Bone Graft Substitute Provides Metaphyseal Fixation for a Stemless Humeral Implant

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Bone Graft Substitute Provides Metaphyseal Fixation for a Stemless Humeral Implant

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abstract

Stemless humeral fixation has become an alternative to traditional total shoulder arthroplasty, but metaphyseal fixation may be compromised by the quality of the trabecular bone that diminishes with age and disease, and augmentation of the fixation may be desirable. The authors hypothesized that a bone graft substitute (BGS) could achieve initial fixation comparable to polymethylmethacrylate (PMMA) bone cement. Fifteen fresh-frozen human male humerii were randomly implanted using a stemless humeral prosthesis, and metaphyseal fixation was augmented with either high-viscosity PMMA bone cement (PMMA group) or a magnesium-based injectable BGS (OsteoCrete; Bone Solutions Inc, Dallas, Texas) (OC group). Both groups were compared with a control group with no augmentation. Initial stiffness, failure load, failure displacement, failure cycle, and total work were compared among groups. The PMMA and OC groups showed markedly higher failure loads, failure displacements, and failure cycles than the control group ($P<.01$). There were no statistically significant differences in initial stiffness, failure load, failure displacement, failure cycle, or total work between the PMMA and OC groups. The biomechanical properties of magnesium-based BGS fixation compared favorably with PMMA bone cement in the fixation of stemless humeral prostheses and may provide sufficient initial fixation for this clinical application. Future work will investigate the long-term remodeling characteristics and bone quality at the prosthetic-bone interface in an in vivo model to evaluate the clinical efficacy of this approach. [*Orthopedics*. 2015; 38(7):e597-e603.]

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Stemmed shoulder arthroplasty has been shown to be an effective treatment for a wide variety of shoulder disorders.[1] Malposition of a humeral implant can result from errors in surgical technique or limitations in prosthetic design due to the presence of a humeral stem.[2-4] The use of stemmed shoulder prostheses is also associated with potential problems relating to additional bone loss, whereas periprosthetic fracture adds additional surgical difficulty with revision surgery.[1] These limitations in stemmed humeral replacement have generated an interest in stemless humeral replacement.[5-8]

Metaphyseal implant fixation for a stemless humeral replacement requires sufficient bone quality to allow for both immediate and long-term fixation. The quality of the trabecular bone diminishes with age and disease, limiting the ability of this type of prosthetic to be used in many patients undergoing total shoulder replacement. Polymethylmethacrylate (PMMA) bone cement, impaction bone grafting, and bone graft substitutes (BGSs) have been introduced to augment fixation.[9-13] Polymethylmethacrylate provides excellent immediate fixation of the implant but has the disadvantages of being a permanent material that will not be resorbed or broken down by the body and having a high exothermic polymerization temperature that can result in tissue damage.[14] In the case of implant failure, removal of the bone cement is difficult and results in a large amount of bone loss. Bone graft substitutes may potentially provide a favorable alternative if they are able to provide initial fixation strength at the time of surgery.[15] A BGS would have the potential of being incorporated into the bone and providing long-term biologic fixation. If the implant were to fail, the BGS would not need to be removed, limiting the bone loss resulting from revision surgery.

In this study, the authors compared the initial fixation strength of a stemless humeral prosthesis that required fixation to occur within metaphyseal bone. They compared fixation with PMMA cement or a BGS to a control group with no additional fixation. A magnesium-based injectable BGS (OsteoCrete; Bone Solutions Inc, Dallas, Texas) was selected because it mixes as a slurry, can be injected, and is self-hardening within bone with a setting time similar to PMMA bone cement. OsteoCrete also has significant adhesive qualities. Unlike PMMA bone cement, OsteoCrete is osteoconductive and replaced by bone and is therefore not a permanent material.[13,16-18] OsteoCrete is US Food and Drug Administration (FDA) approved and is commercially available. For these reasons, the authors believe that this study has clinical relevance and is applicable in humeral head arthroplasty.

