Biomechanical Performance of Screw Locking Mechanisms in Distal Radius Plates

Oliver M. Trapp, MD[1], Michael Gregor [2,], Geert von Oldenburg [3]

[1] Berufsgenossenschaftliche Unfallklinik Murnau/Staffelsee, Germany
[2] Stryker® Osteosynthesis, Freiburg, Germany
[3] Stryker® Osteosynthesis, Schönkirchen, Germany

Summary

Introduction: Several distal radius locking plate systems with different locking technologies are available on the market today. A main differentiating factor is whether the locking screws are fixed to the plate in a given trajectory (fixed angle locking plate systems) or can be fixed to the plate within an arch of angulation (variable angle locking plate systems). The **SmartLock** technology utilized in the Stryker® VariAx Distal Radius plating system provides the flexibility of variable angle screw placement within ±15 degrees of freedom. This paper shall document the mechanical capabilities of the SmartLock mechanism and compare it to competitors offering variable angle (Medartis Aptus) and fixed angle (Synthes LCP) locking plate systems for the treatment of distal radius fractures.

Materials & Methods: Cantilever bending tests on a single locked screw were carried out for Stryker® VariAx, Synthes® LCP and Medartis® Aptus distal radius locking plates. Furthermore, dynamic construct tests utilizing a simplified anatomical test setup were conducted to compare the fatigue strengths of Stryker® VariAx and Synthes® LCP implants.

Conclusion: At 0° screw angle the Stryker® VariAx locking mechanism is statistically significantly stronger than the Medartis® Aptus locking mechanism. The cantilever bending strength of the Stryker® VariAx locking mechanism is even statistically significantly higher than the fixed angle locking mechanism of Synthes® LCP plates. At 15° screw angle the Stryker® VariAx locking mechanism is again statistically, significantly stronger than the Medartis® Aptus locking mechanism. The results of the construct testing for the Stryker® VariAx and the Synthes® LCP distal radius plating systems revealed higher fatigue strength of the Stryker® implants.

1. Introduction

The SmartLock technology utilized in the Stryker® VariAx DR plating system provides the flexibility of variable angle screw placement within ±15 degrees of freedom. This paper shall document the mechanical capabilities of this locking mechanism and compare it to competitive systems offering variable angle and fixed angle screw locking options.

The function of the SmartLock mechanism is illustrated in figure 1. The locking screw heads are designed with threads on the underside, which upon insertion engage the circular "lip" within the locking holes of a VariAx DR plate. The locking mechanism allows free pivoting of a screw in all directions to a maximum of 15° from the orthogonal position.

The variable angle locking technology used by Medartis® Aptus is called TriLock®. The blocking of the screw in the plate is achieved by means of a spherical 3-point-cotter blocking. The spherical design of the screw head allows for the same amount of free stepless pivoting of a screw within ± 15°.

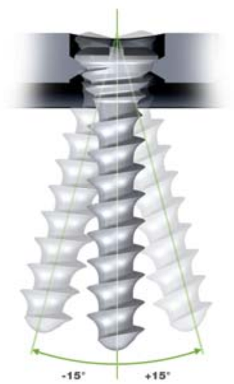

Figure 1: SmartLock mechanism, variable angle locking screw positioning within ± 15°

Synthes® offers a fixed angle locking technology with LCP (locking compression plate) holes in the shaft and threaded locking holes in the distal part of the plates. Locking of the screw in the plate is achieved by means of a threaded screw head engaging threaded plate holes.

In order to compare the mechanical performance of Stryker®´s SmartLock locking mechanism to competitors, cantilever bending tests were performed. The dynamic load tests conducted for Stryker® and Synthes® implants were based on the constructs´ resistance against deformation/gross failure affected by bending loads and were used to determine their fatigue strength.

2. Materials & Methods

All samples used for testing are listed in table 2.1.

