effective for humeral lengthening[19].

Is there a difference in the HR-QoL between the two techniques?

We did not identify any studies which compared the quality of life of children treated with motorized lengthening nails and external fixators. However, HR-QoL was the outcome for two non-comparative studies. The authors concluded that patients have lower quality of life scores during the course of treatment[20]. One study[20] compared patient satisfaction following lengthening nails to a previous session of lengthening using external fixation in 13 patients. Patients reported less pain, more satisfaction, easier physiotherapy, and better cosmetic appearance following magnetic nails compared to previous lengthening using external fixators. It is worth mentioning that this study did not utilize a validated outcome questionnaire and there was high probability of recall bias since the QoL scores were recorded at the time of final interview[21]. The pediatric quality of live inventory (PedsQL) was used in studies for children treated with external fixation. The children and their parents reported significantly lower HR-QoL scores on all PedsQl domains compared with a normal healthy population.

The HR-QoL of motorized nails compared to external fixators for femoral lengthening in children is not known. It is clear that both techniques have a negative impact on HR-QoL. There is limited evidence suggesting that this negative impact is greater for external fixators than for motorized nails.

What is the cost effectiveness of the two techniques?

A cost comparison of the two techniques has not previously been reported. However Richardson *et al*[12] did estimate the cost of lengthening with the PRECICE nail to be approximately $44449 (£34650, €40110). This value was calculated after reviewing hospital costs and surgeon fees from the lengthening surgery up until the time of union in 39 femora. This study included adults and children, neither the surgical costs of nail removal nor the costs of loss of income, hospital visits and outpatient medications were included.

Table 2 Findings of the included publications

Black *et al*[14]					
Comparison of FITBONE and circular fixation with respect to several treatment outcomes					
Outcome	FITBONE		Circular fixator		*P* value
Length achieved (cm)	4.4		4.8		0.63
Time to full weight bearing (mo)	7.7		8.8		0.27
Length of F/U (yr)	3		3.6		0.6
Classification of complications according to the authors					
Grade	Definition		Example		
I	Minimal intervention required; goal still achieved		Pin site infection, mild joint contracture		
II	Change to treatment plan, goal still achieved		Unplanned return to theatre, delayed union requiring bone graft.		
IIIA	Fail to achieve plan, no new pathology		Premature union, inability to tolerate lengthening, fracture		
IIIB	Fail to achieve goal, new pathology/permanent complications		Dislocations, deformity, nerve injury, deep infection		
Comparison of FITBONE and circular fixation with respect to adverse events					
Complication	FITBONE		Circular fixator		*P* value
	No. of complications (*n* = 15)	*n* (%) of lengthening sessions affected by complications	No. of complication (*n* = 14)	*n* (%) of lengthening sessions affected by complications	
I	7	5 (33)	15	11 (79)	0.03
II	6	6 (40)	8	6 (43)	0.88
IIIA	4	3 (20)	4	4 (29)	0.68
IIIB	3	3 (20)	6	5 (36)	0.43
Any complication	20	11 (73)	33	14 (100)	0.10
Szymczuk *et al*[13]					
Comparison of PRECICE and LRS fixation with respect to ROM					
ROM	PRECICE		LRS fixator		*P* value
	Extension	Flexion	Extension	Flexion	
Preoperative	0.83	127.7	0.47	123.3	0.35
Post-distraction	0.93	96.3	-0.6	69.9	0.0007

Post-consolidation	-0.4	121.5	0.74	81.3	< 0.0001
Final follow up	-0.4	119.6	-0.7	120.2	0.9
Comparison of PRECICE and LRS fixation with respect to several treatment outcomes					
Outcome	PRECICE		LRS fixator		*P* value
Lengthening goal (cm)	4.97		5.58		0.15
Length achieved (cm)	4.75		5.55		0.052
Healing Index (d/cm)	34.77		29.33		0.08
Comparison of complication rates between PRECICE and LRS[22]					
Complication	PRECICE		LRS fixator		*P* value
	Total events	Affected segment	Total events	Affected segments	
Problems[1], *n* (%)	8 (25.8)	7(23.3)	32 (55)	20 (62.5)	< 0.001
Obstacle[1], *n* (%)	19 (61)	11 (36.7)	20 (34.5)	10 (31.3)	0.66
Complications[1], *n* (%)	4 (12.9)	4 (13.3)	6 (10.3)	5 (15.6)	0.99
Total, *n* (%)	31	18(60)	58	26 (81.3)	0.07

[1]Problems, obstacles, complications: A classification system of adverse events associated with limb lengthening.
Problems include incidents that do not need operative intervention. Obstacles were the incidents requiring operative but did not lead to permeant complications. Complications included intraoperative injuries and non- resolved problems before the end of treatment.

Table 3 Quality assessment of included publications

Strengths	Limitations
Black *et al*[14]	
(1) Clear methodology: Objective, design, inclusion / exclusion criteria, outcome, and results; (2) Age matched participants; (3) All participants had the same underlying diagnosis; and (4) Complications were described in detail	(1) Clinical and radiological outcome results were not declared due to compassionate use policy; (2) Selection bias; (3) All participants were skeletally mature (not fully representing the Paediatric population); (4) No validated scores were used; (5) No attempt was made to avoid observer bias; and (6) Sample size calculations were not undertaken
Szymczuk *et al*[13]	
(1) Clear methodology: Objective, design, inclusion/exclusion criteria, outcome, and results; (2) The study focused only on children; (3) All participants had the same underlying diagnosis; (4) Probability values (*P* values) were reported; and (5) Complications were described in detail	(1) Bias such as selection and follow up; (2) There is no mention of potential confounders or how they may have varied between groups; (3) No validated scores were used; (4) No attempt was made to avoid observer bias; (5) Nails were used only in older children, resulting in uneven distribution of the intervention especially in the higher-risk younger age group; and (6) Sample size calculations were not undertaken

The cost effectiveness of motorized nails compared to external fixators for femoral lengthening in children is not known.

Critical appraisal of the included publications

The objectives of and interventions used in both studies were clearly mentioned and inclusion and exclusion criteria were specified. The measured outcomes were mentioned clearly in the methods and in the results sections. Statistical analysis was clear with appropriate statistical test (*t*-test) in Szymczuk *et al*[13]. Authors of both studies classified the complications according to severity and reported the complications accurately.

Limitations were also identified in both studies. Both focused on one indication for femoral lengthening (congenital femoral deficiency), excluding all other causes of femoral shortening such as trauma and infection. There was a high possibility of selection bias in both studies, given their non-randomized retrospective designs. At the time of the study, the Fitbone nail did not have FDA (Food and Drug Administration agency) approval for use in the United States; therefore patients recruited to the study by Black *et al*[14] were treated on a compassionate-use basis. This suggests that the selection of patients was based on meeting the criteria for inclusion on a compassionate basis rather than matching the nails and external fixator groups. Szymczuk *et al*[13] did not specify their selection criteria. Neither study was blinded; this would have been difficult given the nature of the interventions being compared.

The age of patients both groups in the study by Szymczuk *et al*[13] were not matched. Nails were used for children over 9 years and fixators for children as young as 3 years. This policy might have affected the overall complication rates due to increased use of fixators in the higher risk group of younger children. Black *et al*[14] included patients of matched age groups, however all the patients who were treated with nails were skeletally mature and all of the nails were inserted retrograde sparing the trochanteric region. This might suggest that although the participants of this group were younger than 18 years, they had adult bones and the results might not be representative for children.

CONCLUSION

There is no literature comparing the cost effectiveness and patient satisfaction of femoral lengthening with motorized lengthening nails and external fixators in children. Further research is necessary in order to ascertain the efficacy of these treatment methods, to optimize patient outcomes and to ensure health care resources are spent appropriately.

ARTICLE HIGHLIGHTS

Research background

For decades external fixation was the only reliable, safe, and reproducible technique for bone lengthening. The use of external fixation declined recently due to the development of motorized lengthening nails. Lengthening nails are expensive.

Research motivation

Is the extra cost of the motorized intramedullary nails compared to external fixation in children justified?

Research objectives

The main objective was to review the literature to compare the clinical effectiveness of motorized lengthening nails to external fixation. Other objectives were to identify differences in the health-related quality of life between the two techniques in current literature.

Research methods

Electronic databases (MEDLINE, CINAHL, EMBASE, Cochrane) were searched, and all relevant studies were considered for analysis based on predetermined inclusion/exclusion criteria. The subject headings "distraction osteogenesis", "motorized nails", '' external fixation'' and their related key terms were used.

Research results

Only 2 studies out of 452 studies met the inclusion criteria. The ages of the patients ranged from 9 to 21 years. Lengthening nails were effective in achieving the target length with less prevalence of adverse events.

Research conclusions

The clinical effectiveness of lengthening nails was comparable to external fixation. No report on the quality-of-life difference between the 2 techniques during lengthening. No reports on the cost effectiveness of lengthening nails compared to external fixations.

Research perspectives

Further research is necessary in order to ascertain the efficacy of these treatment methods, to optimize patient outcomes and to ensure health care resources are spent appropriately.

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META-ANALYSIS

Role of coatings and materials of external fixation pins on the rates of pin tract infection: A systematic review and meta-analysis

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Abstract

BACKGROUND

Infection at the pin tract is a frequent and feared complication of external fixators (EF). The type of pin material and coatings have been regarded as possibly influencing infection rates. Over the last 20 years, few prospective clinical studies and systematic reviews addressed the role of coated pins on the rate of pin site infection in human clinical studies.

AIM

To assess the EF literature over the past 20 years on the clinical benefits of pins manufactured from varied materials and coating systems and their possible role in pin tract infection rates.

METHODS

We performed a systematic review according to the PRISMA and PICOS guidelines using four scientific platforms: PubMed, LiLacs, SciELO, and Cochrane. We searched the literature for related publications over the past 20 years.

RESULTS

A literature search yielded 29 articles, among which seven met the inclusion criteria. These studies compared stainless-steel pins and pins coated with

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hydroxyapatite (HA), titanium and silver. The pin tract infection definitions were arbitrary and not standardized among studies. Most studies included a low number of patients in the analysis and used a short follow-up time. Three meta-analyses were carried out, comparing stainless steel *vs* silver pins, stainless steel *vs* HA-coated pins, and titanium *vs* HA-coated pins. None of this analysis resulted in statistically significant differences in pin tract infection rates.

CONCLUSION
Currently, no clinical evidence supports the advantage of EF pins manufactured with materials other than stainless steel or coated over uncoated pins in reducing the rates of pin tract infections. A standardized definition of pin tract infection in external fixation is still lacking.

Key Words: External fixator; Pin tract infection; Stainless steel pin; Coated pin; Coating systems; Pin site infection

Core Tip: There is no consensus in the literature that different materials or pin coatings of external fixators can interfere with the infection rates. This is the first manuscript that evaluates related publications over the last 20 years and develops a meta-analysis evaluating three different types of metallic coatings.

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INTRODUCTION

External fixators (EF) are used for bone stabilization using minimally invasive percutaneous insertion of pins, thin and olive wires, interconnected by threaded shafts, bars, and metal rings. These devices provide robust support in the management of fractures and cases of long bone nonunions, malunions, infections, and serious limb malalignment deformities[1]. At the same time, pins are a pathway of contact between the external environment and the skin, subcutaneous tissue, muscle, and bone. Consequently, infection is one of the main complications[1,2]. When infection is superficial, clinical treatment entails local measures and orally administered antibiotics for control. Cases where the infection progresses from the skin and soft tissues into bones and consequently results in pin loosening usually require pin removal or replacement and long-term intravenous antibiotic therapy for chronic osteomyelitis, increasing the cost and complexity of treatment[3].

Infections associated with implants are usually caused by microorganisms that grow in biofilms attached to the implant surface, which is also the case with pin tract infections. A biofilm is a well-controlled and protected environment favoring sessile microorganisms to develop a multi-factorial tolerance to antibiotics and host defenses. This tolerance has been attributed to restricted penetration of the antibiotics, restricted growth at low-oxygen tension, expression of biofilm-specific genes and the presence of non-dividing microorganisms[4]. The formation of biofilms is a major contributor to the clinical challenges encountered in treating pin tract infections.

Therefore, previous studies have assessed different measures to control infectious pin complications, from pin base local care protocols to nonmetallic (ceramic) manufactured pins and coating systems to avoid biofilm formation[5-8]. Clinical benefits regarding infection and loosening of coated vs. uncoated pins have yet to be well defined[9,10]. Indeed, many published articles failed to reach definitive conclusions regarding the impact of different pin materials and coatings on the reduction of pin tract infections[11]. In a 2005 clinical review on hydroxyapatite-coated pins, Moroni *et al*[12] concluded that this type of coating system could reduce the rate

of post-operative complications, including infections. Nevertheless, current research assessing the real clinical benefits of tapered pins coated with hydroxyapatite is still lacking. A 2010 systematic review by Saithna *et al*[11] that included only four randomized controlled trials failed to show a clear clinical benefit of using hydroxyapatite-coated pins to decrease pin loosening and pin tract infection rates.

A few types of pin materials have been assessed in previous published clinical studies, including ceramic and metallic (stainless steel and titanium), and also coatings such as hydroxyapatite (HA), HA plus fibroblast growth factor 2 (FGF-2), silver coating and iodine-coated systems[6,11,13-15]. Even though HA coating is one of the most studied coating systems, whether this and other products can effectively reduce the number of infections remains unclear[11,15-18]. Indeed, over the last 20 years, few prospective clinical studies and only two systematic reviews addressed the role of coated pins on the rate of pin site infection in human clinical studies. Moreover, only a hydroxyapatite coating system was assessed in these published reviews. Considering the advances in materials and surfaces in recent years, we aimed at assessing the clinical benefits and rates of infectious complications of EF pins manufactured from varied materials with different coating systems. This systematic review and meta-analysis compiled comparative data on superficial and deep infectious complications found in different types of external fixation pin materials and coatings in human clinical studies.

MATERIALS AND METHODS

Literature sources

A systematic review was carried out according to the preferred reporting items for systematic reviews and meta-analyses (PRISMA) guidelines in the following databases: PubMed, LiLacs, SciELO and Cochrane. The search period spanned from January 2000 to December 2020, encompassing all relevant articles published in the last 20 years. The search was performed using key words related to the subject: "External Fixators", "Fixation Devices, External", "Pin Site", "Pin Tract", "Coated Pin", "Hydroxyapatite Coated", "Stainless Steel Pin" and "Hydroxyapatite-coated". We used English terms when searching all databases and Spanish and Portuguese terms when searching the LiLacs and SciELO databases.

