

Biomechanical Performance of the VariAx Foot Plating System

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Summary

Introduction: Stryker has developed a polyaxial locked plating system for trauma and reconstructive treatment of the foot. This paper gives a comparison of the biomechanical performance of the Stryker® VariAx Foot Locked Plating System to other products. **Materials & Methods:** Torque to failure tests and pull out tests of screws were performed. Additionally, fatigue tests utilizing simplified anatomical test set-ups and representative VariAx Foot Locked Plate and screw configurations were conducted. For this purpose a new generic model for testing of foot plating systems was developed. The results for the VariAx Foot Locked Plating System were compared to products for the same applications made by Darco®. **Results:** The components of the VariAx Foot Locking Plating System showed higher mechanical strength than components of the competitor Darco. **Conclusion:** A generic approach for comparative testing of foot plating systems has been established. The results of these tests prove the superior mechanical strength of the VariAx Foot plating implants compared to the competitor devices tested.

1. Introduction

Stryker® has developed a new polyaxial locked plating system for trauma and reconstructive treatment of the foot, called the VariAx Foot Locked Plating System (Figure 1).



Figure 1: Examples of plates and applications of VariAx Foot plates.

To assess the mechanical performance of the new system, it was compared to products available on the market and used for the same indications, i.e. Darco® Modular Forefoot Set and Darco® Modular Rearfoot Set.

A generic approach for comparative testing of the biomechanical strength of foot plating implants was developed. Standard screw tests were performed as well.

2. Materials & Methods

All samples used in the following tests are listed in table 1.

Sample	Cat. No.
Stryker® VariAx 2.7mm Non-Locking Screw	40-27040
Stryker® VariAx 2.7mm Locking Screw	40-27640
Stryker® VariAx 3.5mm Non-Locking Screw	40-35040
Stryker® VariAx 3.5mm Locking Screw	40-35640
Darco® 2.7mm Locking screw	DC 2825-026
Darco® 3.5mm Locking screw	DC 2820-040
Stryker® VariAx Curved plate, 4 holes	40-15011
Stryker® VariAx Rectangular Compression plate, Size1	40-15031
Stryker® SPS Calcaneus Plate, Medium	40-10114
Darco® UPS 3.5mm Plate	DC 2801-020
Darco® UPS 2.7mm Plate	DC 2801-120
Darco® MPG Fusion I Plate	DC 2805-015
Darco® CPS Plate, Medium	DC 2805-002

Table 1: Test samples

2.1 Screw tests - Torque to failure

The torque to failure test (Figures 2 and 3) determines the maximum torque applied to the screws, until failure occurs. For this test the screw is inserted by means of the screwdriver blade using a torsion test machine (Zwick Z020) into a cortical bone substitute block (RENSHAPE® BM 5166, [13]). Torque is applied until failure. Tests were conducted with screws from the VariAx Foot Locked Plating System, and from the Darco® system (see Table 1). The significance of these tests is that higher values for the maximum torque to failure and indicates that the screws are less likely to break during insertion into bone.

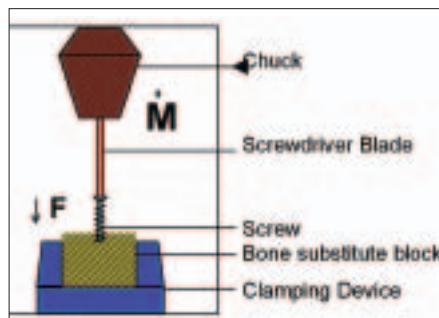


Figure 2: Test set up for the Torque to Failure test

Respectively, six single measurements were performed for statistical reasons.

