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PRECISION IN FIXATION

Biomechanical Tests of Distal Humerus Plates

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Introduction

Distal humerus fractures represent between 2% and 6% of all skeletal injuries in the adult population [1]. Due to their complexity they are recognized as one of the most important challenges in elbow surgery [2] and are usually treated by ORIF [3]. Obtaining satisfying results with the currently available ORIF systems is sometimes difficult [4]. Medartis has therefore developed a distal humerus plating system featuring its TriLock variable angle locking technology.

A biomechanical fatigue test setup was developed to compare the mechanical stability of the polyaxial Medartis distal humerus system to one of its leading competitors in a 90° plate arrangement.

Materials and Methods

An anatomically accurate fixture was designed based on the 3D model of a human distal humerus. Using CAD software, an intra-articular fracture of the distal humerus (AO 13-C1) was incorporated along with all elements needed for load transfer and clamping. Parts were 3D-printed in glass fibre reinforced polyamide resulting in highly reproducible fixtures of high strength and toughness.

Loading was introduced via an asymmetric rocker using bearings (to minimize friction) to simulate physiological force distribution (40% trochlea and 60% capitulum) during flexion and extension.

The following two distal humerus locking plate systems were tested in a 90° plate arrangement:

- Medartis APTUS 2.8 Distal Humerus Plates (A-4856.34 and .54) with corresponding 2.8 mm TriLock locking (A-5850.xx) and non-locking (A-5800.xx) screws.
- Distal humerus plates of a leading competitor with corresponding monoaxial locking screws (2.7 mm distal and 3.5 mm proximal).

Both systems were used as per their respective surgical techniques using manufacturer supplied instruments, screw holes placed over the fracture were left empty (Figure 1).

Fatigue testing was performed using an electromechanical testing actuator (Zwick Z 2.0) following a modified Locati approach: load was increased after 50 000 cycles and every subsequent 10 000 cycles until hardware failure (fracture or deformation, d_{max} >5 mm). Initial load was 300 N, subsequent load increases were 15% each (Figure 2, green lines). Sinusoidal loading was carried out at 5 Hz and the ratio (F_{min}/F_{max}) was 0.1. Load and displacement were recorded.

Results and Conclusion

Results are shown in Figures 2 and 3 below: Figure 2 gives the detailed displacement and load curves over time, Figure 3 summarizes the results. The Medartis plates showed significantly higher fatigues strength and therefore also a longer fatigue life (Student's t-test, confidence level 95%). Failure mode for the Medartis construct was a fracture of the first screw proximal to the fracture gap (at the posterio-lateral plate). The competitor's plate construct showed a fracture of the posterio-lateral plate at the first screw hole proximal to the fracture gap.

The Medartis system offers superior fatigue performance compared to a leading competitor, the possibility to place more screws into the periarticular area and the advantages of a variable angle locking system.

Figure 1: *Constructs used for biomechanical testing (left: Medartis, right: Competitor); arrows indicate typical failure sites*

Literature

[1] Korner et al., *Injury, Int J Care Injured*, **34:** S-B20, 2003.
[2] McKee et al., *J Shoulder Elbow Surg*, **18:** 13, 2009.
[3] Greiner et al., *Arch Orthop Trauma Surg,* **128:** *123, 2008.*
[4] Celli et al., *Chir Organi Mov,* **91:** 57, 2008.

