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Mechanical Fatigue Analysis Comparing Two Locking Plates in a Metaphyseal Fracture Model of the Distal Ulna

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Abstract

The purpose of the study was to test the mechanical fatigue properties (fatigue limit and fatigue strength) of two locking plates designed for the distal ulna. Distal Ulna Plate 2.5 (Medartis, Basel, Switzerland) and 2.0 mm LCP Distal Ulna Plate (DePuySynthes, West Chester (PA), USA) were used. A metaphyseal fracture situation was chosen (AO 23-A1.3). Six plate-screw constructs of each design were mounted on custom made fixtures using a Sawbone's 3D ulna model. Testing was performed on monoaxial material testing machines. Endpoints were fatigue strength (load) and fatigue limit (cycles) when the sample fails. Initial load was set at Fmax 10 N. Sinusoidal loading was carried out at 4 Hz. After 50'000 cycles load was increased by 15% and again by 15% after each additional 10'000 cycles. 2.5 mm plates showed median fatigue strength of 40.5 N (range 5.3) and median fatigue limit of 141'307 cycles (range 5'436). 2.0 mm plates 13.2 N (range 5.2) and 67'287 cycles (range 28'718) respectively. Distal Ulna Plate 2.5 showed better mechanical properties.

Keywords

Distal ulna, Fracture, Plate, Fatigue

Introduction

Isolated distal ulnar fractures are extremely rare, but they are much more common in combination with a distal radius fracture. Fractures of the ulnar distal metaphysis are less common and occur in 6% (19/320) of distal radius fractures [1].

In the literature there is still controversy whether these fractures affect wrist function after operative fixation of the distal radius, given that distal ulnar fractures may lead to chronic instability of the distal radio-ulnar joint. These concerns are related to the fact that the radio-ulnar ligaments are primary stabilizers of the distal radio-ulnar joint and attach to the base of the ulnar styloid [2,3]. In addition to the risk of instability McKee et al. reported an association of distal radius fracture nonunion with ulna fracture in elderly women [4].

For displaced metaphyseal distal ulna fractures rates of union exceed 96% with proper fixation techniques [5]. Currently there is no clear evidence that one method of fixation or even operative versus nonoperative treatment is superior in the treatment of distal ulnar shaft and metaphyseal fractures [6]. On the other hand fracture reduction and fixation is indicated for mid and distal ulna shaft fractures with a displacement of more than 50% and angulation greater than 10°. Such fractures may imply disruption of the interosseous membrane (IOM) and cause longitudinal instability of the forearm [7].

Many different plates for open reduction and internal fixation of unstable ulna fractures have been developed and the use of locked plates has become very common. Several studies have shown biomechanical advantages of this technique especially in osteoporotic bone and in metaphyseal fractures [8,9]. A recent biomechanical study by Collins et al. could however not show any clear advantage of locked plating for fractures of the distal ulna [10].

The aim of this study was to test the mechanical properties (fatigue strength and fatigue limit) of two titanium-alloy locking plates commonly used and designed for distal ulnar fractures. Given the high rates of nonunion and instability associated with this injury we hypothesized that stronger mechanical strength of internal fixation would ensure enough time for bony union to occur.

Materials and Methods

Specimen preparation

Two different plates that cover the same indications were compared in our test; a simple fracture model (see Test Set-Up explained below) was employed. In our clinic we use the Distal Ulna Plate 2.5 (Medartis, Basel, Switzerland). For comparison we chose the 2.0 mm LCP Distal Ulna Plate (DePuySynthes, West Chester (PA), USA) since it is also a locking plate. Both plates are made from titanium-alloy and indicated for distal ulnar fixation. The detailed specifications are given in table 1. Only the short Medartis plate (46 mm) was used in current study.

Testing was performed on monoaxial material testing machines Thelkin (Winterthur, Switzerland) and Zwick-Roell (Ulm, Germany) at the Medartis AG research laboratory in Basel (Switzerland). Fatigue strength was defined as the load at which failure occurs, whereas the fatigue limit was defined as the number of load cycles when the sample fails.

The plates were mounted on the fracture model according to the

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Table 1: Plate specifications.

