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Reverse total shoulder arthroplasty with proximal bone loss: a biomechanical comparison of partially vs. fully cemented humeral stems

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Abstract

Background: The appropriate amount of cementation at the time of reverse total shoulder arthroplasty with significant proximal bone loss or resection is unknown. Extensive cementation of a humeral prosthesis makes eventual revision arthroplasty more challenging, increasing the risk of periprosthetic fracture. We analyzed the degree of subsidence and torque tolerance of humeral components undergoing standard cementation technique vs. our reduced polymethyl methacrylate (PMMA) protocol. Reduced cementation may provide sufficient biomechanical stability to resist physiologically relevant loads, while still permitting a clinically attainable torque for debonding the prosthesis.

Methods: A total of 12 cadaveric humeri (6 matched pairs) underwent resection of 5 cm of bone distal to the greater tuberosity. Each pair of humeri underwent standard humeral arthroplasty preparation followed by either cementation using a 1.5-cm PMMA sphere at a location 3 cm inferior to the porous coating or standard full stem cementation. A 6-degree-of-freedom robot was used to perform all testing. Each humeral sample underwent 200 cycles of abduction, adduction, and forward elevation while being subjected to a physiologic compression force. Next, the samples were fixed in place and subjected to an increasing torque until implant-cement separation or failure occurred. Paired *t* tests were used to compare mean implant subsidence vs. a predetermined 5-mm threshold, as well as removal torque in matched samples.

Results: Fully and partially cemented implants subsided 0.49 mm (95% CI 0.23–0.76 mm) and 1.85 mm (95% CI 0.41–3.29 mm), respectively, which were significantly less than the predetermined 5-mm threshold ($P < .001$ and $P < .01$, respectively). Removal torque between

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Supplementary Data

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This study was considered nonhuman, cadaveric subject research and did not require institutional review board review or approval.

fully cemented stems was 45.22 Nm (95% CI 21.86–68.57 Nm), vs. 9.26 Nm (95% CI 2.59–15.93 Nm) for partially cemented samples ($P = .021$). Every fully cemented humerus fractured during implant removal vs. only 1 in the reduced-cementation group. The mean donor age in our study was 76 years (range, 65–80 years). Only 1 matched pair of humeri belonged to a female donor with comorbid osteoporosis. The fractured humerus in the partially cemented group belonged to that donor.

Conclusion: Partially and fully cemented humeral prostheses had subsidence that was significantly less than 5 mm. Partially cemented stems required less removal torque for debonding of the component from the cement mantle. In all cases, removal of fully cemented stems resulted in humeral fracture. Reduced cementation of humeral prostheses may provide both sufficient biomechanical stability and ease of future component removal.

Level of evidence: Basic Science Study; Biomechanics

Keywords

Reverse total shoulder arthroplasty; humeral stems; implant subsidence; shoulder biomechanics; proximal humerus fracture; bone cement

Proximal humeral fractures are among the most common type of injuries among patients 65 years of age or older, and with an aging population these will only become more frequent.¹⁶ There is a lack of ex vivo studies evaluating the mechanical benefits of using bone cement (polymethyl methacrylate [PMMA]) during reverse total shoulder arthroplasty (RTSA). Indications for RTSA have expanded over the last 2 decades since the procedure was approved by the Food and Drug Administration in 2003.²² Initially, RTSA was a favorable surgical intervention compared to anatomic total shoulder arthroplasty for those with a pseudoparalytic shoulder.²⁶ The altered biomechanics and fixation of RTSA have proven to be beneficial in other pathologies requiring surgical intervention including proximal humerus fractures in the elderly, tumors requiring en bloc resection, and revision of primary total shoulder arthroplasty (TSA).^{15,18,26,34} In the elderly population, underlying osteoporosis, rotator cuff pathology, and high rates of 3- and 4-part fractures make traditional locking plate or hemiarthroplasty fixation susceptible to failure and poor function.²⁷ Furthermore, open reduction internal fixation of proximal humerus fractures is often associated with significant arthrofibrosis and range of motion deficits. However, RTSA for displaced proximal humerus fractures has proven to be associated with lower complication rates and better functionality.^{16,20,23,25} Moreover, patients suffering from oncologic processes whose treatment results in proximal humerus bone defects can also benefit from RTSA, which allows for improved function while removing diseased tissue.^{9,14}

Primary RTSA has proven to be a beneficial intervention for numerous pathologies, but this procedure is not without complications. Instability, infection, and humeral and glenoid component loosening are the largest contributors to revision for RTSA and are estimated to occur in 10% of primary RTSA.^{4,17,19} Furthermore, prior studies have shown that >5 mm of implant migration is a definite measure of instability^{11,30} likely requiring revision and increasing the risk of complications. In particular, the frequency of intraoperative fractures in revision cases increases significantly, from 2.9% to 13.9%.¹⁰ Humeral fractures tend to

occur most frequently (51%–81%) during component removal or removal of the cement mantle and can result in additional bone loss.^{4,10,33} Identifying ways to reduce the risk of intraoperative fracture during revision RTSA would be of significant benefit to patients and health systems as this would likely lessen the use of salvage fixation (eg, circumferential cables and locked plating constructs) and improve efficiency of operating room and ancillary resources.

