Radiographic Stability of Ingrowth Humeral Stems in Total Shoulder Arthroplasty

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Abstract

Background Cemented and uncemented stem types are available for TSA. An early uncemented stem designed for bone ingrowth had radiographic loosening of approximately 10% at intermediate followup (mean 4.6 years). Subsequent stem modifications included circumferential metaphyseal porous coating to enhance ingrowth and reduce loosening rates.

Questions/purposes We asked whether the radiographic loosening rates would be lower after this design modification and whether the pain score and ROM would be improved.

Patients and Methods We reviewed the medical records and radiographs of 76 patients undergoing primary TSA with circumferential metaphyseal porous-coated stems for osteoarthritis between 1995 and 2005. All patients had a complete standardized series of radiographs preoperatively, postoperatively, and at final followup. Humeral stems were evaluated for any radiolucent lines by zone, progression of lucencies, and shift in component position.

The minimum radiographic followup was 25 months (average, 52 months; range, 25–90 months).

Results There were no radiolucencies seen on the initial postoperative radiographs. Five stems had 1-mm radiolucent lines in one to four of eight zones at final followup. One had a glenoid component judged at risk. None of the humeral components were judged at risk or loose or to have shifted. The pain scores and ROM improved postoperatively.

Conclusions Proximally coated humeral stems for TSA showed few radiolucencies and no loosening at short- to midterm followup, reflecting an improvement over previous series. We now use these stems for primary TSAs and reserve cemented stems only when uncemented fixation is not possible owing to bony deficiency.

Level of Evidence Level IV, case series. See Guidelines for Authors for a complete description of levels of evidence.

Introduction

The TSA has become a reliable alternative treatment for degenerative conditions of the glenohumeral joint. Several reports suggest reliable pain relief with long-term survivorship of 84% to 96% at 3.3 to 12.2 years [3, 22, 24]. However, as with all arthroplasties, complications, including infection, aseptic loosening, instability, and mechanical failure, present therapeutic challenges in long-term management of patients. Although much of the discussion regarding TSA complications has centered on the glenoid component, loosening of the humeral stem is a potential long-term problem. Few studies to date have focused on humeral loosening as a major mode of failure in TSA [1, 2, 8, 12, 18–20].

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Each author certifies that his or her institution has approved the reporting of these cases, that all investigations were conducted in conformity with ethical principles of research, and that an informed consent for participating in the study was obtained.

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Investigators have reported varying degrees of success with cemented, press-fit, and ingrowth humeral stem designs. In one study, cemented humeral stems had a reported 2% rate of radiographic loosening at a mean of 6.6 years [18]. In contrast, reports of press-fit stems have been more variable. For instance, Torchia et al. [22] found 49% of uncemented stems had shifted in position at 12 years of followup and Sanchez-Sotelo et al. [19] reported 55.6% of the 72 press-fit Neer II stems were at risk for loosening at an average followup of 4.2 years. However, Matsen et al. [8] reported no loosening in 131 press-fit stems in a mixed population of patients undergoing either TSA or hemiarthroplasty, whereas Roper et al. [16] noted only one of 25 press-fit stems were loose at a mean followup of 5 years. Finally, in a joint registry analysis of 1584 primary shoulder replacements, 108 had humeral component revision [2].

Ingrowth humeral stems were developed to provide a more biologic solution to humeral fixation, similar to the evolution of uncemented stems in THA. Early series with small numbers of patients had a radiographic loosening rate of approximately 10% at 3 to 5 years [9, 24]. A larger series of 62 first-generation ingrowth stems confirmed this finding, with 9.7% of stems judged at risk at an average of 4.6 years' followup [20]. The stems in that series had porous coating applied only under the humeral head. In 1995, that stem was modified to include circumferential porous coating around the proximal $\frac{1}{4}$ in an effort to improve humeral fixation.

In this study, we determined (1) whether this metaphyseal porous-coated design would improve loosening rates compared with rates reported in previous studies and (2) the pain score and ROM, for this stem at intermediate followup.

Patients and Materials

Between 1995 and 2005, we performed 447 TSAs in 393 patients for primary osteoarthritis. Of these, 67 did not use a stem with proximal porous coating, leaving 380 for further analysis. Two hundred nine of the 447 shoulders had incomplete followup or followup with radiographs sent from an outside facility and were excluded, leaving 171 arthroplasties in 169 patients (45% of the total eligible TSAs) with at least 2 years of radiographic surveillance at our institution. In these 171 replacements, 78 used a pegged glenoid component whereas 93 used a keeled implant. Several studies have shown differences in radiographic and biomechanical behavior of glenoid components fixed with a keel versus those with pegs [5–7, 13]. Other studies indicate differing designs of glenoids may have different radiographic and clinical performances

affecting the fixation of the humeral component [1, 2, 21]. Therefore, we controlled this variable by equalizing the number of cases and duration of followup of the two common, contemporary all-polyethylene glenoid implant types. To minimize the effect of the glenoid component on stem performance, 40 pegged implants placed later in the study period and 55 keeled glenoids placed earlier in the study period were excluded, leaving 76 shoulders to comprise the study group; 38 with pegged glenoid components and 38 with keeled implants with similar lengths of followup.