2.2 Screw tests – Pull out



Figure 3:
Torque to
Failure of
screws

The aim of the pull out test is to measure the maximum pull out force of a screw from a 2mm thick cortical shell (bone substitute RENSHAPE® BM 5166). In the author's experience, this value of

shell thickness is typical for foot indications [12]. Figures 4 and 5 show the test configuration. The screws are inserted through the cortical shell until they extend 3mm from the opposite side. They are then pulled out with a velocity of 0.1mm/s. The maximum force required during pull out is measured and recorded. These pull-out tests were performed with locking screws only because they have a thread design that is equivalent to the threads in non-locking screws. Again, six single measurements per screw type were performed.

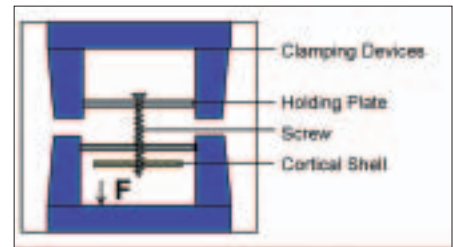


Figure 4: Test configuration of the pull out test

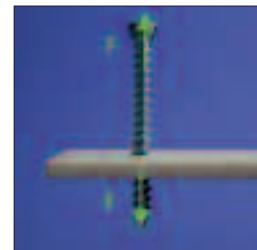


Figure 5:
Pull out test

The significance of this test is that a higher pull out force will result in a lower risk of a screw pulling out of bone during loading.

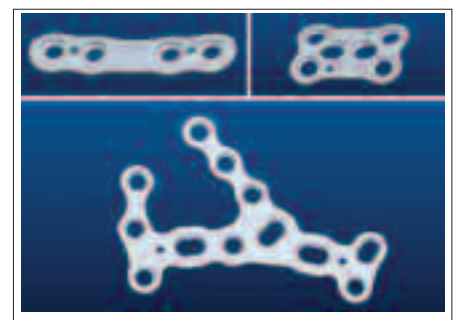


Figure 6: Examples of VariAx Foot Plates that were tested

2.3 Fatigue tests of bone-plate-screw-assemblies

In addition to testing individual plates and screws, fatigue tests of complete assemblies consisting of one plate and multiple screws mounted onto a bone substitute also were performed. These tests were conducted with the mechanically weakest plate for each application, thus representing the weakest mechanical performance scenario of the VariAx Foot Locked Plating System (for test samples, see Figure 6 and Table 1).

To represent the state of the art, locking screws were used exclusively in this test.

Four main load cases were identified:

- 4-point out of plane bending (following [1]).
- 4-point in plane bending (following [1]).
- Compression.
- 3-point bending (calcaneal application only).

A bone gap of 5mm representing a mechanical “worst case scenario” was used in all test configurations.

Bending loads are mechanically the most demanding to the constructs, because bending leads to high stresses in the plate, which can result in a fatigue fracture. They occur as a result of load bearing, when muscle and tendon forces are created during patient gait (see Figure 7). The majority of implants fail due to bending loads. Additionally, during load bearing, compression forces also appear, as is similarly demonstrated in Figure 7.

The load cases were chosen to simulate the likely loads to which the plates will be subjected when implanted in a spectrum of cases in the foot. The calcaneus plates were tested in 3-point bending according to anatomy and recommendations from M. Richter et al. [2].



Figure 7: Schematic picture demonstrating mechanical loads [13]

For every load application, servo hydraulic test machines (e.g. MTS 858 Mini Bionix®) were used (Figure 8). The maximum frequency of the dynamic pulsating load was 10 Hz. This frequency is higher than the physiological loading frequency, but the accelerated testing has no mechanical influence on the test results. The number of load cycles was set to 500,000, which represents the typical number of load cycles until bony fusion in a patient during a three month healing period (including a safety factor of two). The fatigue strength was determined using a staircase method [3].

