

Use of a Low Profile Ultra-High Molecular Weight Polyethylene Diaphyseal Humeral Cement Restrictor in Shoulder Arthroplasty

Journal of Shoulder and Elbow
Arthroplasty
Volume 8: 1–8
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DOI: [10.1177/24715492241291328](https://doi.org/10.1177/24715492241291328)
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Abstract

Background: When implanting a cemented humeral stem, a reliable method to prevent inappropriate extension and enable pressurization of cement in the intramedullary canal is required. The aim was to assess the outcomes of a dedicated humeral diaphyseal cement restrictor.

Methods: In total 218 shoulders (207 patients) were included in the study, all of whom underwent a cemented total shoulder arthroplasty and a retrospective review was performed. The primary outcomes of interest were device stability in the medullary canal, successful occlusion of the canal, cement extrusion and quality of cement mantle.

Results: The majority of the cohort was female (63.3%) males and the average patient age was 71.7 years (SD 8.45). In 81.7% the device was deemed to be stable in the medullary canal. The device was significantly more stable in primary (84.2%) compared to revision cases (64.3%, $p = 0.02$). In 69.7% Barrack grade A mantle quality was achieved, this was higher in primary cases (74.2%) compared to revision cases (39.3%) ($p = 0.00006$).

Discussion: We noted excellent cementation outcomes using a cement restrictor specifically designed for the diaphyseal humerus anatomy. However, this humeral specific restrictor was noted to be more stable in primary as compared to revision cases.

Keywords

Shoulder arthroplasty, cement, cement restrictor, reverse shoulder arthroplasty, revision shoulder arthroplasty, cement mantle

Received 1 July 2024; accepted 23 September 2024

Introduction

The number of shoulder arthroplasty procedures performed annually in the USA is increasing with future demand projected to continue to rise over the next decade at a faster pace than either total hip or total knee arthroplasties.¹ Thus, proportionately, reverse shoulder arthroplasty is becoming increasingly more common.^{1,2} There are more than 800,000 people estimated to be living with a shoulder replacement.¹ Unsurprisingly, revision shoulder replacements are also on the increase and are estimated to cost the healthcare system in excess of \$200 million.¹ While registry data shows a trend toward uncemented stems,^{2,3} there are still benefits to using bone cement for humeral fixation. This is especially the case in the revision setting, for elderly patients

and patients with fractures or proximal humerus bone loss. Cemented humeral stems have been shown to have lower rates of tuberosity resorption and stress shielding and have also been found to have improved range of motion than uncemented implants.⁴ They also have lower rates of intraoperative periprosthetic fracture than uncemented humeral stems.⁵ Extrusion of cement in shoulder arthroplasty, however, can

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cause adverse events, specifically nerve or thermal injury.¹ In addition, excessive extrusion of cement within the canal may present additional surgical challenges should future stem revision become necessary and inadequate pressurization of the cement may lead to poor cement-bone interdigitation.

A reliable method to prevent progression and enable pressurization of cement in the intramedullary canal is required, along with familiarity and understanding of third generation cementing technique, in order to maximize the benefits and minimize the risk of cement use in shoulder arthroplasty. Figure 1 shows an example of a case where a cement restrictor was not utilized. Unfortunately, most commercial cement restrictors are not of adequate sizing for the humerus. Restrictors made for the femur and/or tibia are too big for the humerus and need to be trimmed intraoperatively or they risk fracture or incarceration with inadvertent proximal placement. Restrictors made for total elbow arthroplasty (TEA) are available and are of the appropriate diameter for the humeral canal. However, the instrumentation is not specific to the shoulder and the device is therefore more difficult to insert.⁶ The purpose of this study is to review the use and outcomes of a low profile ultra-high molecular weight (UHMW) polyethylene diaphyseal humeral cement restrictor in the setting of shoulder arthroplasty. To date, there are no other studies in the literature looking at the quality of cementation and the use of a dedicated humeral cement restrictor in shoulder arthroplasty and there is no published data relating to this particular device.

