Biomechanical Performance of Distal Humerus Locking Plate Systems Influence of Implant Design and Plate Location

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Abstract

Introduction: Several locking plate systems for the treatment of distal humerus fractures are available on the market. They differ in implant design as well as attachment locations to the bone. The newly developed VariAx Elbow Plating System (Stryker) offers the choice for different plate locations on the bone by means of five different plate types. The purpose of this investigation was to compare the strength of the VariAx Elbow Plating System to other available systems and to determine the influence of plate location on biomechanical strength. **Method:** A previously developed biomechanical protocol was used to test paired plates on Sawbones 4th generation composite bones which were modified to simulate an AO C2.3 fracture. The special test fixture allows physiological load sharing between the humero-ulnar joint (40%) and the humero-radial joint (60%). **Results:** When loaded in extension the parallel plating exceeded the perpendicular plating in fatigue strength and stiffness. The VariAx Elbow Plating System in perpendicular plate configuration showed a fatigue strength in between the LCP Distal Humerus Plating System (Synthes) which uses the perpendicular plate configuration and the Mayo Clinic Congruent Elbow Plate System (Acumed) which uses the parallel plate configuration. Overall highest fatigue strength was reached by the VariAx Elbow Plating System in parallel plate configuration. Loading the constructs in flexion leads in four of five cases to stiffness values of less than half of the values obtained in extension loading. **Conclusion:** The tests conducted on distal humerus constructs indicate the mechanical safety and efficacy of the newly developed VariAx Elbow Plating System for distal humerus fracture treatment.

1 Introduction

The incidence of distal humerus fractures increases with age and associated osteoporosis. These fractures are often highly comminuted and present association of the humero-ulnar joint. In the past few years a number of angular stable and anatomically shaped implants were introduced into clinical practice. These implants are thought to provide a higher primary stability than conventional small fragment implants facilitating early rehabilitation.

Multiple implant designs enabling different attachment locations are available. The most popular plating techniques are parallel plating with medial and lateral plates and perpendicular plating with medial and postero-lateral plates.

The new VariAx Elbow Plating System consists of five anatomically shaped polyaxial locking plates for distal humerus fractures. Those include a medial (M) plate, an extended medial plate (EM), a posteriomedial plate (PM), a lateral plate (L) and a posterolateral plate (PL).

Paired plate configurations in a 90° or 180° setup give the surgeon the opportunity to choose the desired construct per fracture indication.

The purpose of this investigation was twofold: First, the newly developed VariAx Elbow Plating System was compared to the already established systems with respect to their biomechanical performance. Second, two different 90° plate configurations and one 180° configuration available in the VariAx Elbow Plating System were compared with respect to mechanical stiffness and fatigue strength.

2 Material

Competing anatomically shaped locking plate construct configurations and systems for distal humerus fracture fixation were compared as illustrated in Figure 1.

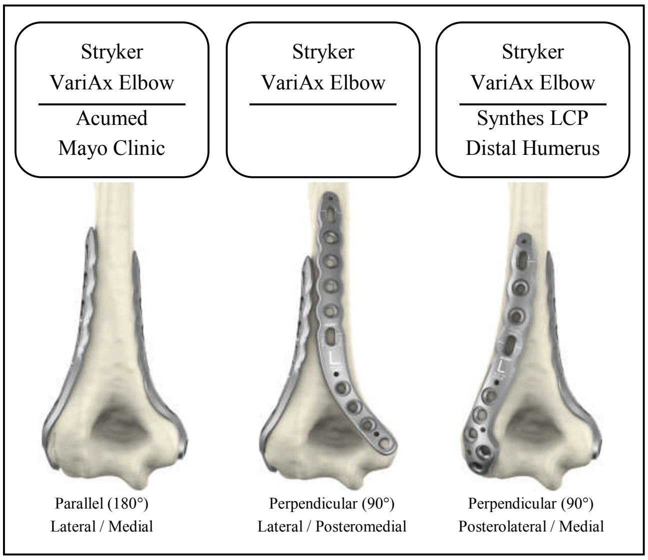

Figure 1: Locking plate constructs for distal humerus fractures

The plating systems have several optional screw types and locking mechanisms to choose from (Table 1). All plate holes were occupied with screws as long as no screw collisions occured and for the distal fragments only locking screws were used.

