Nail Versus Plate: A Biomechanical Comparison of a Locking Plate Versus an Intramedullary Nail With an Angular Stable Locking System in a Shoulder Simulator With Active Muscle Forces Using a Two-Part Fracture Model

Susanne Strasser, MD, PhD,[a] Franz Kralinger, MD,[b] Michael Blauth, MD,[c] and Werner Schmoelz, PhD[c]

Objectives: To compare a locking compression plate versus an intramedullary nail with an angular stable locking system (ASLS) using a 2-part fracture model in a shoulder test bench.

Methods: Twelve fresh frozen humeri were used for biomechanical testing in a shoulder simulator. A 2-part fracture model, with and without medial cortical support, was used to compare the locking plate and a nail with an ASLS. The varus impaction, varus per cycle motion, tilt, and tilt per cycle were analyzed.

Results: No significant differences for the resulting forces in the glenoid fossa were evaluated. The stable fracture model showed no significant differences for the 2 groups. The median varus impaction was −0.96 degrees (range −0.55 to −4.26 degrees) in the plate group and 0.5 degrees (range −3.06 to 0.98 degrees) in the nail group, after 500 cycles of cyclic loading in the unstable fracture model. The plate group showed a significantly higher median varus impaction per cycle motion and median varus impaction at the 200th, 300th, and 400th cycle of physiological loading.

Conclusions: The intramedullary nail with the ASLS could be an alternative for patients suffering from osteoporosis and comorbidities.

Key Words: proximal humeral fracture, shoulder, biomechanic, osteoporotic

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From the [a]Department for Orthopedic Surgery, Medical University of Innsbruck, Innsbruck, Austria; [b]Department for Trauma Trauma Surgery, Wilhelminenspital, Vienna, Austria; and [c]Department for Trauma Trauma Surgery, Medical University of Innsbruck, Innsbruck, Austria.

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Reprints: Susanne Strasser, MD, PhD, Medical University of Innsbruck, Department for Orthopedic Surgery, 6020 Innsbruck, Austria (e-mail: susanne.kathrein@i-med.ac.at).

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INTRODUCTION

Proximal humeral fractures represent 4%–5% of all fractures, and its incidence increases with age.[1] Besides the distal radius, the vertebral spine, and the proximal femur, it is the most common fracture location in geriatric patients.[2] Most proximal humeral fractures are nondisplaced or minimally displaced and can be treated conservatively. Conservative treatment consists of prescribing a sling and early range of motion exercises. However, 20% of proximal humeral fractures may benefit from surgery.[3] Several operative treatments have been described, including K-wires, intramedullary nails, plate fixation, and arthroplasty. The choice for the optimum treatment is still challenging for the trauma surgeon because there is no consensus for the standard of care.[4,5] One limitation of the selection is when the fracture has occurred because of poor bone quality. In that case, complication rates up to 76% have been reported.[6] Loss of fixation may yield to displacement of the fractured parts or nonunion. Therefore, a second operative treatment could be mandatory. Patients with osteoporosis have a high rate of comorbidities; thus, a minimally invasive operative treatment with a low complication rate would be essential.[7] The locking compression plate and the intramedullary nail have been established for the treatment of proximal humeral fractures. An advantage of the intramedullary nail is its minimally invasive implantation technique. The Expert Humerus Nail with the Angular Stable Locking System (ASLS) has been developed to provide angular and axial stability. The most common failure of the intramedullary nail is its rotational instability along the humeral shaft axis.[8] High complication rates for the locking compression plate are reported due to varus impaction of the humeral head.[9–11] So far, no biomechanical investigation has compared a locking compression plate with an intramedullary nail with an ASLS for the rotation in the frontal and sagittal plane using a shoulder test bench simulating physiological loading of the proximal humerus. Therefore, the aim of the presented study was to compare the intramedullary nail with an ASLS versus the locking plate for their rotational stability in the frontal and sagittal plane in a shoulder simulator with active muscle forces using a 2-part fracture model. We hypothesize that the intramedullary nail with an ASLS could be an alternative for the treatment of proximal humeral fractures.

