Original article

Is there any advantage in placing an additional calcar screw in locked nailing of proximal humeral fractures?

J.C. Katthagen a, *, M. Schwarze b, L. Bauer a, J. Meyer-Kobbe a, C. Voigt a, C. Hurschler b, H. Lill a

a Department of Reconstructive and Trauma Surgery, Diakoniekrankenhaus Friedenskrankenhaus gGmbH, Humboldtstr. 5, 30169 Hannover, Germany
b Laboratory of Biomechanics and Biomaterials, Medizinische Hochschule Hannover (MHH), Anna-von-Borries-Str. 1-7, 30625 Hannover, Germany

A R T I C L E   I N F O

Article history:
Received 1st May 2014
Accepted 6 January 2015

Keywords:
Proximal humerus
Fracture
Calcar screw
MultiLoc®
Locked nail

A B S T R A C T

Background: The objective of this study was to evaluate the biomechanical effect of an additional unlocked calcar screw compared to a standard setting with three proximal humeral head screws alone for fixation of an unstable 2-part fracture of the surgical neck.

Hypothesis: The additional calcar screw improves stiffness and failure load.

Methods: Fourteen fresh frozen humeri were randomized into two equal sized groups. An unstable 2-part fracture of the surgical neck was simulated and all specimens were fixed with the MultiLoc®-nail. Group I represented a basic screw setup, with three locked head screws and two unlocked shaft screws. Group II was identical with a supplemental unlocked calcar screw (CS). Stiffness tests were performed in torsional loading, as well as in axial and in 20° abduction/20° adduction modes. Subsequently cyclic loading and load-to-failure tests were performed. Resulting stiffness, displacement under cyclic load and ultimate load were compared between groups using the t-test for independent variables (α = 0.05).

Results: No significant differences were observed between the groups in any of the biomechanical parameters. Backing out of the CS was observed in three cases.

Discussion: The use of an additional unlocked calcar screw does not provide mechanical benefit in locked nailing of an unstable 2-part fracture of the surgical neck.

Level of evidence: Level III. Experimental biomechanical study with human specimen.

© 2015 Elsevier Masson SAS. All rights reserved.

1. Introduction

Common indications for nail fixation of the proximal humerus are dislocated two-part fractures of the surgical neck and three-part fractures with involvement of the greater tubercle [1,2]. Though good clinical results can be achieved with locked nail fixation, loss of reduction demands for surgical revision in up to 10% [3–6]. Humeral head subsidence with varus malreduction has been identified as risk factor for inferior clinical outcome, as the humeral head settles into a non-anatomic position of stability [4–12].

A newly designed intramedullary nail 1 offers the option to place an additional ascending (135° angle) calcar screw. This development derives from locked plating, for which additional medial cortical support with calcar screws was proven to be beneficial [10,13]. With this nail 1, the treating surgeon has the option to choose between an unlocked and a locked calcar screw. However, backing out and migration of screws was a major complication of unlocked nailing leading to the development of locked nail constructs [1,7,14].

First biomechanical investigations of this new intramedullary nail 1 with additional use of a locked calcar screw plus two posterior “screw-in-screw” (additional locking screw anchored in the proximal humeral head screws) demonstrated higher number of cycles to failure and less varus deformation compared to the same screw configuration without supplementary screws [15]. The isolated mechanical effect of the calcar screw without further mean of additional fixation in locked nailing remains unclear to author’s knowledge.