Screw Type	Ø2.7mm	Ø3.5mm	Poly-Axial	Mono-Axial	Conventional Cortex Screw
VariAx Elbow Plating System (Stryker)	X	(X)	X	-	X
LCP Distal Humerus Plating System (Synthes)	X	X	-	X	X
Mayo Clinic Congruent Elbow Plate System (Acumed)	-	X	X	X	X

Table 1: Implants used for construct testing. Note that one additional VariAx construct was tested with Ø3.5mm screws

Clinically, the VariAx System provides the option for Ø3.5mm as well as Ø2.7mm screws [1]. For testing, Ø2.7mm screws were used to simulate worst case conditions regarding construct strength and stiffness. For LCP Distal Humerus plates, Ø2.7mm screws were used in the distal fragment and Ø3.5mm screws in the shaft [2]. The Mayo Clinic Congruent Elbow Plate System was applied with Ø3.5mm screws [3].
As bone surrogate, large 4th generation composite humerus Sawbones were used to simulate non osteoporotic adult bone (Cat.-№ 3404; Sawbones Europe AB, Krossverksgatan 3, 216 16 Malmö, Sweden). High strength surrogate bone was choosen to provoke implant failure.

3 Method

3.1 Test Fixture

Various test methods using human cadaver or composite bones have been previously reported [4][5][6][7][8][9]. The testing configuration in this investigation was designed following Schuster et al [9] (Figure 2). It allowed for direct comparison of different implant designs and supported the physiological load sharing between humero-ulnar (40%) and humero-radial joint (60%).

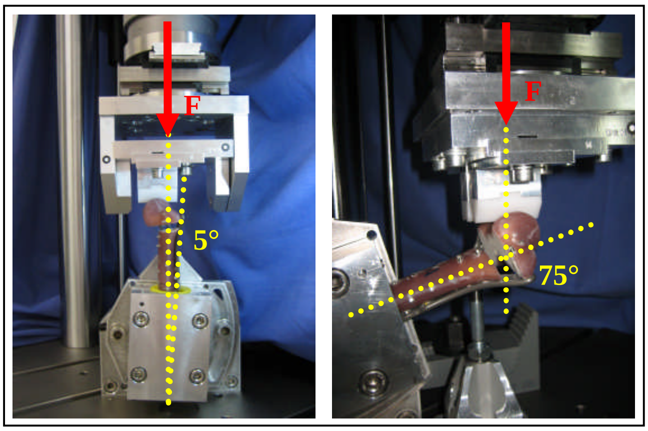

Figure 2: Test fixture in the materials testing machine – Extension (left) and flexion (right) load setup.

The constructs were loaded in an electro-hydraulic test machine (Instron 8874). The load vectors were set 5° relative to the humerus shaft axis in extension loading and 75° in flexion loading (Figure 2).

3.2 Sample Preparation

An AO C2.3 fracture was modeled with a 5-7mm fracture gap parallel to the humero-ulnar joint axis, starting at the widest point of the distal humerus. Additionally, a 0.5mm gap in the sagital plane at the deepest point of the trochlea was created [10].
Distal humeral plates were attached to the bone following the respective surgical procedures [1][2][3].
Composite bones were cut 17cm proximal to the joint axis and then fixated at the proximal 10cm with cast resin.

3.3 Stiffness Testing

One preliminary static test to failure of the construct was performed in each loading direction to determine the elastic load range. The other samples of each configuration were loaded in the elastic load range to determine their stiffness in extension and flexion.

Clinical relevance: The stiffness describes the elastic deformation of the construct allowing limited movement at the fracture site. Movement is reported to be a key factor in stimulating callus formation and therefore promoting fracture healing [11].

3.4 Fatigue Testing

The constructs were loaded with a sinusoidal load at 3Hz until either 250'000 load cycles were completed, an implant failed or a displacement of the construct by 4mm along loading axis occurred [12]. The median fatigue strength was calculated according to Little [13].

Clinical relevance: Dynamic testing was performed in extension where according to Morrey et al. [14] the greatest exposure to mechanical loading is expected. Creating a construct with higher fatigue strength may provide benefits in vivo.

3.5 Statistics

The results were analyzed using two tailed, unpaired Student t-tests whereas a p value of 0.05 or less was considered as statistically significant.

4 Results

4.1 Stiffness

Stiffness was measured in extension and flexion (Figure 3). Construct stiffness in flexion did not differ significantly between the Acumed 180° (M/L) and the VariAx 90° (EM/PL). For the VariAx 90° (EM/PL), the construct stiffness did not differ significantly in extension or in flexion. All other construct comparisons were significantly different.

