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Factors associated with failure of locking plate fixation in proximal humerus fractures

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ABSTRACT

Background: Locking plate fixation remains the mainstay of surgical fixation of unstable proximal humerus fractures, however rates of failure remain high. The aim of this study was to identify risk factors that could be used to predict the likelihood of fixation failure.
Method: Patients with proximal humerus fractures managed with locking plate fixation between 2010 and 2019 at a Level 1 trauma centre were included. Radiographs were evaluated for parameters that could be used to predict failure of fixation. Pre-operative factors included were the Neer classification, cephalomedullary angle, medial calcar length, disruption of the medial hinge, and anatomical neck fracture. Post-operative factors included the cephalomedullary angle, medial calcar reduction gap, presence of anatomical tuberosity reduction, presence of medial calcar screws, screw distance to articular surface, and number of screws present in the humeral head.
Results: There were 189 patients included; 54 % male, mean age 49.9 (intact fixation) group and 56.1 (failure). The rate of fixation failure was 22 %. Factors associated with increased risk of failure following multivariable analysis included increasing age (OR 1.04 per year, CI 1.01–1.07), varus pre-operative cephalomedullary angle (OR 2.84, CI 1.03–7.83), and non-anatomical calcar reduction (OR 2.31, CI 1.05–5.08). The presence of calcar screws was associated with decreased risk of fixation failure (OR 0.30, CI 0.10–0.90). This analysis was used to create a predictive model including the Neer classification, age, pre-operative cephalomedullary angle, post-operative cephalomedullary angle, anatomic reduction of the medial calcar, and presence of medial calcar screws.
Conclusion: Rates of locking plate fixation failure in proximal humerus fractures remain high. This study has identified key pre-operative and intra/post-operative factors that can be used to predict the risk of failure. Further work is required to validate this model.
Level of Evidence: Level II

Introduction

Proximal humerus fractures are amongst the most common orthopaedic injuries. Whilst most fractures can be managed non-operatively, surgical management is undertaken for displaced fracture patterns with the goal of improving function and allowing early mobilisation. Where fixation is required locking plate fixation has been the mainstay of operative management of proximal humerus fractures over the last two decades [1]. However locking plate fixation is a technically demanding procedure and has been associated with high rates of complications [2]. Common technical errors in performing locking plate fixation which have been associated with poor outcomes include intra-articular screw penetration, varus malreduction, and poor plate position leading to impingement [3,4].

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Internal fixation has been associated with high rates of reoperation, particularly in older patient populations [4–8]. Numerous factors contributing to failure have been described in the literature, both pre-operative fracture characteristics and reduction characteristics [4,7, 9–14]. These studies have typically focused on a single risk factor such as the cephalomedullary angle, presence of calcar screws, or the success of anatomical reduction, and to date there is no comprehensive criteria that predicts failure of locking plate fixation.

The aim of this study was to identify radiological factors, both pre-operative and postoperative, that are associated with failure of locking plate fixation and create a predictive tool to allow surgeons to determine the risk of failure of internal fixation.

Method

Setting and participants

Ethics approval was obtained through the institutional Human Ethics Committee. The study was conducted using available radiology of patients presenting between January 2010 and February 2019 to a Level 1 trauma centre. Eligible patients were identified using the relevant International Statistical Classification of Diseases and Related Health Problems, Tenth Revision, Australian Modification (ICD-10-AM) coding (code S42.2 – fracture of upper end of humerus) [15]. Radiographs and computed tomography of these patients were reviewed to identify patients that met the study inclusion criteria. Inclusion criteria consisted of all adult patients (18 years and over) presenting with a proximal humerus fracture within two weeks of injury, including fractures with dislocation, that had undergone internal fixation with a locking plate. Exclusion criteria were pathological fracture due to underlying tumour or metastatic disease, or insufficient radiological follow up/loss to follow up post-operatively. Sufficient follow up was defined as follow up to fracture union or 12 months.

Procedures

Baseline demographic variables including patient age and gender were obtained from the medical record. Radiology was independently evaluated by two senior orthopaedic trainees. Where there was disagreement, radiographs and computed tomography were reviewed and discussion was undertaken to reach a consensus. Following this process there was no disagreement regarding radiological classifications.