Given the large breadth of patient populations RTSA can benefit, it is important to optimize surgical interventions to ensure best outcomes for patients undergoing such procedures. The goal of this investigation was to compare the degree of subsidence and implant removal torque tolerance of humeral stems in cadaveric bone undergoing standard cementation vs. a reduced-cementation technique. We hypothesized that approximately 1.75 cubic cm of PMMA (cement sphere of 1.5 cm diameter) applied at the proximal smooth portion of a humeral stem would provide sufficient biomechanical stability to resist physiologically relevant axial loads, yielding less than 5 mm of subsidence. Additionally, this cement protocol would also permit a clinically attainable torque threshold sufficient to result in debonding of the prosthesis from the cement mantle without an associated humerus fracture.

Methods

Sample preparation

A total of 12 cadaveric human shoulders (6 matched-pairs) from donors 65 years of age or older were screened for prior history of humeral fracture, or evidence of shoulder surgery. One side from each matched pair was randomized to undergo reverse shoulder arthroplasty using standard PMMA cementation technique of the entire smooth portion of the humeral component. The matched contralateral shoulder was then designated to undergo the minimal cement protocol. The paired upper extremities were separated at the elbow, the forearms were discarded, and all soft tissue was resected from the remaining humeri. Next, each humerus was resected 5 cm distal from the lateral portion of the greater tuberosity to simulate bone loss due to fracture or tumor (Fig. 1, A) as previously described in biomechanical models of humeral bone loss.^{6,8,12} Following proximal humerus bone resection, the humeri were potted into PMMA cylinders at the distal end to facilitate subsequent mechanical testing (Fig. 1, B). The specimens were then stored at -20°C and thawed at room temperature for at least 24 hours before cementation of the implant and biomechanical testing.

Before implant cementation, the humeri were reamed to the appropriate size and underwent broaching per the manufacturer's recommended protocol. Humeral prostheses of the appropriate size with rounded, smooth stems that are FDA approved for use in the setting of proximal humerus fractures (Global Unite, DePuy) were used in all testing conditions. Every matched-humerus pair used implants of the same size in order to standardize testing. Application of gentle torque with 2 fingers by an experienced shoulder surgeon resulted in minimal implant resistance, indicating instability. Humeral prostheses in the reduced cement group were installed by evenly spreading a 1.5-cm PMMA sphere ($\sim 1.75\text{-cm}^3$) at a location 3 cm inferior to the implant's proximal porous coating (Fig. 2, A). Next, the humeral implant with attached centered epiphyseal component (set to 0°) was inserted into

the previously prepped humeral medullary canal with approximately 20° of retroversion. Conversely, stems in the full cementation group were fixed by prefilling the medullary canal with PMMA, finger-packing the cement, and then inserting the humeral implant in the appropriate orientation as stated above. Any excess cement that extruded out of the medullary canal during insertion was removed. In both cemented conditions, care was taken to prevent cement from accumulating on the implant's porous coating. Prior to testing, a 6 × 38-mm polyethylene tray was secured into the epiphyseal component per manufacturer's recommended protocol. In both cement conditions, the fixated implant's most superior position was 5 cm above the resected bone, and the implant's metaphyseal fins minimally engaged the remaining cortex (Fig. 1, B).

To re-create the glenoid component in our robot-based model, a standard glenoid baseplate was potted into a PMMA cylinder and secured to the test base to maintain a fixed position (Figs. 1, B and 3). The baseplate was captured by the PMMA such that the glenosphere component had adequate vertical clearance from the PMMA cylinder to allow for full unrestricted range of motion without impingement of the components throughout the biomechanical testing.