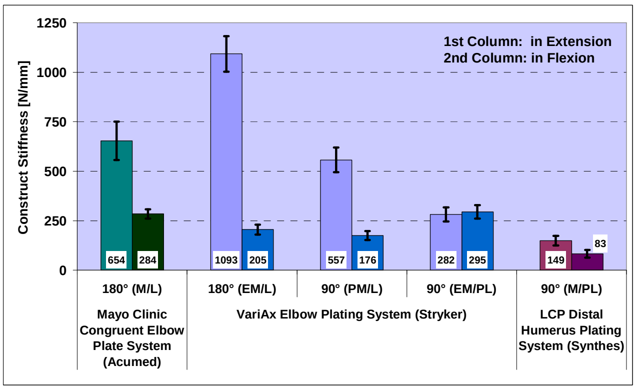

Figure 3: Construct stiffness in extension and in flexion. Values are presented by means and standard deviations.

The effect of varying screw configurations will be subject to another White Paper and is therefore not further discussed herein. However, to provide a brief overview VariAx plates in parallel plating configuration with Ø3.5mm screws and a medial column screw were tested to evaluate the construct stiffness (Figure 4).

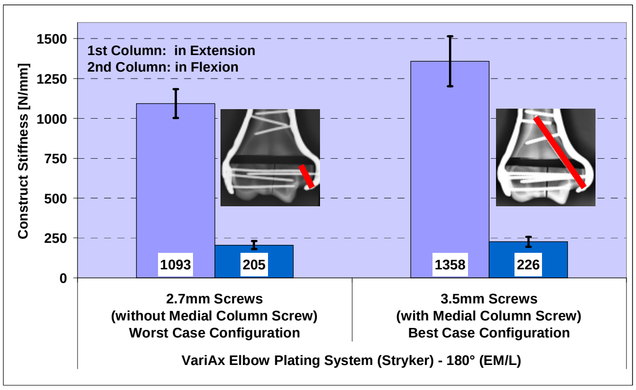

Figure 4: Construct stiffness in extension and in flexion. Values are presented by means and standard deviations.

Note the increased construct stiffness values when using the larger Ø3.5mm screws and additionally strengthen the construct with a medial column screw starting at the most distal-medial plate hole ending in the proximal metaphyseal cortex [15]. Only the values in flexion did not differ significantly from each other.

4.2 Fatigue Strength

In Figure 5, the fatigue strength of three manufacturers and three different plate configurations is shown. Respective failure patterns are listed in Table 2.

Only the Acumed 180° (M/L) and the VariAx 90° (PM/L) constructs did not differ significantly from each other.

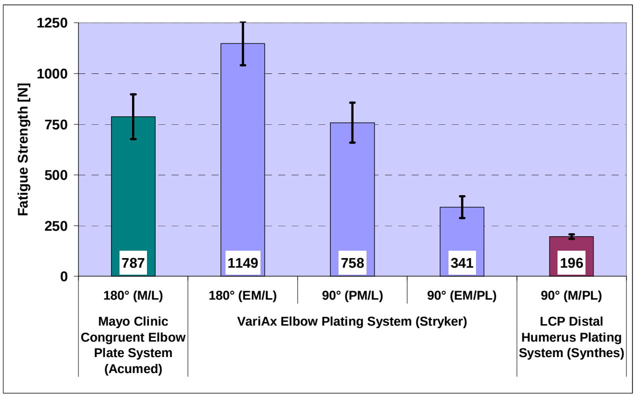

Figure 5: Fatigue strength in extension is given by means and a 95% confidence interval as calculated following Little [13].

Failure Location	Mayo Clinic Elbow Plate System (Acumed)	VariAx Elbow Plating System (Stryker)			LCP Distal Humerus Plating System (Synthes)
	180° (M/L)		90° (PM/L)	90° (M/PL)	
Plate Breakage	-	X	X	X	X
Screw Breakage	-	-	X	-	X
Loss of Axial Stability	-	-	X	-	-
Failure of the Composite Bone	X	X	-	-	-

Table 2: Typical failure pattern as observed during fatigue testing

5 Discussion

Comparison among the implants of different manufacturers revealed that the VariAx Elbow Plating System showed the overall highest stiffness and fatigue strength.

