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# Improved Outcomes for Proximal Humerus Fracture Open Reduction Internal Fixation Augmented with a Fibular Allograft in Elderly Patients: A Systematic Review and Meta-Analysis

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1 <u>ABSTRACT</u>

2 **Background:** To date, no meta-analysis has been performed on the efficacy of fibular allograft 3 augmentation for the management of proximal humerus fractures. The purpose of this study was 4 to evaluate the radiographic and clinical outcomes of proximal humerus fractures treated with a 5 locking compression plate (LCP) with or without fibular allograft augmentation. **Methods:** The 6 Cochrane Database of Systematic Reviews, the Cochrane Register of Controlled Trials, PubMed, 7 MEDLINE, Web of Science, and SCOPUS were queried in June of 2021 for literature comparing the radiographic and clinical outcomes for patients with proximal humerus fractures that were 8 treated with a LCP only or a LCP augmented with a fibular allograft. Data describing study 9 design, level of evidence, demographic information, final follow-up, radiographic changes in 10 humeral head height (HHH), radiographic changes in neck shaft angle (NSA), final American 11 12 Shoulder and Elbow Surgeons (ASES) scores, final Constant-Murley scores, and major 13 complications were collected. Risk of bias was assessed using the Methodological Index for Non-Randomized Studies (MINORS) criteria. A meta-analysis was performed using pooled 14 weighted mean differences (WMD) to compare changes in HHH, NSA, final ASES and final 15 Constant-Murley scores between the two groups; a pooled odds ratio was used to compare 16 17 complications between the groups. Results: Ten studies with a total of 802 patients were identified. There was a significant difference that favored patients augmented with a fibular 18 allograft for change in HHH (WMD = -2.40; 95% CI, -2.49 to -2.31; p < 0.00001), change in 19 20 NSA (WMD = -5.71; 95% CI, -6.69 to -4.72; p < 0.00001), final ASES scores (WMD = 5.08; 21 95% CI, 3.69 to 6.48; p < 0.00001), and odds ratio for developing a major complication (OR = 22 0.37; 95% CI, 0.23 to 0.59; p < 0.0001). There was no significant difference in final Constant-23 Murley scores (WMD = 3.36; 95% CI, -0.21 to 6.93; p = 0.06) or revision surgery rate (p =

0.182) between the two groups. Conclusion: The pooled WMD and prediction interval suggest
that 95% of patients with proximal humerus fractures treated with a LCP augmented with a
fibular allograft will have improved radiographic outcomes, improved ASES clinical outcome
scores, and decreased odds of a major complication when compared to patients treated with a
LCP alone. Limitations of this study include a relatively short average final follow-up time (< 2
years) and a potential lack of standardization for radiographic outcomes among included studies.
Level of Evidence: Level III; Systematic Review/Meta-Analysis
Keywords: Fibular Allograft, Proximal Humerus Fracture, Locking Compression Plate, Strut
Allograft, Endosteal Graft, Meta-Analysis
Proximal humerus fractures are the third most common fracture in the elderly patient
population. <sup>17</sup> The relatively high incidence of this fracture can be attributed to decreasing bone
quality and the resulting osteoporosis or osteopenia associated with increasing age.30
Consequently, these injuries usually occur as a result of minimal trauma such as a ground-level
fall. <sup>6, 32</sup> The economic impact of these injuries on the health care system is significant, estimating
185,000 visits to the emergency department in the United States per year. <sup>15</sup> Additionally, those
who suffer these fractures may suffer from significant morbidity, with a 10% mortality rate at
one-year post-injury. <sup>24</sup>
A variety of treatment options are available for proximal humerus fractures and are
predominately guided by the fracture pattern and the patients' pre-injury level of activity. <sup>32</sup> The

most common options include nonoperative management with a sling, open reduction and internal fixation (ORIF), or shoulder arthroplasty.<sup>13</sup> However, the best treatment option for displaced fractures remains controversial.<sup>11</sup> Unfortunately, regardless of the treatment option selected, many studies report poor clinical outcomes for these injuries, including residual shoulder pain, limited shoulder range of motion, and decreased quality of life.<sup>32</sup>

With the increasing use of proximal humeral locking compression plates (LCP), studies have demonstrated relative ineffectiveness in preventing varus collapse of the fracture with this technique.<sup>28</sup> When managing these injuries, medial column restoration is an important consideration to minimize varus malalignment.<sup>16</sup> One strategy to address medial column stability is the use of a fibular allograft augment, first introduced by Gardner *et al* in 2008.<sup>9</sup> Subsequent studies have demonstrated excellent postoperative radiographic and clinical outcomes following the use of a LCP with fibular allograft augmentation.<sup>12, 21, 26</sup>

In an effort to analyze the available data, two recent systematic reviews have examined the use of fibular allograft augmentation in the treatment of proximal humeral fractures.<sup>1, 30</sup> In 2016, Saltzman *et al* conducted a systematic review of four studies that reported therapeutic clinical outcome scores following fibular strut allograft adjunct to a LCP.<sup>30</sup> Biermann *et al* performed a similar study in 2019 that included 15 biomechanical and 30 clinical studies that investigated fibular allograft augmentation for proximal humerus fractures.<sup>1</sup> With the data available at that time, neither of these systematic reviews were able to conduct a meta-analysis. Most of the studies included in those reviews were either biomechanical or level of evidence IV

and V. Furthermore, since the publication by Biermann *et al*, nine additional studies have been published that directly compare a LCP augmented with a fibular allograft to a LCP alone.

