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APTUS TriLock 1.5: A Multidirectional Locking System For The Phalanges

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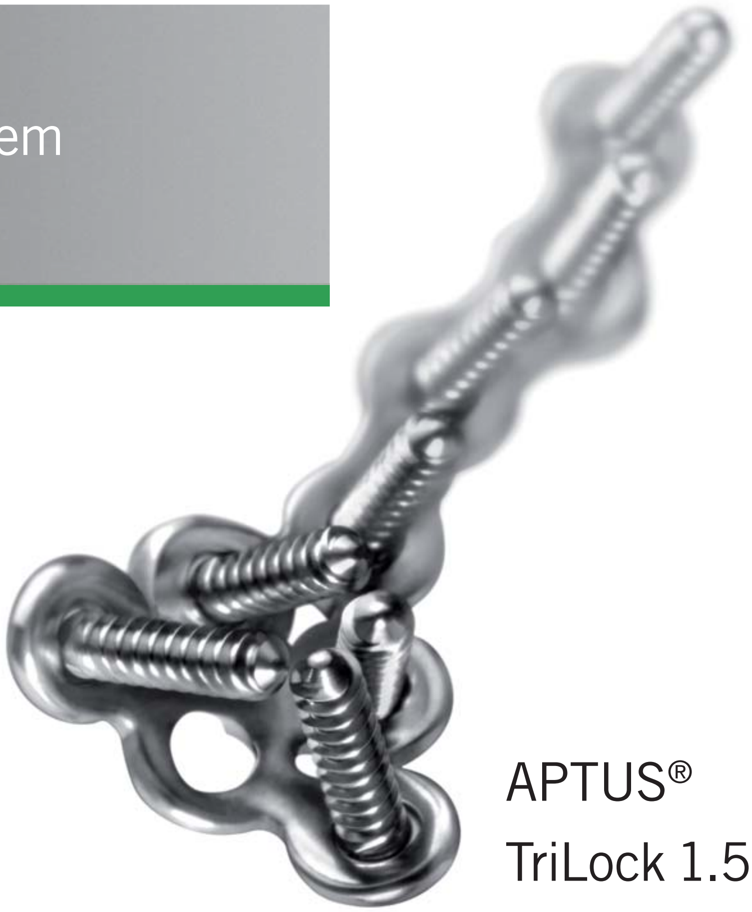

APTUS®
TriLock 1.5

INTRODUCTION

Over the past decades, locking plates have established themselves in the treatment of fractures in the hand and wrist. The increasing number of hand fracture systems that include locking plates reflect the trend of hand surgeons to use internal fixation systems, especially for complex fractures [1]. The treatment with angular stable systems has the advantage of achieving a more stable fixation in fractures with bone loss and of having a reduced risk of secondary displacement [2]. Additionally, they offer the possibility of indirect reduction of metaphyseal fractures [3]. Due to the complex anatomy of the hand in general and the phalanges in particular, the plates should be as small as possible to spare soft tissue, but strong enough to bridge a defect zone.

PLATE DESIGN

Medartis developed the APTUS TriLock 1.5 plates particularly for the phalanges (Figure 1). The plates are designed to provide higher stability, especially in comminuted and/or intra-articular phalangeal fractures or fractures close to the joint compared to non-locking plates.

Plate designs include both ‹traditional› straight, T- and grid plates as well as novel types such as the rotation correction plate, featuring a horizontal oblong hole or the double row T-plate for complicated fractures of the epiphysis (Figure 2).

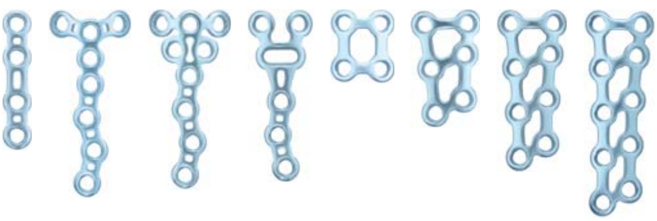

Figure 1 *APTUS TriLock 1.5 from left to right: A-4350.01, -14, -41, -23, -50, -56, -62, -66*