The objective of this study was to evaluate the biomechanical effect of an additional unlocked calcar screw compared to a standard setting with three proximal humeral head screws alone for fixation of an unstable 2-part fracture of the surgical neck. We hypothesized that the additional calcar screw would improve stiffness and failure load.

http://dx.doi.org/10.1016/j.otsr.2015.01.018
1877-0568/© 2015 Elsevier Masson SAS. All rights reserved.
2. Material and methods

For biomechanical testing, 14 fresh frozen humeri from female human donors (median age: 75 (56 to 91) years) were randomized into two groups \((n=7 \text{ each})\). Humeral head bone mineral density (BMD) of specimens was osteoporotic \((0.41 \pm 0.05 \text{ g/cm}^2)\), mean neck-shaft-angle (NSA) was physiologic \((129.3 \pm 3.9)\). No significant difference was observed between parameters used to compare the groups as tested with the \(t\)-test for independent variables \((\text{donor’s age}, P=0.21; \text{weight}, P=0.58; \text{height, } P=0.39; \text{BMD, } P=0.92; \text{NSA, } P=0.51; \text{bone length, } P=0.29; \text{circumference at the surgical neck, } P=0.69)\).

The distal part of the humerus was cut 22 cm from the most proximal point of the humeral head. The long axis of the humerus was aligned vertically in coronal and sagittal planes and the distal 4 cm of the shaft were potted into an aluminum cylinder with casting resin. In order to simulate an unstable 2-part proximal humeral fracture of the surgical neck with comminuted medial cortex, a defined transverse wedge osteotomy was created using an oscillating saw. The osteotomy was positioned with the aid of a custom made alignment jig in order to attain high comparability among specimens, and a 10 mm gap was left at the surgical neck. The nail \((9.5 \text{ mm diameter, } 160 \text{ mm length})\) was inserted according to the manufacturer’s user manual. In order to avoid contact between the nail’s proximal end and the material testing machine’s actuator, the nail was inserted far enough to achieve subchondral positioning.

Three proximal humeral head screws \((4.5 \text{ mm locking screws }^{1})\) and two shaft screws \((4.0 \text{ mm non-locking screws }^{1})\) were placed in a standardized configuration in all specimens. No additional means of fracture fixation were used in the specimens of group I \((\text{basic; Fig. 1})\). In group II \((\text{Calcar})\) an additional unlocked inferomedial calcar screw \((4.0 \text{ mm, non-locking; Fig. 1})\) was placed using the manufacturers aiming device. The technique of screw-depth sounding was used for all humeral head screws to avoid iatrogenic intra-articular penetration.

All stiffness and strength tests were performed on a material testing machine \(^3\) with a linear actuator and a custom control protocol. Angle and axial displacement, moment and force were recorded at the actuator with 1024 Hz.

2.1. Stiffness tests

The test setup was based on previous biomechanical investigations \([9,16]\). Stiffness tests were performed in torsional loading, as well as in axial and in 20° abduction and 20° adduction modes.

For torsion stiffness tests, the humeral head was positioned centrally inside a cylindrical aluminum chamber and fixed with ten blunt screws on two levels leaving the plate spared. Universal joints connected to both cylinders eliminated off-axis moments. Torsional load was applied to the humeral head at a constant speed of 0.1deg/s with a load limit of ±3.5Nm \((\text{Fig. 2})\). Displacement of the humeral head was measured “grip to grip”, no slippage was observed. To account for the partly non-monotonically increasing moment-displacement correlation, stiffness for each specimen was calculated using maximum load \((3.5 \text{ Nm})\) and corresponding displacement \((\text{deg})\) from moment-displacement curves. Torsional stiffness was assessed three times each for external and internal rotation of the actuator after one preconditioning cycle; the mean values were calculated and analyzed.

For the remaining stiffness tests, cyclic loading and failure test, fracture gap displacement was to be determined three dimensionally by an ultrasound based device \(^4\). The sensors were placed on each side of the fracture gap on the posterior aspect of the humerus with a distance of 8 cm between and fixed with bone-cement \(^5\) \((\text{Fig. 2})\). The proximal cylinder was removed and forces were transmitted through a dynamic plate, which allowed free movement of the humeral head, to eliminate shear forces during loading \((\text{Fig. 2b})\). The potted part of the humerus was mounted rigidly to a tilting block, which was left in horizontal position for axial stiffness test. For stiffness tests in 20° abduction and 20° adduction the tilting block was moved in the corresponding direction and shifted sideways to achieve central humeral head positioning below the plate \((\text{Fig. 2b})\). Vertical load was applied to the apex of the humeral head at 0.1 mm/s with a load limit of 200 N in each mode. One preconditioning cycle with a load of 200 N was

---

\(^1\) Huntsman Advanced Materials; Basel, Switzerland; Ren cast FC 53™.

