Biomechanical testing of a new plate system for the distal humerus compared to two well-established implants

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Abstract

Purpose A biomechanical study was performed to test the hypothesis that a new anatomically preformed, thinner, soft-tissue protecting plate system for distal humeral fractures (Tifix®-hybridplate [HP]) would show comparable results in the quasi-static and dynamic testings compared to two conventional implants: The 3.5-mm reconstruction plate (RP) providing primary stability with normal bone mineral density (BMD), and a multidirectional locking plate (Tifix®-plate [P]) which can be used with poor bone quality. **Methods** The Tifix®-HP was developed by the working group. The biomechanical testing was performed on a C2-fracture-model in 24 synthetic humeri. Three groups, each with eight bone-implant-constructs, were analysed in quasi-static and dynamic tests.

Results The quasi-static measurements showed that under extension loading both locking plates (Tifix®-P, Tifix®-HP) were significantly stiffer than the reconstruction plate, and that the Tifix®-HP had a significantly lower stiffness than the two other implants under flexion loading. In the dynamic tests the Tifix®-P allowed significantly less fracture motion compared to the Tifix®-HP and the reconstruction plate. In an osteopaenic bone model locking plates failed only under

much higher dynamic force than the reconstruction plate. The reconstruction plate and the Tifix®-P always failed through screw loosening, whereas the newly developed Tifix®-HP showed screw loosening in only one third of cases.

Conclusion The hypothesis that the newly designed plate system showed comparable results in the quasi-static and dynamic tests compared to the conventional implants with a significantly lower implant volume and thickness was confirmed.

Introduction

The number of osteoporotic fractures is increasing owing to an increase in the number of elderly people. The incidence of distal humeral fractures is predicted to triple by 2030 [1, 2]. Thus, more attention needs to be paid to the management of these fractures [2]. AO 13-C2-fractures are described as the most prevalent fracture type [3, 4]. The risk of functional impairment following conservative treatment is high [5]. So, surgical treatment, open reduction and internal plate fixation, is recommended, but may be technically demanding. While in younger patients with a normal BMD non-locking plates are appropriate [6], in the elderly with an osteoporotic bone structure locking plates have improved outcomes. Disadvantages of the locking plates are high costs and unavailability in some markets [7, 8]. Bending and contouring of plates can be difficult and time consuming.

Double plate fixation has become the gold standard for fixation of intra-articular distal humeral fractures. The parallel- and 90°-plate configuration have been discussed and investigated [9]. Biomechanical tests concluded that there is no significant difference in stiffness between the two configurations [10, 11]. Shin et al. [12] compared the clinical outcomes

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of both plate configurations and found no significant difference between the outcomes. Currently, in clinical use the 90°-configuration is the recommended standard-procedure. However, the optimal plate design and placement remains controversial. The functional results after double plating are satisfactory [13], but the complication rates remain high [14].

The purpose of our study was to compare the biomechanical properties of a newly developed, anatomically preformed, thinner, soft-tissue protecting plate system (Tifix®-hybridplate [HP]) with two established plates: The 3.5-mm reconstruction plate (RP) and the multidirectional locking Tifix®-plate (Tifix®-P). The hypothesis that the newly designed plate system would show comparable results in the quasi-static and dynamic tests compared to the two conventional implants was investigated.

Materials and methods

Fracture model

Twenty-four left synthetic humeri (Sawbones, Malmö, Sweden) were investigated. These synthetic bones have comparable mechanical properties to human bones and are manufactured especially for in vitro testing. They consist of a core of polyurethane (PU)-foam, the cancellous bone structure, and a mixture of epoxy resin and short glass fibres (modulus of elasticity 16 GPa, density 1.6 g/cm³) which is equal to the quality of bones of a healthy, middle-aged population [15].

Before preparing the fracture, model plates were formed with a bending device. Screw-holes were predrilled and pretapped. With a diamond belt-grinder (Exact company, Norderstedt, Germany) a standardised C2-fracture model was performed using a three centimetre transcondylar saw cut to simulate the intraarticular fracture. At the level of the medial epicondyl perpendicular to the humerus shaft axis a five millimetre wide gap was made and constituted the metaphyseal comminuted zone (Fig. 1). The predrilled holes enable fixation of the condylar fragments in their initial position after osteotomy.