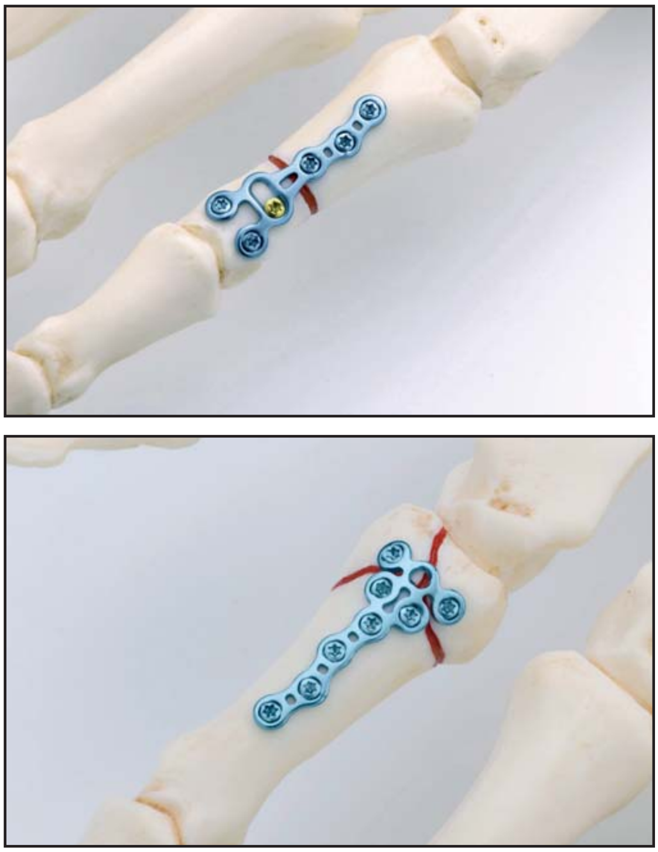

Figure 2 *APTUS TriLock 1.5 plates. Top: rotation correction plate A-4350.23, bottom: double row T-plate A-4350.41*

PLATE DESIGN & BENCH TESTING

Low Profile With TriLock Technology

Multidirectional locking is achieved by using the patented TriLock technology. The TriLock mechanism allows for an extremely thin plate with a locking screw that is completely flush with the plate (Figure 3). The low profile construct combined with rounded edges may reduce soft tissue irritation (Figure 4).

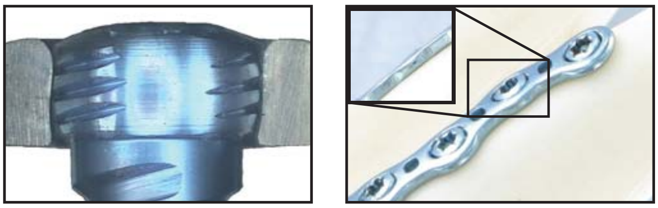

Figure 3 *Low profile TriLock mechanism. Left: cross-section, right: plate on artificial bone*

Figure 4 *Left: Plate with matte finish, right: Plate with rounded edges and a highly polished surface*

Plate Design Supported by FEA

The TriLock 1.5 plates have a minimal plate thickness of 0.8 mm. Compared to other micro fragment locking plates (e.g. Stryker's VariAx 1.7 or Synthes' LCP 1.5) the plates feature a lower profile. Using Finite Element Analysis (FEA) plates were optimized for a combination of high strength and good adaptability. A design featuring two connecting bars instead of a single larger one was developed. The designs were further optimized to reduce stress concentrations leading to better fatigue properties.

BENCH TESTING

Fatigue tests were performed comparing the TriLock 1.5 system to the APTUS 1.2/1.5 non-locking hand system which has been in clinical use since 2004.

Method and Materials

Testing was performed at the Medartis research laboratory in Basel on a Zwick LTM-1000 universal test system. To simulate loading under worst case conditions, an opening-wedge set-up was chosen, a situation typically occurring after dorsal plating of phalangeal fractures. Plates were mounted on machined fixtures with pre-drilled screw holes for improved reproducibility. Load was transferred at a defined distance from the distal screw through a steel plate flush with the sample fixture; to minimize torsional forces, load is transferred using a bearing. Based on the plates' indication, it is safe to assume that the maximum time of load bearing varies somewhere between 3 and 6 months after which the bone should have consolidated. This time roughly corresponds to 50'000 – 100'000 load cycles (assuming a recuperating person performs about 1000 load cycles per day). Sinusoidal loading was carried out at 7.5 Hz following a modified Locati approach.

Samples were tested under load control for a defined number of load cycles after which load was increased; different load profiles were used for the plates due to their differing geometries (Figure 6). Load ratio, R (F_{min}/F_{max}) was 0.1. Testing was stopped after hardware failure (plate, screw, or locking mechanism) or after deformations of 5 mm (non-locking plate) and 4 mm (TriLock plates) respectively. Load and displacement were recorded.