Materials and Methods

Study Design

Fifteen fresh-frozen human male humerii were implanted by the senior author (J.P.I.) with a humeral prosthesis having a smooth surface designed for metaphyseal fixation. Samples were randomized to fixation methodology such that 5 of the components (median age, 68 years; range, 67-69 years) were fixed with PMMA bone cement (Surgical Simplex P; Stryker, Mahwah, New Jersey [PMMA group]), 5 (median age, 67 years; range, 62-68 years) were fixed with magnesium-based injectable BGS (OsteoCrete [OC group]), and the remaining 5 (median age, 65 years; range, 57-86 years) were press-fit into the humerii with no cement (control group). Patient demographics, including age, race, sex, height, weight, and body mass index, were recorded for each pair of humerii.

Measurement of Bone Mineral Density of the Proximal Humerus

Prior to placing the prosthesis, the bone mineral density (BMD) of the proximal portion of the humerii was measured by dual-energy x-ray absorptiometry (DEXA) scan (Lunar Prodigy; GE Healthcare, Diegem, Belgium). To maintain consistent conditions between specimens, the proximal part of the humerus was horizontally fixed in a custom-made jig with the lesser tuberosity in the 12-o'clock position for assessment of BMD.[19] The region of interest for BMD was a square whose superior extent was the articular surface at the level of the greater tuberosity and whose inferior extent was the anatomic neck. All scans were performed and analyzed by the same operator (D.K.).

Prosthesis Design

The prosthesis was designed specifically for this study to fit the shape of the proximal humeral metaphysis and was manufactured as a prototype using 304 stainless steel (**Figure 1**). To improve initial metaphyseal fixation, a fin design was used to allow impaction of the prosthetic in a press-fit manner. The prosthetic finishing surface was smooth to allow for comparison between the press-fit (ie, control) and augmentation (ie, PMMA and OC) groups. This prosthesis is not associated with any commercial entity to avoid any industry-related conflicts. Currently, there are no FDA-approved stemless humeral devices available in the United States, although 3 clinical investigational device exemption trials are currently under way (Tornier/Simpliciti Stemless Shoulder, Biomet/Comprehensive Nano Stemless Shoulder, and Arthrex/Eclipse Stemless Shoulder Arthroplasty).

Specimen Preparation and Implantation Technique

Fresh-frozen human shoulders were dissected of all soft tissue, resulting in the isolation of the entire humerus. The specimens were stored frozen at -20°C until surgical preparation and fixation of the implant. The specimens were thawed at room temperature for 24 hours before bone preparation and implantation. Humerii were randomly selected for im-

plant fixation with PMMA bone cement, OsteoCrete BGS, or no cement. All humerii were anatomically normal and free of any disease within the bone.

All surgical bone preparation instruments were specifically designed and fabricated for this study. The head of the humerus was removed at the anatomic neck. A threaded guide pin was inserted perpendicular to and in the center of the osteotomy surface using a cannulated centering guide. A cannulated central drill bit was placed over the guidewire, and a hole was drilled corresponding to the length and width of the central portion of the fixation portion of the device. A cruciform box osteotome was then impacted into the metaphyseal bone, over the guidewire, to be collinear with the reamed central hole. The resulting bone void exactly matched the outer dimensions of the implant. A plastic deformable cement restrictor (Stryker) was inserted in the medullary canal at the bottom of the defect made for the implant. Irrigation and suction of the void was performed for 90 seconds using a pulsatile irrigation gun (Pulsavac; Stryker) with a thin-tip adapter.

One 40-g packet of bone cement (Surgical Simplex P) containing the powder component was mixed with 1 ampule containing the liquid component of methylmethacrylate monomer with a spatula for 90 seconds, yielding a total volume of 20 mL. The mixture was placed into a syringe and immediately injected into the bone void created for the implant (**Figures 2A-B**). Preparation of the BGS used 37.5 g of OsteoCrete powder mixed for 90 seconds with 11 mL of modified saline solution, resulting in a 20-mL slurry that was placed into a syringe. The OsteoCrete slurry was allowed to set for 3.5 minutes in the syringe before placing the material into the humerus (**Figures 2C-D**). The additional setting time for the Osteocrete allowed for the slurry to have a consistency similar to that of the PMMA. For both experimental groups, the humeral implant was impacted into the void containing the bone augmentation material. No augmentation material was used in the control group. In all groups, the implant was placed such that the collar of the prosthetic was flush with the osteotomy surface.