Methods

This investigation is a single institution study of retrospective data from a cohort of 238 patients who underwent a shoulder arthroplasty procedure with a cemented humeral component utilizing the Tornier low profile UHMW polyethylene cement restrictor (Figure 2; Stryker, Denver CO) between 1 January 2014 and 28 November 2021. This investigation was partially funded by Stryker (Denver, CO). After obtaining IRB approval (Duke University, Pro00111574), data was extracted from the Duke University electronic medical record system using Epic SlicerDicer (Epic, Verona, WI). Inclusion criteria were patients over the age of 18 years who underwent primary or revision shoulder arthroplasty with usage of this particular cement restrictor. Exclusion criteria included inadequate post operative imaging to assess the quality of cementation and absence of adverse event data collection. Chart review was performed using REDCap and data was exported into the Duke Protected Analytic Computer Environment (PACE) for analysis.^{7,8} Sex is legal sex as recorded in the medical record. In total, 238 patients and 251 shoulders were identified. In total, 33 shoulders were excluded – 23 because they did not have adequate post operative imaging available for assessment, seven because they were found to have had uncemented implants when records were reviewed, one because the canal was too small for the restrictor to be

placed (7 mm diameter), one because the restrictor was not placed in the humerus and one because the case using the cement restrictor was not a shoulder arthroplasty. This left a total of 207 patients and 218 shoulders for inclusion in the study. Adverse events were collected up to one year post-operatively.

The primary outcomes of interest were device migration and stability in the medullary canal, successful occlusion of the medullary canal, cement extrusion and quality of cement mantle. Successful cement restrictor stability was determined by position of the device less than 15 mm below the tip of the humeral stem as 10 mm is the recommended depth of insertion in the device technique guide⁹ and felt to be the length of cement “tail” that a typical surgeon would aim for, an additional 5 mm was added to allow for intra operative margin of error. Anything greater than this was deemed to be progression of the device. Successful occlusion of the canal was determined to be present if there was an absence of cement distal to the device in diaphysis. Cement extrusion was assessed by looking for cement presence outside of the intramedullary canal. Cement mantle quality was determined by the criteria described by Barrack et al with the four grade Barrack classification, which was described for the femur in the setting of total hip arthroplasty.¹⁰ Grade A relates to a perfect cement filling of canal and absence of radiolucencies between the cement mantle and bone. Grades B and C involve up to 50% or 50%-99% of radiolucencies in the bone-cement interface, respectively. Grade D demonstrates 100% radiolucency or the absence of cement distal to the tip of the femoral stem. The presence or absence of bubbles within the cement mantle, on radiographic imaging, was also recorded as an indication of mantle quality. The thickness of the cement mantle was also used as measure of cement quality. The thickness of the cement mantle was measured at the midpoint of the humeral stem with the thickness between the inner cortex and humeral implant at this level recorded both medially and laterally for each patient and the mean of the two figures calculated. Figure 3 demonstrates an example of good quality cement mantle. Based on total hip arthroplasty literature an average thickness of 2 mm or more with no radiolucent lines was deemed to be an adequate thickness.^{10,11}

All radiographic assessments were made on the earliest adequate post operative radiograph so as to eliminate the effect of any aseptic or septic loosening and other changes over time. Of the 218 patients, 199 (91.3%) had an x-ray on the day of surgery that was adequate for assessment, 19 (8.7%) patients did not and the earliest adequate post operative x-ray was used. Of these 19 patients, the average time from surgery to the imaging that was included in the study was 42.3 days. All radiographic images were reviewed and assessed by a fellowship-trained orthopaedic surgeon.

Secondary outcomes of interest were adverse events including revision procedures. The operative notes for each