\(^2\) MTS; Eden Prairie, MN, USA; MiniBionix 858™.

\(^3\) Zebris Medica; Germany; CMS 205™.

\(^4\) Heraeus Kulzer GmbH; Hanau, Germany; Palacos™.
performed. Stiffness was calculated using corresponding total displacement at maximum load (200 N). All tests were repeated three times and average stiffness analyzed.

2.2. Cyclic loading and failure

Stiffness tests were followed by cyclic axial loading. Five thousand cycles of 50 to 250 N were applied at 1 Hz in a sinusoidal waveform. Maximum displacement at cycle number 5, 50, 100, 2500 and 5000 were calculated. All specimens were finally loaded to failure applying vertical force at 0.1 mm/s. Failure was visually observed and defined as:

- fracture around the humeral head or shaft;
- gap closure;
- implant failure.

2.3. Statistics

Normal distribution of all variables could be assumed as tested with the Kolmogorov-Smirnov-Test. T-test for independent variables was performed to compare stiffness of each loading mode and load-to-failure tests between groups. T-test with repeated measures was used to tests for significant difference between groups during cyclic loading. An alpha of 0.05 was used as significance threshold.

2.4. Ethics

This study has been approved by the local institutional review board (No. 1395-2012) on 28th March 2012.

3. Results

Analysis of results revealed only minimal fracture gap deflection. Resolution and accuracy of the additional ultrasound based device intended to measure fracture gap motion in a 3D fashion were not sufficient. Results were therefore calculated using axial and angle displacements, torque and load recorded from the actuator.

No significant differences were observed in torsional stiffness (Table 1, Fig. 3a) neither for internal ($P=0.89$) nor for external rotation ($P=0.97$). Furthermore, no significant differences in axial stiffness ($P=0.45$) and in $20^\circ$ abduction ($P=0.88$) or in $20^\circ$ adduction ($P=0.83$) modes were observed (Table 1, Fig. 3b).

Actuator displacement progression was similar during cyclic testing of both groups (Fig. 4a). No significant difference ($P=0.84$) was observed between actuator displacement of groups I & II. Failure load of the constructs of both groups showed no significant difference ($P=0.27$; Table 1, Fig. 4b). Failure mode was shaft fracture in all cases. The calcar screw backed out laterally (Fig. 5) in 3 cases of group II (3/7).

4. Discussion

The objective of this study was to evaluate the biomechanical effect of an additional unlocked calcar screw compared to a standard setting with three proximal humeral head screws alone for fixation of an unstable 2-part fracture of the surgical neck. Contrary to hypothesis, no significant difference in stiffness, actuator displacement, or failure load was observed between the groups with and without an additional unlocked calcar screw.

The 2-part fracture model used in this study is common in biomechanical testing of locked nailing of proximal humerus fractures [17,18]. Specimen age, gender and BMD were appropriate to represent the patient population that suffers most frequent from proximal humeral fractures. Load levels for all test modes were orientated on the results of glenohumeral load transmission of in vivo measurements and previous investigations [9,16,19–21].

As a major limitation to our findings, results apply only to time of initial fixation and do not reflect conditions under physical loading. Especially, the varus traction of the rotator cuff deemed responsible for loss of reduction was not simulated [15–22]. Specimens were not matched paired which also might have affected results. Furthermore, information about 3D fracture gap deflection could not be attained. Failure mode was shaft fracture in all specimens.

**Table 1**

Mean stiffness of all testing modes and mean load-to-failure with standard deviations.

