Biomechanical Performance of Stryker® XXL Volar VariAx™ Distal Radius Plates

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Abstract

Introduction:
New distal radius (DR) plates for the treatment of unstable comminuted fractures including metaphyseal and diaphyseal part of the radius were developed. In this study the influence of screw diameter and number of screws on plate fixation was investigated. Furthermore, biomechanical performance of these new plates was examined and compared to competitor products.

Materials and Methods:
Screw configuration was investigated performing a dynamic pull-out test. With a Finite Element Analysis (FEA) the new Stryker® XXL Volar DR Plate and the DR plate of the competitor Zimmer® were compared. Furthermore, a dynamic Cantilever Bending Test was conducted to obtain the Median Fatigue Limit (MFL) of the new Stryker® XXL Volar DR VariAx Plate and compare it to the DR plates of the competitor Synthes® and Zimmer®.

Results:
The utilisation of a larger screw diameter (3.5mm) showed no statistical significant increases in pull-out strength. However, adding a fourth screw raised the pull-out resistance significantly in the poor quality bone model. In the good quality bone model the three 2.7mm VariAx Bone screws were strong enough to securely fix the plate.
The new Stryker® XXL Volar DR VariAx Plate showed significantly statistical higher fatigue strength than the DR plates of Synthes® and Zimmer®.

Discussion and Conclusion:
This investigation showed that the new Stryker® VariAx XXL Volar DR Plate is safe and effective for the fixation of distal radius fractures including the metaphyseal and diaphyseal part. The new Stryker® XXL Volar DR VariAx Plate offers improved fatigue characteristics which lead to a higher safety against plate failure during prolonged healing e.g. in the elderly

Abbreviations:

DR	Distal Radius	LCP	Low Compression Plate
FEA	Finite Element Analysis	MFL	Median Fatigue Limit
CBT	Cantilever Bending Test		

Keywords: distal radius, biomechanics, fractures, plate, screws, osteosynthesis

1. Introduction

Fractures of the distal radius (DR) are common fractures ([1],[2],[3],[4],[5],[6]). Due to the elderly population ([2],[5]), oesteoporosis [7] and the activity of this population group [5] the appearance of DR fractures will increase continuously ([2],[5],[7]). Plate fixation of DR fractures is reported to be a satisfying treatment [8]. Stryker® provides a polyaxial plating system for this indication – the VariAx DR System. These plates cover the indication of intra- and extra-articular fractures of the distal radius. Recently, the VariAx DR portfolio was extended with plates for unstable comminuted fractures of the distal radius extending into the shaft – the VariAx XXL Volar DR Plates.

The purpose of this investigation was twofold. First, the optimal screw diameter for the new system was identified. Therefore, a screw pull-out test with different screw configurations and bone substitute materials was performed.

Second, the safety and effectiveness of the plate design has to be demonstrated. Therefore a Finite Element Analysis (FEA) was performed, followed by a cantilever bending test.
Prior testing established DR plating systems were identified. Biomechanical performance of the VariAx XXL Volar DR plates was then compared against the predicate devices.

2. Materials

The following plates and screws were investigated.

Table 1: Test samples

Manu-facturer	Description	Ref
Stryker®	2.7mm XXL Volar DR VariAx Plate, 15 hole, Titanium	54-25420
	2.7x16mm VariAx DR Bone Screws, Titanium	53-27216E
	SPS Waisted Compression Plate 130mm, Titanium	621150
	3.5x16 mm SPS Cortical Screw, self tapping, Titanium	603016
Zimmer®	Distal Volar Radial Radius Plate, Left, 12 Holes, Stainless Steel	2348-014-12
Synthes®	11 hole , right LCP Dia-Meta Volar Distal Radius Plate, Titanium	04.110.111

3. Method

Screw Pull-out

The pull-out force of the construct was examined using a servo hydraulic test machine (Instron 8874, Instron, UK) equipped with a 1kN load cell. The plate construct was loaded 1000 times with a defined force (Figure 1) in a sinusoidal manner (load ratio R=0.1, frequency 5Hz). Loading started at 30N and was raised by 10 N, if no failure (screw pull-out) was detected.