Twenty-two (29%) patients were women and 54 (71%) were men. Their average age at the time of surgery was 68.4 years (range, 52–80 years). The operative side was the left in 37 (49%) patients and the right in 39 (51%). Six patients had small or medium-sized rotator cuff tears at the time of surgery and underwent repair. There were no large or massive tears. The minimum clinical followup was 10 months (average, 63.6 months; range, 10–125 months). All patients had a minimum of 2 years' radiographic followup with an average of 51.5 months (range, 25–90 months). No patients were lost to followup.

Two of us (JWS, RHC) performed all surgery. The humeral implants were modular (Cofield 2; Smith and Nephew, Memphis, TN). Stems were made of cobalt-chrome material with a sintered porous coating on the undersurface of the plate that rested on the top of the cut cancellous surface of the proximal humerus and additional sintered, beaded material extending down the stem for $\frac{1}{4}$ of its length. The more distal portion of the stem was polished. There were six stem diameters, increasing in diameter by 2-mm increments. There were 26 modular humeral heads that could be implanted on these stems to create stability in the soft tissue envelope without causing the joint to be too tightly filled.

The humeral canal was prepared with circular reamers such that there was a tight fit of the distal aspect of the humeral component in the diaphysis of the humerus. The metaphyseal osteotomy was made using a guide with intramedullary and extramedullary referencing. A trial component cut the slots for the fins of the implant. The selected humeral head and stem were impacted together on the back table and then seated firmly in the humerus. All implants, after positioning, were tight proximally and distally in the humerus.

Postoperative care included a supervised physiotherapy program stressing early passive ROM and 6 weeks later active assisted ROM in forward elevation and external rotation. Active ROM, strengthening, and return to full activity commenced at 3 months.

All patients underwent a standardized series of clinical and radiographic evaluations at their preoperative visit, at the initial postoperative visit (6 weeks), and then at 1, 2, 5, and 10 years until last followup. The clinical data were

assessed by the treating surgeons (JWS, RHC) and included pain level and active ROM, including forward elevation, external rotation, and internal rotation. Postoperatively, patients were evaluated again for pain, ROM, and any postoperative complications. The score used to grade the level of pain was as follows: 1 = no pain, 2 = slight pain, 3 = pain after unusual activity, 4 = moderate pain, and 5 = severe pain [1, 6]. Forward elevation and external rotation were recorded in degrees of motion and internal rotation was noted at the most cephalad vertebral level the patient could reach.

We obtained a three-view radiographic series of the shoulder including a 40° posterior oblique in external rotation, a 40° posterior oblique in internal rotation, and an axillary lateral at the postoperative visits; the standard three-view series was supplemented by at least two fluoroscopically assisted views of the glenoid. The number of supplementary views was determined by their ability to clearly show the cement mantle of the glenoid component and the interface between the bone of the humeral osteotomy and the ingrowth surface on the proximal plate of the humeral implant. Two sets of films were analyzed. The first was at 1 to 2 months postoperatively and the second at the time of last radiographic followup. Four observers (TWT, PCZ, JWS, RHC, including the two treating surgeons) as a group simultaneously evaluated the standard and supplementary sets of films for any radiolucent lines around the humeral stem or the glenoid component and for any shift in position of the components from the initial postoperative films to the films at the time of final followup, and a consensus was reached [10, 11, 14, 15, 18–20]. Patients' clinical histories were not available at the time of reading of the radiographs, however, the observations were not blinded for patient name or number so one of the four observers would have been familiar with each of the cases (radiographs) being reviewed. Radiolucencies were graded using the zone system analogous to that of Gruen et al. for THA [11] (Fig. 1). In this system, the humeral stem is divided into thirds and Zones 1 to 3 correspond to the lateral aspect of the stem extending from proximal to distal. Zone 4 is at the tip of the stem and Zones 5 to 7 extend from distal to proximal on the medial aspect of the stem. Zone 8 is directly underneath the humeral head. Lines were graded according to size as 1 mm, 1.5 mm, 2 mm, or greater than 2 mm. If radiolucencies were present at final followup, previous films were evaluated for evidence of progression. We are unaware of previous reports of interobserver reliability for radiographic evaluation of humeral stem components and performed no such study here but there has been good interobserver reliability reported regarding evaluation of glenoid components with a Cronbach alpha score of 0.87 [3]. We judged a humeral stem to be radiographically “at risk” for clinically

