Aims
The management of mid-shaft clavicle fractures (MSCFs) has evolved over the last three decades. Controversy exists over which specific fracture patterns to treat and when. This review aims to synthesize the literature in order to formulate an appropriate management algorithm for these injuries in both adolescents and adults.

Methods
This is a systematic review of clinical studies comparing the outcomes of operative and nonoperative treatments for MSCFs in the past 15 years. The literature was searched using PubMed, Google scholar, OVID Medline, and Embase. All databases were searched with identical search terms: mid-shaft clavicle fractures (± fixation) (± nonoperative).

Results
Using the search criteria identified, 247 studies were deemed eligible. Following initial screening, 220 studies were excluded on the basis that they were duplicates and/or irrelevant to the research question being posed. A total of 27 full-text articles remained and were included in the final review. The majority of the meta-analyses draw the same conclusions, which are that operatively treated fractures have lower nonunion and malunion rates but that, in those fractures which unite (either operative or nonoperative), the functional outcomes are the same at six months.

Conclusion
With regard to the adolescent population, the existing body of evidence is insufficient to support the use of routine operative management. Regarding adult fractures, the key to identifying patients who benefit from operative management lies in the identification of risk factors for nonunion. We present an algorithm that can be used to guide both the patient and the surgeon in a joint decision-making process, in order to optimize patient satisfaction and outcomes.

Cite this article: Bone Jt Open 2022;3-11:850–858.

Keywords: Midshaft clavicle fracture, Operative treatment, Conservative treatment, Algorithm, Triage, Systematic review, Management

Introduction
The clavicle is an elongated S-shaped bone, horizontally placed between the sternum and the acromion of the scapula and overlying the superior part of the ribcage. Clavicle fractures account for 5% to 10% of all adult fractures. Overall, 70% to 80% are in the middle third as classified by Allman. The management of mid-shaft clavicle fractures (MSCFs) has evolved over the last three decades. The publication of a prospective multicentre randomized control trial in 2007, by the Canadian Orthopaedic Trauma Society (COTS), led to a shift in practice in certain centres. The absolute indications for surgery remain unchanged: open fractures, clavicle fractures associated with a floating shoulder, and those associated with neurovascular compromise, requiring immediate exploration. Beyond these indications, there is controversy over which specific fracture patterns to treat and when.

In the UK, clavicle fractures may not be treated by a specialist trauma or upper limb...
surgeon in the setting of a general fracture clinic. The current literature can be difficult to interpret, leading to potential variation in treatment. The authors have witnessed both over- and under-treatment, unnecessary follow-up, and inconsistent management with unnecessary imaging. Patients with these fractures require clear and specific plans, based both on their personal needs, physiology, and the fracture morphology.

This review aims to synthesize the literature in order to formulate an appropriate management algorithm for these injuries in both adolescents and adults. We present an algorithm that can be used to guide both the patient and the surgeon in a joint decision-making process, in order to optimize patient satisfaction and outcomes. The review is intended to provide structure and guidance for the treating surgeon, but should not replace clear clinical judgement.

Methods

Eligibility criteria. All papers comparing the outcomes of operative and nonoperative treatments for MSCFs in the past 15 years were included.

Information sources. The literature was searched between 2006 and 2021 using PubMed, Google scholar, OVID Medline, and Embase. All databases were searched with identical search terms: mid-shaft clavicle fractures (± fixation) (± nonoperative).

Study selection. Studies identified by the electronic search were screened initially by title and abstract to exclude any unrelated topics. The focus of this review was to assess the evidence base of operative and nonoperative treatment lines of MSCFs. As such, general review articles and papers focusing on financial outcomes were excluded. Additionally, studies comparing management options of lateral and medial thirds fractures of clavicle were excluded.

After the initial screening, the remaining abstracts were scrutinized and any duplicate articles were extracted. The remaining articles were included in the systematic review. Articles were assessed by two independent reviewers (AK, DT), and any differences in article inclusion were discussed and resolved by consensus.

Data collection process. Multiple standardized outcome measures in the studies were identified. Constant-Murley score (CMS), Disabilities of Arm, Shoulder and Hand (DASH) score, and duration of follow-up, and outcome measures were used in each study where appropriate, and their results were identified.