Fig. 1 C2-fracture model (eight-hole reconstruction plate, 90°-plate configuration)

For the dynamic testing of an osteopaenic bone model, condylar fragments were replaced with PU-foam (specific density 0.13 g/cm³). This PU-foam should enable the typical failure pattern of screw loosening in osteopaenic bone.

Implants

The new plate system was designed from the author's working group. Litos Company (Litos GmbH, Ahrensburg, Germany) manufactured this as a prototype (Tifix®-HP). Biomechanical properties were investigated in this study and compared to those of two well-established plates: RP (Marquardt Medizintechnik, Spaichingen, Germany) for non osteoporotic bone, and the multidirectional locking Tifix®-P (Litos GmbH, Ahrensburg, Germany) for osteoporotic bone. The advantage of the Tifix®-HP was a thinner plate design close to the joint with less compromise of soft tissue. All implants used were eight-hole plates. At the level of the metaphyseal fracture gap a screw-dummy (separated screw head) was inserted in the Tifix®-HP which increased the stiffness of the plate by cold welding.

Measurement assembly

The measurement assembly follows the set up of Schuster [16], whereby bones could be fixed up to a maximal force of 150 N. Introduction of forces between 5° and 80° were possible. To avoid errors in measurements by transverse movements, a force in the precise sensor axis was important. A ball-joint between the mounting assembly and shifting plates permitted different introduction of force in extension and flexion. Force introduction took place via a rocker in the joint unit. By setting moveable lever lengths, anvils were able to transmit the physiological force distribution of 60:40 between capitulum and trochlea humeri [17]. The anvils were adapted to the anatomical form of the ulnar and radial joint surface to avoid force peaks. Forces were taken up with the Sensor Zwick Typ U2A, with 2 kN nominal force, and the pathed distance recorded internally. Maximum force was 150 N. The synthetic bones were fixed using a negative mould proximally (potting was with PMMA-resin [Technovit 4006; Kulzer, Wehrheim, Germany]).

Load tests

In tests 1 and 2 the whole groups ($n=8$) were analysed, in tests 3 and 4, three samples of each group were investigated.

Testing 1: stiffness

The stiffness was quasi-statically analysed in the ZWICK materials testing machine Nr. 1456 (Ulm, Germany) by loading in extension and flexion (Fig. 2). Models were

Fig. 2 Measurement assembly

loaded within the elastic range. With a speed of 0.1 mm/s testing was performed with a maximum force of up to 50 N. Stiffness was calculated by a regression line over a range of 20–40 N and determined each in flexion and extension loading. Each fracture model was loaded four times per load direction, whereas the first measurement was for preconditioning and was not used in analysis. Data from the force and distance sensors were recorded by the internal Zwick statistic program (TestXpert II V 3.1, Zwick-Roell, Ulm, Germany).

Testing 2: dynamic testing

The fatigue strength of the osteosyntheses was simulated during the bone-healing period. Samples were loaded in flexion, each 5,000, times with a sinusoidal force between 20 N and 150 N in the Dynamic materials testing machine (DHM 100824, Clausthal-Zellerfeld, Germany; Syscon easyTest software DHM). This testing speed comes closest to physiological motion. The number of cycles was based on the consideration that the callus formation starts to stabilise the fracture after approximately four weeks [16]. Therefore, a loading period of five weeks was chosen. Statistically, movements of once every five minutes in a 12 hour day are reported for humans, this corresponds to 5,040 cycles over five weeks [16]. With the help of microscope-cameras and software microcapture (DNT, Dietzenbach, Germany), photographs were taken at minimal and maximal load after cycles: 0, 50, 100, 200...500, 1000, 1500...5000 and the amplitude was

determined. The failure criterion was a fracture gap motion of more than two millimetres [18].

Testing 3: determination of the yield strength

Three samples per group were quasi-statically tested up to failure. After a riveting cycle up to the force of 100 N and subsequent release to 25 N the samples were loaded at a loading speed of 0.1 mm/s up to failure. To determine the yield strength in the interval from 100–150 N the regression line of the force-displacement-curve was measured. A line parallel to the regression line was shifted 0.2 % based on the height of the fracture gap of five millimetres. The yield strength was obtained from the intersection on this line and the measurement graph.