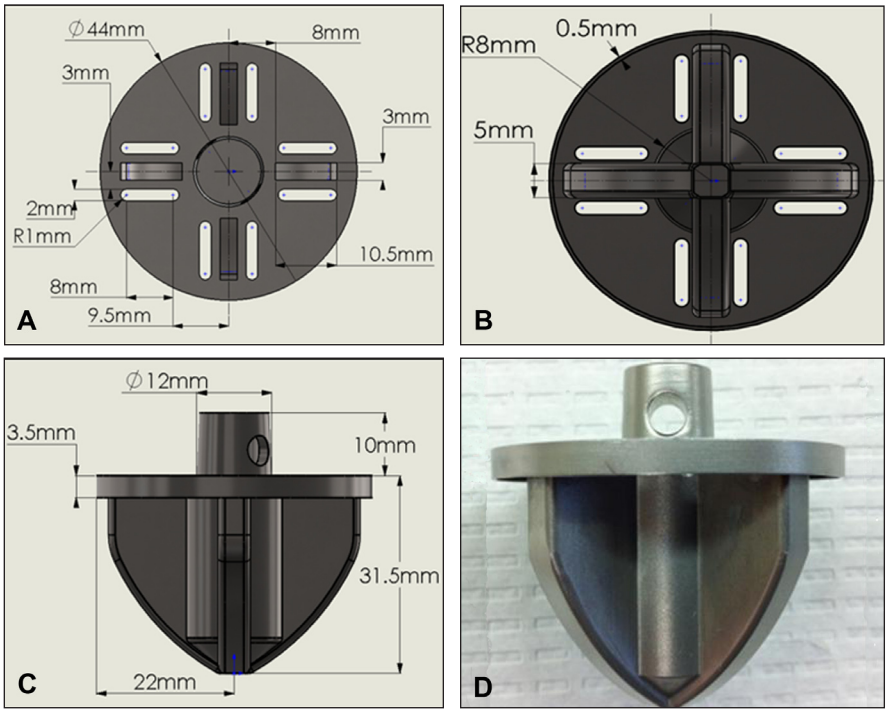

Figure 1: Computer-aided design drawings with specifications (superior profile [A], inferior profile [B], and lateral profile [C]) and representative photograph of the stemless humeral prosthesis (D).

After hardening of the bone cement or OsteoCrete, all implanted humerii were checked with anteroposterior and lateral radiographic views of the proximal humerus to confirm the proper prosthetic placement (PMMA: **Figures 2E-F**; OC: **Figures 2G-H**). The implanted specimens were stored in a -20°C freezer until mechanical testing.

Mechanical Testing

Humerii were secured in a custom-designed potting fixture with cerrobismuth alloy (Cerrobend; McMaster-Carr, Robbinsville, New Jersey) (**Figure 3**). A metal retaining collar was placed over the potted humerus to isolate the implant for pullout testing. Samples were preloaded to 5 N and then cycled from 10 to 250 N for 10 cycles at 5 mm/min, with the load and displacement data recorded at 30 Hz. The load was increased by 250 N for each subsequent 10 cycles until failure occurred. Initial stiffness was defined as the slope of the load vs displacement data from valley to peak, averaged over the first 10 loading cycles. Failure was defined as the specimen being unable to achieve the defined maximum load for a given cycle. Total work was defined as the area under the load-displacement curve from the onset of testing until the point of failure. Differences in initial stiffness, failure load, failure displacement, failure cycle, and total work were compared among the PMMA, OC, and control groups.

