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Biomechanical Testing of Total Wrist Fusion Plates

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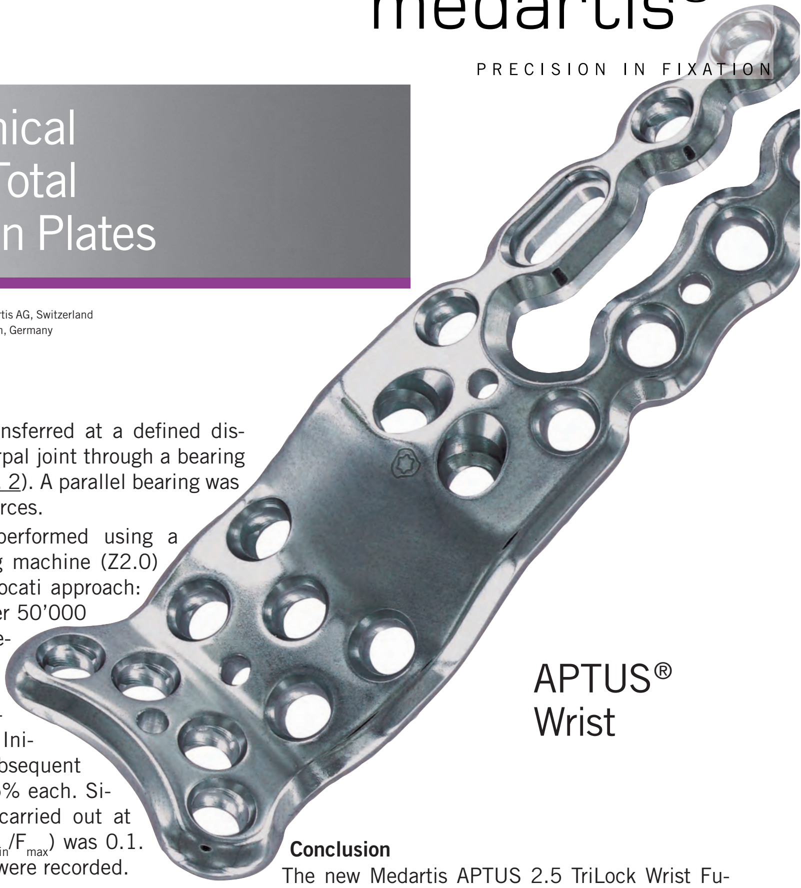

APTUS®
Wrist

Introduction

Total wrist arthrodesis is a reliable treatment for painful wrist conditions, caused e.g. by arthritic or post-traumatic joint degradation [1]. Depending on the medical condition wrist arthrodesis may include the midcarpal joints including or excluding the third carpometacarpal joint (CMCJ-3) or even CMCJ-2 [2].

Medartis is one of the first companies to offer a wrist fusion plate sparing the CMCJ. This reduces complications such as painful pseudarthrosis in the CMC joint and the need for post-op plate removal due to distal plate irritation. Additionally, motion across the CMCJ is maintained.

Different test set-ups were developed to compare the biomechanical stability of this novel approach to a traditional AO total wrist fusion (which includes the CMCJ).

Method and Materials

In a first attempt a CAD-designed wrist model (Fig. 1, top) approximating the anatomical situation (including bones and simulated soft tissue) was used for testing. Bones were produced out of glass-fibre reinforced polyamide (PA) while rubber (80 shore) was used for the soft tissue. Tests showed however that this model proved too fragile in the simulated joints; therefore, a more simplified model was developed and used for testing (Fig. 1, bottom).

Implants were mounted with a gap of 1 mm to the substrate to ensure that plate, screw and locking mechanism are all subjected to the bending moments introduced.

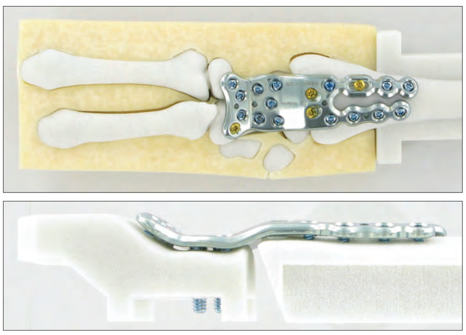

Figure 1: *Top: wrist fusion plate spanning the radiocarpal and midcarpal joint; bottom: simplified PA wrist model.*

Figure 2: *Test setup; left: Medartis, right: Predicate Device*

The axial load was transferred at a defined distance from the radiocarpal joint through a bearing onto the PA fixture (Fig. 2). A parallel bearing was used to inhibit shear forces.

