Biomechanical testing of a novel osteosynthesis plate for the ulnar coronoid process

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Abstract

Background: The present study aimed to biomechanically evaluate a novel locking plate intended for osteosynthesis of coronoid fracture compared to mini L-plates and cannulated screws.

Methods: Biomechanical tests were performed on a fracture model in synthetic bones. Three groups, each with eight implant-bone-constructs, were analyzed in quasi-static and dynamic tests. Finally, samples were tested destructively for maximum strength.

Results: The mean (SD) highest stiffness was measured for the novel plate [693 (18) N/mm], followed by the mini L-plate [646 (37) N/mm] and the cannulated screws [249 (113) N/mm]. During the cycling testing of the novel plate and the mini L-plate, no failures occurred, although three of the eight samples of cannulated screws failed during the test. The mean (SD) maximum strength during the destructive testing was 1333 (234) N for the novel plate, 1338 (227) N for the mini-L-plate and 459 (56) N for the cannulated screws. No statistical differences were found during the destructive testing between the two plates ($p = 0.999$), although statistical differences were found between both plates and the cannulated screws ($p = 0.000$ each).

Conclusions: Osteosynthesis of the coronoid process using the novel plate is mechanically similar to the mini L-plate. Both plates were superior to osteosynthesis with cannulated screws.

Keywords

Anatomic plate, coronoid process, fracture treatment, locking plate; ulna

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Introduction

The ulnar coronoid process is an important stabilizer of the elbow in the sagittal plane and against varus stress.^{1–4} Biomechanical research shows instability of the elbow joint, which leads to dorsal luxation despite an intact joint capsule and ligaments related to a fracture of the coronoid process of more than 50% of the height.^{4,5} In the case of a missing radial head, a fracture of the coronoid process of only 25% will already lead to instability.⁵ Fractures of the coronoid process are rare. They occur typically in 2% to 11% of elbow luxations,^{6,7} which corresponds to an incidence of 5.21 per 100,000 persons/year.⁸ Coronoid process fractures are treated operatively in 23% to 61% of cases.^{9,10} However, only a few implants designed specifically for this indication are currently available.¹¹

Because the clinical results of surgical therapy of coronoid fractures are sometimes poor,¹² a novel locking plate specifically designed for coronoid process was developed in an effort to improve clinical outcome. The design goal was to utilize a large area to stabilize the coronoid process against secondary loss of reduction at the same time as ensuring that the surrounding soft tissue is saved and easy re-fixation of the capsule and ligaments is possible. The geometrical shape of the

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Figure 1. Osteosynthesis with the novel coronoid plate.

novel plate is matched to the anatomy of the coronoid process and the proximal ulna, whereas the insertion of the brachialis muscle, which has a well-described size and position,¹³ is preserved (Fig. 1). The shaft of the novel plate has a thickness of 1.5 mm and offers two holes for locking screws with one long hole between them. In the area of the coronoid process, the maximum thickness of the plate is 2.5 mm with three holes perpendicular to the long axis. Additionally, three small holes with a diameter of 1.4 mm in the area of the coronoid process allow for the repair of the capsule. The total length of the plate is 59 mm.

The present study aimed to compare the novel locking plate to the often-used nonlocking mini L-plates and cannulated screws with biomechanical tests in an anatomically fashioned synthetic bone model. Our hypothesis was that the novel plate would show equivalent mechanical properties in load-bearing capacity and endurance.

Materials and methods

Specimen preparation

The present study was performed with large left fourth-generation composite bone (Item 3426, ulna; Sawbone, Malmö, Sweden) intended for biomechanical testing. Similar to natural bone, a hard cortical shell, which is made from epoxy resin, surrounds cancellous core material made from solid rigid polyurethane foam. Because the synthetic bone is produced industrially, availability, comparability and reproducibility are superior to natural bone.¹⁴ In the first processing step, the distal third of the bone was cut with a diamond belt grinder (Exakt 310; Exakt, Norderstedt, Germany), which gave a length of 180 mm to allow for standardized mounting in the test set-up.

The novel locking coronoid plate (Coronoid TiFix-plate, 4 hole left, ref. no.2905907LT; Litos, Ahrensburg, Germany) made from commercial grade 2 pure Titanium was tested in comparison with two clinically established implants: a retrograde screw osteosynthesis with two cannulated screws (ASNIS

III, 4.0 mm, Ti-6Al-4 V; Stryker Corp., Kiel, Germany) and nonlocking mini L-plates (stainless steel with 3.2-mm screws; Synthes, Freiburg, Germany). Initially, the plates were mounted on the synthetic bone with intact coronoid process. For the locking coronoid plate (Fig. 1), two 2.6-mm self-cutting locking and one nonlocking (in the sliding hole) titanium screws with lengths of 20 mm to 22 mm in the shaft were bicortically fixed and 32 mm to 36 mm in the coronoid process were unicortically fixed. The holes were drilled with a diameter of 1.9 mm.