The tests were stopped after gross failure such as screw cut out, plate

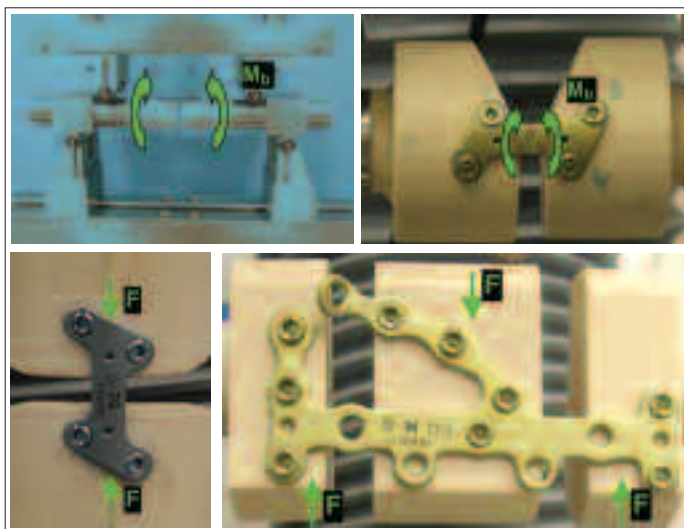


Figure 8: Test set-ups for fatigue tests, Top left: 4-point out of plane bending, Top right: 4-point in plane bending, Bottom left: compression, Bottom right: 3-point bending (calcaneal application).

breakage, screw breakage or after a total subsidence of more than 1mm.

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

For each test, six single measurements were performed. The test procedure of fatigue testing does not allow a comparison for statistical significance.

3. Results

3.1 Screw tests – Torque to failure

The Stryker® VariAx Foot screws have approximately 20% greater maximum torque to failure than Darco® screws (Diagram 1 and 2). The values of all 2.7mm and 3.5mm Stryker® locking and non-locking screws show statistically significant differences compared to Darco® (two tailed student-t tests, $p=0.05$). The failure mode for all screws was that

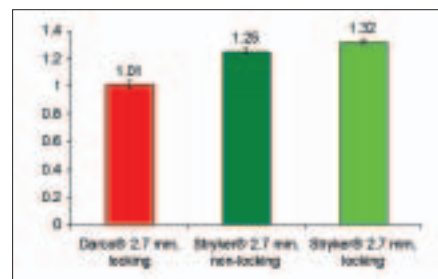


Diagram 1: Maximum torque of 2.7mm Darco® and Stryker® screws (vertical indicator: standard deviation)

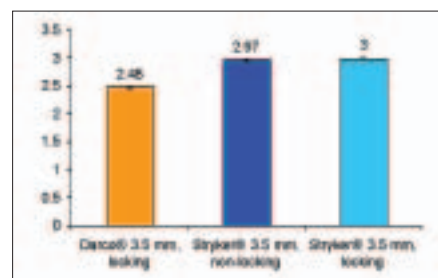


Diagram 2: Maximum torque of 3.5mm Darco® and Stryker® screws (vertical indicator: standard deviation)

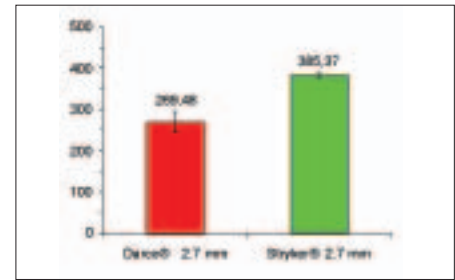


Diagram 3: Pull out forces of Darco® and Stryker® 2.7mm locking screws

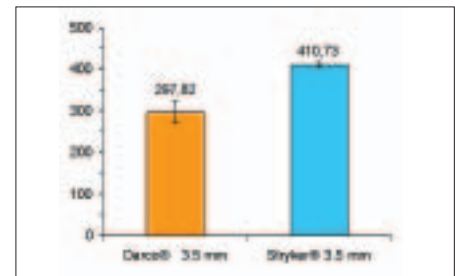


Diagram 4: Pull out forces of Darco® and Stryker® 3.5mm locking screws

the screw sheared off in the thread section.