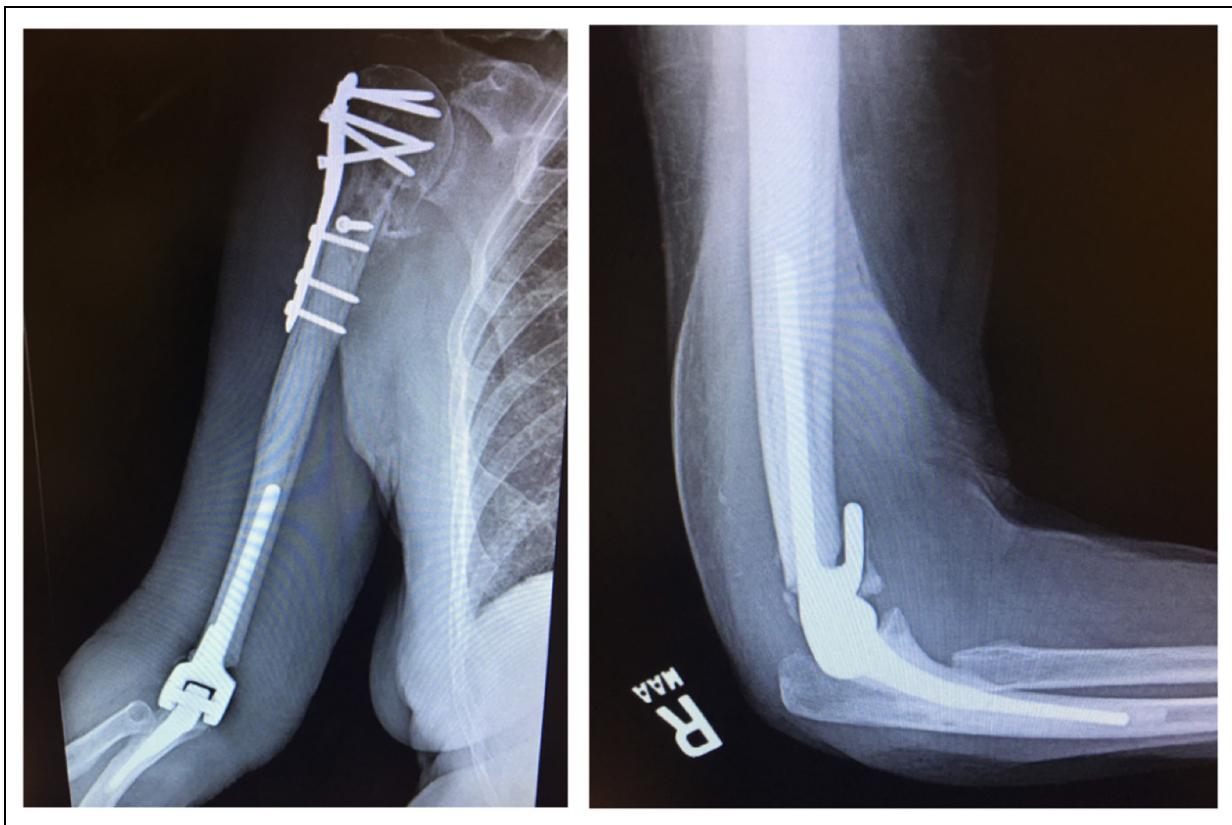


Figure 1. Example of a total elbow arthroplasty case where a cement restrictor was not utilised.

patient were reviewed looking for evidence of trimming or adaptation of the device. Data on adverse events including revision procedures were collected and those related to the cementation were further separated and analyzed.

Descriptive statistics for patient characteristics and outcomes were compiled using R Statistical Software version 4.0.2 (2020-06-22).¹² Packages used were Tidyverse¹³ and Hmisc.¹⁴ The relationship between mantle quality and progression of the cement restrictor was evaluated using the Fisher's exact test.

TECHNIQUE

The cement restrictor (Stryker, CO) under investigation in this study comes with streamlined and dedicated instrumentation for sizing and implantation of the cement restrictor in the proximal humerus. This restrictor is a diaphyseal plug designed to occlude the medullary cavity prior to the introduction of acrylic cement. It is designed to prevent cement progression in the diaphysis and therefore facilitate cement pressurization. It is composed of UHMW polyethylene with a central stainless steel x-ray marker. The flexible wings make it adaptable to varying diameters of the medullary canal. The restrictor is available in three sizes – small (13 mm diameter) which is indicated for diaphyseal diameters 5 to 7 mm; medium (24 mm diameter), indicated for

diaphyseal diameters from 7 to 15 mm and large (38 mm diameter), indicated for diaphyseal diameters from 12 to 20 mm although medium is the most commonly used for shoulder arthroplasty.¹⁵ All cement restrictors used in the study population were size medium.

With regard to the technique, the manufacturer guidelines were followed including measuring the canal diameter of the humerus pre operatively and using the appropriate size restrictor, calculating the insertion depth by adding 10 mm to the length of the humeral stem and positioning the plug in the shaft with the dedicated inserter which is removed prior to insertion of acrylic cement. Third generation cementing techniques^{16,17} were used (including cement mixing under vacuum conditions) with standard implant specific humeral canal preparation, the canal was cleaned and irrigated, cement restrictor depth measured and inserted, canal suctioned and dried prior to cement insertion with a gun, pressurization and finally implant insertion. The operating surgeon's standard technique was utilized for the remainder of the arthroplasty procedure.

