Unscrewing instability of modular reverse shoulder prosthesis increases propensity for in vivo fracture: a report of two cases

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Reverse total shoulder arthroplasty (RSA) is an effective alternative to conventional total shoulder arthroplasty for patients with shoulder instability.\textsuperscript{21,23} RSA has especially improved stability for rotator cuff–deficient patients.\textsuperscript{19,21} Increased use of RSA over total shoulder arthroplasty for revision surgery, instability, and tumor and fracture sequelae has been reported.\textsuperscript{13} However, RSA complications have concurrently increased and include dislocations, infections, hematomas, glenoid loosening, glenosphere unscrewing, scapular notching, polyethylene wear, and metallosis.\textsuperscript{20,21,23}

RSA complications are frequently attributed to failure of the glenoid component. Nonetheless, humeral failure has been noted in several studies, and it is more often associated with modular designs.\textsuperscript{8,10,12,20,22} Dissociation of modular humeral components at the proximal metaphysis and distal diaphysis has been reported with only low frequency (1%-2%).\textsuperscript{8,14,21,22,26} However, dissociation can lead to severe consequences including in vivo disassembly and device failure.\textsuperscript{20} In this study, we examine 2 retrieved RSA modular devices from patients with proximal humeral bone loss: both unscrewed in vivo and one fractured in vivo.

\textbf{Case study}

\textbf{Case 1}

A modular cemented Tornier Aequalis RSA (Tornier, Bloomington, MN, USA) was retrieved from the left shoulder of a 79-year-old male patient after 9 years 2 months in vivo (Fig. 1, A). The patient’s proximal humerus initially fractured during a ground-level fall. Surgery was then performed with open reduction and internal fixation with a proximal humeral locking plate. This fixation failed, and a hemiarthroplasty surgery was then performed. Because the tuberosity fixation failed, revision hemiarthroplasty surgery was performed. After the third surgical procedure, the tuberosities resorbed with subsequent anterior-superior escape of the prosthesis. There was also a 5-cm area of proximal humeral bone loss. Another revision surgery was then performed with conversion to a reverse prosthesis. Preoperative radiographs showed partial disassembly of the screw joint between the metaphysis and diaphysis on the humeral stem (Fig. 1, B). The implant had not yet fractured or dissociated completely (Fig. 1, C). Extensive metallosis was observed in the retrieved peri-prosthetic tissue (Fig. 1, D).

Retrieval analysis including optical and metric evaluation showed a gap at the junction of the metaphysis and diaphysis. The 2 components were disassembled ex vivo,
and optical microscopy of the screw threads was conducted. Evidence of fretting wear was observed (Fig. 2). The screw was noted to have a 3-mm-diameter transverse hole near the proximal end of the threads that was filled with a nylon bushing (Figs. 1, C, and 2).

**Case 2**

A fractured modular Tornier Aequalis RSA was retrieved from the right shoulder of a 60-year-old male patient with rheumatoid arthritis after 4 years 5 months in vivo (Fig. 3, A and B). Initially, multiple surgeries were performed for a massive rotator cuff tear including direct repair, latissimus dorsi transfer, and then pectoralis subcoracoid transfer. Finally, RSA was performed. The initial implant was in vivo for 17 months before revision was performed because of humeral loosening. At the time of revision to the implant that is the subject of this study, the greater tuberosity was fractured. This bony fragment was fixed to the implant with Kinamed cables (Camarillo, CA, USA), and the implant was secured with antibiotic-impregnated methylmethacrylate cement. During follow-up, the patient had progressive resorption of the greater tuberosity fragment causing a bone deficiency in the metadiaphyseal region. Before the device fractured, he had 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 at the junction of the metaphysis and diaphysis just above the remaining humeral bone while the patient was golfing. The implant was immediately

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**Figure 1** (A) Case 1 presented with in vivo unscrewing without dissociation or fracture. The implant is shown after retrieval (B) and unscrewing (C). The screw had an approximate 3-mm-diameter hole with a nylon bushing. (D) Extensive metallosis was present at the time of retrieval.

**Figure 2** The threads in case 1 displayed areas of damage consistent with fretting wear, highlighted by the rectangles.
retrieved. Extensive metallosis was observed in the peri-prosthetic tissue and down the humeral canal (Fig. 3, C). Grade II scapular notching was also noted.

