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1	The importance of locking plate positioning in proximal humeral fractures
2	as predicted by computer simulations
3	
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## **30 Abstract**

Multifragmented proximal humeral fractures frequently require operative fixation. The 31 32 locking plates commonly used are often placed relative to the greater tuberosity, however no 33 quantitative data exists regarding the effect of positional changes. The aim of the study was to 34 establish the effects from variations in proximal-distal PHILOS humeral plate positioning on predicted fixation failure risk. Twenty-one left-sided low-density virtual humeri models were 35 36 created with a simulation framework from CT data of elderly donors and osteotomized to mimic an unstable three-part malreduced AO/OTA 11-B3.2 fracture with medial comminution. 37 38 A PHILOS plate with either four or six proximal screws was used for fixation. Both 39 configurations were modelled with plate repositioning 2 and 4 mm distally and proximally to its baseline position. Applying a validated computational model, three physiological loading 40 41 situations were simulated and fixation failure predicted using average strain around the 42 proximal screws – an outcome established as a surrogate for cycles to failure. Varying the craniocaudal plate position affected the peri-implant strain for both four and six-screw 43 44 configurations. Even though significant changes were seen only in the latter, all tests suggested 45 that more proximal plate positioning results in decreased peri-screw strains whereas distalizing creates increases in strain. These results suggest that even a small distal PHILOS plate 46 malpositioning may reduce fixation stability. Plate distalization increases the probability of 47 being unable to insert all screws within the humeral head, which dramatically increases the 48 49 forces acting on the remaining screws. Proximal plate shifting may be beneficial, especially for 50 constructs employing calcar screws.

51

## 52 Keywords

53 Proximal humerus fracture, PHILOS plate, plate positioning, fixation failure, finite element54 analysis

## 55 Introduction

56 Locking plates have transformed the treatment of proximal humerus fractures, dramatically reducing complications. However, fixation failures continue to occur, being seen 57 58 in approximately 20% of cases<sup>1</sup>. The biomechanics of proximal humerus plating are complex due to the specific bone characteristics and variations in patient anatomy. In decreased bone 59 density, fixations fail mainly due to insufficient mechanical competence of the bone<sup>2</sup>. 60 61 Additionally, the bone density within the humeral head exhibits considerable variation<sup>3</sup>. Reliable screw placement is needed in the areas where the bone competence and biomechanical 62 63 benefits will be greatest. Given the fixed-angle design of some current proximal humeral 64 plating systems, such as the PHILOS implant (DePuy Synthes, Zuchwil, Switzerland), accurate screw placement is dependent upon the position of the plate. However, consensus is lacking on 65 66 what is the correct position<sup>4</sup>. Whilst the recommended PHILOS plate positioning in the surgical manual is 5-8 mm distal to the greater tuberosity<sup>5</sup>, actual placement varies (Figure 1). 67 Moreover, suggestions for ideal placement include a greater range of 5-10 mm distal to the 68 69 superior edge of the greater tuberosity in anteroposterior (AP) view<sup>6; 7</sup>. In clinical practice, 70 plates are positioned both more distal and more proximal than recommended, in part due to 71 anatomical variations and operative challenges (Figure 1a). Whilst it has been reported that fixation failure can occur if plate or screw placement is inadequate<sup>8-10</sup>, the effect of these 72 variations on primary bone-implant stability still remains unquantified. 73



Figure 1: Positioning of the PHILOS plate to fix proximal humerus fractures in clinical cases
(A) may deviate from the alignment suggested by the surgical guide. This advises the use of a
guiding block and a K-wire, which was virtually reproduced in this study to define the baseline
models (B).

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81 Plates must be positioned within a range insuring that they risk neither subacromial impingement by being too proximal, nor extraosseous calcar screw placement by being too 82 distal (Figure 1a); hence, a compromise is needed. Surgical concerns seem to exist more with 83 proximal positioning causing impingement than distal placement not allowing proper calcar 84 85 screw insertion, perhaps because the former may be harder to disprove as a causative event if 86 a patient has ongoing postoperative symptoms. The reported rate of subacromial impingement due to plate positioning and malunion is between 0 and 21.4%<sup>11-14</sup>. However, it is unclear what 87 88 exactly constitutes clinically relevant post-operative plate impingement, as well as what 89 percentage of postoperative patients can acquire active shoulder abduction necessary for 90 subacromial impingement to occur. Reports of improvement in range of motion (ROM) 91 following removal of plates can be difficult to interpret due to confounding factors related to 92 arthrolysis and/or subacromial decompression that are likely to have been performed together 93 with the metalwork removal.