Table 2.1: Test samples

Sample	Cat.-No.
Synthes 2.4mm LCP Locking Screw, self-tap	412.830
Synthes Screwdriver Shaft, Stardrive T8, selfholding	314.467
Synthes LCP Distal Radius Plate, volar, left	442.492
Medartis 2.5mm Aptus Radius 2.5, Locking Screw	A-5750.16
Medartis Aptus Radius 2.5, Screwdriver, Hexa Drive 7	A-2710
Medartis Aptus Radius 2.5, Locking Correction Plate, Long, volar, left	A-4750.15
Stryker VariAx, 18mm Locking Screws, Diam. 2.7mm, Cross-Pin	DR 190254
Stryker VariAx, 22mm Locking Screws, Diam. 2.7mm, Cross-Pin	DR190256
Stryker Screwdriver, Cross-Pin Blade 2.3mm/2.7mm	62-27007
Stryker Volar SmartLock DR Plate, Stand, Right, Short	54-25386

2.1 Cantilever bending tests

The test setup is illustrated in figures 2 and 3.

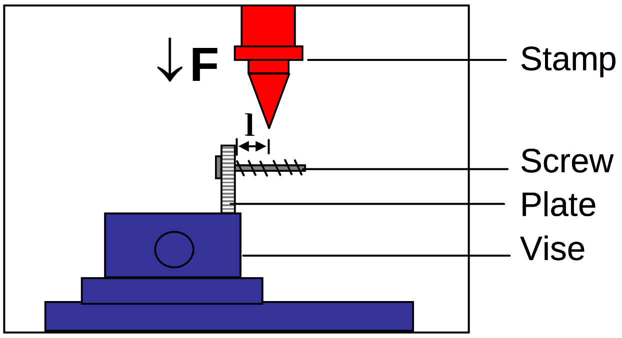

Figure 2: Schematic test setup cantilever bending test, lever arm l = 8mm

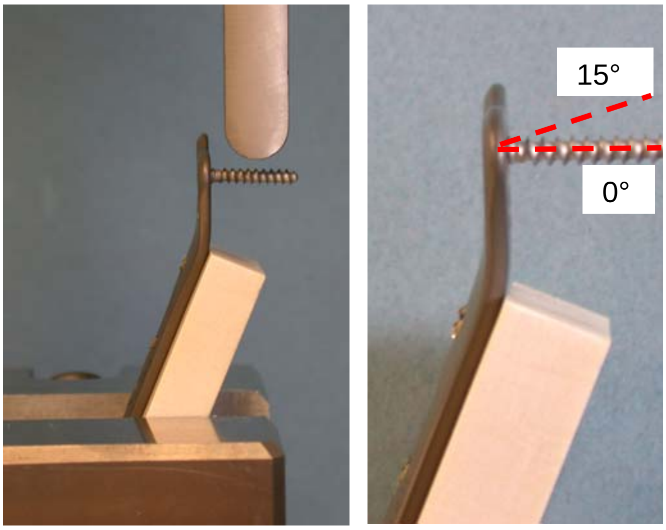

Figure 3:
left: Test setup for cantilever bending test at 0°
right: Screw trajectories at 0° and 15°

Locking screws were inserted at

- 0° (all systems)
- 15° (variable angle locking systems)

into the plate holes (figure 3, right). Screws were locked by applying 70% of the torque-to-failure value which have been determined for each compared system. The insertion torque applied was 1.75Nm for Synthes® LCP, 0.56Nm for Medartis® Aptus and 1.25Nm for Stryker® VariAx respectively. The plate with locked screw is clamped to a vise. The locking screw is loaded by a stamp of the test device with a constant speed of 0.1mm/s. The bending moment $M_{b0.1}$ is recorded. The value is the beginning of plastic deformation, i.e. remaining deformation after load reduction, thereby representing the beginning of reposition loss. At least 5 tests were performed per series.

To determine differences between results, a statistical analysis was performed (two tailed student t-test, p= 0.05).

2.2 Dynamic construct loading

In addition to testing single plate and screw connections, complete constructs comprising of one plate and multiple screws mounted onto a bone substitute were dynamically loaded to asses the fatigue strength of the Stryker® VariAx and Synthes® LCP distal radius plating systems.

The representative test setup is illustrated in figure 4. The force was transferred by a rigid load arm with pointed tip (diameter 4.7 mm). A 5mm gap was created (distance between two Cibatool blocks) to simulate a dorsal bony defect that can typically present in clinical practice. The tests were carried out with a lever arm of 4mm to the plate shaft.