Optical evaluation of the shoulder explant showed that the fracture occurred through the metaphysis screw at the location of a 3-mm-diameter through hole that was plugged with an intact nylon bushing (Figs. 3, B, and 4). Measurements of the remaining screw lodged in the diaphysis and the fractured screw fragment exposed a gap between the superior surface of the humeral stem and inferior mating surface of the metaphyseal component. Furthermore, optical microscopy of the metaphysis screw showed fretting wear of the threads that may have contributed to the extensive metallosis observed at retrieval (similar to the fretting wear seen in case 1).

Scanning electron microscopy of the fracture surface did not show any evidence of fatigue damage (Fig. 5). The surface features were consistent with brittle fracture, suggesting breakage during an overload event while the patient was golfing. Failure analysis of the implant considering no proximal bone support was performed by use of composite beam theory under pure bending to evaluate the stresses at the screw joint and then compared with analysis of an implant with proximal bone support. An annulus cross section (Fig. 6) was used to model the composite beam. Stresses were calculated as

\[
\sigma_s = \frac{E_s M_y}{\sum E_i I_i}
\]

where \(\sigma_s\) is the maximum normal stress in the metaphyseal screw and \(E_s\) 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); \(E_i\) is the elastic modulus of each contributing material; and \(I_i\) is the second moment of inertia for each material cross section, calculated as

\[
I_i = \frac{\pi}{64} (d_o^4 - d_i^4)
\]

where \(d_o\) is the outer diameter and \(d_i\) is the inner diameter. Geometries and material properties used in the analysis are shown in Table I.

Given the same dimensions and bending moment applied to the device, the proximal bone deficiency was shown to increase stresses in the implant by 400%. Unscrewing at the metaphysis-diaphysis joint further reduced the cross-sectional diameter, resulting in an exponential decrease in

\[\text{Figure 3} \quad (A) \text{ In case 2, a fracture occurred in vivo at the metaphysis-diaphysis screw junction. The device is shown at retrieval (B) and after removal of the remaining screw fragment from the housing (C), showing that the component fractured at the through hole, leaving a nearly intact nylon bushing. (D) Extensive metallosis was observed at retrieval.}\]

\[\text{Figure 4} \quad \text{Metaphyseal component. The fracture} \: (\text{dashed black line}) \: \text{occurred at a through hole incorporated in the screw design.}\]
the moment of inertia of the humeral stem (Equation 2) and exacerbation of implant stresses (Equation 1) with loosening of the device. Furthermore, the addition of a through hole in the implant could elevate stresses 3-fold with tension under elastic loading conditions.25

Discussion

Glenoid component failure is the primary reason for revision in RSA.21,23 Yet, humeral complications can have devastating consequences including complete dissociation of modular components.21 Unscrewing of the metaphysis-diaphysis joint in modular humeral stems has been reported.8,10,12,20,22 Roberts et al20 presented radiographs of 2 modular RSA implants that partially and completely unscrewed in vivo, but they claimed that modifications of these early European designs have since eliminated this complication. Two of three humeral component failure cases reported by De Wilde and Walch12 included partial disassembly due to unscrewing. To our knowledge, this is the first study in which a case of metaphysis-diaphysis junction unscrewing was coupled with fracture of the component during an overload event.

Both cases of unscrewing examined in this study featured extensive metallosis in the patients at the time of removal. This suggests that even before fracture, fretting wear at the unstable screw joint can cause serious tissue damage due to metal debris release. The screw threads displayed evidence of low-volume wear at higher magnifications, showing that even minimal metal debris release can significantly compromise periprosthetic tissue. In addition to soft tissue damage, a more severe consequence of unscrewing can be seen in the fracture in case 2, which was influenced by 3 factors. First, composite beam analysis showed that a lack of proximal bone support can lead to a 400% increase in stresses for a fully intact stem. Second, this stress is exponentially increased by unscrewing, which reduces the cross-sectional diameter and thus increases the moment of inertia. Finally, the addition of a through hole provides a stress concentration. Even though the hole was plugged with a nylon bushing, presumably to prevent unscrewing, the location of fracture through this hole reflects the vulnerability of this design. All 3 of these factors—the lack of proximal bone support, the unscrewing mechanism, and the through hole—contributed to a weaker metaphysis-diaphysis interface that predisposed the implant to failure during an overload event. The observations during retrieval and ex vivo optical analysis provided evidence of the failure mechanism presented in Figure 7.
The suggested mechanism for in vivo unscrewing is attributed to several factors. De Wilde and Walch proposed that unscrewing can be attributed to the blockage of tuberosity movement against the anterior wall of the glenoid in maximal internal rotation during forearm flexion. Several authors recommend vigorous tightening of the screw junction during implantation to prevent such a mechanism for disassembly. However, even with sufficient tightening of the modular components, the absence of external proximal support has been frequently cited as a cause for unscrewing. Our cases, as well as those in the case report of De Wilde and Walch, involved patients with deficient humeral bone above the metaphysis-diaphysis junction. Cuff et al. showed a higher rate of rotational micromotion and eventual failure under cyclic loading for modular stems in no-bone models compared with both modular and monoblock systems in fully intact bone models. As shown with our composite beam analysis, proximal bone loss not only contributes to unscrewing but also elevates stresses under bending conditions. Clinical evidence further supports the need for allograft support in place of a deficient proximal humeral bone with reports of higher patient satisfaction and lower complication rates.

