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DESIGN ANALYSIS: MODULAR REVERSE TOTAL SHOULDER PROSTHETIC FAILURE WITHOUT PROXIMAL BONE SUPPORT

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INTRODUCTION

Reverse total shoulder arthroplasty (RSA) serves as an effective alternative to total shoulder arthroplasty (TSA), especially for patients with rotator cuff deficiency [1]. Long-term performance of RSA has been limited by a variety of complications including dislocation, infection, humeral fracture, glenoid loosening, glenoid unscrewing, scapular erosion and polyethylene debris [1-2]. Dissociation between the proximal metaphyseal component and distal humeral prosthetic stem (disaphysis) in modular RSAs has been reported with low frequency (1-2%) [2]; however, cases have led to severe consequences including *in vivo* disassembly [3]. Most cases of unscrewing have occurred due to insufficient support for the prosthesis resulting from proximal humeral bone deficiency [4-5]. In this study, we evaluate a retrieved RSA that unscrewed and subsequently fractured *in vivo* in a patient with proximal bone deficiency.

METHODS

A modular Tornier Aequalis RSA which relies on screw fixation of the proximal body to the distal stem was retrieved (August 2011) from the left shoulder of a 60 yr old male patient (**Figure 1**). At the time of implantation (March 2007), the proximal bone was noted as deficient above the metaphyseal-diaphysis junction. The patient experienced episodes during which his shoulder was caught in external rotation and had to be manually rotated back in place to restore function. The device failed when the screw junction between the metaphysis and diaphysis fractured while the patient was golfing. The implant was immediately retrieved. Extensive metallosis was observed throughout the soft tissue and down the humeral canal. The fracture occurred just above the remaining humeral bone shaft. Grade II scapular notching was noted. There was no bone or soft tissue support fixed to the implant above the metaphysis-diaphysis junction.

Optical microscopy and scanning electron microscopy (SEM) were used to characterize the fracture surfaces of the retrieval. Failure analysis utilizing composite beam theory under pure bending was performed to evaluate the stresses in the component with and without proximal bone support. An annulus cross section was used to model the composite beam, as seen in **Figure 2**. Stresses were calculated as:

$$\sigma_s = \frac{E_s M y}{\sum E_i I_i} \qquad \textbf{[Eq. 1]}$$

where $\boldsymbol{\sigma_s}$ is the maximum normal stress in the metaphyseal screw and $\mathbf{E_s}$ is its elastic modulus; **M** is the bending moment applied about the neutral axis of the composite beam; **y** is the maximum distance from the neutral axis of the composite beam (the radius of the stem); $\mathbf{E_i}$ is the elastic modulus of contributing material; and $\mathbf{I_i}$ is the second moment of inertia for each material cross section (**Table 1**).

RESULTS

Optical and metric analysis of the retrieval confirmed that unscrewing occurred before fracture of the metaphyseal screw. Measurements of the remaining screw lodged in the diaphysis and of the fractured screw exposed a gap between the superior surface of the humeral stem and the inferior mating surface of the metaphyseal component just before fracture. Removal of the remaining screw from the humeral stem revealed that the fracture had occurred at a 3mm diameter through-hole in the metaphyseal screw (**Figure 3**). Optical microscopy of the screw revealed some fretting wear of threads which may have contributed to the extensive metallosis observed at retrieval.

Composite beam analysis compared stresses in the humeral stem (assuming no unscrewing had occurred and ignoring any stress concentrations due to the through-hole) with and without proximal bone support. Under the same dimensions and bending moment applied, proximal bone deficiency was shown to increase stresses in the implant by 60%. Unscrewing would reduce the cross section geometry and thus exponentially decrease the moment of inertia of the humeral stem, presumably driving the stresses even higher as shown by **Eq. 1**. Addition of a through-hole could elevate stresses threefold in tension [7]. SEM of the fracture surface revealed brittle mechanisms consistent with an overload event with no evidence of fatigue crack propagation.

DISCUSSION

Glenoid component failure is the primary reason for revision in RSA [1-2]. However, several cases have shown humeral complications with severe consequences including fractures [3]. Unscrewing and disassembly of modular humeral stems have been noted in a small number of cases [3,6]. To our knowledge, this is the first study in which unscrewing of the metaphysis-diaphysis junction was coupled with fracture of the component during an overload event.