Testing protocol

A 6-degree-of-freedom robotic manipulator was used to perform all biomechanical testing (KR210; KUKA Robotics Corp., Clinton Township, MI, USA). The humeral assembly was attached to the robot's end effector, and the glenosphere assembly attached to a grounded base (Fig. 3). Synthetic humeri (Sawbones, solid foam, 36 cm length and 9.5 mm canal diameter [model 1019]; Pacific Research Company, Vashon Island, WA, USA) were used during pretesting to calibrate the robot and help define the kinematic trajectories for the subsidence and torque tests. The center of rotation for the glenosphere was used as the reference coordinate system for applying forces and moments around the reverse joint structure. The KUKA robot is equipped with sensors capable of measuring forces and torques at the end effector, as well as changes in position with a resolution of 0.1 mm. During a pretesting of synthetic humeri, we found that 25 test cycles were necessary to reach a steady state (meaning we did not observe any significant subsidence from cycles 26 to 200); therefore, a total of 200 test cycles were selected for analysis of our cadaveric specimen to provide an acceptable test margin.

Subsidence testing—Prior to testing, a reference point on the polymer spacer of each humeral implant was calibrated while attached to the KUKA to define the origin of the humerus coordinate frame. The humerus would then be controlled to move throughout the fixed glenosphere frame. Every humerus underwent a total of 200 test cycles. Each cycle started with the glenohumeral prosthesis abducted at 90°. This was followed by adduction down to 20°, then forward elevation from 0° to 135°, along a plane that was at a 45° angle relative to the torso (virtual) to simulate physiologic scaption. Next, the motion was reversed from 135° of forward elevation down to 0°, and from 20° of abduction up to 90° of abduction, thus completing 1 test cycle. Each cycle lasted 24 seconds, with the KUKA traveling at approximately 17°/s. At the end of the 200 test cycles, every sample had been subjected to 200 adductions, 200 forward elevations, and 200 abductions (a total of 600

motions). Because of the orientation of the robot in the laboratory, 2 identical trajectories were developed, 1 for the left humerus and 1 for the right, in order to properly simulate anatomic shoulder motion (Supplementary Figures S1–S6).

Physiologic compression and shear forces (Supplementary Table S1) were maintained throughout the entire test cycle in order to simulate shoulder joint kinetics. The forces were computed for every humeral sample based on recorded cadaver total body weight as previously reported.² Next, the joint reaction forces were transformed to their respective components in the robot's reference frame to maintain the test trajectory via automatic closed-loop control. Transformation calculations are included in the Supplementary Data (Supplementary Table S2 and Figure S7). Finally, the implant's pre- and post-test cycle positions in space were captured via the KUKA's sensor to determine if there was any implant migration, and the difference between these 2 values was recorded as the stem's subsidence.

Removal torque testing—Following subsidence testing, the polyethylene tray and humeral epiphyseal component were removed, and the proximal portion of the humeral stem component was clamped perpendicularly to the test base (Fig. 4). A constant rotation at a rate of approximately 1°/s was applied via the robotic arm at the distal end of the humerus to generate a continuously increasing torque load in external rotation. No axial loading was applied or maintained to prevent undesirable bending moments. The implant and clamp geometry prevented any slipping from occurring. Visual inspection of the bone-implant margin in conjunction with active torque monitoring was used to determine if implant failure had occurred. Failure was determined as bone-cement separation, implant-cement separation (debonding), or bone fracture. The final maximum torque required for sample failure was recorded as the implant's removal torque load.

Statistical analysis

Descriptive statistics for age, sex, weight, height, and body mass index of the cadaveric samples were calculated. Each side from the matched-pair humeri was randomized to receive standard cementation or the experimental cement protocol. The physiologic compression forces applied by the robot were averaged over the 200 cycles and reported as a function of the glenohumeral trajectory angle. Removal torque was simply reported over time to failure. All raw experimental data were collected via the KUKA's sensor, and MATLAB (MathWorks, Inc., Natick, MA, USA) was used for data processing and statistical analysis. Results are reported as mean values with 95% confidence intervals (CIs), and average compression forces are reported as median (interquartile range). Student *t* tests were used to compare mean sample subsidence vs. our predetermined 5-mm failure threshold (a value reported on by others¹), as well as to compare torque loads between matched pairs. A *P* value <.05 was considered statistically significant.

Results

Descriptive cadaveric data are included in Table I. The mean donor age in our study was 76 years (range, 65–80 years), with a mean weight and height of 141.6 lb (SD 41.7 lb) and 68.8 in. (SD 5.3 in.), respectively. Only 1 matched pair of humeri belonged to a female,

and she was the sole donor with comorbid osteoporosis in our study group. Subsidence and removal torque data are included in Table II and Fig. 5. We found that fully and partially cemented humeral implants had a mean subsidence of 0.49 mm (95% CI 0.23–0.76 mm) and 1.85 mm (95% CI 0.41–3.29 mm), respectively, which were significantly less than the predetermined 5-mm failure threshold ($P < .001$ and $P < .01$, respectively). The median compression forces used in our study for fully cemented and partially cemented humeri were 176.8 N (interquartile range 149.7–231.7 N) vs. 177.4 N (interquartile range 147.5–230.8 N), respectively. Curves comparing the average compression forces between matched pairs for the entire 200 test cycles are included in Supplementary Figures S1–S6. Post hoc analysis indicated no statistically significant difference in the kinematic compression forces between matched pairs maintained by the KUKA robot.