Computed tomography scans of the initial fracture where available and subsequent anteroposterior and lateral radiographs were reviewed at the pre-operative stage, immediately post-operatively and then at six weeks, three months, six months, and twelve months post-operatively. Initial fracture patterns were classified using the Neer classification [16]. Other pre-operative measurements included the pre-operative cephalomedullary angle, the medial calcar length, and whether there was disruption of the medial hinge or anatomical neck fracture as described by Hertel [17]. Post-operative measurements included the post-operative cephalomedullary angle, medial calcar reduction gap, whether anatomical tuberosity reduction was achieved, presence of medial calcar support, screw distance to the articular surface, and number of screws present in the humeral head. The medial calcar reduction gap was defined as the distance between the humeral head fragment and the shaft at the medial calcar and measure in millimetres. Measurements were made on digitalised radiographs with measurements calibrated using the known length of the locking plates.

At follow-up, failure of fixation was defined as fracture migration of 5 mm or more of the humeral head fragment on anteroposterior or lateral radiographs to allow for differences in radiological projection. Other complications evaluated included delayed union and non-union, varus malunion, screw penetration of the articular surface, requirement for revision surgery and avascular necrosis. The definition of fracture union was based on previous literature [18]. Union was considered achieved when three cortices demonstrated bony bridging on anteroposterior and lateral radiographs. Normal union was expected within 60 days of initial management, delayed union between 60 days and 89 days, and a non-union was defined as a lack of bony bridging within 90 days or a documented non-union in the medical record requiring a change of prescribed management. Definitions of malalignment and malunion were based on previous literature with a cephalomedullary angle $\geq 160^{\circ}$ considered valgus malalignment and a cephalomedullary angle $\leq 120^{\circ}$ considered varus malalignment [11].

Statistical analysis

Statistical analysis was performed comparing two groups, patients with and without failure of fixation. Baseline patient and fracture characteristics were compared between groups with student *t*-test and Chi-square test for normally distributed data and Mann-Whitney U test for non-normally distributed data. Univariable logistic regression was undertaken to determine the association between failure of fixation and variables that could be potential predictors of failure. Variables with a p-value of 0.25 or less on the univariable analysis were entered into a multivariable model and the coefficients of the variables used to create a tool to predict the likelihood of failure of fixation of proximal humerus fractures. Results of the multivariable logistic regression were reported with odds ratios and 95 % confidence intervals. Statistical analysis was performed using STATA Version 13.1 (StataCorp LP, College Station, Texas, USA). Significance was set at $p < 0.05$.

Results

Patient overview

A total of 1700 patients with proximal humerus fractures were managed over the study period. Of these 189 patients underwent locking plate fixation for an acute traumatic fracture and met the study inclusion criteria. Within this cohort there was a rate of failure of fixation of 22 % ($n = 41$). Characteristics of the two groups (fixation intact ($n = 148$) and failure of fixation ($n = 41$)) are shown in Table 1. The failure of fixation group was associated with a higher mean age (56.1 years vs 49.9 years), a higher percentage of Neer 2 and 4-part fractures, a higher percentage of patients with a disrupted medial calcar hinge at time of injury and a lower mean cephalomedullary angle.

Table 1
Cohort characteristics.

Factor	Fixation Intact ($n = 148$)	Failure of Fixation ($n = 41$)	p-value
Age (years), mean (SD)	49.9 (16.0)	56.1(16.4)	0.03
Sex			0.51
Female	70 (47.3 %)	17 (41.5 %)	
Male	78 (52.7 %)	24 (58.5 %)	
Neer Classification			<0.01
1-part	0 (0.0 %)	2 (4.9 %)	
2-part	61 (41.2 %)	21 (51.2 %)	
3-part	56 (37.8 %)	6 (14.6 %)	
4-part	31 (20.9 %)	12 (29.3 %)	
Calcar length (mm), median (IQR)	9 (4, 17)	9 (0, 15)	0.56
Medial hinge intact			<0.01
No	82 (55.4 %)	32 (78.0 %)	
Yes	66 (44.6 %)	9 (22.0 %)	
Anatomic neck fracture			0.80
No	132 (89.2 %)	36 (87.8 %)	
Yes	16 (10.8 %)	5 (12.2 %)	
Cephalomedullary angle (degrees), mean (SD)	132.6 (36.1)	108.2 (34.2)	<0.01

Factors affecting fixation

Surgical variables are shown in Table 2. On univariable analysis there was an association with failure of fixation and a non-anatomical reduction of the medial calcar, a varus post-operative cephalomedullary angle and a lack of screws in the medial calcar region.

