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A comparison of patient-specific instrumentation to navigation for conducting humeral head osteotomies during shoulder arthroplasty



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Background: The humeral head osteotomy during shoulder arthroplasty influences humeral component height, version and possibly neck-shaft angle. These parameters all potentially influence outcomes of anatomic and reverse shoulder replacement to a variable degree. Patient-specific guides and navigation have been studied and utilized clinically for glenoid component placement. Little, however, has been done to evaluate these techniques for humeral head osteotomies. The purpose of this study, therefore, was to evaluate the use of patient-specific guides and surgical navigation for executing a planned humeral head osteotomy.

Methods: The DICOM images of 10 shoulder computed tomography scans (5 normal and 5 osteoarthritic) were used to print 3D polylactic models of the humerus. Each model was duplicated, such that there were 2 identical groups of 10 models. After preoperative planning of a humeral head osteotomy, Group 1 underwent osteotomy via a patient-specific guide, while group 2 underwent a real time navigated osteotomy with an optically tracked sagittal saw. The cut height (millimeters), version (degrees) and neck-shaft angle (degrees) were recorded and statistically compared between groups.

Results: There were no statistically significant differences between patient-specific guides and navigation for osteotomy cut height ($P = .45$) and humeral version ($P = .059$). Navigation, however, resulted in significantly less neck-shaft angle error than the patient specific guides ($P = .023$). Subgroup analysis of the osteoarthritic cases showed statistical significance for navigation resulting in less version error than the patient specific guides ($P = .048$).

Conclusion: No significant differences were found between patient specific guides and navigation for recreation of the preoperatively planned humeral head cut height and version. Neck-shaft angle, however, had significantly less deviation from the preoperative plan when conducted with navigation.

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Shoulder arthroplasty, including anatomic and reverse, is an effective treatment for osteoarthritis, cuff tear arthropathy, massive rotator cuff tears, fractures, rheumatoid arthritis, and failed arthroplasty.^{6,23,40} For predictable outcomes, proper positioning of the implants is imperative. At times, intraoperative bony resection can dictate final implant position. The location of the humeral head osteotomy can impact humeral component height, version, and neck-shaft angle.^{13,27,31} Humeral height, if reconstructed too high, can result in joint overstuffing,¹⁵ which is an established risk factor for early failure.^{1,9} Alternatively, an osteotomy conducted too low can result in damage to the rotator cuff insertion, resection of part of the greater or lesser tuberosity, and potentially joint laxity or

instability.³¹ As such, humeral head osteotomy location and orientation is important.

Although humeral component positioning is important, more attention, resources, and research have been spent on optimizing glenoid component positioning. Several studies on patient-specific instrumentation^{5,14,32,36} and surgical navigation^{21,30,34,35} have demonstrated improved glenoid component placement when compared with traditional methods. Unfortunately, limited literature exists on the use of these advanced techniques for humeral component placement.⁷ The purpose of this study, therefore, was to evaluate and compare patient-specific guides to surgical navigation for execution of a preoperatively planned humeral head osteotomy. Specifically, this study compared each technique's ability to recreate a desired humeral head cut height, version, and neck-shaft angle. We hypothesized that patient-specific guides and surgically navigated osteotomies would have no significant differences

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between them in obtaining the desired osteotomy plane for all parameters measured.

Materials and methods

Five nonosteoarthritic and five osteoarthritic shoulder computed tomography (CT) scans were selected at random from our database at the Hand and Upper Limb Centre Bio-Engineering Research Lab (Western University, London, ON, Canada). The non-osteoarthritic database included 112 CT scans (32 female, 80 male), and the osteoarthritic database included 88 CT scans (35 female, 53 male). CT DICOM files were imported into the Mimics software (Materialise, Leuven, Belgium), and 3D models of the shoulder were created. The proximal and distal humeral sections were separated within SolidWorks, to facilitate 3D printing. Bony geometry within the diaphyseal portion of the humerus was removed to expedite 3D printing and to facilitate proximal filling with a cancellous bone surrogate. Evaluation of the models showed an average of four millimeters of cortical thickness. This is in agreement with the range of previous literature on humeral head cortical thickness.^{20,33} Using a three-dimensional printer (MakerBot Replicator 5th Gen; Brooklyn, NY), the 10 proximal humerus models and corresponding epicondyles were printed using polylactic acid in duplicate (20 models) to create two identical groups. The deleted diaphyseal bone portion between the proximal and distal humeral segments was replaced with a metal rod at the correct length and rotation. Group 1 consisted of 10 humerus models for osteotomy with patient-specific guides, and group 2 consisted of 10 corresponding duplicates for osteotomy with navigation. To replicate cancellous bone, the proximal intramedullary canal was filled in a retrograde manner with a cancellous bone surrogate (Henkel Corporation, Mississauga, ON, Canada). This cancellous bone surrogate replicated the characteristics of cancellous bone when cut with a sagittal saw.

