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Revision Arthroplasty with Use of a Reverse Shoulder Prosthesis-Allograft Composite

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Investigation performed at Florida Orthopaedic Institute, Tampa, Florida

**Background:** Patients with disabling pain and loss of shoulder function with associated proximal humeral bone loss following shoulder arthroplasty have limited reliable treatment options. Our objective was to report the results, obtained as part of a prospective outcomes study, of the use of a reverse shoulder prosthesis-allograft composite in these patients.

**Methods:** Between 2002 and 2005, 353 patients treated with a reverse shoulder prosthesis were enrolled in a prospective cohort study. Twenty-five patients received, in addition, a proximal humeral allograft for the management of severe proximal humeral bone loss, and they comprise the study group. The average bone loss measured 53.6 mm (range, 34.5 to 150.3 mm). Patients were followed clinically with use of the American Shoulder and Elbow Surgeons (ASES) score, the Simple Shoulder Test (SST), and a scale with which the patients rated their satisfaction, and they were followed radiographically to detect mechanical failure, loosening, notching, and graft healing. All patients were followed for a minimum of two years (average, 30.2 months).

**Results:** The total average ASES score improved from 31.7 points preoperatively to 69.4 points at the time of follow-up (p < 0.0001), and the average SST score improved from 1.4 to 4.5 points (p < 0.0001). Nineteen patients (76%) reported a subjective good or excellent result, five reported a satisfactory result, and one reported that the result was unsatisfactory. The range of motion improved in forward flexion (from 32.7° to 82.4°; p < 0.0001), abduction (from 40.4° to 81.4°; p < 0.0001), and internal rotation. Radiographic evaluation at the time of final follow-up showed incorporation of the allograft in the metaphyseal region in 84% (twenty-one) of the twenty-five patients and incorporation of the allograft in the diaphyseal region in 76% (nineteen) of the patients. Four patients had complications.

**Conclusions:** Use of a reverse shoulder prosthesis-proximal humeral allograft composite for the treatment of shoulder dysfunction following arthroplasty associated with substantial proximal humeral bone loss has shown promising early results. The allograft may restore proximal humeral bone stock, thereby helping to maintain the height of the prosthesis bone construct and thus deltoid tension. Additional, long-term studies are needed to evaluate the longevity of this construct.

**Level of Evidence:** Therapeutic Level IV. See Instructions to Authors for a complete description of levels of evidence.

Shoulder dysfunction following an arthroplasty is a complex problem for which there are limited reliable treatment alternatives. Neer first described the challenges of arthroplasty in this setting, and others have subsequently discussed the problem.

With the added problem of proximal humeral bone loss, surgical reconstruction is an even greater challenge. Proximal humeral bone loss is often associated with tuberosity resorption or nonunion and can be observed in the setting of periprosthetic infection. Bone loss may also be encountered after removal of a well-fixed prosthesis. Regardless of the etiology, the absence of proximal humeral bone and the consequent lack of attachment of the rotator cuff tendons limit the available effective alternatives for the management of failed shoulder arthroplasty. Insufficient proximal support for a humeral component also limits the treatment options. This deficiency can extend to in-
clude muscular insertion sites, making the problem even more disabling.

We previously reported on a series of patients treated with a reverse shoulder prosthesis after failure of a hemiarthroplasty that had been performed to treat a fracture. A small subset of these patients with substantial proximal humeral bone loss was treated with a reverse shoulder prosthesis together with a proximal humeral allograft. The initial results of the structural allograft reconstruction were encouraging, with improvements in the range of motion, clinical outcomes, and self-reported patient satisfaction. The purpose of this study was to expand on that previous series by reporting the results in a larger group of patients who were followed prospectively after treatment with a reverse shoulder prosthesis-structural allograft composite.