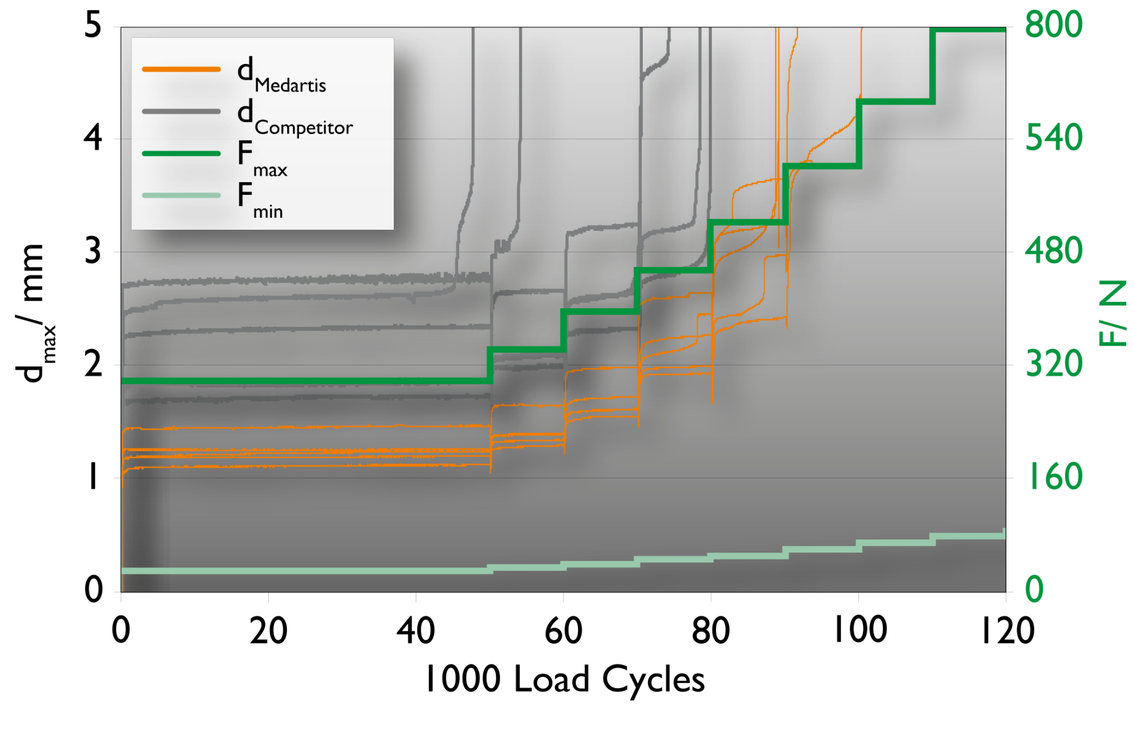

Figure 2: *Displacement and load curves (over time) for all distal humeral plating systems tested*

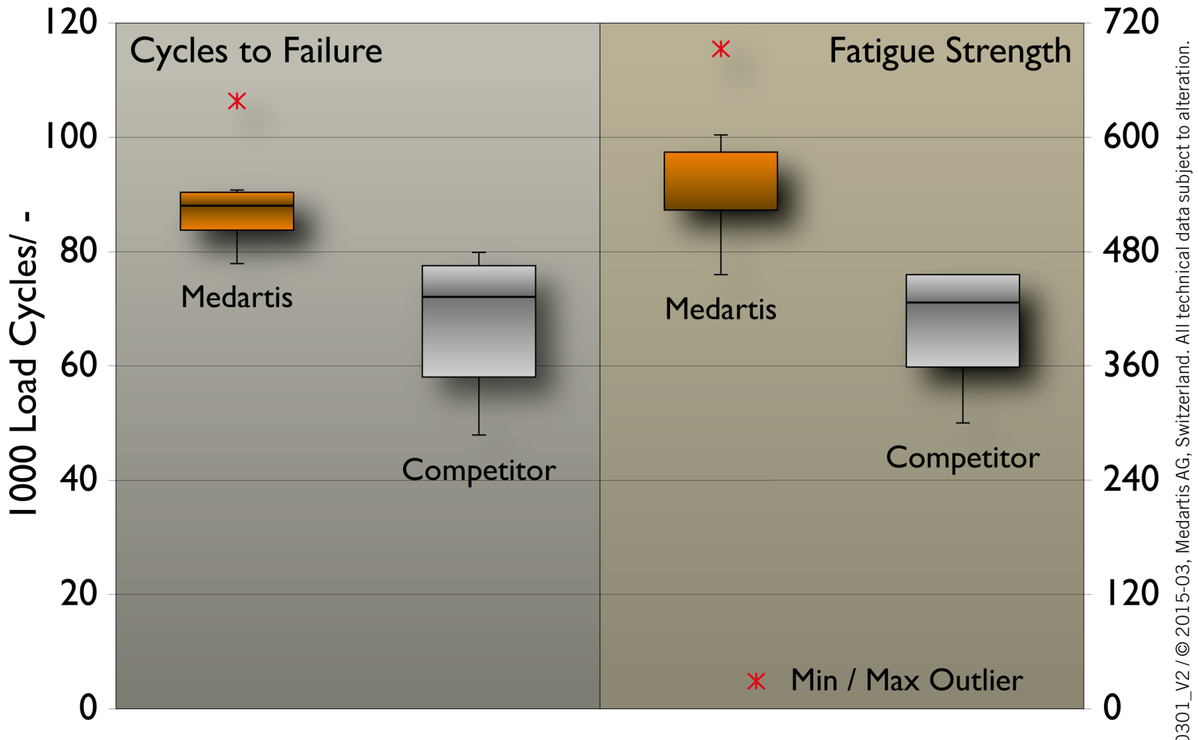

Figure 3: *Fatigue life (left) and fatigue load (right) of Medartis and Synthes distal humeral plating systems*