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Screw configuration in proximal humerus plating has a significant impact on fixation failure risk predicted by finite element models

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Background: Proximal humeral fractures occur frequently, with fixed angle locking plates often being used for their treatment. No current quantitative evidence for the effect of different screw configurations exists, and the large number of variations makes biomechanical testing prohibitive. Therefore, we used an established and validated finite element osteosynthesis test kit to quantify the effect of variations in screw configuration on predicted failure risk of PHILOS plate fixation for unstable proximal humerus fractures.

Methods: Twenty-six low-density humerus models were osteotomized to create malreduced unstable 3-part fractures that were virtually fixed with PHILOS plates. Twelve screw configurations were simulated: 6 using 2 screw rows, 4 using 3 rows, and 1 with either 8 or 9 screws. Three physiological loading cases were modeled and an established finite element analysis methodology was used. The average peri-screw bone strain, previously demonstrated to predict fatigue cutout failure, was used to compare the different configurations.

Results: Significant differences in peri-screw strains, and thus predicted failure risk, were seen with different combinations. The 9-screw configuration demonstrated the lowest peri-screw strains. Fewer screw constructs showed lower strains when placed further apart. The calcar screws (row E) significantly ($P < .001$) reduced fixation failure risk.

Conclusion: Screw configurations significantly impact predicted cutout failure risk for locking plate fixations of unstable proximal humerus fractures in low-density bone. Although requiring clinical corroboration, the result of this study suggests that additional screws reduce peri-screw strains, the distance between them should be maximized whenever possible and the calcar screws should be used.

Level of evidence: Basic Science Study; Computer Modeling

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Keywords: Proximal humerus fracture; PHILOS plate; fixation failure; screw configuration; finite element

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Proximal humeral fractures occur frequently and with an increasing incidence, in part due to the rising rates of osteoporosis and increasing life expectancy.² Although many fractures are nondisplaced and can be successfully managed nonoperatively, internal fixation remains one of

the main joint-preserving treatments for complex fracture patterns.¹⁹ Fixed angle locking plates are the most common operative treatment of choice for displaced proximal humeral fractures.³⁰ These osteosynthesis systems allow loads within the healing bone to be distributed throughout the whole construct, rather than being concentrated at a single screw, as may occur with nonlocking plate constructs.²⁷ However, despite their use, failure rates still remain high, up to 35%.^{13,16} This, in part, may be due to difficulties in optimizing the plate application due to the learning curve required, as well as inability to create the most appropriate construct configuration for the given fracture pattern.¹⁸ With proximal humeral plates, there are numerous possible screw configurations due to the number of proximal plate holes. The PHILOS plate (DePuy Synthes, Zuchwil, Switzerland)⁷ is equipped with 9 screw holes to secure the proximal fragments and least 3 screw holes for distal shaft fixation. Its operative manual states that the plate should be applied with at least 4 proximal screws and that, in poor bone stock, multiple fixation points using all screws are recommended. In addition, if the minimally invasive approach is used, the surgical guide of the implant manufacturer advises to use only the most 4 proximal screw holes to avoid injuring the axillary nerve.⁶ Given the variety of possible proximal screw arrangements, it is unclear what is the ideal baseline configuration. Also, the quantitative effects of different screw combinations, which aspects are most crucial in reducing the risk of fixation failure and whether placement of any screws should be prioritized over others remain unknown. The variability of human bone means that biomechanical analysis of different configurations would be nearly impossible to perform at an appropriate power whilst maintaining justifiable ethical standards and financial costs. However, by using a recently developed³² and validated³¹ osteosynthesis test kit, various aspects of locking plate fixation of proximal humerus fractures, such as screw configurations, can be compared. The aim of this study was to establish the quantitative effect of variations in screw configuration on predicted mechanical failure risk after PHILOS plate fixation of unstable proximal humerus fractures using computer simulations. The hypothesis was that calcar screws would provide proportionally greater reductions in peri-screw strains than other screws.