The purpose of this study was to systematically review all available studies that directly compared a LCP augmented with a fibular allograft to a LCP alone. By incorporating only comparative clinical studies, a meta-analysis was conducted to compare radiographic outcomes, clinical outcomes, and complication rates between the two groups. The authors hypothesized that intramedullary fibular allograft augmentation of a LCP will lead to superior radiographic outcomes, superior clinical outcomes, and a reduced rate of major complications relative to a LCP alone for the management of proximal humerus fractures in the elderly population.

## **METHODS**

## **Article Identification and Selection**

This meta-analysis was conducted in accordance with the 2009 Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA) statement (**Figure 1**).<sup>23</sup> The Cochrane Database of Systematic Reviews, the Cochrane Register of Controlled Trials, PubMed, MEDLINE, Web of Science, and SCOPUS were queried on June 14<sup>th</sup> 2021 for literature comparing the radiographic and clinical outcomes for patients with proximal humerus fractures that were treated with a locking compression plate (LCP) only or a LCP augmented with a fibular allograft. The following search terms were used: "fibular allograft AND proximal humerus" OR "strut allograft AND proximal humerus" OR "endosteal strut AND proximal humerus" OR "endosteal graft AND proximal humerus." Inclusion criteria were as follows: directly compared a LCP only against a LCP

augmented only with a fibular allograft, clinical and/or radiographic outcomes, patients treated for a proximal humerus fracture, clinical study, and English language literature. Exclusion criteria included non-fibular grafts, cadaveric studies, in-vivo animal studies, in-vitro studies, editorial articles, surveys, letters to the editor, special topics, expert reviews, and non-comparative studies (level of evidence IV or V). Three investigators (S.P.D., B.K., P.R.) independently screened articles by title, abstract, and full text, when appropriate. For any disagreements, these three authors discussed the study and a consensus decision was made.

## **Outcome Measures and Data Extraction**

The primary outcome measures evaluated in this meta-analysis were (1) change in humeral head height (HHH) in mm, (2) change in neck shaft angle (NSA) in degrees, (3) patient reported American Shoulder and Elbow Surgeons (ASES) scores, (4) patient reported Constant-Murley scores, and (5) major complications, which were defined as malunions, avascular necrosis, screw perforation, screw cutout, or major adverse events subjectively defined and reported by respective authors. Humeral head height is defined radiographically as the distance between the upper end of the plate to the upper end of the humeral head, while the measured NSA is defined as the angle between the humeral head and the shaft in an anteroposterior view.<sup>34</sup> A customized data extraction spreadsheet was created to record all relevant data from the included studies including publication information, study design, level of evidence, demographic information (age, gender), time until final follow-up, and the aforementioned outcome scores. Prior to inclusion, all data was qualitatively analyzed based on their methods, results, discussion, and conclusion.

## **Risk of Bias Assessment**

Two investigators (L.M.F. and B.K.) independently assessed risk of bias using the MINORS criteria.<sup>31</sup> Any disagreements between the two reviewers were resolved by consensus. To summarize, the numerical scale is composed of 12 questions for non-randomized studies. Items are scored as 0 for not reported, 1 for reported but inadequate, and 2 for reported and adequate. For a comparative study, an ideal score would be 24 points.

# **Statistical Analysis**

Regardless of the variance among the data extracted from the included studies, a random effects model was chosen based on the design of the studies included and the methodology used for sampling the data. This model was used to compare five outcomes: change in HHH (mm) between initial postoperative radiographs and radiographs at final follow-up, change in NSA (degrees) between initial postoperative radiographs and radiographs at final follow-up, patient reported ASES at final follow-up, patient reported Constant-Murley at final follow-up, and complications as defined previously. A weighted mean difference (WMD) and 95% confidence interval (CI) were used to assess the average and range of true means for each respective outcome measure based on the studies included. An alpha < 0.001 was assigned as significant. The percentage of variance in the true effect value and the percentage of variance from sampling error was determined using I-squared tests ( $I^2$ ). The true effect size in 95% of the population (95% prediction interval or PI) was calculated using the variance of true effects ( $I^2$ ) and thus the standard deviation of true effects ( $I^2$ ).

Among each set of outcomes, the age, follow-up, gender distribution, and Neer classification fracture distribution were compared between the LCP only group and the LCP augmented with a fibular allograft group. For continuous numerical variables, a Shapiro-Wilk test was performed to determine distribution of the variables. For variables with a normal distribution, an unpaired two-tailed Student's t test was used to compare differences between the groups. For variables with an abnormal distribution, a Mann-Whitney U test was used for the same purpose. Gender and fracture distribution were compared using a  $\chi 2$  test with 1 or 2 degrees of freedom, respectively. Alpha was set at 0.05 for these outcomes. Statistical analysis was performed using Review Manger 5 (The Nordic Cochrane Center, Copenhagen, Denmark) and IBM SPSS Statistics for Macintosh (Version 28.0; IBM, Armonk, NY, USA).

149 <u>RESULTS</u>

## **Study Characteristics**

The database query yielded a total of 241 studies after duplicates were removed (**Figure 1**). Ten studies satisfied all prespecified inclusion criteria. All studies were cross-referenced, and there was no potential for duplicate data on the same patients presented across different studies. Study characteristics of all studies that met the inclusion criteria, even those with data that was not used for meta-analysis, are presented in **Table 1**. All ten studies were retrospective cohort studies (level of evidence III). When combining the patients from all studies included in this systematic review, there was a total of 436 proximal humerus fracture patients that were treated with a LCP only and a total of 366 patients that were treated with a LCP augmented with a fibular allograft. The mean age of patients treated with a LCP only was 65.76 ±6.74 years (range, 54.30 to 73.30 years), while the mean age of patients treated with a LCP augmented with a

fibular allograft was  $68.24 \pm 4.88$  years (range, 59.90 to 75.60 years). The mean follow-up for patients treated with a LCP only was  $17.70 \pm 8.45$  months (range, 6.50 to 35.70 months), and the mean follow-up for patients in the LCP augmented with a fibular allograft group was  $18.28 \pm 8.14$  months (range, 7.83 to 33.50 months).