94 The aim of this study was to assess the effects of variations in proximal-distal PHILOS
95 plate positioning on predicted fixation failure risk using a validated osteosynthesis test kit<sup>15; 16</sup>.
96 We hypothesized that variations in plate positioning would generate quantifiable differences
97 in predicted failure risk.

98

99 Methods

100 Finite element (FE) models of osteotomized and plated proximal humeri were created with a previously established simulation framework<sup>16</sup>. This virtual osteosynthesis test kit 101 102 incorporates a database of digital bone samples, fracture models, implants and loading schemes, as well as a validated FE simulation methodology<sup>15</sup> to investigate and improve 103 104 fixation stability. In this study, twenty-six, left-sided, low-density humeri from 14 female and 12 male elderly donors (mean  $\pm$  standard deviation (SD) age 83.9  $\pm$  8.1 years (range 64 – 98 105 years)) were selected from the digital sample collection of the test kit. Bone mineral density 106 (BMD) was evaluated via the method of Krappinger et al.<sup>17</sup> using high-resolution peripheral 107 108 quantitative computer tomography (HR-pQCT, XtremeCT, Scanco Medical AG, Brüttisellen, Switzerland) images of the bones. Median BMD was 107.4 HAmg/cm<sup>3</sup>, with a range of 68.9 – 109 110 129.6 mg/cm<sup>3</sup>. Low density samples were chosen as these represent the greatest surgical challenge. The humerus models were osteotomised to create an unstable three-part malreduced 111 fracture AO/OTA 11-B3.2 with medial comminution – defined as gapping between the 112 fragments – and were virtually fixed with a PHILOS plate. The plate was positioned as per the 113 114 surgical technique guide<sup>5</sup>, using virtual Kirschner wires and targeting blocks to ensure correct 115 placement for its baseline neutral position (Figure 1b).

Five different plate positions were investigated: the baseline position as defined according to the recommendations in the surgical guidelines<sup>5</sup>, as well as positions with proximal shifts of 2 mm and 4 mm, and distal shifts of 2 mm and 4 mm relative to the baseline

119 position. Two different clinically relevant screw configurations were chosen for analysis, one with four screws (inserted into rows A and B of the plate; mimicking the minimally invasive 120 121 operative technique using a percutaneous aiming system) and a second with six screws (using 122 rows A, B and E; comprising the 4-screw configuration plus the two calcar screws) (Figure 2). For both configurations, the selection criteria of the samples required that the tips of all 123 proximal screws were contained within the humeral head in all plate positions. Screws were 124 125 inserted at 6 mm distance from the subchondral surface (tip-joint distance (TJD)). Noncommercial screws lengths were implemented to ensure that the TJD remained constant 126 127 regardless of anatomy. The FE models were meshed with tetrahedral elements using Simpleware v7.0 (Simpleware Ltd., Exeter, UK) with a previously determined appropriate 128 mesh density<sup>15</sup>. Material properties, including BMD-based stiffness assignment for bone 129 elements, and interface models were taken from a previous validation study<sup>15</sup>. The models were 130 loaded in three physiological loading cases  $-45^{\circ}$  abduction with  $0^{\circ}$  internal rotation,  $45^{\circ}$ 131 abduction with  $45^{\circ}$  internal rotation, and  $45^{\circ}$  flexion with  $0^{\circ}$  internal rotation – where the joint 132 133 and muscle forces were sourced from musculoskeletal simulations performed with Anybody software (v5.0, AnyBody Technology A/S, Aalborg, Denmark). The FE analyses were run in 134 Abaqus v6.13-3 (Simulia, Dassault Systemes, Velizy-Villacoublay, France) and the average 135 bone strain within cylindrical regions around the proximal screws tips was evaluated. This 136 137 strain was reported to be an authenticated surrogate measure for prediction of biomechanical 138 cyclic fixation failure<sup>15</sup>. All pre-processing, analysis and post-processing methods used had been previously established<sup>15; 16</sup>. 139



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Figure 2: The effect of plate positioning was assessed by 2 mm and 4 mm shifts proximally
and distally with respect to the baseline. These analyses were repeated for a four-screw (screws
rows A and B) and a six-screw (screw rows A, B and E) configurations.

