## On the Concerning Early Failure of a Short Stem Press-Fit Humeral Component

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INTRODUCTION: Our institution has a shoulder arthroplasty registry of all cases performed between 2004 and present. There is also an ongoing implant retrieval study for all shoulder arthroplasty implants removed. Concern was elevated for a specific implant with multiple early failures due to apparently aseptic humeral loosening and unique radiographic characteristics. Clinical, radiographic, and histologic analysis of these cases was performed. METHODS:

A short (mini-) stem of rectangular shape, grit blast surface and variable neck angle option for anatomic TSA and hemiarthroplasty was evaluated.

Of the 117 humeral stems of this type, implanted over a 3 year period, 13 (11.1%) required revision due to radiographic loosening, and clinical symptoms of pain at an avg. of 23.8 mn (range 1.8-92.5 mn) after index arthroplasty. The avg. age at index arthroplasty was 56.3 years and at revision 58.3 years. There were 9 males and 4 females. There were no infections. Clinical and radiographic evaluations were performed on all patients. Tribological and histological analyses were performed on the retrieved implants and the soft tissue membranes surrounding the failed implants, respectively.

Radiographic loosening was defined as a radiolucent line greater than 2 mm in more than two zones, progression of the lucency, and/or implant position shift. Revised implants were assessed for damage using a stereomicroscope. Damage to the modular tapers, metal humeral bearing surface, the stem hinge, and the polyethylene (PE) surface were graded. Periprosthetic membrane tissues were stained with H&E, sectioned and evaluated for extent and type of cellular response. A grading system was used to score (rare to marked) the overall presence of particle-laden macrophages, foreign body giant cells (FBGCs), lymphocytes and neutrophils throughout the tissue. Additionally, the type of implantrelated debris (metal, polyethylene (PE), bone cement, and suture), was recorded. **RESULTS:** 

A unique radiographic loosening pattern was noted, with expanding lucent lines, but with lateral subsidence of the humeral component and thinning of the lateral, proximal humeral endosteal cortex in 9 of 13.

Histologic evaluation of the membranes revealed a marked macrophage response to implant wear debris in 67%. Fifty percent had a marked FBGC response and in one patient, the response was moderate. These implants also had marked hinge damage scores, moderate PE and metal bearing surface damage scores. Metal particles, PE, bone cement, suture were present throughout the tissues of all the patients. Implant damage evaluation revealed hinge damage scores averaging 3 (moderate). Stem and head tapers had a mean damage score of 2 (mild). All cases required revision to reverse TSA.

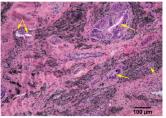
## DISCUSSION AND CONCLUSION:

There has been an evolution to shorter humeral stems in recent years. Aseptic humeral implant loosening is rare. This implant has no in-growth material and multiple metal on metal surfaces. This specific short (mini-) stem had a higher than expected rate of early (avg. 23 month) failure and a unique radiographic loosening pattern.

Further analysis is necessary, however an 11% failure and revision rate due to aseptic humeral loosening at an average of 23 months is cause for concern. Wear debris caused a marked macrophage and FBGC response in the periprosthetic tissues of patients with failed implants. Cases with the most severe tissue response had the most damage seen at the hinge surfaces. and bearing



Figure 1. Severe damaged (score 4) to the roughened surface of the hinge on an Apex humeral stem encompassing >75% of the surface. This implant was in situ for 2 years and was removed for pain, dysfunction, and glenoid loosening.



e 2. Periprosthetic joint capsule with numerous dark-stained, metal particle- laden macrophages and FBGC surrounding suture debris (yellow arrows). The implant from this patient was removed for aseptic loosening. (H&E, polarized light, X100).