Testing 4: dynamic tests on the osteopaenic fracture model

For this test a dynamic level protocol was chosen. At defined intervals the applied force was increased up to the failure of osteosynthesis. The failure criterion was the fragment contact (joint–shaft). The process started with a sinusoidal force introduction of 20–150 N. The maximal load was contingently increased by 10 N every 5000 cycles. The frequency was 1 Hz. DHM 100824 was used. After every 1000 cycles a photograph was taken under maximal loading. Tests were performed under flexion load, because in this direction the load of the distal screws in the radial plate was greatest.

Statistics

Data were collected in Excel databases and transferred for statistical analysis to WinSTAT (R. Fitch Software, Bad Krozingen, Deutschland). Measured values were checked for outliers (double standard deviation) which were excluded. With the χ^2 -test a normal distribution was examined. Significance analysis was performed with the t-test (normal distribution) or the Mann–Whitney-test (non-normal distribution). The significance level was 0.05.

Results

Testing 1: stiffness

Extension loading

Examining the measured values for outliers showed two outliers in extension loading which were excluded, both in the RP-group (Fig. 3). With a mean of 52.1 ± 11.7 N the RP was significantly weaker ($p < 0.010$) than the Tifix®-P (67.9 ± 4.4 N) and Tifix®-HP (68.4 ± 2.3 N). Neither Tifix®-plates differed significantly ($p = 0.738$).

Fig. 3 Implant stiffness under extension loading

Flexion loading

One outlier was excluded. Tifix®-P (394 ± 25 N) showed a significantly higher stiffness than the other two implants. Tifix®-HP (216 ± 34 N) had a significantly lower stiffness than the RP (280 ± 41 N) ($p=0.053$) (Fig. 4).

Testing 2: dynamic testing

During the dynamic testing no sample failed. Neither fracture motion of over two millimetres, nor ongoing irreversible deformation was seen. The amplitude and the elastic deformation between minimal and maximal loading remained constant under cyclical introduction of force. The amplitude size was anti-proportional to the stiffness.

Tifix®-P (0.36 ± 0.05 mm) allowed significantly less fracture motion compared to the RP (0.58 ± 0.1 mm) and the Tifix®-HP

(0.55 ± 0.13 mm) ($p < 0.010$). No significant difference between the RP and the Tifix®-HP was found ($p=0.580$) (Fig. 5).

Testing 3: yield strength

Yield strength of the implants differed slightly. The highest yield strength showed the Tifix®-P with 163.7 ± 6.4 N. The Tifix®-HP achieved a mean of 160.3 ± 9.7 N, and the RP 155.0 ± 6.6 N. Because of the small group size ($n=3$) no statistical tests were performed.

Testing 4: dynamic tests on the osteopaenic fracture model

The behaviour of osteosyntheses in soft material demonstrated that locking plates failed only under much higher dynamic forces. Fragments touched under 173.3 ± 15.3 N in the RP, at 256.7 ± 11.5 N in the Tifix®-P and at 256.7 ± 5.8 N in the Tifix®-HP. This was an interval of approximately 57,000 cycles in the Tifix®-P and 56,000 cycles in the Tifix®-HP. The RP failed after nearly 13,000 cycles. The RP and the Tifix®-P always failed through screw loosening, whereas the Tifix®-HP showed screw loosening only in one third of cases.

Discussion

In our study biomechanical properties of a newly designed, anatomically preformed and thinner locking plate system (Tifix®-HP) were compared to those of a well-established locking plate (Tifix®-P) and a non-locking RP under quasi-static and dynamic testing. The hypothesis that the new Tifix®-HP, with a significantly lower implant volume and thickness, would show comparable results in the quasi-static and dynamic testing was confirmed. Quasi-static measurements showed that under extension loading both locking

Fig. 4 Implant stiffness under flexion loading

Fig. 5 Mean amplitude in dynamic testing

plates (Tifix®-P, Tifix®-HP) were significantly stiffer than the RP, and that the Tifix®-HP had a significantly lower stiffness than the two other implants under flexion loading. This could be caused by the screw dummy, the effect of which depends on the force direction. Because of its wedge shape, stiffness increased in extension loading (large contact pressure) and reduced in flexion loading (less contact pressure). The Tifix®-P was significantly stiffer than the RP in both directions. This might be due to the greater thickness of the Tifix®-P and the angular stability [19]. In summary, quasi-static tests provide limited information about the in vivo situation during the fracture-healing period because they only represent a single cycle load. Therefore, additional dynamic testing was performed. None of the osteosyntheses showed signs of fatigue during cyclic loading. The Tifix®-HP and the RP allowed significantly more fracture motion compared to the Tifix®-P.