Risk of bias. As the majority of studies were papers showing success or feasibility of surgeries, we acknowledge that there will be a degree of reporting bias, given that published articles are more likely to publish positive results and data collection was heterogeneous.

Results

Using the search criteria identified, 247 studies were deemed eligible. Following initial screening, 220 studies were excluded on the basis that they were duplicates and/or irrelevant to the research question being posed. Overall, 27 full-text articles remained and were included in the final review (Figure 1).

The papers selected consisted of a number of prospective/retrospective case series, cohort studies, and systematic reviews/meta-analyses. All studies were validated using Critical Appraisal Skills Programme (CASP) checklists. There was heterogeneity between the papers with regard to the severity of injuries, as well as the outcome measures observed. We subdivided our results into retrospective and prospective studies, as well as randomized controlled trials and meta-analyses. The results of our search are detailed in Table I.

There were four retrospective studies, five randomized controlled trials (RCTs), six non-randomized prospective trials, nine meta-analyses, one systematic review, and two systematic reviews of meta-analyses.

The multiple meta-analyses and systematic reviews have analyzed the merits of each of these papers. In this review we have tried to identify the ‘take home message’ which would facilitate decision-making.

Prospective studies. There are a significant number of well-run studies which conclude that fixation provides better union rates and clinical outcomes at most time-points, however many also conclude that there is no significant difference in clinical outcome by six months post-injury.

The COTS study, published in 2007, indicated that fixation of displaced clavicle fractures resulted in improved functional outcomes, and a lower rate of malunion and nonunion, when compared to nonoperative treatment at one year of follow-up. Subsequent prospective, multicentre trials were published supporting operative intervention.

Ahrens et al conducted a multicentre RCT and observed that DASH score and CMS, as well as patient satisfaction, were all significantly better in the fixation group at six weeks and three months. They concluded that fixation is a safe and reliable intervention with better early functional outcomes.

Qvist et al published a multicentre, prospective parallel RCT and concluded that fixation resulted in faster functional recovery and a higher rate of union. However, shoulder function remained equal after six months and at one year.

The findings of these trials were not universally reproduced. Smaller trials, such as the prospective study by Khorami et al, found no significant changes in outcome in either group. Echalier et al published a non-randomized prospective study measuring CMS and DASH. These were significantly better in the surgical group from the second
to the sixth week, but there was no significant difference between three and six months. Return to work was earlier in the surgical group.

Dhakad et al13 published a prospective study and concluded that early primary plate fixation for MSCF resulted in improved patient-oriented and surgeon-oriented outcomes, along with an earlier return to function and decreased rates of nonunion and malunion. Naveen et al18 published a prospective study and concluded that the time to union was reduced, rate of malunion and nonunion was lower, and CMS scores were higher in the surgical group.

Purushothaman et al15 observed significant improvement in the rates of fracture union and functional scores with operative management in a prospective study over two years. Ban et al17 published a partially blinded prospective RCT, and they observed that the number needed to treat to avoid one symptomatic nonunion was 6.2. They concluded that they could not advocate for either an all-operative or an all-nonoperative approach.

Robinson et al35 conducted a prospective multicentre RCT and observed that fixation was associated with better functional outcomes. Nicholson et al12 concluded that acute plate fixation of displaced MSCFs was not associated with earlier return of normal shoulder function when union was achieved.

**Systematic reviews and meta-analyses.** A number of large systematic reviews have been conducted. These generally conclude that surgical fixation leads to a faster return to activity, sport and employment.

Martin et al28 observed that surgical fixation demonstrated a lower risk of nonunion compared to nonoperative management, resulting in significantly less disability early after surgery. Liu et al27 concluded that operative treatment reduced the nonunion, malunion, and neurological complication rates of clavicle fractures, but did not affect the delayed union rate.

