The incidence of total shoulder replacements (TSRs) is increasing and is projected to continue to rise.¹ One study showed that the annual number of TSRs has increased by 10.6% between 1993 and 2007,² whereas another demonstrated a 2.5-fold increase in TSRs in the past decade.³ Reported complication rates of TSR surgery range from 10% to 20%.⁴⁻⁶ Bohsali et al⁷ reported a complication rate of 14.7% in a recent review of 2810 TSRs, with the most common complication being glenoid component loosening, accounting for 34% of complications. Fixation has become a focal point of implant design in all total joint replacements, including TSRs.

The authors are from the Department of Sports Medicine and Shoulder (JGC, JB, EVC, RFW, DMD, LGV) and the Department of Biomechanics (ME, AC, TMW), Hospital for Special Surgery, New York, New York.

Dr Calcei, Dr Berhouet, Ms Elpers, and Dr Catanzano have no relevant financial relationships to disclose. Dr Wright’s institution has received research support from Lima Corporate. Dr Craig receives royalties from and has a patent with Zimmer-Biomet. Dr Warren is a paid consultant for Zimmer-Biomet. Dr Dines receives royalties from Zimmer-Biomet. Dr Gulotta is a paid consultant for Zimmer-Biomet.

Correspondence should be addressed to: Jacob G. Calcei, MD, Department of Sports Medicine and Shoulder, Hospital for Special Surgery, 535 E 70th St, New York, NY 10021 (calceij@hss.edu).

Received: October 22, 2016; Accepted: April 6, 2017.
doi: 10.3928/01477447-20170522-04
Traditional bone-cement implant interfaces have been shown to cause degeneration of peri-implant host bone due to thermonecrotic processes, possibly leading to implant loosening and failure. Porous metal implants represent an un cemented option to total joint replacements by inducing osteointegration and biologic fixation of the host tissue. The inability of cement to adapt to extrinsic loading forces is believed to contribute to eventual failure of cemented implants, whereas implants with sufficient host bone ingrowth better withstand extrinsic loading forces. Despite extensive work on porous metals in total hip and knee replacements, little attention has been devoted to analyzing this technology in a model of anatomic total shoulder. Porous metal technology in TSR has been introduced to the humeral component, as well as the central post of a polyethylene glenoid component. Bertollo et al examined osteointegration in porous coated titanium dowels implanted into sheep and found bone ingrowth to the titanium core.

Applying bone ingrowth/ongrowth technology to polyethylene glenoid components may increase osteointegration, subsequently leading to increased TSR survivorship. The purpose of the current study was to assess the amount of bone ingrowth and ongrowth of a novel hybrid polyethylene glenoid component with a porous titanium central peg using retrieved components from patients who underwent revision TSR surgery for reasons other than glenoid component loosening. The authors hypothesized that explanted titanium posts would exhibit both bone ingrowth and ongrowth with scanning electron microscopy.

**MATERIALS AND METHODS**

Six Regenerex Comprehensive Hybrid Glenoids (Biomet Orthopedics, Warsaw, Indiana) were identified in the authors’ ongoing institutional review board implant retrieval program. The glenoids were retrieved during a 5-year period, and all explanted hybrid glenoids were included in this study. The charts of these patients were then retrospectively reviewed for surgical details after institutional review board approval was obtained. Patient demographic information was collected including age, weight, height, length of implantation, indication for original arthroplasty, and reason for explantation.

When retrieving the glenoids, the polyethylene portion was removed, leaving the post in the bone. A trephine was then used around the metal post to remove the implant and a shell of the surrounding bone in a dowel fashion, as described in the technique guide for the implant. All retrievals were cleaned in a 10% bleach solution and mild detergent bath and then were cataloged into the implant database.

Next, the components were dehydrated, embedded, sectioned in the midportion of the post, and analyzed for osteointegration (Figure 1). Each implant was dehydrated in an increasing series of alcohol (75% dehydration alcohol to acetone). Specimens were embedded in a low viscosity resin (SPURRS; EMS, Hatfield, Pennsylvania), sectioned using an IsoMet 1000 precision saw (Buehler, Lake Bluff, Illinois), and subsequently ground and polished for scanning electron microscopy (SEM) analysis. The 15-mm posts were sectioned at 5 and 10 mm (Figure 1). A single cross-section from each section of the post was imaged for bone ingrowth and ongrowth analysis using a scanning electron microscope at 50x magnification. The entire segment was placed under the SEM, which sees the cross-section as a 2-dimensional image. The SEM was equipped with a backscatter detector to improve imaging of the implant-bone interface. Energy dispersive x-ray analysis was also used to verify the presence of bone in regions of interest.

Each 50x image section was segmented for titanium, resin, and bone using BIOQUANT Image Analysis Software (BIOQUANT Image Analysis Corp, Nashville, Tennessee). For the analysis, 2 measurements were taken: bone volume fraction and bone ongrowth. The bone volume fraction, or bone ingrowth, was calculated from the fraction of available pore space that was filled with bone.