146 Statistical analysis was performed with the use of 'R' v3.3.3 (R Foundation for Statistical Computing)<sup>18</sup>. Effects from plate repositioning were compared by averaging the 147 strain around all proximal screw tips for the respective construct and summating the values 148 149 from the three loading modes. For these comparisons, each shifted plate position was compared to the baseline position and to every other position, with the Related-Samples t-test or 150 151 Wilcoxon Signed-Rank test depending on the normality of distribution as checked with the Shapiro-Wilk test. Following, individual screw strains and lengths were analyzed to screen for 152 153 changes when the plate was shifted, comparing repositioned plates to their baseline positions. 154 Statistical significance was defined as p<0.05 with Bonferroni corrections for multiple 155 comparisons.

## 157 **Results**

Five (19%) humeri models were excluded as at least one of the calcar screws (row E) was not sited within the humeral head in all configurations. All analyses were performed with the remaining 21 samples. Plate position affected the distribution and magnitude of the deformation in the trabecular bone region around the screw tips for both four and six-screw constructs (Figure 3).





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Figure 3: Contour plots of the compressive principal strain distribution in a sagittal section,
illustrating higher bone deformations for the four-screw configuration versus the six-screw
construct and, for the latter, indicating the increase and decrease of the strain magnitudes with
distal and proximal plate shifts, respectively.

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For the six-screw configuration, both 2 and 4 mm shifts generated significant (p<0.001) changes in average peri-screw bone strains in comparison to the baseline neutral position; proximal shifts reduced strains (for 2 and 4 mm shifts, p=0.0008 and 0.00005, respectively), whilst distal movement increased them (p=0.00074 and 0.00001, respectively) (Figure 4). With four proximal screw configurations, mild trends toward increased strain with distal shifts of the plate and decreased strain with proximal shifts were observed; however, all comparisons between the plate positions were of non-significant. The average strain values of all screws were significantly lower in the six-screw configuration compared to the four-screw
configuration for each plate position (p=0000001, 0.000002, 0.000064, 0.000064 and
0.000001 for distal 4 mm, distal 2 mm, baseline, proximal 2 mm and proximal 4 mm positions,
respectively).

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∎ Dist 4 mm ■ Dist 2 mm ■ Baseline ■ Prox 2 mm ■ Prox 4 mm

■ Dist 4 mm ■ Dist 2 mm ■ Baseline ■ Prox 2 mm ■ Prox 4 mm

Figure 4: Average compressive principal strains in the bone region around the screw tips show
a non-significantly incising trend with distal plate shift in the four-screw construct. The same
trends become clearly significant (\* indicates p<0.05) for the six-screw configuration and here</li>
a more proximal plate position is associated with a decreased peri-implant strain and thus a
reduced fixation failure.

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The change in the individual peri-screw bone strains with shifted plate positions is illustrated in Figure 5, showing that, when comparing changes in strains around the same screw between different plate positions, an increase in strain values occurred for most of the screws after distal plate movements in the six-screw configurations only. Reciprocally, decreased strains in six-screw configurations were found after proximal plate movements. The changes in strains after both distal and proximal plate movements were significant only for the four most proximal screws within the six-screw construct (p<0.001).



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Figure 5: Average bone strains around the individual screws are, in general, not significantly
changing in the four-screw configuration when shifting plate. These results are more sensitive
for the plate position in the six-screw construct.