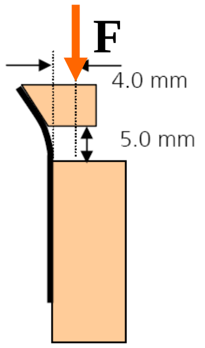

Figure 4: Load transfer and attachment of bone plates. The position of the load transfer is indicated by an orange arrow.

The shaft of each plate was fixed by three screws to a Cibatool block. The plates were fixed distally with four (Stryker® VariAx) and five (Synthes® LCP) locking screws respectively (figure 5).

Figure 5: left: Screw positions of the Synthes® LCP plate (marked with blue dots), **right:** Screw positions of the Stryker® VariAx plate

For load application, a servo hydraulic test machine was used. The frequency of the dynamic pulsating sinusoidal load was 20Hz. This frequency is higher than the physiological loading frequency, but the accelerated testing has no influence on the test results.

The number of load cycles was set to 500000, which represents the typical number of load cycles during a three month healing period until bony fusion is achieved (including a safety factor of two) [4]. Samples which lasted 500000 load cycles without failure were classified as run outs.

The tests were stopped after gross failure such as screw cut-out, plate breakage, screw breakage or after a total subsidence of more than 1mm, i.e. begin of reposition loss.

The significance of these tests is that greater fatigue strength should reduce the likelihood of construct failure in cases of delayed bony union or patients' non-compliance.

3. Results

3.1 Cantilever bending tests

Locking at 0°

The Stryker® VariAx variable angle locking mechanism is statistically significantly stronger than the Medartis® Aptus variable angle locking mechanism. The cantilever bending strength of the Stryker® VariAx locking mechanism is even statistically significantly higher than the fixed angle locking mechanism of Synthes® LCP plates.The Medartis® Aptus variable angle locking mechanism is statistically significantly weaker than the Synthes® LCP locking mechanism (figure 6).

Both variable angle systems fail due to overload of the mechanism while the fixed angle locking mechanism of Synthes® fails due to plastic deformation of the screws.

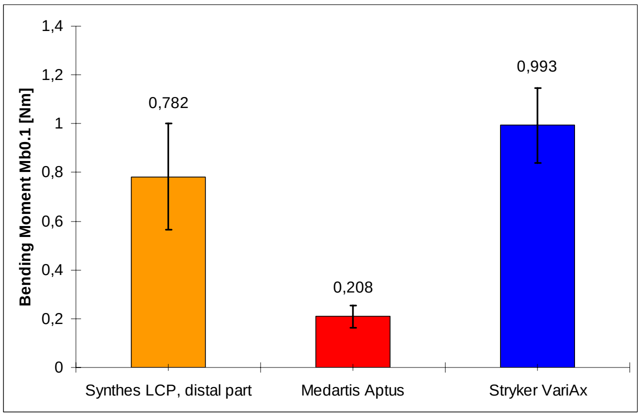

Figure 6: Results of cantilever bending tests at 0° locking angle, mean values ± standard deviations

Locking at maximum angle (15°)

At 15° locking angle the Stryker® VariAx locking mechanism is statistically significantly stronger than the variable angle locking mechanism used by Medartis® Aptus (figure 7).

Both variable angle systems fail due to overload of the mechanism.

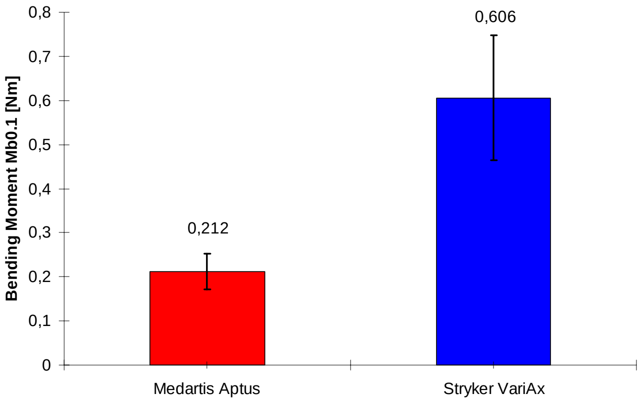

Figure 7: Results of cantilever bending tests at 15° locking angle, mean values ± standard deviations

3.2 Dynamic construct loading

The Stryker® VariAx distal radius plates demonstrated higher fatigue strengths than the Synthes® LCP distal radius plates (figure 8). The VariAx plates have fatigue strength of 363N (363Nx4mm=1.45Nm bending moment) while the LCP plates have fatigue strength of 294N (294Nx4mm=1.17Nm bending moment).