To obtain this measurement, a region of interest surrounding the porous coating was identified. Specifically, the region of interest is the area covered by the outermost edge of the porous metal material. Given the shape of the glenoid post, the region of interest is typically close to a circle. Within that region, each feature (metal, bone, and possible pore space) was segmented using the BIOQUANT Image Analysis Software, which identifies the gray value of pixels in each SEM image, where metal, bone, and void had different values. To ensure the reproducibility of the segmentation process and measurements, repeated measurements were taken for the first sample. This method is similar to that used by Bertollo et al to quantify osteointegration.

Bone ongrowth was defined as the percentage of the perimeter of the porous coating that had bone adjacent to the surface. The boundary of the region of interest along the outer border of the post was used as the perimeter to establish surface area available for bone ongrowth. The percentage of the perimeter of the post that had bone directly adjacent was reported as bone ongrowth.

The bone ingrowth and ongrowth values were averaged from each section of the post to get an overall value.

---

**Figure 1**: Porous titanium-coated Regenerex glenoid peg of the Biomet Comprehensive Total Shoulder System (Biomet Orthopedics, Warsaw, Indiana). Vertical lines mark the areas of the post at 5 and 10 mm, where each post was sectioned for scanning electron microscopy analysis.
RESULTS

For the 6 patients included in the analysis, average±SD age at the time of revision was 59±10 years, with an average length of implantation of 16.3 months (range, 5-48 months). The reasons for revision included isolated subscapularis rupture (2 patients), subscapularis rupture and infection (1 patient), and rotator cuff tear other than subscapularis (3 patients) (Table). During the time period these implants were collected, no patient underwent revision for isolated glenoid loosening. All glenoids were found to be grossly stable at the time of revision surgery. At the time of revision, 1 patient received an antibiotic spacer for infection, and the remaining 5 patients underwent revision to a reverse total shoulder.

On visual inspection, adherent bone was seen on all 6 implants (Figure 2). The gross observations were confirmed with SEM analysis. These specimens that were solidly fixed at the time of surgery had an average±SD of 23%±23% ingrowth (range, 5%-55%) and 54%±36% ongrowth (range, 22%-100%) (Table, Figures 3-6). A wide range of bone ingrowth and ongrowth was observed, with examples of less bone ingrowth and ongrowth seen in Figure 3 and Figure 4, whereas Figure 5 and Figure 6 are posts with the greatest osteointegration.

DISCUSSION

This study evaluated the amount of bone ingrowth and ongrowth into the porous titanium post of a glenoid component in clinically failed shoulders. Despite the limited overall study size and short follow-up time, the retrieval analysis provides insight into host bone response and short-term viability of these implants, as well as a look into the microscopic reasons for failure.

A previous study showed that this same implant had similar clinical and radiographic findings when compared with conventional all-polyethylene cemented pegged components at early follow-up.14

<table>
<thead>
<tr>
<th>Specimen No.</th>
<th>Length of Implantation, mo</th>
<th>Reason for Revision</th>
<th>Ingrowth</th>
<th>Ongrowth</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>16</td>
<td>SS rupture</td>
<td>9%</td>
<td>41%</td>
</tr>
<tr>
<td>2</td>
<td>14.5</td>
<td>RC rupture</td>
<td>5%</td>
<td>27%</td>
</tr>
<tr>
<td>3</td>
<td>6.5</td>
<td>SS rupture</td>
<td>7%</td>
<td>35%</td>
</tr>
<tr>
<td>4</td>
<td>48</td>
<td>RC rupture</td>
<td>12%</td>
<td>22%</td>
</tr>
<tr>
<td>5</td>
<td>5</td>
<td>SS rupture, infection</td>
<td>55%</td>
<td>100%</td>
</tr>
<tr>
<td>6</td>
<td>8</td>
<td>RC rupture</td>
<td>51%</td>
<td>100%</td>
</tr>
<tr>
<td>Average</td>
<td>16.3</td>
<td></td>
<td>23%</td>
<td>54%</td>
</tr>
</tbody>
</table>

Abbreviations: RC, rotator cuff (other than subscapularis); SS, subscapularis.

These findings were particularly encouraging because bone was found to grow onto the central post on computed tomography scans of well-functioning implants, providing hope that long-term studies may show lower rates of loosening.14
In the current study, specimens were analyzed from an explantation retrieval library. Three patients experienced postoperative subscapularis rupture and the other 3 patients had rotator cuff tears other than the subscapularis, which has been shown to contribute to instability and eccentric loading of the humeral component on the glenoid surface after primary TSR.

These complications have been shown to lead to TSR failure secondary to glenoid component loosening from eccentric head loading and the rocking-horse phenomenon. In the current study, 1 patient with a subscapularis tear also had an infection, which could create an unfavorable environment for bone ingrowth, limited fixation and possible early failure. These cases are examples of TSR failure for causes other than glenoid implant fixation. However, despite these compromising situations, bone ingrowth and ongrowth were seen in each specimen in the current study.

