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Fatigue testing results of the newly redesigned PROMOS® STANDARD Modular Shoulder System

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1 Research goal

To determine if a redesigned total shoulder arthroplasty (TSA) system can mitigate the risk of humeral head instability due to screw loosening and fracture.

2 Type of evidence

3 Clinical relevance

- The original PROMOS® stem construct (Smith & Nephew, Inc.) has demonstrated acceptable clinical performance and return to function.[1] However, screw loosening and fracture are documented complications that can lead to humeral head instability and procedure failure in some instances.
- A newly developed design (**Figure 1**) was tested under worst case loading conditions to fully assess component fatigue performance and screw fracture risk.

4 Key result

- No fractures were observed for the new design following 7.5 million testing cycles, simulating 15-years of clinical use. Furthermore, there was no loss of screw torque.
- These results suggest that screw loosening and fracture are not expected to cause humeral head instability and failure in vivo.

5 Important considerations

- Additional research would be required to confirm component performance during mid to long-term clinical follow-up.

Figure 1: PROMOS® STANDARD Modular Shoulder System (redesigned inclination set circled).

Background

The PROMOS° STANDARD Modular Shoulder System (Smith & Nephew, Inc., Memphis, TN, USA) is a shoulder arthroplasty implant featuring an adjustable inclination set and a clinically successful diaphyseal, rectangular cementless stem fixation design.[2] Biomechanical testing has demonstrated that this design has a higher torsional stability than the cylindrical shafts, without increased fracture risk.[3] Clinically, the PROMOS stem provides intraoperative flexibility when addressing native anatomy, and has demonstrated good functional outcomes.[1] However, an analysis of complaint data and failure modes for the original stem construct revealed cases where loosening and slipping of the saddle joint caused failure of the inclination set-screw. This can lead to instability of the humeral head and clinical failure. Therefore, the PROMOS inclination set was redesigned for improved stability and fatigue strength (**Figure 2**). Construct changes include:

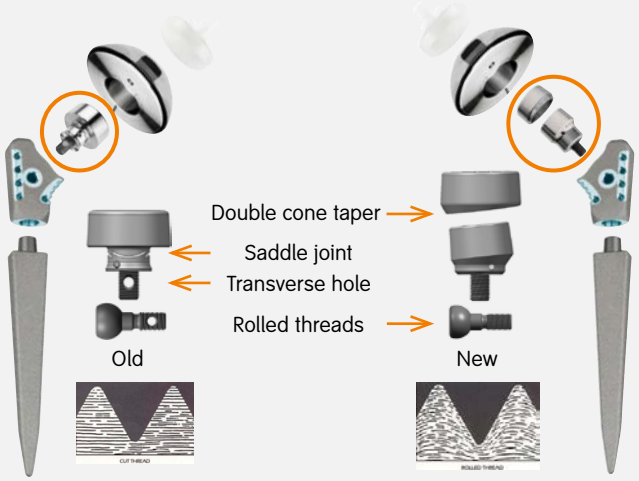

Figure 2: PROMOS° STANDARD Modular Shoulder System design changes

- Removal of transverse screw hole and polyethylene pin.
- Removal of saddle joint.
- Addition of double cone taper.
- Screw is now manufactured with rolled threads, as opposed to weaker, machined threads.

The purpose of the current study was to assess the mechanical strength of the re-designed system under simulated worst-case clinical loading conditions.

Methods

- A published in vitro model of the shoulder was referenced so that a rigorous and mechanically appropriate testing load could be applied to the newly redesigned components.[4]
- A total of six PROMOS STANDARD stem constructs were tested.
- Testing set-up generated a loosening torque about the longitudinal axis of the screw. Simulation protocol was designed to simulate 15-years of clinical use (maximum of 7.5 million joint cycles).
- All components were tested in a lubricated, physiologically correct liquid environment set at human body temperature (37°C).
- Set screw torque was assessed using a torquemeter before (5.6 N-m set point) and after testing to assess loosening. After the completion of testing, all modular components were disassociated and imaged to assess interface integrity.

Results

- No failures were observed during construct fatigue testing (Figure 3).
- The maximum testing cycles achieved was 7.5 million, designed to simulate 15-years of clinical use.
- Screw torque was largely unchanged following completion of post-fatigue testing (5.54 N m ± 0.52 N m; $p > 0.05$).
- Taper disassociation was successfully achieved for each construct after completion of testing. Furthermore, imaging results of tapered surfaces did not show notable patterns of damage or wear.

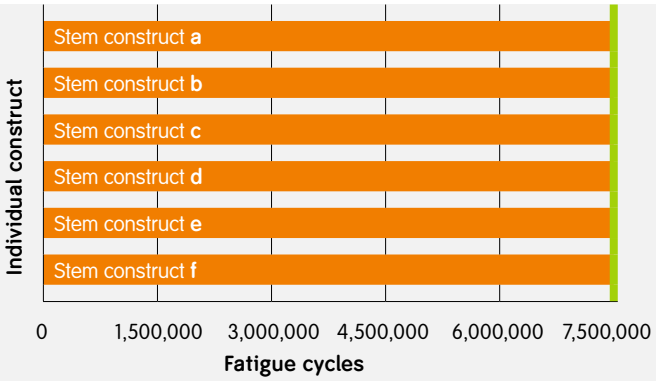

Figure 3: Fatigue testing results for PROMOS° STANDARD stem constructs.
All stem constructs (a–f) reached the maximum number of cycles (7.5 million, shown by green line) without failure.

Conclusion

The current testing results suggest that screw loosening and fracture are not expected to occur, and therefore are not expected to contribute to humeral head instability and clinical failure following implantation of the redesigned PROMOS° STANDARD Modular Shoulder System. However, additional research is necessary to confirm this finding over mid to long-term clinical follow-up.

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