Is loss of fixation following locked plating of proximal humeral fractures related to the number of screws and their positions in the humeral head?

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Abstract

The aim of the study was to examine the correlation between the chosen position of screws and the complications observed in patients who underwent locked plating of proximal humeral fractures. We evaluated radiographs of 367 patients treated by locked-plating for proximal humeral fractures. Radiographs were taken at one day, 6 weeks, 3 months and 6 months after surgery, and were analyzed for secondary fracture displacement, loss of fixation, cutting out of screws and necrosis of the humeral head. Secondary loss of fixation occurred in 58 cases (15.8%) and among those cutting out of screws was observed in 25 cases (6.8%). In cases of secondary loss of fixation a mean of 6.7 screws were used to fix the fracture (vs 6.6, P=0.425). There was neither significant correlation between position of screws and the occurrence of postoperative loss of fixation in Spearman correlation nor relationship from backward logistic regression analysis. Loss of fixation following locked plating of proximal humeral fractures does not relate to the number of screws and their positions in the humeral head. In consequence, anatomic fracture reduction and restoration of the humeral head-shaft angle are still important factors and should not be disregarded.

Introduction

The incidence of proximal humeral fractures in the elderly is increasing due to an increase of falls and osteoporosis for this population.14 While non-displaced and stable fractures can be treated conservatively, the treatment of displaced fractures with medial comminution is challenging due to insufficient bone quality for implant anchorage.2 Over the last fifteen years new techniques in the operative treatment of proximal humeral fractures were developed, including minimal invasive approaches,3,5 and implants that aim to increase the fixation strength. One of the most performed procedures in the surgical treatment of displaced proximal humeral fractures is locked plating. Radiographic and clinical studies showed that locked plating leads to better results than conventional methods with complication rates ranging between 10-30%.6,7 including secondary fracture displacement, screw cut-out, mal- and non-union, as well as avascular necrosis of the humeral head.8,9 Südkamp et al. observed that 1/3 of patients treated by locking plates develop postoperative complications and 19% would undergo an unplanned revision in the first year after primary surgery.7 Loss of fixation is one of the most frequently observed complications and in locking plates this means a cutting out of screws and impending joint destruction.10 One reason for loss of fixation is an insufficient anchorage of screws in the humeral head, thus research for the optimal screw position is ongoing. Several studies showed that the humeral head varies in terms of bone mineral density and that the highest amount of bone mineral density is found in the superior and posterior regions of the humeral head.11-14 In a biomechanical study by Brianza et al. screws purchasing the superior and posterior aspect of the humeral head showed higher torque strength compared to screws inserted in the other regions,15 suggesting that it is advantageous to place screws in these specific regions potentially reducing the risk for loss of fixation. Another recent finding is the importance of an inferomedial support screw in fixed angle plating of proximal humeral fractures. In a biomechanical study by Erhardt et al. a screw placed obliquely in the inferomedial region of the humeral head significantly increased the number of cycles before loss of fixation occurs and usage of more screws additionally enhanced the fixations strength.16 However, to the authors’ knowledge, despite biomechnical studies, no clinical study could verify these findings in a larger cohort of patients. Hence, aim of the study was to evaluate the relationship between loss of fixation following locked plating of proximal humeral fractures and the number and position of screws purchasing the humeral head.

Materials and Methods

Study cohort

Between February 2002 and February 2012, 519 patients were treated by locked plating for a proximal humeral fracture at our institution. Eighty-seven patients were excluded from the study that either died within 6 months from surgery or did not undergo complete follow-up X-rays. Furthermore, 17 patients were excluded because anteroposterior (a.p.) x-rays showed a rotational error of >20° (non-true a.p.). Another 48 patients were excluded because locked plating was performed by use of polyaxial implants and therefore the screw positions were not comparable with those of a monoaxial locking system. The remaining 367 patients with a mean age of 65.5 years (95% CI: 63.9; 67.2, 66.8% female) made up the study cohort. The fracture pattern, according to AO/OTA fracture classification,17 was A1: n=6 (16%), A2: n=57 (15.5%), A3: n=64 (17.4%), B1: n=71 (19.3%), B2: n=64 (17.4%), B3: n=11 (3%), C1: n=14 (3.8%), C2: n=66 (18%), C3: n=14 (3.8%).