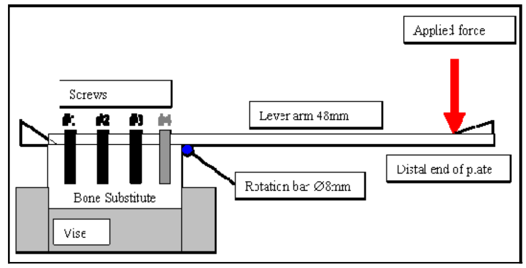


Figure 1: Schematic test setup of pull-out test.

The following screw configurations and bone qualities, simulated by defined foam densities, were tested (Table 2).

Table 2: Bone model and Screw configuration

Bone Model	Screw Type	Plate Type	Qty. of screws
Poor bone quality (SawBone®, 10pcf)	Stryker® 2.7mm VariAx DR Bone Screw	2.7mm Stryker® XXL Volar DR VariAx Plate	3
			4
	Stryker® 3.5mm SPS Bone Screw	SPS Waisted compression plate	3
Good bone quality (SawBone®, 20pcf)	Stryker® 2.7mm VariAx DR Bone Screw	2.7mm Stryker® XXL Volar DR VariAx Plate	3
	Stryker® 3.5mm SPS Bone Screw	SPS Waisted compression plate	3

Finite-Element-Analysis (FEA)

FEA's were performed to compare the new Stryker® XXL Volar DR VariAx Plates with the Distal Volar Radial Radius Plate (Zimmer®). Thereby, the most critical load case was identified [9]. In this load case the load is applied over a screw hole which is off plate axis resulting in an additional torsion load.

Cantilever Bending Test

Based on the results of the FEA the DR Plates were tested in a dynamic Cantilever Bending Test and loaded with a defined force in a sinusoidal manner (R=0.1, frequency 20Hz) until run out (500,000 load cycles) or plate failure. The load was applied on a screw hole off plate axis using a servo hydraulic test machine (MiniBionix 858, MTS®). For comparison reason the loads were converted into moments by multiplying the force with the respective lever arm. This was necessary due to the different plate geometries. The applied load was converted into a torsional moment and a bending moment at the most distal shaft screw. Respective lever arms for each plate type were determined (Figure 2).

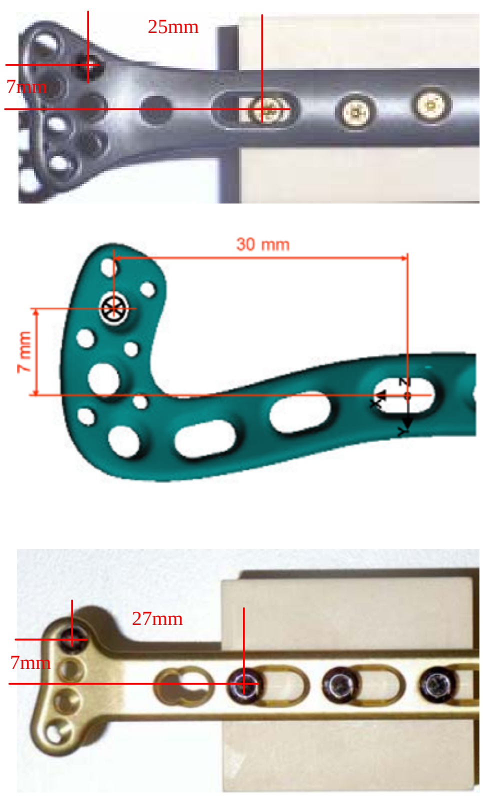


Figure 2: Lever arms of the different test setups (Upper: Stryker® XXL Volar DR VariAx Plate, Middle: Zimmer® Distal Volar Radial Radius Plate, Lower: Synthes® LCP Dia-Meta Volar Distal Radius Plate)

The median fatigue limit (MFL) was calculated according [11].