Study selection

In the search, the population subject of this review is defined as any human being, regardless of sex or age, who has undergone any type of external fixator device procedure for the treatment of any pathology. In these studies, an objective assessment of pin tract infection rates should be made. One or more types of pin materials and coatings may be studied besides steel pins. We included clinical studies with a level of evidence of 1-2. In vitro, basic science, animal studies and previous systematic reviews are exclusion criteria. Also, studies with a level of evidence of 3-5 are excluded. The main objective of this study is to assess whether different materials and coatings, in addition to stainless steel, play a role in reducing the infection rate of the pin site, using the body of available clinical literature and its level of evidence. The quality of published literature was assessed. Whenever possible, a meta-analysis was performed to assess the effectiveness of coating systems and materials at reducing the rates of pin infection.

Data extraction

Two reviewers (CS, MJCS) independently selected the relevant articles based on reading the abstracts. Articles containing only scientific information on different infection rates and comparisons of the different types of pin materials and coatings were selected. All relevant texts, tables and figures have been revised for data extraction. If additional information was needed, the corresponding authors of the articles would be contacted, but it was not necessary. Discrepancies between the two reviewers were resolved by consensus discussion.

Risk of bias

We used the Cochrane Risk of Bias Tool to calculate the risk of bias, as shown in Table 1. Among the 29 articles selected for the study, seven studies classified as clinical trials were selected for the article, all of these articles presented a low risk of bias for the randomization sequence generation category (Coester, 2006; Masse, 2000; Morone,

Table 1 Cochrane risk of bias tool - clinical trials

Study	Random sequence generation	Allocation concealment	Blinding of patients, personnel	Blinding of outcome assessor	Incomplete outcome data	Selective outcome reporting	Other
Coester, 2006	Low	Low	Unclear	Low	Low	Low	Low
Masse, 2000	Low	Unclear	Unclear	Unclear	Low	Low	Low
Morone, 2001	Low	Low	Unclear	Unclear	Low	Low	Low
Pieske, 2010	Low	Low	Low	Low	Low	Low	Low
Pieske, 2011	Low	Low	Low	Low	Low	Low	Low
Pizà, 2004	Low	Low	Unclear	Unclear	Low	Low	Low
Pommer, 2002	Low	Low	Unclear	Low	Low	Low	Low

2001; Pieske, 2010; Pieske, 2011; Pizà, 2004; Pommer, 2002). Five described how allocation secrecy was carried out to reduce the risk of bias (Morone, 2001; Pieske, 2010; Pieske, 2011; Pizà, 2004; Pommer, 2002). Only two studies blinded patients (Pieske, 2010; Pieske, 2011), and three articles blinded the evaluators (Pieske, 2010; Pieske, 2011; Pommer, 2002). All seven articles presented the follow-up losses of study participants and presented a low risk of bias for the selective outcome reporting category (Coester, 2006; Masse, 2000; Morone, 2001; Pieske, 2010; Pieske, 2011; Pizà, 2004; Pommer, 2002).

Statistical analysis

The meta-analysis was performed using the Mantel-Haenszel statistical method. The model used was of random effects and the measurement of the effect through the relative risk. An alpha value of 0.05 and a 95% confidence interval were considered statistically significant. The statistical heterogeneity of the treatment effects between the studies was assessed by the Cochran Q test. Inconsistency was assessed by the I2 test, in which values between 25% and 50% were considered to indicate moderate heterogeneity and high heterogeneity was shown by values greater than 50%. All analyses were performed using Review Manager software version 5.4 (Cochrane Collaboration).

RESULTS

Study selection

A total of 13951 articles were initially retrieved from different platforms. The abstracts of these articles were downloaded to the EndNote Clarivate™ analytics platform. After analyzing the abstracts of all 13951 articles retrieved from the search platform, both reviewers defined the same group of 29 articles for inclusion in the systematic review.

After the initial selection stage, further screening was carried out in which the 29 articles were read in full, and their contents discussed to reach a consensus on their inclusion in the final results of the study. The final group of articles comprised only clinical studies that focused on infection rates associated with the different external fixator pin materials and coatings in humans within the aforementioned inclusion criteria. Seven of the 29 articles contained data on infection rates involving the different pin materials and coatings in humans.

All stages of search, selection and exclusion of the articles listed in this study, as the 2009 PRISMA guide recommends, are shown as a diagram in Figure 1.

A total of seven scientific articles were selected as consistent scientific sources for inclusion in the systematic review. The selection results, showing the different types of materials and coatings studied and their results with respect to infection rates in the pin tract, are described below. It was possible to perform three meta-analyses

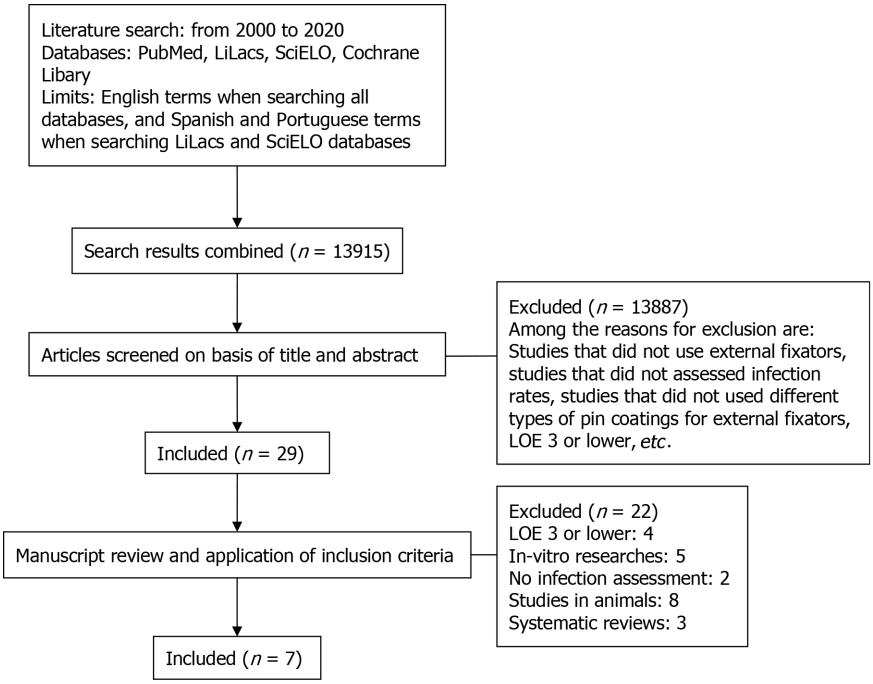

Figure 1 Preferred reporting items for systematic reviews and meta-analyses diagram flow diagram of search and selection strategy for systematic review.

comparing the following coatings: silver-steel, HA-titanium, and HA-steel.

Stainless steel vs hydroxyapatite

In 2001, Moroni *et al*[12] conducted a prospective randomized study comparing infection rates in 20 patients with wrist fractures treated with external fixators divided into two groups. One of the groups used steel pins, and the other one used pins coated with hydroxyapatite. The Checketts-Otterburn classification was used as a criterion for infection, and the patients were followed for 6 wk. There were no reports of infection in both groups[19].

In 2004, Pizà *et al*[14] conducted a prospective randomized clinical study, comparing infection rates between pins coated with hydroxyapatite and steel pins. Overall, 23 patients were evaluated in which 56 external fixators were used, with a follow-up of 530 d. Infection rates between pins were assessed using the Checketts-Otterburn classification and found to be similar, with 30.4% for hydroxyapatite pins and 30.7% for steel pins[14].

In 2010, Pieske *et al*[20] published a prospective randomized study comparing the clinical benefits of traditional stainless-steel pins to hydroxyapatite-coated pins for the treatment of wrist fractures with external fixators. The authors assessed rates of pin tract infection and loosening based on bespoke criteria defining infection. A short period of follow-up (6 wk) was used until EF removal in both groups. Overall, 40 patients were assessed and divided into two groups of 20 patients each. Hydroxyapatite-coated pins showed a tendency toward better clinical outcomes, but no statistical difference was found for pin tract infection or loosening between groups. The prevalence of infections requiring antibiotics was 2.6% for coated pins *vs* 5.3% for uncoated pins. The authors concluded that the superior pin-bone anchorage associated with hydroxyapatite-coated pins was clinically irrelevant, as was the infection rate[10].

Titanium vs hydroxyapatite

In 2002, Pommer *et al*[21] published a randomized clinical trial comparing pins coated with hydroxyapatite and titanium pins. In this study, 46 patients submitted to bone transport or tibial bone lengthening with external fixators were evaluated, divided into two groups according to the type of materials. The follow-up was 38 wk, and the infection criterion used was that of Mahan *et al*[22] (1991). The infection rates found were 0% in the group with pins coated with hydroxyapatite and 13% in the group with titanium pins, showing a statistically significant difference in infection rates[21].

In 2011, Pieske *et al*[20] published a prospective controlled cohort study comparing hydroxyapatite-coated pins with titanium alloy pins for the treatment of wrist

fractures using external fixators. As in their 2010 study described above, the authors assessed pin infection and loosening rates and employed bespoke criteria for defining pin tract infection. The follow-up time was 6 wk until the removal of fixators in both groups. They also assessed 40 patients divided into two groups, each comprising of 20 patients. The results proved comparable to those of the previous study by the same authors, revealing only a tendency of hydroxyapatite-coated pins to yield lower rates of loosening and infection, although this difference did not reach statistical significance[21].

Stainless steel vs silver

Two articles compared infection rates in silver pins with steel pins. In 2000, Masse published a prospective randomized study in which they evaluated 24 patients, comparing, among other variables, the infection rates between silver and steel pins. The infection criterion was based upon Mahan *et al*[22], and the follow-up for the silver and steel groups was 109 d and 113 d, respectively. The infection rate was 30% for silver pins and 42.9% for steel pins, but the difference was not statistically significant. In addition, they observed an increase in serum silver levels in some patients who received silver pins, and as a conclusion, they advised against the use of silver pins[23].

In 2006, Coester *et al*[24] carried out a randomized clinical trial comparing silver pins with steel pins. They evaluated 19 patients over an average period of 16.7 wk. As an infection criterion, they used a bespoke evaluation and found an infection rate of 30% in silver pins against 21% in steel pins, with no statistically significant difference between the two[24].

It is worth mentioning that all selected studies compared only two types of pin materials and coating systems. None included more than two different types of coating for comparison. Additionally, information such as the reasons for external fixator indications and classification for the severity of fractures or deformities were not necessarily mentioned in the studies. Nevertheless, the selected articles met the inclusion criteria and the desired literary quality.

The main characteristics of all selected studies are shown in Table 2.

RESULTS

Stainless steel vs silver

Two studies compared the infection rate between silver pins vs. steel pins[23,24]. The use of silver pins did not show any significant difference (0.92; 95%CI: 0.47 to 1.83; I^2 = 51%; P = 0.82) in the infection rate compared to steel pins, as shown in Figure 2. The meta-analysis showed high heterogeneity and can be explained by the methodological difference in assessing the infection rate, according to criteria described by different authors. Both articles showed good methodological quality.

Stainless steel vs hydroxyapatite

Three articles compared pin tract infection rates between HA-coated pins vs. stainless steel pins[10,14,19]. No statistically significant difference was found in the rate of infection when comparing HA-coated with stainless steel pins (0.88; 95%CI: 0.71 to 1.08; I^2 = 0%, P = 0, 23), as shown in Figure 3.

Titanium vs hydroxyapatite

Two studies compared the infection rate between HA-coated pins vs. titanium pins[20,21]. The use of HA-coated pins had no significant difference in the rate of infection compared to titanium pins (0.35; 95%CI: 0.00 to 79.17; I^2 = 86%, P = 0, 71), as shown in Figure 4. The heterogeneity of this meta-analysis is characterized as high, possibly because these articles evaluate the rates of infection using different scales. Both articles have good methodological quality.

DISCUSSION

The following coatings and materials were studied in addition to steel in the studies selected for analysis according to our inclusion criteria: (1) Silver: Known for its antimicrobial and bacteriostatic activity, is used in medical equipment such as special dressings and urinary catheters. Its potential antimicrobial mechanisms are the

Table 2 Characteristics of seven studies selected and included for analysis

Author	Year	Level of evidence	Number of patient (*n*)	Coatings	Follow-up	Infection criteria	Infection rate	Conclusion
Masse	2000	2	24	Silver *vs* Steel	109 d *vs* 113 d	Mahan *et al*[22] criteria	30% *vs* 42.9%	No statistical difference
Moroni	2001	1	20	Hydroxyapatite *vs* Steel	6 wk	Checketts-Otterburn	0	No statistical difference
Pommer	2002	1	16	Hydroxyapatite *vs* Titanium	38 wk	Mahan *et al*[22] criteria	0% *vs* 13%	Statistically significant
Pizá	2004	1	23	Hydroxyapatite *vs* Steel	530 d	Checketts-Otterburn	30.4% *vs* 30.7%	No statistical difference
Coaster	2006	1	19	Silver *vs* Steel	16,7 wk	Bespoke	30% *vs* 21%	No statistical difference
Pieske	2010	2	20 *vs* 20	Steel *vs* Hydroxyapatite	65 d	Bespoke	5.3% *vs* 2.6%	No statistical difference
Pieske	2011	2	20 *vs* 20	Titanium *vs* Hydroxyapatite	56 d	Bespoke	0% *vs* 10%	No statistical difference

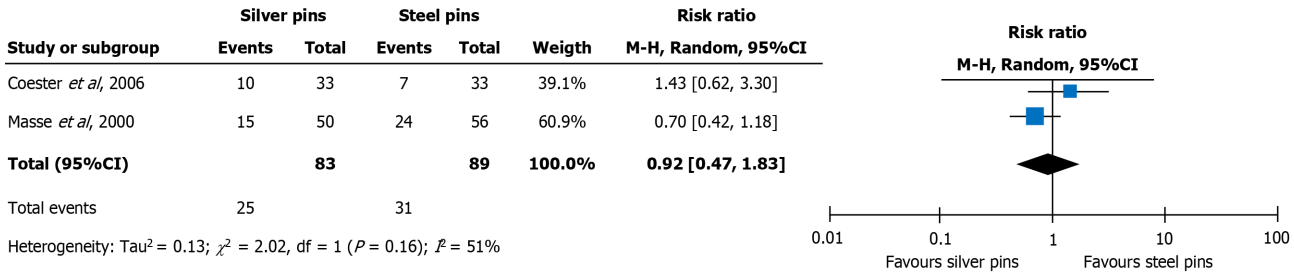

Figure 2 Stainless steel vs silver.