Planned osteotomy and experimental protocol

All 10 proximal humerus specimens underwent preoperative planning in Mimics to create an ideal humeral head osteotomy plane. The virtual osteotomy plane was conducted at the junction of the humeral head and the anatomic neck as previously described.^{17,39} This osteotomy plane allowed for neck-shaft angle and version calculation. The neck-shaft angle was calculated in the coronal plane, from the angle of the long axis of the humerus and the normal of the osteotomy plane. The version was calculated from the epicondylar axis and a plane perpendicular to the osteotomy. The epicondylar axis was defined as a line between selected points on the medial and lateral epicondyles (Fig. 1). Planned osteotomies were initially created by one author (J.T.C.) and confirmed or adjusted by an experienced fellowship-trained shoulder arthroplasty surgery (G.S.A.). This method has been shown to be highly repeatable with an intraclass correlation coefficient of 0.87.⁴

Two identical models had been created for each of the ten specimens. These were divided in to two identical groups, group 1 for osteotomy with patient-specific guides and group 2 for osteotomy with navigation. The order of osteotomies was randomized. A random list of unique specimen identifiers was generated for each specimen. These unique identifiers were then randomized to an order set, which created a cutting order.

All specimens were prepared and set up identically. The humerus model was mounted securely to a stand which was within the field of view of the optical tracking camera (Intellijoint Surgical Inc., Waterloo, ON, Canada). In addition, an optical tracking array was rigidly attached to the proximal humerus for digitization of the

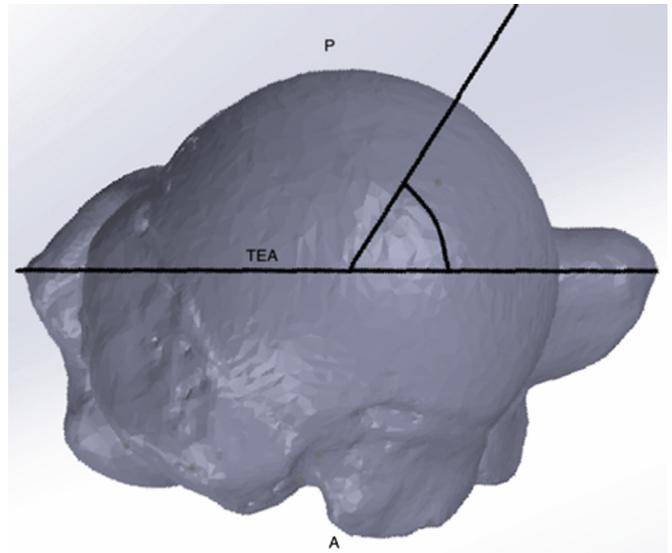


Figure 1 Three-dimensional axial view of a right humerus. The transepicondylar axis is labelled TEA. The angle shown between the TEA and humeral head orientation is version in degrees. Bottom of image is anterior (A), and the top is posterior (P).

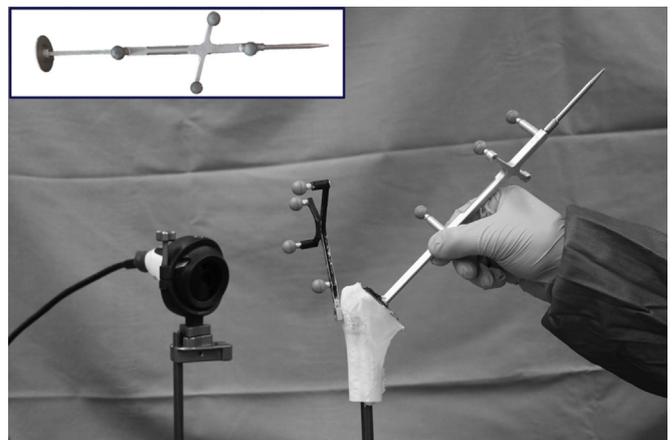


Figure 2 An optically tracked stylus (inset) is used to capture the final coordinates of the humeral head osteotomy plane. Also shown are the infrared tracking camera and the optical tracking array attached to the proximal humerus.

model and for final measurements of the osteotomy plane orientation and position (Fig. 2).