Hill et al30 demonstrated an earlier return to work among motivated young patients who underwent intramedullary nailing. Wang et al22 concluded that operative fixation improved functional outcomes and
Table I. Studies: category, sample size, and outcome.

| Author                      | Outcome measures                                      | Study type (patients) | Conclusions                                                                 |
|-----------------------------|--------------------------------------------------------|-----------------------|-----------------------------------------------------------------------------|
| Heyworth et al¹¹            | 1. Clinical course 2. Complications                    | Prospective RCT (909) | Nonoperative and operative treatment of adolescent fractures leads to similar complication rates, satisfaction, and functional outcomes |
| Nicholson et al¹²           | DASH                                                   | Prospective RCT (162) | Comparable return of normal shoulder function between surgical and conservative treatment when union was achieved |
| Dhakad et al¹³              | 1. Functional outcome 2. Fracture union time 3. Associated complications | Prospective (50)     | Early fixation of comminuted fractures leads to improved patient-oriented outcomes, improved surgeon-oriented outcomes, earlier return to function, and decreased rates of nonunion and malunion |
| Echalier et al¹⁴            | CMS and DASH scores                                   | Prospective (65)      | Functional recovery is better in the first 6 weeks when there is fixation with anatomical plate for displaced fractures |
| Purushothaman et al¹⁵       | 1. Functional recovery 2. Complications                | Prospective (274)     | Improvement in the rates of fracture union and functional scores with operative management |
| Ahrens et al (UK clavicle trial)¹⁶ | CMS and DASH score                                | Prospective RCT (301) | Fixation of clavicle fractures improved the union rate at 9 months |
| Canadian Orthopaedic Trauma Society⁴ | CMS and DASH score                        | Prospective RCT (132) | Fixation improved functional outcomes and lower rates of malunion and at one year |
| Song et al⁶                 | CMS and DASH scores                                   | Prospective (64)      | No difference in treatment methods                                          |
| Ban et al¹⁷                 | 1. Functional outcome 2. Rate of union                 | Prospective RCT (120) | Improved function scores at 6 months. Improved union rates.                 |
| Naveen et al¹⁸              | 1. Functional outcome 2. Rate of union and malunion 3. Local complications | Prospective (60)      | Surgical intervention leads to better outcomes and early functional recovery in young active adults |
| Khorami et al¹⁹             | 1. Functional outcome 2. time to union                 | Prospective (65)      | Duration to union is improved with fixation, with no functional difference at 6 months |
| Jiang et al¹⁰               | CMS                                                    | Meta-analysis (721)   | Intramedullary pin fixation is the optimal treatment                       |
| Guerra et al¹¹              | 1. Functional outcome 2. Rate of union and malunion 3. Time to union | Meta-analysis (1,546) | Surgical treatment of MCFs significantly reduces the nonunion rate and shortens the time to union |
| Wang et al²²                | 1. Functional outcome 2. Rate of union and malunion 3. Rate of complications | Meta-analysis (956)   | Functional outcomes and union rates were improved with fixation             |
| Nawar et al²³               | 1. Time to union 2. Time to return to activity 3. Rate of complications | Meta-analysis (522)   | No significant difference between operative and nonoperative management in young patients |
| Zhao et al²⁴                | 1. Treatment failure 2. Functional outcomes 3. Rate of complications | Meta-analysis (unspecified) | Surgical treatment provides a lower rate of overall treatment failure and a better functional outcome, but is associated with more implant-related complications |
| Devji et al⁵                | 1. Need for further surgery 2. Functional outcomes 3. Rate of complications | Meta-analysis (716)   | No significant difference in treatment methods                             |
| Ahmed et al³¹               | 1. Rate of union 2. Functional outcomes                | Meta-analysis (1,027) | Significant reduction in nonunion and favourable early functional outcomes are associated with fixation |
| Woltz et al²⁶               | 1. Need for further surgery 2. Functional outcomes 3. Rate of union | Meta-analysis (614)   | Fixation reduces the risk of nonunion, but does not have a clinically relevant advantage regarding final functional outcome |
| Liu et al²⁷                 | 1. Time to union 2. Incidence of nonunion 3. Neurological complications | Meta-analysis (663)   | Fixation reduced nonunion, malunion, and neurological complication rates of clavicle fractures |
| Martin et al²⁸              | 1. Rates of union 2. DASH and CMS                    | Meta-analysis (1,783) | Operative fixation carries lower risks of nonunion, with early improved functional outcomes and less disability |
| Robertson et al²⁹           | Time to return to sporting activity                    | Systematic review (304) | Fixation resulted in quicker return to sporting activity                    |
| Hill et al³⁰                | DASH and CMS                                          | Systematic review (229) | Nailing provides superior functional results                                |
| Herzog et al³¹              | Isokinetic testing                                    | Retrospective (20)    | Poorer function in non-operated arm                                         |

Continued
union rates. Devji et al\(^1\) demonstrated that one in four patients developed a complication regardless of the treatment modality. Functional outcomes were superior in the operative group. The authors were unable to conclude that the evidence supported routine operative fixation of displaced MSCFs.