Figure 3 Stainless steel vs hydroxyapatite.

production of reactive oxygen species with direct effects on DNA and cell membranes. Bacterial resistance to silver is rare[25]; and (2) Hydroxyapatite: A molecule composed of calcium and phosphate, is the main mineral component of human bone and is used on a large scale in orthopedic surgery. It has osteoconductive properties and has been used in an attempt to decrease infection and loosening rates in the pins of external fixators[11,26].

Titanium has anti-corrosion and mechanical properties that favor its use in external fixators. With exposure to oxygen, a spontaneous stable oxide layer forms and leads to biocompatibility[27].

We also found studies evaluating other materials that did not meet the inclusion criteria: ceramic pins, pins with bisphosphonate coating, titanium pins with iodine coating, and pins with FGF-2-apatite coating.

Study or subgroup	Hydroxyapatite-coated pins Events	Total	Titanium alloy pins Events	Total	Weigth	Risk ratio M-H, Random, 95%CI
Pieske *et al*, 2011	2	76	0	80	49.4%	5.26 [0.26, 107.81]
Pommer; Murh; Dávid, 2002	0	165	20	169	50.6%	0.02 [0.00, 0.41]
Total (95%CI)		**241**		**249**	**100.0%**	**0.35 [0.00, 79.14]**
Total events	2		20			

Heterogeneity: Tau² = 13.07; χ^2 = 6.92, df = 1 (P = 0.009); I^2 = 86%

Test for overall effect: Z = 0.38 (P = 0.71)

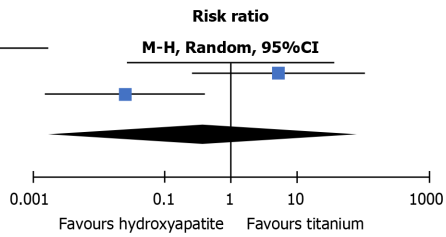

Figure 4 Titanium *vs* hydroxyapatite.

Ceramic pins produced low interference in the MRI signal, an advantage over metal pins in the event that CNS imaging assessment is required. However, rates of infection and aseptic loosening of ceramic pins were significantly higher than for titanium alloy pins. The infection rate in ceramic pins was 27.3% (12/44) *vs* 13.3% (35/263) in titanium pins (P = 0.031). Hence, the advantage of lesser interference in MRI for ceramic pins was outweighed by their higher complication rates. The study was not included due to its low level of evidence (LoE)[28].

Bisphosphonate-coated pins have been shown to increase adherence to bone in dental implants. In a randomized clinical trial published in 2013, the possibility of decreasing the rates of loosening of pins in human diaphyseal bone was evaluated. This study was not included because it did not aim to evaluate infection rates between different coatings[16].

Iodine-coated titanium pins were studied in a prospective cohort study published in 2014 that assessed the infection rates in iodine-coated titanium pins in 39 external fixators involving 38 patients. The infection rate was 3.6% (17/476 pins), and all cases were superficial. After comparing with other published studies, the authors concluded that coating titanium with iodine reduced infection rates in external fixator pins. The study was not included due to its low LoE[2].

FGF-2-apatite coating was evaluated in a prospective controlled study comparing titanium pins with and without FGF-2-apatite coating published in 2018. Overall, no significant difference between groups for pin tract infection or loosening was found. The study results concluded that pins coated with FGF-2-apatite were safe, and no severe pin tract infections were observed[29].

In addition to the materials and coatings discussed above, a review study published in 2013 by Jennison *et al*[30] commented on the possible effect of other materials and coatings such as copper, nitric oxide, chitosan and antibiotics, concluding that at that time, none of them had shown a reduction in infection rates in human clinical trials [30].

Only seven relevant publications with LoE 2 or more were available comparing different pin materials and coating systems with rates of infections in human clinical studies over the past 20 years. The main complications investigated were pin tract infections, torque force for pin removal and loosening rates. The results revealed a lack of standardized criteria established to define and classify pin tract infection. Overall, among the seven studies reviewed, only four systematically adopted a published pin infection classification system, such as the Checketts-Otterburn or the Mahan classification. The other three studies used the authors' own criteria to classify the degree of infection, potentially leading to disparities between evaluators[10,21,24]. The data retrieved from these studies warranted three meta-analyses, in which two studies compared silver with steel pins[23,24], three studies compared steel pins with HA-coated pins[10,14,19] and two studies compared titanium pins with HA-coated pins [20,21]. Interestingly, none showed a statistically significant impact on the outcome of pin tract infection, which corroborated and confirmed the information shown by other systematic reviews and studies previously carried out[11,12,30].

Despite the limited number of clinical studies addressing new materials and coated pins proposed to prevent infections, some modern strategies have been developed [31]. However, outcomes often depend on coating systems that use different antibiotic compounds, polymers or antibiotic film peptides, silver or nitric ions, nanoparticles or even antiseptics such as chlorhexidine or silver sulfadiazine[1,5,31]. Unfortunately, none of these materials have progressed to clinical trials.

CONCLUSION

In conclusion, a small number of clinical studies assessing the impact of different coatings and materials on the EF pin tract infection rates have been published over the last 20 years. Currently, there are no standardized methods of defining and classifying pin tract infections. The lack of a clear and universal definition renders existing studies difficult to evaluate and compare. We identified seven quality clinical trials, comparing three different types of coatings, that enabled us to carry out three meta-analyses. The meta-analysis showed high heterogeneity, and none of the coating systems and materials was superior at reducing the pin tract infection rates. Under these circumstances, no scientific evidence supports materials other than steel pins to control infection rates of EF pins. Prospective multicenter clinical trials involving modern pin materials and new coating systems are very much welcomed to find a way to reduce infection rates, which are considerable in the use of EF.

ARTICLE HIGHLIGHTS

Research background

Few clinical studies assessed the impact of pin materials and coating systems on infection rates over the last 20 years.

Research motivation

Few studies identified significant differences between pin materials in the rate of infection. There has been a lack of standardized criteria for defining and grading pin tract infection of external fixators.

Research objectives

Search the literature of the last 20 years for evidence on the influence of coating systems and different materials of external fixator pins on infection rates.

Research methods

A systematic review was carried out, over the last 20 years, according to the preferred reporting items for systematic reviews and meta-analyses guidelines in the following databases: PubMed, LiLacs, SciELO and Cochrane.

Research results

Seven studies met the inclusion criteria and allowed for three different meta-analyses between similar coating systems and materials used. Due to the heterogeneity of the studies, it was not possible to carry out a meta-analysis that encompassed all selected works.

Research conclusions

Currently, no significant clinical benefit to control infection rates has been achieved with our coating pins systems.

Research perspectives

Prospective multicenter clinical trials involving pin materials and new coating systems should be carried out.

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CASE REPORT

Allergic dermatitis after knee arthroscopy with repeated exposure to Dermabond Prineo™ in pediatric patients: Two case reports

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Author contributions: Robinson J, Smidt KP, Houk G, and Massey P drafted and revised the manuscript; McKie J, Massey P, and Barton RS supervised data collection, project progression and contributed to topic conceptualization; all authors issued final approval upon submission of the manuscript.

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Abstract

BACKGROUND

Allergic contact dermatitis (ACD) secondary to Dermabond Prineo™ is rare, but documented. To our knowledge, there are no described reports of this ACD reaction within the pediatric population following arthroscopic surgery.

CASE SUMMARY

We report two cases of pediatric ACD upon second exposure to Dermabond Prineo™ after knee arthroscopy. Both cases presented within two weeks of the inciting second exposure. The cases resolved with differing described combinations of sterile cleaning, diphenhydramine, and antibiotic administration. No long-term sequelae were found.

CONCLUSION

This case report elucidates the rare complication of allergic dermatitis secondary to Dermabond Prineo™ repeat exposure use in pediatric arthroscopy.

Key Words: Dermabond; Prineo; Arthroscopy; Sports medicine; Contact dermatitis; Case report

Core Tip: Dermabond Prineo™ has shown to be advantageous as a wound closure

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device with regards to operative efficiency, cosmetic results, and decreased postoperative restrictions. With the increased use of Prineo™ as a wound closure alternative, surgeons should be aware of potential risks, especially in cases with previous exposure to Dermabond™ or Prineo™. Both cases in this series resolved with differing described combinations of sterile cleaning, diphenhydramine, and antibiotic administration.

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INTRODUCTION

Efforts to decrease total operative time during a given surgical procedure are becoming more critical as both surgeons and administrators consider cost savings for hospital systems and surgical centers. It is estimated that one minute in the operating room can cost up to over $130 depending on the facility[1,2]. With the advent of rapid wound closure products such as Dermabond™ and Dermabond Prineo™ (Ethicon Endo-Surgery, Cincinnati, OH), operative times can be shortened, resources saved, and operative efficiency and post-operative patient comfort increased[3-5].

Prineo™ is a wound closure system that utilizes a self-adhering polyester-based mesh in combination with a monomeric 2-octyl cyanoacrylate formulation and the colorant D&C Violet No. 2. The wound closure system is intended to be used in conjunction with deep dermal stitches. Reported benefits of Prineo™ include a protective microbial barrier, greater skin holding strength when compared to skin staples or subcuticular sutures, more evenly distributed tension away from wound edges, easy removal, and reduction in overall wound closure time[3,6-8].

While there are reported cases of post-operative allergic contact dermatitis (ACD) with the use of Dermabond™, there are few reported cases of such dermatitis associated with the Prineo™ wound closure system, and even fewer associated with a pediatric age group[9-11]. This case report describes instances of ACD following exposure to Prineo™ in a pediatric age group.

CASE PRESENTATION

Chief complaints

Case 1: Six days after an arthroscopic left medial meniscus repair and bone marrow aspirate injection, a 15-year-old female reported increasing itching and a burning sensation around the incision sites that progressed to feeling like her left knee was "on fire."

Case 2: The second patient is a 12-year-old female who presented one week after her left medial meniscal allograft transplantation and reconstruction of anterior cruciate ligament (ACL), posterior cruciate ligament (PCL), and medial collateral ligament (MCL) with complaints of two days of itching around her operative sites.

History of present illness

Case 1: The patient underwent an arthroscopic left medial meniscus repair and bone marrow aspirate injection in which the portal incision sites were closed with Prineo™. Thrombo-Embolus-Deterrent (TED) hose were applied after the surgical drapes were taken down. The procedure was uncomplicated. Upon the patient's return for her one-week postoperative follow up appointment, she was noted to have large blisters covering the anterior portal sites (Figure 1A). The Prineo™ mesh dressing was removed and it was noted that there were large blisters to the anterior left knee.

Case 2: The patient underwent a left meniscal allograft transplantation with reconstruction of the ACL, PCL, and MCL for congenital absence of these structures.

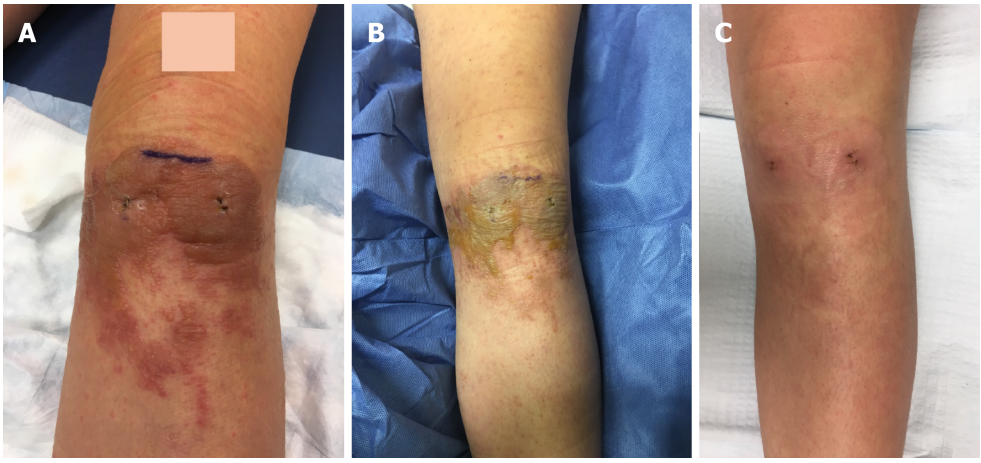

Figure 1 Patient 1. A: Left knee operative site, one week post-operation and use of Prineo™ for wound closure; B: Left knee operative site, two weeks post-operation; C: Left knee operative site, three weeks post-operation.

All incisions and portal sites were closed with Prineo™. Surgical drapes were taken down and TED hose were applied bilaterally. The procedure was uncomplicated. The patient then returned for her one-week postoperative follow-up appointment with a red papular rash surrounding the anterior knee and surgical sites. She complained of itching around these sites.

History of past illness

Case 1: This patient had a right knee ACL reconstruction two years prior in which the incisions were closed with Prineo™. There was no allergic reaction to the closure device at that time. She then sustained a left knee injury while playing softball. She was found to have a medial meniscus tear that was subsequently treated surgically as presented in this case.

Case 2: She had previously undergone a right medial meniscal allograft transplantation with ACL and MCL reconstruction a year and a half prior for congenital absence of these structures, performed by the senior author. Dermabond™ was used for wound closure during her first surgical procedure and Prineo™ was used in this case.

Personal and family history

Case 1: This patient had an unremarkable personal and family medical history.

Case 2: This patient had an unremarkable family medical history with a personal medical history of congenital absence of bilateral ACL, MCL and medial meniscus.

Physical examination

Case 1: The blisters were intact and raised. She also had pruritic scattered papules on the thigh and lower leg. She had a negative Homan sign and the remainder of her physical exam was unremarkable for her postoperative course.

Case 2: One week post-operatively, the dressings covering the operative knee were removed and she was noted to have significant skin inflammation with blisters and welts along the entirety of her surgical incisions (Figure 2A). She also had scattered papules from her groin to her left ankle that were erythematous but not draining nor pustular. The surgical incisions and portal sites were noted to be well approximated with no evidence of drainage.