The extensive degree of metallosis observed suggests that even minimal metal debris from fretting wear can widely impact periprosthetic tissue. Optical analysis revealed that fracture occurred at the site of a through-hole in the metaphyseal screw. Composite beam analysis confirmed an increase in stress due to a lack of proximal bone support in a fully intact stem. This internal implant stress was increased by the effects of unscrewing on the geometry and moment of inertia. All three of these factors including the through-hole, the lack of proximal bone support and the unscrewing mechanism contributed to the weaker interface which predisposed the implant to failure during an overload event such as the golf swing. Observations during retrieval and optical analysis provided evidence for the failure mechanism presented in **Figure 4**.

This case demonstrates that both clinical and design considerations contributed to a premature failure of a modular RSA. Previous literature has suggested several clinical measures to prevent unscrewing of modular implants *in vivo*, including the use of an allograft composite or retentive humeral cup to reduce torsional instability in patients with proximal humeral bone deficiency [4,6]. While clinical actions can prevent unscrewing, our work shows that designs that include stress concentrations can significantly reduce mechanical integrity, especially during daily patient activity.

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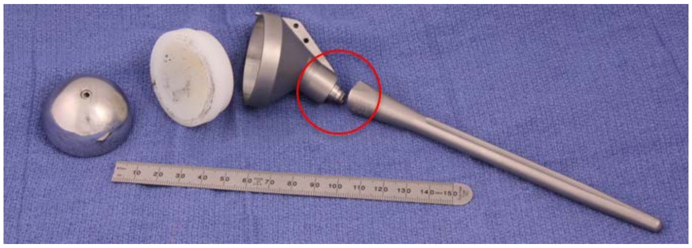

Figure 1 | The retrieved TSR, in which fracture occurred at the metaphyseal-diaphysis screw junction (circled).

Table 1 | Values used in composite beam analysis.

Material	E (GPa)	Diameter (mm)
Cortical Bone	16 [8]	35
Diaphysis - Phynox (ISO 5832-4)	204	14
Metaphysis - Alacrite (ISO 5832-7)	248	8

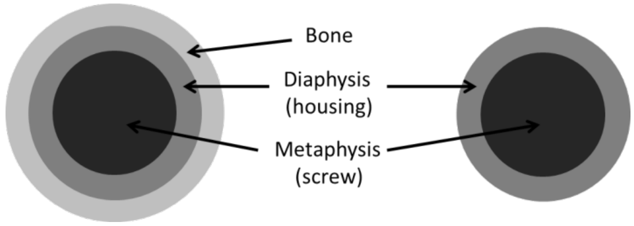

Figure 2 | Cross sectional geometry used in composite beam analysis.

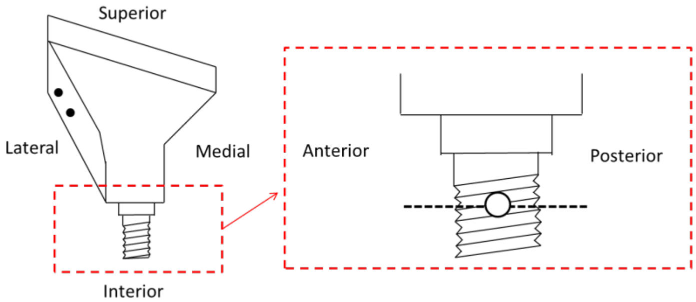

Figure 3 | Illustration of metaphyseal component. The fracture (dotted line) occurred at a through-hole incorporated in the screw design. The through-hole was filled with a nylon plug.

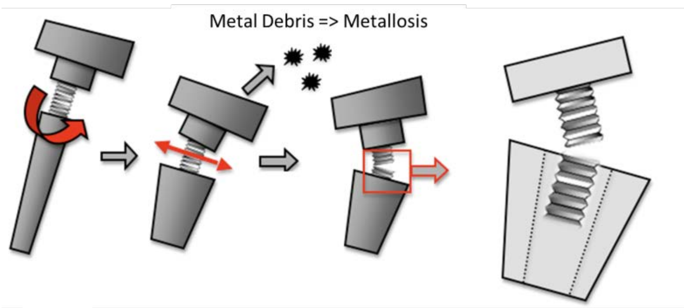

Figure 4 | Optical analysis suggests the following failure mechanisms: unscrewing, fretting wear (metallosis), and fracture due to overload.