The risk of bias assessment was performed using the MINORS criteria and is presented in **Table 2**. Of the ten included retrospective cohort studies, seven had a total MINORS score of 16. The studies by Wang et al and Cha et al had a total MINORS score of 18.<sup>3, 34</sup> The study by Lee et al had a total MINORS score of 19, which was the highest among the included studies in this meta-analysis.<sup>19</sup>

## **Outcome Measures**

## **Humeral Head Height**

Five studies assessed the difference in change in HHH from initial postoperative radiographs to radiographs on final follow-up between the LCP group (162 patients) and the LCP augmented with a fibular allograft group (154 patients) (**Figure 2**). The mean age for the LCP only group and the LCP group that was augmented with a fibular allograft was  $69.33 \pm 3.72$  years (range, 64.10 to 73.30 years) and  $70.59 \pm 4.40$  years (range, 64.10-75.60 years), respectively. This difference was not significant (p = 0.638). The mean follow-up for the LCP only group was  $17.95 \pm 8.14$  months (range, 12.00 to 32.23 months) compared to  $18.29 \pm 7.90$  months (range, 12.00 to 31.56 months) for the group augmented with a fibular allograft. The difference was not significant (p = 1.000). There were no differences in gender (p = 0.592) or in the distribution of Neer type 2/3/4 fracture patterns (p = 0.665) between the two groups.

There was a smaller change in HHH in the LCP groups augmented with fibular allografts compared to groups that were treated with a plate alone: this difference was statistically significant (WMD = -2.40; 95% CI, -2.49 to -2.31; p < 0.00001). Thus, the null hypothesis can be rejected, and it can be concluded that, on average, in a universe of populations comparable to the studies sampled in this analysis, there was a reduced change in HHH for patients treated with a LCP augmented with a fibular allograft compared to a LCP alone. For this set of data, the variance of true effects ( $T^2$ ) was 0.00, and the I $^2$  is 0%, indicating that variance is estimated to be 0.

To put this measurement into clinical context, several of the included studies defined a loss of anatomic fixation as a change in HHH of over 3 mm.<sup>3, 7, 19, 26</sup> The weighted mean for change in HHH in the groups augmented with the fibular allograft was 1.5 mm compared to 4.1 mm in the groups treated with a LCP alone. This suggests that, on average, the groups augmented with a fibular allograft did not lose anatomic fixation at final follow-up. This is further supported by the finding that all five included studies reported a change in HHH less than 3 mm for groups augmented with a fibular allograft. Conversely, the groups treated with a LCP alone had an average change in HHH that exceeded 3 mm, suggesting that this treatment option was more likely to result in a loss in anatomic fixation. Furthermore, in each individual study, the LCP alone group consistently demonstrated an average change in HHH that was greater than 3 mm.

## **Neck Shaft Angle**

Seven studies assessed the difference in change in NSA from initial postoperative radiographs to radiographs on final follow-up between the LCP group (280 patients) and the LCP augmented with a fibular allograft (254 patients) (**Figure 3**). The mean age for the LCP only group was 67.64  $\pm$ 6.72 years (range, 54.30 to 73.30 years) and was 69.34  $\pm$ 4.87 years (range, 62.30-75.60 years) for the LCP group that was augmented with a fibular allograft. This difference was not significant (p = 0.798). The mean follow-up for the LCP only group was 16.46  $\pm$ 7.97 months (range, 6.50 to 32.23 months) compared to 16.90  $\pm$ 7.59 months (range, 7.83 to 31.56 months) for the group augmented with a fibular allograft. The difference was not significant (p = 0.918). There were no differences in gender (p = 0.339) or in the distribution of Neer type 2/3/4 fracture patterns (p = 0.609) between the two groups.

There was a smaller change in NSA in the LCP groups augmented with fibular allografts (weighted mean: 5 degrees) compared to groups that were treated with a LCP alone (weighted mean: 10 degrees). This difference was statistically significant (WMD = -5.71; 95% CI, -6.69 to -4.72; p < 0.00001). Thus, the null hypothesis can be rejected, and it can be concluded that, on average, in a universe of populations comparable to the studies sampled in this analysis, there was a reduced change in neck shaft angle for patients treated with a LCP augmented with a fibular allograft compared to a LCP alone.

For this set of data, the  $I^2$  is 80%, indicating that only 20% of the variance between the true mean difference and the observed mean difference was due to standard error. More importantly, the variance of true effects ( $T^2$ ) was 0.98 with a standard deviation of true effects ( $T^2$ ) of 0.990. This suggests that in 95% of patients from a population comparable to those

involved in this data set, the true mean difference for the change in neck shaft angle would be smaller in the LCP groups augmented with fibular allografts relative to the LCP only groups (95% PI, -7.69 to -3.73).

