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Factors associated with maintaining reduction following locking plate fixation of proximal humerus fractures: a population-based retrospective cohort study

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Background: Loss of reduction (LoR) can occur after locking plate fixation of proximal humerus fractures (PHFs). This study determined biomechanical features of fracture fixation associated with preventing LoR postoperatively. One-year reoperation rates were also compared between those with/without LoR.

Methods: Population-based administrative data for 359 adults treated using a locking plate for PHF between 2010 and 2016 were examined. Two trained assessors reviewed standardized shoulder radiographs. LoR (Yes/No) was defined as any fracture displacement >0.5 cm, and/or >10° change in neck-shaft angle (NSA) alignment relative to intraoperative imaging. Multiple logistic regression assessed how the following affected maintaining reduction: (1) sex, (2) age, (3) Neer classification, (4) shaft impaction (SI), (5) shaft medialization (SM), (6) calcar reduction (CR), (7) NSA alignment, and (8) screw use.

Results: LoR was seen in 79 (22%) patients. LoR was significantly associated with increasing age (odds ratio [OR] = 1.06/yr, $P < .001$), fracture severity (4-part vs. 2-part fracture; OR = 4.63, $P = .001$), and varus NSA alignment (<125° vs. ≥145°: OR = 5.6, $P = .02$; <125° vs. 125–145°, OR = 2.2, $P = .02$). Patients achieving simultaneous SI, SM, and CR were significantly less likely (OR = 0.009, $P < .001$) to lose reduction, after controlling for age, fracture severity, and NSA alignment. If only SI was achieved, patients were still significantly less likely to lose reduction relative to achieving none of these mechanical features (OR = 0.17, $P = .006$). Reoperations were higher when LoR occurred ($n = 26/77$ [33.4%]) compared with no LoR ($n = 20/276$ [7.2%]) ($P < .001$).

Conclusions: SI was strongly associated with preventing LoR in patients treated using a locking plate for PHF. SI with concurrent SM, CR, and a neutral or valgus NSA had the lowest rates of LoR. LoR was associated with higher rates of reoperation.

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Proximal humerus fractures represent one of the most common fractures in the older adult population and are commonly associated with poor bone quality.^{10,16} Minimally displaced fractures are

treated without surgery, but with increasing displacement, surgical intervention becomes more common, with multiple fixation techniques described.³ Locking plate fixation is one of the most common surgical techniques, but reported complication rates range from 3% to 54%.^{3,13,24} One of the most common complications following locking plate fixation is loss of reduction.^{1,25}

Many studies have suggested interventions to enhance biomechanical stability of fixation construct, including ensuring anatomic

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calcar reduction, using inferomedial or calcar screws, avoidance of varus reduction, fixing the shaft in a medialized and impacted position with respect to the humeral head, and ensuring sufficient fixation in the head itself.^{1,2,4,7,8,12,14,18–21,27–29} The aim of this study was to radiographically evaluate factors that either enhance or reduce fracture site stability after locking plate fixation for proximal humerus fractures. Secondly, we compared reoperation rates between those with loss of reduction and those who maintained reduction postoperatively. Our main hypothesis was that patients achieving simultaneous shaft impaction (SI), shaft medialization (SM), and calcar reduction (CR) would be less likely to lose reduction and undergo revision surgery than those who did not.

Methods

Study design

This was a population-based cohort study using patient-level data extracted from the provincial administrative data repositories. We identified 390 adult patients treated with open reduction internal fixation (ORIF) using a locking plate for proximal humeral fractures between 2010 and 2016 in Edmonton, Canada.

Inclusion and exclusion criteria

Patients were ≥ 18 years of age and had a proximal humeral fracture treated with ORIF using a locking plate within 2 weeks of injury. In addition, complete radiographic data were needed for inclusion: a preoperative radiograph to assess fracture severity, an immediate postoperative radiograph, and at least 1 follow-up radiograph within 1 year. Cases that used bone grafts were excluded.