Robertson and Wood\(^29\) found that operative management of displaced mid-shaft fractures was found to offer improved return rates and times to sport compared to nonoperative management.

Jiang et al\(^20\) compared nonoperative measures, plate, and intramedullary pin fixation in a meta-analysis. They observed that there were no differences in the effectiveness assessed by the CMS at six weeks, three, 12, and 24 months, and suggested that intramedullary pin fixation might be the optimal therapeutic approach.

Woltz et al\(^26\) concluded that plate fixation significantly reduced the risk of nonunion, but did not have a clinically relevant advantage regarding final functional outcome. They observed that secondary operations were common after both treatments. There was not enough evidence to support routine operative treatment for all patients with a displaced MSCF.

Ahmed et al\(^25\) concluded that a considerable reduction in nonunions, together with early functional outcomes, was encountered more with fixation. However, due to the similarity in other outcome measures, the authors concluded that there was inconsistent evidence regarding the best treatment for displaced MSCFs.

Guerra et al\(^21\) concluded that surgical treatment of MSCFs significantly reduces the nonunion rate and shortens the time to union compared with the nonoperative approach and, despite a slightly higher incidence of complications, leads to better shoulder functional scores at short- and long-term follow-up.

Zhao et al\(^24\) concluded that surgical fixation provided a lower rate of overall treatment failure and a better functional outcome, but was associated with more implant-related complications.

### Adolescent fractures

Five studies have looked specifically at the management of these fractures in the younger patient (adolescent). Most papers indicated that there was no benefit in surgery, except in the older paediatric cohort where the cosmetic result of surgical management was superior.

Nawar et al\(^23\) presented a meta-analysis study of seven studies covering 528 mid-diaphyseal clavicle fractures in patients aged eight to 18 years. Those patients were followed up from two weeks to 3.7 years. The authors concluded that there was no significant difference in the time to achieve union, the time to return to activity, and the overall complication rate between the operative and the nonoperative groups.

Heyworth et al\(^11\) conducted a prospective RCT at eight large paediatric centres. Nonoperative treatment of patients in this younger cohort demonstrated lower complication rates and similar satisfaction and functional outcomes.

Prinz et al\(^33\) looked at a total of 60 displaced MSCFs in children and adolescents. All patients under the age of ten were treated conservatively and had very good functional and cosmetic results. Patients over the age of ten received either conservative treatment, or fixation with a Kirschner wire or intramedullary nailing. Functional outcome, irrespective of treatment modality, was as good as in younger children, but the global and cosmetic satisfaction score was much lower. Older patients treated nonoperatively suffered from more pain, and were dissatisfied with the long immobilization. The authors recommended consideration of intramedullary fixation in this group.

Herzog et al\(^31\) conducted a retrospective study on 20 patients. The patient cohort was followed from the time of their injury for a year and a half. They reported that the amount of variability in functional outcomes for the nonoperative group suggested that some of these patients may have developed dysfunction. The authors did acknowledge that their results should be interpreted with caution, as their sample size was small.

Song et al\(^14\) treated 23 adolescent patients with nonoperative management and compared them to 18 patients treated with fixation in terms of radiological, functional outcome, and complications. Nonunion developed in neither group. No significant intergroup differences were observed for the occurrence of delayed union or time to union. Both operative and nonoperative groups

| Author                          | Outcome measures                        | Study type (patients) | Conclusions                                                   |
|---------------------------------|----------------------------------------|-----------------------|---------------------------------------------------------------|
| Lake et al\(^32\)               | Physical Fitness Test                   | Retrospective (247)   | Functional outcome significantly improved in the operative group |
| Napora et al\(^7\)             | 1. Complications                       | Retrospective (138)   | No differences in complications or functional outcomes       |
| Prinz et al\(^33\)             | 1. Constant Shoulder Score, 2. Cosmetic result | Retrospective (59)   | Functional outcomes were equal but cosmetic result poorer in older children |

DASH, Disabilities of the Arm, Shoulder and Hand; RCT, randomized controlled trial.