	Medartis	DePuySynthes
Material	Titan	Titan (also available in Steel)
Thickness (mm)	1.6	1.3
Length (mm)	46 (also available in 67 mm)	46
Screws ø (mm)	2.5	2.0
Locking Head System	TriLock - multidirectional (± 15°) and angular stable locking technology	Monodirectional locking technology
Plate Holes	7 (10 plate holes in 67 mm plate)	7
Position	Ulnar (volar/dorsal position possible)	Ulnar
Special Features	Up to three screws capture and stabilize distal fragment	Pointed hooks and intercrossing locking screws in the head

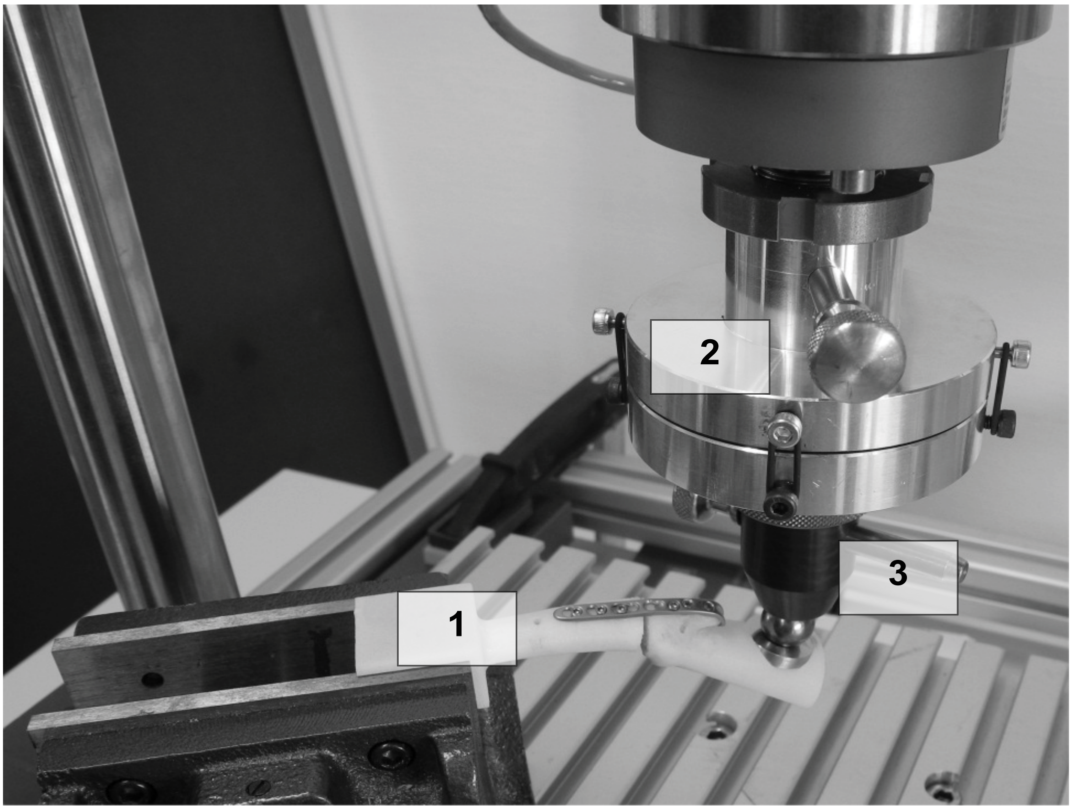

Figure 1: Test set-up with clamped sample (1); parallel (2); ball bearing (3). Arrow indicates the monoaxial (radial-ulnar) load application.

manufacturer supplied surgical techniques [11,12]. Six plate-screw constructs were tested each.

Test set-up

The designs of the various subject plates, including their shapes and dimensions, precluded static and dynamic testing as described in ASTM F382 - Standard Specification and Test Method for Metallic Bone Plates [13] which describes a simple four-point bend test. Instead, a test set-up was chosen according to the following criteria:

- Loading of the plate must be based on an *in-vivo* loading scenario.
- The set-up must also represent a worst case scenario of loading to replicate possible outcomes.
- Design must not favour one plate design over another.