In order to measure the final osteotomy plane orientation and position, and to assist with navigation, the humeral models had to be linked (registered) to the preoperative plan. This registration was conducted by selecting anatomic landmarks on the proximal humerus with an optically tracked stylus. The digitized points included the lesser tuberosity, the superior ridge of the greater tuberosity, and the center point of the humeral head. Traces of the biceps groove and humeral head were also taken.

After digital registration of the humerus, the osteotomies were performed. This was carried out in a blinded, randomized order. The same protocol listed previously was performed before each specimen's osteotomy. After each osteotomy, digitization of the cut surface was performed with the optical tracker stylus. The optical tracking stylus has a flat surface, which can be placed flush on the cut surface to capture the coordinates of the osteotomy plane (Fig. 2). This provided the final resected humeral surface version,

neck-shaft angle, and height of the cut. Height of the cut was relative to the preplanned osteotomies. All osteotomies were performed by the senior shoulder surgeon (G.S.A.).

Patient-specific guides

Patient-specific humeral osteotomy guides were designed to take into consideration the surgical approach, the available surgical exposure, and patient-specific consistent bony landmarks. The focus was on the lesser tuberosity and the bicipital groove with the guide created based on the inverted surface anatomy of the region of interest. The proximal portion of the guide was aligned to the preoperatively planned osteotomy, and to assist with stabilization of the guide on the proximal humerus, two pin track holes were created (Fig. 3).

At the time of patient-specific guide testing, the guide was placed on to the humeral model and keyed on to the lesser tuberosity and biceps groove. The positioning of the guide was confirmed before completing the osteotomy with cross-referencing to the preoperatively planned positioning. This was performed by displaying the guide and humerus models in SolidWorks on a computer monitor. Once confirmed, two guide pins secured the guide in place (Fig. 3). The osteotomy was then conducted, with the patient-specific guide functioning as a cutting block, with a sagittal saw. Once complete, the flat surface of the stylus was used for capturing the final coordinates of the osteotomy for eventual comparison.

Navigation

In order to conduct navigated osteotomies, an optically tracked sagittal saw was used (Fig. 4). A sagittal saw with a 0.8-mm-thick blade was used (ConMed, Utica, NY). Visualization of the preoperatively planned osteotomy and live navigation for the saw blade were made available to the surgeon on a computer monitor. The navigation monitor provided version, neck-shaft angle, and humeral head cut height information. Each of these parameters were displayed as real-time tracked positions of the saw blade and as the targeted numbers. To assist the surgeon with navigation, the custom program was set up with green indicator lights that would light up once the arbitrarily set values of ± 2 mm of humeral head height and ± 2 degrees of neck-shaft angle and version were reached.

Outcome variables and statistics

The primary outcome variables were the resultant cut plane deviation from the preoperative planned humeral osteotomy in terms of cut height (mm), version angle (degrees), and neck-shaft angle (degrees). Each of these outcomes were calculated as the difference between the desired preoperatively planned value and the actual experimentally obtained osteotomy value.

A series of paired, two-tailed T-tests were used for statistical analysis of the comparisons of the error of each osteotomy method (SPSS Version 26.0; IBM, Armonk, NY, USA). For the analysis of the non-osteoarthritis and osteoarthritis groups, a series of unpaired (unequal variance), two-tailed T-tests were performed. Statistical significance was defined as $P < .05$.