Table 3: Physical specifications of test setup

	XXL Volar DR VariAx Plate	LCP Dia-Meta Volar Distal Radius Plate	Distal Volar Radial Radius Plate
Vendor	Stryker®	Synthes®	Zimmer®
Lever arm bending	25mm	27mm	30mm
Lever arm torsion	7mm	7mm	7mm

4. Results

Screw Pull-Out

The results of the screw pull-out test in a PU-foam with 10pcf (bone substitute for poor quality bone) show no significant (α=0.05, p=0.635, exact test following Monte Carlo method) improvement of the pull-out behavior between 3x2.7mm VariAx DR Bone Screws (100±6.3N) and 3x3.5mm SPS Cortical Screw (103±5.2N) (Figure 3). The introduction of a fourth 2.7mm VariAx DR Bone Screw increases the pull-out strength (111±4,1N) significantly (α=0.05, p=0.014, exact test following Monte Carlo method). This was an increase of 11% in pull-out strength. The failure mechanism in the poor quality bone model was screw pull-out in all cases (Figure 4).

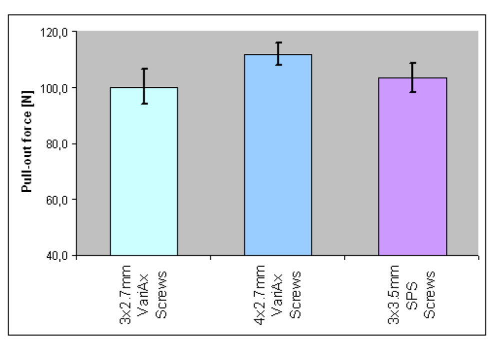


Figure 3: Pull-out strength of different screw configurations in a poor quality bone model (10pcf PU-Foam)

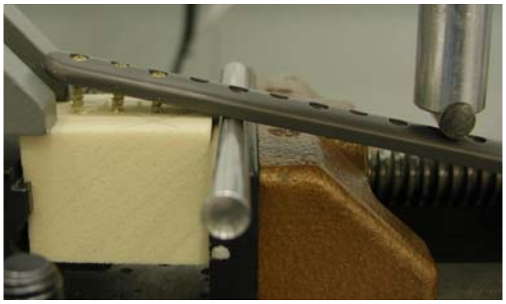


Figure 4: Screw-pull-out - Failure of construct with Stryker® 3x2.7mm VariAx DR Bone screws in poor quality bone model (10pcf PU-foam)

The failure load in the good quality bone model (20pcf PU-foam) of the plate construct of the new Stryker® XXL Volar DR VariAx Plate with three 2.7mm VariAx DR Bone Screws was 250±0N. Whereas, the failure load of the construct of the SPS Waisted Compression Plate with three 3.5mm SPS Cortical Screw was 233±11.5N. The failure mode of the construct in the good quality bone model was in all cases a plastic deformation of breakage of the osteosynthesis plate (Figure 5).

Figure 5: Screw-pull-out – a) Failure of plate, b+c) detailed view of failed plate, b) Stryker® XXL Volar DR VariAx Plate, c) Stryker® SPS plate

Finite-Element-Analysis (FEA)

The FEA mesh plots including the maximal principal stresses (Figure 6) identify a critical stress concentration at the transition of the oblong holes into the shaft.

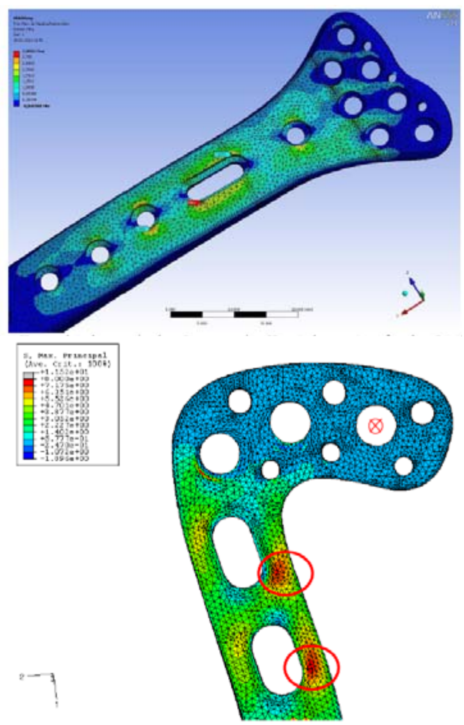


Figure 6: FEA results of Stryker® XXL Volar DR VariAx Plate [10] (upper) and Zimmer® Distal Volar Radial Radius Plate (lower, predicate device) [9] – maximal principal stresses. Red color indicates high stress conditions.