Materials and methods

The PHILOS plate has 9 proximal holes available for fixation (Fig. 1).⁷ The configuration options investigated in this study were focused on combinations using completely occupied screw rows (A, B, C, and E), instead of single screws within rows. Therefore, row D, which has only 1 screw, was generally not considered, being included in only 1 configuration modeled with all 9 screws. Using a minimum of 2 occupied rows creates 12 potential combinations: 6 combinations using 2 proximal rows (ie, 4 screws), 4

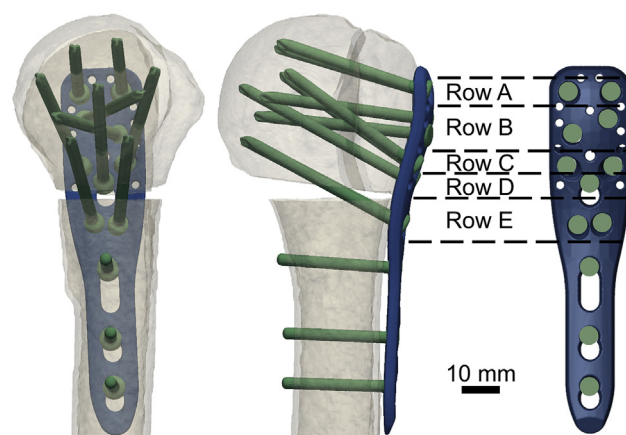


Figure 1 Sagittal and coronal views of the PHILOS plated fracture model with all possible screw holes used. The screw hole rows of the PHILOS plate are labeled with letters as shown in the right.

combinations using 3 proximal rows (6 screws), 1 configuration with 8 screws (rows A, B, C, and E), and 1 with all 9 screws (rows A, B, C, D, and E) (Fig. 2).

A previously developed³² and validated³¹ virtual osteosynthesis test kit was used in this study to predict and compare the risk of fixation failure of the different configurations. The application of this tool ensured reproducible and efficient simulations based on established methods for model generation, analysis, and evaluation.

Twenty-six low-density left-sided virtual humerus models were selected from the database of digital bone samples available in the virtual test kit. These specimens originated from 14 female and 12 male elderly donors (age range: 64-98 years, mean \pm standard deviation: 83.9 ± 8.1 years). The bones had been previously scanned with high-resolution peripheral quantitative computer tomography (HR-pQCT, XtremeCT; Scanco Medical AG, Brüttisellen, Switzerland). The clinical method of Krappinger et al¹⁷ was used to evaluate bone mineral density (BMD) of the humeral head, providing a range of 68.9-129.6 mg/cm³ (median, 107.4 mg/cm³).

Finite element (FE) models of the bones were built based on the HR-pQCT scans, distinguishing the cortical and trabecular bone compartments. The models were osteotomized to mimic an unstable 3-part fracture AO/OTA 11-B3.2 with medial comminution and malreduced proximal fragments, simulated with a 1-mm gap left between the latter (Fig. 1). The definition of the fracture gaps was consistent for all models given the anatomical homology correspondence available between the subjects and is sufficient to mimic any clinical situations where the humeral head fragment is mechanically not supported by other fragments. The osteotomized models were fixed with a PHILOS plate, positioned as per the surgical technique,⁷ using an automated algorithm. This was based on anatomical landmarks such as the superior aspect of the greater tubercle and the bicipital groove, as well as a virtual K-wire attached through the aiming block of the plate and touching the proximal joint surface.³² All screw lengths were set consistently to provide 6-mm tip-to-joint distance, using commercially unavailable lengths as needed. The selection criteria for the subjects included the requirement that all screws had to be sited