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**Table I. Continued**

| Author                          | Outcome measures                        | Study type (patients) | Conclusions                                                   |
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A- A. KHORIATI, Z. FOZO, L. AL- HILFI, D. TENNENT
showed satisfactory outcomes in terms of disabilities of the arm, constant shoulder scores, and shoulder and hand scores. However, recovery of shoulder range of motion was significantly faster in the operative group.

**Discussion**

Nonoperative management of clavicle fractures was the standard in the 1960s and 1970s, with relatively small case series by both Neer and Allman indicating that nonunion was extremely rare, and that nonoperative management should be the treatment of choice.

Trends towards operative management began in the late 1990s. One contributing factor may have been the introduction of locking precontoured plates, as these are associated with a low risk of failure, and previously fixation was achieved with dynamic compression plates.

An increasing body of evidence subsequently published has suggested that equivalent outcomes can be achieved with nonoperative management. Additionally Nicholson et al concluded that routine plate fixation of displaced MSCFs was not cost-effective. They suggested that a targeted approach to fixation of patients who are at higher risk of nonunion would be more efficient.

As a consequence of the shifts in treatment trends, the authors felt that a standardized algorithm based on the current available evidence would be beneficial.

**Development of a treatment algorithm.** The majority of systematic reviews and meta-analyses draw the same conclusions, which are that operatively treated fractures have lower nonunion and malunion rates but that, in those fractures which unite (either operative or nonoperative), the functional outcomes are the same at six months.

The accurate identification of patient cohorts which will potentially do worse with nonoperative management may be the key to determining which patients require surgical management. Robinson et al noted in their prospective RCT that the improvement in function observed in the operatively managed patients was down to the increased union rate. In a previous paper, Robinson et al determined that sex, lack of cortical apposition, and comminution were all independently associated with nonunion. Murray et al identified smoking status, overall fracture displacement, and comminution as independent risk factors for nonunion. They concluded that if all fractures were treated nonoperatively, the number needed to treat to prevent a nonunion would be 7.5. If only fractures with a predicted probability of > 40% were managed operatively, the number of patients managed operatively to prevent a single nonunion would be reduced to 1.7.

The same group also identified the effect of delay in treatment on ultimate displacement of a fracture. They suggested that radiological evaluation at six weeks after injury may have superior predictive value compared with information available at the time of the injury. They indicated that the presence of a high QuickDASH score (≥ 40 points), no callus on radiograph, and movement at the fracture site were all risk factors for nonunion. The presence of two of these three risk factors conferred a nonunion risk of 60%. With none of these present, the risk of nonunion dropped to only 3%.

In a study published in 2021, Nicholson et al reviewed the effectiveness of ultrasound at predicting union by the detection of callus formation. They concluded that the presence of bridging callus on ultrasound was associated with a union in 98.6% of patients studied.

Based on the evidence provided by Hill et al, who suggested that clavicle shortening of 2 cm or more was associated with nonunion, this measure is often cited as an indication for operative management. This figure of 2 cm is controversial and has been disputed. Jones et al demonstrated that standard radiographs of the clavicle were insufficient to reliably determine the degree of shortening, and that surgery should not be based purely on this criterion. Thorsmark et al also noted that existing techniques of measuring clavicular shortening had either reliability or methodological issues. Patient positioning and delays in obtaining imaging were also found to be confounding factors. The solution would appear to be to use radiographs with the arm in a standardized position at a standardized period of time from injury but currently there is no consensus as to what form this should take.

The clinical picture is contradictory. In 2021, Subramanyam et al published a prospective study of 100 patients with displaced fracture of the middle third of the clavicle who were treated conservatively. They concluded that for every 1 mm of shortening or one-unit increase of angulation, there was a reduction in the Constant Score around 14%.

These findings contradicted those of a number of other studies. Goudie et al concluded that no association existed between shortening and functional outcome or satisfaction in patients with healed displaced MSCFs up to one year following injury. A systematic review by Malik et al noted a heterogeneity of imaging projections, and demonstrated that there was no significant association between fracture shortening and outcome score in displaced MSCFs managed nonoperatively. The authors concluded that routine CT imaging to enable accurate measurement with the subsequent risk of radiation exposure could not be justified due to the increased radiation dose of a CT scan of the shoulder (2.06 mSv). This was found to be significantly higher than that of a plain chest radiograph (0.1 mSv).