Procedures

Surgical data were extracted from the Discharge Abstract Database (DAD) that contains all hospital admission and discharge data including diagnostic and procedural codes; this database allowed us to capture any reoperations that occurred within the province and not just at the site of the index surgery. Diagnostic codes (1–25) of S422* (Fracture of upper end of humerus) and Procedure Codes (1–20) of 1TK74LA* (Fixation humerus, open approach) or 1TA74LA* (Fixation shoulder joint, open approach) were used to identify eligible patients between 2010 and 2016 in the initial cohort; a minimum of 12 months since surgery was required to be included in the analysis. Subsequent reoperations within 1 year of the discharge date on the initial cohort used Procedure Codes (1–20) of 1TK* or 1TA* and defined the reoperation cohort. Age and sex were collected for all patients.

Once participants were identified as undergoing locking plate fixation for proximal humerus fracture, the provincial diagnostic imaging database was used to identify all radiographic records associated with that shoulder from time of injury to at least 1 year postoperatively. Two senior orthopedic residents were trained as radiographic assessors by an upper extremity fellowship-trained orthopedic surgeon with more than 15 years of experience. Standard orthogonal views of the affected shoulder were reviewed including a true glenohumeral anteroposterior and a trans-scapular lateral view with data collected using a standardized data collection sheet. For training, both assessors independently reviewed the same 28 radiographic images to determine inter-rater reliability in measuring loss of reduction and biomechanical parameters using standardized operational definitions (provided below). Inter-rater reliability was very high, with Kappa coefficients ranging from 0.79–1.0¹⁷ and correlation coefficients ranging from 0.94–1.0 (Supplementary Table S1).

The first radiographic images of the affected shoulder subsequent to initial operation and operative report determined initial reduction status. Preoperative images determined fracture type based on Neer classification and presence of fracture dislocation. Immediate postoperative images and operative notes were evaluated to determine the type of surgical fixation, alignment (neck-shaft angle [NSA] in degrees), number of screws in the humeral head and humeral shaft, calcar, and/or push screws, the presence of SI, SM, CR, and loss of NSA. SI was defined as shaft impacted into the humeral head with no visible gap. SM occurred if the lateral border of the humeral shaft was sitting ≥ 2 mm medial to lateral border of humeral head. As metaphyseal comminution can result in shortening or impaction of the bone to a point where the width of the humerus is no longer uniform because of the conical nature of the humeral metaphysis, it was possible to “medialize” the shaft while the calcar remained unreduced. CR required anatomic alignment of the medial humeral shaft to junction of the humeral head. NSA was determined on the true anteroposterior radiograph using the method described by Zhu et al.³⁰ We defined anatomic alignment as NSA of $135^\circ (\pm 10^\circ)$ on the true anteroposterior view.

Latest postoperative images within 12 months from surgery or prior to revision were reviewed to determine loss of reduction of any fracture fragment, changes in position of the construct, intra-articular screw penetration, malunion, nonunion (>6 months postoperative), and alignment (NSA in degrees).

Outcomes

The primary outcome was loss of reduction, as defined by Jung et al as (1) fracture displacement >0.5 cm, of any part and/or (2) $>10^\circ$ of change in NSA alignment when compared to intraoperative imaging.¹⁵ Secondly, we compared reoperation rates between those who lost reduction vs. those who did not.

Statistical analysis

Descriptive analysis was performed for all variables using independent *t* tests for continuous and chi-square tests for categorical variables to compare loss of reduction for all of the selected parameters. Reoperation rates were compared between those who lost fixation and those who did not. Purposeful multivariate linear logistic regression modeling identified factors associated with maintaining or loss of reduction. We examined the association between biomechanical parameters (SI, SM, and CR), NSA alignment, and screws (number, type, and location) and maintaining reduction in patients surgically treated with a proximal humeral locking plate after controlling for sex, age, and fracture classification. All statistical analyses were performed using SAS (version 9.4, SAS Institute, Cary, NC, USA), IBM SPSS Statistics (version 26; IBM Corp., Armonk, NY, USA), and the R-project for Statistical Computing (version 3.6.2) and a 2-sided type I error probability of .05.