Results

218 shoulders were included in this study, the demographics of the study population are outlined in Table 1. The

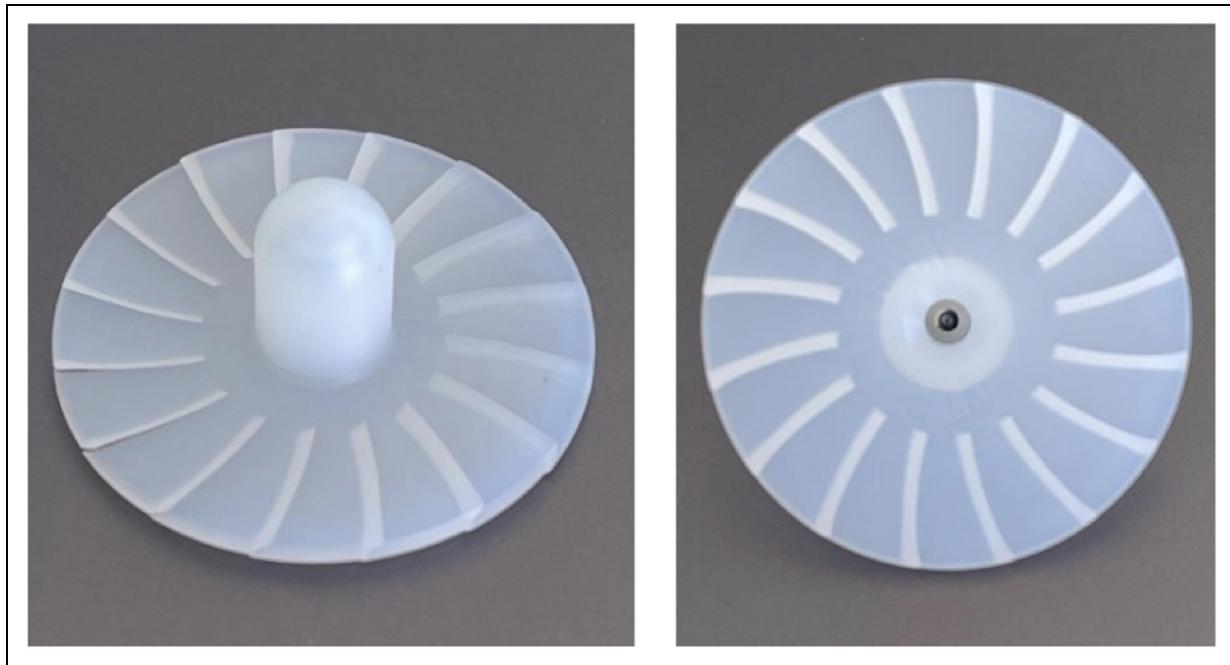


Figure 2. Photograph of the Tornier Cement Restrictor used in this study.