A multivariable analysis was performed adjusting for demographic variables, preoperative fracture characteristics and post-operative fixation characteristics. Variables adjusted for included age, Neer classification, disruption of the medial hinge at time of injury, preoperative cephalomedullary angle, anatomical reduction of the medial calcar, presence of calcar screws, and post-operative cephalomedullary angle. There was an association between increasing age, varus pre-operative cephalomedullary angle, non-anatomical reduction of the medial calcar and a lack of calcar screws with failure of fixation (Table 3).

The multivariable coefficients were used to generate a formula to create a predictive tool determining the risk of failure of proximal humerus fixation (Fig. 1).

An example of this tool is demonstrated in Fig. 2.

Sequelae of fixation failure

Failure of fixation was associated with multiple sequelae including a higher rate of delayed union and non-union, varus malposition, screw penetration of the articular surface, and radiographical avascular necrosis (Table 4). There was a higher rate of requiring a secondary or revision procedure in the group that had loss of fixation (42.4 %) in the recorded follow-up period compared to those that had successful fixation (10.3 %, $p < 0.01$).

Discussion

Surgical management of proximal humerus fractures remains technically challenging and locking plate fixation has been associated with a high rate of failure and complications [4,6,7]. Multiple adjuncts to standard lateral locking plate fixation have been described, including dual plating, cement augmentation, and fibula strut grafting with mixed results reported and heterogenous study populations [19–23]. Whilst these adjuncts may aid in complex fracture patterns with medial comminution, they come with associated increases in cost and risk. Thus improving surgical reduction and implant position has the potential to reduce the failure rate of fixation whilst avoiding an increase in cost and risk profile. Previous studies have found associations with failure of fixation and multiple patient factors and fracture characteristics including cephalomedullary angle, varus mal-fixation and presence of calcar screws [4,7,9–14]. The findings from this study highlight factors associated with fixation failure and apply those factors to create a predictive tool that allows surgeons to determine the risk of failure post fixation.

Table 2
Post-operative radiographic factors.

Factor	Fixation Intact ($n = 148$)	Failure of Fixation ($n = 41$)	p-value
Medial reduction gap (mm), median (IQR)	2 (0, 4.7)	4.6 (0.9, 7.9)	0.01
Tuberosity reduction			0.37
Non-anatomic	32 (29.4 %)	10 (38.5 %)	
Anatomic	77 (70.6 %)	16 (61.5 %)	
Cephalomedullary angle (degrees), mean (SD)	135.4 (11.4)	129.5 (13.3)	0.01
Number of screws in humeral head			0.67
Six or less	35 (23.6 %)	11 (26.8 %)	
More than six	113 (76.4 %)	30 (73.2 %)	
Presence of calcar screws			0.02
No	85 (57.4 %)	32 (78.0 %)	
Yes	63 (42.6 %)	9 (22.0 %)	
Screw distance to articular surface			0.69
0–4.0mm	79 (54.5 %)	16 (48.5 %)	
4.1–8.0mm	50 (34.5 %)	14 (42.4 %)	
>8.0mm	16 (11.0 %)	3 (9.1 %)	

Table 3
Results of multivariable analysis.

Variable	Multivariable logistic regression	
	Adjusted OR (95 % CI)	p-value
Age (per year)	1.04 (1.01 – 1.06)	0.01
Neer Classification		
1 and 2-part (reference)	1.00	
3-part	0.31 (0.11 – 0.91)	0.03
4-part	1.22 (0.47 – 3.17)	0.68
Medial hinge intact	0.85 (0.29 – 2.49)	0.77
Varus pre-op cephalomedullary angle (<120°)	2.84 (1.03 – 7.83)	0.04
Anatomical reduction	2.42 (1.08 – 5.40)	0.03
Presence of 1 or more calcar screws	0.30 (0.10 – 0.90)	0.03
Varus post-op cephalomedullary angle (<120 deg)	1.79 (0.66 – 4.89)	0.25

This study has demonstrated high rates of failure following proximal humerus fracture fixation with locking plates. The rate of loss of fracture fixation in this cohort was 22 % with this group exhibiting a higher rate of non-union, avascular necrosis and varus malposition, along with a greater rate of further surgery. These findings are supported by current literature where rates of failure of fixation remain high, particularly in elderly populations [10,24]. Barlow et al. in a series of 173 patients over 60 years of age undergoing proximal humerus locking plate fixation demonstrated an overall complication rate of 44 % with a failure rate greater than that of this study of 34 % [24]. Similar to the findings of our study, Owsley et al. had a 25 % rate of varus displacement post fixation along with a 23 % rate of screw cutout which was 43 % in those over 60 in their cohort of 53 patients [7]. Further Sudkamp et al. demonstrated an unplanned reoperation rate of 19 % within 12 months of fixation in their series of patients undergoing locking plate fixation [4], and Hardeman et al. in a cohort of 307 patients managed with surgical fixation found a failure rate of 15.3 % with a reoperation rate 23.8 % [10].