<table>
<thead>
<tr>
<th></th>
<th>Group I</th>
<th>Group II</th>
</tr>
</thead>
<tbody>
<tr>
<td>Internal torsional stiffness (Nm/deg)</td>
<td>0.61 ± 0.2</td>
<td>0.63 ± 0.2</td>
</tr>
<tr>
<td>External torsional stiffness (Nm/deg)</td>
<td>0.7 ± 0.1</td>
<td>0.7 ± 0.4</td>
</tr>
<tr>
<td>Axial stiffness (N/mm)</td>
<td>465.9 ± 105.4</td>
<td>419.5 ± 116.2</td>
</tr>
<tr>
<td>20° abduction stiffness (N/mm)</td>
<td>143.2 ± 35.3</td>
<td>146.4 ± 38.5</td>
</tr>
<tr>
<td>20° adduction stiffness (N/mm)</td>
<td>201.4 ± 75.5</td>
<td>192.2 ± 79.5</td>
</tr>
<tr>
<td>Load-to-failure (N)</td>
<td>4288 ± 768</td>
<td>3758 ± 950</td>
</tr>
</tbody>
</table>

**Fig. 3.** a. Torsional stiffness of both groups in internal and external rotation loading modes. Single dots represent outliers with deviation of more than 1.5 × inter-quartile range from the median. b. Stiffness in axial, adduction and abduction modes. Single dots represent outliers with deviation of more than 1.5 × inter-quartile range from the median.
These results are comparable to ours (Table 1). Nonetheless, axial stiffness was described to be significantly higher with than without locked calcar screw in combination with two supplementary “screw-in-screws” [15]. The authors report head migration and varus deformity to be smaller and the number of cycles to failure higher with these three additional screws. Notably, the calcar screw was locked within the nail and had an additional thread close to the screws head for anchorage within the near cortex [15].

The much higher stiffness of the construct in axial direction compared to abduction and adduction modes indicates that the insertion of force close to the rigid implant affects results. However, this is consistent within the two groups and differences in sideways loading, where the additional screw was supposed to have an effect, were not significant as well. The calcar screw backed out visibly a few millimeters in 3 of 7 specimens of group II which can be considered an explanation for the absence of a stiffening mechanical effect of the unlocked calcar screw. Forces acting in a medial and varus direction seemed to push the calcar screw back out in the loading modalities that we investigated (Fig. 5). Backing out of screws was one of the main problems of early intramedullary nails used for fixation of proximal humeral fractures, leading to use of locking screws around the humeral head [1,7,14,23]. Another aspect to be considered regarding the use of an additional inferomedial calcar screw is the potential injury of the axillary nerve due to its anatomic location and the physical variability [24,25].

Few papers in literature deal with the surgical technique and clinical results of this nail [23,26]. Results with the use of the calcar screw are not described. Further evaluation is certainly necessary in order to draw conclusion about the clinical utility of an additional locked calcar screw in locked nailing of proximal humerus fractures.

Fig. 5. Backed out calcar screw during loading to failure (left). Shaft fracture along the shaft screws (right).

Interpretation of the available biomechanical evidence of proximal humerus two- and three-part fracture stabilization using additional screws leads to the conclusion that two additional “screw-in-screws” significantly benefit head migration and varus deformity. These effects are consolidated in combination with an additional locked CS [15]. As demonstrated in this investigation, the use of an additional unlocked CS alone is not useful in knowledge of biomechanical findings and even more regarding the necessity of an extra skin incision, longer duration of surgery and the screw’s extra costs.

5. Conclusion

The use of an additional unlocked calcar screw in locked nailing of an unstable 2-part proximal humeral fracture of the surgical neck does not improve stiffness or bring additional stability. If the additional use of a calcar screw is considered in case of missing medial cortical support, it should be locked regarding the overall available biomechanical evidence.
Disclosure of interest

The authors declare that they have no conflicts of interest concerning this article.

Acknowledgement

This study was funded by an AO-start-up-Grant (S-11-06K) of the AO research foundation (Switzerland). The funding source did not play a role in this investigation.

References