Analysis via paired *t* test indicated a significant difference in the mean removal torque between fully cemented implants at 45.22 Nm (95% CI 21.86–68.57 Nm), compared with partially cemented stems at 9.26 Nm (95% CI 2.59–15.93 Nm) ($P = .021$). Removal torque vs. time curves for all matched humeri in our study are included in Supplementary Figures S1–S6. Interestingly, we found that every humeri with standard cementation fractured during implant removal compared with only 1 in the reduced-cementation group (100% vs. 17% fail rate). Of note, the fractured humerus in the partially cemented group belonged to the female donor with comorbid osteoporosis. To confirm cement coverage, we evaluated the post-test cement mantles for each experimental condition. Postremoval evaluation of all partially cemented humeri showed a mean PMMA mantle superior-inferior length of 4.02 cm (95% CI 3.57–4.47 cm) in the medullary cavity. Because of the implant's geometry, this cement mantle covered the entire stem's diameter proximally (diameter ranged from 12 to 16 mm) and part of the grooved surface distally. Conversely, post hoc evaluation of humeri with standard cementation indicated that the PMMA mantle indeed covered the entire stem (lengths ranged from 121 to 138 mm), a 1–2-cm distal cement mantle, and portions of the grit-blasted proximal stem.

Discussion

We evaluated the subsidence and removal torque associated with 2 cementation techniques for RTSA humeral implants using a human cadaveric model of proximal humerus bone loss. Our results showed that both cementation techniques had a mean subsidence that was significantly less than 5 mm, indicating a likely biomechanically stable construct. We also found that partially cemented stems required less torque load for debonding and that all fully cemented samples resulted in fractures during removal testing. To our knowledge, this is the first study to evaluate the biomechanical stability of a modern shoulder implant with different degrees of cementation using a 6-degree-of-freedom robot and physiologically representative motion and forces. Currently, radiostereometric evaluation is the most precise method of evaluating implant migration in upper extremities, and >5 mm of displacement is considered a definite measure of implant subsidence.^{11,30,32} This is likely due to difficulty in detecting smaller changes in plain radiographs. In our study, we chose to uphold this 5-mm threshold as this has been an accepted standard in available literature discussing RTSA with short stems.³¹ However, we could not find any available association between 5-mm

subsidence and clinically significant inferior shoulder function in standard-length RTSA humeral stems.

More than 2 decades ago, Pepper et al²⁴ conducted one of the only biomechanical studies of humeral stem subsidence in shoulder arthroplasty. The authors used anatomic shoulder implants, did not simulate humeral bone loss, and used 3 different cement conditions applying an arbitrary compression force. In contrast, we used modern RTSA implants, and meticulously analyzed physiologic motion and kinematic forces over an extensive test cycle. These forces have previously been shown to correlate with those applied by the deltoid following RTSA with bone loss.^{1,2} Nonetheless, Pepper's results agree with this study, indicating that there was no significant difference in humeral stem subsidence among implants with full vs. reduced cementation. A more recent clinical study describing the merits of uncemented short stems in RTSA in 139 patients found that even though there was frequent subsidence, it was not clinically significant and did not affect short-term outcomes up to 18-months.³¹ This lends further evidence to support our observation that a mean subsidence of 1.85 mm in partially cemented stems is likely not a clinically significant amount. In a larger study, Werthel et. al analyzed long-term outcomes of receiving cementless vs. cemented humeral prostheses in hemiarthroplasty, total, or reverse shoulder arthroplasty and found an overall implant survival of over 90% up to 20 years for both cement constructs.³⁵ However, in the later study, the authors argue that possible bony destruction needs to be carefully considered with fully cemented stems in cases of revision. Even though we conducted a biomechanical study with a bone loss model, we can appreciate the merits of these 2 clinical papers. It is reasonable to argue that since cementless prostheses are found to be comparable to cemented ones at long-term, our "reduced" cementation protocol could provide even better fixation in cases of reverse shoulder arthroplasty for fracture. This is strengthened by our findings that both of our cement constructs had < 2 mm of subsidence.