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202 There were significant (p<0.001) changes in average screw lengths when shifting the 203 plate compared to the baseline position (Figure 6), with shorter screws being seen as plates 204 were positioned more proximally (for the four-screw configuration: p=3.9E-16, 3.5E-16, 1.1E-205 17 and 1.6E-12 for distal 4 mm, distal 2 mm, proximal 2 mm and proximal 4 mm positions, respectively; for the six-screw configuration: p=0.00087, 2.4E-07 and 7.9E-09 for distal 2 mm, 206 207 proximal 2 mm and proximal 4 mm positions, respectively), except for the 4 mm distal position 208 for the six-screw configuration that was not different compared to baseline. When considering 209 individual screws lengths, with distalization of the plate the calcar screws significantly (p<0.001) shortened, with reciprocal lengthening of the most proximal screws. With proximal 210 211 plate movement, there was significant shortening of the proximal screws, though nonsignificant increases in calcar screw lengths. This proximal screw shortening (Figure 6) was 212 213 not associated with weaker constructs in the four-screw configuration but was associated with decreased peri-screw strains in the six-screw configuration (Figure 4). 214





Figure 6: Screw length shows a clearly increasing trend in the four-screw configuration (left)
when shifting the plate from distal to proximal. In the six-screw construct (right), the length of
the calcars screws is decreased by the proximal plate positioning, resulting in a less clear trend
for the average screw length.

221

## 222 Discussion

223 Plate positioning was found to affect predicted peri-screw bone strains considerably in 224 the presence of calcar screws (six-screw configuration), with increases occurring with distal 225 plate movement and decreases with plate proximalization. Additionally, a similar, though non-226 significant, trend was observed when plates without calcar screws were repositioned (four-227 screw configuration). Given that peri-screw strains have been shown to correlate with cut-out type fixation failure risk, it can be deduced that distalization of the six-screw configurations 228 229 increases failure risk whilst proximalization could be beneficial. Compared to the four-screw constructs for the equivalent plate positions, the presence of calcar screws generated decreases 230 231 in average peri-screw strains (Figures 3 and 4).

## 233 Why computer simulations?

234 By utilizing computer simulations to investigate these clinical scenarios, this study's methodology allows for the unique detection of findings otherwise potentially obscured due to 235 236 the additional variables seen in either clinical or biomechanical studies. Computational modelling of variations in plate position offers significant benefits over these alternative 237 238 methods due to the number of cases that can be tested; such numbers being financially and 239 ethically prohibitive in biomechanical studies. Furthermore, a substantial variable in 240 comparison studies relates to patient anatomy. Pairwise comparisons have been shown to exhibit substantial differences in bone density and anatomy<sup>19</sup>. In our study, computer 241 242 simulations allowed plate, and thus screw, positions to be investigated individually, without bias being introduced through uncontrolled changes in other known variables, such as fracture 243 244 type, quality of reduction or loading modes. For example, screw tip position always remained constant at a 6-mm distance from the subchondral surface. Whilst this meant that non-245 246 commercial screw lengths were modelled, it ensured that variations in screw tip position would not introduce a further variable to the testing; this could not have been controlled in 247 248 biomechanical or clinical testing.

249

## 250 Comparison with previous studies

Metha et al. performed a biomechanical study using cadaveric and artificial humeri to assess the effects of locking plate positions<sup>20</sup> at three different sites, neutrally (calcar screws 3 mm proximal to the apex of the inferior humeral head arch), +8 mm and -8 relative to this, with relatively simple, 2-part fracture configurations being tested. No significant differences between the three plate positions were found in cadaveric specimens in terms of stiffness, torsion or displacement following cyclic loading; however, with proximally positioned constructs, non-significant trends towards less displacement were found following cyclic testing. Nevertheless, contradicting the findings from the present study, Mehta et al. suggestedthat distal plate placement may be beneficial.

260 From a retrospective clinical analysis, Padegimas et al., reviewing 161 patients with 2, 261 3 and 4-part fractures, found that if screws intended to engage calcar bone were placed more than 12 mm proximal to the apex of the inferior humeral head arch, higher failure rates were 262 be observed; calcar screws in fracture fixations that failed were located considerably more 263 proximal  $(19.2 \text{ vs } 9.5 \text{ mm proximal to the arch apex})^{21}$ . However, in poorly reduced fractures, 264 more reflective of the conditions analyzed in our study, their results did not clearly show this. 265 266 Furthermore, screws positioned more proximal than 12 mm may have been sufficiently far 267 away from the calcar to be ineffective as they were outside of the calcar region. We have shown that within the calcar region (±4 mm) it is the distalization that increases failure risk (Figure 268 269 5). These studies being not fully conclusive may be explained by the variations of factors that 270 have been overcome in this study via systematic computer analysis of the isolated effect of 271 plate positioning as described previously.