The mini L-plates were bent to match the shape of the bone with flat-nose pliers. After drilling holes of 2.5 mm in diameter and tapping with a 3.5-mm tap, stainless steel cortical screws with a diameter of 3.5 mm and lengths of 26 mm to 32 mm were placed bicortically in the shaft and unicortically in the coronoid process. The differences in screw length were a result of minor differences in the location of tested plates. In the area of the coronoid process, partially threaded cancellous bone screws of 30–35 mm length were placed unicortically at diverging positions. The cannulated screws were placed retrograde according to common clinical practice.¹⁵ Two 1.4-mm K-wires were placed from the dorsal side into the tip of the coronoid process. Predrilling with a 1.4-mm spiral drill was required as a result of the hardness of the synthetic bone. Guided by the K-wires, holes of 2.7 mm in diameter were drilled and tapped with a thread of 4.0 mm. After countersinking, screws with lengths of 28 mm to 34 mm were unicortically placed.

After removing the implants from the synthetic bone, the coronoid process was osteotomized at a height of 17 mm (equivalent to 75% height) using a diamond belt grinder to generate reproducible instability in the joint.^{4,5} Afterwards, the implants were reattached to the same synthetic bone. In total, eight samples were prepared per group.

Testing procedures

The same test set-up (Fig. 2A) was used for all mechanical testing procedures. The distal part of the ulna was fixed in an imprint of acrylic resin (Technovit 4006; Heraeus Kulzer, Wehrheim, Germany) in a stainless steel pot, thus allowing for reproducible positioning at 0° extension and 5° valgus using a ball joint (Fig. 2B). The straight alignment in extension was chosen to enable a direct force transfer to the coronoid process parallel to the osteotomy line.^{16,17} The 5° valgus is equivalent to the mechanical axis of the arm in full extension.¹⁸ The force was applied via a shaft hinged on ball bearings. The diameter of the shaft was 18 mm to match the size of the internal diameter of the trochlear notch on the synthetic bone. The degrees

Figure 2. (a) Schematic sketch of the complete test set-up. (b) Mounting the synthetic bone in 5° valgus position.

of freedom perpendicular to the test axis were freed using a sliding table. Fragment movement was monitored planar and recorded with a microscopy camera (DigiMicro 2.0 Scale; DNT, Dietzenbach, Germany) during the tests. The resolution of the camera is 35 $\mu\text{m}/\text{pixel}$. Each implant/bone construct was loaded four times in the quasi-static test, whereas the first measurement was for preconditioning and was not used in analysis.

Three mechanical tests were conducted:

1. A nondestructive test to determine the stiffness of the implant/bone construct.

The test set-up was placed in a material testing machine (Zwick 1456; Zwick, Ulm, Germany). The test was performed with a constant deformation rate of 0.1 mm/s controlled by the software testXpert II® (Zwick/Roell, Ulm, Germany). The embedded displacement sensor and a force sensor ($\pm 2 \text{ kN}$, U2A; HBM, Darmstadt, Germany) were used. After a first settling cycle of loading to 30 N and unloading to 5 N, eight samples per group were tested up to 30 N, and the force–displacement curve was recorded. Using Excel 2010 (Microsoft, Redmond Corp., WA, USA), the regression line was calculated in the range between 12 N and 24 N. The slope of the regression line is the sample stiffness (N/mm).

2. Cyclic testing to analyze the long-term endurance.

The test set-up was placed in a pneumatic fatigue tester (DHM, Clausthal-Zellerfeld, Germany).

The same samples (eight per group) were used for this test. The loading profile had a frequency of 2.5 Hz with a minimal force of 20 N and a maximal force of 100 N controlled by the software SysCon easyTest (DHM). The number of cycles was set to 5000. The failure criterion was a displacement of the fracture fragment of more than 2 mm, which was monitored using the microscopy camera. The number of cycles was recorded.

3. Destructive test to access the maximum strength of the samples.

The test set-up was placed in the material testing machine (Zwick) again. The same samples (eight plates per group and the remaining five nondislocated constructs with screws) were tested similar to test 1. The test was stopped after failure of the load displacement curve during testing. The maximum force was read from the force–displacement curve and saved in an Excel spreadsheet (Microsoft). The failure of samples was documented.

