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### The incidence of radiographic aseptic loosening of the humeral component in reverse total shoulder arthroplasty



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**Background:** The reverse total shoulder arthroplasty (RTSA) has been used in the treatment of complex shoulder problems. The incidence of aseptic loosening of the humeral component has not been previously reported.

**Methods:** This is a multicenter, retrospective, blinded, case-control radiographic review of 292 patients to determine the rate of humeral stem loosening. There were 177 cemented and 115 press-fit humeral components. Radiographs were critiqued for radiolucent lines adjacent to the humeral stem based on the method described by Gruen et al.

**Results:** The overall rate of loosening was 0.74%. No radiographic loosening occurred in the press-fit group (115 stems). In the cemented group (177 stems), 2 shoulders (1.18%) were identified with radiographically loose stems. No loosening occurred in the press-fit group. No statistically significant difference was found in humeral stem loosening when the press-fit group and the cemented group were compared (P = .198).

**Discussion:** Our study indicates the cemented or press-fit RTSA system will result in a low incidence of radiolucent lines and radiographic loosening. Compared with historical survivorship of conventional anatomic total shoulder arthroplasty, RTSA shows a lower rate of radiographic stem loosening at a mean of 38.46 months.

**Conclusions:** The RTSA has a low incidence of humeral stem loosening at midterm. These results underscore the importance of careful selection of patients to provide the benefits of this surgical technique. Press-fit fixation may provide a lower risk to stem loosening.

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Reverse total shoulder arthroplasty (RTSA) is a viable option for patients who have substantial shoulder pain and dysfunction that cannot be reliably treated with anatomic total shoulder arthroplasty (ATSA). Reports suggest ATSA may provide reliable pain relief, with long-term survivorship of 84% to 96% at 3.3 to 12.2 years.<sup>10</sup> However, as with all joint replacements, complications, including aseptic loosening, instability, infection, and mechanical failure, present therapeutic challenges in long-term management of patients. Although research regarding RTSA complications has centered on the loosening of the glenoid component as a latent problem.<sup>3,10</sup> there are limited studies to date that have focused on humeral loosening as a mode of failure in RTSA.<sup>13</sup> In comparison with ATSA, investigators have reported varying degrees of success with cemented, pressfit, and ingrowth humeral stem designs.<sup>12</sup>

Studies have revealed a 5-fold increase in volumetric wear between ATSA and RTSA; however, there is not a 5-fold increase in clinical failure. The main cause of failure in the cemented ATSA prosthesis is loosening of the glenoid component, which may occur for several reasons.<sup>1,6</sup> The inflammatory reaction to wear debris may not be the most important factor compared with malalignment of the ATSA components.<sup>8</sup> Among RTSA, the glenoid component has a relatively low rate of loosening.<sup>5</sup> The effect of wear debris in the RTSA may instead be associated with a higher rate of loosening of the humeral stem.<sup>3</sup>

Since approval by the United States Food and Drug Administration in 2004, RTSA prostheses are increasingly used for glenohumeral arthropathy associated with a deficiency of the rotator cuff.<sup>1,15</sup> The medialized and semiconstrained construct restores stability and movement when the muscles of the rotator cuff are deficient. The glenohumeral force is estimated to be reduced by half in a RTSA compared with ATSA.<sup>12,14</sup> Also, the articular surfaces of a reversed prosthesis are more congruent and inferior than those of the anatomic model, and the contact pressure should be significantly lower.<sup>11</sup> However, polyethylene wear in RTSA is not trivial,<sup>13</sup> and the volume of wear particles is greater at lower contact pressures for larger contact surfaces and with larger sliding distances.<sup>2,14</sup> Until recently, problems with wear have mainly been related to scapular notching, but abrasive wear of the humeral component may also be an issue.<sup>7,15</sup>

The surgical technique for RTSA requires a method of secure fixation of the humeral component in the proximal portion of the humerus. Secure fixation of the humeral component is achieved through the insertion of the component into the reamed and broached medullary canal with cement fixation or without cement fixation using a component with the capacity for osseous ingrowth.<sup>11</sup> Each method may be successful; however, whether one approach is superior to the other in terms of future development of loosening remains to be seen.

#### Materials and methods

This is a multicenter, retrospective, blinded, case-control radiographic study of aseptic humeral stem loosening in RTSA. This retrospective study was conducted to review radiographs of 292 individuals who underwent primary RTSA for rotator cuff tear arthropathy using the Equinoxe prosthesis (Exactech Inc, Gainesville, FL, USA) between June 2009 and June 2014. The operations were performed by 9 surgeons as part of a multicenter data collection program. There were 177 cemented humeral components and 115 press-fit humeral components.

Experienced fellowship-trained orthopedic physicians reviewed the radiographs and were blinded to all patient identifiers. An objectivity protocol of postoperative, 6 month, 1 year, 2 year, and 3 year follow-up radiographs was implemented to identify and assess radiolucent lines adjacent to the humeral stem. The appearance of radiolucent lines was classified by location in a manner equivalent to the method described previously by Gruen et al<sup>6</sup> for total hip arthroplasty (Fig. 1).<sup>11</sup> Bone adjacent to the stem was divided into 8 zones. Zones 1, 2, and 3 represent the lateral aspect of the stem at the proximal, middle and distal thirds respectively. Zone 4 is the area around the distal stem tip. Zones 5, 6, 7, and 8 represent the medial portion of the stem from the distal, middle, proximal thirds, and base, respectively. The lines were also classified according to their width as <1.00 mm, 1.0 to 1.50 mm, 1.51 to 2.0 mm or >2.01 mm. A humeral stem was found to be radiographically at risk for essential clinical loosening if a radiolucent line >2 mm was present in >3 zones. If an evaluator identified a shift in stem position between the postoperative and the most recent follow-up radiograph, it was also classified as essential clinical loosening. All patients had a minimum of 2 years radiographic follow-up (range, 24-48 months).

#### Statistical methods

The Wilcoxon rank sum test was used for comparisons of continuous data between press-fit and cemented groups. Differences between means were analyzed with 2-sided *t* tests. Categoric data were compared with the Pearson  $\chi^2$  test or the Fisher exact test. Ordinal ranking scores were compared with the Mantel-Haenszel test.

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