Results

Humeral osteotomy height

The patient-specific instrumentation group had an average osteotomy height deviation of 2.4 ± 1.5 mm (range: 0.1–4.9mm). The surgical navigation group had a mean height deviation of

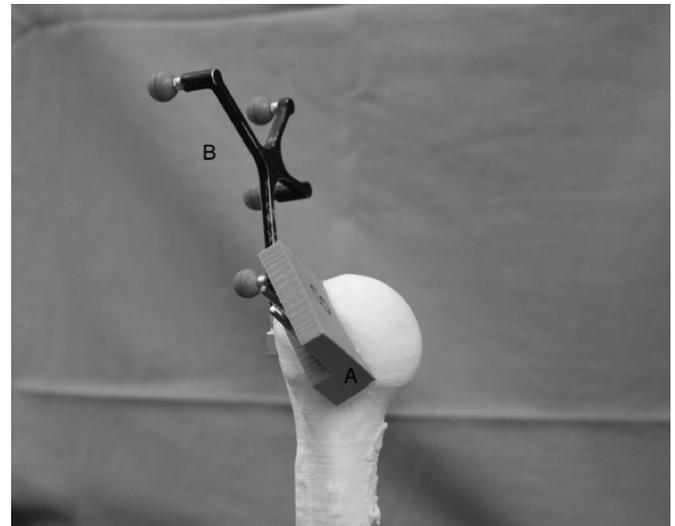


Figure 3 The patient-specific guide experimental set up. The 3D printed patient-specific cutting guide (A) is attached to the proximal humerus interdigitating with the lesser tuberosity and biceps groove. For additional stability, 2 metallic pins are used to temporarily affix the guide to the proximal humeral model. The optical tracking array (B) is attached to the lateral aspect of the greater tuberosity, which allows for final osteotomy plane determination with the optical stylus.

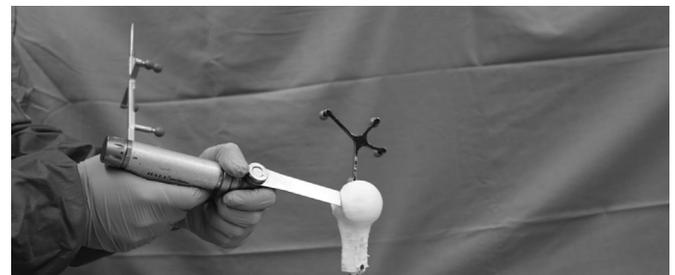


Figure 4 The navigated experimental set up. An optically tracked oscillating saw was used to conduct the navigated humeral head osteotomy. Note the optical tracking array affixed to the saw for real-time tracking.

2.9 ± 1.7 mm (range: 0.3–5.9mm). There were no statistically significant differences ($P = .44$) between groups (Fig. 5)

When comparing each techniques' ability to recreate osteotomy height in the nonosteoarthritic vs. the osteoarthritic groups, there were no statistically significant differences for both patient-specific guides ($P > .55$) and navigation (>0.68). In addition, when combining techniques, there were no significant differences in osteotomy heights between osteoarthritic and nonosteoarthritic groups ($P > .92$).

Version

Overall, the preoperatively planned humeral head osteotomies had a mean retroversion of 34° as referenced to the epicondylar axis (range, $3-65^\circ$ retroversion). The mean version deviation with the patient-specific instrumentation was $2.6 \pm 2.9^\circ$ (range: $0.1-9.2^\circ$), and the mean deviation with navigation was 0.7 ± 0.6 degrees (range: $0.1-1.8^\circ$) (Fig. 6). There were no significant differences between the patient-specific guides and navigation for version deviation from the preoperative plan ($P = .059$).

In the nonosteoarthritic models, there were no significant differences in version between the patient-specific and navigated osteotomies ($P = .26$). However, in the osteoarthritic models, there

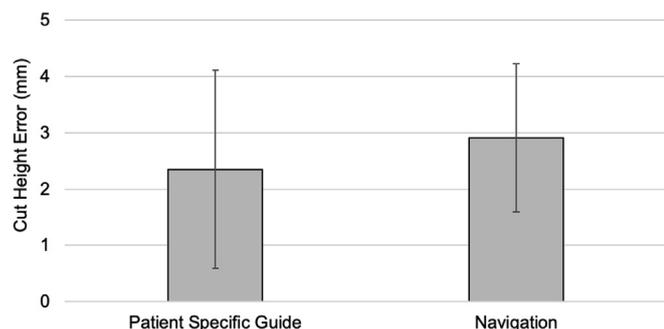


Figure 5 Mean humeral head height (± 1 SD) error in millimeters for patient-specific guides and navigation. The error is measured from the preoperatively planned idealized humeral head osteotomy plane.