Accordingly a system test simulating a comminuted metaphyseal fracture situation without 'bony support' was chosen. This type of fracture is named as an AO 23-A1.3 fracture or a Q3 fracture in combination with a distal radial fracture in the most frequently cited AO Comprehensive Classification System [14]. Fractures of the distal ulna associated with fractures of the distal radius are classified according to a Q modifier [15]. This setup is considered to be clinically relevant, biomechanically unfavourable (i.e., worst case) and highly reproducible.

The actual set-up is shown in figure 1: Six plate-screw constructs of each design were mounted lateral (ulnar) on custom-made fixtures (Figure 2) using Sawbone's Inc.'s (Vashon Island, Washington) 3D ulna model. Using CAD software the models were modified to include clamping and load transfer points, the osteotomy as well as drill holes; additionally, the model was 'hollowed out' to represent the cortical part of the bone only. Fixtures were then printed in glass fiber-reinforced polyamide using rapid prototyping technology and the central cavity filled with polyurethane foam to simulate cancellous bone. Load is transferred at a defined distance from the proximal fragment using a parallel and a ball bearing to minimize shear forces (Figure 1, marks 2 and 3). To make sure that plate, screw and locking mechanism are all tested, a distance of 1 mm was maintained between plates and substrate in the distal fragment (Figure 2, right). By maintaining the point of load transfer at a fixed distance from the proximal fragment for all tests and independent of the hardware used, identical bending moments are guaranteed. Screw-hole usage is based on fracture location and company-provided literature [11,12] (Figure 2).

Testing protocol

Based on the plates' indication we assume that the maximum time of load bearing varies somewhere between 6 and 12 weeks after which the bone should have consolidated; typically, bony consolidation is expected within 6 weeks post-operatively [16]. This time roughly corresponds to 50'000-100'000 load cycles (assuming a recuperating person performs 500-1'000 load cycles per day).

Based on preliminary tests the initial load for fatigue testing was

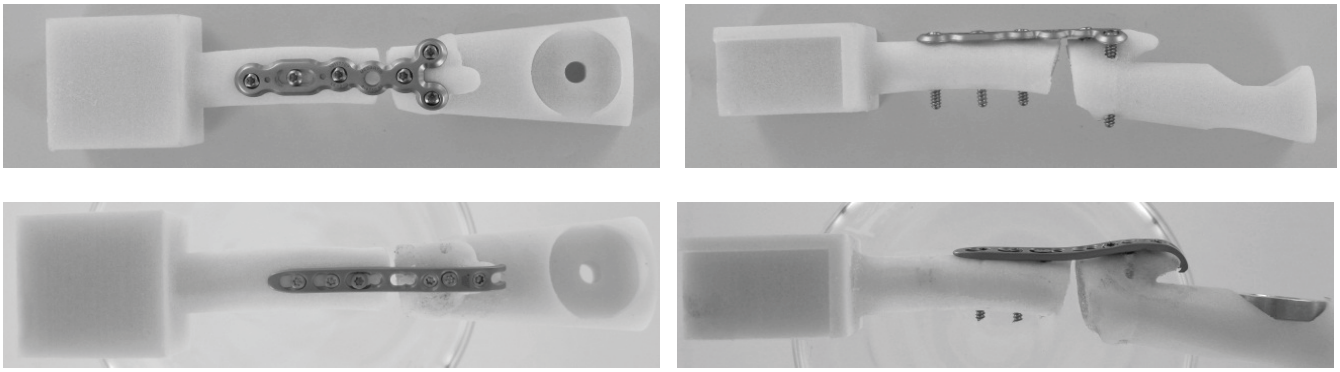

Figure 2: Samples mounted for test. top: Medartis plate, bottom: DePuySynthes plate.

Table 2: Summary of bending tests until plate failure.