This study population identified multiple pre-operative and post-operative radiographic variables that were associated with failure of fixation. Pre-operative non-modifiable factors that were associated with an increased odds of fixation failure included patient age and initial varus displacement of the humeral head fragment. Most notably pre-operative varus cephalomedullary angle of <120° was associated with 2.84 times the odds of failure of fixation. These findings have the potential to be to identify patients that are at a high risk of fixation failure pre-operatively and where adjuncts to locking plate fixation can be employed in an effort to mitigate this risk. Multiple techniques have been described to improve fixation in proximal humerus fractures with mixed results. Dual plating has demonstrated promising results in improving fixation and patient outcomes [21], whilst fibula strut grafting has been shown to be of no additional benefit in a recent randomised controlled trial [23]. Other techniques described include cement augmentation of screw fixation in elderly patients which has been shown to reduce the risk of fixation failure [22]. However these treatments come with an increased cost of treatment, particularly in the setting of using fibula allograft, alongside adding complexity to revision or replacement surgery if required, and thus being able to predict which patients have a higher risk of failure will aid surgeons' decision making and patient selection.

Whilst patient and initial fracture characteristics are non-modifiable risk factors for failure of fixation, the incorporation of post-operative radiographic factors into the model gives the surgeon the ability to predict risk factors for failure using intra-operative imaging and improve fracture reduction and fixation technique. Proximal humerus fractures

Risk of failure = exp(z)/(1+ exp(z))
Where Z = -3.984 + 0.041 (age) + -1.163 (neer3) + 0.199 (neer4) + -0.162 (medial hinge) + 1.043 (preop angle) + 0.883 (reduction) + -1.210 (calcar screws) + 0.585 (postop angle)

Fig. 1. Formula for the predictive tool.
Age = age in years; Neer 3-part: neer3 = 1, Neer 4-part: neer4 = 1; medial hinge: not intact =0, intact =1; preop angle: varus cephalomedullary angle <120 = 1; reduction: non-anatomic medial calcar reduction =1; calcar screws: not present=0, present=1; postop angle: varus cephalomedullary angle <120 = 1.

Example 1
65 year old patient with a Neer 3-part fracture, intact medial hinge, and a cephalomedullary angle of 114°. Post fixation there is non-anatomical medial calcar reduction, no calcar screw and a post-op angle of 118°.

Risk of failure = exp(z)/(1+ exp(z)) = exp(-0.133)/(1+exp(-0.133)) = 47%
Where Z = -3.984 + 0.041 (65) + -1.163 (3-part) + - 0.162 (1) + 1.043 (1) + 0.883 (1) + -1.210 (0) + 0.585 (1) = -0.133

Example 2
34 year old patient with a Neer 2-part fracture, intact medial hinge, and a cephalomedullary angle of 130°. Post fixation there is anatomical medial calcar reduction, two calcar screws and a post-op angle of 140°.

Risk of failure = exp(z)/(1+ exp(z)) = exp(-3.962)/(1+exp(-3.962)) = 2%
Where Z = -3.984 + 0.041 (34) + 0 (2-part) + - 0.162 (1) + 1.043 (0) + 0.883 (0) + -1.210 (1) + 0.585 (0) = -3.962

Fig. 2. Examples of the predictive tool.

Table 4
Complications: Fixation intact vs Fixation Failure.

Factor	Fixation Intact (n = 148)	Failure of Fixation (n = 41)	p-value
Union			<0.01
United	121 (82.3 %)	17 (44.7 %)	
Delayed union	8 (5.4 %)	4 (10.5 %)	
Non-union	18 (12.2 %)	17 (44.7 %)	
Varus Malunion/ Malposition			<0.01
No	123 (83.1 %)	10 (24.4 %)	
Yes	25 (16.9 %)	31 (75.6 %)	
Articular screw penetration			<0.01
0	130 (89.7 %)	19 (57.6 %)	
1	15 (10.3 %)	14 (42.4 %)	
Subsequent surgery			<0.01
No	122 (82.4 %)	22 (53.7 %)	
Yes	26 (17.6 %)	19 (46.3 %)	
Avascular necrosis			<0.01
No	139 (93.9 %)	30 (75.0 %)	
Yes	9 (6.1 %)	10 (25.0 %)	