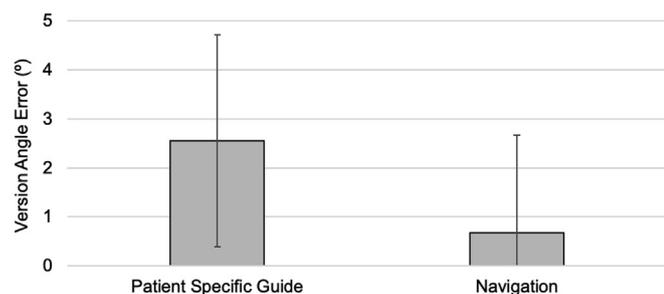


Figure 6 Mean version angle (± 1 SD) error in degrees for patient-specific guides and navigation. The error is measured from the preoperatively planned idealized humeral head osteotomy plane.

were significant differences in version between the patient-specific and navigated osteotomies ($P = .048$). In addition, when combining both techniques, there were no statistically significant differences in the version of the osteotomies between the nonosteoarthritic and osteoarthritic models ($P > .11$).

Neck shaft angle

Overall, the preoperatively planned humeral head osteotomies had a mean neck-shaft angle of 133° (range: 125 – 136°). The mean neck-shaft angle deviation in the patient-specific instrumentation group was $4 \pm 4^\circ$ (range: 0 – 11°), which was significantly greater ($P = .02$) than the navigation group’s mean deviation of $1 \pm 1^\circ$ (range: 0 – 4°) (Fig. 7).

When comparing each osteotomy technique’s neck-shaft angle deviation between the nonosteoarthritic and osteoarthritic groups, there were no statistically significant differences between them ($P > .65$). In addition, when combining both techniques, there were no statistically significant differences ($P > .08$) in the neck-shaft angle deviation between the nonosteoarthritic and osteoarthritic models.

Discussion

The aim of this study was to evaluate two advanced patient-specific methods for executing humeral head osteotomies during anatomic or reverse shoulder arthroplasty. Overall, there were no statistically significant differences between patient-specific guides and real-time surgical navigation in their ability to execute a pre-determined ideal version or humeral head osteotomy height. In contrast, surgical navigation was found to be statistically significantly better than patient-specific guides for recreation of a

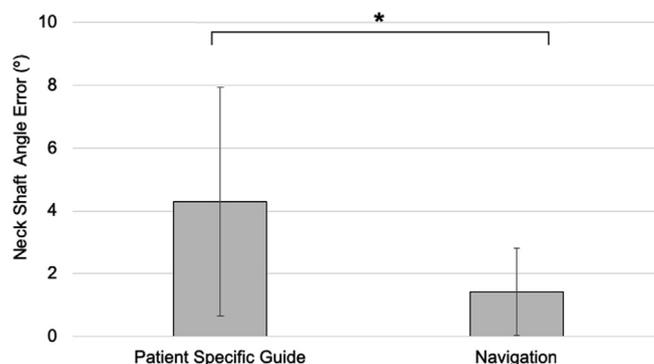


Figure 7 Mean neck-shaft angle (± 1 SD) error in degrees for patient-specific guides and navigation. The error is measured from the preoperatively planned idealized humeral head osteotomy plane. *Statistically significant difference.

preselected neck-shaft angle. The navigation resulted in a mean deviation from the preoperatively planned neck-shaft angle of 1 degree while the patient-specific instrumentation had a mean deviation of 4 degrees. Unfortunately, there is no literature on the minimal clinically important difference in neck-shaft angle that would result in a substantial change in patient outcome. Overall, the authors believe that the 3-degree mean difference in neck-shaft angle between patient-specific instrumentation and navigation is unlikely to manifest as a clinically important difference in patients.