FINAL DIAGNOSIS

The above cases demonstrate the occurrence of pediatric ACD upon second exposure to Prineo™. Both cases presented with this within one week of the surgical procedure.

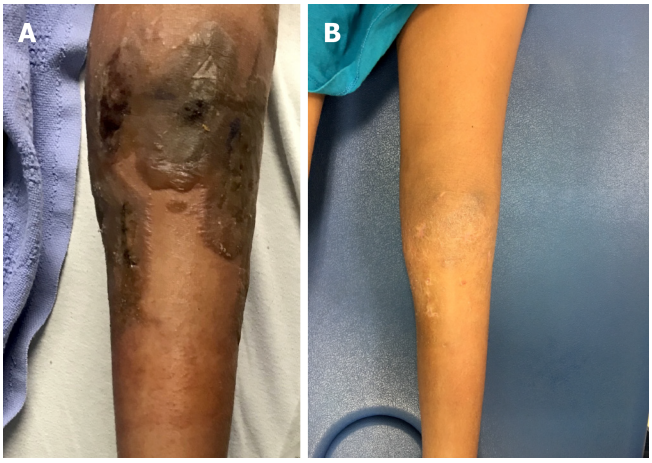

Figure 2 Patient 2. A: Left knee operative site, one week post-operation and use of Prineo™ for wound closure; B: Left knee operative site, six weeks post-operation.

TREATMENT

Case 1: She was prescribed diphenhydramine 25 mg twice daily and placed on doxycycline 100 mg daily for seven days for treatment of concurrent folliculitis. Her wounds were cleaned with sterile water and patted dry. They were then redressed with a nonadherent dressing over the blistering area followed by soft dressings over top. Her TED hose were discontinued until the blisters dried up.

Case 2: The patient's TED hose were discontinued on the operative side (left) and the skin was cleaned above and below the incisions. The incision sites were then redressed with a non-adhesive dressing followed by soft dressings. She was placed on diphenhydramine 25 mg twice daily which was increased to four times *per* day as needed for persistent itching. She underwent daily dressing changes through postoperative day nine when the blisters became flaccid.

OUTCOME AND FOLLOW-UP

Case 1: At her 2-wk post-operative visit, the raised plaques had flattened, the erythema had decreased, and her pruritis had resolved (Figure 1B). She was followed weekly and noted to have significant improvement of the contact dermatitis at her three-week postoperative visit. Her blisters had resolved and no active drainage was appreciated on exam (Figure 1C). The patient was followed two years postoperatively and had no recurrence of any skin reaction surrounding the surgical incisions or elsewhere on her body.

Case 2: On postoperative day fifteen, all blisters had drained and epithelialization of the underlying skin was appreciated. At the patient's three-week postoperative appointment, she was instructed to shower and refrain from using any lotions or creams as scabbing of the blisters was noted. At her six-week postoperative appointment, the allergic dermatitis was completely resolved (Figure 2B). The patient was followed regularly for two years postoperatively and had no recurrence of any skin reaction surrounding the surgical incisions or elsewhere on her body.

DISCUSSION

The occurrence of allergic reaction to Dermabond™ and Dermabond Prineo™ is rare and infrequently reported in the literature. Durando *et al*[12] reported an incidence rate of 1.7% (15 of 912 patients) over a two-year span involving 912 total knee arthroplasty (TKA) cases using Dermabond™. Of these 15 patients who developed a suspected ACD, three agreed to participate in patch testing to determine if they were allergic to Dermabond™ or 28 other possible allergens. Prineo™ was not used in these patient's cases and as such was not studied. Of the three who agreed to participate,

two of the three developed a positive reaction to Dermabond™[12].

Chan *et al*[13] reported 3 cases of allergic reaction to Prineo™ out of 366 patients (1.8%) that were managed by a single surgeon following TKA. Each of the cases presented within 4-9 d postoperatively and the reaction resolved between 4 wk to 12 wk postoperatively. Each patient was referred to a dermatologist and 2 of the 3 patients received a course of topical corticosteroids. Similar to our cases, no long-term sequelae, including recurrence or superficial or deep joint infection, occurred when followed for at least one year[13].

In a study examining wound complications after 2-octylcyanoacrylate skin closure following total joint arthroplasty, Michalowitz *et al*[14] found a 19.2% superficial wound complication rate in hip and knee arthroplasty cases when Dermabond Prineo™ was used. As a retrospective cohort study, the specifics of what defined a superficial wound complication were not described[14].

Davis and Stuart[15] reported a single case of a 72-year-old woman who was found to have severe ACD following a left TKA that subsequently was found to have an extreme patch test reaction to Prineo™ upon patch testing. This patient reported a similar but milder rash a year prior when she underwent right TKA. This case study provides further evidence that occurrence and severity of ACD to Dermabond Prineo™ may be related to second exposure. Similar to other reported cases, it should be noted that their patient's symptoms resolved over a 3-4 wk treatment of topical corticosteroids[15].

Regarding current treatment standards, once surgical site infection is ruled out, the treatment of ACD requires an accurate severity assessment. In the post-operative setting, orthopaedic surgeons need to have a high index of suspicion for any dermatitis following the use of skin adhesives and treat immediately based on the severity of the dermatitis. In accordance with the International Contact Dermatitis Research Group classification, a mild reaction (1+ grade) has light erythema and is nonvesicular[16]. Mild reactions can be monitored for progression and consideration can be given to remove the Prineo™ dressing[17]. Conservative treatment entails dressing removal and oral antihistamines for pruritus. A moderate reaction (2+ grade) has edema, erythema, and discrete vesicles[16]. The removal of the Prineo™ dressing is necessary and the ACD is treated with topical steroids and oral antihistamines[17]. A severe reaction has coalescing vesiculobullous papules and is treated the same as a moderate reaction with the additional consideration of oral steroids[16,17]. The current guidance from the American Academy of Allergy, Asthma, and Immunology is to use 0.5 to 1 mg/kg daily oral steroids for 7 d when more than 20% of the body surface area is affected[16]. The selection of topical steroid potency is based on the location of the dermatitis, the lesion size, and the severity of the reaction[16]. In orthopaedic cases that do not involve flexural surfaces, mid to high potency topical steroids, such as triamcinolone 0.1% or clobetasol 0.05%, are appropriate[18]. Topical steroids application should be after hydration of the skin for optimal effectiveness[16]. In our cases, we did not use corticosteroids due to concerns with wound complications that have been previously reported with steroid use and postoperative incisions[19,20].

In a case report by Dunst *et al*[21], a 44-year-old woman who underwent reduction mammoplasty with Prineo™ wound closure presented 10 d postoperatively complaining of severe itching with an extensive skin reaction in the vicinity of the Prineo™ skin closure device. She was referred to dermatology and underwent allergy testing where a moderate positive allergic reaction to both components of the Prineo™ wound closure device was noted. The authors described a noticeable reduction in operating time in their use of Prineo™ in over 50 cases of excisional body contouring procedures with this case being the only instance of any dermatitis complication[21].

While there are some reports of Prineo™ reactions, there are several studies demonstrating the benefits of shorter operative times. Shippert[1] performed a randomized controlled trial showing decreased operative time, leading to decreased costs[1]. Another randomized study concluded that Prineo™ has significantly faster closure and increased post-operative patient comfort[8]. The low risk of adverse reaction to Prineo™ combined with the benefits of increased patient comfort and operative efficiency provide rationale for its continued use. In the current era with a focus on cost savings, Prineo™ can significantly decrease operative times leading to overall cost savings for hospital systems and surgical facilities. Any previous occurrence of allergic dermatitis following use of Dermabond™ or Prineo™, however, should prompt a thorough history and further use of Prineo™ should be carefully considered, if not completely avoided.

CONCLUSION

This case report elucidates the rare complication of allergic dermatitis following second exposure use of Prineo™. This case report also brings forth the first, to our knowledge, reported cases of such allergic dermatitis in response to Prineo™ within the pediatric population. With the increased use of Prineo™ as a wound closure alternative, surgeons should be aware of potential risks, especially in cases with previous exposure to Dermabond™ or Prineo™.

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CASE REPORT

Pathological humerus fracture due to anti-interferon-gamma autoantibodies: A case report

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Abstract

BACKGROUND

Various etiologies contribute to pathological fractures, including bone infections. Recently, non-tuberculosis *Mycobacterium*-related bone infections among patients with anti-interferon-gamma autoantibody-induced adult-onset immunodeficiency has raised concerns in Southeast Asia, with the common presentations including osteomyelitis. However, it also rarely manifests as traumatic fractures, as reported in this case.

CASE SUMMARY

A diabetic female fractured her humerus after a traumatic accident and received fixation surgery. Abnormal necrotic bone tissue and abscess formation were noted, and she was diagnosed with a pathological fracture due to non-tuberculosis *Mycobacterium* infection. Multiple bone involvement was also revealed in a bone scan. Anti-interferon-gamma autoantibodies were then checked due to an unexplained immunocompromised status and found to be positive. Her humerus fracture and multiple bone infections healed after steroid and anti-non-tuberculosis *Mycobacterium* medication treatment following fixation surgery.

CONCLUSION

Comprehensive preoperative evaluations may help identify pathological fractures and guide the treatment course.

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Key Words: Immunocompromised status; Neutralizing anti-interferon-gamma autoantibody; Non-tuberculosis mycobacterium; Pathological fracture; Pre-operative evaluations; Case report

Core Tip: Identifying neutralizing anti-interferon-gamma autoantibody-related non-tuberculosis *Mycobacterium* bone infections requires careful history taking and physical examinations. While a biopsy of the bone lesion is the gold standard for diagnosis, it is advisable to check co-existing lymphadenopathy, dermatoses, and lung and blood-stream infections, as they provide easily accessible specimens for culturing and cytopathology. Serum tests of immune profiles are also important for atypical or opportunistic infections. These pre-operative evaluations may guide the choice of surgical modality, medical treatment that accompanies surgery, and decide the prognosis of healing.

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INTRODUCTION

Pathological fractures can be secondary to conditions ranging from metabolic diseases to tumors, infections, or neuromuscular pathologies. Unfortunately, those due to infections can be mistaken for malignant tumors[1]. Distinguishing between hematogenous osteomyelitis and bone tumors is difficult when there are no obvious clinical clues, and radiographic changes in osteomyelitis are often mistaken for tumors[2]. Herein, we present a diabetic female diagnosed with a humerus fracture after a traumatic injury. The purpose of this case report is to remind orthopedic surgeons not to overlook the possible diagnosis of a pathological fracture secondary to non-tuberculosis *Mycobacterium* (NTM) bone infections due to anti-interferon-gamma autoantibody (AIGA)-induced adult-onset immunodeficiency, a disease with increasing incidence in Southeast Asia in the recent decade, that can present as a traumatic fracture.

In this case, the AIGA presence itself was proposed to have occurred due to genetic susceptibility of human leukocyte antigen (HLA) genes[3] and through molecular mimicry, such as an epitope of interferon-gamma that mimics *Aspergillus* antigen (Noc-2 protein)[4], a known cause of this type of autoimmunity. The accumulation of environmental *Aspergillus* antigen exposure might gradually trigger an immune response, producing auto-antibody against human interferon-gamma and thereby resulting in opportunistic infections. Among these infections, NTM has prompted greater concern due to its being an important component of opportunistic infections. In this case report, we aimed to elucidate the NTM bone infection due to AIGA-induced adult-onset immunodeficiency that caused pathologic fracture which was overlooked as traumatic fracture.

CASE PRESENTATION

Chief complaints

A 69-year-old diabetic female presented with right upper arm pain with deformity.

History of present illness

The patient fell from her bed during the night and fractured her right humerus (Figure 1). She was then admitted for surgical fixation (Figure 2).

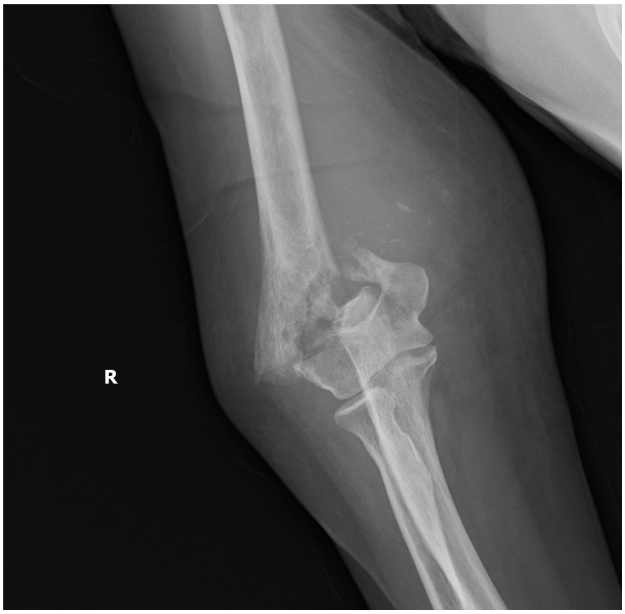

Figure 1 Displaced supracondylar humerus fracture of the right elbow on plain X-ray.

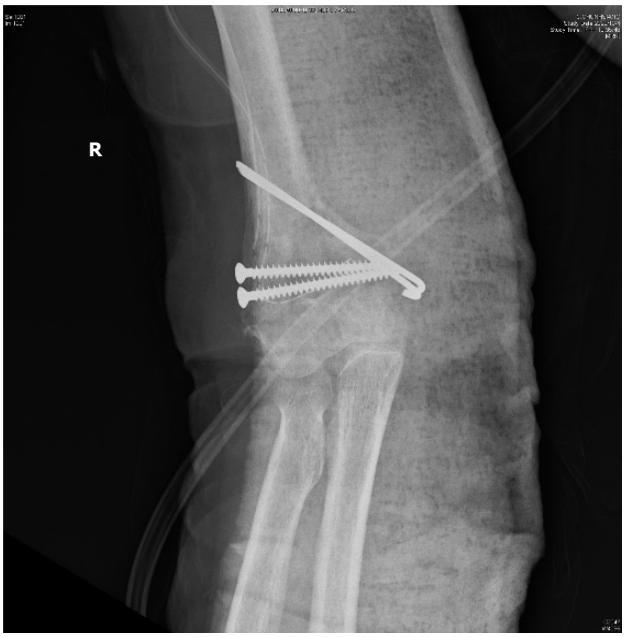

Figure 2 Displaced supracondylar humerus fracture status post-open reduction and internal fixation with screws and Kirschner wires.