## American Shoulder and Elbow Surgeons (ASES) Score

Four studies assessed the difference in ASES scores on final follow-up between the LCP group (154 patients) and the LCP augmented with a fibular allograft (132 patients) (**Figure 4**). The mean age for the LCP only group and the LCP group that was augmented with a fibular allograft was 71.82  $\pm$ 1.92 years (range, 69.00 to 73.30 years) and 72.44  $\pm$ 2.82 years (range, 68.80 to 75.60 years), respectively. This difference was not significant (p = 1.00). The mean follow-up for the LCP only group was 19.36  $\pm$ 9.06 months (range, 12.00 to 32.23 months) compared to 19.04  $\pm$ 8.87 months (range, 12.00 to 31.56 months) for the group augmented with a fibular allograft. The difference was not significant (p = 0.962). There were no differences in gender (p = 0.671) or in the distribution of Neer type 2/3/4 fracture patterns (p = 0.981) between the two groups.

LCP groups augmented with a fibular allograft (weighted mean: 84.3) reported mean ASES scores that were higher than those reported by the LCP only groups (weighted mean: 78.7). This difference was statistically significant (WMD = 5.08; 95% CI, 3.69 to 6.48; p < 0.00001). Based on these results, it can be concluded that in a universe of populations comparable to the studies included in this analysis, there were higher average ASES value reported by patients treated with a LCP augmented with a fibular allograft compared to LCP only

groups. For this set of data, the variance of true effects  $(T^2)$  was 0.00, and the  $I^2$  was 0%, indicating that variance is estimated to be 0.

## **Constant-Murley Score**

Five studies assessed the difference in Constant-Murley scores on final follow-up between the LCP group (169 patients) and the LCP augmented with a fibular allograft (172 patients) (**Figure 5**). The mean age for the LCP only group and the LCP group that was augmented with a fibular allograft was  $69.39 \pm 3.69$  years (range, 64.10 to 73.30 years) and  $70.29 \pm 4.39$  years (range, 69.10-75.60 years), respectively. This difference was not significant (p = 0.735). The mean follow-up for the LCP only group was  $18.13 \pm 8.06$  months (range, 12.00 to 32.23 months) compared to  $18.73 \pm 7.73$  months (range, 12.00 to 31.56 months) for the group augmented with a fibular allograft. The difference was not significant (p = 0.834). There were no differences in gender (p = 0.413) or in the distribution of Neer type 2/3/4 fracture patterns (p = 0.753) between the two groups.

The weighted mean for the Constant-Murley score at final follow-up was 81.9 in the group augmented with a fibular allograft and 79.9 in the group treated with a LCP alone. While the weighted mean difference favored the group augmented with a fibular allograft, this difference was not statistically significant (WMD = 3.36; 95% CI, -0.21 to 6.93; p = 0.06). The null hypothesis could not be rejected, and no conclusions can be made regarding comparisons in Constant-Murley scores between the two groups. Additionally, only 25% of the variance between true and observed mean differences can be attributed to sampling error ( $I^2 = 75\%$ ). The variance of true effects ( $I^2$ ) was 12.08 with a standard deviation of true effects ( $I^2$ ) of 3.476. The

95% prediction interval was -3.592 to 10.312, indicating that it is unclear if there was any benefit to fibular allograft augmentation for LCP in the context of the Constant-Murley score.

## **Major Complications**

The reported major complications included in this meta-analysis included malunions, avascular necrosis, screw perforation, screw cutout, or complications subjectively defined and reported by respective authors. Eight studies reported major complications as defined by this study (**Figure 6**). One study by Kim *et al* reported zero complications for patients treated with a LCP augmented with a fibular allograft. A fixed value of 0.5 was assigned for this zero-count cell, which introduced an undesirable bias toward no difference between the groups.

There were 32 reported complications in 296 total patients treated with LCP augmented with a fibular allograft. There were 87 reported complications in 349 patients treated with LCP only. The mean age for the LCP only group was  $65.60 \pm 5.92$  years (range, 54.30 to 72.50 years) and was  $67.13 \pm 4.47$  years (range, 59.90-72.20 years) for the LCP group that was augmented with a fibular allograft. This difference was not significant (p = 0.571). The mean follow-up for the LCP only group was  $17.12 \pm 8.25$  months (range, 6.5 to 35.20 months) compared to  $17.68 \pm 7.48$  months (range 7.83 to 33.50 months) for the group augmented with a fibular allograft. The difference was not significant (p = 0.903). There were no differences in gender (p = 0.130) or in the distribution of Neer type 2/3/4 fracture patterns (p = 0.388) between the two groups.

There was a statistically significant decrease in the odds ratio for complications in the LCP augmented with a fibular allograft group compared with the LCP alone group (OR = 0.37;

95% CI, 0.23 to 0.59; p < 0.0001). 95% of variance between the observed odds ratio and the true odds ratio can be attributed to sampling error ( $I^2 = 5\%$ ). The variance of true effects ( $T^2$ ) was 0.03 with a standard deviation of true effects ( $T^2$ ) of 0.173. The 95% prediction interval for the odds ratio of complications ranged from 0.014 to 0.716. This suggests that augmentation of a LCP with a fibular allograft was associated with a reduction in the odds of a major complication relative to patients treated with a LCP alone for 95% of patients drawn from a population similar to the study populations sampled.

When examining the rate of revision surgery, only three studies reported the number of patients who underwent a subsequent surgical intervention for the affected shoulder.<sup>8, 25, 34</sup> There was a slightly lower rate of revision surgeries in the groups augmented with a fibular allograft (6.2%) compared to the groups treated with a LCP alone (9.8%); however, this difference was not statistically significant (p = 0.182).