MATERIALS AND METHODS

Specimen

Twelve fresh frozen humeri were harvested from the local Department of Anatomy. The specimens were kept frozen at −20°C and thawed at 4°C overnight before preparation and biomechanical testing. A quantitative computed tomography (LightSpeed VCT 64; General Electrics, Milwaukee, WI) with the European Forearm Phantom (QRM, Möhrendorf, Germany) calibration was performed to measure the bone mineral density (BMD) according to an established technique[12] and to scan for relevant pathologies, such as bony defects due to tumors or old fractures. The specimens were divided into 2 groups with comparable BMD. All soft tissue was carefully removed except for the simulated muscles: for abduction, the deltoideus and supraspinatus, and for adduction, the teres major and pectoralis major. The distal humeri were cut 6.5 cm below the insertion point of the deltoideus and embedded in a custom made potting mould. The specimens were kept moist during testing using saline solution.

Fracture Model and Implants

Two different models simulating a stable and unstable 2-part fracture according to the Neer classification[13] were chosen. To create standardized and reproducible fractures, anatomic landmarks were chosen. For the stable fracture, one osteotomy line transected the humerus 10 mm below the humeral neck. A second osteotomy line was chosen so that the wedge has a lateral height of 10 mm while the medial fracture ends touched (see **Figure**, **Supplemental Digital Content 1**, http://links.lww.com/JOT/B186, which shows the stable fracture model and the 2 treatment options). The wedge osteotomy model was used to simulate a stable 2-part fracture comparable with an 11-A2 fracture according to the OTA/AO classification.[14] Initially, the stable fracture situation was tested for 500 cycles. Afterward, the remaining medial support was removed with the implant still in position to create an unstable fracture situation comparable with an 11-A3 fracture according to the OTA/AO classification[14] (Fig. 1), which was then tested for another 500 cycles.

Two different implants, an intramedullary nail and a locking compression plate, were used for this study according to the manufacturer's guidelines. Six humeri were treated with the Expert Proximal Humeral Nail (Synthes, Salzburg, Austria) with the ASLS. The intramedullary nail is available in different sizes. In this study, nails with a diameter of 9 mm were used for all specimens. The blade size at the proximal end of the nail was chosen individually to accomplish the ideal blade length. The locking screws were combined with bioresorbable sleeves to provide angular and axial stability.

Six humeri were treated with a short Proximal Humeral Internal Locking System with a length of 90 mm (PHILOS plate; Synthes, Salzburg, Austria). This plate provides 9 proximal screw holes distributed in the section A–E for locking compression plate (LCP) locking screws (ø 3.5 mm) and 3 shaft holes for either cortex screws (ø 3.5 mm) or cancellous bone screws (ø 4 mm), as well as LCP locking screws (ø 3.5 mm) (see **Figure**, **Supplemental Digital Content 2**, http://links.lww.com/JOT/B187, which shows the implant with the different sections). In this study, the plate was fixed with appropriate LCP locking screws (ø 3.5 mm) using the holes A–C and the 3 shaft holes. The application of the screws in the upper 3 rows enables a secure fixation of the screws because they are fixed in various directions. Screw length was determined intraoperatively according to the instructions of the manufacturer by a depth gauge in the instrumentation tray.

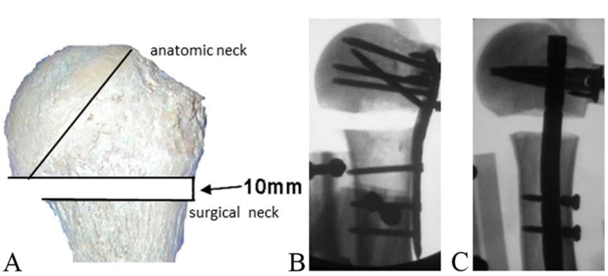

FIGURE 1. A, Unstable fracture model, the anatomic landmarks are labelled. B, Unstable fracture treated with the PHILOS plate. C, Unstable fracture with the Expert Humerus Nail with ASLS.

Biomechanical Testing

Biomechanical testing was performed with a shoulder simulator that mimics physiological loading of the humeral head during abduction and adduction between 15 and 45 degrees induced by active muscle forces (see **Figure**, **Supplemental Digital Content 3**, http://links.lww.com/JOT/B188, which shows the biomechanical test setup). The loading protocol is angle controlled. The detailed test setup is described in a former publication.[15] All data from the load cells of the shoulder simulator and the data from the ultrasound-based measurement system were continuously monitored. The first 20 cycles, and subsequently every 50th and 51st cycle, were recorded with a sample rate of 5 Hz using a custom written LabView routine (LabView 8.5.1.; National Instruments, Austin, TX).