Results

Patient characteristics

Between 2010 and 2016, 390 patients with proximal humerus fractures were treated with ORIF using a locking plate; of these 31 (7.8%) had either incomplete radiographic data ($n = 8$) or received an allograft ($n = 23$), leaving 359 (92.2%) patients for analysis (Fig 1). The average age was 60.6 (SD = 14.9) and 68.9% were female. A total of 39 patients (10.8%) had dislocation of fracture on preoperative radiographic image. Using the Neer classification, 139 (38.8%) patients had a 3-part fracture.

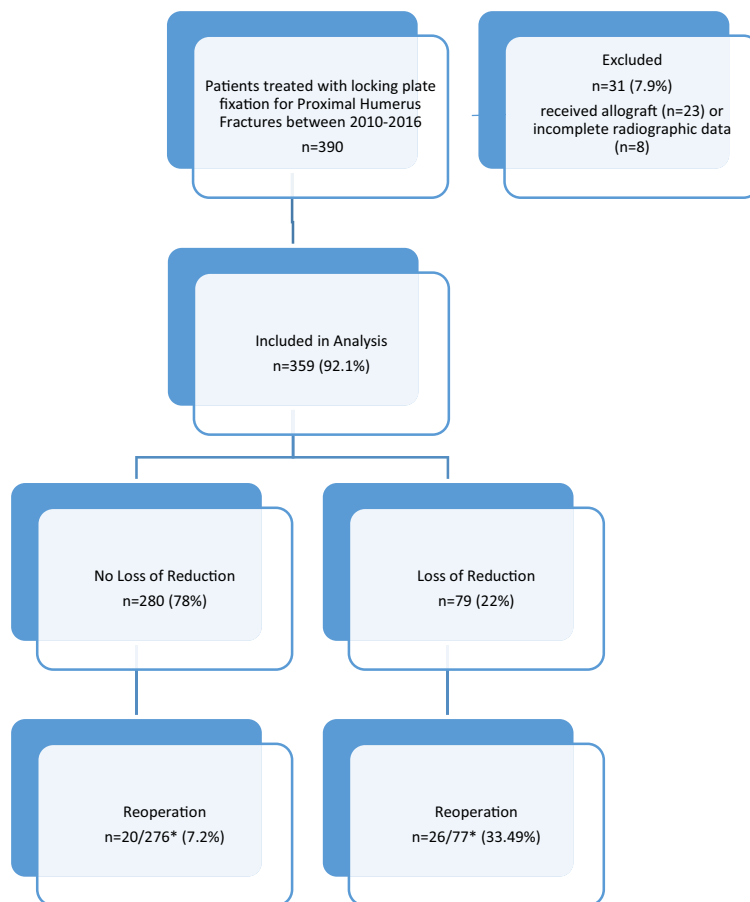


Figure 1 Flow Chart. *Six of 359 could not have reoperation data confirmed as there were no postrevision radiographs or operative reports available, but administrative data indicated reoperation within 1 year.

Surgical characteristics

Overall, 316 (88.0%) patients achieved SI, 211 (58.8%) achieved SM and 164 (45.7%) achieved CR. The mean NSA alignment was 131.4° (SD = 10.7°). Among all included patients, an average of 6.0 (SD = 1.4) screws were placed in the humeral head and 3.3 (SD = 0.86) screws in the humeral shaft. Calcar screws were used in 241 (67.3%) patients, whereas 8 (2.2%) patients received push screws.

Factors associated with loss or retention of reduction

Loss of reduction was seen in 79 (21.8%) patients. Patients with loss of reduction were older ($P < .001$); less likely to achieve SI ($P < .001$), SM ($P < .001$), or CR ($P < .001$); and were more likely to have varus alignment ($P < .001$) (Table I). There were also significantly more calcar screws used ($P = .002$), and the mean number of screws in humeral head was increased ($P = .02$) between patients who maintained reduction compared to those who did not in the univariate analysis (Table I).