Statistical Analysis

Calculations were performed with SigmaPlot version 9.01 statistical software (Systat Software, Inc, Chicago, Illinois). Normality (Kolmogorov-Smirnov test) and equal variance (Levene's median test)

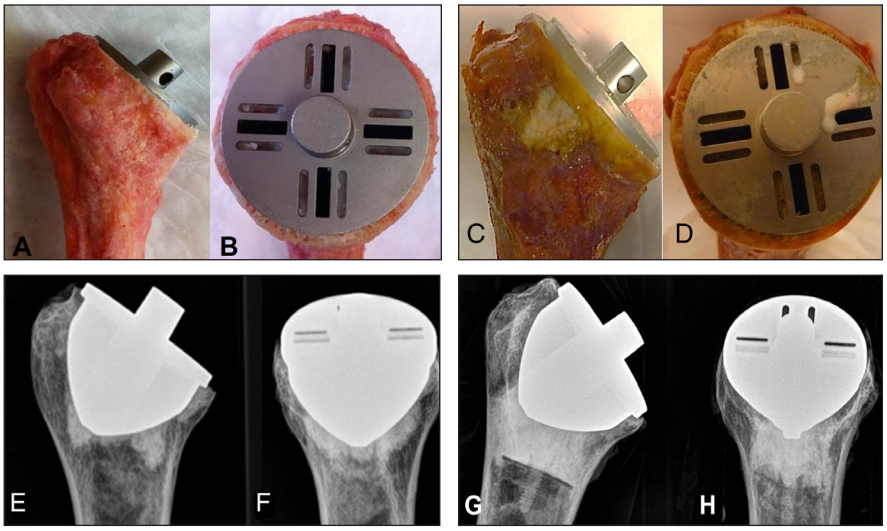

Figure 2: Post-implantation clinical photographs and anteroposterior and lateral radiographic views of the proximal humerii in the PMMA group (A-B, E-F) and OC group (C-D, G-H). Abbreviations: OC, OsteoCrete (Bone Solutions Inc, Dallas, Texas); PMMA, polymethylmethacrylate.

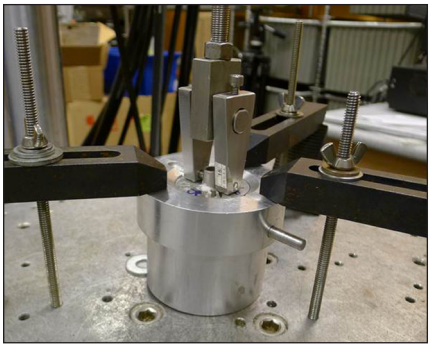

Figure 3: Humeral implant embedded in a custom fixture with Cerrobend (McMaster-Carr, Robbinsville, New Jersey) and attached to the materials testing machine (MTS Systems Corp, Eden Prairie, Minnesota).The central axis of the implant was aligned with the axis of loading.

testing were performed. Outcomes that passed normality and equal variance testing are reported as means±SDs and were compared with *t* tests or 1-way analysis of variance (ANOVA) with Tukey post-hoc testing. For these outcomes, a *P* value less than .05 was considered significant. Otherwise, data are reported as median (range). Nonparametric Kruskal-Wallis ANOVA with Mann-Whitney post-hoc testing was used for groupwise comparisons, and an adjusted *P* value of .0167 was considered significant.

Results

Humerii Characteristics

Humerii characteristics, such as patient age, race, sex, height, weight, body mass index, and BMD, are summarized in **Table 1**. There were no demographic differences among the humerii of the 3 groups (*P*>.26).

Failure Mode

The control group failed at the implant-bone interface. For both the PMMA (**Figures 4A-B**) and OC (**Figures 4C-D**) groups, failure occurred at the implant-cement or implant–bone graft substitute interface.