Fatigue testing was performed using a Zwick universal testing machine (Z2.0) following a modified Locati approach: load was increased after 50'000 cycles and every subsequent 10'000 cycles, until hardware failure (fracture or deformation, dmax, >15 mm). Initial load was 70 N, subsequent load increases were 15% each. Sinusoidal loading was carried out at 4 Hz and the ratio (F_{min}/F_{max}) was 0.1. Load and deformation were recorded.

A locking plate from Medartis was compared to a predicate device, PD (also locking); 6 plates were tested each.

Additionally, the systemic screw pull-out resistance, F_{POS}, of the screws distal of the radiocarpal joint was determined. All four distal screws of the PD were pulled out of artificial metacarpal bone of good quality. Medartis screws (8) were pulled out of lower quality bone to simulate the damaged carpal structure. Good and bad quality bone was simulated using Sawbones biomechanical tesing material of different density:

- metacarpals: 3 mm cortical bone 50 pcf, 40 mm cancellous bone 20 pcf
- carpals: 3 mm cortical bone 40 pcf, 40 mm cancellous bone 15 pcf

Results

As shown in Figures 3 and 4, the Medartis plate has both a fatigue strength and a systemic pull-out resistance (F_{POS}) that is significantly higher than that of the PD.

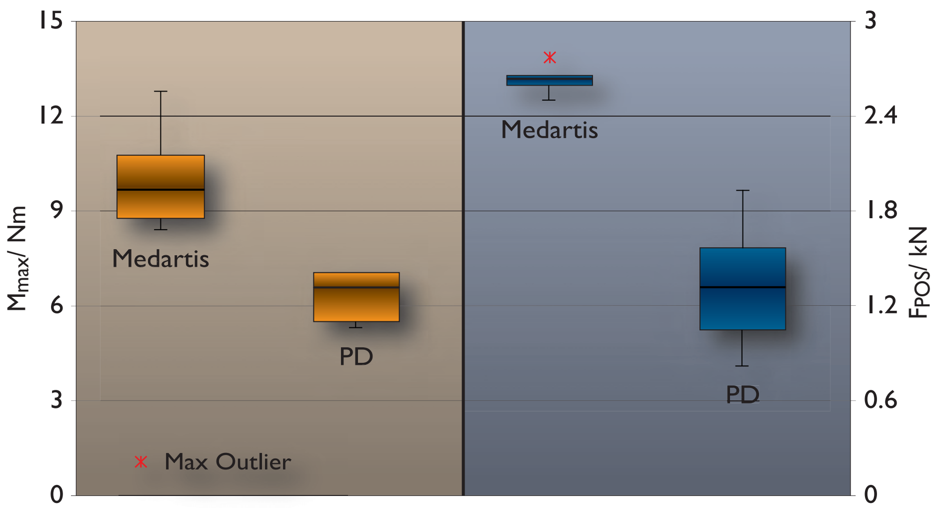

Figure 3: *Results of the fatigue test (left) and the systemic pull-out test (right)*

Conclusion

The new Medartis APTUS 2.5 TriLock Wrist Fusion Plate Long Bend showed superior fatigue resistance when compared to a leading competitor's plate. Results of pull-out resistance pointed out the excellence anchoring of the plate in carpal bones which are typically of poor quality.

References

[1] Hastings H. et al., *Orthopäde*, **22**: 86, 1993.
[2] Nagy L. et. al., *J Hand Surg*, **27A**: 940, 2002.

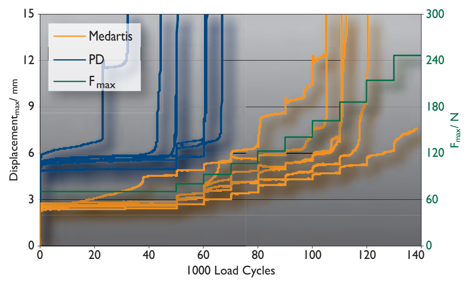

Figure 4: *Displacement and load curves*