In the multivariate analysis, increasing age (OR = 1.06/yr increase, $P < .001$), 4-part fractures (relative to 2-part fracture, OR = 4.63, $P = .001$), and varus NSA alignment were significantly associated with loss of reduction (Table II). Use of calcar screws and increased numbers of screws in the humeral head did not retain their statistical significance in the multivariate analysis (Table II).

When SI, SM, and CR were achieved simultaneously, loss of reduction was significantly less likely (OR = 0.009, $P < .001$) relative to achieving none of those biomechanical parameters, even after

controlling for age, sex, fracture severity, and alignment (NSA) (Table II). Even if only SI was achieved, patients were still significantly less likely to lose reduction when compared to achieving none of these biomechanical features (OR = 0.17, $P = .006$) (Table II).

Reoperation

Overall, 46/353 (13.0%) patients required reoperation within 12 months of surgery; 6 patients (4 no loss of reduction; 2 loss of reduction) could not have reoperations confirmed as there was no postrevision radiograph to confirm the reoperation and no OR report available. Of 79 patients who had loss of reduction, 26 (32.9%) underwent reoperation whereas only 20 (7.1%) of those who did not lose reduction underwent reoperation ($P < .001$) (Fig 1, Table III).

Discussion

The goal of any surgical intervention must be to minimize complications, which in part can be achieved with a stable construct that withstands the physiologic loads applied during fracture healing. Although several studies have reported the importance of biomechanical parameters in achieving stable fixation of proximal humerus fractures,^{1,2,4,7,8,12,14,18-21,27-29} clinical studies confirming these principles are lacking. In a large population-based cohort using administrative health data of patients receiving surgical fixation of proximal humeral fractures using locking plates, we found that clinical results support the

Table I
Unadjusted analysis of characteristics for adult patients treated with open reduction internal fixation (ORIF) using a locking plate for proximal humeral fractures between 2010 and 2016 in Edmonton, Canada, who maintained or lost reduction postoperatively

	No loss of reduction (n = 280)	Loss of reduction (n = 79)	P value
Patient characteristics			
Mean age (SD, range, n)	58.9 (14.6, 21-89, 276)	67 (13.2, 30-91, 79)	<.001*
Females	187 (68.5)	55 (71.4)	.62 [†]
Dislocation	37 (13.2)	8 (10.0)	.80 [†]
Fracture type (Neer classification)			.11 [†]
2-part fracture	84 (30.1)	20 (25.3)	
3-part fracture	113 (40.5)	26 (32.9)	
4-part fracture	82 (29.4)	33 (41.8)	
Surgical characteristics			
Mean number of screws in humeral head (SD, range, n)	6.1 (1.4, 3-10, 280)	5.7 (1.3, 3-9, 79)	.02*
Mean number of screws in humeral shaft (SD, range, n)	3.3 (0.8, 2-8, 280)	3.5 (1.1, 2-10, 79)	.12*
Calcar screws used	197 (70.6)	41 (51.2)	.002 [†]
Shaft impaction achieved	257 (92.1)	56 (70.9)	<.001 [†]
Medialization achieved	191 (68.5)	17 (21.5)	<.001 [†]
Calcar reduction achieved	149 (53.4)	12 (15.2)	<.001 [†]
Alignment achieved (head-shaft angle in degrees)			<.001 [†]
<125	48 (17.1)	36 (45.6)	
125-145	200 (71.7)	40 (50.6)	
≥145	32 (11.4)	3 (3.8)	

SD, standard deviation.

Unless otherwise noted, values are n (%).

* Analyzed with a 2-tailed independent t test.

† Analyzed with a chi-square test.