Time-Zero Mechanical Properties

Biomechanical properties are summarized in **Table 2**. The noncemented control group failed during the first cycle of the test protocol; therefore, initial stiffness could not be analyzed for that group. The PMMA and OC groups showed markedly higher failure loads, failure displacements, and failure cycles than the control group (*P*<.01). There was no statistically significant difference in initial stiffness between the PMMA (5682±698 N/mm) and OC (4360±732 N/mm) groups (*P*=.174). Load vs displacement curves for the failure cycles of the PMMA and OC groups are shown in **Figure 5**. There were no statistically significant differences between PMMA and OC groups for failure load, failure displacement, failure cycle, or total work (*P*>.34).

Discussion

Studies have reported satisfactory clinical outcomes of a currently available stemless shoulder prosthesis with similar functional results when compared with a conventional anatomic shoulder prosthesis, with few complications associated with humeral component fixation,[6,20-23] yet these studies state that the quality of the metaphyseal bone is a limiting factor when using a stemless prosthetic design and recommend the use of a stemmed prosthetic when the bone quality is not sufficient. Augmentation of metaphyseal fixation may be desirable in some cases, and avoidance of a permanent material such as PMMA may have an additional advantage of an improved immediate fixation without using a permanent material.

Various BGSs have been introduced, including calcium sulfate, calcium phosphate, hydroxyapatite, magnesium-based bone cement, and demineralized bone matrix. An ideal BGS would be biocompatible, have osteoinductive and osteoconductive properties, be resorbed over time, allow for injectability, be resistant to infection, and have reasonable mechanical behavior to include being self-setting in situ.[24-27] OsteoCrete has many of these features and also has adhesive properties that are advantageous when augmenting device fixation.

This study demonstrates that OsteoCrete is comparable with PMMA bone cement when tested in tension for initial stiffness, failure load, failure displacement, failure cycle, and total work. The authors observed the same failure mode patterns between PMMA and OC groups. Although this study was underpowered to detect small differences that might exist

Table 1

Humerii Characteristics[a]

Group/Humerus No.	Age, y	Race	Sex	Height, in	Weight, lb	BMI, kg/m²	BMD, g/cm²
Control group							
1	65	W	M	70	200	29	0.538
2	57	W	M	69	190	28	0.54
3	57	W	M	69	190	28	0.482
4	73	W	M	72	225	31	0.665
5	86	W	M	67	120	19	0.591
Median (range) or mean±SD	65 (57-86)			69 (67-72)	185±39	27±5	0.563±0.07
PMMA group							
1	68	W	M	68	230	35	0.549
2	67	W	M	67	190	30	0.452
3	68	W	M	74	160	21	0.48
4	69	W	M	69	125	18	0.558
5	67	W	M	68	147	22	0.425
Median (range) or mean±SD	68 (67-69)			68 (67-74)	170±4	25±7	0.493±0.06
OC group							
1	62	W	M	70	197	28	0.556
2	67	W	M	70	238	34	0.456
3	68	W	M	70	140	20	0.549
4	68	W	M	70	229	33	0.576
5	66	W	M	68	214	33	0.414
Median (range) or mean±SD	67 (62-68)			70 (68-70)	204±39	30±6	0.51±0.07

Abbreviations: BMD, bone mineral density; BMI, body mass index; M, male; OC, OsteoCrete (Bone Solutions Inc, Dallas, Texas); PMMA, polymethylmethacrylate; W, White.
[a]There were no differences in any variable among humerii of the 3 groups (P>.26).

between groups, it demonstrates that clinically important differences in biomechanical fixation, such as catastrophic failure and gross mechanical loosening, between OsteoCrete and PMMA groups do not exist at the time of surgical implantation.

