

1        **Total Elbow Arthroplasty Versus Plate Fixation for Distal Humeral Fractures in**  
2                                    **Elderly Patients: A Systematic Review and Meta-Analysis**

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## 21 **Introduction**

22 Distal humerus fractures represent about 1-2% of adult fractures and about 10% of humeral  
23 fractures.<sup>[1]</sup> The injury has a bimodal distribution with a peak incidence in young males  
24 secondary to high energy trauma and a second peak in osteoporotic elderly (typically female)  
25 patients over the age of 60 years.<sup>[2]</sup> It is predicted that the annual rate of distal humeral  
26 fractures in the elderly population is likely to triple by 2030 due to an increasingly aging  
27 population structure.<sup>[3]</sup> These fractures typically require surgical treatment as non-operative  
28 treatment is associated with a high frequency of complications such as non-union, malunion,  
29 stiffness and pain - any of which can lead to severe functional deficit and a subsequent loss of  
30 independence due to an inability to perform activities of daily living.<sup>[4-9]</sup> It is for this reason  
31 that non-operative management is typically only advocated for those patients who are unfit  
32 for anaesthesia and surgery.<sup>[10]</sup>

33 The AO classification of distal humeral fractures defines Type C injuries as comminuted  
34 intra-articular fractures<sup>[11]</sup> and these injuries provide a significant surgical challenge. The  
35 choice of surgical intervention is controversial and forms the basis of this meta-analysis.  
36 Surgical options include open reduction and internal fixation (ORIF), which in the  
37 contemporary literature is most frequently performed with either orthogonal or parallel  
38 plating according to AO principles.<sup>[12, 13]</sup> However, osteoporotic bone and highly  
39 comminuted fracture patterns often preclude anatomic reduction and early mobilisation, and  
40 predispose to failure of fixation, revision surgery, stiffness and a high rate of functional  
41 limitation (though still preferable to non-operative treatment). An alternative surgical option  
42 is total elbow arthroplasty (TEA). However, this strategy is also associated with a risk of  
43 complications such as infection, dislocation, peri-prosthetic fracture, nerve palsy, skin  
44 complications and revision for other causes.<sup>[14-16]</sup>

45 Although the literature has previously compared ORIF versus TEA there remains a lack of  
46 consensus regarding the optimum treatment choice. The aim of this meta-analysis was to  
47 determine which procedure provided superior clinical outcomes for elderly patients with  
48 distal humeral fractures.

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## 50 **Methods**

51 A systematic review of the literature was conducted in accordance with the PRISMA  
52 guidelines <sup>[17]</sup> using the online databases Medline and EMBASE. The searches were  
53 performed independently by two authors on the 1<sup>st</sup> September 2016 and repeated on the 12th  
54 September 2016 to ensure accuracy. The Medline search strategy is illustrated in Table I.

55 We included only studies that were published in English. Both cases series and comparative  
56 studies reporting outcomes after TEA and ORIF in patients aged 60 years and above with an  
57 acute distal humerus fracture were included. Studies reporting outcomes of patients with a co-  
58 existent diagnosis of rheumatoid arthritis were included. The TEA could be of any design via  
59 any approach and the ORIF group could include any type of plate fixation via any approach.  
60 The study must have reported either a functional outcome measure or associated  
61 complications. Studies were excluded if participants included chronic injuries, non-unions or  
62 cases of failed plate fixation. In addition, only primary research was considered for review  
63 with any abstracts, comments, review articles and technique articles excluded.

64 The studies were appraised independently by two authors using a validated quality  
65 assessment scale for non-controlled study, <sup>[18]</sup> STROBE checklist <sup>[19]</sup> for comparative studies  
66 and the CONSORT statement for randomised controlled trials (RCT). <sup>[20]</sup>

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**68 Statistical methods**

69 Results were pooled from different studies using meta-analysis techniques. If the required  
70 data was not provided in the original article, the corresponding author of the respective article  
71 was contacted to request these. Patient related outcome measures were only included in the  
72 meta-analysis if they were reported in at least two studies. Data regarding complications and  
73 revision surgery was also included.