History of past illness

The patient had diabetes mellitus type 2 with a hemoglobin A1c level of 5.8, under treatment with glipizide 1# twice daily.

Personal and family history

The patient had no hereditary malignancies or bone diseases and denied smoking cigarettes or drinking alcohol.

Physical examination

A painful right elbow deformity, tenderness, and limited range of motion were noted. After the fracture fixation surgery, the patient's family found a non-healing wound with abscess formation that had developed on her chest wall near the sternum. Bilateral axillary lymphadenopathy was also noted.

Laboratory examinations

Unlike an acute traumatic fracture, necrotic bone tissues were noted and sequestrated intraoperatively (Figure 3). The specimen consisted of more than 10 tissue fragments, measuring up to 1.9 cm × 1.2 cm × 0.5 cm. Representative sections were taken, showing bone and fibrosynovial tissue with necrosis, granulation tissue proliferation, and marked acute and chronic inflammatory cell infiltration. A malignancy-related pathological fracture was suspected. Sternum abscess excision and pathology revealed skin tissue with subcutaneous necrosis, fat necrosis, and dense acute and chronic inflammatory cell infiltration, without malignancy. *Mycobacterium intracellulare* was cultured *via* pus drainage. A lymph node excision biopsy was also performed, and the pathology revealed necrotizing granulation without malignancy. An immunosuppression status was suspected due to opportunistic infections. The patient had a normal lymphocyte subpopulation and tested negative for human immunodeficiency virus (HIV). Neutralizing (n)AIGAs were then considered. Serologically, high titers of AIGAs ($1:10^6$) were observed.

Imaging examinations

Plain X-ray revealed a displaced supracondylar humerus fracture of the right elbow (Figure 1). A bone scan revealed increased uptake over the skull, spine, bilateral pelvis, femur, tibia, tarsal bones, scapulae, clavicles, humeri, right forearm, sternum, and rib cage, indicating probable multiple metastases (Figure 4).

FINAL DIAGNOSIS

Disseminated (d)NTM infection with lymphadenopathy and multiple bone lesions causing a right humerus pathological fracture and sternum abscess formation. nAIGA-induced adult-onset immunodeficiency.

TREATMENT

The patient was treated with open reduction and internal fixation with cancellous screws and Kirschner wires (Figure 2) for the fracture. She was administered cortisone (4 mg) 1# orally twice daily for the autoantibodies, and rifampicin, ethambutol, and clarithromycin for the dNTM infection.

OUTCOME AND FOLLOW-UP

After a 1-mo treatment course, a physical examination showed that the humerus fracture had healed, and the sternum infection had also gradually healed along with the other infected bones. The patient will continue to receive regular treatment during future outpatient visits.

DISCUSSION

Etiologies of pathological fractures include bone infection, malignancy, endocrinopathy, osteomalacia, drug-related, rheumatological diseases, and inflammatory bowel disease[5]. While the underlying mechanism of a pathological fracture is important, as a general rule a pathological fracture is caused by minor trauma that typically would not cause the type of fracture observed. In bone infection-induced pathological fractures, the infection must be treated first, and the fractures can only heal once a favorable metabolic environment has been restored[1].

Various pathogens can cause bone infections, among which NTM is a rare but noteworthy cause, as is the present case. The incidence of NTM infection has increased in recent years, likely due to advances in diagnostic technology. In addition, the rate of dNTM infection in HIV carriers has fallen from 16% in 1996 to less than 1% today due to the introduction of effective anti-viral therapy for HIV and macrolide prophylaxis [6]. The cause of other non-HIV-related immunocompromising conditions in patients with dNTM infection is thus of concern, most notably nAIGA-induced adult-onset immunodeficiency. nAIGAs are detected in 88% of Asian adults with multiple

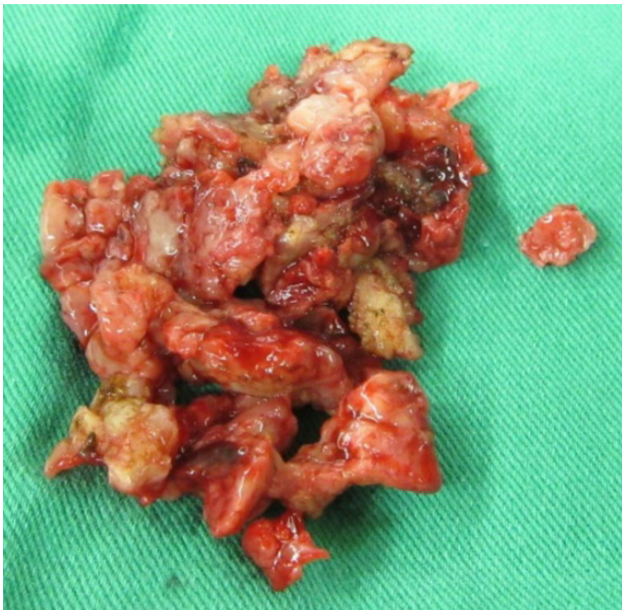

Figure 3 Intraoperative finding of unusual necrotic bone tissues, status post-sequestrectomy.

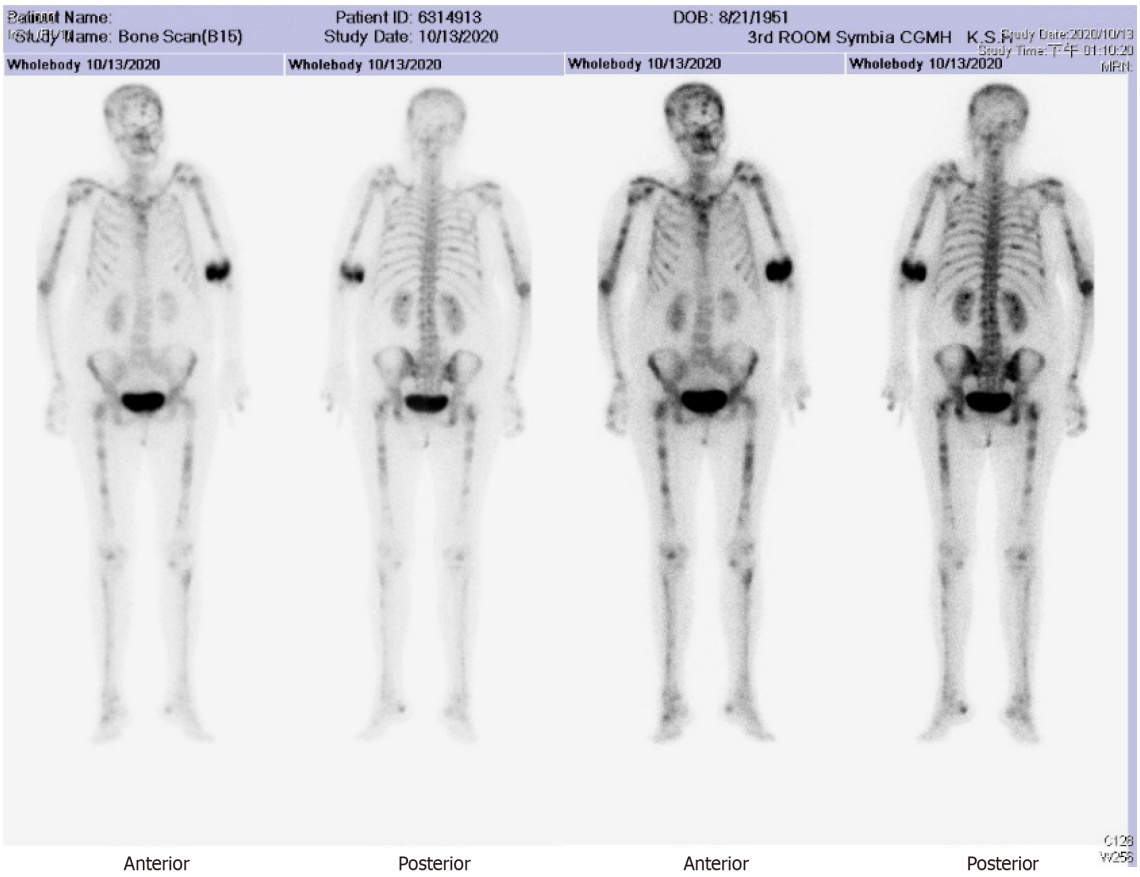

Figure 4 Bone scan revealed multiple uptake.

opportunistic infections without HIV infection[7]. nAIGA-induced adult-onset immunodeficiency is an autoimmune disease associated with HLA-DQB1/DRB1 and depleted interferon-gamma/interleukin 12-mediated cellular immunity, with increased susceptibility to opportunistic NTM infections frequently involving the lungs, lymphadenopathy, cutaneous, and the musculoskeletal system, as in our case.

However, an acute and accurate diagnosis of musculoskeletal NTM infection is often difficult because of the indolent clinical course and difficulty in isolating

pathogens[8]. A recent prospective case-control study in Taiwan[9] reported an average 1.6 year delay in the diagnosis of nAIGA-related dNTM due to protean manifestations mimicking other systemic illnesses, including mycobacterial tuberculosis, malignancy, and connective tissue diseases. Multivariate analysis revealed that slow-growing NTM species (*i.e., Mycobacterium intracellulare*) in nAIGA cases were associated with multiple bone involvement. These findings are comparable with our case. Osteomyelitis and bone marrow infections have also been associated with bone manifestations of dNTM in nAIGA patients in previous studies. In contrast, a pathological fracture was the initial presentation in our case. It is important to note that NTM osteomyelitis often arises from previous trauma or surgical sites among patients with weak immunity and dNTM infection, and osteomyelitis is also considered to be a presentation of immune reconstruction inflammatory syndrome[8].

Our case also impressed as a traumatic fracture initially according to the patient's injury history but was later found to have an NTM bone infection-related pathological fracture mimicking metastatic malignancy. Interestingly, in addition to granulomatous disease-induced bone loss, nAIGA can also induce an increase in osteoclast formation and bone resorption *via* RANKL-induced activation of the NF-kB pathway, thereby worsening NTM infection-induced bone erosion[10]. We therefore suggest that nAIGA should be considered an independent risk factor for pathological fractures.

As relatively few reports on NTM-related pathological fractures are available, our case provides valuable insight into the comparison with malignancy-related pathological fractures. Risk factors associated with the prognosis of malignancy-related pathological fractures include primary cancer type, spinal involvement, Eastern Cooperative Oncology Group status, and whether the patient received chemotherapy/radiotherapy. The median survival is 4.1 mo. Surgical treatment for pathological fractures includes intramedullary nails, plate fixation, and arthroplasty.

A retrospective cohort study[11] found that fracture site, method of fixation, and use of cement augmentation did not have a statistically significant impact on survival post-fracture. Another case-control study[12] found that cement fixation, in addition to open reduction and internal fixation, could result in immediate stabilization and thus better pain control without impairing the range of motion. In our case, the orthopedic doctor discussed the risks and benefits of different treatment methods with the patient. She chose to receive open reduction and internal fixation and subsequently underwent cancellous screw with Kirschner wire fixation for the humerus fracture. However, if we had noticed her sternum abscess lesion prior to surgery, we may have chosen a more intense fixation method under the suspicion/evidence of a pathological fracture. A more complete physical examination with preoperative planning may be helpful in such cases. In addition, further studies are warranted to investigate the preferred method of surgery, prognostic factors, and median survival of bone infection (such as NTM)-related fractures.

CONCLUSION

As T lymphocyte dysfunction predisposes patients to dNTM infection, we advise screening for nAIGA in HIV-negative Asian patients with NTM bone infection-related pathological fractures, especially when combined with other unexplained opportunistic infection history such as zoster, salmonellosis, histoplasmosis, and aspergillosis[7]. The histopathologic features of NTM bone infection show a spectrum of inflammatory changes, including granulomatous lesions with or without caseation [13]. With regards to treatment, it is necessary to differentiate nAIGA-related dNTM bone disease from Pott's disease, monoclonal gammopathies, and other malignancies sharing similar features. Efficacy and drug resistance should be carefully evaluated for long-term anti-NTM treatment, and it is important that this is accompanied by surgical debridement and fracture treatment[8].

The immunosuppressants used for nAIGA include corticosteroids and cyclophosphamide, while rituximab has also been reported to be effective[7,14]. nAIGA titers have been reported to decrease over time even without immunosuppressive treatment. However, rates of chronic opportunistic infections and death remain high[10]. Screening for nAIGA in dNTM-related pathological fractures is recommended to allow for appropriate treatment, thereby decreasing morbidity. A careful preoperative survey is important in potential pathological fracture cases.

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CASE REPORT

Spontaneous pneumothorax in a 17-year-old male patient with multiple exostoses: A case report and review of the literature

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Author contributions: Shimamoto A and Kaneda S were the patient's surgeons; Nakamura K and Asanuma K wrote the manuscript; Nakamura K collected the previous reports; and All authors were involved in revising the first draft and approved the final version of the manuscript.

Informed consent statement: Written informed consent was obtained from the patient and his parent.

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Abstract

BACKGROUND

Multiple exostoses generally develop in the first decade of life. They most frequently arise from the distal femur, proximal tibia, fibula, and proximal humerus. Costal exostoses are rare, contributing to 1%–2% of all exostoses in hereditary multiple exostoses (HME). They are usually asymptomatic, but a few cases have resulted in severe thoracic injuries. Pneumothorax caused by costal exostoses is rare, with only 13 previously reported cases. We report a new case of pneumothorax caused by costal exostoses.

CASE SUMMARY

A 17-year-old male with HME underwent surgery for removal of exostoses around his right knee. Four months following the operation, he felt chest pain when he was playing the trumpet; however, he did not stop playing for a week. He was referred to our hospital with a chief complaint of chest pain. The computed tomography (CT) scan revealed right pneumothorax and multiple exostoses in his right ribs. The CT scan also revealed visceral pleura thickness and damaged lung tissues facing the exostosis of the seventh rib. We diagnosed that exostosis of the seventh rib induced pneumothorax. Costal exostosis resection was performed by video-assisted thoracoscopic surgery (VATS) 2 wk after the onset. The patient's postoperative course was uneventful, and there was no recurrence of pneumothorax for 2 years.