For optimized shoulder arthroplasty outcomes, proper positioning of the components is believed to be important. Component positioning, in most circumstances, is based on the intraoperative bony resection. As such, the intraoperative osteotomy of the humeral head impacts humeral component version, neck-shaft angle, and head/prosthesis height.^{13,31} Humeral osteotomy height, if reconstructed too high, can cause overstuffing of the glenohumeral joint,¹⁵ which is an established risk factor for early failure.^{1,9} An osteotomy that is too low or aggressive can result in damage to the rotator cuff insertion, resection of part of the greater or lesser tuberosities, and/or result in potential joint laxity.³¹ Humeral component version is also important and has been linked to idealized range of motion, correct tensioning of soft tissue, stability, and implant survival.^{2,3,16,25} In reverse total shoulder arthroplasty, the selection of humeral version is controversial. Some authors recommend neutral component version, while others recommend a consistent predetermined version for all patients, such as 20 degrees. Finally, some authors recommend a patient-specific version with osteotomy at the anatomic humeral head-neck junction. Interestingly, anatomic positioning of the reverse humeral component has been shown to influence range of motion,^{18,29} but not the actual muscle forces required for obtaining range of motion.¹¹ Similarly, Oh et al reported improved outcomes and range of motion in patients who had their implant retroversion matched with their anatomic retroversion.²² This may indicate that similar to anatomic total shoulders, retroversion of the reverse humeral component may result in improved outcomes when matched to patient anatomy.

The mean native neck-shaft angle in humans is 135 degrees and ranges from 123 to 150 degrees.^{15,16,24,26,28} Several options exist for recreation of the anatomic neck-shaft angle during total shoulder arthroplasty, such as, the use of a stemmed implant with an adjustable head-to-stem junction, using a stem with several neck angle options, or the use of a stemless implant to anatomically reconstruct the neck-shaft angle. The use of patient-specific instrumentation and surgical navigation will also allow more anatomic osteotomies. For reverse shoulder arthroplasty, the

selection of neck-shaft angle is more controversial, and it was typically dictated by the predetermined neck-shaft angle of the implant. The available neck-shaft angles for reverse humeral implants range from 127.5 to 155 degrees.³⁸ The neck-shaft angle in reverse total shoulder arthroplasty has been widely studied, and it has been reported to influence joint stability, range of motion, contact stresses, and scapular notching.^{8,10,12,19,37} Overall, there are pros and cons to each neck-shaft angle for reverse arthroplasty, and the selection presently is based on surgeon experiences and preferences.

At present, little literature exists examining the role of patient-specific instrumentation and surgical navigation for humeral preparation during shoulder arthroplasty. The results of our preliminary study demonstrate that both advanced patient-specific techniques are effective in conducting a humeral head osteotomy with precision and accuracy. For the outcomes of humeral version and humeral osteotomy height, both techniques were equivalent. However, for restoration of humeral neck-shaft angle, navigation was statistically better than patient-specific instrumentation, although the 3-degree difference may not be clinically important. One of the strengths of this study is that an identical set of models were used to evaluate the surgical techniques. In addition, an ideal scenario was tested to determine the baseline precision and accuracy of the techniques. A cadaver study would have provided realistic soft tissues; however, it would have been difficult to directly compare techniques because of the potential side-to-side variability in paired specimens.

This study does have limitations. Unfortunately, the surgeon could not be blinded to the technique or the disease state of the specimen (*viz.* normal vs. osteoarthritic). In order to minimize the surgeon's familiarity with the models, all specimens and the techniques were randomized. In addition, to provide 2 identical specimen groups for direct comparison of the techniques, 3D models had to be developed and printed. Although every effort was made to make the bone models as realistic as possible, they still were models without normal anatomic soft tissues. Finally, the endpoint for this study was the orientation of the osteotomy surface, not the final position of the humeral implant. As such, it is conceivable that if humeral implantation had occurred, the final results may have been different.

Conclusion

The humeral head osteotomy during shoulder arthroplasty influences humeral component height, version, and neck-shaft angle. These parameters all influence outcomes of anatomic and reverse shoulder replacement to a variable degree. To improve the precision and accuracy of the osteotomy, patient-specific guides and navigation may be used. Our comparative anatomic study demonstrated no significant differences between patient-specific guides and navigation for recreation of the preoperatively planned humeral head cut height and version. Neck-shaft angle, however, had significantly less deviation from the preoperative plan when conducted with navigation.

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Conflicts of interest: Dr. Athwal is a consultant for Wright Medical-Tornier Inc. No company had any input in to the study design, protocol, testing, data analysis, or manuscript preparation. The other authors, their immediate families, and any research foundations with which they are affiliated have not received any financial payments or other benefits from any commercial entity related to the subject of this article.

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