3.2 Screw tests – Pull out

The Stryker® VariAx Foot screws have approximately 40% greater pull out forces than comparable Darco® screws, see diagrams 3 and 4. [7]. This result was statistically significant for screw diameters 2.7mm and 3.5mm (two tailed student-t tests, $p=0.05$). The failure mode that was exhibited during testing was always local fracture of the bone substitute, and no screw damage occurred.

3.3 Fatigue tests of bone-plate-screw-assemblies

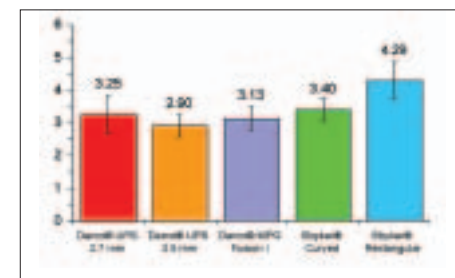


Diagram 5: Fatigue strength of Stryker® plates and Darco® plates, 4-point bending out of plane, locking screws used for fixation

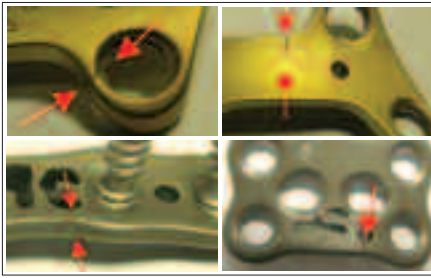


Figure 9: Failure patterns, 4-point out of plane bending; Top: Darco® UPS 3.5mm plate, Bottom left: VariAx Foot curved plate, Bottom right: VariAx Foot rectangular plate.

4-point bending out of plane

In “4-point bending out of plane” tests, the Stryker® VariAx Foot plates demonstrated greater fatigue strength than the Darco® plates. The Stryker® rectangular plate shows higher fatigue strength values compared to Darco®, as well as Stryker® curved plates. For values (incl. 95% confidence intervals), see Diagram 5.

The failure results of the 4-point bending out of plane tests are shown in Figure 9.

4-point bending in plane

In contrast to the Darco® UPS 3.5mm plate, it was not possible to damage the Stryker® curved plate or screws in plane. Damage of the bone substitute (abrasion) occurred leading to screw loosening when the load was increased above the tested load level. The fatigue strength of the Stryker® curved plate is at least twice as high as the value of the Darco® UPS plate (Diagram 6).

The failure patterns of the Darco®

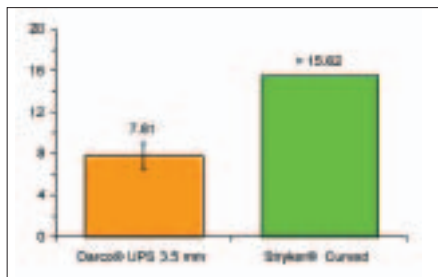


Diagram 6: Fatigue strength of Stryker® plates and Darco® plates, 4-point bending in plane

Sample	Bending Moment [Nm]	Axial Force [N]
Stryker® VariAx Curved plate, 4 holes	0.81 ± 0.08	81.3 ± 8.2
Stryker® VariAx Rectangular compression plate, size 1	1.26 ± 0.11	126.1 ± 10.9
Darco® UPS 3.5mm plate	0.76 ± 0.08	75.9 ± 8.2
Darco® UPS 2.7mm plate	0.63 ± 0.05	63.0 ± 5.0
Darco® MPG Fusion I plate	0.60 ± 0.09	60.0 ± 9.0

Table 2: Fatigue strength (bending moments and axial forces) of Stryker® plates and competition, compression

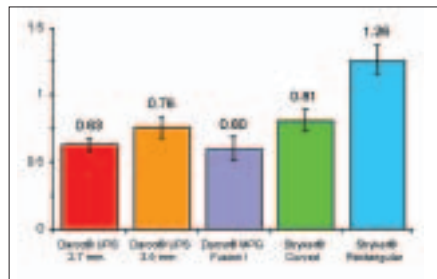


Diagram 7: Fatigue strength (bending moment) of Stryker® plates and Darco® plates, load case compression

UPS 3.5mm plate due to in plane bending are the same as for out of plane bending.