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## 273 Importance of calcar screws

When calcar screws were used, their peri-screw strains increased with plate 274 distalization, yet after plate proximal movement the strains did not change considerably 275 276 compared to the baseline values (Figure 5). In the six-screw constructs, the proximal four 277 screws all showed significant reductions in peri-screw strains after proximal movements, and 278 increases seen after plate distalization. The explanation postulated to be by the presence of 279 calcar screws in a more proximal part of the humeral head shielding the proximal screws (rows 280 A and B) from greater deforming forces compared to more distal calcar screw positions. This 281 may, in part, be explained by the ability to insert longer calcar screws when the plate is more 282 proximally positioned, and/or by the presumption that more of the calcar screw threads are 283 located in the fracture fragments and/or in higher density bone, though these aspects were not investigated in the current study. The importance of calcar screws has been shown 284 biomechanically and computationally in previous studies<sup>22-24</sup>, and retrospectively in clinical 285 286 reviews<sup>21</sup>; this study's findings add to their justification by showing that these screws directly and indirectly support the function of other screws within the constructs. These findings could 287 encourage surgeons to prioritize the placement of calcar screws over others, given their 288 289 dominant role in reducing failure risk. However, their significant effect may be limited to 290 unstable fractures that have no medial support, like those simulated in this study.

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## 292 Effect of screw length

293 The volume and density of bone available for purchase will affect the forces encountered by the screws and the plate. Due to its fixed-angle design, plate positioning 294 295 dictates the trajectories of screw insertion, with the anatomy and curvature of the humeral head 296 then prescribing the lengths of the screws that can be used. Indeed, only variations in plate position were responsible for changes in average screw lengths through changes in the bone 297 298 available for each screw hole trajectory, as the TJD was always constant. To some extent, it is logical to think that longer average screw lengths within a construct could reduce average peri-299 300 screw strains due to more bony purchase being available, assuming that the fracture 301 configuration allows for more screw threads to gain purchase in each fragment. However, our 302 results revealed no correlation between greater average screw length and reduced average peri-303 screw strains. Moreover, reduced peri-screw strains were seen when average screw lengths 304 shortened. This reduction in average screw length, associated with proximal plate positioning and no increase in peri-screw strains, potentially highlights the assumption that the locations, 305 306 rather than the average lengths of the screws, seem to be more critical for fixation stability. 307 However, whilst average screw lengths may not be critical, specific individual screw lengths 308 may be. With proximal movement of the six-screw construct, whilst average screw lengths 309 decreased and the most proximal screws (row A) significantly (p<0.001) shortened, the calcar 310 screws (row E) non-significantly lengthened, which was associated with reduced predicted 311 failure risk. Whilst the TJD was kept constant, there was no assessment of the proportion of screw threads within the medial humeral head fragments, which may be more important for 312 313 anchorage than the screw lengths themselves. Bone density does vary in different regions of 314 the humeral head<sup>3</sup>, and may also be partially responsible for the changes seen in the strain of individual screws and the purchase they gained in different areas. There may be some surgical 315 316 concerns that proximalizing the plate to ensure good calcar placement requires reducing the 317 length of its proximal screws. However, our results have shown that shorter proximal screws 318 do not lead to increases of their peri-screw bone strains or the averaged strain over the whole 319 construct.

320

## 321 Impingement risk versus missing the calcar screws

Proximalization of humeral plates raises concerns about mechanical impingement with 322 323 shoulder movements, especially on abduction. Conversely, distalization may result in an inability to place calcar screws inside the humeral head. Investigations into these factors have 324 325 had varied results. Thienthong et al. positioned plates in 30 cadaveric shoulders at the level of the proximal bicipital groove and did not report any passive impingement<sup>25</sup>, whereas more 326 327 distal positioning of 30 contralateral plates at the level of the lesser tuberosity prominence 328 resulted in distal screw perforation in 87% of cases. Interestingly, even with the proximal 329 positioning in 30 of these cases, two still resulted in calcar perforation. Whilst their study 330 assessed passive subacromial impingement, it shows the narrow margin that some patients' 331 anatomies allow regarding calcar screw placement. We have shown that even a distal shift of 332 4 mm from the recommended position resulted in 19% of the humeri being unable to receive 333 at least one of the calcar screws. Other biomechanical studies have encountered this problem with calcar screw insertion, with varied interpretations of the potential consequences. 334 335 Extraosseous screw placement will reduce fixation potential due to the screw threads not being 336 engaged to provide resistance to shear motion. However, it has been suggested that they may act as a buttress to varus collapse; Mehta et al. used the LCP proximal humeral plate with three 337 proximal screws and found that the buttress provided by calcar screws increased initial 338 construct stiffness<sup>20</sup>. Their results did not show proximal positioning resulting in any reported 339 impingement but did show distal positioning causing occurrences of calcar screw perforation 340 341 and a non-significant trend towards more displacement with cyclic loading.