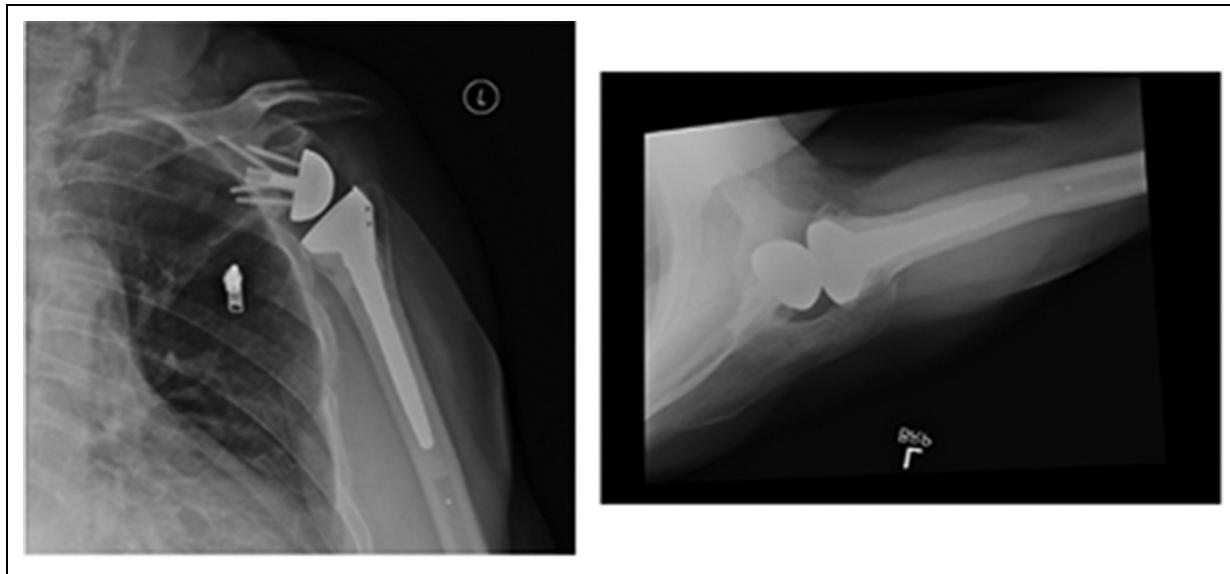


Figure 3. Xray demonstrating Grade A cement mantle with no progression of cement into the diaphyseal canal and stability of the device.

individuals in this study population tended towards female, over age 65 and Caucasian. A significant number of patients had a pre operative diagnosis of osteopenia or osteoporosis (36.2%).

Primary Outcome Measures

Device Stability in the Intramedullary Canal. In 178 of 218 cases (81.7%), the device was deemed to be stable in the

medullary canal with an appropriate length of cement tail. In 40 of 218 cases (18.3%) the device was sitting more than 15 mm distal to the tip of the humeral implant. When analyzed in subgroups by primary or revision procedure, the device was stable in 160 (84.2%) of primary cases and 18 (64.3%) of revision cases. There was a statistically significant relationship between device stability and surgery type (primary or revision) ($p=0.02$).

Table 1. Demographics of Study Population.

| Population Demographics | | | |
|-------------------------|--|---|---|
| Age | 71.72 years | (SD 8.45) | |
| Sex | Male 80 (36.7%) <i>76 unique</i> | Female 138 (63.3%) <i>131 unique</i> | |
| Ethnicity | White 193 (88.5%) <i>184 unique</i> | Black 16 (7.3%) <i>15 unique</i> | Other 9 (4.2%) <i>8 unique</i> |
| BMI | Mean 30.18 | (SD 8.53) | |
| Smoking status | Current 17 (7.8%) <i>17 unique</i> | Never 95 (43.6%) <i>91 unique</i> | Quit 106 (48.6%) <i>99 unique</i> |
| Comorbidity | Diabetes 45 (20.7%) <i>45 unique</i> | Obese (BMI >30) 91 (41.7%) <i>85 unique</i> | |
| Bone density | Osteoporosis 57 (26.1%) <i>55 unique</i> | Osteopenia 22 (10.1%) <i>19 unique</i> | |

Occlusion of the Intramedullary Canal. In 201 (92.2%) cases the device was found to have successfully occluded the medullary canal. In 17 (7.8%) of cases cement was present in the intramedullary canal distal to the device. In 11 (5.1%) of these cases the amount distal to the device was deemed to be very small (< 10 mm in length and not filling the entire canal), there was no progression of the device and the cement mantle quality was maintained with no apparent impact related to the small amount of cement that passed the restrictor. In four (1.8%) of these 11 cases the device was not stable in the medullary canal as determined by the above criteria. In 2 cases (0.9%) the device was sitting in appropriate position but there was a significant amount of cement present in the canal distally.

Cement Extrusion Outside the Intramedullary Canal. In 2 of the 218 cases (0.9%) cement was noted to be present outside the cortical bounds of the humerus and therefore deemed to have extruded. Of note, both of these cases were complex revision procedures.

Cement Mantle Quality. Grading of the cement mantle quality as per Barrack et al,¹⁰ average cement mantle thickness and presence of absence of bubbles is outlined in Table 2. On post-hoc subgroup analysis there was a significant relationship between surgery type (primary or revision) and mantle quality (perfect vs imperfect) ($p = 0.00006$). There was a significant correlation ($p = 0.02$) between mantle quality ('perfect' ie Grade A and 'imperfect' ie Grade B, C or D) and device progression in the canal as measured in the methods described above for the primary arthroplasty cases ($n = 190$). For the revision cases there was no significant relationship ($p = 0.7$) for the revision arthroplasty cases ($n = 28$). Five cases (2.3%) were deemed to have grade D cement

Table 2. Cement Mantle Quality.

| Cement Mantle Quality | | | |
|---------------------------------|----------------------|----------------------|----------------------|
| | Total (n = 218) | Primary (n = 190) | Revision (n = 28) |
| Barrack Grade | A 152 (69.7%) | 141 (74.2%) | 11 (39.3%) |
| | B 51 (23.4%) | 39 (20.5%) | 12 (42.9%) |
| | C 10 (4.6%) | 6 (3.2%) | 4 (14.3%) |
| | D 5 (2.3%) | 4 (2.1%) | 1 (3.6%) |
| Presence of bubbles | 54 (24.8%) | 43 (22.6%) | 11 (39.3%) |
| Mantle thickness >2mm | 191 (87.6%) | 164 (86.3%) | 27 (96.4%) |

mantle and in all three this was due to a lack of cement being present distal to the humeral stem but proximal to the cement restrictor.