Removal torque was immediately assessed following the subsidence cycles as this would closely mimic a real-world approach following any implant loosening or periprosthetic fracture. We found that fully cemented stems required significantly more torque for removal than partially cemented stems (Table II). What is perhaps more interesting and supports prior literature, is that all our fully cemented samples fractured during implant removal following application of a torque load. In a recent biomechanical study, Gorman et. al used a "cement-within-cement" technique in revision RTSA to show that larger humeral stems have more rotational stability.¹³ In that study, the authors used synthetic humeri with 2.5 cm of bone loss as supposed to our cadaveric models with 5 cm of bone loss. Furthermore, their test protocol utilized a cyclic-torque load over 1000 cycles, compared to our approach of applying a continuously increasing torque load. In another test, using a similar torque protocol and setup as Gorman et al, other authors compared standard RTSA vs. a bone loss model using cemented modular humeral components.⁸ They found that RTSA in the proximal bone loss model had an increased risk of failure, which was defined as rotational micromotion. In contrast, our study defined failure as separation at the cement-bone or cement-implant interfaces, or bone fracture. We found that the most common failure mode in partially cemented humeri was cement-implant separation and the most common failure in fully cemented RTSA implants was bone fracture. In this regard, our results disagree

with Cuff et al⁸ because all our fully cemented implants fractured between 24 and 87 Nm (Supplementary Figures S1–S6) as opposed to becoming loose or unstable. This is most likely associated with their use of synthetic humeri and our use of cadaveric specimens.

Pretest radiographic evidence of cement coverage was not readily available; however, post-test analysis of all humeri did demonstrate the degree of cement coverage in both partially and fully cemented specimens. A 1.5-cm PMMA sphere evenly spread 3 cm from the proximal grit-blasted portion of stems with 12–16 mm diameter (Fig. 2, B), as described in this investigation, is a clinically relevant and practical method to provide supplemental cement fixation for a humeral stem in the setting of proximal humerus bone loss. This approach may also help decrease the risk of thermal injury, particularly if there is a humeral shaft fenestration or defect (known or unknown to the surgeon); however, we were not able to assess those conditions in this study. Other studies have argued that cement augmentation reaches temperatures between 40°C and 43°C, which is unlikely to produce thermal injury; however, we used significantly more PMMA in our fully cemented models.^{3,5} Interestingly, some authors postulate complications in up to 17% of cases, as well as overall revision rates between 3.6% and 11% in primary RTSA for proximal humerus fractures.^{7,21,28,29} Hence, the “ease of removal or revision” is arguably more important given the benefit that can theoretically be conferred by reduced cementation, because more than 50% of intraoperative fractures happen during component extraction.¹⁰ Our study indicates that reduced cementation of humeral prostheses may provide both sufficient biomechanical stability and ease of future humeral component removal in the setting of proximal humeral bone loss. Of note, this decreased torque for humeral component removal also applies to humeral stems of a similar conformation as the prosthesis used in this study, which has implications for anatomic TSA or RTSA even in the absence of significant bone loss when cementless fixation is deemed inappropriate.

Limitations

The primary limitations of our study are those common to biomechanical cadaveric experiments. Even though we replicated physiologic motion of the humerus using robotic control, we were not able to mimic all the clinically relevant forces seen by the humerus during more advanced shoulder activities. Instead, we maintained a constant average compression force to maintain the components reduced over a finite number of test cycles. Hence, our findings should not necessarily be interpreted as representing the maximum physiologic forces seen by the glenohumeral joint in vivo. Additionally, our results represent only the very short-term strength of cement augmentation in RTSA and provide no discernable findings on the long-term outcomes of PMMA fixation or any biologic healing associated with shoulder replacements. Moreover, we conducted our study in a nonaqueous environment at room temperature in cadaveric bone with no supportive soft tissue that could theoretically improve force and torque tolerance. Lastly, we conducted a somewhat limited characterization of biomechanical properties in a relatively small sample size that does not appropriately address physiologic conditions, nor does it provide meaningful clinical implications of our results.