The principal stresses calculated during the FEA's were 7.5MPa for the Stryker® XXL

Volar DR VariAx Plate and 7.7MPa for the Zimmer® Distal Volar Radial Radius Plate [9].

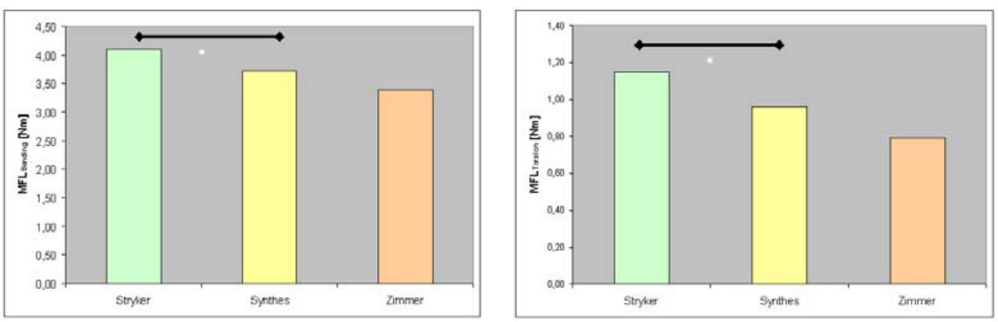
With respect to the limitations of the FEA (regarding e.g. material compensation and inaccuracies of the 3D-Scan of the Zimmer plate) it can be concluded that these two plate types show a similar stress condition, which should result in similar plate strengths.

Dynamic Cantilever Bending Test

The results of the dynamic Cantilever Bending Test show a statistical significant (two tailed student-t-test, $\alpha=0.01$, $p=0.001$) difference between the Stryker® XXL Volar DR VariAx Plate ($MFL_{bending}$: 4.13 Nm, $MFL_{torsion}$: 1.16NM) and the Synthes® LCP Dia-Meta Volar DR Plate ($MFL_{bending}$: 3.73Nm, $MFL_{torsion}$: 0.97Nm) (Table 4) (Figure 7). The MFL of the Zimmer® Distal Volar Radial Radius Plate ($MFL_{bending}$: 3.39Nm, $MFL_{torsion}$: 0.79Nm) was calculated from a Wöhler Curve [9]. Therefore, no standard deviation could be given.

Table 4: MFL's for the three investigated plates (MFL of the Zimmer DR plate is calculated on the basis of a Wöhler Curve estimated [9])

Plate	$MFL_{Bending}$ [Nm]	$MFL_{Torsion}$ [Nm]
Stryker® XXL Volar DR VariAx Plate	4.13	1.16
Synthes® LCP Dia-Meta Volar DR Plate	3.73	0.97
Zimmer® Distal Volar Radial Radius Plate	3.39	0.79



Bending direction **Torsion direction**

Figure 7: Comparison of the MFL of the three plate types, the Stryker® XXL Volar DR VariAx Plate shows significant higher median fatigue limits than comparable plate types (* indicates statistical significant difference)

5. Discussion

First, investigation of the optimal screw diameter and number showed that three 2.7mm VariAx DR Bone Screws perform similar ($\alpha=0.05$, $p=0.635$) to three 3.5mm SPS Bone Screws in the poor quality bone model (10pcf PU-foam). With the introduction of an additional fourth 2.7mm VariAx DR Bone Screw the pull-out strength could be increased by 10%. This was statistical significant ($\alpha=0.05$, $p=0.014$). In the good quality bone model (20pcf PU-foam) the construct failed by plate deformation or breakage. There was no screw related failure.

Utilizing FEA the worst load case for thiese DR plates was identified. This loading scenario was then utilized to investigate the Stryker® XXL Volar DR VariAx Plate regarding its safety and efficacy. In the dynamic Cantilever Bending Test the new Stryker® XXL Volar DR VariAx Plate showed a superior fatigue performance compared to competitor products.

6. Conclusion

This study showed that the new Stryker® XXL Volar DR VariAx Plate is safe and effective for the fixation of unstable comminuted fractures of the distal radius extending into the shaft. The new Stryker® XXL Volar DR VariAx Plate offers improved fatigue characteristics which lead to a higher safety against plate failure during prolonged healing e.g. in the elderly [7].

7. References

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