## 313 DISCUSSION

This study included ten papers published between 2017 and 2020 evaluating the outcomes of fibular allograft augmentation in addition to a LCP compared to a LCP alone in proximal humeral fractures. Neither of the previous two recent systematic reviews on this technique directly compared the outcomes of plating alone to plating augmented with a fibular allograft. The major findings of this meta-analysis were as follows: 1) radiographic changes in NSA and HHH were significantly lower for patients treated with fibular allograft augmentation; 2) functional outcome scoring for ASES was significantly higher with the fibular allograft augmentation group, while a nonsignificant difference was demonstrated for Constant-

Murley scoring between the two groups; 3) complication rates were significantly lower with the application of fibular allograft augmentation.

## **Radiographic Findings**

The radiographic measurements for change in HHH and change in NSA were reported in five and seven of the analyzed studies, respectively. Both HHH and NSA were found to have a statistically significant reduction in change from postoperative radiographs to final follow-up radiographs for the group augmented with a fibular allograft. Cha *et al* evaluated the radiographic outcomes after surgical management for 52 patients with proximal humeral fractures.<sup>3</sup> The authors reported a significantly lower change in HHH and NSA for groups augmented with a fibular allograft relative to groups treated with a LCP alone. Two other publications included in this meta-analysis demonstrated that regardless of the Neer classification fracture pattern, the addition of a fibular allograft showed superior radiographic results in both NSA and HHH than plating alone.<sup>7, 35</sup> Similar to Cha *et al*, Tuerxun *et al* reported that three of the 22 patients who underwent LCP alone had changes in NSA greater than 10° and six patients had changes in HHH greater than 3 mm.<sup>33</sup> Additionally, Lee *et al* determined the rate of varus malignment and loss of HHH were significantly decreased to 8.9% and 4.4%, respectively, when a fibular allograft was used during plate fixation.<sup>19</sup>

Noncomparative studies examining the use of fibular allograft augmentation in ORIF of proximal humerus fractures have reported similar radiographic outcomes, further supporting the potential benefit of this surgical technique. An interesting study by Gardner *et al* examined 35 patients who underwent plating alone and found that patients who had adequate mechanical

medial support had an average loss of HHH of 1.2 mm, whereas those without adequate medial support had an average HHH loss of 5.8 mm (p < 0.001). These results drove the authors to propose augmentation with a fibular allograft for medial support in their subsequent 2008 publication, where they initially introduced the technique.

From a biomechanical standpoint, the addition of a fibular allograft complex is potentially beneficial with comminuted fracture patterns, especially those involving loss of medial calcar support. This is because the increased purchase and head support with grafting allows for increased stiffness of the bone-implant interface, increased test load failure, and improved osteosynthesis in complex proximal humeral fractures.<sup>5, 18, 22, 27</sup>

## **Functional Outcomes**

In the present study, functional outcome ASES scoring was significantly higher with fibular allograft augmentation, while nonsignificant results were demonstrated for Constant-Murley scoring amongst the publications that reported functional outcomes. Kim *et al* deduced that the application of a minimally invasive plate osteosynthesis with a fibular graft demonstrated no significant differences in scores for visual analog score (VAS) or Constant-Murley scores at one year postoperatively in comparison to ORIF alone. <sup>14</sup> Comparatively, Zhao *et al* retrospectively looked at 21 elderly patients who received a fibular allograft in addition to plating as well as 21 patients with ORIF alone and reported that Constant-Murley scores were significantly higher for those in the augmentation group and DASH scores were significantly lower for the augmentation group. <sup>35</sup>

The functional outcomes reported in the present study are on par with the heterogeneity of the previously mentioned studies. The impact of clinical outcomes, such as ASES and Constant-Murley, must be put in context of total follow-up time and correlated to improvements in range of motion. Given that the follow-up time varied drastically amongst the studies reporting ASES and Constant scores, ranging from an average of 13.6 to 32.23 months, the nonsignificant changes in Constant scores between the groups may not allow for adequate conclusions to be made. It is imperative that surgeons who are assessing the efficacy of surgical techniques for proximal humeral fractures take note of the variability in follow-up time and initial morbidity investigated in previous studies, as the functional outcomes in their own patients may reflect certain subgroups of the population that have been previously studied.

## **Complication Rates**

Complication rates were significantly lower with the application of fibular allograft augmentation in this meta-analysis. Myers et~al determined that despite a decrease in overall total fluoroscopy time (63 vs. 83 seconds; p=0.04) with fibular allograft use, the length of operation and blood loss were similar. They also found a statistically significant decrease in the need for revision surgery in Neer 3 or 4-part fractures (16% vs 0%; p<0.01) for the fibular allograft group. Chen et~al, Zhao et~al, and Tuerxun et~al also reported statistically significant decreases in complication rates observed for the group augmented with a fibular allograft. And Stratified for both age (<65 years vs >65 years) and gender they still were not able to parse out significant differences in complication rates of ORIF alone compared to ORIF augmented with a fibular allograft.

While the data presented in this meta-analysis suggests that fibular allograft augmentation reduces major complications, it is important to emphasize that the majority of complications reported were subjectively defined by authors and were not uniform between studies. Additionally, this study did not address complications associated with the need for future surgery such as conversion to total shoulder arthroplasty (TSA). Revision surgery can be challenging after failed ORIF augmented with a fibular allograft because ingrowth leads to the formation of an intramedullary canal that is resistant to reaming and prosthesis stem placement during a salvage procedure. <sup>20, 29</sup> Despite this, there have been reports of successful reverse TSA with improvements in pain, patient satisfaction, and ASES scores for these complex cases of humeral head collapse and screw penetration secondary to AVN. <sup>20, 29</sup> The fibular allograft also has disadvantages related to its high cost and, like other allografts, its risk for disease transmission. <sup>7</sup> Neither of these disadvantages were adequately explored in this study.