Surgical procedure

Placed in beach-chair-position on a radiolucent table, patients were operated under general anesthesia by a senior trauma surgeon. A delto-pectoral approach was used for open reduction and internal fixation of all fractures. Fracture fixation was conducted by use of the Proximal Humeral Internal Locking

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System® (PHILOS, Synthes Depuy GmbH, Oberdorf, Switzerland) and sutures (FibreWire® size 5, Arthrex 1370 Creekside Boulevard Naples, Florida, USA) were used to restore the tubercle. During all procedures, a radiographic intensifier was used to check accurate fracture reduction and correct positioning of screws 5 mm from the medial cortical layer.

**Radiographic evaluation**

Two individuals (MM, LG) evaluated all radiographs twice in separate sessions including radiographs one day, six weeks, three months and 6 months after surgery. The screws purchasing the humeral head were assigned a plate based code number as applied by Brianza et al.15 (Figure 1). The total number of screws used in each plate was documented. The head-shaft-angle was measured drawing a line from the superior to the inferior border of the articular surface through the anatomical neck of the humerus (A line) and then a perpendicular line to the A line through the center of the humeral head (B line). The angle (α) between the B line and the line bisecting the humeral shaft (C line) was measured as the head-shaft angle (Figure 2). Loss of fixation was defined as a varus displacement of more than 10 degrees in true a.p. X-rays. Screw cutout was defined by radiographic evidence of bridging bone on true a.p. and outlet-view radiographs.

**Statistical analysis**

Continuous variables are given in means and 95% confidence intervals and categorical variables are described in percentages. Chi-square-test was used to examine effect of different screw positions on secondary varus displacement, screw cutout, delayed union or osteonecrosis and hardware failure. A univariate analysis of variance (ANOVA) was used to compare the number of screws used for each fracture type and Spearman’s correlation was performed to identify a relationship. A binary logistic regression model was conducted to evaluate a relationship of the different screw positions on the occurrence of loss of fixation. The level of significance was set at P<0.05. Statistical analysis was performed using SPSS version 20 (SPSS Inc, Chicago, IL, USA).

**Figure 1. Plate based code number of screws. Each screw is assigned a plate based code number to identify its position in the humeral head. (According to Brianza et al.15 shown for a right shoulder, in left shoulders screws were numbered oppositional).**

**Figure 2. Measurement of the head-shaft-angle.** Drawing a line from the superior to the inferior border of the articular surface of the humerus (A line) and then a perpendicular to the A line through the center of the humeral head (B line). The angle (α) between the B line and the line bisecting the humeral shaft (C line) was measured as the head-shaft angle.

**Results**

A mean of 6.6 screws were used to fix the fracture. In percentage screws were purchased according to the plate based code number as following: screw 1: 96.7% (95% CI: 94.9; 98.6), screw 2: 95.4% (93.2; 97.5), screw 3: 85.3% (81.6; 88.9), screw 4: 85.0 (81.3; 88.7), screw 5: 81.7 (77.7; 75.8), screw 6: 83.4 (79.6; 87.2), screw 7: 45.2 (40.1; 50.3), screw 8: 42.8 (37.7; 47.9), screw 9: 42.8 (37.7; 47.9).

There were no significant differences in number and position of screws for each type of fracture (P=0.33, Figure 3). The mean measurement of the head-shaft-angle at the first postoperative day was 133° (95% CI: 131.7; 134.4) and at the last follow-up X-ray (6 months) it was 126.8° (95% CI: 125.3; 128.3).

Head shaft angle significantly decreased over time with the most decreased head-shaft angle for the group of loss of fixation at final follow-up (122.7°, 95% CI: 119.2; 126.1, P=0.001).

Of the 367 patients investigated in this study, in 281 patients (76.6%) the fracture healed in six months from surgery without signs of displacement. In 28 cases (7.6%) surgical technique related complications were identified, including malreduction of the fracture or primary screw perforation. In 58 cases (15.8%) the primary well-reduced and correctly fixed fracture resulted in secondary loss of fixation. Among these, cutting out of screws was seen in 25 cases (43%). Revision surgery was necessary in 34 patients (58.6%) with loss of fixation, treated by early hardware removal in 19 cases, revision osteosynthesis in 11 cases and secondary arthroplasty in 4 cases.