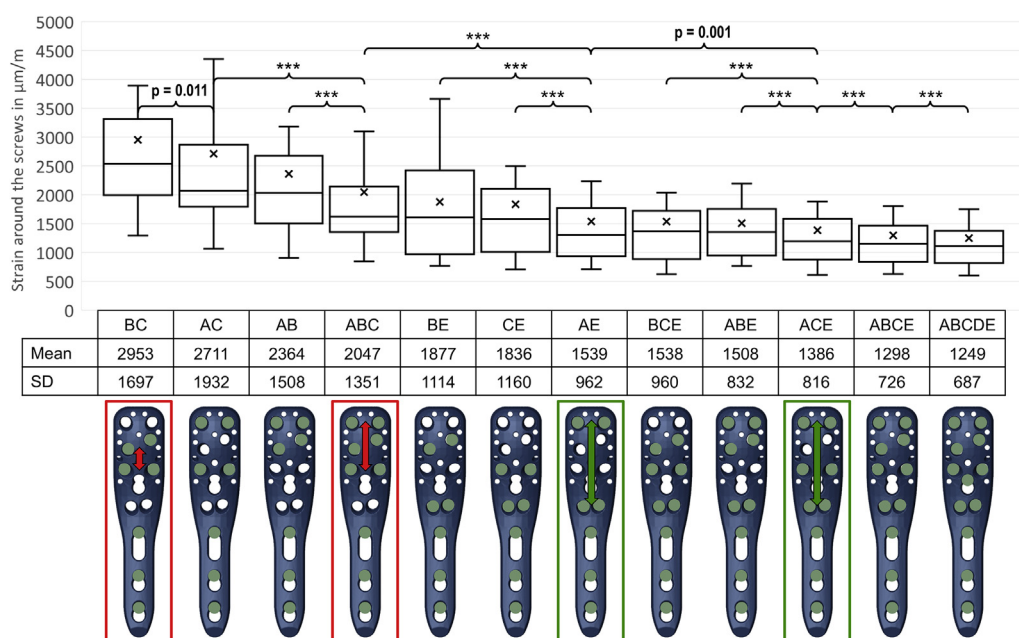


Figure 2 All investigated screw configurations, ordered according to the measured average peri-screw bone strain, that is, predicted fixation stability (left: weakest → right: strongest) for all 26 samples. The best and worst configurations are indicated with green and red rectangles, respectively, for both the 4-screw and the 6-screw constructs. The closest significant comparisons between adjacent configurations in this ordering are shown with the exact P values provided for $.001 < P < .05$ and *** indicating $P < .001$. The mean and standard deviation (SD) values of the bone strain around the screws are shown quantitatively for each configuration. Note that the best 4-screw configuration (rows A and E) is considerably better than the worst 6-screw configuration, indicating the importance of the calcar screws and a large distance between the filled screw rows. Only the best 6-screw construct (rows A + C + E) is a 6-screw configuration that is significantly better than the best 4-screw construct. The lowest fixation failure risk is predicted to be achievable using all 9 proximal screws.

within the humeral head for the 9-screw configuration. The FE models of each subject and screw configuration were generated and meshed by means of Simpleware v7.0 (Simpleware Ltd., Exeter, UK) with linear tetrahedral elements. Material properties were assumed to be linear elastic and simulated titanium alloy for the implant components, having a Young's modulus of 105 GPa and a Poisson's ratio of 0.3. Heterogeneous elastic properties were assigned to the bone elements based on the underlying HR-pQCT-based BMD values using a previously published conversion law.¹⁰ The details of FE mesh density, material property assignment, and interface configurations were in line with the methods established in a previous validation study.³¹ Three physiological loading cases (45° abduction with 0° internal rotation, 45° abduction with 45° internal rotation, and 45° flexion with 0° internal rotation) were simulated. These represented simple motions within a restricted range that may be performed by patients in the early postoperative period, for example, during physiotherapy. The corresponding glenohumeral load and the forces of the infraspinatus, supraspinatus, subscapularis, and deltoid muscles were obtained with musculoskeletal models in Anybody (AnyBody Technology A/S, Aalborg, Denmark), which estimated these forces for each motion via inverse dynamics simulations.³² The magnitude (ranging between 317 N and 342 N; corresponding to approximately 40% body weight of an average person of 80 kg) and direction (angle in the frontal plane vs. vertical ranging between 22.8° and 38.9°) of the joint reaction forces were in good agreement with the data available in the OrthoLoad database (www.orthoload.com) that were acquired using instrumented prostheses.^{3,33} The average compressive

principal strain was evaluated in cylindrical bone regions around the tips of the proximal screws, with a cylinder diameter of 8 mm and a total length of 20 mm, of which 5 mm was beyond the tip and 15 mm was toward the screw head. This strain-based measure has been demonstrated to predict the experimental number of cycles to cutout type construct failure of PHILOS plate fixations of 3-part proximal humerus fractures ($R^2 = 0.90$, $n = 19$).³¹ The peri-screw bone strains were averaged for the 3 loading modes.