Statistical analysis

Initially, we made a sample size calculation for an unpaired *t*-test. The basis for this calculation was the results of a previously conducted study with a similar study design.¹⁹ We estimated a necessary sample size of eight per group (calculation parameters: significance level $\alpha = 0.05$, SD = 15, effect = 21, statistical power = 0.8). The recorded data were saved in an Excel spreadsheet and analyzed in cooperation with a

Figure 3. Stiffness of the implant/bone constructs (significant differences between all groups).

statistician employing SPSS, version 20 (IBM Corp., Armonk, NY, USA). The data underwent descriptive statistical analysis, comprising single factor analysis of variance with Dunnett T3 post-hoc tests. Dunnett T3 was chosen because the variances are not homogeneous. Pearson's chi-squared test was used on categorical variables. Mean numbers of groups were rounded to integers and significances were rounded to the third decimal place.

Results

Stiffness of the implant/bone construct

The mean (SD) highest stiffness was measured for the novel plate [693 (180) N/mm] followed by the mini L-plate [646 (37) N/mm] and the cannulated screws [249 (113) N/mm] (Fig. 3). Significant differences were found between the novel plate and the mini L-plate ($p = 0.024$), between the novel plate and the cannulated screws ($p = 0.000$) and also between the mini L-plate and the cannulated screws ($p = 0.000$).

Cyclic testing

During the cycling testing of the novel plate and the mini L-plate, no failures occurred and also no

movement of the fracture fragment was visible. Three samples of cannulated screws failed during the test: one immediately after the start of the test, one at 566 cycles and one after 1472 cycles. The remaining screws showed an average micro motion from 0.39 to 1.08 mm (Table 1). Statistical evaluation using Pearson's chi-squared test showed a significant correlation ($p = 0.032$) between failure and the fixation method.

Destructive testing

The maximum strength was 1333 (234) N for the novel plate, 1338 (227) N for the mini-L-plate and 459 (56) N for the cannulated screws (Fig. 4). Statistical evaluation showed no significant difference between the two plates ($p = 0.999$), although it did show a significant difference between the both plates and the cannulated screws ($p = 0.000$ each).

The failure of osteosynthesis was documented in all three groups:

- For the novel plate, a loosening of the cancellous bone screws and bending of the plate was seen in six of the eight constructs, whereas the bicortical fixation in the shaft remained fixed (Fig. 5A). An impression from the articular surface of the

Table 1. Results of the cyclic testing of the cannulated screws.

Sample number	Average motion (mm)	Failure occurred at:
1	0.39	
2	0.43	
3	1.05	
4	1.08	
5	>2	566 cycles
6	0.59	
7	>2	1472 cycles
8	>2	1 cycle

coronoid occurred in four synthetic bones (Fig. 5B).

- The screws of the mini L-plate remained fixed, although the coronoid process was destroyed during the test in eight of eight constructs (Fig. 6).
- In all cases, the cannulated screws lost fixation with the fracture fragment (Fig. 7).

Discussion

Mobilization-stable osteosynthesis is essential for the treatment of fractures of the coronoid process.²⁰ An immobilization of more than 3 weeks can lead to impairment of the range of motion.^{12,21,22} In the case of osteoporotic patients or comminuted fractures, implants are required to allow for stable reconstruction and retention of the coronoid process. The present study aimed to evaluate a novel locking plate with commonly used implants. All relevant mechanical parameters of the implants were tested in full extension and with an osteotomy equivalent to a fracture of type III according to Regan and Morrey,¹⁰ leading to a reproducibly unstable joint.^{4,5} Testing was performed in extension because the highest force transmission occurs in this motion⁶ and the force is transmitted parallel to the osteotomy so that the osteosynthesis construct is directly forced.

No similar biomechanical analysis of coronoid fracture fixation was found in the literature. The applicable force for the nondestructive test was initially calculated from literature on the distal humerus.²³ A linear force-displacement curve was described up to 50 N using cadaver specimens. Using a force transmission ratio

of 60% to the radius and 40% to the ulna,²⁴ we calculated a force of 20 N for nondestructive testing. We increased the load in the quasi-static test to 30 N because, in pretests, the linear range of the synthetic bones was found to be higher than for the cadaver specimens. The novel plate showed a significantly higher level of stiffness than the mini-L-plate, even though the novel plate is made of the more ductile pure titanium and the mini-L-plate is made of tougher stainless steel. However, because the fracture gap after plate fixation is very small and because bicortical screws can be used in the shaft, a high stability of the bone/implant construct can be achieved with only a minor influence of the plate itself. The stiffness of the unicortically fixed, partially threaded, cannulated screws was significantly lower than that of either plate.