**Materials and Methods**

Between October 2002 and October 2005, 353 patients treated with a reverse shoulder prosthesis at our institution were enrolled in a prospective outcomes study (IRB [institutional review board] numbers 100881 and 106273). Ninety patients had the procedure because of a failed arthroplasty and instability associated with rotator cuff deficiency, shoulder pain, and dysfunction. Twenty-five of these patients satisfied our inclusion and exclusion criteria and were included in the present study. The inclusion criteria were pain associated with instability and rotator cuff deficiency following a failed arthroplasty, proximal humeral bone loss requiring augmentation with a structural proximal humeral allograft, a functional deltoid muscle, stable medical comorbidities that allowed surgical treatment, and failed previous attempts at nonoperative treatment. The exclusion criteria were a dysfunctional deltoid muscle, a duration of follow-up of less than twenty-four months (two patients died less than two years postoperatively and were excluded), and/or augmentation with another source of structural allograft (three patients had a proximal femoral allograft and were excluded).

A reasonable trial of nonoperative treatment, including pain management, physical therapy, and activity modification, had failed for all twenty-five patients. The nonoperative treatment was not standardized since many of these patients were referred from other institutions.

The duration of follow-up averaged 30.2 months (range, twenty-four to fifty-four months). There were twenty-three women and two men. The bone loss was secondary to a failed hemiarthroplasty that had been done to treat a fracture in twenty-four patients and a failed bipolar hemiarthroplasty in one patient (Fig. 1). The patients had an irreparable rotator cuff tear confirmed at the time of surgery.

The patients were treated with a reverse shoulder arthroplasty augmented with a structural proximal humeral allograft for the management of severe proximal humeral bone loss with use of a previously described technique. The decision to use a proximal humeral allograft was made intraoperatively on the basis of soft-tissue balancing, the stability that was obtained, and the severity of bone loss. Bone loss was anticipated preoperatively and confirmed intraoperatively after the existing prosthesis was removed. A glenosphere with a center of rotation lateral to the glenoid (6 mm lateral in twenty-one patients and 10 mm lateral in four patients) was used in each case.

Implantation of the Reverse Shoulder Prosthesis (DJO Surgical, Austin, Texas) in conjunction with a fresh-frozen proximal humeral allograft (University of Miami Tissue Bank, University of Miami Miller School of Medicine, Miami, Florida) was performed by the senior author (M.F.). The humeral stem was removed, and specimens were obtained from all patients for intraoperative frozen-section analysis and culture. The previous cement mantle was left intact when it was stable, except when the frozen-section analysis revealed more than five polymorphonuclear neutrophils per high-power field, in which case the entire cement mantle was removed. Patients who were known to have had a preoperative infection (three patients), those who had positive results on culture, and those for whom frozen-section analysis revealed more than five polymorphonuclear neutrophils per high-power field were managed with a minimum of six weeks of intravenous antibiotics as directed by an infectious disease specialist. All others were treated with prophylactic intravenous antibiotics for a minimum of two weeks postoperatively, which was the time necessary for the final results of the aerobic and anaerobic cultures of the intraoperative specimens to be reported. The three pa-
tients who were known to have had a previous infection had, prior to the index revision arthroplasty and before presenting to us, at least one surgical débridement with removal of the prosthetic components and replacement with antibiotic-laden cement spacers. The spacer was in place for one month in one patient, for four months in another, and for more than seven years in the third.

**Surgical Technique for Use of the Proximal Humeral Allograft**

Intraoperatively, the proximal humeral allograft was fashioned with the goal of restoring the proximal bone necessary to provide adequate deltoid tension and hence prosthetic stability. The proximal humeral allograft was cut to address the deficiency of the proximal part of the native humerus. In order to do this, we cut the allograft humeral head at the level of the anatomic neck and removed all of the cancellous allograft bone from the medullary canal. We then determined the appropriate height of the allograft by inspecting how much diaphyseal bone was remaining and estimating how much of the proximal part of the humerus would need to be replaced to restore the bone stock and allow a stable reduction (Fig. 2). An oscillating saw was used to create a step-cut within the allograft bone such that 5 cm of bone remained laterally, resulting in a lateral bone plate, and 1 to 2 cm of bone remained medially (Fig. 3). All soft tissues were removed from the graft with the exception of the subscapularis tendon stump, which could be used to later repair the native subscapularis. The allograft was then fixed to the native humerus with two 1.7-mm cables, and a humeral guide was used to ensure correct orientation of the humeral stem (Fig. 4). The humeral component was then cemented into this construct, and the cables were tightened.