All statistical tests were performed with "R" software, v3.3.3²⁴ (R Core Team, <https://www.r-project.org/>). Normality of data distribution was screened with the Shapiro-Wilk test. The average peri-screw strain for each screw configuration was compared with all others with a paired Student's t -test or the Wilcoxon signed-rank test, depending on the normality of distribution. Statistical significance was defined with $\alpha = 0.05$ with Bonferroni corrections for multiple comparisons. To gain insight into the effect of BMD, the samples were divided based on the median threshold of 107 mg/cm³ into 2 equal-sized groups, generating medium (median, 116.5 mg/cm³) and low (median, 99.5 mg/cm³) density groups. The statistical analyses were repeated for the peri-screw strains for these 2 groups separately.

Results

Significant differences in the peri-screw strain values, and thus predicted failure risk, were registered with different combinations of proximal screws (Fig. 2). Every additional

screw row provided a significant ($P < .001$) reduction in peri-screw strains with the 9-screw configuration demonstrating the lowest value. For different variations with the same number of screws, there were some significant differences between the different configurations. The most decisive parameter in this regard was the distance between the sited screw rows. Accordingly, the worst 4-screw and 6-screw constructs were those with screws only in the B + C rows and the A + B + C rows, respectively. The best 4-screw and 6-screw configurations were the A + E and the A + C + E combinations, respectively. The presence of calcar screws (row E) significantly ($P < .001$) reduced fixation failure risk compared with any configuration with the same number of screws but without calcar screws. Within the low BMD sample group, all significant comparisons remained the same as with all samples. In the 13 cases with lowest density, every additional screw provided significant decreases in strain and therefore reductions in the predicted failure risk (Fig. 3). Yet, in the 13 cases with higher density, no significant benefit was noted once the best 6-screw construct had been achieved (Fig. 4), that is, compared with the B-C-E or the A-C-E row configurations, there was no further significant reduction in predicted failure risk with the insertion of an eighth ($P = .40$) or ninth screw ($P = .11$) for these samples. Nevertheless, the 9-screw construct was still better than the 8-screw configuration.

Discussion

The configuration of proximal screws within the PHILOS plate significantly affects the predicted risk of cutout type fixation failure of unstable 3-part proximal humerus fractures. With the 9-screw configuration generating the lowest peri-screw strains, a benefit from inserting more screws is demonstrated.

The different role of each row of screws is indicated with these results. A key finding is the role the spread of the occupied screw rows plays; the greater the distance between the used rows, the less the predicted failure risk. This is likely due to the principles of locking plate fixations, with the increased moment arms created with greater distances between screws reducing bone strain around the screws. Locking plates act as internal “external fixators”; thus the principle of “near-far” should be, and indeed appears to be, valid. When investigating screw rows, we considered the screw head locations in Figure 2. However, the location of the screw tips is different, as in some of the rows, the trajectories of the screws diverge both in the axial and coronal planes, whereas in other rows, they are comparatively convergent (Fig. 1). The spread of the screw tips may be of great relevance regarding failure risk in addition to which screw rows are used.

Comparisons of 4 and 6 screw constructs highlight the importance of where screws are sited and how constructs are assembled. The best 4-screw construct, with the

screws in rows A and E, was associated with a significantly lower predicted failure risk than the poorest 6-screw construct combining screws in rows A, B, and C. Again, this is likely due to the reduced spread of screws and the absence of calcar screws. Indeed, the presence of calcar screws was an important finding in the current study, with their use considerably reducing failure risk compared with configurations where they were absent. Thus, the hypothesis of the study could be accepted. Their use within a construct also consistently generated substantial reductions compared with when absent within fixations with the same total number of screws. In line with our findings, the importance of calcar screws in these configurations has been previously shown biomechanically^{23,26} and clinically, with the results from this study adding to the existing beneficial evidence.^{4,11,23,36} Interestingly, only the best 6-screw configuration (rows A, C, and E) led to a significantly better construct compared with the best 4-screw configuration (rows A and E). Compared with the best 6-screw construct, ongoing improvements could be achieved using 8 or all 9 screws.