Table II
Risk-adjusted analysis of characteristics associated with loss of reduction in adult patients treated with ORIF using a locking plate for proximal humeral fractures between 2010 and 2016 in Edmonton, Canada

Loss of reduction predictors	Odds ratio (95% CI)	P value
Gender (reference = male)	1.57 (0.73, 3.39)	.25
Age (per year increase)	1.06 (1.03, 1.09)	<.001*
Fracture classification (reference = 2-part fracture)	1.00	
3-part fracture	2.14 (0.91, 5.0)	.08
4-part fracture	4.63 (1.91, 11.26)	.001*
Biomechanical features (reference = none achieved)	1.0	
Achieve CR only	0.48 (0.05, 4.388)	.52
Achieve SM only	0.27 (0.048, 1.476)	.13
Achieve both SM and CR	0.14 (0.016, 1.165)	.07
Achieve SI only	0.17 (0.045, 0.603)	.006*
Achieve SI and CR	0.098 (0.010, 0.961)	.046*
Achieve SI and SM	0.03 (0.006, 0.171)	<.001*
Achieve SI, SM, and CR	0.009 (0.002, 0.049)	<.001*
Alignment (NSA) (reference = <125°)	1.00	
125°-145°	0.45 (0.22, 0.90)	.02*
>145°	0.18 (0.04, 0.75)	.02*
Calcar screws (reference = no)	0.66 (0.33, 1.30)	.23
Number of humeral head screws (per screw increase)	0.96 (0.72, 1.28)	.76
Number of humeral shaft screws (per screw increase)	1.32 (0.93, 1.88)	.12

ORIF, open reduction and internal fixation; CR, calcar reduction; SM, medialization; SI, shaft impaction; NSA, neck-shaft angle; CI, confidence interval.

NOTE: Reference indicates the group to which comparisons were made. OR <1.0 indicate reduced risk for loss of reduction whereas OR >1.0 indicate increased risk for loss of reduction; any confidence interval containing 1 indicates statistical nonsignificance.

* Significant at P = .05.

available biomechanical evidence.^{1,2,4,7,8,12,14,18-21,27-29} As expected, our clinical cohort was older and primarily female. Older patients were at higher risk of loss of reduction as were those who experienced 4-part fractures and had varus alignment as measured by their NSA.

However, even after controlling for these patient and fracture characteristics, we determined that SI is the most important biomechanical parameter to achieve, with further surgical construct stability gained with the addition of SM and/or CR. If all 3 of these parameters were achieved, the likelihood of losing reduction was very low compared with achieving none of these parameters (3% vs. 59%). Interestingly, although there appeared to be a significant benefit of calcar screws in the univariate analysis,

this parameter was not significant in our multivariate analysis when we considered other factors. Finally, those patients who lost reduction were more likely to require surgery than those who did not (P < .001).

Previous studies have shown that SI and SM are important for biomechanical stability of locking plate constructs using cadaveric models.^{9,28} Weeks et al²⁸ demonstrated that SI substantially increased load to failure in cyclical testing. The technique demonstrated similar fatigue limit to a similar previous study comparing fibular strut augmentation by Chow et al.⁹ If SI and SM eliminated the fracture gap and restored the medial column integrity, the construct withstood greater than 25,000 cycles of loading at physiologic levels. Chen et al⁸ confirmed these findings in

Table III

Reasons for reoperation for adult patients treated with open reduction internal fixation (ORIF) using a locking plate for proximal humeral fractures between 2010 and 2016 in Edmonton, Canada, who lost or did not lose reduction postoperatively

	No loss of reduction, n (%) (n = 276 [†])	Loss of reduction, n (%) (n = 77 [†])	P value [‡]
Reoperation	20 (7.2)	26 (32.9)	<.001
Reasons for reoperation			
Loss of reduction	1 (5.0) [§]	10 (38.4)	
Avascular necrosis	5 (25.0)	5 (19.2)	
Infection	3 (15.0)	4 (15.4)	
Pain	3 (15.0)	0 (0.0)	
Nonunion	0 (0.0)	1 (3.9)	
Not specified [§]	8 (40.0)	6 (23.1)	

* Missing reoperation status (yes in administrative data; no second reoperation confirmed)

[†] Analyzed with a chi-square test.[‡] As specified in operating room report by attending surgeon.[§] No specific reason detailed in operative report or operative report not available because the revision surgery was performed at a different hospital.

computer-generated models simulating normal and osteoporotic bone. Further, Carbone et al⁶ demonstrated that because these fractures occur in patients with osteoporosis, subsidence of the construct, even though it is rigidly fixed, can occur in the first 3 months postoperatively. Providing SI during initial fixation likely limits this subsidence, preventing loss of reduction.