74 Two main sets of analyses were performed. The first set of analyses compared TEA and  
75 ORIF using results from the comparative studies only. Four outcomes were used for  
76 comparisons; the Mayo Elbow Performance Score (MEPs), the Disability of Arm, Shoulder  
77 and Hand score (DASH), complications and re-interventions. MEPS and DASH scores are  
78 continuous and their differences in means were pooled assuming they are normally  
79 distributed. The complications and re-interventions reported as binary and percentage  
80 differences from identified studies were pooled. For the second set of analyses, TEA and  
81 ORIF were compared using results from both comparative studies and case series. In order to  
82 include data from case series as well from comparative studies, data from the TEA and ORIF  
83 arms were pooled separately. The means for MEPS and DASH scores were pooled assuming  
84 they were normally distributed. Complication and re-intervention rates were pooled assuming  
85 the number of complications and revisions were distributed binomially. The packages “meta”  
86 and “metaphor” in the R statistical program were used to perform these calculations. In both  
87 sets of analyses, a random-effects meta-analysis was used because it was believed that studies  
88 have inherent differences.

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## 92 **Results**

93 The search strategy identified 27 studies eligible for inclusion; one randomised controlled  
94 trial,<sup>[21]</sup> four comparative studies,<sup>[22-25]</sup> 14 ORIF cases series<sup>[26-39]</sup> and 8 TEA case series.  
95<sup>[40-47]</sup> A flow chart of the search strategy is shown in Figure I. The total number of  
96 participants in all studies was 1307; comparative studies (n=330), ORIF case series (n=777)  
97 and TEA case series (n=200). Concise details of included studies are given in Table II to V.

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## 99 **Comparative Studies**

100 Of the five studies included, one was a randomised controlled trial providing level I evidence  
101 and the remaining four were level III retrospective comparative studies. The lack of  
102 randomisation in the retrospective comparative studies risks selection bias, and the failure to  
103 define a primary outcome measure or inclusion of a power calculation reduces the strength of  
104 these studies further. The study quality varied as demonstrated by the wide-ranging  
105 adherence to the STROBE checklist and CONSORT statement (Table VI and VII).  
106 McKee et al.<sup>[21]</sup> performed a multi-centre randomised controlled trial of 40 patients which  
107 provided the highest level of evidence reviewed. The authors reported a statistically  
108 significant improvement in MEPS at every time point up to 2 years ( $p=0.015$ ) and in the  
109 DASH ( $p=0.04$ ) up until six months in the TEA group. However, the study failed to  
110 demonstrate a statistically significant difference in complication rate ( $p=0.40$ ) which was the  
111 study's defined primary outcome measure. A limitation of this study is the use of a  
112 combination of locking and non-locking plates in the ORIF treatment arm. It is clear from the  
113 contemporary literature that locking plates confer a significant biomechanical advantage and  
114 therefore the use of non-locking plates could be considered a possible confounder<sup>[23, 24]</sup> that  
115 may potentially have resulted in poorer outcomes in the ORIF group. The power calculation

116 was based on the intention to detect a 40% difference in reoperation rates, however a lower  
117 rate of reoperation would be an important clinical difference to distinguish, and therefore the  
118 high rate set has the potential to result in an under powered study. In addition, during the  
119 study 5 patients originally allocated to the ORIF group were transferred to the TEA group at  
120 the time of surgery as the surgeon deemed the fracture to be unfixable. This cross-over of  
121 these patients has the potential to unbalance the two groups by concentrating patients with  
122 more complex fractures within the TEA group. Patients with more complex fractures may  
123 have additional known and unknown confounding factors that may independently affect  
124 outcomes.

125 Ellwein et al. <sup>[23]</sup> retrospectively reviewed 29 patients, of whom 19 were in the subgroup over  
126 the age of 60 years included in the meta-analysis. The authors reported that those undergoing  
127 TEA had improved functional outcomes, DASH ( $p=0.023$ ) and MEPS ( $p=0.078$ ), and a 4.4  
128 times lower risk of a major complication (95% CI 0.65-29.30). However, the study has  
129 limitations that include variations in characteristics between the two groups (ORIF group had  
130 a lower mean age, higher proportion of male patients and less severe fracture patterns), lack  
131 of details regarding reasons for treatment allocation and a variable length of follow up. The  
132 described difference in study populations may reflect true clinical practice as young male  
133 patients are deemed a relative contraindication to TEA due to the lifetime restrictions in  
134 function and concern regarding longevity of the implants.

135 Frankle et al. and Egol et al. <sup>[22, 24]</sup> performed retrospective comparative studies and  
136 demonstrated comparable results between the treatment modalities. Common limitations  
137 included the absence of randomisation, lack of clarity over the treatment allocation process  
138 and variation in patient characteristics. In addition, Frankle et al. <sup>[22]</sup> reported only female  
139 patients and 67% of patients in the TEA group suffered from rheumatoid arthritis compared  
140 to 0% in the ORIF group. Obert et al. <sup>[25]</sup> report a combination of a retrospective review

141 (n=410) and prospective study (n=87) focused on the complication rate associated with these  
142 procedures. Despite showing a higher complication rate after ORIF (44% versus 23%), the  
143 failure of the paper to describe further patient characteristics, surgical technique and  
144 functional outcome limits the information that can be obtained from this study.

