

Static and Dynamic Loading of the Univers II Humeral Implant

Arthrex Research and Development

Objective

The purpose of this testing was to determine the compressive yield load and the fatigue life of the humeral implant from the Univers II Total Shoulder System.

Methods and Materials

Mechanical testing was performed by MarTest, Inc. (Cincinnati, OH). Each sample was positioned in the materials testing machine so that loads could be applied at a 15° angle to the axis of the humeral head, and at a version angle of 0°. This direction was used to represent a worst-case-scenario loading condition for the implant.

Static load testing was performed in compression at 0.1mm/sec, using a bearing plate to eliminate shear forces. The static yield load was determined from the point of slope change in the load-displacement curve. Cyclic fatigue testing was conducted to a maximum of 2400N, at 5 Hz, with an R-ratio of 0.1, for a maximum run-out of 10,000,000 cycles.

Results

The average yield load of the statically loaded sample was 6031N, and the mode of failure was the trunion slipping. All fatigue samples achieved run-out of 10,000,000 cycles without failure at a maximum load of 2400N.

Discussion

ASTM Standard F2028-02 recommends axial loads of 750N to represent typical loads. The standard also recommends 100,000 cycles of fatigue testing to represent 25 higher loading activities each day for ten years. The fatigue loading performed in this testing exceeds the recommended load by a safety factor of 3.2. Also, the number of cycles would be equivalent to about 250 high load activities each day for one hundred years.

Bergmann et al. (2006), measured the maximum load in the glenohumeral joint in vivo and found it to be approximately 150% of body weight (approximately 1500N for an average individual).¹ This load occurred while attempting to turn a locked steering wheel. Other activities of daily living (ADLs) resulted in forces between 14% and 128% body weight (approximately 140N – 1200N). In addition, Anglin et al. (2000) determined the average glenohumeral contact forces for five different activities were between 930N and 1720N.² Based on the Univers II yield load of 6031N, the device has a safety

factor of 3.5 over the largest experimental forces reported in the literature. Furthermore, the Univers II survived 10 million cycles at a load 680N larger than the max load reported by Anglin. Of note, according to DePuy Orthopaedics³ the Global AP Adjustable Prosthesis withstands 10 million load cycles at one body weight. Comparatively and assuming a body weight of 180lbs, the Univers II mechanisms withstand 10 million load cycles at three times body weight.

The use of a flat plate to administer the load during Univers II testing resulted in a point load. Actual loads in the glenohumeral joint are more distributed because of the concave nature of the glenoid.

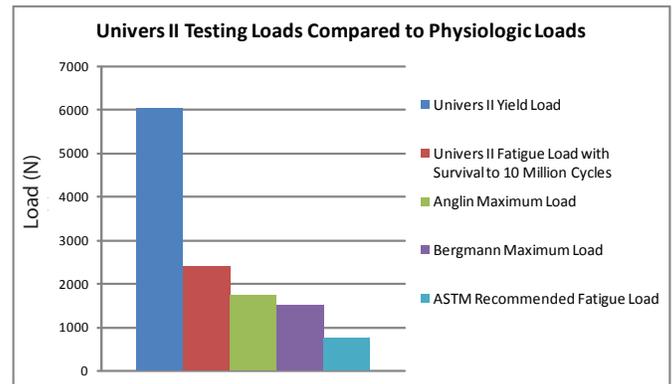


Figure 1: The Univers II yield load and fatigue load are greater than the ADL loads measured by Anglin and Bergmann, and the fatigue load recommended by ASTM.

Conclusion

The aforementioned Univers II test protocol and results demonstrate the considerable humeral construct strength under loading conditions that are worse than would occur physiologically.

References

1. Bergmann, G., F. Graichen, et al. (2007). "In vivo glenohumeral contact forces--measurements in the first patient 7 months postoperatively," *J Biomech* 40(10): 2139-49.
2. Anglin, C., U. P. Wyss, et al. (2000). "Glenohumeral contact forces," *Proc Inst Mech Eng [H]* 214(6): 637-44.
3. Global AP Adjustable Prosthesis: *Fixed and Variable Geometry Total Shoulder Arthroplasty*. 2007, DePuy Orthopaedics, Inc.