are technically challenging to manage surgically and anatomical reduction with ideal plate position is not always possible. The key post-operative radiographic factors, and thus modifiable risk factors intra-operatively, identified in this study include restoration of the medial calcar with anatomical reduction of the medial calcar within 2 mm, the presence of medial calcar screws and a post-operative cephalomedullary angle of greater than 120° all being protective factors for preventing failure of fixation. These elements in the predictive model allow the surgeon to ensure that with intra-operative imaging, varus mal-fixation with non-anatomical medial calcar reduction can be avoided and that screw trajectory can be guided to the medial calcar to provide calcar support to the fracture either with a modified plate position or the use of variable angle screw systems. Prior studies support these findings with increased rates of failure of fixation having been demonstrated with non-anatomical restoration of the medial calcar support and varus mal-fixation [9,10]. The parameters included in the predictive model are all readily available from pre-operative radiographs and intra-operative fluoroscopy making them applicable in a wide setting without the requirement for advanced imaging in all patients.

The design of this model could potentially allow the surgeon to counsel the patient and in older adults weigh the merits of fixation compared to arthroplasty more closely when managing fractures with a high risk of fixation failure. Further this model will external validation could have utilisation in future research, particularly as current literature comparing operative and non-operative management has failed to quantify the quality of reduction and its effect on patient outcomes when undergoing internal fixation [25]. The factors included in this model may be able to be used to classify the quality of surgical technique (eg. poor, moderate, good) to allow future comparative studies to determine differences in patient reported outcomes based on the quality of reduction.

The group of patients that had loss of fixation in this study were associated with high rates of non-union (45 %), avascular necrosis (25 %) and almost half of the patients in this cohort required revision surgery. Further 76 % of this cohort collapsed into varus with prior studies demonstrating worse patient reported outcomes with varus malunion of these injuries [10,14,26]. These findings demonstrate the importance of optimising reduction and fixation to reduce the risk of subsequent surgery, particularly as revision surgery and conversion to arthroplasty is associated with worse patient outcomes and higher healthcare costs [27, 28].

This study is not without limitations. The lack of a comprehensive classification system for proximal humerus fractures and the wide potential for variation in fracture pattern creates a heterogenous group of injuries to be compared. Further the Neer classification alongside other classification systems for these fractures are associated with poor interobserver reliability making accurate classification difficult [29]. Whilst anatomical parameters in addition to the Neer classification were included within the radiographic parameters, there is no discrete classification system that allows surgeons to readily differentiate higher energy injuries with severe comminution from lower energy injuries with preservation of bone stock. This has the potential to introduce bias into the results and effect the success of surgical fixation. This study was performed at a Level 1 trauma centre and thus the cohort of patients includes a wide array of injury mechanisms and demographic differences which may not reflect the cohort presenting to all orthopaedic units. The observational nature of this study likewise introduces the potential for bias, particularly noting the high rates of non-union and avascular necrosis within the fixation failure group and whether these factors were influenced by the failure of fixation or whether they were the cause of the failure. Lastly this model requires further validation in a separate cohort of patients to determine its accuracy at predicting failure in order to be able to confirm its utility as a clinical tool.

Conclusion

Rates of locking plate fixation failure in proximal humerus fractures remain high. This study has identified key pre-operative and intra/post-operative factors that can predict the risk of failure of fixation and be used to guide surgeons in their management. Whilst these injuries remain technically challenging to treat, this study has identified parameters that the surgeon can use, including restoration of the medial calcar, cephalomedullary angle, and presence of calcar support screws, to reduce the risk of fixation and failure and reduce the risk of avascular necrosis, varus malunion, non-union and the requirement for further surgery.

Ethics approval

Ethics approval was obtained through the institutional Human Ethics Committee (Alfred Health Ethics Committee – Project 73/19)

Statements and declarations

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CRediT authorship contribution statement

Filip Cosic: Writing – review & editing, Writing – original draft, Visualization, Validation, Resources, Project administration, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Nathan Kirzner:** Writing – review & editing, Investigation, Data curation. **Elton Edwards:** Writing – review & editing, Supervision, Methodology, Conceptualization. **Richard Page:** Writing – review & editing, Supervision, Conceptualization. **Lara Kimmel:** Writing – review & editing, Supervision, Methodology, Formal analysis, Conceptualization. **Belinda Gabbe:** Writing – review & editing, Supervision, Project administration, Methodology, Formal analysis, Conceptualization.

Declaration of competing interest

The authors have no relevant financial or non-financial interests to disclose.

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