Fig. 1 Humeral stems were evaluated for radiolucent lines using the zone system for Neer implants [18]. Zone 1 corresponds to the superior lateral aspect of the stem near the greater tuberosity. Zones proceed sequentially moving distally around the tip and back up the medial side. Zone 8 corresponds to the area under the humeral head. (Reprinted with permission from Elsevier from Sperling JW, Cofield RH, O'Driscoll SW, Torchia ME, Rowland CM. Radiographic assessment of ingrowth total shoulder arthroplasty. *J Shoulder Elbow Surg.* 2000;9:507–513.)

important loosening if it had a radiolucent line 2 mm or greater in three or more zones or when the observers identified a shift in stem position between the postoperative and the final followup radiographs [15, 18–20].

Descriptive statistics are reported as mean (range) for continuous measures and number (percentage) for discrete assessments. For clinical outcomes, we used a paired *t* test to compare preoperative versus postoperative changes in pain, forward elevation, external rotation, and internal rotation at last clinical contact. Owing to the sample size of 76 patients, we chose to use parametric tests (central limit theorem). Using nonparametric tests, we arrived at the same conclusions as we did with the parametric tests. There were no missing data. Statistical analyses were performed using SAS®/STAT Version 9 software (SAS Institute Inc, Cary, NC).

Results

We observed no radiolucent lines around any of the humeral stems during the early postoperative period (Fig. 2). At

Fig. 2 This initial postoperative radiograph shows no radiolucent lines. No humeral stems in this series had any evidence of radiolucency observed on these early followup films.

an average of 52 months (range, 25–90 months), no implants had shifted position. Five stems had radiolucent lines: one had an isolated 1-mm line in Zone 2 whereas another had a similar lucency in Zone 7; another stem had a 1-mm radiolucency in Zones 2 and 7; one stem had 1-mm radiolucent lines in Zones 1, 2, and 6 (Fig. 3); the remaining stem had 1-mm lines in Zones 2, 3, 6, and 7. Of these five stems, three were associated with keeled components whereas the remaining two had pegged implants. Only one of these stems was associated with a glenoid component graded as at risk for loosening. The remaining 71 stems had no radiolucent lines. There were no progressive radiolucencies. None of the stems were judged at risk for loosening (Fig. 4).

At last followup, the average pain score decreased ($p < 0.001$) to 1.6. Average forward elevation improved ($p < 0.001$) to 151° . Similarly, external rotation increased ($p < 0.001$) to 57.1° and internal rotation improved ($p < 0.001$) to L1. Preoperatively, the average pain score was 4.6. Average forward elevation was 103.3° , external rotation was 29.7° , and internal rotation was to L5.

There were five complications. Two patients had glenohumeral instability and one patient had glenoid loosening develop. There were two neurologic complications: one patient had a brachial plexopathy that resolved by final followup and one patient had a delayed onset of

neuropathic pain. The patient with a loose glenoid component underwent a revision operation, but no other patients had additional surgery.

Discussion

Although much of the discussion surrounding failure modes of TSA has focused on the glenoid component, aseptic loosening of the humeral implant is another potential long-term problem after this procedure. Multiple TSA systems with various methods of humeral fixation have been advanced. Although cemented stems are associated with a low rate of radiographic loosening, difficulty with revising these components with infection, component malposition, or aseptic loosening is a challenge to the surgeon owing to difficulty with stem extraction, complete removal of the remaining cement, and bone loss [18]. Therefore, many surgeons turned to uncemented fixation as an alternative. Unfortunately, early studies of press-fit and ingrowth humeral stems showed loosening rates between 4% to 56% at 4 to 12 years of followup [16, 19, 22]. We asked whether a modified stem using metaphyseal ingrowth surfacing would result in improved loosening rates compared with other previously reported designs and determined pain levels and ROM associated with this stem.

The study has certain limitations. First, this is a retrospective case series lacking a control group. Although we contrasted our results with those available in the literature, we did not have an internal control with which to compare our results. Second is the possibility for selection bias, as we did not include all patients treated during the study period. Rather, we attempted to minimize the potential impact of the glenoid component by analyzing equal numbers of patients with pegged versus keeled glenoid components with similar lengths of followup. However, pegged glenoid components came into routine use at a later date in our institution than keeled implants. Therefore, some patients more remote from surgery, with an increased likelihood of loosening, may have been excluded. Third, not all patients had 2 years of clinical followup in this series. This was owing to the difficulty in equalizing the duration of radiographic followup between pegged and keeled glenoid implants. However, the average duration of clinical surveillance was more than 5 years. Fourth, given the interobserver variability in determining lucencies around other types of implants, the lack of blinded evaluations of the radiographs can lead to bias with either underinterpretation or overinterpretation of lucencies.