Conclusion

We found that both partially and fully cemented humeral prostheses had a subsidence that was significantly less than 5 mm, a previously documented acceptable standard. Interestingly, our analysis also found that partially cemented stems required significantly less removal torque for successful debonding of the component from the cement mantle compared with the fully cemented components. Furthermore, in all cases, torque-induced removal of fully cemented stems resulted in humeral fracture. Our study indicates that reduced cementation of humeral prostheses may provide both sufficient biomechanical stability and ease of future humeral component removal, if needed for subsequent revision shoulder arthroplasty.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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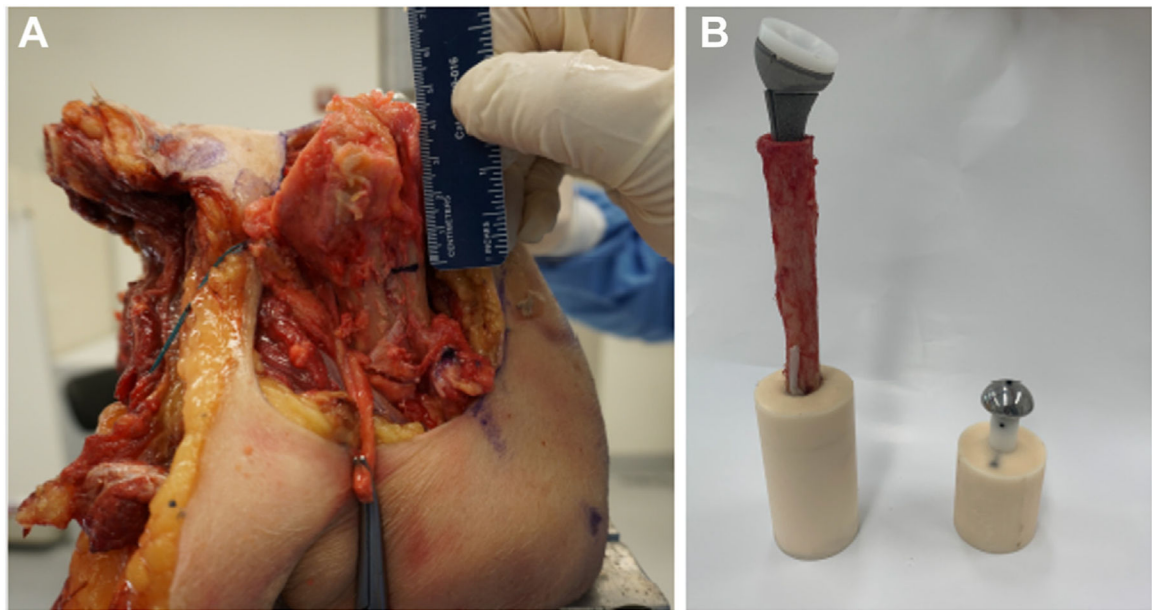


Figure 1.

(A) Initially, 5 cm of bone was resected distally from the humerus greater tuberosity.

(B) Next, the resected humerus was potted in a PMMA cylinder in conjunction with the glenosphere component. *PMMA*, polymethyl methacrylate.