Compression

In compression, the Stryker® plates also have greater fatigue strength than the Darco® plates. Diagram 7 shows the results of the bending

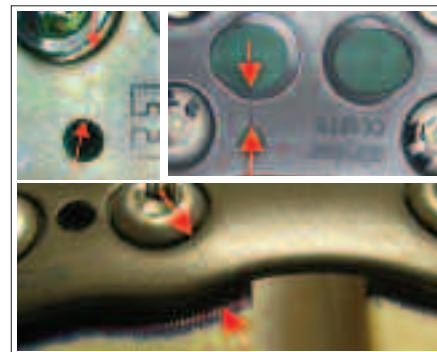


Figure 10: Failure patterns, compression; top Left: Darco® UPS 3.5mm plate, Top right: VariAx Foot rectangular plate, Bottom left: VariAx Foot curved plate

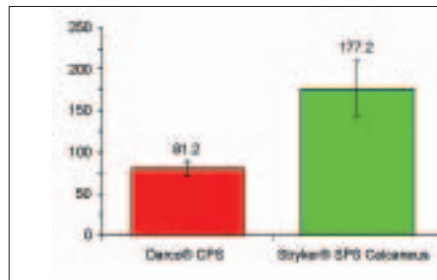


Diagram 8: Fatigue strength of Stryker® and Darco® calcaneus plates, under a 3-point bending load case

moment and Table 2 shows the bending moment plus the corresponding axial force. The Stryker® VariAx Foot rectangular compression plate has the greatest strength followed by the curved plate [8, 9].

The plates failure patterns are shown in figure 10.

3-point bending of calcaneus plates

The results of the testing the calcaneus plate are shown in Diagram 8. The fatigue strength of the Stryker® SPS calcaneus plate, medium is more than twice as high as the value of the Darco® CPS plate, medium [10, 11].

During testing, plastic deformation of the Stryker® VariAx calcaneus standard plate was visible, but breakages did not occur. In contrast, the Darco® CPS plate broke at a screw hole close to the middle of the plate (Figure 11).



Figure 11: Failure pattern of Darco® CPS plate, medium, 3 point bending, (no figure of VariAx plate since no fracture occurs)

4. Discussion & Conclusion

Since the goal of these tests was to determine the mechanical properties and the biomechanical performance

of the Stryker® VariAx Foot Locked Plating System, screw and construct tests were performed to compare the Stryker® VariAx Foot Locked Plating System to competitor Darco's® equivalent foot system.

The torque to failure screw tests were performed to determine resistance against screw breakage upon insertion. The Stryker® screws show significantly higher torque to failure values compared to the Darco® screws. Pull out screw tests were made to determine the pull out forces. The higher the pull out force, the higher the expected resistance against screw pull out even in thin and weak bone. The results of this test demonstrated that Stryker® VariAx Foot screws had significantly higher values versus the Darco® screws.

A new and enhanced fatigue testing method was used when testing complete constructs (consisting of a plate and several screws). Although statistical comparison between groups is not possible for these tests, the Stryker® plate constructs show obviously higher fatigue strength compared to the Darco® constructs. These results strongly suggest that Stryker® VariAx Foot plate constructs will withstand loads and be less likely to fail, even in cases of delayed bony union, patient non-compliance or high patient weight relative to Darco.

In summary, there are two main conclusions that can be derived from the results of our testing: First, the Stryker® VariAx Foot Locked Plating System possesses enhanced mechanical strength properties compared to competitive products from Darco® [4 - 11]. Second, a new test method for comparative biomechanical testing of foot plating systems was developed and successfully used for the first time.

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