Mechanical Testing of Reverse Shoulder Prosthesis Stability

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Introduction: For patients with cuff tear arthropathy (CTA) or severe rotator cuff (RC) deficiency, a reverse shoulder prosthesis is a clinical option for treatment and offers the potential for improved function. The aims of this study were to develop a clinically relevant test method to evaluate the stability of the modular connection between the ultra-high molecular weight polyethylene (UHMWPE) liner and the humeral implant, and then apply the test in the development process of a new implant design.

Methods: Clinically, a joint reaction force pointing outside the humeral cup will cause a tilting moment, which tends to lever the PE liner out from the cup, as shown in Figure 1. During such a loading situation, the modular connection must withstand a combination of shear forces and axial pull-out forces. Since a snap fit connection only compensates for axial forces, the modular connection must have an additional feature to compensate for shear forces, in this design a central rod.

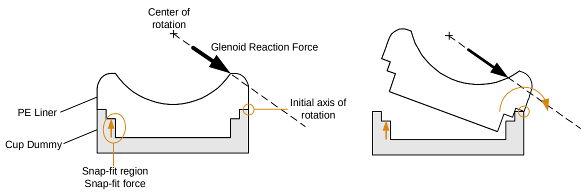

Figure 1. Levering out of UHMWPE liner due to edge loading

Mroczkowski et al. calculated the joint reaction force acting on the humeral component of a reverse shoulder prosthesis during active loading using a biomechanical model[2]. The reported force values and directions were used to analyze the loading of UHMWPE liner prototypes of the Anatomical Shoulder Inverse/Reverse prosthesis (Zimmer GmbH, Winterthur, Switzerland). During normal abduction the joint reaction force will not cause a lever out moment (Figure 2). However, joint instability due to soft tissue laxity is a known possible complication with reverse shoulder prostheses and, thus, subluxation causing severe edge loading as shown in Figure 1 must be taken into account as a possible loading scenario.

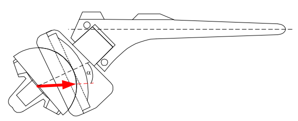

Figure 2. Joint reaction force acting on the humeral component of the reverse prosthesis at 90° abduction.

The static subluxation test (Figure 3) simulated a single abduction with a 2 kg hand load followed by a forced subluxation, applied by a horizontal displacement of 50 mm/min. The constant axial load of 600 N mimics the joint reaction force in magnitude and direction at 90° abduction[2]. Assuming that abduction with less hand load might occur more often, a dynamic subluxation test was also carried out. 250,000 subluxation cycles simulating abduction with 1kg hand load (F_{axial} = 500 N) were applied at a displacement speed of 10 mm/s. For both static and dynamic subluxation, the test was passed if the UHMWPE liner did not lever out. In order to prove whether the modular connection's ability to maintain its integrity under severe edge loading could be predicted also by a simple uniaxial test, additional specimens were subjected to a standard push-out test according to Figure 3[1]. All tests were performed in water at 37° C. Three different design variations of UHMWPE liners were tested (Table 1).

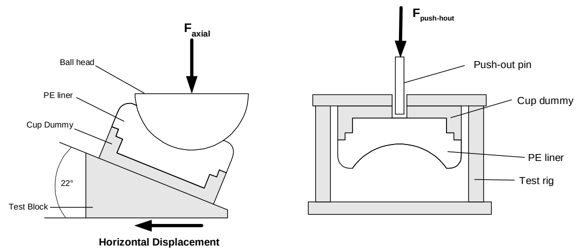

Figure 3. Subluxation (left) and push-out test set-up (right)

Results / Discussion: Table 1 gives an overview of the tested design variations and the results from the subluxation tests. The first design did not pass the static subluxation test. After optimizing the snap-fit feature, the push-out force was increased by 30% and the design passed the static subluxation test. Only after adding an additional shoulder to compensate for shear forces did the design pass the dynamic subluxation test.

	Feature compensating for		Subluxation test	
UHMWPE Liner	**axial forces**	**shear forces**	**static**	**dynamic**
Design 1	snap-fit	central rod	failed	-
Design 2	optimized snap-fit	central rod	passed	failed
Design 3	optimized snap-fit	central rod + circumferential shoulder	passed	passed

Table 1. Test results for different design variations.

Conclusions: The results from this study indicate that pure push-out tests cannot predict the stability of the modular connection between UHMWPE liner and humeral implant under severe *in-vivo* loading. The proposed subluxation test also takes into account possible *in-vivo* shear loading and shows clinically relevant differences among modular connection designs. Using a dynamic subluxation test it was possible to design a modular connection which allows the UHMWPE liner to remain stable even after repetitive edge loading due to subluxation.

References:
1. ASTM Standard F120-97 (Reapproved 2003)
2. Mroczkowski, ML. Abstract submitted to SFB 2006