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Proximal Humerus Locking Plates in Simulated Osteoporotic Bone

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Introduction

Proximal humerus fractures are one of the most common skeletal injuries in the adult population [1] and usually due to osteoporosis. Despite improvements in the fixation of these fractures, complication rates (loss of reduction, screw perforation into the glenoid, malunion and avascular necrosis) remain high [2].

Medartis has developed a proximal humerus plating system featuring TriLock multidirectional locking technology and a spiral blade for additional calcar support. In case of poor bone quality stable support in the calcar region is crucial [3].

The Medartis proximal humerus system (with and without spiral blade) was compared to one of its leading competitors in simulated osteoporotic bone.

Materials and Methods

A test system was designed that simulates a Neer type 2-part fracture at the surgical neck of the proximal humerus. Using CAD software, all elements needed for load transfer and clamping were incorporated directly into the fixtures. The shaft was 3D printed polyamide allowing good screw purchase; for the head fragment Sawbone with a low density of 5 pcf was used to simulate highly osteoporotic bone.

The following systems were tested (Figure 1):

- Medartis APTUS 3.5 TriLock Proximal Humeral Plate with corresponding 3.5 mm locking screws and 50° spiral blade.
- Medartis APTUS 3.5 TriLock Proximal Humeral Plate with corresponding 3.5 mm locking screws.
- A proximal humerus plate with corresponding locking screws from a leading competitor.

Both systems were used as per their respective surgical techniques with 6 proximal locking screws, screw holes placed over the fracture were left empty (Figures 1 and 2). To better visualize screw cut-out, plates were mounted with a 1 mm gap to the substrate.

Fatigue testing was performed at 275 N axial loading for 150 000 cycles or until hardware failure ($displacement_{max}$ > 6 mm). Sinusoidal loading was carried out at 4 Hz and the ratio (F_{min}/F_{max}) was 0.1. Load and displacement were recorded.

Figure 2: *Test set-up*

Results and Conclusion

Figure 3 shows the Sawbone substrates after testing illustrating the screw cut-out of the different constructs. While the Medartis plate with spiral blade has minimal screw cut-out, the competitor's construct shows formation of long holes in the bone resulting in hardware loosening. This could make subsequent re-fixation of the fracture difficult.

Figure 3: *Sawbones substrate after testing (from left to right: Medartis with spiral blade, Medartis, Competitor)*

Figure 4 gives detailed displacement curves over time. While the competitor's construct fails at around 30 000 load cycles, the Medartis plate typically withstands more than 150 000 cycles. Adding the spiral blade further improves fatigue strength as illustrated by the reduced displacement. Load cycles to failure are shown in Figure 5.

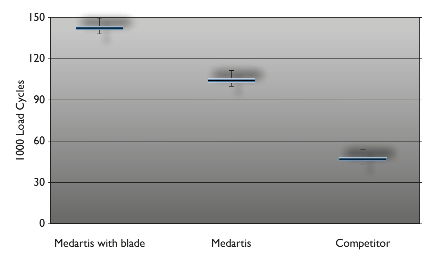

Figure 5: *Load Cycles at failure of different Proximal Humerus Plates*

In osteoporotic bone fixation systems with high stiffness (as is typical for thread-in-thread locking systems such as those used by the competitor) may result in increased cut-out and subsequent screw perforation.

The good clinical results of the Medartis system [4] have been confirmed by in-vitro testing: it offers superior fatigue performance in osteoporitic substrate compared to a leading competitor. The possibility to place a spiral blade for additional calcar support further improves cut-out resistance of the system.

Bibliography

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[2] Owsley et al., *J Bone Joint Surg Am*, **90(2):** 233, 2008.
[3] Gardner et al., *J Orthop Trauma*, **21(3):** 185, 2007.
[4] Beirer et al., *Eur J Med Res*, **20:** 57, 2015.

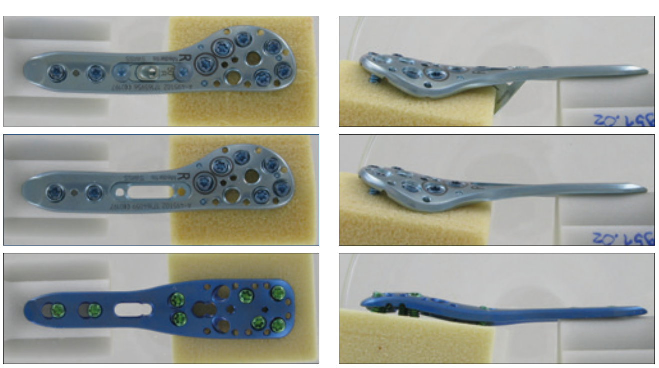

Figure 1: *Constructs used for biomechanical testing (from top to bottom: Medartis with spiral blade, Medartis, competitor)*

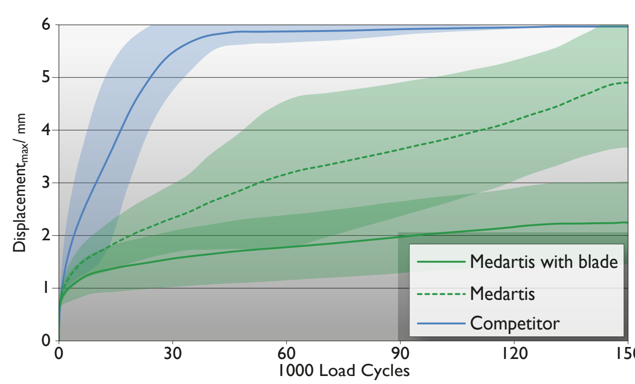

Figure 4: *Displacement over time of different proximal humerus plating systems (average and standard deviaton)*