These results suggest that the best surgical approach is to ensure fixation with maximal distance between the inserted screw rows. They also imply that calcar screws should be used and potentially prioritized. The benefits from ensuring calcar screw usage for these more complex fractures have been reflected in the literature, in reducing complications and enhancing patient-reported outcomes.^{15,20,35} The space constraints of low-volume humeri are used to explain why calcar screws cannot always be placed. Our data indirectly indicate that, when using 4 screws without having enough space to occupy rows A + E, the row combinations C + E and B + E are still better than A + B or A + C. Similarly, the results of the 6-screw construct showed the benefit of occupying the more distal rows compared with the more proximal rows; using rows B, C, and E generated reduced screw strains compared with A, B, and C. This suggests that the most proximal row screws could be sacrificed in favor of calcar screw insertion, even if this may require proximal translation of the plate to achieve the required calcar screw trajectories. Concerns may arise that proximalization of the plate could result in an increased risk of impingement; however, what plate positions cause clinically relevant impingement are unknown and were not investigated in this study. Furthermore, FE analysis of plate positioning indicated that small proximalization of the PHILOS plate is beneficial in reducing predicted failure risk.¹² Reduction of the fracture fragments is key with these multifragmented fracture patterns, and the size of the surgical exposure required to achieve adequate reduction is likely to mean that placement of calcar screws should be possible due to the access, assuming that the humeral head is large enough. Nevertheless, these suggestions remain theoretical as all humeri used in this study were selected as being able to receive all 9 proximal screws.

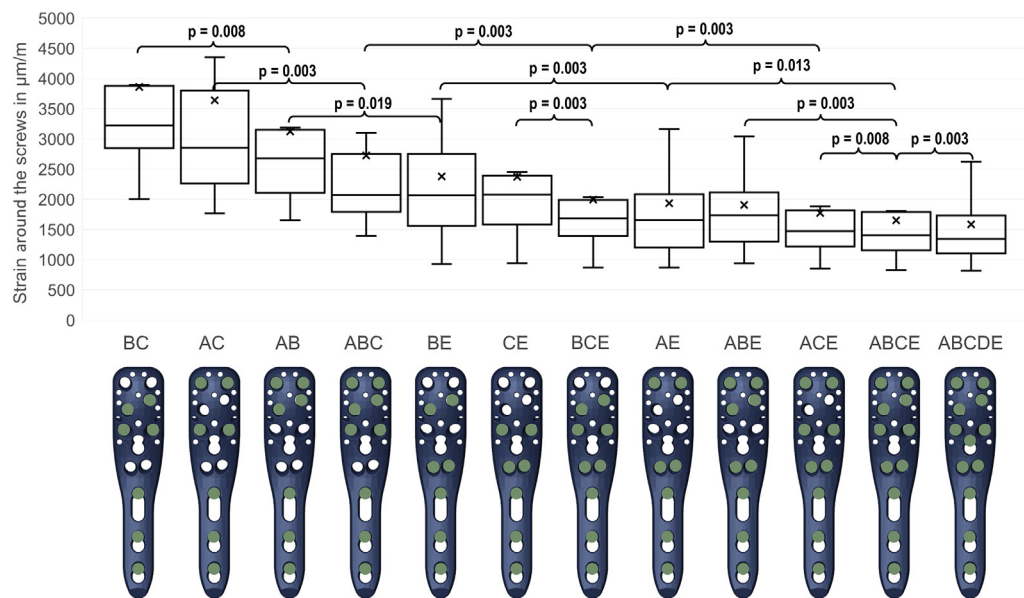


Figure 3 All investigated screw configurations, ordered according to the measured average peri-screw bone strain, that is, predicted fixation stability (left: weakest → right: strongest) for the 13 lowest density samples. The closest significant comparisons between adjacent configurations in this ordering are shown together with the *P* values.