The 12 specimens were divided into 2 groups as follows: 6 samples were tested using the plate and 6 samples were tested using the nail. Each bone implant construct was loaded for 500 cycles first using the wedge osteotomy model. Afterward, the medial support was removed with the implant in position, and the specimens were tested for another 500 cycles. To measure the fracture gap movement during the cyclic loading, an ultrasound-based analysis system was used (Winbiomechanics, Zebris, Isny, Germany) (see **Figure**, **Supplemental Digital Content 4a**, http://links.lww.com/JOT/B189, which shows the ultrasound-based analysis system). The varus impaction was defined as the change at the minimum value of abduction during a cycle that equates to the plastic deformation of the humeral head along the y axis. The tilt was defined as the change at the minimum value of abduction during a cycle along the z axis. The direction of the tilt could be in 2 ways as follows: "+" represents tilt in the direction of the measurement component, and "−" tilt represents rotation away from the measurement component. The per cycle range of motion (ROM) was defined as the relative motion of the humeral head to the plate during a cycle of abduction and adduction for the y axis and z axis (see **Figure, Supplemental Digital Content 4b**, http://links.lww.com/JOT/B189, which shows the used coordinate system).

Statistical Analysis

The BMD of the 2 tests group was evaluated for statistical difference. The resulting forces measured in the 6-component load cell were statically analyzed after the 20th, 100th, 200th, 300th, 400th, and 500th cycle in both the fracture models. To compare the behavior of the 2 different osteosynthesis techniques through 500 cycles of physiological loading, the tilt and tilt per cycle motion, varus impaction, and varus impaction per cycle motion were analyzed after the 20th, 100th, 200th, 300th, 400th, and 500th cycle. For all statistical analyses, the Mann–Whitney test was used in SPSS (SPSS 18, Chicago, IL). The statistical significance value was set at $P < 0.05$.

RESULTS

Specimens

The average age at the time of death was 76 years (SD 14.4 years) in the nail group and 76 years (SD 9.37 years) in the plate group. The median BMD for the nail group was 104.32 mg/cm^3 (range 92.3–140.7 mg/cm^3) and for the nonaugmented group was 116.02 mg/cm^3 (range 107.9–176.9 mg/cm^3) (see **Table**, **Supplemental Digital Content 5**, http://links.lww.com/JOT/B190, which shows age, sex, and BMD of the donors).

After biomechanical testing of the unstable fracture, one specimen in the plate group with the lowest BMD (66.84 mg/cm^3) showed a screw migration of the 2 most proximal screws. This was considered as failure of the implant. One specimen of the nail group with a low BMD (92.3 mg/cm^3) showed the highest tilt during biomechanical testing. This specimen also showed a higher varus impaction as the other specimen. The varus impaction per cycle motion and the tilt per cycle motion did not increase during biomechanical testing. Therefore, we considered that the implant failed.

Force Analysis

After 500 load cycles with medial support, the maximum median resulting force on the humeral head was 454 N (range 393–487 N) in the plate group and 435 N (range 434–546 N) in the nail group in the test sequence. For the fracture without medial support, the median maximum resulting force at the 500th cycle was 461 N (range 439–525 N) and 482 N (range 449–582 N) for the nail and plate groups, respectively. The evaluated forces during abduction and adduction are comparable with the in vivo data provided by Bergmann et al.[16] No significant differences between the 2 fracture models and the 2 implants were evaluated (see **Table**, **Supplemental Digital Content 6**, http://links.lww.com/JOT/B191, which shows the median resulting forces, minimum, maximum, range, and P values of the analyzed cycles).

Fracture Gap Movement

All data are presented as median and range.

Two-Part Fracture Model With a Medial Hinge—Stable Fracture

With medial support, the measured values were very low, and some of them below the detectable capabilities of the system. No significant differences were detected (see **Table**, **Supplemental Digital Content 7**, http://links.lww.com/JOT/B192, which shows the median, minimum, maximum, range, and P values of the stable fracture test sequence).

Two-Part Fracture Model Without a Medial Hinge—Unstable Fracture

Tilt—Rotation Along the Z Axis

The median tilt after 500 cycles of loading in the unstable fracture model was 0.54 degrees (range −3.51 to 0.82 degrees) in the plate group and 1.27 degrees (range 0.55–2.23 degrees) in the nail group (Fig. 2). This difference was not significant.