We used partially threaded screws to induce compression in the fracture gap.²⁵ This operative procedure was published as a standard surgical procedure.¹⁵ The manufacturer (Stryker Corp.) recommended the insertion of the cannulated screws only to an appropriate depth; bicortical fixation was not demanded. The bicortical fixation of a screw osteosynthesis probably has a higher mechanical load capacity compared to unicortical fixation.²⁶ Perhaps the use of different screw types would also yield different results.^{26–30} On the other hand, there is still the difference of a missing osteosynthesis plate and it can be assumed that other types of screw osteosynthesis also do not reach the fixation strength of a plate osteosynthesis.²⁵ The forces during the elbow motion are difficult to quantify because of the complex interplay of muscles.³¹ In different biomechanical analyses of internal fixation of the distal humerus, a load of 150 N^{19,23} and 200 N³² was used. During normal daily activity, forces of up to 300 N act on the arm.^{33,34} Again, considering the force transmission ratio between the radius and ulna, we calculated a typical load of 60 N to 80 N, which was increased to 100 N to give worst-case conditions in the dynamic testing. The number of cycles was set given that, typically, 4 weeks to 5 weeks are necessary for the onset of bony bridging in the fracture gap.^{35,36} During the first weeks, the implant alone carries the load. Under the assumption of one arm movement per 5 minutes over 12 hours per day, the number of movements was 5040 in the relevant postoperative timespan.²³ The failure criterion of 2 mm was chosen based on scientific findings of successful fracture healing.^{37–39}

During the nondestructive tests and the cyclic testing, none of the plate samples failed. No fragment displacement ≥ 2 mm was visible using the microscopy camera. The stiffness of the implant/bone construct matched the nondestructive testing. Thus, it can be concluded that either plate is appropriate in the fracture treatment of the coronoid process in so far that one

Figure 4. Maximum strength of the three groups in the destructive testing.

Figure 5. Failure of the novel coronoid plate (a) and impression of the articular surface (b) in destructive testing.

large fragment with good bone quality is present. Nonetheless, the applied loads under cyclic testing are able to produce failure of the osteosynthesis if the cannulated screws are used. Three of the eight samples failed during this test (Table 1). In clinical practice, routine screw osteosynthesis of coronoid fractures is commonly used with good clinical results.^{15,40,41}

Very high force values on the humerus of up to 1900 N have been reported during the chair rising test³⁴ and of 2500 N when carrying objects.^{6,33} To analyze the behaviour of the implants even under peak loads, the force during the destructive test was increased until complete mechanical failure of the

samples. The novel coronoid plate and the mini-L-plate had similar strengths. The mini L-plate has a smaller contact area with the coronoid and is made of stainless steel, which is very tough, so that the bone failed in destructive testing. The larger area of the novel plate and the more ductile pure titanium can better avoid break-off of the bone fragment, although half of the constructs also showed an impression from the articular surface in destructive testing too. The loss of retention was seen in six of the eight constructs because the novel plate was bent in the curved area excluding the attachment point of the musculus brachialis. The positioning of the mini L-plate during the

Figure 6. Failure of the mini L-plates in destructive testing.

Figure 7. Failure of the cannulated screw in destructive testing.

tests yielded optimum fixation at the ulna but would sacrifice a considerable fraction of the brachialis muscle attachment point clinically.

An advantage of the composite bones is that their variability is significantly lower than that of cadaveric specimens for all loading regimes.^{42,43} A limitation of the use of currently available anatomically designed synthetic bone is that the geometries and biomechanical properties are based on bones from an 890-N (90.8 kg), 183-cm tall male.⁴⁴ Because of this limitation in available sizes, it is not possible to perform testing with smaller geometries. Foam blocks mimicking osteoporotic bone are not available in the anatomic form of the human ulna. The biomechanical effects of locked osteosynthesis on osteoporotic bone have been evaluated in the past;⁴⁵ we therefore aimed to determine the stability of an anatomically precountered plate on the bone for which it is designed.

Other limitations of the present study result from the testing procedure. The plates were first mounted on the bone and then removed again, and the osteotomy was performed. Subsequently, the plates were re-fixedated, which could alter the holding strength, especially of

the screws in the cancellous bone area. Furthermore, we performed serial testing on the constructs up to the destructive testing. The influence of these procedures is unclear and subject to debate.

A simple fracture model with only one fragment was used to simplify the testing despite comminuted fractures, which are more problematic to treat clinically. Furthermore, we examined only the longitudinal loading of the coronoid; the rotational stability was not compared.

Conclusions

Our *in vitro* biomechanical study suggests that plate fixation with the novel locking coronoid plate, as well as the nonlocking mini L-plate, was superior to screw fixation.

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Declaration of conflicting interests

None declared

Level of evidence

Basic science study; biomechanical study

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