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## 147 **Meta-analysis of comparative studies**

### 148 **Functional outcomes**

149 There were three eligible studies that compared TEA to ORIF using the MEPS score, <sup>[21-23]</sup>  
150 and the results of the meta-analysis for this outcome are presented in Figure II. In all studies,  
151 the mean MEPS score for TEA patients was greater than for ORIF patients. The pooled mean  
152 difference is 13.1 (95% CI 9 to 17) indicating TEA is associated with better outcomes with  
153 respect to MEPS. Two of the included studies compared TEA versus ORIF using the DASH  
154 score. <sup>[21, 23]</sup> The results of the meta-analysis are summarised in Figure III. In both studies,  
155 the mean DASH scores for TEA patients was superior to the mean DASH scores for ORIF  
156 patients. The pooled mean difference is 14.2 (95% CI 4 to 22) indicating TEA is statistically  
157 better than ORIF with respect to DASH.

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### 159 **Complications**

160 Four of the included studies compared the complication profiles of TEA verses ORIF. <sup>[21-23,</sup>  
161 <sup>25]</sup> Figure IV summarises the results for the meta-analysis of percentage complications  
162 differences. In all studies complications were higher in the ORIF group. The pooled  
163 percentage complications difference was 21 (95% CI 12 to 29) indicating TEA was  
164 associated with fewer complications than ORIF.

## 165 **Re-interventions**

166 Two studies compared the need for re-intervention after TEA and ORIF. The results are  
167 conflicting with McKee et al. [21] reporting a lower re-intervention rate with TEA and Egol et  
168 al. [24] the opposite (Figure V). Meta-analysis of the data from these two studies showed that  
169 the pooled percentage re-intervention difference is -8 (95% CI -29 to 13) suggesting that TEA  
170 is associated with lower risk of re-intervention than ORIF but the difference is not  
171 statistically significant.

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173 To summarise, TEA is statistically superior to ORIF based on three outcomes (MEPS score,  
174 DASH score and complications) but not in terms of revision rate.

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## 177 **Case Series**

178 In total 22 case series were reviewed, 14 ORIF cases series [26-39] and 8 TEA case series. [40-47]

179 The size of the studies varied from 7 to 342 participants. 777 patients with a mean age of 77.8  
180 years were analysed in the ORIF case series and 200 patients with a mean age of 75.7 years  
181 in the TEA case series. These studies provide only level IV evidence and hence have  
182 significant limitations that must be taken into account when interpreting the pooled data. The  
183 study quality varied as demonstrated by the wide-ranging adherence to the Rangel criteria  
184 (Table VIII and IX). Significant heterogeneity was encountered in study methodology that  
185 included treatment allocation, fracture pattern, surgical approach, type of implants and length  
186 of follow up.

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## 189 **Single arm meta-analysis**

### 190 **Functional Outcomes**

191 Three comparative studies <sup>[21-23]</sup> and seven TEA case series <sup>[40-42, 44-47]</sup> reported MEPS score  
192 and the meta-analysis is shown in Figure VI. The pooled mean MEPS score from the ten  
193 TEA studies is 91.5 (95% CI = 88-95). Three comparative studies <sup>[21-23]</sup> and three ORIF case  
194 series <sup>[28, 38, 39]</sup> reported MEPS, the meta-analysis is shown in Figure VII. The pooled mean  
195 from the six studies is 82.8 (95% CI = 77-89). The 95% confidence intervals for MEPS in the  
196 TEA (88-95) and ORIF (77-89) groups overlap and therefore this difference is not  
197 statistically significant.

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### 199 **Complications**

200 Eleven studies; seven case series <sup>[40-44, 46, 47]</sup> and four comparative studies <sup>[40-42, 44]</sup>, reported  
201 complications for TEA (Figure VIII). The pooled percentage of complications in all eleven  
202 studies is 25% (95% CI = 19-32). Seventeen studies, thirteen case series <sup>[26-32, 34-39]</sup> and four  
203 comparative studies, <sup>[21-23, 25]</sup> reported complications for ORIF (Figure IX). The pooled  
204 percentage of complications in all seventeen studies is 34% (95% CI = 28-42). The 95%  
205 confidence intervals for complications in TEA (19-32%) and ORIF (28-42%) overlapped  
206 meaning the difference is not statistically significant.