OsteoCrete is a magnesium-based BGS that is both injectable and moldable at different times after mixing. It is composed of magnesium oxide, monopotassium phosphate, and a small percentage of tricalcium phosphate. The magnesium gives the cement a binder quality that allows it to resist tensile forces, thereby potentially limiting the motion between interfacing materials. OsteoCrete has been shown in preliminary studies to have a peak tensile load to failure 3 times that of calcium-based bone cements in both bone-bone and tendon-bone attachments in cadaveric models, and in in vivo models it has been shown to promote bone formation (ie, significantly greater total bone volume), improve tensile load to failure at 6 weeks,[16] and resorb by 26 weeks.[28] Most commercially available bone cements are calcium based with limited adhesive properties and exhibit little or no biodegradability. Drosos et al[24] reported the compressive and flexural strength of various commercially available BGS ceramic cements in their initial as-mixed condition and compared them with PMMA bone cement. All BGS cements are brittle, and

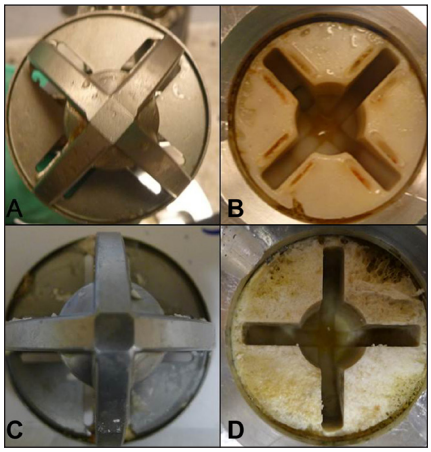

Figure 4: Representative photographs of the failure mode of the PMMA group (A, B) and OC group (C, D). Abbreviations: OC, OsteoCrete (Bone Solutions Inc, Dallas, Texas); PMMA, polymethylmethacrylate.

Table 2

Summary of Initial Stiffness, Failure Load, Failure Displacement, Failure Cycle, and Total Work

	Median (Range) or Mean±SD				
Group	Initial Stiffness, N/mm	Failure Load, N	Failure Displacement, mm	Failure Cycle, No.	Total Work, mJ
Control (n=5)	-	110±53[a,b]	0.1±0.0[a,b]	1 (1-1)[a,b]	3 (1-10)[a,b]
PMMA (n=5)	5682±698	826±381[a]	0.4±0.2[a]	31 (11-51)[a]	67 (3-123)[a]
OC (n=5)	4360±732	1058±252[b]	0.5±0.1[b]	42 (27-48)[b]	47 (27-92)[b]
P A	-	.003	.001	.008	.056
P B	-	<.001	<.001	.008	.008

Abbreviations: A, PMMA vs control; B, OsteoCrete vs control; OC, OsteoCrete (Bone Solutions Inc, Dallas, Texas); PMMA, polymethylmethacrylate.
Note. Like lowercase letters indicate significant differences for an outcome between groups by Tukey (failure load, failure displacement) or Mann-Whitney rank sum (failure cycle, total work) post-hoc test.