Tilt per Cycle Motion

The median tilt per cycle motion at the 500th cycle was 0.22 degrees (range 0.07–1.50 degrees) for the plate group and 0.1 degree (range 0.05–0.12 degrees) for the nail group (Fig. 3). Comparing the plate group versus the nail group after 500 cycles of physiological loading the plate group showed a significant higher tilt per cycle motion ($P < 0.05$).

Varus Impaction—Rotation Along the Y Axis

The median varus impaction was −0.96 degrees (range −0.55 to −4.26 degrees) in the plate group and 0.5 degrees (range −3.06 to 0.98 degrees) in the nail group after 500 cycles of cyclic loading (Fig. 4). The median varus impaction per cycle motion after 500 cycles was 0.62 degrees (range 0.38–2.31 degrees) in the plate group and 0.14 degrees (range 0.05–0.17 degrees) in the nail group (Fig. 5). Significant differences of the varus impaction and varus impaction per cycle motion occurred at the 200th, 300th, and 400th cycle of physiological loading.

All data and P values are shown in **Supplemental Digital Content 8** (see **Table**, http://links.lww.com/JOT/B193).

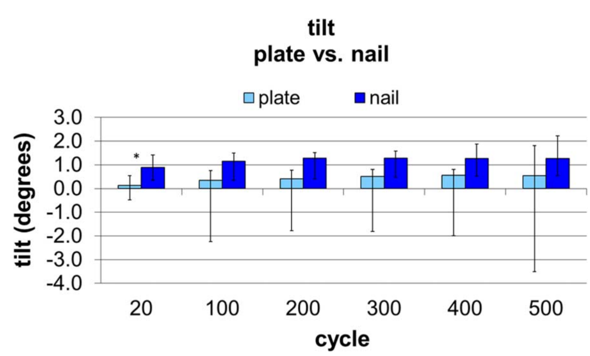

FIGURE 2. Median tilt of the plate group (light blue) versus the nail group (dark blue) over 500 cycles in the unstable fracture model. Significant differences are marked with an asterisk.

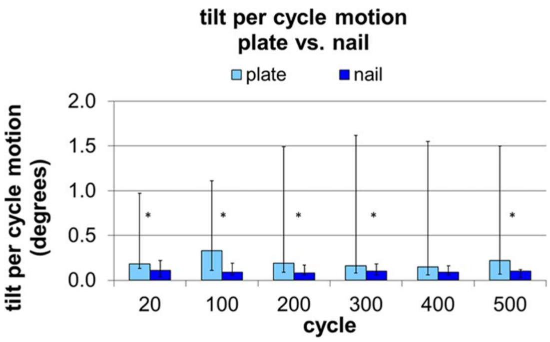

FIGURE 3. Median tilt per cycle motion of the plate group (light blue) versus the nail group (dark blue) over 500 cycles in the unstable fracture model. Significant differences are marked with an asterisk.

DISCUSSION

The main aims of the operative treatment of proximal humeral fractures are anatomic repositioning and fracture stabilization. Intramedullary nails have been developed as an alternative for locking compression plates in the treatment of proximal humeral fractures. These have the advantage of a minimally invasive approach, which minimizes the accompanying risks of surgery.[3,8,17–21] Proximal humeral fractures often belong to the osteoporotic fractures and have an unimodal distribution in men and women.[22] Patients suffering from osteoporosis often have a high rate of comorbidities and could benefit from a minimally invasive operative treatment. Therefore, the aim of this study was to compare the rotational stability in the frontal and sagittal plane of a locking compression plate and an intramedullary nail with an ASLS. The presented study evaluated 2 different implants in a shoulder simulator that applies physiological loading to the humeral head by simulating active muscle forces.

As expected, the median varus impaction, median tilt, median varus impaction per cycle motion, and median tilt per cycle motion showed no significant differences in the stable fracture model. Clinical studies have reported that an appropriate reduction of fracture fragments is the key for good functional results.[20,23–26]

Although there was a higher tilt in the group treated with the intramedullary nail compared with the locking compression plate after 500 cycles of biomechanical loading, the difference was not significant. This study did reveal a significant difference in the varus impaction per cycle motion after 500 cycles of biomechanical loading. The value was up to 5 times higher (eg, 400th cycle median varus impaction per cycle motion in the nail group was 0.11 degrees compared with 0.64 degrees for the plate group). Varus impaction is a common complication in the operative treatment of proximal humeral fractures. The nail group showed a significant lower varus impaction per cycle motion in the 200th, 300th, and 400th cycles.