207

### 208 **Re-intervention rates**

209 Two cases series <sup>[41, 42]</sup> and two comparative studies <sup>[21, 24]</sup> reported re-intervention rates for  
210 TEA. The pooled percentage of re-interventions for these four studies is 20% (95% CI = 14-  
211 28). Four cases series <sup>[26, 31-33]</sup> and two comparative studies <sup>[21, 24]</sup> reported re-intervention  
212 rates for ORIF. The pooled percentage of re-interventions for these six studies is 15% (95%

213 CI = 8-25). Overlapping of the confidence intervals suggests the difference in re-intervention  
214 rates for TEA and ORIF is not statistically significant.

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## 217 **Discussion**

218 Meta-analysis of data from the included comparative studies has demonstrated that TEA is  
219 associated with superior outcomes with respect to MEPS, DASH and frequency of

220 complications when compared to ORIF and that these findings are statistically significant.

221 The pooled mean differences between TEA and ORIF of 13.1 for MEPS and 14.2 for DASH  
222 are higher than the recognised minimal clinically important differences for these metrics (10

223 for MEPS and 7-10 for DASH).<sup>[48-50]</sup> The only level 1 evidence from McKee et al.<sup>[21]</sup> also

224 reported a statistically significant improvement in functional outcome after TEA with

225 excellent or good outcomes according to the MEPS in 84% of TEA patients compared to

226 53% in the ORIF group. ORIF was associated with a 21% (95% CI 12 to 29) pooled increase

227 in complications compared to TEA. These results demonstrate that TEA is associated with

228 clinically superior outcomes with fewer complications when compared to ORIF.

229 Inclusion of five studies for the comparative meta-analysis resulted in 330 patients being

230 available for analysis. Although combination of data increases the power of a meta-analysis,

231 the low availability of studies still risks under powering. The RCT from McKee et al.<sup>[21]</sup> was

232 conducting in keeping with the CONSORT statement providing high quality level I evidence.

233 The four comparative studies were appraised against the STROBE statement which provides

234 22 criteria to assess the quality of the study against. The number of criteria met varied from 7

235 to 20 demonstrating that the quality of the evidence varied. Common weaknesses included

236 the limited information provided on the methods of recording data, techniques used to

237 minimise bias, study limitations and statistical tests used. Obert et al. <sup>[25]</sup> only achieved 7 of  
238 the 22 criteria. Although the authors provided important data on risk of complications the  
239 limited information on sample selection, data collection, patient demographics and functional  
240 outcomes limits the strength of their results.

241 When single arm meta-analysis was performed for all studies, including comparative studies  
242 and case series, any differences in outcomes did not reach statistical significance. The failure  
243 of this part of the analysis to demonstrate significant results may be explained by the need to  
244 compute 95% confidence intervals for TEA and ORIF separately, which is more conservative  
245 estimate than calculating the confidence intervals for the difference in comparative studies.  
246 Furthermore, the inclusion of non-comparative studies increases the risk of bias and  
247 confounding.

248 Despite the meta-analysis of comparative studies demonstrating that TEA had a lower  
249 complication rate than ORIF, this analysis does not take into account the severity of the  
250 complication and the impact of the complications on patients. When performing arthroplasty,  
251 it is necessary to take into account the survivorship of the implant and the burden of any  
252 salvage procedures on the patient. The risk of TEA failure, in the form of component  
253 loosening, osteolysis or bushing failure, are all more likely after 5 years and this was not  
254 assessed in the included studies. The longevity of TEA in fracture patients has only recently  
255 been explored, Prasad et al. analysed 37 TEA non-rheumatoid trauma patients and reported  
256 implant survivorship of 89.5% at ten years. The study also showed that at ten years only 53%  
257 of the original cohort were alive, highlighting the typical patient demographic selected for  
258 TEA. <sup>[51]</sup> An attempt was made to compare the rate of re-intervention following the two  
259 procedures, however only two of the five included studies reported this outcome, their results  
260 were contradictory and the length of follow up in these studies was only 24 months. This

261 highlights the need for long-term comparative studies with explicit reporting of complications  
262 and re-operations.