One patient with very severe bone loss required additional plate fixation of the graft in order to provide sufficient construct stability. In twenty-two patients, the subscapularis tendon was repaired to the allograft subscapularis tendon stump. An end-to-end repair was performed in cases with a poorly mobile subscapularis, and a pants-over-vest repair was used when the subscapularis was fairly mobile. In sixteen patients, the humeral component was cemented within a pre-existing cement mantle without complete removal of that mantle. A humeral implant with a long (175-mm) stem was selected when a cement mantle was not present, when the cement mantle was removed completely at the time of surgery, or when the medial aspect of the graft exceeded 120 mm. Five long humeral stems were used. The remaining twenty procedures were performed with use of a 109-mm or shorter stem.

**Preoperative and Postoperative Clinical Assessment**

Patients were assessed preoperatively, at three months postoperatively, and at several follow-up points until at least two years postoperatively. Patients completed forms that included the American Shoulder and Elbow Surgeons (ASES) assessment for pain and function, the Simple Shoulder Test (SST), and a scale for rating overall satisfaction with the outcome of the surgery (unsatisfactory, satisfactory, good, or excellent). Preoperative SST scores were not available for one patient, who did not complete the questionnaire.

In addition, each patient was videotaped preoperatively and postoperatively while demonstrating the range of motion of the shoulder with their best effort at active direct forward flexion, abduction, and external rotation. Research assistants who were not involved in the treatment of the patients measured the range of shoulder motion preoperatively and postoperatively with use of a digital goniometer as the videotapes were played on a computer. Internal rotation was visually estimated during videotape playback by noting the level of the spine, ranging from the sacrum to T4, that the patient could reach with the thumb. If the patient was not able to reach the sacrum, the level reached was noted as the greater trochanter. The preoperative external rotation measurement was not available for one patient.

**Radiographic Assessment**

**Preoperative**

All patients were evaluated with anteroposterior, Y lateral, internal and external rotation Grashey, and axillary plain radiographs, according to a standard protocol at our institution. These views allowed us to identify instability and loss of glenoid bone as well as evidence of humeral loosening with use of es-
Established criteria. Instability was evaluated according to the position of the humeral head with respect to the glenoid and the extent to which the head was subluxated. Grade 0 indicated no subluxation of the humeral head, grade 1 indicated <25% subluxation with respect to the glenoid, grade 2 indicated 25% to 50% subluxation, and grade 3 indicated >50% subluxation.

Glenoid bone loss was evaluated according to the degree and location of glenoid bone erosion. Grade 0 indicated no erosion, with a visible subchondral plate, grade 1 indicated <5 mm of erosion, grade 2 indicated 5 to 10 mm of erosion approaching the lateral aspect of the base of the coracoid, and grade 3 represented severe erosion beyond the base of the coracoid.

Evidence of humeral loosening was measured with use of the grading system described by Sperling et al. The last available postoperative radiographs were analyzed for baseplate radiolucency (radiolucency around the baseplate and/or screws), humeral radiolucency, inferior glenoid notching, instability (dislocation of the polyethylene humeral cup from the glenosphere), and hardware failure. The allograft was also evaluated for incorporation, resorption, and fragmentation, in both the metaphyseal and the diaphyseal region, as seen on orthogonal radiographs. The allograft junction was considered to be incorporated into the host bone when the junction line was no longer visible (Fig. 6) or the junction was seen to be bridged with periosteal bone on at least two orthogonal views. Resorption was defined as disappearance of >25% of the allograft bone on the last available radiographs when compared with the appearance on an equivalent immediate postoperative radiographic view. Fragmentation was defined as the presence of two or more pieces of the allograft on the last available radiographs. If the allograft did not meet the above criteria for incorporation, resorption, or fragmentation, it was noted simply as not incorporated.