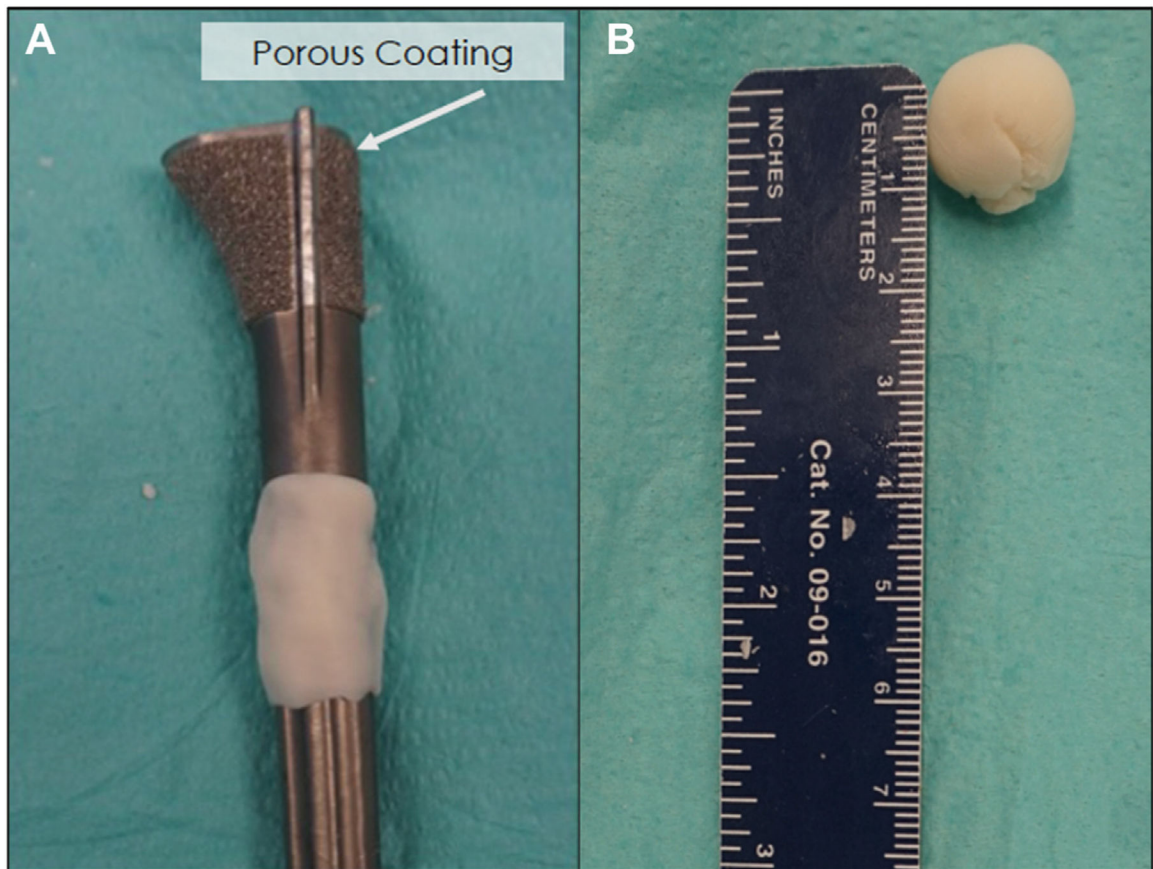


Figure 2.
(A) Humeral stem with a 1.5-cm cement sphere evenly spread 3 cm from the porous coating.
(B) Sphere measurement prior to application.

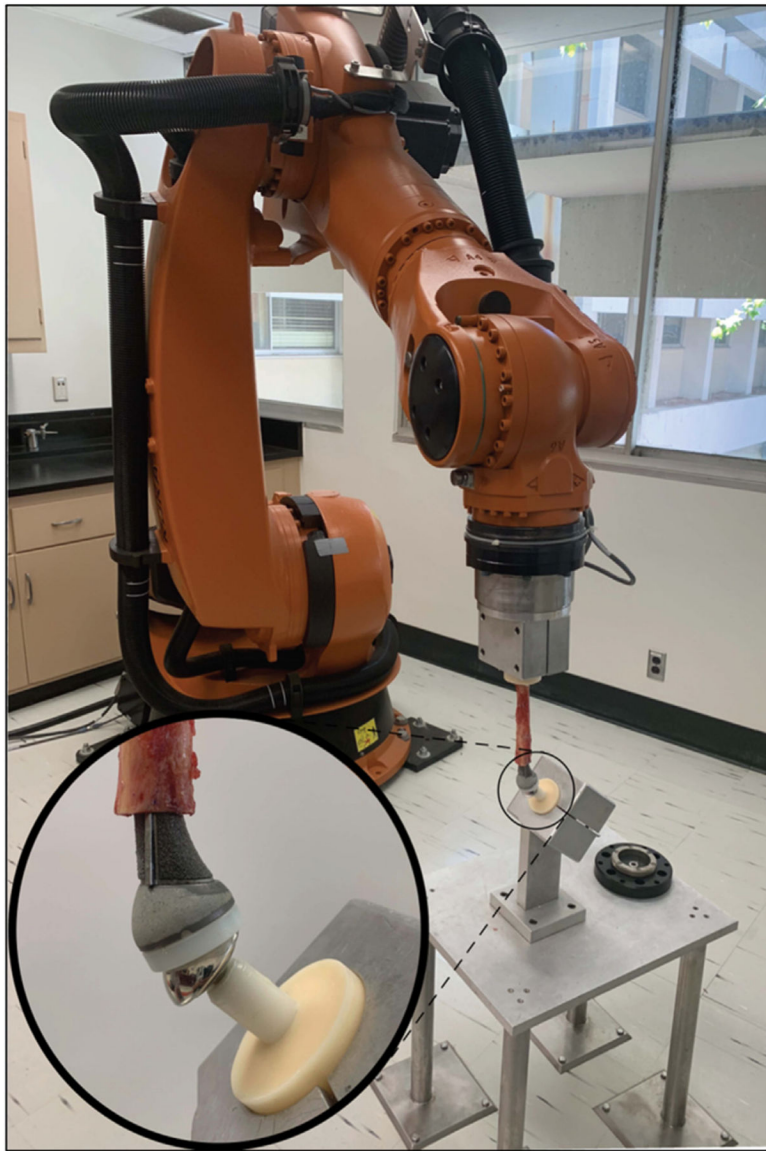


Figure 3.
Robotic manipulator (KUKA) with the test humerus attached to the sensor and the glenosphere secured to the test base.