Clinical experience have shown that the RP is sufficient in normal BMD [16]. But the conclusion that therefore the Tifix®-HP would also be also sufficient could not be drawn, because the Tifix®-HP is a thinner implant and daily load peaks could trigger an implant failure. However, the anatomical shape and an additional tap at the distal end of the radial plate might ensure a more stable fixation of the joint unit. The Tifix®-P showed the highest yield strength. In the osteopaenic bone model locking plates failed under much higher dynamic force than RP. RP and Tifix®-P always failed through screw loosening, whereas the Tifix®-HP showed screw loosening only in one third of cases.

For ethical and hygienic reasons, instead of human bones, synthetic bones with comparable biomechanical properties were used. Advantages were the avoidance of infections (hepatitis, HIV) and frequent disinfection of the testing device associated with (dis-)connection and resulting potential measuring errors as well as any measuring errors due to different bone structures, anatomy or body weights. Synthetic bones were identical, so fixation in the same negative form was possible. Because of the homogenous form and material structure a significantly smaller standard deviation was achieved compared to human bones [16]. A disadvantage was that the synthetic bones did not conform with osteoporotic bones. So, typical failure mechanisms such as screw break out/-dislocation [7] during dynamic testing were not observed.

In the C2-fracture model used, (one of the most frequently seen fracture types in the elderly) [20], the metaphyseal gap avoided bone contact during testing period, so that only the osteosynthesis was tested.

The greatest force is applied to the distal humerus during a 20° and 130° forearm-flexion [17]. The force vectors aim to the longitudinal axis of the humerus at 5° and 80°.

Different information was found about the forces during the elbow motion. The actual forces are difficult to quantify

because of the complex interplay of muscles. Data vary between 30 N and 2,500 N [21, 22]. With Newtons balance laws for a 90°-flexed elbow, forces of 32 N were calculated [22]. An additional one kilogram of weight bearing increased these forces to 82 N [22]. Because of tensing of the antagonistic muscles, a force of 150 N seems to be realistic [16]. Previous studies loaded their samples with 150–200 N [16]. The results correlated with the clinical experiences and have been adopted as appropriate and used in fatigue strength evaluations [16]. By contrast, forces of up to 300 N in the elbow during eating and dressing were described [21]. So, it could be argued that higher forces would have provoked screw pull-outs. However, this could have led to a plate-failure which is relatively rare in clinical practice [23].

The measurement assembly used allowed a standardised and reproducible testing as well as a direct comparison of osteosyntheses. The ball joint allowed an exact adjustment of the force transmission of 5° and 80° perpendicular to the axis of the humeral shaft, in accordance with the load peaks during flexion and extension [17]. During the dynamic analyses only flexion loading was tested, because in this direction the load of the distal screw in the radial plate was greatest. Under extension loading the distal screws were barely stressed, because plates were exposed to a pressure load. However, the initial tests falsely showed a low stiffness of the osteosynthesis due to a lever arm that was too long in extension loading. After preliminary tests a support was developed to stiffen the testing device.

A rocker realised the different physiological strength ratio between capitulum and trochlea humeri (60:40). The sample holder and the negative form allowed quick changes of samples and a very stable fixation.

During the dynamic testing no osteosynthesis failure was observed. But it was conspicuous that the new plate showed an increased weakness during quasi-static measurements under flexion loading compared to the two well-established implants. To improve this issue the plate should not taper so much.

Limits of the study are the use of synthetic bones which represent the bone structure of healthy adults and not the osteoporotic bone structure of the elderly risk group. So, a typical clinical failure mechanism of these patients, screw drop-out, could not be observed. This was caused by the relatively stronger synthetic-cortex more than by the intensity of the transferred force, because previous studies described screw drop-outs with comparable forces [16].

Furthermore, in the dynamic testing the complete sequence of arm motion could not be simulated. Thus, the results are only conditionally transferable to the in vivo situation.

Further studies in osteoporotic bone models and concomitant in vivo studies are necessary to obtain more information about the properties of this new implant in reduced bone quality.

Conflict of interest The authors declare that they have no conflict of interest.

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