## Limitations

This systematic review is not without limitations. The average final follow-up time was relatively short (< 2 years), and there was significant heterogeneity in the presentation of both subjective outcomes and objective outcomes. Several studies emphasized physical exam/functioning outcomes such as range of motion changes while others focused heavily on radiographic differences in the two groups. Additionally, despite finding a statistically significant difference in ASES scores between the two groups, the minimal clinically important difference for ASES scores does not currently exist in the literature for ORIF of proximal humerus fractures. This made it challenging to place these findings in the appropriate clinical context.

Another major limitation of this study is that the HHH radiographic outcome may not have been standardized between studies and may differ based on the view, rotation, and magnification of the radiographs. Given the inherent design of systematic reviews, it is possible that relevant papers were not included in this study based on how search terms were defined during the initial database query. Furthermore, the retrospective nature of this meta-analysis and included studies limits the generalizability that can be extrapolated. While the results presented are promising, a randomized controlled trial is needed to determine the true efficacy of fibular allograft augmentation in the management of proximal humerus fractures treated with a LCP.

# 423 <u>CONCLUSION</u>

The results of this meta-analysis favored the use of fibular allograft augmentation for the management of proximal humerus fractures treated with a LCP. When generalizing the results of this study, this data set would suggest that 95% of patients sampled from populations representative of those included in this study would experience improved radiographic outcomes, improved ASES clinical outcome scores, and decreased odds of a major complication if treated with a LCP augmented with a fibular allograft compared to patients treated with a LCP alone. Limitations of this study include the relatively short final follow-up time and a potential lack of standardization for radiographic outcome measures among the included studies.

## FIGURE LEGENDS

**Figure 1:** PRISMA flowchart of the study selection criteria.

**Figure 2**: Forest plot demonstrating the mean difference for change in humeral head height from initial postoperative radiographs to radiographs at final follow-up for patients treated with either a LCP alone or a LCP augmented with a fibular allograft. This includes a summary estimate

439	(center of the diamond) and a 95% confidence interval (width of the diamond) for the true mean
440	difference. The size of each square represents the relative weight given to each respective study.
441	
442	Figure 3: Forest plot demonstrating the mean difference for change in neck shaft angle from
443	initial postoperative radiographs to radiographs at final follow-up for patients treated with either
444	a LCP alone or a LCP augmented with a fibular allograft. This includes a summary estimate
445	(center of the diamond) and a 95% confidence interval (width of the diamond) for the true mean
446	difference. The size of each square represents the relative weight given to each respective study.
447	
448	Figure 4: Forest plot demonstrating the mean difference between ASES scores on final follow-
449	up for patients treated with either a LCP alone or a LCP augmented with a fibular allograft. This
450	includes a summary estimate (center of the diamond) and a 95% confidence interval (width of
451	the diamond) for the true mean. The size of each square represents the relative weight given to
452	each respective study.
453	
454	Figure 5: Forest plot demonstrating the mean difference between Constant-Murley scores on
455	final follow-up for patients treated with either a LCP alone or a LCP augmented with a fibular
456	allograft. This includes a summary estimate (center of the diamond) and a 95% confidence
457	interval (width of the diamond) for the true mean. The size of each square represents the relative
458	weight given to each respective study.
459	
460	Figure 6: Forest plot demonstrating the odds ratio for reported major complications in patients
461	treated with either a LCP alone or a LCP augmented with a fibular allograft. This includes a
462	summary estimate (center of the diamond) and a 95% confidence interval (width of the
463	diamond). The size of each square represents the relative weight given to each respective study.
464	Complications were defined as malunions, avascular necrosis, screw perforation, screw cutout,
465	or subjectively by respective authors.
466	
467	<b>Table 1</b> : Study characteristics table. M = Male; F = Female; LCP = Locking Compression Plate;
468	FA = Locking Compression Plate Augmented with a Fibular Allograft
169	

470	Tabl	e 2: Methodological Index for Non-Randomized Studies (MINORS) criteria. For this bias
471	asses	ssment, an ideal score would be 24 points.
472		
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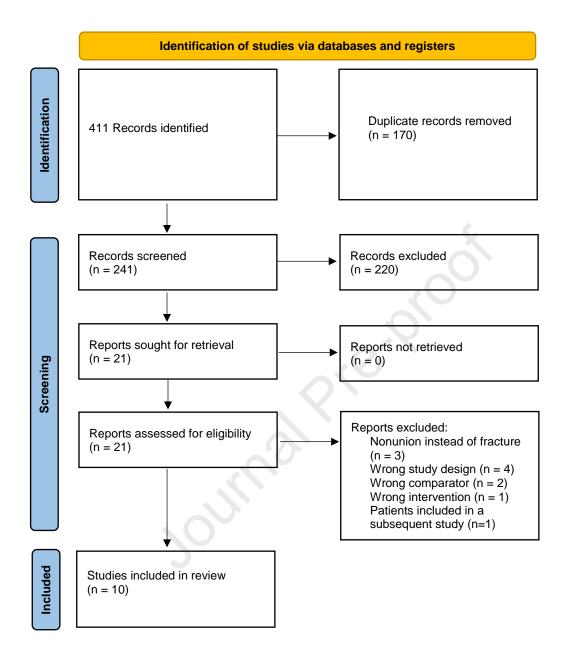
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Table 1: Study Characteristics