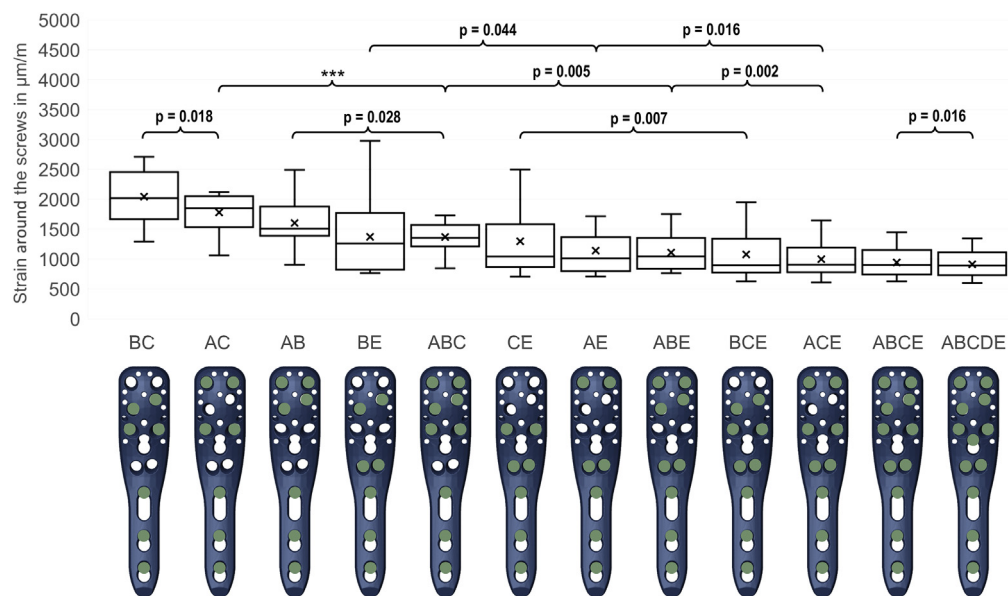


Figure 4 All investigated screw configurations, ordered according to the measured average peri-screw bone strain, that is, predicted fixation stability (left: weakest → right: strongest) for the 13 highest density samples. The closest significant comparisons between adjacent configurations in this ordering are shown with the exact *P* values provided for $.001 < P < .05$ and *** indicating $P < .001$.

With minimally invasive techniques, using an aiming arm, the surgical guide advises against placement of screws in rows C-E to reduce the risk of nerve injury and the aiming arm does not provide the possibility of using screw holes other than rows A and B.⁶ Combinations using rows A and B create constructs that, although not being the worse, are significantly weaker than the best available 4-screw construct, of rows A and E. A previous study

proposed that row C and, with great caution, potentially even row D of the PHILOS plate can be used in a minimal invasive technique when operating with shoulder abduction.¹ Nevertheless, row E remains unusable even with that approach. Sacrificing calcar screws may therefore be a less than optimal approach if used for 3-part unstable fractures as, in addition to not having the biomechanical fixation in that part of the humeral head, the distance

between the sited screws is reduced in comparison with other configurations. When considering the patients with the lowest density, this advice remains valid, but with the awareness that every additional screw reduces average periscrew strains. These findings correlate with the PHILOS plate operative technique,⁷ as this suggests placing at least 4 proximal screws under normal circumstances, but all screws if poor bone stock is encountered.

Clinical evidence critiquing the effects of different screw configurations is limited. In the 19 failures seen within their 161 patients, Padegimas et al²¹ found no significant difference because of the placement of screws. They discovered, when retrospectively reviewing 2-, 3-, and 4-part fractures over a spectrum of reduction qualities, neither differences between the total number of proximal screws (6.2 [failure] vs. 5.8 [healed]; $P = .28$) and the number of inferior screws (2.4 [failure] vs. 2.9 [healed]; $P = .13$) nor the number of distal screws (2.9 [failed] vs. 3.0 [healed]; $P = .72$). This demonstrates the difficulty with using clinical data to elucidate the effects of these variables given that fixation failures are multifactorial. It is even postulated that the number of screws does not affect the probability of fracture impaction postoperatively;⁵ however, it is more likely that other confounding factors frequently predominate in cases of fracture impaction such as the quality of reduction, and mask the effects from different screw configurations. The fracture reduction and the preservation of the remaining viable vascularity are crucial, with the chosen fixation being critical to the maintenance of stability whilst bone healing occurs. This is especially true in fracture patterns with medial comminution where the fixation may be the only initial connection between the head and the shaft. Only by performing experimentation where all other factors can be controlled can investigations into specific aspects, such as screw configuration, be performed.