CONCLUSION

Costal exostoses causing thoracic injuries should be resected regardless of age. VATS must be considered in cases with apparently benign and relatively small

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exostoses or HME.

Key Words: Costal exostosis; Pneumothorax; Video-assisted thoracoscopic surgery; Hereditary multiple exostoses; Case report; Treatment

Core Tip: We report a case of pneumothorax caused by costal exostoses in a patient with hereditary multiple exostoses (HME). The computed tomography scan revealed exostoses and clarified the relationship between exostoses and the surrounding structures, which enabled us to identify the cause of the pneumothorax. Costal exostoses causing thoracic injuries should be removed regardless of age; thoracic complications are serious, and there is no apparent correlation between age at the time of operation and recurrence of thoracic complications after surgery. The application of video-assisted thoracoscopic surgery (VATS) is worthy of consideration for patients with apparently benign and relatively small exostoses or patients with HME as redo VATS may be easily offered.

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INTRODUCTION

Multiple exostoses generally develop in the first decade of life and stop growing with skeletal maturity[1]. Exostoses most frequently arise from the distal femur, proximal tibia, fibula, and proximal humerus[2]. Exostoses of the ribs are rare, contributing to approximately 1%–2% of all exostoses in hereditary multiple exostoses (HME)[2,3]. Exostosis can transform into chondrosarcoma in up to 10% of patients with HME[4]. A differential diagnosis is Ewing sarcoma, which is more common among children[5]. Suggestive malignant costal bone tumor and worsening visible deformity are operative indications.

Costal exostoses are usually asymptomatic; however, in a few cases, they can induce specific yet severe symptoms due to the nature of the ribs. Costal exostoses have been reported to cause hemothorax, pneumothorax, pericardial injuries, diaphragmatic injuries, and visceral pleural injuries[6-9]. Surgical treatment was performed in many of these cases.

To the best of our knowledge, only 13 cases of pneumothorax caused by costal exostoses have been reported to date. Here, we report a new case of pneumothorax caused by costal exostoses that was successfully treated by video-assisted thoracoscopic surgery (VATS).

CASE PRESENTATION

Chief complaints

A 17-year-old male with HME was referred to Mie University Hospital with a chief complaint of consistent chest pain.

History of present illness

The patient felt chest pain when he was playing the trumpet; however, he did not stop playing for a week.

History of past illness

The patient was diagnosed with HME at the age of 6 years and had undergone surgery

for removal of exostoses around his right knee 4 mo before chest pain.

Personal and family history

The patient had multiple bony protrusions in the bilateral humerus, scapula, clavicle, fibula, tibia, femur, and ilium. The patient's father had bony protrusion around his knees, but his family members did not undergo a full body skeletal imaging.

Physical examination

The patient's temperature was 36.8°C, heart rate was 95 bpm, respiratory rate was 16 breaths per minute, blood pressure was 147/79 mmHg, and oxygen saturation in room air was 96%. There was no subcutaneous swelling, coughing, or sputum.

Laboratory examinations

Laboratory examinations were normal.

Imaging examinations

Chest X-ray showed right-sided pneumothorax (Figure 1A). Computed tomography (CT) scan confirmed the presence of a pneumothorax (Figure 1B) and revealed four exostoses in his right ribs and one exostosis in his left rib (Figure 2). Exostoses arising from the right first and seventh ribs were protruded into the thoracic cavity; in particular, the exostosis from the right seventh rib was sharp and directly in contact with the visceral pleura. CT scan also revealed thickness of the visceral pleura and damaged lung tissues facing the exostosis of the right seventh rib (Figure 3).

MULTIDISCIPLINARY EXPERT CONSULTATION

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FINAL DIAGNOSIS

Pneumothorax caused by the exostosis of the seventh rib.

TREATMENT

A chest tube was not inserted because the sharp margin of the exostosis would have scratched the re-expanded lung again. Since the exostosis of the right seventh rib could potentially cause the recurrence of the thoracic complications, we decided to remove the costal exostosis.

Resection of costal exostosis was performed by VATS 2 wk after the onset of symptoms. After induction of anesthesia, the patient was positioned in the left lateral decubitus position. The first incision was made in the midaxillary line of the right eighth intercostal space to insert the 5.5 mm thoracoport. A 5 mm camera was then inserted through the thoracoport, which revealed the bony protrusion of the right seventh rib; the protrusion was a bone mass measuring 5 mm in length on the midaxillary line directed toward the intrathoracic cavity (Figure 4). The second port was placed in the anterior axially line of the right seventh intercostal space to operate the forceps. Thoracoscopic observation revealed that the exostosis of the right seventh rib had sharp margins and the parietal pleura was lacerated; it was the apparent cause of injuries in the visceral pleura. The bony spur of the right seventh rib was removed using forceps and the arthroscopic burr was used to scrape down the spinous lesion. Other spurs were not treated because their edges were dull, and parietal pleura on the spurs was not peeled off. Mechanical pleurodesis was accomplished by abrasing the damaged visceral pleura using electrocautery. A 20 F chest tube was placed in the apex of the thoracic cavity.

Pathological examination revealed that the resected specimen was histologically composed of mature bone, hyaline cartilage, and fibrocartilage with no sign of

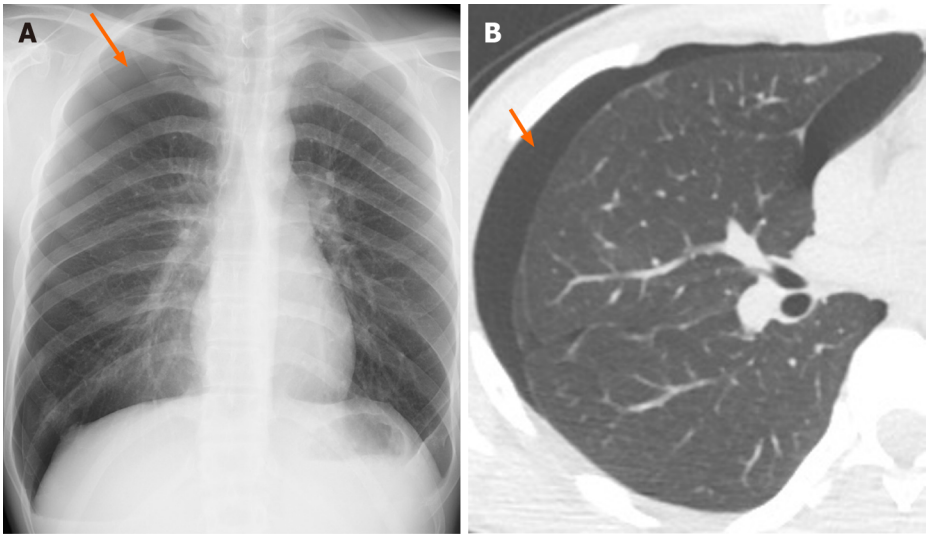

Figure 1 Chest X-ray and computed tomography scan revealed right-sided pneumothorax. A: Chest X ray in anterior-posterior view; B: Computed tomography scan in axial plane.

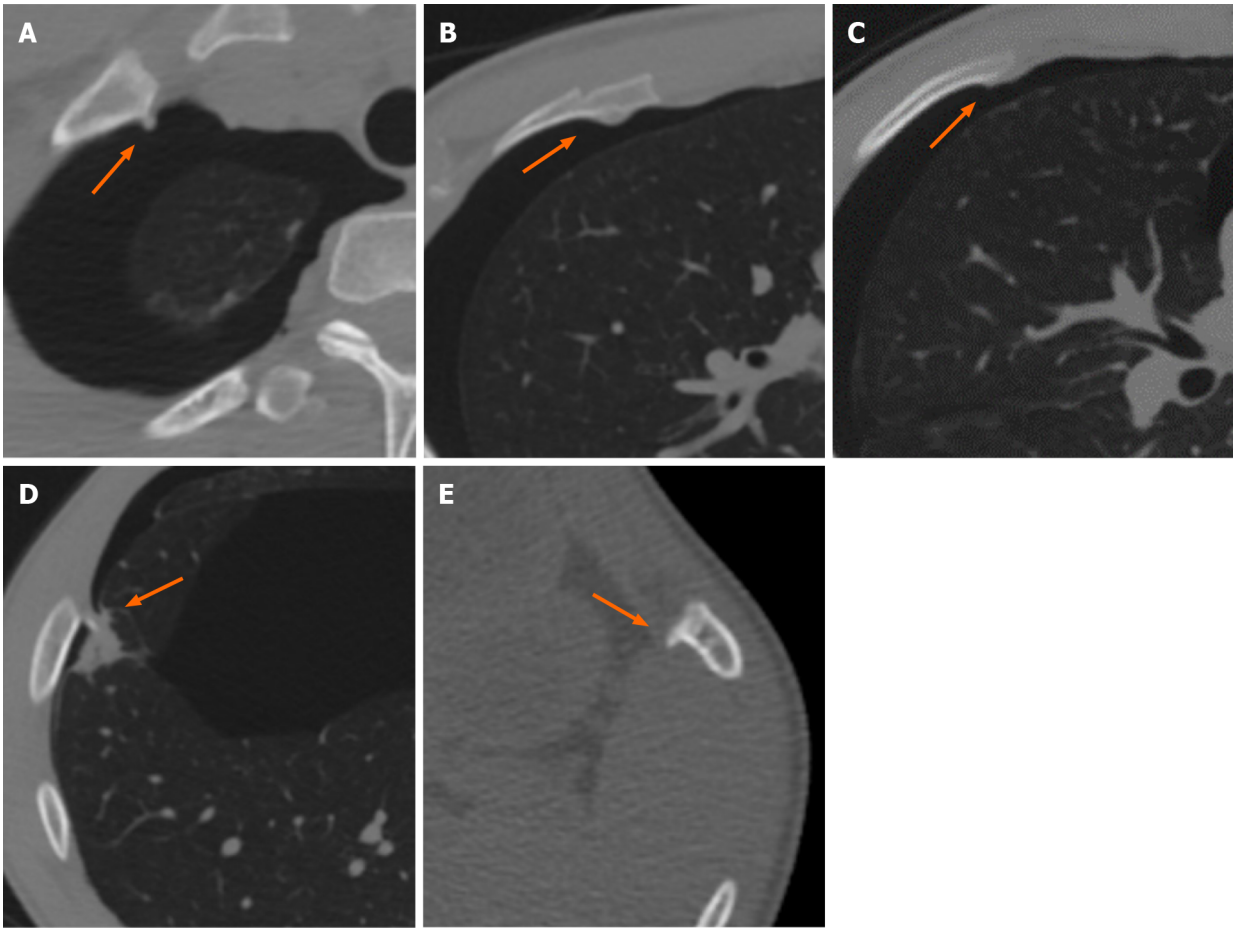

Figure 2 Computed tomography scan shows exostoses of five ribs. The right first and seventh ribs were sharp and protruded into the thoracic cavity. A: Rt. (right) first rib; B: Rt. third rib; C: Rt. fourth rib; D: Rt. seventh; E: Left ninth rib. Rt.: Right.

malignant transformation (Figure 5). These findings confirmed the diagnosis of exostosis.

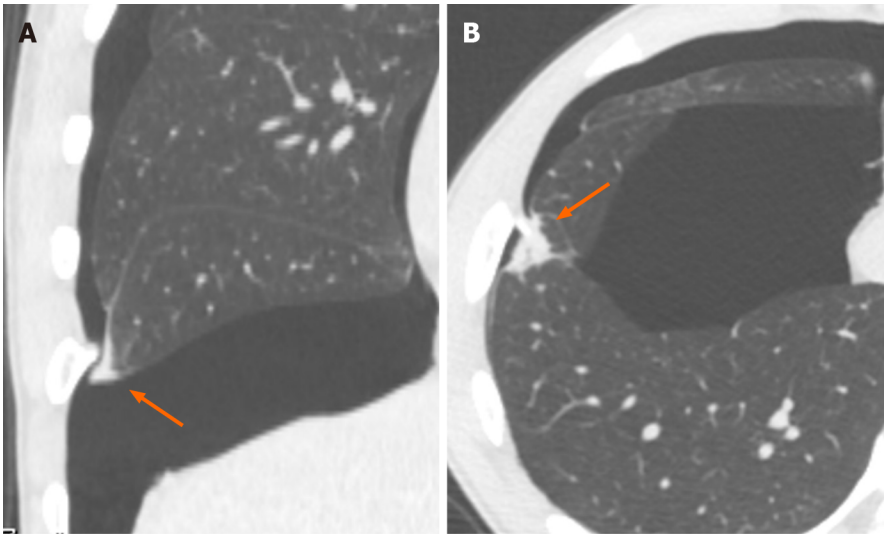

Figure 3 Damaged pleura and lung tissues confronted with the exostosis of the right seventh rib. A: Coronal plane, thickness of visceral pleura; B: Axial plane, damaged lung tissues.