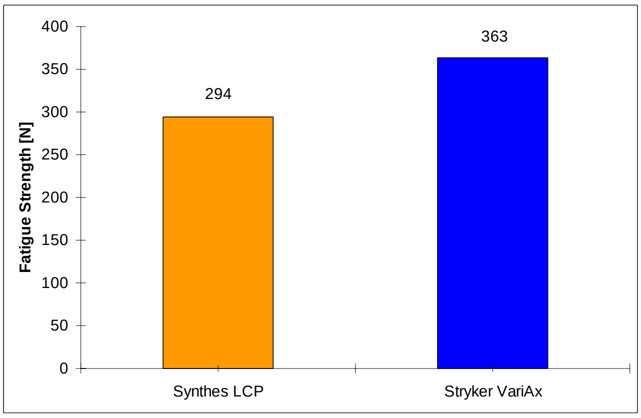

Figure 8: Dynamic load tests resulting in higher fatigue strength of Stryker® VariAx plates

The failure patterns of the tested plates are shown in figure 9. The areas of fatigue failure are marked with arrows. The Stryker® plates failed at the second row of holes in the distal part of the plates. The Synthes® LCP plates failed in the plate shaft.

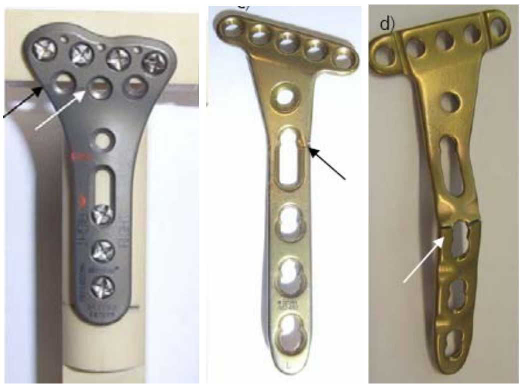

Figure 9: Failure patterns, **left:** Stryker® VariAx, **middle and right:** Synthes® LCP, cracks are marked with arrows

4. Discussion & Conclusion

The goal of this study was to determine the mechanical performance of different locking systems for distal radius plating systems. For this purpose cantilever bending tests were performed generating strength data for the different variable angle locking mechanisms utilized by Stryker® and Medartis® as well as the fixed angle locking mechanism used by Synthes®.

Dynamic load tests with Stryker® VariAx and Synthes® LCP distal radius plate constructs were performed to compare the fatigue strength of both systems.

The cantilever bending test results at 0° prove that the SmartLock locking mechanism used for the Stryker® VariAx distal radius plating system is statistically significantly stronger than the variable angle locking mechanism used by Medartis®. The cantilever bending strength of the Stryker® VariAx locking mechanism is even statistically significantly higher than the fixed angle locking mechanism of Synthes® LCP plates.

Considering the cantilever bending test results at 15°, it can also be concluded that TriLock®, the variable angle locking mechanism of Medartis® Aptus plates is statistically significantly weaker compared to Stryker® VariAx plates when screws are locked at their maximum possible angle.

Overall, the biomechanical data indicates that the locking capabilities of the Stryker® VariAx DR locking plates possess adequate fixation strength, with statistically significant higher values compared to the fixed angle locking mechanism of Synthes®, while providing the surgeon with intra-operative flexibility for screw placement within ±15° of freedom. The dynamic load tests also revealed higher fatigue strengths of Stryker® VariAx DR plates compared to the Synthes® LCP plates.

Although the Medartis® Aptus plates also allow for locking within ±15° of freedom, the TriLock® locking mechanism has shown statistically significantly lower results compared to the other systems in all scenarios tested.

5. References

[1] Ti 1739: Cantilever bending tests on distal radius locking mechanisms

[2] Ti 1912/08: VariAx DR, Cantilever bending on locking mechanism of ∅2,7mm system at angles of 0° and 15°

[3] Ti 1915/08: Distal Radius Plates, Fatigue testing

[4] ASTM F382-99 (reapproved 2003): Standard Specification and Test Method for Metallic Bone Plates