Several biomechanical studies investigating locking compression plates and intramedullary nails have been conducted. The results we presented are comparable with studies published in the literature.[2,27–30] However, so far, biomechanical testing has been performed using simplified test setups and without active muscle forces.[1,2,27–29,31–39] In vivo, the pull of the muscles yields to a change of compression and tension in the fracture gap, leading to failure of the bone–implant construct. The shoulder test setup presented in this study simulates a more physiological loading by applying load through active muscle forces. The in vitro measured resulting forces in the glenoid were compared with the in vivo data evaluated by Bergmann et al.[16] The maximum forces at 45 degrees in both testing sequences—stable and unstable fracture—were in the range of in vivo occurring forces and showed no significant differences.

This study has several limitations. A 2-part fracture model with and without medial support was used for biomechanical testing. It is well known that in clinical studies the treatment of 3-part and 4-part fractures is more challenging and often accompanied by higher complication rates. However, for biomechanical testing, a 2-part fracture model is common and has been used by several authors before.[1,2,31] The sample size of the presented study is low because the availability of fresh frozen specimens is limited. However, the

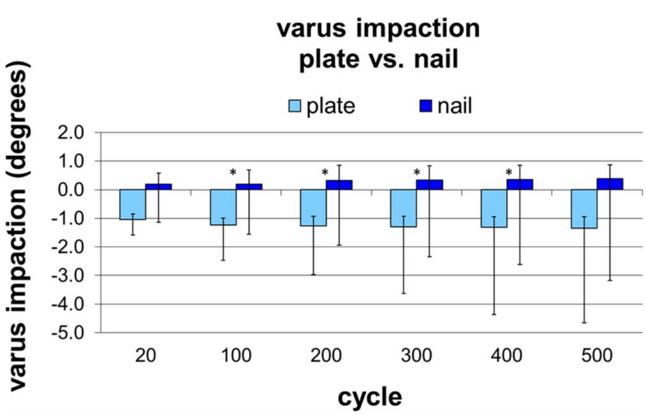

FIGURE 4. Median varus impaction of the plate group (light blue) versus the nail group (dark blue) over 500 cycles in the unstable fracture model. Significant differences are marked with an asterisk.

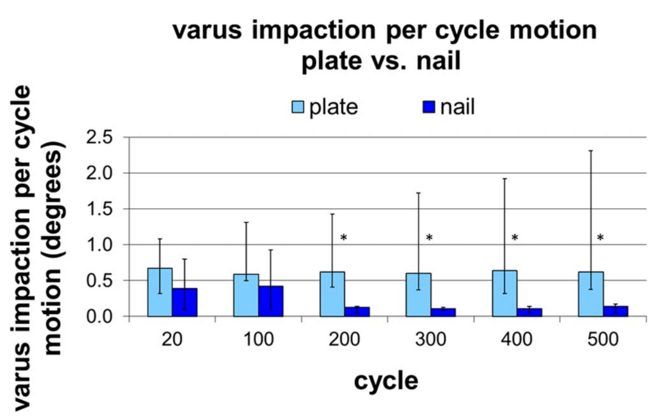

FIGURE 5. Median varus impaction per cycle motion of the plate group (light blue) versus the nail group (dark blue) over 500 cycles in the unstable fracture model. Significant differences are marked with an asterisk.

quantity of 6 is generally accepted to be sufficient for biomechanical studies. The biomechanical comparison with the 2 implants was not performed on left/right paired humeri; however, the BMD of the humeri used for both implants was comparable and showed no significant differences. The applied shoulder test setup only simulates the deltoideus, supraspinatus, teres major, and pectoralis major for the motion of the glenohumeral joint, despite more muscles being involved in vivo.

CONCLUSION

In summary, it can be concluded that the intramedullary nail with the ASLS showed a good rotational stability in the frontal and sagittal plane, after 500 cycles of physiological loading. The intramedullary nail with the ASLS could be an alternative for patients suffering from osteoporosis and comorbidities. Further investigations are warranted for biomechanical evaluation using a 3-part fracture model, and additional clinical trials are also required to investigate the clinical performance of the intramedullary nail with the ASLS.

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