Screw fixation of a modular metallic interface provides a source of micromotion between the modular components. Micromotion may result from torsional as well as bending stresses. The distal stem in both cases in this report was well fixed before failure. The observation that modular implants fixed with a unidirectional screw thread unscrewed from both right and left shoulders in vivo indicates that it is unlikely that torsional stresses alone led to the failures and suggests that bending forces associated with micromotion at the modular interface also contributed to the failure mechanism. This is further supported by the 2 cases presented by De Wilde and Walch, in which unscrewing occurred in both right- and left-sided reverse humeral stems, as was observed in our study. Furthermore, our study shows that unscrewing had not been resolved by the addition of a polyethylene bushing.

The consideration of monoblock versus modular humeral stem components in patients with severe bone deficiency highlights the role of implant design in contributing to catastrophic failure such as disassembly or fracture. Levy and colleagues allude to a 5-cm lateral bone deficiency as an appropriate threshold for allograft placement. Because this point lies very close to the metaphysis-diaphysis junction, the threshold for modular implants may need to be 2 or 3 cm of lateral bone deficiency to mitigate the risk of unscrewing. The addition of stress concentrations in both modular implants in our study also highlights the need for more extensive preclinical bench testing in assessing implant mechanical function under reduced stability (ie, unscrewing). ASTM International and International Organization for Standardization standards for cyclic fatigue and fretting corrosion of modular joints only exist for hip prostheses. No testing standards exist specifically for RSA, and current standards for shoulder prostheses only consider glenoid component dissociation. ASTM F2028-08 for glenoid loosening or dissociation is currently being revised to include tests for reverse shoulder prostheses. However, there is no indication that this standard will address humeral stem testing. Our review of unscrewing events in RSA supports the need to extend current ASTM International standards for fatigue and fretting assessments of modular hip stems to similar standards for reverse shoulder components. Ideally, these standards should account for overload events under varying degrees of dissociation of modular implants, especially if indicated for patients without allograft bone support.

Although modular humeral stems can present complications as seen in this study, the need for modularity in shoulder arthroplasty should not be ignored. Monoblock systems may avoid potential dissociation and associated catastrophic failure, but they have the disadvantage of not permitting the versatility in restoring bone length and soft tissue tension that modular implants provide. However, the introduction of a modular connection with a threaded interface over the more traditional Morse taper warrants implementation of more rigorous modular component testing to evaluate both fretting prevention and mechanical stability. Such testing should evaluate the degree of unscrewing that leads to instability, both with and without proximal bone support. In addition, laboratory studies should be combined with clinical know-how to understand the mechanisms of

Table 1: Summary of values used in composite beam analysis

<table>
<thead>
<tr>
<th>Material</th>
<th>E (GPa)</th>
<th>Diameter (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cortical bone</td>
<td>16</td>
<td>35</td>
</tr>
<tr>
<td>Diaphysis—Phynox (ISO 5832-4)</td>
<td>204</td>
<td>14</td>
</tr>
<tr>
<td>Metaphysis—Alacrite (ISO 5832-7)</td>
<td>248</td>
<td>8</td>
</tr>
</tbody>
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unscrewing in vivo and thoroughly vet designs that seek to prevent them (such as the nylon bushing in cases examined in this study).

**Conclusion**

Our work shows that both clinical and design considerations contributed to the premature failure of 2 modular RSAs. Previous literature has suggested several clinical measures to prevent unscrewing of modular implants in vivo, including the use of an allograft composite to reduce torsional instability in patients with proximal humeral bone deficiency. Although clinical actions can prevent unscrewing, our work shows that designs that include stress concentrations can significantly reduce mechanical integrity, especially during daily patient activity.

**Disclaimer**

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