263 Although this meta-analysis has shown an improved functional outcome and lower rate of  
264 complications after TEA in comparative studies, it is important to highlight that these  
265 findings should not be generalised to younger patients. Patients included in TEA groups had a  
266 trend to more complex fracture patterns as selection bias resulted in simpler fractures entering  
267 the ORIF groups. Therefore the role of TEA in a subgroup of younger patients (60-70 years)  
268 with less complex fractures perhaps provide the greatest clinical conundrum, where the  
269 survivorship and functional limitations of TEA must be balanced against the risks of ORIF. It  
270 is important to note that the lack of significant difference between the groups with respect to  
271 revision and complication rates should be interpreted with caution due to this selection bias  
272 and further randomised controlled study is appropriate to more clearly define the roles of  
273 each procedure in management of type C distal humerus fractures particularly in this sub-  
274 cohort of younger patients.

275 Alternative treatment options for distal humeral fractures are available that have not been  
276 included in this meta-analysis. Two recent retrospective studies report modest results when  
277 treating low-demand or medically unfit patients non-operatively. <sup>[10, 52]</sup> Both papers conclude  
278 that that non-operative treatment can be considered in these patient categories in order to  
279 avoid the risks of surgery whilst TEA can still be used as a salvage procedure if non-  
280 operative treatment fails. <sup>[10, 52]</sup> Hemiarthroplasty of the distal humerus is another surgical  
281 option that is gaining in popularity. A recent study reported at a mean of 3 years follow up  
282 that the functional outcomes were a mean MEPS score of 90 and a mean DASH score of 20,  
283 a complication rate of 19% and a 12% rate of revision surgery. <sup>[53]</sup> Further work and research  
284 is required to fully delineate the role of these different surgical options in these fractures and

285 assess whether there are further subgroups who would particularly benefit from the differing  
286 surgical techniques.

287 The small number of comparative studies available meant case series were also evaluated to  
288 increase the data available for analysis. The inclusion of this lower quality evidence increases  
289 the risk of introducing bias into the results with the main limitations being the lack of a  
290 comparative group and randomisation. The case series were appraised against Rangel's  
291 criteria which showed a wide variation in quality; this system includes 16 criteria to measure  
292 quality with scores ranging from 6 to 15. Common themes of study limitation included  
293 restricted information on the surgeons carrying out the procedure, the peri-operative care, the  
294 handling of missing data and the details regarding patient selection. These weaknesses were  
295 mitigated to some extent by performing statistical analyses on comparative and non-  
296 comparative studies separately. However, the failure of the non-comparative part of the meta-  
297 analysis to demonstrate any significant differences between groups may actually be as a  
298 result of the lower quality evidence and the variation in study quality. Therefore the ability of  
299 the comparative studies, which provide more robust evidence, to demonstrate statistically  
300 significant improvements after TEA form the basis for the studies conclusion.

301

## 302 **Conclusion**

303 Meta-analysis of comparative studies demonstrates that TEA is associated with statistically  
304 significant and clinically superior MEPS and DASH when compared to ORIF in elderly  
305 patients.

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**308 Conflicts of Interest**

309 All authors confirm that they have no conflicts of interest related to this manuscript that  
310 might lead to bias or a conflict of interest. Professor Adnan Saithna has no conflicts of  
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497 **Table I: Search strategy for Medline**

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499 **Table II – Summary of the comparative studies included**

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501 **Table III – Complications and revision rate in comparative studies**

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503 **Table IV: Summary of the included ORIF case series**

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505 **Table V: Summary of the included TEA case series**

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507 **Table VI: STROBE Statement, checklist of items that should be included in reports of**  
508 **observational studies**

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510 **Table VII: CONSORT 2010 checklist of information to include when reporting a**  
511 **randomised trial\***

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513 **Table VIII: Adequacy of reporting of TEA case series based on criteria proposed by**  
514 **Rangel et al.**

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516 **Table IX: Adequacy of reporting of ORIF case series based on criteria proposed by**  
517 **Rangel et al.**

518

519 **Figure I: Flow diagram of review process**

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521 **Figure II: Forest plot comparing MEPS scores for TEA and ORIF from comparative**  
522 **studies**

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524 **Figure III: Forest plot comparing DASH scores for TEA and ORIF from comparative**  
525 **studies**

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527 **Figure IV: Forest plot comparing percentage complications for TEA and ORIF for**  
528 **comparative studies**

529

530 **Figure V: Forest plot comparing percentage revisions for TEA and ORIF from**  
531 **comparative studies**

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533 **Figure VI: Forest plot for mean MEPS scores for TEA in comparative and case series**

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535 **Figure VII: Forest plot for mean MEPS scores for ORIF in comparative and case series**

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537 **Figure VIII: Forest plot for percentage of complications for TEA in case series and**  
538 **comparative studies**

539

540 **Figure IX: Forest plot for percentage of complications for ORIF in case series and**  
541 **comparative studies**