Author	Year	Study Design	Level of Evidence	Intervention	Patient (Sex)	Mean Age (Years)	Follow-up (Months)	Neer Classification (2/3/4)
Davids <sup>9</sup>	2020	Retrospective	III	LCP	75 (N/A)	59.9	17.6	40/35/0
Davius	2020	Cohort	111	FA	27 (N/A)	59.9	17.6	13/14/0
Kim <sup>15</sup>	2020	Retrospective	III	LCP	39 (32F, 7M)	68.1	15.9	20/19/0
Killi	2020	Cohort	111	FA	38 (33F, 5M)	69.8	17.2	24/14/0
Myers <sup>25</sup>	2020	Retrospective	III	LCP	72 (41F, 31M)	54.3	6.5	47/25/0
Wryers	2020	Cohort	111	FA	61 (45F, 16M)	62.3	7.83	35/26/0
Tuerxun <sup>34</sup>	2020	Retrospective	III	LCP	22 (13F, 9M)	64.1	16.3	3/10/09
Tucixuii		Cohort	111	FA	41 (29F, 12M)	64.1	19.3	6/19/16
Cui <sup>8</sup>	2019	Retrospective	III	LCP	35 (24F, 11M)	72.46	32.23	0/25/10
Cui		Cohort	111	FA	25 (18F, 7M)	73.16	31.56	0/17/8
Lee <sup>20</sup>	2019	Retrospective	III	LCP	52 (38F, 14M)	73.3	14.2	25/22/5
Lee	2019	Cohort	111	FA	45 (33F, 12M)	75.6	13.6	21/20/4
Wang <sup>35</sup>	2019	Retrospective	III	LCP	46 (33F, 13M)	72.5	19	0/0/46
vv ang	2019	Cohort	111	FA	39 (23F, 16M)	72.2	19	0/0/39
Zhao <sup>36</sup>	2019	Retrospective	III	LCP	21 (9F, 12M)	69	12	0/15/6
Znao	2019	Cohort	111	FA	23 (12F, 11M)	68.8	12	0/14/7
Chen <sup>5</sup>	2018	Retrospective	III	LCP	42 (27F, 15M)	69.12	35.2	0/10/32
CHEH	2016	Cohort	111	FA	47 (35F, 12M)	68.6	33.5	0/12/35
Cha <sup>4</sup>	2017	Retrospective	III	LCP	32 (24F, 8M)	67.8	15	8/21/03
Cila	2017	Cohort	III	FA	20 (15F, 5M)	71.3	15	3/15/02

Table 2: MINORS Bias Score

Author	Year	Title	Study Design	Total Score
Davids <sup>9</sup>	2020	Comparison of Locked Plating of Varus Displaced Proximal Humeral Fractures With and Without Fibula Allograft Augmentation.	Retrospective Cohort	16
Kim <sup>15</sup>	2020	Comparison between MIPO and the deltopectoral approach with allogenous fibular bone graft in proximal humeral fractures.	Retrospective Cohort	16
Myers <sup>25</sup>	2020	Improved Outcomes Using a Fibular Strut in Proximal Humerus Fracture Fixation.	Retrospective Cohort	16
Tuerxun <sup>34</sup>	2020	Locking Plate Combined With Endosteal Fibular Allograft Augmentation for Medial Column Comminuted Proximal Humeral Fracture.	Retrospective Cohort	16
Cui <sup>8</sup>	2019	Fibular strut allograft influences reduction and outcomes after locking plate fixation of comminuted proximal humeral fractures in elderly patients: a retrospective study.	Retrospective Cohort	16
Lee <sup>20</sup>	2019	Outcomes of locking plate fixation with fibular allograft augmentation for proximal humeral fractures in osteoporotic patients: comparison with locking plate fixation alone.	Retrospective Cohort	19
Wang <sup>35</sup>	2019	Locking Plate Use with or without Strut Support for Varus Displaced Proximal Humeral Fractures in Elderly Patients.	Retrospective Cohort	18
Zhao <sup>36</sup>	2019	Comparison of the Effects of Proximal Humeral Internal Locking System (PHILOS) Alone and PHILOS Combined with Fibular Allograft in the Treatment of Neer Three- or Four-part Proximal Humerus Fractures in the Elderly.	Retrospective Cohort	16
Chen <sup>5</sup>	2018	The Augment of the Stability in Locking Compression Plate with Intramedullary Fibular Allograft for Proximal Humerus Fractures in Elderly People.	Retrospective Cohort	16
Cha <sup>4</sup>	2017	Treatment of comminuted proximal humeral fractures using locking plate with strut allograft.	Retrospective Cohort	18



	Fibula	r Allograft		LCI	P Only			Mean Difference		Mean Difference
Study or Subgroup	Mean [mm]	SD [mm]	Total	Mean [mm]	SD [mm]	Total	Weight	IV, Random, 95% CI	Year	IV, Random, 95% CI
Cha 2017	1	1	20	4	4	32	0.4%	-3.00 [-4.45, -1.55]	2017	
Cui 2019	1.18	1.08	25	4.16	4.2	35	0.4%	-2.98 [-4.43, -1.53]	2019	<del></del>
Lee 2019	1.8	0.2	45	4.2	0.3	52	81.9%	-2.40 [-2.50, -2.30]	2019	
Zhao 2019	2.14	0.33	23	4.54	0.42	21	16.3%	-2.40 [-2.62, -2.18]	2019	<del>-</del>
Tuerxun 2020	1.1	1.1	41	3.4	2	22	1.0%	-2.30 [-3.20, -1.40]	2020	<del></del>
Total (95% CI)			154			162	100.0%	-2.40 [-2.49, -2.31]		•
Heterogeneity: Tau <sup>2</sup> =	= 0.00; Chi <sup>2</sup> =	1.31, df =	4 (P =	$0.86$ ); $I^2 = 0\%$	6					1 1 1
Test for overall effect	: Z = 51.90 (P)	< 0.00001	L)							Favors Fibular Allograft Favors LCP Only