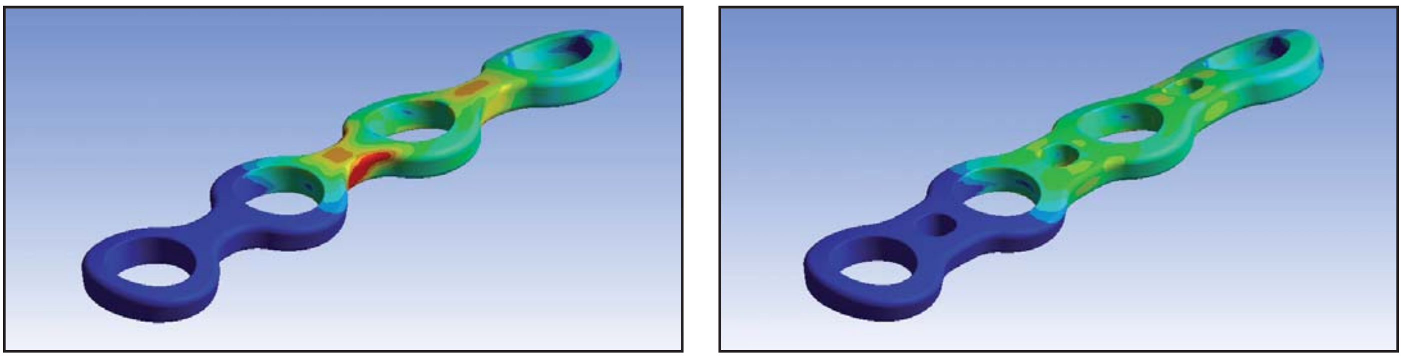

Figure 5 *FE of a design featuring a single bar (left) and double bars (right). Red indicates regions of high stress.*

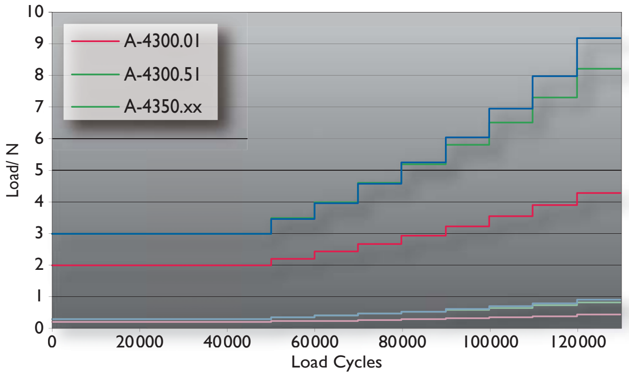

Figure 6 *Load profile (dark colors: F_{max}, light colors: F_{min})*

TriLock plates were mounted with a gap between plate and fixture to make sure the locking mechanism is tested (Figure 7, left), non-locking plates without gap.
Medartis APTUS A-4300.01 and A-4300.51 non-locking plates were compared to A-4350.01 and A-4350.50 TriLock plates; these plates represent the worst case geometries.

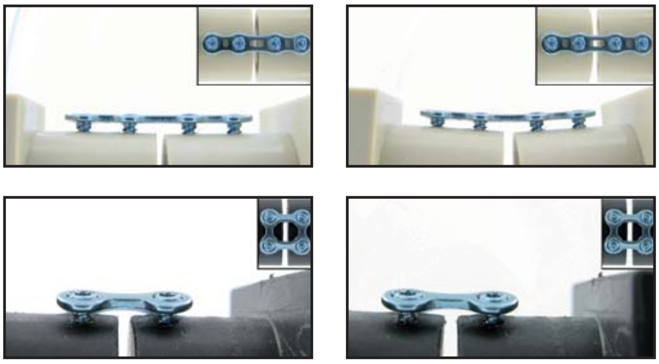

Figure 7 *TriLock 1.5 plates before (left) and after (right) testing. Top: A-4350.01, bottom: A-4350.50*

Results

Figure 7 shows TriLock plates before and after testing. None of the TriLock plates failed by breakage; straight TriLock plates failed through excessive deformation, grid plates through a gradual weakening of the locking mechanism. Non-locking plates failed either through buckling or through breakage (Figure 8).

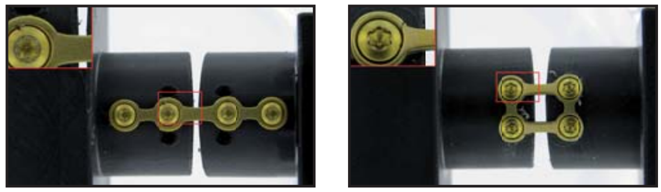

Figure 8 *Non-locking plates after testing. Left: A-4300.01 (buckled), right: 4300.51 (fractured)*

Compared to the non-locking plates, the failure mechanisms of the TriLock plates are slower and less critical as some residual rigidity remains. As a result, fatigue strength is significantly higher for the TriLock plates compared to the non-locking plates; fatigue life can not be compared directly due to differing load profiles (Figure 9).