Achieving a neutral or valgus NSA also proved beneficial in maintaining reduction. Solberg et al²² reported that even a varus malreduction of 5° increased the risk of varus subsidence of the humeral head. Further, Agudelo et al¹ showed that a varus malreduction of less than 120° was associated with an early loss of fixation. Although Capricciosco et al⁵ determined that initial varus displacement increased postoperative complication rates, it did not translate into a worse functional outcome. However, multiple other studies have demonstrated that restoring the NSA to resemble the uninjured side translated into improved functional recovery, with increasing degrees of varus malreduction resulting in significantly lower postoperative Constant scores.^{2,18,19,23,26} As our review was retrospective, we cannot comment on the impact of a neutral NSA on function, but this parameter was associated with reduced likelihood of losing fixation.

Interestingly, our results did not support that more screws in the humeral head added value relative to the more important biomechanical factors described above. In cadaveric models, Erhardt et al¹² reported that least 5 screws in the head along with presence of calcar screws were important to maintain reduction, whereas Donahue et al¹¹ demonstrated the superiority of 6 screws over 3 screws but were unable to show that inferiorly placed screws provided significant improvement in stability compared with superiorly positioned screws. Zhang et al²⁹ demonstrated in synthetic bone constructs that in the absence of adequate medial column support, inferomedial screws significantly enhanced mechanical stability, so perhaps calcar screws provide value when SI and SM cannot be achieved. We were unable to show the benefit of calcar screws when considering other variables concurrently in the current analysis.

To our knowledge, our population-based review is one of the largest radiographic evaluations examining factors associated with loss of reduction (or preventing loss of reduction) after locking plate fixation for proximal humerus fractures. We also used standardized operational definitions of radiographic measurements and outcomes and evaluated inter-rater reliability of these parameters; inter-rater reliability was excellent, adding support that our evaluation could be repeated by others.

There are some limitations that warrant discussion. Despite being a population-based review, it is a retrospective radiographic review, so we lack functional and patient-reported outcomes. We were also unable to detail differences in surgical techniques in plate

fixation. Further, we focused on loss of reduction, and although loss of reduction was associated with higher reoperation rates, not all patients who lost reduction required reoperation. Because not all reoperations occurred at the index surgical hospital, we do not have all the reasons for reoperation, but clearly loss of reduction was the most common reason for reoperation in the those defined as having loss of reduction.

We also used the Neer Classification for fractures, which has not been proven to be reliable. However, our senior residents, who were trained in reviewing the radiographs by a fellowship-trained upper extremity surgeon were able to achieve excellent inter-rater reliability in assessing the radiographic parameters (Supplementary Table S1). Finally, we did not contact any patients for follow-up and used only available data in the hospital and provincial diagnostic imaging databases. We assumed that all patients who experienced issues related to their surgery returned for further evaluation, and because our administrative data were provincial, we were unlikely to have missed a substantial number of reoperations or patients with symptomatic loss of reduction. However, we may be underestimating the number of patients with loss of reduction. Nonetheless, we believe that this potential underestimation is unlikely to change the results, because in the patients we followed up there was a clear and strong pattern regarding factors associated with loss of reduction (or prevention thereof).

Conclusion

Our radiographic review of proximal humeral fractures treated with locking plates confirmed that older patients with 4-part fractures were at higher risk of losing reduction. However, constructs achieving SI, SM, CR, and a neutral NSA alignment had the lowest rates of loss of reduction. When these factors are achieved, the number of screws in the humeral head did not appear to significantly enhance fracture stability. Further work is needed to understand how these factors affect clinical outcomes.

Disclaimer

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Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.jseint.2020.07.022>.

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