Secondary Outcome Measures

Adverse Events Including Revision Procedures. With regard to reoperation, four primary arthroplasties underwent a second procedure during the one year follow up time frame with three (1.6%) of these being a revision arthroplasty. Three revision cases were reoperated on with one (3.6%) of these being revised again. Deep venous thrombosis was recorded in two primary cases and pulmonary embolus in three primary cases. Two primary arthroplasties had subsequent infections, one of which was deep. Intra and perioperative fractures were found in both the revision and primary groups. The revision arthroplasty group had two intra-operative fractures and the primary arthroplasty group had four intra-operative fractures and three early post operative fractures.

Discussion

This study has shown that Barrack grade A or B quality cement mantle can be achieved in 93.1% of overall cases and 90.7% of primary shoulder arthroplasty. Adequate cement mantle thickness was achieved in 87.6% of cases and bubbles were absent in 75.2%. This is excellent and shows that the device in question can successfully occlude the humeral canal in a majority of cases to enable pressurization and interdigititation of bone cement. Comparable literature on mantle quality for shoulder arthroplasties is lacking and to our knowledge this is the first paper assessing this, therefore comparisons have been made with the hip arthroplasty literature. Comparable studies^{18–20} investigating the quality of femoral cement mantle in hip arthroplasty, show that Barrack grade A cement mantle was recorded in 5.8%, 39.25% and 33% of cases, with 56.5%, 53% and 69% having grade B mantle respectively. With regard to the thickness of the cement mantle, there is some variation with respect to Gruen zones, but between 47% and 92% had a cement mantle greater than or equal to 2 mm. Only one study reported the presence or absence of bubbles independently¹⁸ and found that they were present in between 1% and 44% of cases with significant variation between Gruen zones. The results of this study are comparatively positive when looking at the femoral literature. This may be due in part to cementing technique and an overall smaller volume of cement to be pressurized along with anatomical differences in the femoral and humeral necks. Regardless, the results show that an excellent cement mantle can be obtained in shoulder arthroplasty. The correlation between presumed progression of the cement restrictor (based on the length of cement tail) and decreased quality of cement mantle is biologically plausible as it is likely one cannot achieve excellent pressurization without a stable restrictor distally. This finding emphasizes the importance of correctly sizing and accurately placing the chosen cement restrictor as well as the use of third generation cementing technique in order to obtain a good quality cement mantle. The results also show that one is significantly more likely to achieve device stability and a grade A cement mantle in primary cases when compared to revision cases.

The relevance of cement mantle quality in shoulder arthroplasty is more difficult to elucidate. In the femur, poor cement mantle quality is linked to an increased rate of aseptic loosening, which is a significant cause of failure in total hip arthroplasty.²¹ Cement mantle thickness has been directly correlated with femoral loosening due to increased risk of radiolucent lines with higher mantle thickness, and increased risk of fracture from mantles that are too thin.²² Another relevant study²³ looked at cement mantle quality in TEA and showed that 64% of revisions for aseptic loosening were attributed to poor cement mantle quality. There were no inadequate cement mantles in the group without loosening. It is difficult to know if the association between

poor cement mantle quality and loosening would translate to the humerus, because the humerus is not a weight bearing bone unlike the femur and the cement is therefore not loaded in the same manner. In addition, humeral loosening in TSA is a less common cause of failure particularly compared to TEA and the cement mantle may be less relevant due to a lower frequency of cases with aseptic loosening. Regardless, intuitively it makes sense to optimize the cement mantle in TSA and remove a potential contributor to early failure.