Among the 58 patients with loss of fixation, C2 (41%) and C3 (64%) type fractures had the highest prevalence (P=0.004). A mean of 6.7 screws were used for primary fracture fixation (95% CI: 6.5; 6.9), in comparison, in cases of regular fracture healing the mean number of head screws were 6.6 (95% CI: 6.4; 6.7, r=0.042, P=0.425, Figure 4). In cases of postoperative loss of fixation the percentage of screws positioned according to the plate based code number was for screw 1: 96% (95% CI: 92.2; 100), for screw 3: 87.1% (95% CI: 80.5; 93.8) and for screw 6: 86.1% (95% CI: 79.3; 93.0) and were not different to cases of regular fracture healing (P=0.647, P=0.539 and P=0.381). There was neither significant correlation between position of screws and the occurrence of postoperative loss of fixation in Spearman correlation (Table 1) nor relationship from backward logistic regression analysis (screw 2: B=0.899, r=0.501, Beta=0.407, 95% CI Beta 0.153-1.086, P>0.07).
Discussion

The main finding of our study is that loss of fixation following locked plating of proximal humeral fractures is not related to the number of screws and their positions in the humeral head. Although the humeral head may represent differences in the regional bone quality and thus screws purchasing regions of high bone quality may theoretically be beneficial from biomechanical studies, this retrospective evaluation of radiographs from 367 patients treated by locked plating for proximal humeral fractures may not verify clinical consequence.

Locked plating has become an established treatment for displaced fractures of the proximal humerus. The advantage over conventional plating is that it preserves blood supply to the humeral head by decreasing the contact pressure between the plate and the periosteum in addition to its biomechanical characteristics to work as an internal fixator.18 Biomechanical in vitro studies confirmed the superior mechanical strength of locking plates in comparison to conventional plating.19,20 The bone-implant interface is less likely to fail during strength testing with locking plates and this is of considerable clinical relevance in patients with diminished bone quality (i.e., osteoporosis) or in the presence of medial comminution. Numerous studies have shown that the outcome after locked plating of proximal humeral fractures is satisfactory in the majority of cases, however, the reported rate of postoperative complications ranges between 10-30%, and the rate of an unplanned second surgery accounts up to 19%.6,7,9,21 One of the most frequently observed complications following locked plating of proximal humeral fractures is loss of fixation.6 Loss of fixation results at the bone-implant interface, when the construct’s strength fails the forces that arise to the humeral head and healing does not take place.18 While in a young patient with strong bone the construct’s strength that can be achieved by locking plates is usually high, in predominantly older patients suffering from proximal humeral fractures the osteoporotic bone gives less potential for screws to anchor, thus the construct is prone to fail. In order to facilitate for the best anchorage, screws should be placed in the regions of strongest bone quality. For this reason a variety of studies investigated the regional differences in bone quality of the humeral head.11-13,15 Tingart et al. evaluated the bone mineral density of the humeral head and divided the head into five regions of interest (superior-anterior, superior-posterior, central, inferior-anterior, and inferior-posterior).15 One of the results was that the superior and posterior region had a higher trabecular bone mineral density than all other regions of the humeral head. The authors’ suggested that placement of screws in regions with a higher trabecular density may help to prevent implant loosening and may