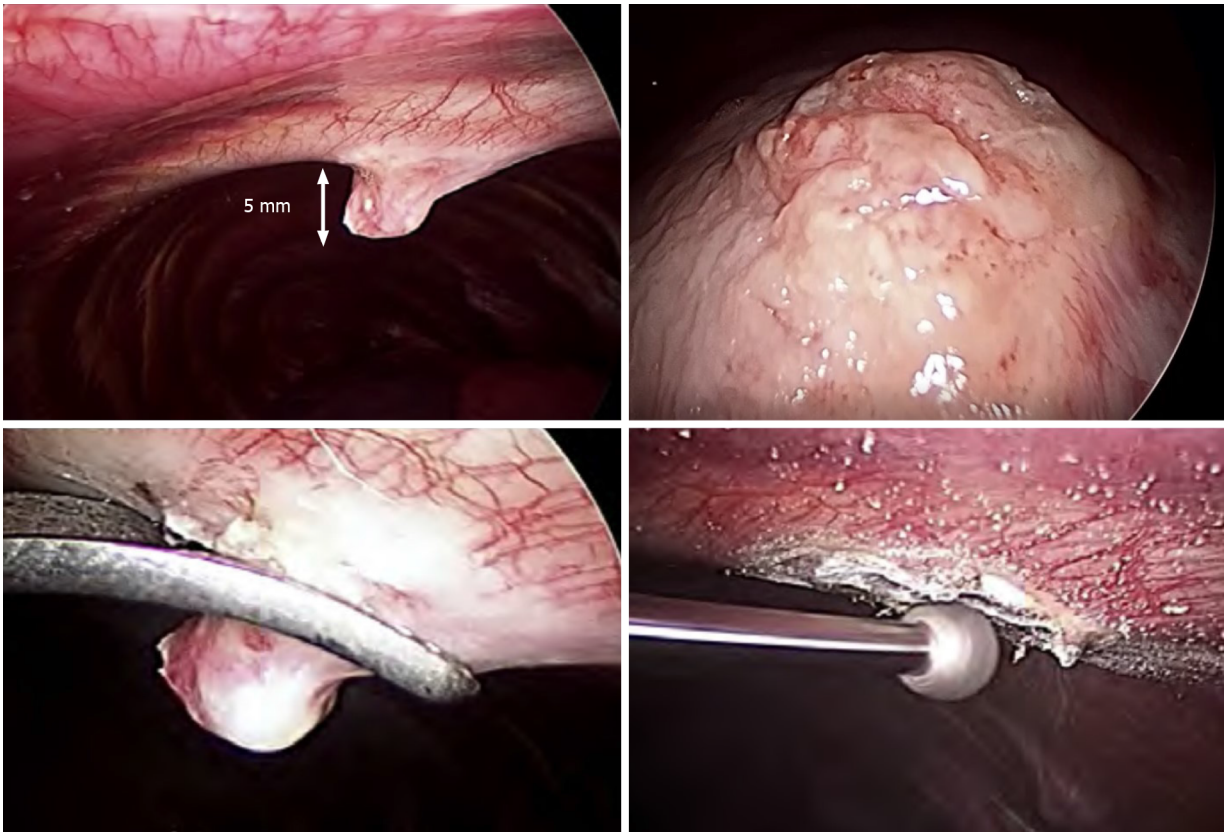

Figure 4 Intraoperative findings and treatment. The bony spur was removed using forceps. The spinous lesion of the rib surface was scraped down by arthroscopic burr.

OUTCOME AND FOLLOW-UP

The patient's postoperative course was uneventful, and there was no recurrence of pneumothorax during 2 years of follow-up.

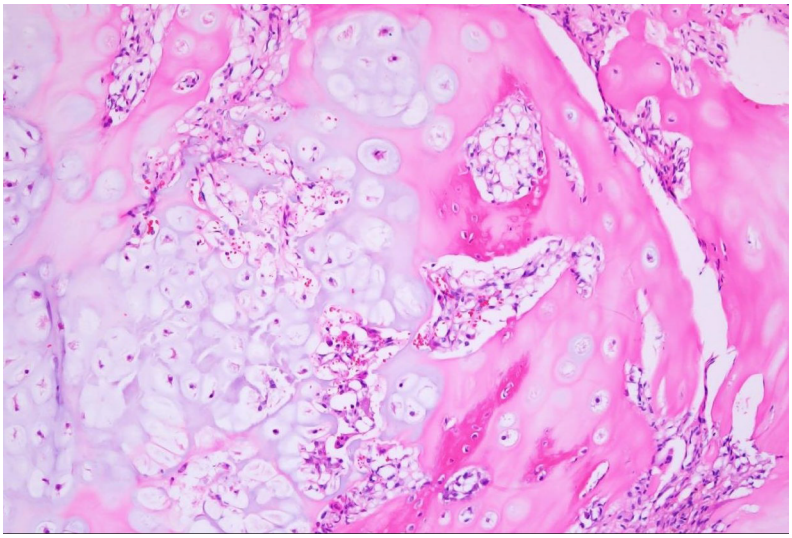

Figure 5 Pathological findings (hematoxylin and eosin stain, ×200). The resected specimen was histologically composed of mature bone, hyaline cartilage, and fibrocartilage with no sign of malignant transformation.

DISCUSSION

Most cases of costal exostoses are asymptomatic; therefore, thoracic complications caused by costal exostoses are rare[7,10,11]. Resection of costal exostoses has been reported for at least 87 cases, whereas hemothorax caused by costal exostoses has been reported in 38 cases. Pneumothorax caused by costal exostoses has only been reported in 13 cases. The details of which are presented in Table 1.

During review of literature, we found that tumor size was ≥ 1 cm in cases of pneumothorax or hemothorax caused by costal exostoses[3,6,12]. In our case, the maximum tumor size was 5 mm, which was smaller than that reported in previous case reports describing the thoracic complications caused by costal exostoses.

Significant traumatic events prior to symptom onset were not described in most of the case reports. However, a few patients with HME had a history of athletic activity and labor prior to pneumothorax[3,13]. In our case, pneumothorax might have been caused by a synergetic effect of the respiratory motion while playing the trumpet and the sharpness of the bony spur. In our case, costal exostoses were too small to be identified with chest X-ray; however, a CT scan revealed the presence of costal exostoses. Thus, a patient with HME who presents with an acute onset of symptoms in the chest should be assessed for pneumothorax and should undergo CT scanning to determine the cause of the symptoms in the chest.

Among the 13 previously reported cases, pneumothorax was treated with supportive care in the form of rest, wait, and see in seven cases; chest drainage in five cases; and unknown in one case.

In general, asymptomatic costal exostoses are not treated prophylactically[14]. Surgical management of costal exostoses is done for symptom control, establishing a histological diagnosis, and prevention of thoracic complications[4]. Among the cases reviewed by us, including our case, 13 cases required surgical treatment for costal exostoses.

Among all cases of pneumothorax, including ours, 10 cases occurred in patients under the age of 18 years. Of these, nine underwent surgery. Furthermore, the review of literature revealed that costal exostoses were actively resected in cases of thoracic complications caused by exostoses, even if prior to adolescence[4,15]. Thoracic complications caused by costal exostoses are serious. Therefore, similar to our case, regardless of age, risk aversion of thoracic injuries was considered more important than the risk of reoperation in previous case reports.

Compared to major thoracotomy, VATS has become an increasingly popular method for treating the intrathoracic lesions because it is a minimally invasive procedure[3]. VATS appears to be the best option for surgical resection of exostoses to prevent thoracic complications in cases of apparently benign exostoses[15,16]. In addition, VATS may be easily offered in cases of HME because redo VATS is less invasive[15]. The application of VATS for the removal of suggestive malignant exostoses has not been fully discussed; however, small tissue fragments may spread

Table 1 Review of the pneumothoraxes caused by costal exostoses

No	Ref.	Year	Age	Exostosis location	Tumor size	Primary treatment	Treatment		Outcome
1	[26]	1952	27	Lt. 8th rib	2-5 cm	Rest	Thoracotomy	Wide resection of the rib. Rubbed over talc to the pleura	Recurrence
2	[27]	1991	21	Rt. 6,7th ribs	N/A	Rest	Thoracotomy	Wide resection of the ribs. Suturing of lung and pleura	Good
3	[3]	2010	17	Lt. 5th rib	2.8 cm	Rest	VATS	Bony spur resection. Scraped down the surface	Good
4	[31]	2011	15	Lt. rib	3 cm	Rest	Observation		Good
5	[28]	2012	30	Rt. 4th rib	1.3 cm	Rest	VATS and Thoracotomy	Wide resection of the rib. Wedged resection of the lobe. Reconstruction with metal plate	Good
6	[32]	2013	12	Lt. 4th rib	N/A	Drainage	VATS	Bony spur resection	Good
7				Rt. rib	N/A	Drainage	VATS	Bony spur resection	
8	[23]	2013	12	Rt. 5th rib	2.5 cm	Drainage	VATS	Bony spur resection	Good
9	[4]	2014	15	Lt. 3rd rib	N/A	N/A	Thoracotomy	Bony spur resection	Good
10	[24]	2014	16	Rt. 7,8th rib	N/A	Drainage	VATS	Bony spur resection	Good
11	[29]	2017	13	Lt. 5th rib	N/A	Drainage	VATS	Bony spur resection. Wedged resection of the lobe	Good
12	[25]	2018	32	Lt. 4,5th rib	N/A	Rest	VATS	Bony spur resections	Good
13	[13]	2020	15	Lt. 6th rib	4 cm	Rest	VATS	Bony spur resection. Diathermic coagulation of the pleura	Good
14	Our case	2021	17	Rt. 7th rib	5 mm	Rest	VATS	Bony spur resection. Scraped down the surface	Good

Lt.: Left; Rt.: Right; N/A: Not available; VATS: Video-assisted thoracoscopic surgery.

accidentally into the pleural cavity[15].

Thoracotomy is mainly done in cases of extensive rib resection. Thoracotomy enables surgeons to cope with active bleeding from the diaphragm[6] and bowel obstruction caused by the diaphragmatic ruptures[17] or malignant tumors[4]. Extensive rib resections or relatively large tumor resections are often performed with thoracotomy only or by mini-thoracotomy using thoracoscopic-guidance[18]. Among the cases reviewed by us, five had a tumor measuring ≥ 5 cm, and four were treated by thoracotomy[16,19-22] and one with VATS[20]. However, it seems that there is no correlation between age at the time of operation and operative approach[15].

Of the 14 cases of pneumothorax caused by costal exostoses, including ours, nine were treated with VATS[3,23-25], three with thoracotomy[4,26,27], one with a combination of VATS and mini-thoracotomy, and one with observation (Table 1). Of the 12 previously reported cases of pneumothorax since 2000, 10 were treated with VATS (83.3%).

Most case reports did not describe their method of resection in detail; however, in general, forceps or a rongeur was used. After bone spur resection, an arthroscopic burr was used to scrape down the spinous lesion in only one previous case and our case[9]. In our case, forceps in combination with an arthroscopic burr enabled us to treat costal exostosis by complete VATS.

Furthermore, review of literature revealed that the damaged lung tissues were treated by wedge resection of the lobe[28,29]. Mechanical pleurodesis was accomplished by abrasing the pleura with an electrocautery scratch pad[13,28]. A partial rib defect was reconstructed with a metal plate to stabilize the anterior chest wall[28]. In a 2-year-old girl, a Gore-Tex sheet was used to cover a 12 cm × 6 cm defect of the chest wall caused by rib resection[30].

Morphology of sharp tip of the exostosis and laceration of the parietal pleura are suggestive of the potential risk of lung injuries. The location of the costal exostosis is associated with lung injuries because the respiratory motion of the lower lobe is greater than that of the middle and upper lobe[24]. In our case, exostosis of the right seventh rib was removed due to the risk of re-injury of the lung. In contrast, other costal exostoses were not removed because their tips were dull, and no parietal pleura

laceration was found. The spurs of the right first, third, and fourth ribs were not confronted with the lower lobe. Moreover, their spurs were less likely to grow further and re-injure the lung due to the completion of bone maturity.

The outcomes of surgical management of the costal exostoses were favorable in most of the cases with no significant complications, except for in two cases; pneumothorax recurred in one case reported more than a half century ago[26], and thoracic pain did not disappear for 2 years after surgery due to intercostal nerve damage in another case[15]. It appears that there is no correlation between age at the time of operation and recurrence of pneumothorax after surgery. In our case, VATS was successful and the post-operative course was uneventful; this was also observed in previous reports.

The present case has the following limitation: Postoperative follow-up period was short (2 years), and treatment experience was compared between different institutions and different times. It is necessary to investigate long-term results after the surgery.

CONCLUSION

We reported our experience of pneumothorax caused by costal exostoses because it is extremely rare. Damaged lung tissues due to costal exostoses should be suspected in HME patients with symptoms in the chest. CT scan was useful in diagnosing thoracic damage caused by costal exostoses. Costal exostoses causing thoracic injuries should be removed regardless of age; thoracic complications are serious, and there is no apparent correlation between age at the time of operation and recurrence of thoracic complications after surgery. VATS enabled us to resect the costal exostoses using a less invasive approach. VATS is worthy of consideration in patients with apparently benign and relatively small exostoses or patients with HME because redo VATS may be easily offered.

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CASE REPORT

Management of acute length-unstable Monteggia fractures in children: A case report

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Abstract

BACKGROUND

Monteggia fractures are uncommon injuries in paediatric age. Treatment algorithms assert that length-unstable fractures are treated with plate fixation. In this case report, intramedullary fixation of an acute length-unstable Monteggia fracture allowed a stable reduction to be achieved, along with an appropriate ulnar length and alignment as well as radio capitellar reduction despite the fact that the orthopaedic surgeon did not use a plate for the ulnar fracture. The scope of treatment is to avoid the use of a plate that causes periosteal stripping and blood circulation disruption around the fracture.

CASE SUMMARY

A four-year-old girl presented at the Emergency Department following an accidental fall off a chair onto the right forearm. The X-ray highlighted a length-unstable acute Bado type 1 Monteggia fracture of the right forearm. On the same day, the patient underwent surgical treatment of the Monteggia fracture. The surgeon preferred not to use a plate to avoid a delay in fracture healing and to allow the micromotion necessary for callus formation. The operation comprised percutaneous fixation with an elastic intramedullary K-wire of the ulnar fracture and, subsequently, humeroradial joint reduction through manual manipulation.

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The orthopaedic surgeon assessed the stability of the radial head reduction under fluoroscopic control through flexion, extension, pronation and supination of the forearm. Healing of the fracture occurred within six weeks after surgery, as indicated by the presence of calluses on at least three cortices on standard radiographs. Dislocation/subluxation or loss of ulnar reduction was not apparent at the final X-ray examination.

CONCLUSION

Intramedullary fixation of unstable Monteggia fractures results in excellent outcomes, provides reliable reduction and causes fewer complications.

Key Words: Monteggia fractures; Children; Management; Outcome; Case report

Core Tip: Treatment algorithms assert that acute length-stable Monteggia fractures are treated with an intramedullary device, while acute length-unstable fractures are treated with plates. Intramedullary devices have the advantage of smaller skin incisions, less soft tissue disruption, shorter operative times and easier device removal. Plates allow more anatomical restoration of the ulnar fracture and the radial bow, although they can cause delayed union due to blood circulation disruption around the fracture. Intramedullary wires can be used for the treatment of acute length-unstable Monteggia fractures instead of plates as these are associated with excellent results and fewer complications.

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INTRODUCTION

Monteggia fractures are uncommon injuries in paediatric age. In the nineteenth century, an Italian surgeon named Giovanni Monteggia described a traumatic injury involving a fracture of the proximal ulna with an associated dislocation of the radial head and disruption of the radioulnar joint[1]. Subsequently, these fractures were classified by Bado[2] into four types according to the direction of dislocation of the radial head.