	Fatigue Strength (N)		Fatigue Limit (Cycles)	
Sample	**Medartis**	**DePuySynthes**	**Medartis**	**DePuySynthes**
1	35.2	15.2	136897	72906
2	35.2	11.5	138519	50266
3	40.5	13.2	141612	67977
4	40.5	13.2	141632	66597
5	40.5	10.0	141002	57997
6	40.5	15.2	142333	78984
Median	40.5	13.2	141307	67287
Range	5.3	5.2	5436	28718
P value	0.003		0.004	

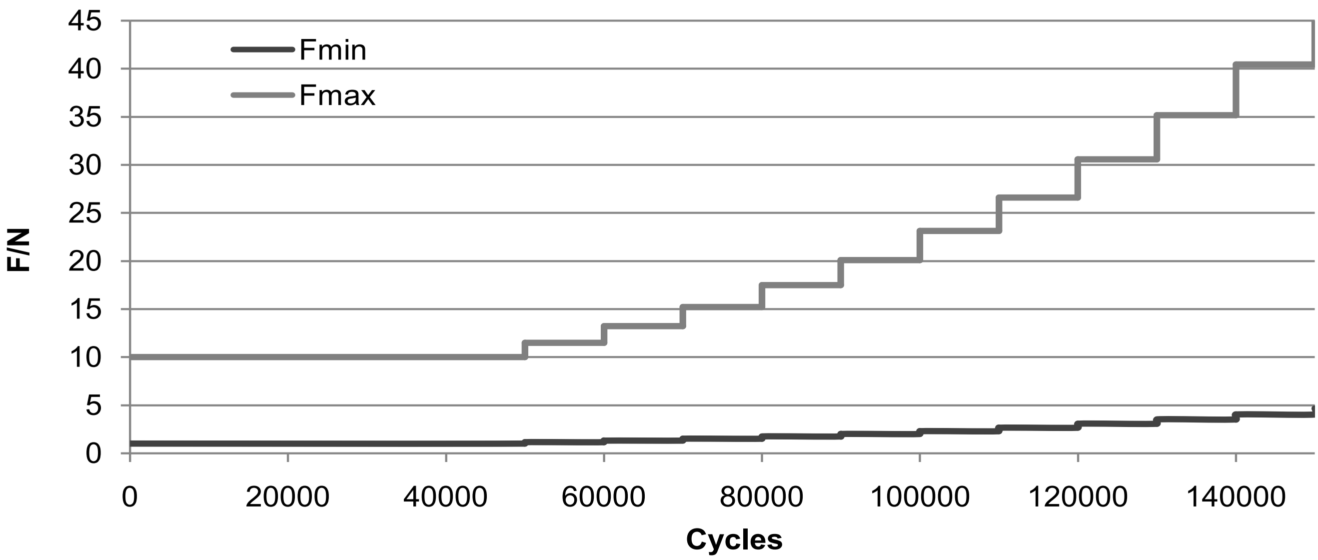

Diagram 1: Load profile for fatigue testing.

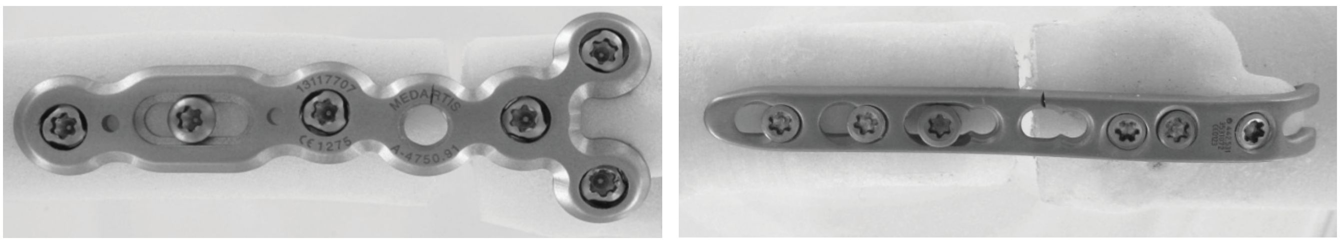

Figure 3: Site of failure at the level of the screw hole over the fracture site.

set at Fmax 10 N. Sinusoidal loading was carried out at 4 Hz following a modified Locati approach [17,18]. After 50'000 cycles load was increased by 15% and again by 15% after each additional 10'000 cycles (Diagram 1). The advantage of the Locati approach compared to other methods such as Wöhler diagrams or staircase testing is that testing always occurs in the device's 'critical load range' as all tests lead to fracture. Therefore a lot of information can be gained with relatively few samples and load cycles. While the results are not directly comparable to results obtained with methods such as Wöhler diagrams, the results are valid and generally accepted [17]. When comparing two devices the Locati method is in our view preferable to a Wöhler diagram since more informative value can be obtained with fewer samples. The load ratio, R (Fmin to Fmax), was 0.1. Ending criterion was mechanical failure (plate or screw fracture).