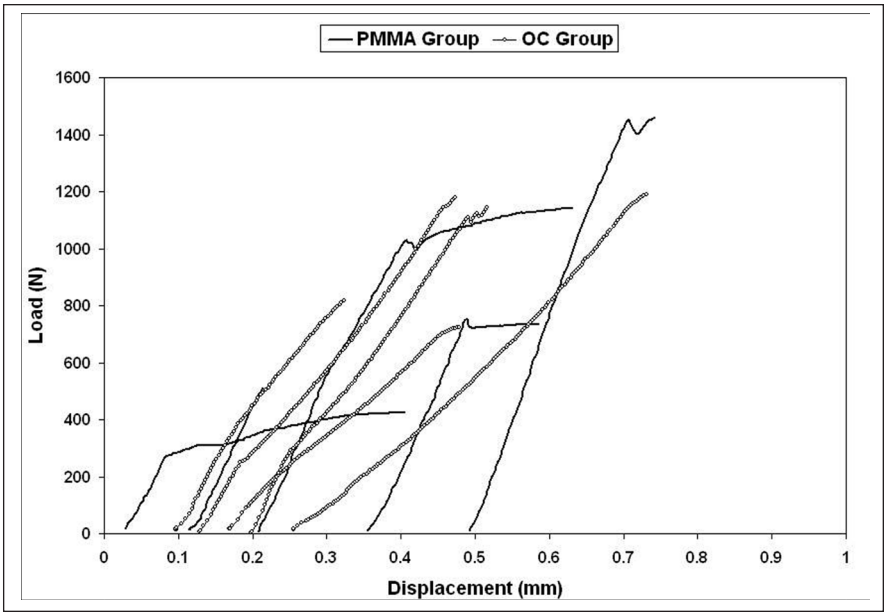

Figure 5: Load as a function of displacement for all 10 humeral implant specimens. Solid lines indicate PMMA group and round dotted lines indicate OC group. Abbreviations: OC, OsteoCrete (Bone Solutions Inc, Dallas, Texas); PMMA, polymethylmethacrylate.

when subjected to mechanical stress, they all failed under sudden crack propagation. Both in compression and bending, all BGS cements failed under loads lower than those of PMMA. In compression strength, the CS extra-strength cement showed a strength value approximately 60% (52.9±3.6 MPa) of that of PMMA. In bending strength, all BGS ceramic cements showed strengths 22% less than that of PMMA (11.9±3.6 MPa). However, the compression strength of OsteoCrete is approximately 70% of that of PMMA (62.0 MPa) at 3 hours, which showed the highest compressive strength compared with all BGS ceramic cements.[24]

These different mechanical characteristics of OsteoCrete, such as more adhesive bonding and higher compressive strength, may help explain the findings in this study. Despite the fact that OsteoCrete does not have the same strength as PMMA, it has strength that exceeds the interface (bonding) strength with the implant. Because the interface is the weak link in both groups, the surgical constructs have similar biomechanical properties. These results suggest that OsteoCrete can be an acceptable alternative to PMMA bone cement for the initial fixation of this type of prosthetic. Based on the current study, the authors cannot provide insight on the in vivo bone remodeling characteristics of this BGS. However, recent work in a revision hip replacement animal model with proximal femoral bone deficiency found that hip prostheses implanted with a putty composite material consisting of a polymer, beta-tricalcium phosphate, and recombinant human bone morphogenetic protein-2 led to new bone completely filling the defect at 12 weeks, which was not seen in the control group.[29]

The limitations of the current study include tensile loading of the implant, which is not the typical mechanism of implant loading in vivo. Tensile testing was performed to best evaluate the bonding qualities of these 2 materials.[30] In addition, the results of this study are only relevant to immediate fixation at the time of surgery. An in vivo model would be required to investigate whether this BGS could result in better bone quality to improve long-term fixation of the implant with bone remodeling that occurs after resorption of the OsteoCrete compared with PMMA. Changes in the finishing surface properties and metaphyseal geometry of the prosthesis (cage-screw design vs fin system) could result in differences in fixation properties between these 2 materials. Moreover, this study's small sample size was underpowered to detect small differences that might exist between groups, yet it provides foundational data for design-

ing future studies examining differences in stemless implant fixation. Finally, the study did not directly compare the commercially available stemless humeral prosthetics currently in use in Europe (Biomet/TESS and Zimmer/Sidus) with the prototype used in this study.

OsteoCrete is osteoconductive and biocompatible and resorbs over time while supporting bone formation, whereas PMMA does not have these properties. This study demonstrates that OsteoCrete has short-term fixation similar to that of PMMA bone cement and may therefore provide sufficient mechanical support of a metaphyseal implant in patients with poor bone quality where augmentation of implant fixation is desired. Future work may focus on directly comparing the initial fixation strength of currently available stemless humeral prosthetics with an experimental prototype augmented with a BGS.

Conclusion

There were no significant differences in the fixation properties of a magnesium-based BGS (OsteoCrete) when compared with PMMA bone cement with the designed stemless humeral prosthesis. Although a magnesium-based BGS may be a useful material for initial fixation of stemless humeral prostheses and an alternative to PMMA bone cement, an in vivo model evaluating the long-term remodeling characteristics and bone quality at the prosthetic-bone interface is needed to evaluate the clinical efficacy of this approach.

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