Previous biomechanical attempts to investigate the effects of screw configuration have been limited in part due to the numerous variables associated with testing and the number of samples needed for appropriate power. Donohue et al⁹ did not show any difference in cycles to failure between 3 superior or 3 inferior humeral head screws, when used to fix an AxSOS plate²⁹ to a 3-part fracture in biomechanical testing. They did find a significant difference between using 6 screws rather than either of the 3 screw constructs; however, the implant used is only designed to be secured with 6 screws,²⁹ limiting any information from testing constructs with only 3 screws. With the PHILOS plate, a minimum of 4 screws are recommended; thus as all tests had at least 4 screws, it ensures that any of the tested constructs within this study are potential options based on the operative guide. Although some clinical studies involving PHILOS plates have shown that commonly 6 screws are placed within the proximal 9 holes,²¹ some surgeons only use 5 screws.²² The results presented here show the advantages of the best 6-screw configuration in reducing the risk of failure.

Finite element analysis complements existing biomechanical research methods. Although reliant on biomechanical validation, FE simulations answer questions that are practically unanswerable with any other currently available research techniques. Because of the small differences in results, and the large variations in confounders such as surgical techniques and BMD (even between contralateral pairs⁸), it can be difficult to detect variances with in vitro biomechanical studies. Only when 1 variable is isolated can it be accurately measured. For example, being able to standardize surgical techniques, such as plate positioning and screw insertion depth, removes several significant variables from the assessment and evaluation. Indeed, differences in surgical experience and technique alone could explain the lack of conclusive findings from a leading clinical trial into the role of proximal humeral plating.^{25,28} With this current study, 26 patients' humeri were modeled in 3 loading modes, each for 12 different screw configurations. This means the osteosynthesis tool kit simulated the equivalent of 936 humeral fixations, a number that would be ethically and financially impractical for biomechanical testing.

There are limitations associated with the study. Although highly predictive of biomechanical cyclic fixation failures,³¹ the modeling is reliant on the accuracy of the corroboration testing. With this model having been validated to predict cutout-type fatigue failure of fracture fixations in vitro, the findings may not be directly transferable to all clinical realities. The models used are restricted to linear analyses with elastic material properties. The simple strain-based measure does not truly describe the complex failure event; however, it is an efficient surrogate measure as it has been demonstrated to be tightly correlated with biomechanical cyclic construct failure. The previous validation study providing the basis of this work was performed with contact between the humeral head and greater trochanter fragments,³¹ but the FE models in this study simulated the worst-case scenario of the head not being supported by the other fragments. Previous unpublished data and the preliminary results of a currently running investigation indicate that the same strain-based measure remains a strong predictor of cyclic failure also in the absence of contact between the fragments. The 3 loading modes modeled may not accurately represent all post-operative movements, given the complex motions possible at the glenohumeral joint. Moreover, these do not include isolated loading modes like pure compression, bending, or torsional, which are used in biomechanical studies.¹⁴ However, these modes do provide a greater attempt to recreate the forces encountered postoperatively than previous models.^{23,34} The patients used were all of lower bone density and had unstable malreduced 3-part fractures. Although these patient and fracture characters generate the greatest surgical challenge, the findings may neither be applicable to higher density bone nor to other

fracture patterns and have not been investigated in designs other than the PHILOS plating system.

Conclusions

Screw configurations have a significant impact on predicted cutout-type mechanical failure risk for locking plate fixation of unstable proximal humerus fractures in low-density bones. Although these findings are predicted by a virtual osteosynthesis tool and require clinical validation, maximization of the spread of the sited screw rows and the use of calcar screws is suggested to reduce predicted failure risk.

Acknowledgments

All authors contributed to study design. P. Varga acquired the data. P. Varga, J. W. A. Fletcher, and M. Windolf interpreted the data. J. W. A. Fletcher wrote the manuscript. P. Varga, M. Windolf, R. G. Richards, and B. Gueorguiev provided critical revision. All authors have read and approved the submitted version.

Disclaimer

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