Statistical Methods
Preoperative and postoperative pain and function scores and range-of-motion values in forward flexion, abduction, and external rotation were compared by an independent statistician with use of a paired t test (MedCalc, version 9.2.0.1; MedCalc...
Source of Funding
DJO Surgical provided research support to the Foundation for Orthopaedic Research and Education. However, DJO Surgical did not have input into this study as it was an investigator-initiated study.

Results
Clinical Outcomes Measures
The clinical outcomes are summarized in Table I. The average total ASES score improved from 31.7 points preoperatively to 69.4 points postoperatively (a change of 37.7 points; p < 0.0001). The average ASES pain score improved from 18.4 points preoperatively to 38.1 points postoperatively (a change of 19.7 points; p < 0.0001). The average ASES function score improved from 13.3 points preoperatively to 31.3 points postoperatively (a change of 18.0 points; p < 0.0001). The average SST score improved from 1.4 points preoperatively to 4.5 points postoperatively (a change of 3.1 points; p < 0.0001).

Nineteen (76%) of the twenty-five patients subjectively rated the result as good or excellent at the time of final follow-up. Five patients (20%) rated the outcome as satisfactory, and one patient (4%) was unsatisfied. The unsatisfied patient had a cement spacer in place for more than seven years prior to the reconstruction to treat an infection. The patient had a postoperative dislocation, and the prosthesis remained unstable despite attempts at closed reduction. Instability was perceived to be secondary to severe deltid atrophy, and no additional surgical management was performed.

The range of motion improved significantly in forward flexion and abduction as compared with the preoperative values. The average forward flexion improved from 32.7° preoperatively to 82.4° postoperatively (a change of 49.7°; p < 0.0001). The average abduction improved from 40.4° preoperatively to 81.4° postoperatively (a change of 41.0°; p < 0.0001). The average external rotation improved from 9.9° preoperatively to 17.6° postoperatively (a change of 7.7°; p = 0.0793). The average internal rotation improved from the sacrum to the L4 vertebral level.

Radiographic Analysis
Preoperative
The preoperative radiographs of one patient could not be located, leaving twenty-four patients for the analysis of the preoperative radiographic findings.

Analysis of the preoperative radiographs revealed severe instability in six patients, moderate instability in six, mild instability in three, and no instability in six. The most common direction of the subluxation or dislocation of the humeral head was superior (in eight of the fifteen patients with instability). The position of the humeral head with respect to the glenoid could not be evaluated in the three patients with a prior infection because a cement spacer was in place.

Glenoid erosion was rated as moderate in two patients, mild in eight, and not present in six. Glenoid erosion could not be evaluated on the plain radiographs of eight patients because adequate visualization of the entire glenoid was not possible.

According to the criteria described by Sperling et al., ten patients had no radiographic evidence of humeral loosening, two had radiolucencies around the humeral component without being “at risk” for loosening, and nine were deemed to be “at risk” for humeral component loosening when evaluated preoperatively. The three patients with a prior infection were not evaluated for humeral loosening because the humeral component had been removed previously. Nineteen of the twenty-one patients who did not have a preoperative infection had a cemented humeral stem in place. One patient had a humeral shaft fracture distal to the tip of the hemiarthroplasty humeral stem.

Postoperative
The average bone loss measured on the immediate postoperative radiographs was 53.6 mm (range, 34.5 to 150.3 mm). On final radiographic evaluation, there were no cases of inferior scapular notching, dislocation, broken hardware, humeral loosening, or loosening of the glenoid baseplate. Sixteen of the twenty-five reverse-prosthesis stems had been implanted within or adjacent to a preexisting cement mantle, without complete
removal of that mantle. One patient had a subluxation of the humeral socket with respect to the glenosphere without complete dislocation. One patient had the graft removed, as described in the Complications section below, and thus could not be evaluated for graft incorporation. Of the remaining twenty-four patients, twenty-one (88%) had incorporation of the allograft in the metaphyseal region whereas one had graft resorption in that region. Radiographic evaluation of the diaphyseal region showed graft incorporation in nineteen patients (79%), graft resorption in one, and graft fragmentation in none. Nonincorporation of the graft in the absence of resorption or fragmentation was noted in the diaphyseal region in four patients. No reaction or change in the appearance of the allograft-host junction was noted in any of these four patients when the follow-up radiographs were compared with the immediate postoperative radiographs.