| Screw | Total, % (95%CI) | Yes, % (95%CI) | No, % (95%CI) | Chi-square | Spearman r | P |
|-------|-----------------|----------------|----------------|-------------|-------------|---|
| 1     | 96.7 (94.9; 98.6) | 96.0 (92.2; 100) | 97.0 (94.9; 99.1) | 0.647 | -0.024 | 0.65 |
| 2     | 95.4 (93.2; 97.5) | 92.1 (86.7; 97.4) | 96.6 (94.4; 98.8) | 0.065 | -0.096 | 0.07 |
| 3     | 85.3 (81.6; 88.9) | 87.1 (80.5; 93.8) | 84.6 (80.2; 89.0) | 0.539 | 0.032 | 0.54 |
| 4     | 85.0 (81.3; 88.7) | 86.1 (79.3; 93.0) | 84.6 (80.2; 89.0) | 0.710 | 0.019 | 0.71 |
| 5     | 81.7 (77.7; 75.8) | 79.2 (71.2; 87.3) | 82.7 (78.1; 87.3) | 0.438 | -0.041 | 0.44 |
| 6     | 83.4 (79.6; 87.2) | 86.1 (79.3; 93.0) | 82.3 (77.7; 86.9) | 0.381 | 0.046 | 0.38 |
| 7     | 45.2 (40.1; 50.3) | 46.5 (36.6; 56.4) | 44.7 (38.7; 50.8) | 0.757 | 0.016 | 0.76 |
| 8     | 42.8 (37.7; 47.9) | 46.5 (36.6; 56.4) | 41.4 (35.4; 47.3) | 0.370 | 0.047 | 0.37 |
| 9     | 42.8 (37.7; 47.9) | 45.5 (35.7; 55.4) | 41.7 (35.8; 47.7) | 0.509 | 0.034 | 0.51 |

Percentages of screws according to the plate based code number in relationship to the occurrence of loss of fixation. Note that 28 patients (7.6%) with primary malreduction were excluded.

Figure 3. Number and position of screws for each type of fracture. Mean number and confidence interval (95% CI) of screws positioned in the humeral head in accordance to AO/OTA fracture type classification showing no significant differences (P=0.33, ANOVA).
improve patients’ outcome. In another study by Hepp et al. the medial and posterior aspects of the proximal humeral head were the regions of highest bone strength.13 Barvenčik et al. confirmed the results and in addition found that independent from age and sex, the highest bone mass of the posterior medial and superior regions may therefore be considered as the best location for screw placement.14 In a biomechanical cadaver study by Brianza et al., bone quality in the different regions of the proximal humerus head was examined using high resolution peripheral quantitative computed tomography, in addition to measuring the breakaway torque at those regions.15 Through a plate based code number (Proximal Humeral Interlocking System, PHILOS®) the screws’ positions were evaluated with regards to regional bone mineral density of the humeral head. The authors demonstrated that the superior and posterior aspects of the humerus are characterized by significantly better cancellous bone. They also reported that not all screws purchase the humeral head with the same bone quality and that the use of certain screws (Nr.: 1, 3 and 6) may be advantageous compared to other screws with regards to the fixation’s strength.

In our study we adopted the plate based code number model of Brianza et al.15 and retrospectively evaluated radiographs taken up to 6 months after surgery. The results of our study showed no correlation between the usage of certain screws (Nr.: 1, 3 and 6) and the maintenance of reduction. In comparison to the biomechanical studies loss of fixation was equally seen if screws were locked in regions with reported higher bone quality. One explanation for this result may be that the regional bone quality varies in a cohort of 367 patients and that earlier cadaver studies may have been underpowered to assess the regional differences in bone quality of the humeral head. Another explanation for the lacking consent could be that in clinical practice the plate’s position may vary considerably compared to a standardized biomechanical setup. Although the ideal position for a locking plate is in close proximity posterior to the bicipital groove on the lateral site of the humeral head, and low enough so that it does not impinge underneath the acromion, in clinical practice the plate’s position alters with respect to anatomic consti-
tutions, fracture morphology and degree of fracture reduction. While in certain cases anatomic reduction may not be fully accomplished, in consequence the plate holes and by that means screws purchasing the humeral head in a monaxial manner alter in comparison to a biomechanical model. As surgery was undertaken according to the surgical technique described by the manufacturer, and the reported complication rate is in consensus with other studies, we propose that other factors may rather influence the outcome, e.g. accurate fracture reduction and restoration of the humeral head-shaft angle.