The literature suggests variable loosening rates with press-fit humeral stems when loosening is used as an end point. One early study from Roper et al. [16] showed only one of 25 press-fit stems was loose at an average of 5 years'

Fig. 3A–B Five patients had radiolucent lines around the humeral prosthesis at final followup. (A) This patient was judged to have 1-mm radiolucencies in Zones 1, 2, and 6. (B) These are better seen on the magnified view (solid arrows).

Fig. 4 There were no radiolucent lines around the humeral prosthesis in 71 of 76 patients at the final evaluation. This patient had no evidence of radiolucency at a followup of 8.2 years.

followup (Table 1). However, another study of 72 press-fit Neer II prostheses graded 40 of them (55.6%) at risk for radiographic loosening at a mean of 4 years' followup [19]. A review article from this era argued against the use of

press-fit components for TSA, although the results for hemiarthroplasty had lower loosening rates [4]. In contrast, a more recent series of press-fit stems with a tapered metaphyseal segment in a mixed hemiarthroplasty and TSA population documented no stem subsidence or shift in position [8]. However, 11 stems had radiolucencies greater than 1 mm at an average followup of approximately 3 years. There were no differences in the number of radiolucent lines between patients undergoing TSA versus those having hemiarthroplasty [8]. The high loosening rate (as much as 55.6%) of press-fit stems concurrent with the evolution of bone ingrowth technology spawned investigation into the use of porous-coated components. Early series were small but documented promising results. Weiss et al. [24] showed, in a series of nine English-Macnab humeral components, one stem was loose at an average of 5 years' followup. McElwain and English [9] reported a similar rate of loosening at an average of 3 years postoperatively. In a larger series of first-generation ingrowth humeral implants, the outcomes of 62 patients followed for a mean of 4.6 years were analyzed [20]. In that study, six stems (9.7%) were judged at risk for loosening [20]. A more recent study compared the outcomes of three different TSA systems [17]. Although the focus of that study was on the redesigned glenoid component, the authors noted no loosening in 137 ingrowth stems [17]. Although the first-generation stem we used had porous coating limited to the area just under the humeral head, the stem was redesigned in 1995 to include bone ingrowth surfacing circumferentially around the proximal 1/4. We found no evidence of loosening at an average of more than 4 years of followup. However, five stems had some radiolucencies seen at the final radiographic evaluation. These results reflect an improvement over

Table 1. Radiographic analysis of humeral stem fixation

Study	Stem type	Number of shoulders	Radiographically loose/or at-risk stems	Percent loose/at risk	Duration of radiographic followup (years)	Postoperative pain	Average postoperative forward elevation (degrees)
Sanchez-Sotelo et al. [18]	Cemented	43	1	2	6.6	88% None/mild	97
Roper et al. [16]	Press-fit	25	1	4	5	100% Good/excellent	70
Sanchez-Sotelo et al. [19]	Press-fit	72	40	55.6	4.1	83% None/mild	125
Matsen et al. [8]	Press-fit	131	0	0	3	N/A	N/A
Verborgt et al. [23]	Press-fit	37	7	19	9.2	N/A	112
Weiss et al. [24]	Ingrowth	9	1	11	5	93% improved	84
McElwain and English [9]	Ingrowth	13	1	8	3	85% None/mild	84
Sperling et al. [20]	Ingrowth	62	6	10	4.6	$p < 0.0001$	130
Rosenberg et al. [17]	Ingrowth	137	0	0	3.2–6.4 (two groups)	N/A	N/A
Current study	Ingrowth	76	0	0	4.3	$p < 0.001$	151

N/A = Not assessed.

previously published series using cemented, press-fit, and ingrowth components for patients with osteoarthritis or some with a mix of diagnoses (Table 1).

We found pain levels and ROM for this stem similar to reported levels (Table 1). These studies showed improvements in pain, function, and ROM at followup intervals similar to those of our patients [9, 16, 19, 20, 23, 24]. These improvements are commensurate with our findings, in which pain score, forward elevation, external rotation, and internal rotation all improved by the final evaluation.

We present a retrospective review of our experience with circumferential proximal ingrowth humeral components for TSA. In addition to improvements in clinical outcomes similar to previously reported outcomes, we found a low rate of radiolucent lines at intermediate-term followup and no evidence of humeral loosening. However, additional studies are necessary to determine the long-term performance of these implants. Nevertheless, owing to the low rates of loosening of these components, we now reserve the use of cemented stems only when there is substantial proximal humeral bone deficiency where ingrowth fixation is not possible.

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