	Fibular	Allograft		LC	P Only			Mean Difference		Mean Difference
Study or Subgroup	Mean [Degrees]	SD [Degrees]	Total	Mean [Degrees]	SD [Degrees]	Total	Weight	IV, Random, 95% CI	⁄ear	IV, Random, 95% CI
Cha 2017	3	3	20	10.2	7	32	8.5%	-7.20 [-9.96, -4.44] 2	017	<del></del>
Wang 2019	14.7	3.1	39	18.6	5.7	46	13.1%	-3.90 [-5.81, -1.99] 2	019	<del></del>
Zhao 2019	3.42	0.71	23	9.82	1.02	21	24.0%	-6.40 [-6.92, -5.88] 2	019	-
Cui 2019	3.12	3.13	25	9.94	9.92	35	6.0%	-6.82 [-10.33, -3.31] 2	019	<del></del>
Lee 2019	3.2	0.6	45	10.3	1.1	52	25.0%	-7.10 [-7.45, -6.75] 2	019	•
Myers 2020	1.8	5.6	61	4.7	8.5	72	10.1%	-2.90 [-5.31, -0.49] 2	020	<del></del>
Tuerxun 2020	3.3	2.2	41	7.6	4.2	22	13.3%	-4.30 [-6.18, -2.42] 2	020	<del></del>
Total (95% CI)			254			280	100.0%	-5.71 [-6.69, -4.72]		•
Heterogeneity: Tau <sup>2</sup> = Test for overall effect			0.0001)	$I^2 = 80\%$					-	-10 -5 0 5 10
. csc .o. sveran enece		00001,								Favors Fibular Allograft Favors LCP Alone

Fibular Allograft				LC	P Only	/		Mean Difference		Mean Difference			
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	Year	IV, Random, 95% CI			
Cui 2019	78.64	9.18	25	72.8	9.73	35	8.3%	5.84 [1.01, 10.67]	2019				
Lee 2019	83.1	8.5	45	78.5	7.6	52	18.6%	4.60 [1.37, 7.83]	2019	<del></del>			
Wang 2019	87.2	3.6	39	82.2	4.5	46	65.4%	5.00 [3.28, 6.72]	2019	_ <del></del>			
Zhao 2019	87.76	7.15	23	81.62	9.62	21	7.6%	6.14 [1.09, 11.19]	2019				
Total (95% CI)			132			154	100.0%	5.08 [3.69, 6.48]		•			
Heterogeneity: Tau <sup>2</sup>					= 0.95	); $I^2 = C$	)%			-10 -5 0 5 10			
Test for overall effect	Z = 7.1	5 (P <	0.0000	1)						Favors LCP Favors Fibular Allograft			

Fibular Allograft				LC	P Only	/		Mean Difference		Mean Difference			
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	Year	IV, Random, 95% CI			
Cui 2019	78.96	9.71	25	73	9.94	35	17.7%	5.96 [0.93, 10.99]	2019	•			
Lee 2019	87.8	5.6	45	83.5	6.5	52	24.4%	4.30 [1.89, 6.71]	2019				
Zhao 2019	86	7.56	23	79.71	9.14	21	17.9%	6.29 [1.31, 11.27]	2019				
Kim 2020	78.3	7.5	38	81.8	9.1	39	21.1%	-3.50 [-7.22, 0.22]	2020	<del></del>			
Tuerxun 2020	83.7	8.6	41	79.1	8.9	22	18.9%	4.60 [0.04, 9.16]	2020	-			
Total (95% CI)			172			169	100.0%	3.36 [-0.21, 6.93]					
Heterogeneity: Tau <sup>2</sup> =	= 12.08;	Chi <sup>2</sup> =	16.25,	df = 4 (	P = 0.0	003); I <sup>2</sup>	= 75%			-10 -5 0 5 10			
Test for overall effect	z = 1.8	5 (P =	0.06)							Favors LCP Favors Fibular Allografi			

	Fibular All	ograft	LCP O	nly		Odds Ratio		Odds Ratio
Study or Subgroup	Events	Total	<b>Events</b>	Total	Weight	IV, Random, 95% CI	Year	IV, Random, 95% CI
Cha 2017	1	20	4	32	4.4%	0.37 [0.04, 3.56]	2017	<del></del>
Chen 2018	8	47	17	42	21.5%	0.30 [0.11, 0.80]	2018	<del></del>
Wang 2019	3	39	5	46	9.7%	0.68 [0.15, 3.06]	2019	<del></del>
Zhao 2019	1	23	7	21	4.6%	0.09 [0.01, 0.82]	2019	<del></del>
Davids 2020	6	27	16	75	18.5%	1.05 [0.36, 3.05]	2020	<del></del>
Kim 2020	0	38	3	39	2.5%	0.14 [0.01, 2.71]	2020	-
Myers 2020	10	61	29	72	29.1%	0.29 [0.13, 0.66]	2020	<del></del>
Tuerxun 2020	3	41	6	22	9.7%	0.21 [0.05, 0.95]	2020	<del></del>
Total (95% CI)		296		349	100.0%	0.37 [0.23, 0.59]		•
Total events	32		87					
Heterogeneity: Tau <sup>2</sup> =	= 0.03; Chi <sup>2</sup> =	= 7.40, d	lf = 7 (P	= 0.39	); $I^2 = 5\%$			
Test for overall effect	t: $Z = 4.10$ (P	< 0.000	1)					0.01 0.1 1 10 100
								Favors Fibular Allograft Favors LCP Only