Figure 4. Torque tolerance testing setup with stationary vice capturing the humeral component. The humerus is potted in a PMMA cylinder, and the cylinder is attached to the KUKA robot, which applies progressive torque. *PMMA*, polymethyl methacrylate.

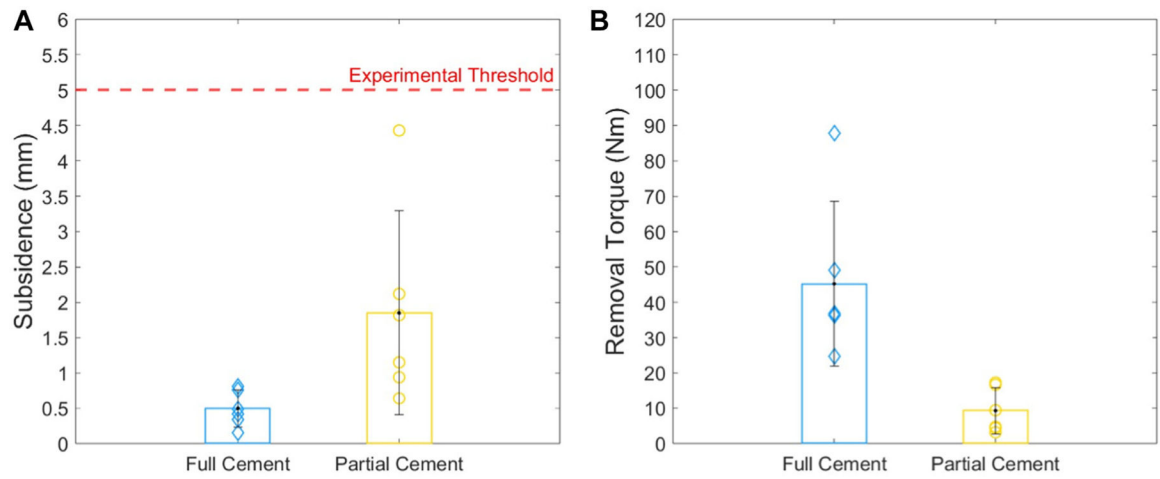


Figure 5.

(A) Scatterplot of subsidence with 5-mm predetermined subsidence threshold. (B) Removal torque for each experimental cement condition. Bar graphs indicate mean subsidence and mean torque with respective 95% confidence intervals.

Table 1

Descriptive cadaveric data for each humeral specimen

Specimen	Cadaver characteristics				BMI
	Sex	Age, yr	Weight, kg (lb)	Height, cm (in)	
1	M	80	63.5kg (140lb)	170.2cm (67 in)	21.9
2	M	79	77.1kg (170lb)	190.5cm (75 in)	21.2
3	M	76	95.3kg (210lb)	175.3cm (69 in)	31
4	M	65	49.9kg (110lb)	172.7cm (68 in)	16.7
5	M	78	54.4kg (120lb)	157.5cm (62 in)	21.9
6	F	78	45.4kg (100lb)	152.4cm (60 in)	19.5
Mean (SD)		76 (5.5)	64.2kg (141.6lb) (SD 18.9kg (41.7lb))	174.8cm (68.8 in) (SD 13.5cm (5.3 in))	22.03 (4.82)

SD, standard deviation; *M*, male; *F*, female; *BMI*, body mass index.

Table II

Subsidence and removal torque of fully cemented vs. partially cemented stems

Specimen	Implant size, mm	Subsidence, mm (side)		Removal torque, Nm (side)	
		Full cement	Partial cement	Full cement	Partial cement
1	14 × 130	0.42 (R)	1.15 (L)	36.47 (R)*	4.68 (L)
2	16 × 138	0.81 (R)	4.43 (L)	36.30 (R)*	4.36 (L)
3	12 × 121	0.34 (L)	2.12 (R)	87.86 (L)*	3.16 (R)
4	12 × 121	0.15 (R)	1.82 (L)	49.05 (R)*	9.37 (L)
5	12 × 121	0.49 (L)	0.94 (R)	36.85 (L)*	17.28 (R)
6	14 × 130	0.76 (L)	0.64 (R)	24.77 (L)*	16.71 (L)*
Mean (SD)		0.49 (0.25)	1.85 (1.38)	45.22 (22.26)	9.26 (6.36)
95% CI		0.23–0.76	0.41–3.29	21.86–68.57	2.59–15.93

SD, standard deviation; CI, confidence interval; R, right; L, left.

* Humeral specimen fractured during implant removal test.