Results

Load and displacement were recorded. Fatigue strength for an individual sample is defined as the load at which failure occurs; the fatigue limit is defined as the number of load cycles when the sample fails. Median and range of fatigue strength (N) and fatigue limit (cycles) are calculated for both plates (Table 2).

The fatigue strength of the six Medartis plates has a median value of 40.5N (range 5.3), and the fatigue limit has a median value of 141'307 cycles (range 5436). For the six DePuySynthes plates the fatigue strength has a median value of 13.2N (range 5.2), and the fatigue limit a median value of 67'287 cycles (range 28'718). Power analysis shows a statistical power of 100% for fatigue strength and fatigue limit with a confidence interval of 95% each. And the Mann-Whitney U test proves significance with a P value of 0.003 (fatigue strength) and 0.004 (fatigue limit) respectively. All plates failed at the level of the screw hole over the fracture site in between the proximal and the distal screw (Figure 3).

Discussion

The lack of bone for fixation in the distal end of the fractured ulna often represents a challenge to hold the reduction in place. Despite the newest findings by Collins et al., which put in question any advantage of locked plating for fractures of the distal ulna [10] in our opinion the head screws in particular offer such an advantage as cannot penetrate the second cortex due to the distal radioulnar joint (DRUJ) to avoid an intra articular position of the screw.

There is no clear evidence that one method of fixation or even operative versus nonoperative treatment is superior in the treatment of distal ulnar shaft and metaphyseal fractures [6]. However previous studies have indicated a risk for nonunion with distal ulnar fractures [4,19]. The surgical approach to the distal ulna places the dorsal sensory branch of the ulnar nerve at risk. This branch emerges from the deep fascia approximately 1 to 4 cm proximal to the ulnar styloid [20]. Neurapraxia of these nerve branches has been reported in up to 40% of patients, although it is often transient and resolves completely [21].

Issues related to hardware prominence of a lateral plate location result in a second surgery for hardware removal in 30-35% [21,22]. Nevertheless several authors report good to excellent results after open reduction and internal plate fixation of unstable distal ulnar fractures with concomitant distal radial fractures [23-25].

In our study we were able to simulate a repetitive radial-ulnar bending force on the plates, similar to in vivo stresses. Given the risk of nonunion in distal ulnar fractures, using plates with a stronger strength profile may be indicated. Considering the repetitive monodirectional load in this experimental set-up and the fact that the wrist in a below elbow splint without any load bearing during the time of recuperation would hardly be exposed to a force of > 10N 1500-3000 times per day both plates would probably not reach mechanical failure during bony consolidation. By using a glass fiber reinforced polyamide 3D Ulna model we were able to simulate an ideal bone quality even in the distal fragment, which provides maximal grip to the 'monocortical' head-screws. In comminuted or osteoporotic bone the distal part might present the weakest part of the system and it would rather fail by screw loosening than plate breakage.

The limit of this study is that the two plates are similar in term of material (titan) but different in thickness (1.6 mm vs. 1.3 mm) and screw size (2.5 mm vs. 2.0 mm) respectively.

Conclusion

According to results of our testing in the above described near clinical setup, the Distal Ulna Plate 2.5 (Medartis, Basel, Switzerland) showed better mechanical properties compared to the 2.0 mm LCP Distal Ulna Plate (DePuySynthes, West Chester (PA), USA).

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Declaration of Conflicting Interests

All named authors hereby declare that they have no conflicts of interest to disclose. Implants used for testing were donated by Medartis AG (Basel, Switzerland). The results and interpretation were not influenced by commercial interests of the hosting company.

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