Given the heterogeneity of outcome measures and imaging projections used, it is impossible to determine to what extent—if any—shortening has an effect on functional outcomes. Authors commenting that shortening...
may have an effect on outcomes have themselves stipulated that the complex 3D configurations of fractures cannot be fully appreciated on radiographs. Thus, without standardization of imaging methods, functional outcomes, and measurement methods the conclusion cannot be drawn that shortening is an indication for surgery.

As with all literature-based studies, there is an inherent publication bias in the evidence we have reviewed and we have attempted to mitigate this as much as possible. No trauma management algorithm will be perfect, and we have not attempted to make an all-encompassing protocol. The intention is to provide clinicians who may be less familiar with the management of MSCFs with an evidence-based management plan. It is up to the individual to adapt this based on the patient they have in front of them.

Based on the evidence identified, the authors propose an algorithm for the treatment of displaced MSCFs (Figure 2). This accounts for consideration of risk factors, controversies surrounding displacement, and patient factors. This will allow the treating surgeon in the outpatient setting to discuss the options available based on the existing evidence, and to provide a cost-effective and balanced care plan.

**In the outpatient setting.** If a patient is under 18 years old, they should be counselled for nonoperative management (as per Nawar et al). If they are over 18, it should be explained to the patient that under optimal settings (without risk factors for nonunion), there is a 70% to 90% chance of union at six weeks, with 96% at 12 weeks. Those who have risk factors for nonunion should be offered operative intervention (Robinson et al and Murray et al). In the clinical setting, the role of the treating surgeon is to simplify the decision-making process for the patient. The presence or otherwise of the following risk factors should be identified and explained to the patient: 1) if the patient is a smoker, their odds of nonunion are almost four times higher; 2) if they have a comminuted fracture, their odds are almost twice as high; 3) if there is a lack of cortical apposition, the risk of nonunion is almost twice as high; and 4) if they are female, they have a slightly higher risk of nonunion.

If the patient’s life circumstances dictate that they require improved functional outcomes at six weeks, they may be offered surgery (Echalier et al). In patients with highly physical jobs (e.g. active military personnel or sportsmen) or those with active lifestyles, surgery can be offered to improve functional outcomes, as suggested by Lake et al.

Shortening on its own is not an indication for surgery, in accordance with the evidence presented by Goudie et al and Malik et al. In line with the management strategy developed by Nicholson et al, all patients should be reassessed at six weeks for the following criteria. If they have
two of the following three features — a QuickDASH score greater than 40, no callus on radiograph, and movement at the fracture site — they should be advised that there is a 60% chance of progressing to a nonunion, and operative intervention should be considered. If ultrasound is available, this should be used to confirm the presence of bridging callus.

All patients being counselled for surgery should be made aware of all risk factors as well as the purpose of the surgery, which is primarily to reduce the risk of nonunion and to improve acute functional outcomes. A shared decision on treatment should then be taken.

With regard to the adolescent population, the existing body of evidence is insufficient to support the use of routine operative management. Although there is some evidence to support an earlier return to function,\textsuperscript{6,31} the largest study reviewed indicated that there was no benefit observed with operative intervention.\textsuperscript{21}

Regarding adult fractures, it is difficult to interpret the apparently contradictory findings contained in the literature over the last two decades. The heterogeneity in treatment methods with both nonoperative (sling vs brace vs return to free movement) and operative (nail vs plate) means that the findings above must be interpreted with care. The use of different outcome measures further complicates decision-making.

In summary, the authors recommend the use of an algorithm to facilitate shared decision-making between the patient and the treating surgeon in order to optimize any treatment given to suit the unique circumstances of the patient, supported by the existing body of evidence. We would encourage treating surgeons to make use of their algorithm, and feedback their experiences for further refinement of the treatment process.

**Take home message**
- This study summarizes the available evidence on clavicle fracture fixation.
- This evidence is used to synthesize a practical algorithm for orthopaedic surgeons in the treatment of clavicle fractures.

**Supplementary material**
Search methodology.

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Funding statement:
- The authors received no financial or material support for the research, authorship, and/or publication of this article.

ICMJE COI statement:
- D. Tennent receives royalties, teaching payments, and patents from Arthrex which do not have any relationship to the subject of this study.

Open access funding
- The authors confirm that the open access fee for this study was self-funded.

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