Complications
Four patients had complications. One patient fell nineteen months after the surgery. The injury resulted in dislocation of the prosthesis as well as fracture of both the allograft and the polyethylene component. Revision surgery consisted of replacement of the polyethylene component and replacement of the proximal humeral allograft with a proximal femoral allograft as another proximal humeral allograft was not available. Postoperatively, the patient experienced recurrent instability, and the arthroplasty was subsequently revised with use of a larger-diameter glenosphere. At the time of the last follow-up, there had been no additional episodes of instability and the patient rated her outcome as excellent. The second complication occurred in the patient who had had a cement spacer in place for more than seven years. This patient experienced a dislocation of the reverse shoulder prosthesis seven months postoperatively, and she had severe deltoid atrophy. In view of the severity of the atrophy, we believed that additional surgery would be unsuccessful in achieving joint stability. She continued to have instability and rated her outcome as unsatisfactory. The third complication was an allograft fracture, first noted radiographically thirteen months postoperatively and treated conservatively because of the absence of clinical symptoms. After twenty-nine months of follow-up, this patient rated her outcome as satisfactory. The fourth complication was a non-displaced fracture of the acromion observed three months postoperatively. It was managed successfully with a sling and activity modifications. This patient also rated her outcome as satisfactory at twenty-nine months postoperatively.

As mentioned in the Materials and Methods section, two patients were not included in this study because they died less than two years postoperatively (the minimum duration of follow-up required for inclusion). One of these patients had a methicillin-resistant Staphylococcus aureus infection noted eight days postoperatively and underwent débridement twice. The allograft was removed without replacement during the first débridement, performed at eleven days postoperatively, and the
polyethylene component was exchanged at the second surgery twenty-eight days postoperatively. The other patient without a two-year follow-up had no known complications when she was last seen twelve months postoperatively.

Discussion

Proximal humeral bone loss not only contributes to shoulder dysfunction after arthroplasty, but may also be a major contributor to failure of the prosthesis. Such bone loss is seen following aggressive tumor resection, trauma, severe infection, and revision of a shoulder reconstruction. Bone loss can be exacerbated in revision surgery during extraction of a well-fixed humeral stem or as a result of intraoperative fracture. Proximal humeral bone loss can result in high rates of instability, early humeral loosening, and rotational weakness. Many patients with severe bone loss have poor function secondary to loss of the rotator cuff attachment.

Patients with a failed arthroplasty associated with proximal humeral bone loss have been treated with hemiarthroplasty, osteochondral allografting, arthrodesis, and the use of a massive tumor prosthesis. Hemiarthroplasty alone has been associated with high rates of complications, including a high rate of humeral stem loosening, in the setting of proximal humeral bone loss. Therefore, extensive bone loss is often addressed with use of an allograft-prosthesis complex or a long-stem prosthesis. It has been our experience that hemiarthroplasty does not provide reliable improvements in function in patients with extensive proximal humeral bone loss.

Use of the reverse shoulder replacement in the setting of proximal humeral bone loss has been shown to both relieve pain and improve function. Kassab et al. reported on seven patients who had been treated with a proximal humeral allograft-reverse prosthesis composite. As compared with patients treated with other methods in the series, these individuals had the best results, with a mean Musculoskeletal Tumor Society score of 88% at a mean of eighty-five months postoperatively. In a previous study, we reported on the use of the reverse prosthesis following failure of a humeral hemiarthroplasty that had been done to treat a fracture. After encountering humeral component loosening due to severe proximal humeral bone loss in two of the six patients treated initially in this series, we managed eight of the remaining twenty-three patients with a proximal humeral allograft-reverse shoulder prosthesis composite. While we described the concept of restoring anatomy with use of a proximal humeral allograft, there were too few patients in the series to enable us to draw any statistical conclusions regarding its benefits. Nonetheless, we observed a much higher rate of good-to-excellent patient-reported satisfaction in the subset of patients treated with the allograft (six of eight) compared with the patients treated without an allograft (ten of twenty-one).