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- 343

# 344 Achieving the desired plate position clinically

345 To aid accurate screw placement, targeting devices are provided with the PHILOS surgical kit and were used in the positioning of plates in this study<sup>5</sup>. Here a targeting block is 346 attached to the proximal aspect of the plate to enable using of a Kirschner wire as a reference 347 348 to the dome of the humeral head. Further to this, more advanced targeting aids have been developed, using the real-time plate location to predict the screw positions and lengths that can 349 350 be used<sup>26</sup>. Until these devices become available on the market, we recommend using the current 351 targeting Kirschner wire and prioritizing calcar screw placement first, then referencing the plate position to these before proximal screw insertion, even if this requires proximalization of 352 353 the plate and shorter proximal screws. Further work into the effects of different screw 354 configurations would help corroborate this advice.

#### 356 Limitations

This study is computational, and though well validated, is ultimately limited by the 357 accuracy of the model and may not exactly mimic all clinical situations. The findings are also 358 359 restricted to fixation stability and modelling a cut-out type failure and do not consider other 360 effects, such as secondary screw perforation. Our findings may be restricted to being only 361 relevant for the malreduced unstable three-part fracture model investigated here. While this 362 represents a clinically challenging scenario especially, regarding the missing medial support, 363 our findings may not apply to the even more complex unstable four-part fractures. No 364 assessment of potential impingement was considered, though the clinical relevance of this has 365 already been questioned. The loading modes modelled attempt to replicate movements 366 exhibited by patients in the early postoperative phase, though they will not characterize the 367 activities of all patients. However, using three loading modes exceeds the quantity and quality of conditions applied in other modelling and biomechanical studies<sup>22; 27</sup>. Only left sided bones 368 369 were investigated while the PHILOS plate exhibits an asymmetric screw pattern. Even though unlikely, a different finding in right specimens cannot be excluded. Whilst the statistical 370 371 analysis combined the strain values for all three loading modes to increase the generalizability 372 of the findings, this may have overlooked smaller changes occurring after specific movements. 373 No assessment of the effects from tilting the plate nor from changes in plate elevation were 374 considered. However, proximal humeral anatomy greatly limits the range of alternative plate 375 positions available, hence only craniocaudal positional differences were studied. Virtual 376 subjects with lower bone quality were selected for modelling in this study; the failure risk with 377 plate movement in patients with higher bone density may be different. There may have been 378 considerable benefits from proximalizing four-screw constructs, however, the greater average 379 and variation of the strain values for these constructs may have prevented the detection of those 380 significant changes; the same trends were seen with the six-screw construct, but at significant

levels (Figures 3 and 4). Additionally, it is advised by the surgical guide<sup>5</sup> that in patients with
poor bone stock even more screws should be used, i.e. all nine proximal screws, neither six nor
four. The basis of this advice can be seen in the reduction of the average screw strain by adding
calcar screws to the constructs.

385

## 386 **Conclusions**

Distal PHILOS plate positioning resulted in an increased risk of cut-out type failure in 387 our virtual cases. This study demonstrated that even small distal malpositioning of the plate 388 389 may decrease fixation stability of unstable 3-part fractures in low density humeri, whilst 390 proximal shifting of the plate may be beneficial. These findings were most prominent for the six-screw configuration. Furthermore, regardless of the plate position, utilizing calcar screws 391 significantly reduces peri-screw strains around the other screws. Whilst these findings require 392 clinical validation through longitudinal observational studies, they suggest that plate placement 393 394 should be performed carefully with calcar screw placement being prioritized.

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