During flexion in the 180° configuration, lower stiffness was obtained for the VariAx Elbow Plating System compared to the Mayo Clinic Congruent Elbow Plate System. This may be related to different distances of the screws proximal and distal to the fracture gap. Hereby, a longer plate span potentially creates more flexibility in the VariAx Elbow Plating System. Comparing those implant types in the extension loading condition, the VariAx Elbow Plating System shows significantly higher stiffness values. This might be advantageous as the highest loads in vivo occur in extension [14].

Comparing the different plate configurations within the same implant type (VariAx Elbow Plating System) revealed a higher stiffness and fatigue strength for the parallel (180°) plate configuration in extension loading. The perpendicular plate configurations with medial and posterolateral plates showed the lowest stiffness and fatigue strength values in extension, but the highest stiffness values in flexion.

Except for one perpendicular plating configuration, the stiffness values were much smaller in flexion than in extension loading. This is most likely related to the larger lever arms between the load application at the joint surfaces and the distal fixation of the humeral shaft.

Screw configurations in elbow plating systems are known to influence both fatigue strength and stiffness [7][8]. However, in order to keep the loading scenario comparable among implant types and plate configurations these configurations were not altered throughout the study. The only exception was one additional VariAx parallel plating construct with larger screws.

5.1 Verification of the Test Procedure

Schuster et al [9] tested LCP distal humerus plates (Synthes) with human cadaver bone measuring stiffness in flexion and extension. Results are in good conformance with the measurements in the current study.

5.2 Clinical Relevance

Early postoperative rehabilitation is needed to provide an excellent outcome and acceptable range of motion of the elbow joint [16][17]. Until now, early and aggressive rehabilitation was restricted by a limited primary stability of the osteosynthesis. Therefore, patients often present a limited range of motion after fracture consolidation [16].

The first generation osteosynthesis implants for the distal humerus were non-locking plates. These were associated with fixation failure by screw loosening and pseudarthrosis [18][19]. An improvement was seen in the second generation Osteosynthesis implants with angular stable plates, such as LCP reconstruction plates [8][17]. The third generation osteosynthesis plating are the angular stable anatomical implants tested in this study. They offer additional fixation stability and facilitate accuracy of anatomical reduction of these complicated fractures. Therefore, primary stability may be improved and an early postoperative rehabilitation is enabled [17].

5.2.1 Elbow Load Information

Postoperative rehabilitation of elbow fractures begins with motion. Only muscle forces are acting (approximately 100N) one day postoperatively [20]. After six weeks the elbow will be loaded directly in physiotherapy [21].

As an example for elbow joint forces, one handed push-up exercises result in peak axial joint forces of about 65±8% body weight or 442±61N [22]. Two handed push-up exercises result in peak axial joint forces of about 247N [23].

An et al [24] predicted that in flexion to extension movement the force at the elbow corresponds to 6 to 16 times wrist force, while in normal daily activities the forces in the elbow correspond to 0.3 to 0.5 times body weight. Therefore, a person with a body weight of 75kg would have an elbow force of about 220N to 370N.

5.2.2 Construct Stiffness Information

Fracture healing is influenced by biomechanical and biological factors. One important biomechanical factor is the stiffness of a fixation construct. With anatomic reduction of the fracture, a rigid fixation leads to successful healing. However, reduction with remaining gaps requires some mechanical micro-motion to induce bone formation [11]. With extremely rigid fixation, bone formation may be suppressed and may cause non-unions [25][26]. Moderate axial fixation stability has shown to result in most beneficial healing outcome [27]. As suggested by previous studies, healing outcome may be worsened for very flexible and very stable fixation constructs. These findings have been confirmed by Terjesen & Apalset who observed a trend to best healing results when using moderate rigid fixation [28], assuming sufficient bony contact between the fragments.

6 Conclusion

The newly developed VariAx Elbow Plating System showed fatigue strength over 340N which is higher than the approximated loads for postoperative physiotherapy (100N) and two handed push-up exercises (247N). Together with the favorable results from comparative testing within this investigation, this indicates the new VariAx Elbow Plating System to be safe and effective for fixation of distal humerus fractures until bony union occurs.

According to the results of this study, in simple fractures the 90° configurations are probably the best alternative because they showed moderate stiffness in combination with fatigue strength beyond the approximated loads for physiotherapy. In comminuted fractures higher stability is required to retain fragment apposition so that here the 180° configuration should be preferred.

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Publisher: Stryker Trauma AG
Selzach, Switzerland

VAX-WP-13, 05-2019