We did not observe a relationship between usage of screws Nr. 8 and 9 and maintenance of reduction. This finding is of particular interest, as screws Nr. 8 and 9 are considered medial support screws and several biomechanical studies have shown that those screws are important contributors on the fixation’s strength in medially comminuted and varic displaced fracture types. In a study by Liew et al. the grasping force of a screw placed in the medial and inferior region was comparably stronger than that of a screw placed either in the middle of the humeral head or in the lateral and superior region.22,23 Also, Erhardt et al. could show in a biomechanical study that the construct’s strength benefits from an infero-medial supporting screw in terms of load to failure.14 Although, placement of inferomedial screws may be beneficial in biomechanical studies, in this clinical study of 367 patients this effect could not be verified. However, Gardner et al. demonstrated in a radiographic study of 35 patients that placing a superiorly directed oblique locked screw in the inferomedial region of the proximal fragment, may achieve more stable medial column support and allow for better maintenance of reduction.24 Osterhoff et al. reported in 60 patients that placement of calcar screws in the angular stable plate fixation of proximal humeral fractures is associated with less secondary loss of reduction by providing inferomedial support.25 One reason for this contradiction may be seen in the fracture patterns. While in the studies of Gardner and Osterhoff the fracture type had no effect on the maintenance of reduction, we noticed that fracture types C2 and C3 according to the AO/OTA fracture classification had the highest prevalence for secondary loss of fixation and among these screws 8 and 9 were placed more frequently. Taken together the two observations one might suggest that in the highly unstable fracture types the surgeon tries to enhance the fixation by use of calcar screws, but locked plating resulted in loss of fixation regardless of the usage of such screws. While in both studies cited above loss of fixation was defined as a decrease of the distance between the proximal end of the plate and the tip of the humeral head in our study loss of fixation was defined through measurements of the head-shaft angle in accordance to previously published studies.5,26 Thus, a lacking support may be due to a difference in the evaluation of postoperative loss of fixation. However, the benefit of an obliquely placed screw in the inferior part of the humeral head for the maintenance of reduction in proximal humeral fractures remains unclear and it’s effect needs to be evaluated from a prospectively randomized clinical study.

Another hypothesis in the treatment of proximal humerus fracture is that more screws means more stability and leads to less secondary loss of reduction. In the biomechanical

Figure 4. Complication and number of screws placed in the humeral head. Comparison of the number of screws placed in the humeral head in cases of regular fracture healing (n=266, no complication) to cases with occurrence of loss of fixation (n=101) r=-0.042, P=0.425.
study by Erhardt et al. it was shown that the load to failure rate in fixed angle plated proximal humeral fractures was significantly higher when at least five screws were used. In our study, a mean of 6.6 screws were used to fix the fracture, and we could not see a relationship between the number of screws at primary fracture fixation and the occurrence of secondary loss of fixation. While in a biomechanical model the stability may increase with more screws, this may not necessarily be true clinically. A reason could be due to the biology of fracture healing and a decreased amount of bone in between screws may inhibit fracture healing.18

Limitations
There are several limitations to our study. First, the bone mineral density was not evaluated thus a differentiation between patients of generally strong bone quality to patients of weaker bone was not possible. As insufficient screw anchorage and loss of fixation is mostly a problem in the osteoporotic patient the results may be different if patients with generally good bone quality were excluded.

Secondly, the evaluation of postoperative radiographs may be inaccurate due to an error in projection. We excluded 17 patients because radiographs taken from postoperative day 1 to six months showed rotational inconsistency, however a minor rotational difference <10° may be still existent within the evaluated radiographs in this study and may affect head-shaft-angle measurements. Although all screws were positioned so that the screw tip remained approximately 5 mm within the subchondral layer, verified by intraoperative X-rays, a variance of screws’ positions is possible. A more precise investigation would be the use of CT-scans, which were not undertaken postoperatively due to radiation exposure. However, conventional X-ray is still the standard for postoperative verification of fracture healing and implant position in locked plating for proximal humeral fractures.

Conclusions
Loss of fixation following locked plating of proximal humeral fractures is not related to the number of screws and their positions in the humeral head. Although there is evidence for regional differences of the bone quality within the humeral head and placement of screws in regions of high bone quality may suggest a stronger fixation, the clinical consequence may not be verified as loss of fixation is observed independently to the plate based screw position. As a consequence, anatomic fracture reduction and restoration of the humeral head-shaft angle are more important factors and may not be disregarded.

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