Both cemented and uncemented implants are valid options for TSA with two systematic reviews showing similar functional outcomes between the two groups.^{24,25} Kao et al²⁴ found that there were no significant differences between American Shoulder and Elbow Surgeons Shoulder Scores (ASES) or overall complication rates, while cemented rTSA procedures had significantly higher Constant scores (CS). However, while statistically significant, these findings are likely not clinically significant. Phadnis et al²⁵ found that while uncemented stems had a higher incidence of early stem migration and radiolucent lines, they had a significantly lower rate of acromial stress fracture. In contrast, the cemented group had a greater risk of infection, nerve injury and thromboembolic complications. Importantly, there was no difference in the risk of stem loosening or revision and both groups had similar functional outcome and range of motion. Early periprosthetic fractures are more common in cementless procedures^{26,27} and uncemented implants may not be appropriate for some patients. As a result cemented technique remains an important option for those with poor bone stock, osteoporosis, revision TSA or humeral fractures where adequate fixation cannot be obtained with an uncemented implant. The cemented procedure is also often preferred due to its association with lower tuberosity resorption and stress shielding.^{4,28} The demographics of the study population under investigation here reflect these common indications for the use of a cemented implant, with an older population (average age 71.7 years), a high prevalence of osteoporosis and osteopenia (combined 36.3%), and a significant proportion of the group having fracture as the indication for their TSA.

Limitations of this study include the fact that it is impossible to know the exact intended and actual position of the cement restrictor intra-operatively. Thus, we are making assumption that the surgeon would have planned a cement tail less than 15 mm from the tip of the stem and executed this intent accurately intra operatively. In addition, we did not analyze our data by surgeon and there may be some variation in cementation technique, familiarity and skill level. However, all cases were performed by an attending surgeon and the variety likely reflects real world experience. All cement restrictors in this study were a size medium and no comment was made regarding sizing or trimming and adjustment of the device in the operative note. It may be that the cement mantle could be further optimized by more

careful sizing of the device and the usage of a large size in some may have reduced the incidence of device progression in the canal. Regardless of this, the vast majority of shoulders in this study had an adequate cement mantle which suggests the device is forgiving and can accommodate a range of canal diameters. The revision group was too small to reliably comment on a statistical relationship between device progression and mantle quality. Finally, measurements of cement mantle thickness rely on the quality of the imaging available for analysis. Wherever possible the most immediate post operative film was used to eliminate the effect of change over time on the cement mantle. This did result in day of surgery films (often in the recovery room) being used in most cases and as such, the rotation of the film and implant profile was not standardized. The follow up time period for adverse events was one year, which is short in terms of monitoring for complications associated with humeral cement mantle quality. Future research should look at the association between initial mantle quality and outcomes including humeral loosening over a longer time frame to assess for any association.

Conclusion

The use of a low profile UHMWPE cement restrictor results in Barrack grade A or B cement mantle in 93.1% of cases. The device was shown to be stable in the canal in 81.7% of cases and occluded the canal in 92.2% of cases. It is more likely that the device will be stable and more likely that a grade A cement mantle will be achieved in primary cases compared to revision arthroplasty cases.

Acknowledgements

This work was funded in part by Stryker. Duke's PACE is supported by Duke's Clinical and Transitional Science Award (CTSA) grant (UL1TR002553) and by Duke University Health System. The CTSA initiative is led by the National Center for Advancing Translational Sciences (NCATS) at the National Institute of Health.

Declaration of Conflicting Interests

Author GEG would like to declare the following potential conflicts of interest American Shoulder and Elbow Surgeons: Committee member, Arthroscopy Association of North America: Committee member, Academic Orthopaedic Consortium: Associate Chief medical officer, Enovis/DJO: IP royalties; Other financial or material support; Paid consultant; Paid presenter or speaker, Elsevier: Textbook royalties for "Skeletal Trauma of the Upper Extremity.", Aevumed: Stock or stock options, Genesys: Stock or stock options, Sparta: Stock or stock options, CultivateMD: Stock or stock options, Patient IQ: Stock or stock options, Journal of Shoulder and Elbow Surgery: Editorial or governing board, Restor3d: Paid consultant; Stock, Mitek/DePuy: Paid consultant, Stryker/Tornier: IP royalties; Paid consultant, ROM 3: Stock or stock options. Author TEL would like to declare the following consultant for Lima and Tornier; IDE and author OAA would like to declare the following, consultant for Lima,

Exactech, Responsive Arthroscopy and Smith & Nephew. The remaining authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding

The authors disclosed receipt of the following financial support for the research, authorship, and/or publication of this article: This work was supported by the Stryker, (funded in part).

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