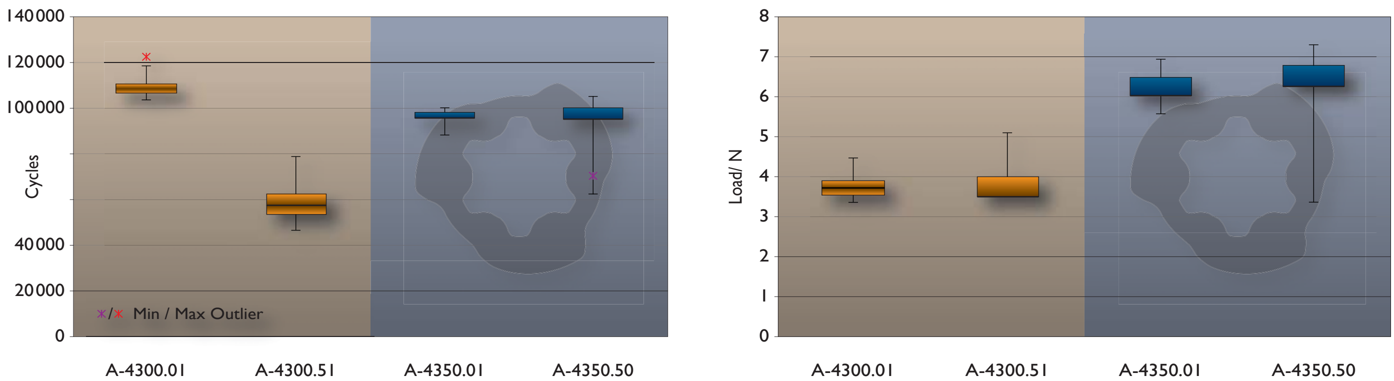

Figure 9: *Results of fatigue testing of conventional (yellow background) and TriLock plates (blue background); Left fatigue life, right: fatigue strength. Fatigue strength is significantly higher for the TriLock plates, fatigue life can not be compared directly due to the differing load profiles (Figure 6).*

CLINICAL RESULTS & CONCLUSION

CLINICAL RESULTS

A 48-year-old patient presented himself with pain and swelling in his right hand after a bicycle accident (C. Ranft, MD, Kiel, Germany). Pre-operative X-rays (Figure 10) as well as intra-operative pictures show a large comminuted zone close to the MCP-joint in the proximal phalanx of the fifth finger of the right hand (Figure 11).


Figure 10 *Pre-operative X-ray images*


Figure 11 *Intra-operative images*

This case was subsequently treated using an eight hole grid plate (A-4350.62) from the APTUS TriLock 1.5 system (Figure 12). The grid plate can be placed in close proximity to the joint and allows the secure fixation of small fragments. An additional fixation screw was used in the center of the grid plate to

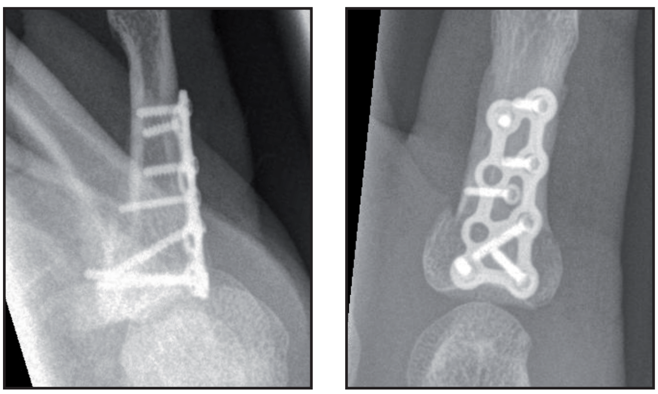
Figure 12 *Post-operative X-ray images*

stabilize a small bony fragment. The use of TriLock plates allowed a good anatomical reconstruction without the need to use allograft making the surgery both faster and safer.

CONCLUSION

Medartis developed the new APTUS TriLock 1.5 systems specifically for applications in the phalanges. The designs are adapted to treat complex fractures as well as rotation corrections. Designs have been optimized using FE resulting in a novel double bar design which combines high strength with good adaptability to the anatomy.

Experience gained during the limited release phase in selected clinics showed very good clinical results. Even complicated fractures of the phalanges were treated successfully. The APTUS TriLock 1.5 system is an addition to the existing APTUS 1.2/1.5 system giving the surgeon a wider choice of surgical options.

LITERATURE

[1] Ruchelsmann et Al., *Hand Clin,* **26** (2010).

[2] Figl et Al., *J Trauma*, **68** (2010).

[3] Fricker et Al. in: Herren and Nagy (eds): *Osteosynthesis in the Hand, Current Concepts. FESSH Instructional Course 2008*, Basel, Karger, (2008).

FURTHER INFORMATION

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