Overall, the current results showed the presence of bone ingrowth and penetration, which appeared to provide good fixation to host bone because all glenoid pegs were grossly stable at the time of explantation. The overall results appear to be consistent with a previous study with individual samples that showed bone ingrowth penetration to the titanium core, giving reason for optimism, although these are early results with a small sample size. The current study assessed bone ingrowth in suboptimal growth environments, and it can be expected that currently intact implants are in better growth conditions and should display greater bone ingrowth than our retrieved samples. As seen in specimen 5, which showed 100% bone ongrowth and 55% bone ingrowth at 5 months, with evidence of bone as deep as the titanium core, these retrievals provide optimism that there are initial signs of osteointegration even at early stages of recovery (Figure 5).

The 2 patients with the greatest bone ingrowth and ongrowth (specimens 5 and 6) had shorter lengths of implantation (Table). Whether this points to stability being strongest early on after initial osteointegration and decreasing over time or if it is an artifact of a small sample size is unclear. Regardless, samples such as this give reason to believe that if there is early bone ingrowth in these poor growth environments, there should be greater growth and integration in more stable replacements.

The efficacy of porous titanium technology has been proven in animal models and has been used extensively in hip replacements with success. Bertollo et al analyzed porous titanium rods similar to those used in the glenoid component in this study. These rods were placed in ovine femurs to assess for bone integration. They found an average of more than 75% new bone formation, with an average of 45% in peripheral zones and nearly 15% in central zones of the porous titanium implants. In more clinically applicable studies, the porous metal technology has performed well in hip replacements with both titanium and tantalum biomaterials. Baad-Hansen et al showed no significant difference between either metal in terms of acetabular cup translation. Just 3 of 240 hip replacements needed revision in a study of trabecular metal cups done by Malizos et al with a minimum 3-year follow-up. Although the human shoulder model presents a different environment, this technology shows similarly good results in the shoulder as it does in animal models and human total hip arthroplasty, as mentioned above. Unlike the shoulder joints in animal models or the hip joint of humans, the human shoulder is not naturally a weight-bearing joint. Stress of the bone through weight bearing is a significant factor for bone integration because the cancellous bone of the joint reactively grows in response to the mechanical force placed on the joint. Without this weight loading, human shoulder implants may not experience the necessary amount of force to induce proper bone formation. In addition, the human shoulder joint has a large range of motion, leading to increased incidence of eccentric loading compared to concentric loading, and subsequent implant shifting or movement secondary to mechanical instability. Any type of implant movement can cause eccentric loading and improper reactive forces for bone formation.

The limitations of this study must be noted when evaluating the results. First, the sample size of only 6 patients with failed total shoulder arthroplasty is small, although the study included all explanted porous titanium posts from a single high volume institution, where approximately 250 Regenerex TSRs are done per year. In addition, bone ingrowth and ongrowth were only examined in a single slice at the midportion of the post. Although this method of analysis does not take into account different sections of the peg, the current authors decided that the midportion of the peg would be the single most representative slice of overall bony ingrowth and ongrowth.

Despite all of above-mentioned obstacles to ideal bone integration in the shoulder, the porous titanium technology represents potential for the future of TSRs and its continued use is warranted. This analysis is only the beginning of evaluation and innovation for this model. Many future
studies are necessary to not only better assess those implants that remain intact, but also continue to further the technology and improve the bone-implant interface. It is necessary to follow the intact implants using radiographic evidence, assessing any radiolucent lines surrounding the implant as well as any shifting or movement of the implant suggestive of loosening. This will provide better insight to the clinical efficacy and longevity of these porous titanium implants. In addition, as more of these implants are revised, it will be important to continually evaluate the failed samples at further endpoints, and assess osteointegration over time.

Finally, finding a more applicable model to represent the human shoulder would allow for continued experimentation. Due to the limited bipedal animal species that have analogous eccentrically loaded shoulder joints to humans, a more applicable model may be to non-weight bear the front limbs of a 4-legged animal model and control the weight bearing the joint receives. This would decrease range of motion but would allow for proper weight loading to be applied to the implant and joint.

Overall, the current results show that bone integration occurs into a porous titanium glenoid peg. By further assessing the factors that lead to the loosening of porous titanium glenoid implants, the authors believe that it may be possible to decrease the rate of glenoid component failure in anatomic shoulder arthroplasty.

CONCLUSION

Glenoid fixation has been a focus of recent developments in TSR implants. Porous metal implants, which promote biological fixation through osteointegration, have provided an uncemented alternative to the traditional cemented implant. In this preliminary study, the authors focused on the bone ingrowth and ongrowth of a specific porous titanium glenoid peg. The current results show that osteointegration into a porous titanium ingrowth glenoid component is possible in the short term, even in the presence of an unfavorable biomechanical environment, such as instability and rotator cuff dysfunction, as well as infection.

REFERENCES