The mechanism of injury is caused by direct trauma and hyperpronation as well as hyperextension[3]. The occurrence of paediatric Monteggia fractures covers between 1. Of 5% and 3% of all childhood elbow injuries[3,4]. Monteggia fractures remain a challenge for paediatric orthopaedic surgeons because of the difficulty involved in diagnosis and in the treatment of missed radial head dislocation and late instability. The aim of treatment is to achieve stable reduction of the ulnar fracture and radial head dislocation. Nowadays, the surgical treatment modalities available for these acute fractures include plates, intramedullary Kirschnerwires or elastic stable intramedullary nailing and, more recently, external fixation devices[5]. Although plates and intramedullary devices have comparable outcomes and complications, nailing or K-wires have the advantage of smaller skin incisions, less soft tissue disruption, shorter operative times and easier device removal. Furthermore, intramedullary wire fixations, due to their lack of rigidity, allow micromotion and callus formation[5]. Mechanical properties of intramedullary wires are based on a three-point fixation of the inner cortex and on a spread of the interosseous membrane [5]. Nowadays, there is no consensus regarding the preferred nail diameter, although, in the literature, authors suggest that the diameter of the wire should be approximately two-thirds of the medullary canal, measured atthe isthmus level[6]. Intramedullary devices may cause skin irritation, refractures, malunion, secondary displacement and nerve injury. The use of plates is associated with a more anatomical

restoration of the ulnar fracture and the radial bow, and a more rigid fixation, which requires reduced post-operative immobilization[6]. Despite this, open reduction and plate fixation cause periosteal stripping and blood circulation disruption around the fracture, resulting in a greater likelihood of delayed union or more rarely non-union [6].

The aim of this case report was to assess the efficacy of intramedullary wires for the treatment of acute length-unstable Monteggia fractures instead of plate fixation and to review the literature.

CASE PRESENTATION

Chief complaints

A four-year-old right-hand-dominant girl presented at the Emergency Department of our hospital following an accidental fall off a chair onto the right forearm. The mother reported a direct trauma to the floor of the right forearm with hyperextension and hyperpronation.

History of present illness

Post-trauma, the child reported pain in the right forearm along with inability to bend the elbow.

History of past illness

The patient had a free previous surgical history.

Physical examination

The child had forearm deformities with swelling and local tenderness around the elbow. Furthermore, active and passive motion of the elbow was impossible and accompanied by pain.

Imaging examinations

The X-rays appeared to show a fracture of the proximal ulna with an associated anterior dislocation of the radial head of the right elbow (Figure 1). The ulnar injury consisted of a long oblique fracture with a line measuring more than twice the cortical diameter. Radial head dislocation may be diagnosed when the radiocapitellar line, drawn through the axis of the radial neck on a lateral radiograph, regardless of the degree of flexion or extension of the elbow, crosses the humeral capitellum anterior to this normal position.

FINAL DIAGNOSIS

The X-ray highlighted a length-unstable acute Bado type1 Monteggia fracture of the right forearm.

TREATMENT

On the same day, the patient underwent surgical treatment of the Monteggia fracture. The surgeon preferred not to use a plate to avoid a delay in fracture healing and to allow the micromotion necessary for callus formation. The operation comprised percutaneous fixation with an elastic intramedullary K-wire of the ulnar fracture and, subsequently, humeroradial joint reduction through a combination of longitudinal traction and manual manipulation. The wire was inserted through the tip of the olecranon and advanced across the fracture site after a reduction is obtained. The reduction of the radial head may be considered stable under fluoroscopic control if the intramedullary fixation of the ulnar fracture maintains its reduced position through flexion, extension, pronation and supination. Alignment of the ulnar injury by K-wire had simultaneously reduced and stabilized the radial head dislocation. No other K-wire was used to maintain the reduction of the radial head. The K-wire can be bent and cut outside the skin to facilitate easy removal. A long arm cast was applied at the end of the operation with the elbow at 90° of flexion and the forearm in supination. Adequate analgesia was provided after surgery, the affected limb was elevated,

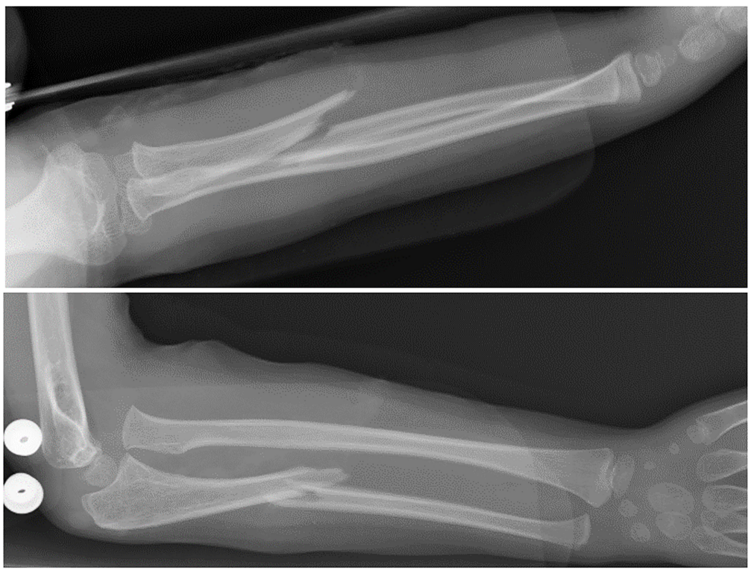

Figure 1 Plain X-ray taken at the time of injury revealing a fracture of the proximal third of the ulna andanterior dislocation of the radial head.

cryotherapy applied and circulation of the fingers monitored. The girl's parents were taught how to manage post-operative swelling and pain over the following days. Cast immobilization was used after the surgical treatment until there was radiographic evidence of fracture union.

OUTCOME AND FOLLOW-UP

At the first (5 d) and second (10 d) follow-up, control two-plane radiographs were obtained to assess any possible loss of articular contact between the proximal radius and humeral capitellum and loss of ulnar reduction (> 10 degree increase in the ulnar angle). Healing of the fracture occurred within six weeks after surgery. In children, although the fracture may still be visible at six weeks, adequate healing is represented by a callus on at least three cortices on standard radiographs (Figure 2). At the last follow-up (6 wk), the cast and the intramedullary wire were removed. Dislocation /subluxation, defined as a loss of articular contact between the proximal radius and capitellum, or loss of ulnar reduction, was not apparent in the final X-ray examination. Active range of motion exercises were started on the first day after removal of the cast and K-wire with the aid of a physiotherapist until full elbow range of motion was achieved. No pain, limitations in range of motion or function, or any complications (recurrent dislocation, elbow dysfunction or stiffness, refracture, transient neuropraxias) were observed at the end of the rehabilitative treatment. The patient had excellent results and complete return of elbow motion at short-term clinical follow-up (6 wk after physiotherapy). Complete fracture healing, defined as full return to activities of daily living and sports, occurred four months after the trauma.

DISCUSSION

If the radial head dislocation or subluxation in Monteggia fractures is not diagnosed and adequately treated, it may lead to chronic elbow disability, pain, progressive valgus deformity, neurologic problems (posterior interosseous nerve palsy), radial head dysplasia and degenerative arthritis, elbow stiffness and loss of motion, particularly supination and pronation[4,7,8]. Foran *et al*[4], in a retrospective study performed on 94 patients, asserts that 83% of patients are successfully managed with a cast and do not require surgical stabilization. Reduction of the deformity of the ulnar fracture is achieved through a combination of longitudinal traction, elbow rotation and manual manipulation; when the ulnar length has been re-established, the radiocapitellar joint will often reduce spontaneously or as a result of pressure on the radial head. The author asserts that paediatric Monteggia fractures, including in patients

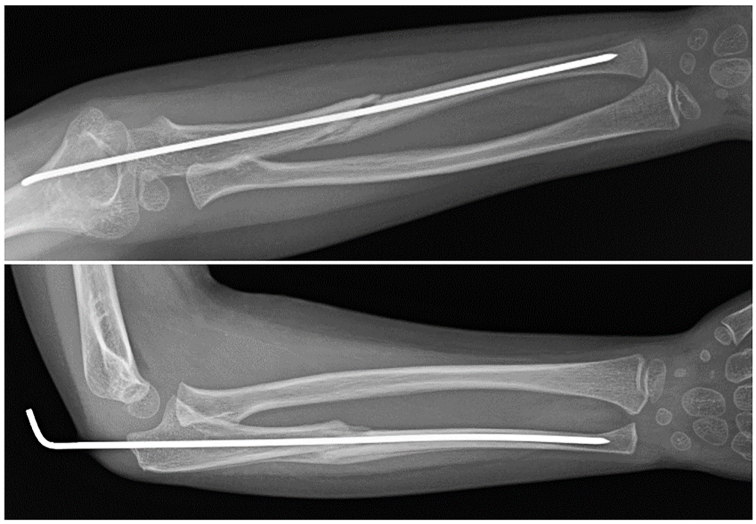

Figure 2 Radiographs at six weeks of follow-up showing reduction of the radial head dislocationand adequate healing of the proximal ulna fracture.

with length-unstable ulna fractures, can initially be managed non-operatively, without compromising outcomes or complications; surgery should only be pursued when a conservative approach fails, with the aim of avoiding surgical overtreatment of these injuries. Compared with adults, children with Monteggia fractures have a higher chance of success without surgery for several reasons, including their thicker periosteum (which helps maintain stability of the ulna), less complex ulna fracture patterns, typically lower energy mechanisms, faster healing times and greater remodeling potential[9,10]. Failure or loss of reduction and late instability may occur in up to 20% of cases with this conservative treatment because of the deforming muscular forces and joint disruption[11,12]. Therefore, although most acute Monteggia fractures are treated non-operatively, certain fracture patterns require surgical stabilization[4]. The indications for surgical treatment are complete fracture, unstable and irreducible fractures, open fractures, and fractures with neurovascular compromise[5]. Variations in the treatment of Monteggia fractures can be found among multiple authors. Ring *et al*[13] affirmed that maintaining ulnar length and anatomic alignment was the key to treating acute Monteggia injuries, because the radial head will remain reduced through healing of the ulnar fracture. Treatment algorithms, based upon the ulnar fracture pattern, have the purpose of minimizing complications and maximizing outcomes through restoration and maintenance of ulnar alignment. The treatment algorithms assert that length-stable fracture patterns with incomplete fracture or plastic deformation of the ulna are treated with closed reduction and casting; length-stable fractures with a complete fracture of the ulna (transverse or short oblique) are treated with intramedullary pin fixation; and length-unstable fractures with comminution of the ulna or a long oblique fracture (fracture line measuring more than twice the cortical diameter) of the ulna are treated with plate fixation[13]. The objective of this algorithm is to avoid loss of reduction and its associated morbidity. Ramski *et al*[11], in a retrospective study performed on 112 patients, asserts that recurrent instability of the radial head and loss of ulnar fracture reduction only occurred in patients who were not treated according to the ulnar-based algorithm. Failures occurred in patients treated less rigorously than the recommended algorithm, and in particular, failures occurred in complete fractures treated non-operatively with closed reduction and cast immobilization[11]. Furthermore, the authors observed that although the algorithm strategy recommends plate fixation for all long oblique or comminuted fractures, there were no failures of intramedullary pin fixation of long oblique fractures in this clinical study.

Nevertheless, several authors advocate more aggressive treatment with open reduction and plate fixation for unstable fractures[14]. Leonidou *et al*[14], in a retrospective study of 40 paediatric Monteggia fractures, asserts that although conservative management has been shown to correlate with good results, unstable fractures of the ulna need to be treated with plate fixation to ensure good reduction of the radial head and to avoid the possibility of prolonged immobilization leading to elbow stiffness in children[14]. Moreover, Hetthéssy *et al*[3] in a retrospective analysis of 23

acute pediatric Monteggia fractures, affirms that if the dislocation of the radial head is accompanied by an unstable fracture of the ulna, a more stable osteosynthesis plate is required.

Nowadays, intramedullary nailing fixation is the main method of fracture stabilization in acute, stable and unstable Monteggia injuries, while plate fixations are widely used in patients with neglected Monteggia fractures[15]. Many authors use a cut-off of fourweeks before considering a Monteggia fracture to be "neglected". He *et al*[15], through a retrospective comparison study of 42 patients, showed that the rate of patients that needed open reduction or complex immobilization methods was higher in the neglected group than in the acute group. Therefore, only for early diagnosis of Monteggia injury can we rely upon minimally invasive methods such as intramedullary pin fixation[15-17]. Open reduction combined with ulnar plate fixation is the most common approach to treating missed Monteggia fractures or acute Monteggia fractures in the case of failure of closed radiocapitellar joint reduction[15].

In contrast to short oblique or transverse ulna fractures, long oblique and comminuted fractures are considered "length unstable" and therefore are treated with plate and screw fixation; open reduction and plate fixation are frequently indicated by some orthopaedists because angulation, malalignment and shortening of the ulna often occur after closed reduction and intramedullary wire fixation. In this case report, intramedullary fixation of the ulna allowed a stable reduction and ulnar length and alignment to be achieved as well as radio capitellar reduction despite the fact that the orthopaedic surgeon did not use the plate and screws for ulnar fracture. Therefore, even if not indicated in treatment algorithms, length-unstable Monteggia fractures can be successfully treated with an elastic intramedullary device with the aim of using a minimally invasive technique and enablinga low complication rate.

CONCLUSION

Treatment of acute paediatric Monteggia fractures is still being debated and there is currently no standard treatment. In fresh Monteggia fractures, the decision to treat the ulna with an intramedullary device or plateismade according tothe surgeon'sown preference with the aim offacilitating the correct alignment of the radiocapitellar joint and avoiding recurrent dislocation. In recent years, the use of intramedullary nails for the management of acute Monteggia fractures in children has gained popularity regardless of the ulnar fracture type. Delayed diagnosis and inadequate treatment of radial head dislocation will cause complications such as elbow pain, decreased joint range of motion, increased valgus deformity and neurologic problems. Flexible nails or wires are excellent devices combining stability and elasticity in children with fractures. Intramedullary fixation of unstable Monteggia fractures results in excellent outcomes, providing reliable reduction and causing fewer complications.

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