In our present study, the decision to use a proximal humeral allograft was not made preoperatively. The intraoperative decision to use an allograft was based on the amount of proximal bone loss that was present following removal of the humeral stem combined with an assessment of the soft-tissue tension of the shoulder. When proximal humeral bone loss extends beyond the area of the normal rotator cuff insertion, restoring this bone can facilitate cuff reattachment. In the current study, the allograft provided a stump of residual subscapularis tendon that was sutured to the native subscapularis tendon in twenty-two of the twenty-five patients. We believe that the subscapularis tendon may play an important role in achieving initial stability of the reverse prosthesis, although this has not been clinically proven, and we recommend repair when possible. In this study, only one patient had instability unrelated to trauma. Interestingly, this patient did not have a subscapularis repair since there was no identifiable native subscapularis tendon at the time of surgery.

An additional advantage of using a proximal humeral allograft may be improvement in the stability of the humeral stem. Substantial rotational forces are transmitted to the humeral stem of the reverse shoulder replacement. Achieving secure fixation and long-term stability of the humeral stem is therefore paramount. A previous cement mantle is often encountered in the revision setting, and when there is proximal

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*The data are given as the mean with the range in parentheses.
humeral bone loss this mantle may need to be removed to facilitate placement and cementation of a long-stem implant. Alternatively, a proximal humeral allograft may be used to provide sufficient structural and rotational support for the humeral component. In the absence of infection, the allograft-prosthesis composite can be cemented within the preexisting cement mantle, as was done in sixteen patients in this series. In many cases, this eliminates the need for potentially destructive attempts to remove the preexisting cement mantle.

The allograft also reestablishes the natural contour of the proximal part of the humerus and serves to lateralize the line of pull of the deltoid muscle. This increases the total resultant force of the deltoid as a pulley\textsuperscript{2,23} and provides additional bone stock should future reconstructions become necessary. Additionally, the allograft serves to maintain the height of the prosthesis-bone construct, thus helping to optimize deltoid tension. In patients with poorly compliant soft tissue, however, the addition of an allograft may overtension the available soft-tissue envelope and should not be used.

A high complication rate has been reported following reverse shoulder arthroplasty without a proximal humeral allograft in the setting of extensive proximal humeral bone loss\textsuperscript{2,24,25}. The reasonably low rate of complications in our study may be related to the extensive surgical experience of the senior author, and these reconstructions may be best performed by orthopaedic surgeons with considerable experience with shoulder reconstruction.

The study has several limitations. The results cannot be compared with those in a control group in which reverse shoulder arthroplasty was performed without the use of a proximal humeral allograft in the setting of substantial bone loss. Since the intraoperative decision to augment the reconstruction depended on both osseous and soft-tissue deficiencies, the ability to prospectively compare these two groups would be hindered by the differences in the soft-tissue deficiencies that were ultimately treated by osseous augmentation. We also encountered difficulty in accurately assessing the exact amount of bone loss intraoperatively. A final, yet important, limitation of this study is the short-term follow-up. We will continue to follow these patients to observe whether these outcomes are sustainable.

Use of a reverse shoulder prosthesis-proximal humeral allograft composite to treat shoulder dysfunction following failure of an arthroplasty associated with extensive proximal humeral bone loss has shown promising early results. We believe that the use of a structural proximal humeral allograft should be considered in the setting of severe bone loss involving the entire rotator cuff insertion with a compliant soft-tissue envelope. The allograft may restore proximal humeral bone stock, thereby helping to maintain the height of the prosthesis-bone construct and thus deltoid tension. In addition, it may provide sufficient humeral stem stability to avoid removal of a preexisting cement mantle. Additional studies are necessary to evaluate the long-term outcomes of this procedure as well as the longevity of this construct.


