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Complications following intramedullary nailing of proximal humerus and humeral shaft fractures: a systematic review

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Hypothesis: The purpose of this study was to systematically review complications arising from intramedullary nailing (IMN) of proximal and humeral shaft fractures. This study hypothesized that there would be a low rate of complications and revision among patients treated with IMN for humerus fractures.

Methods: Two independent reviewers performed a literature search in the PubMed database based on Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines. Studies were included if they reported on outcomes following the use of intramedullary nails for proximal humerus fractures or humeral shaft fractures. Variables that were collected included complications, visual analog scale pain scores and revision operations.

Results: Overall, 179 studies met the inclusion criteria, with 7984 shoulders. The average age of patients in this study was 55.2 years and 60.7% of patients were female. The mean follow-up was 16.6 months. The overall complication rate for all fractures treated with intramedullary nails was 18.9%, and the overall revision rate was 6.8%. Among the complications were fracture complications (7.5%), hardware complications (7.2%), soft tissue complications (1.8%), neurovascular complications (1.6%), and infection (0.8%). Four-part proximal humerus fractures (52.9%) and open fractures (36.7%) had the highest rates of complication. Among the reasons for revision were hardware removal or replacement (5.0%), conversion to arthroplasty (0.6%), and other (1.2%). The mean visual analog scale pain score at last follow-up was 1.6.

Conclusion: Overall, there was a moderate rate of complications but low rate of revision following IMN of humerus fractures. Open fractures and 4-part proximal humerus fractures had the highest complication rates.

Level of evidence: Level IV; Systematic Review

Keywords: Proximal humerus; humeral shaft; fracture; intramedullary; nail; IMN; complications

Humerus fractures are a common problem, especially among elderly patients, with proximal humerus fractures comprising over 50% of humeral fractures.[11,95] Both proximal humerus and humeral shaft fractures follow a bimodal distribution, with peak incidence in patients over the age of 60 due to ground-level falls and a smaller peak in

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younger patients following high-energy trauma.[32,38,190] While the majority of humerus fractures may be managed nonoperatively, operative treatment may be warranted in specific cases, including polytrauma, open fractures, pathological fractures, associated brachial plexus or radial nerve lesions, or when closed treatment fails to achieve satisfactory healing rates or alignment.[27,32]

The operative treatment strategy of humeral fractures depends on location and morphology and includes arthroplasty, open reduction and internal fixation, closed reduction percutaneous pinning, and intramedullary nailing (IMN), with IMN becoming increasingly utilized.[9,201] Despite achieving similar union rates, IMN has been associated with higher incidences of shoulder impingement, limited range of motion, hardware failure, and need for reoperation compared to alternative operations. However, these concerns are often related with older data and older implants, with modern nailing techniques designed to minimize these complications. As a result, there is a need for an updated systematic review of complications after IMN of humerus fractures.

Therefore, the purpose of this study was to systematically review complications arising from IMN of proximal humerus and humeral shaft factures. This study hypothesized that there would be a low rate of complications and revision among patients treated with IMN for humerus fractures.

Methods

Study selection

Two authors (K.A., K.L.) conducted a comprehensive literature search following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines.[112] Discrepancies were resolved through arbitration by a senior author (E.H.). All potential studies were assessed based on titles and abstracts, followed by a thorough full-text review.

Search strategy

In the PubMed database, a search algorithm using the terms (humerus or humeral) and (nail or intramedullary) was employed in December 2023. Publications between 2000 and 2023 were included.

Eligibility criteria

Inclusion criteria encompassed clinical studies addressing IMN usage, involving at least 5 patients, and published in the English language in a peer-reviewed journal. Exclusion criteria comprised review articles, cadaver-based studies, biomechanical studies, and abstract-only articles.

Data extraction

Two blinded reviewers (K.A., K.L.) systematically collected study characteristics utilizing a predesigned Microsoft Excel data sheet. Data included study design, patient demographics, complications, revisions, and pain assessments. Additionally, the level of evidence and methodological quality of evidence (MQOE) was calculated. The level of evidence was determined using criteria that adhered to the Oxford Centre for Evidence-Based Medicine guidelines.[73] MQOE was assessed utilizing a modified Coleman Methodology Score.[34] Studies were categorized as excellent quality if they scored between 85 and 100, good quality within the range of 70 to 84, fair quality between 55 and 69, and poor quality if the score was below 55. This assessment aided in stratifying the studies according to their methodological rigor. Fracture types were categorized into subgroups such as humeral shaft, open, pathological, and proximal humerus fractures (further classified according to Neer criteria).[147] Complications were categorized into fracture complications, hardware complications, soft tissue complications, neurovascular complications, and infection. Revisions were subcategorized into hardware removal or replacement, conversion to arthroplasty, and others. Complications and revisions for each fracture type were summated and averaged; the number of studies reporting complications and revisions was also collected. Pain assessments were conducted using the visual analog scale (VAS) pain scores, ranging from 0 to 10.[81]

Statistical analysis

Statistical analysis was performed using Microsoft Excel version 16.80 from Box, Inc. Raw data were collected and summarized as total and continuous variables. Descriptive statistics summarized patient demographics, complications, and revisions, presenting continuous variables as weighted means.

Results

Literature search

The initial literature search yielded a total of 1984 studies. After removing duplicates, 275 studies underwent screening based on inclusion and exclusion criteria from their titles and abstracts. Ultimately, 179 unique studies remained after the full-text review.[1-6,8,10,12,15,16,18-28,30,31,33,35-37,39-68,70-72,74-80,82-94,96-111,113-125,127-145,146,148-153,155-165,167-189,191-194,196-200,202] A visual representation of this process is illustrated in Figure 1.

Patient demographics

Among the 179 included studies, there were 8160 patients and 7984 fractures. The mean MQOE was 58.3. The patient cohort was predominantly female (60.7%), with an average age of 55.2 years (range 32-82.1 years) and a mean follow-up duration of 16.6 months (range 6-84 months). The study characteristics and patient demographics are shown in Table I.

Overall complication rate

Within the 7984 humerus fractures treated with IMN, the overall complication rate was 18.9%. Fracture

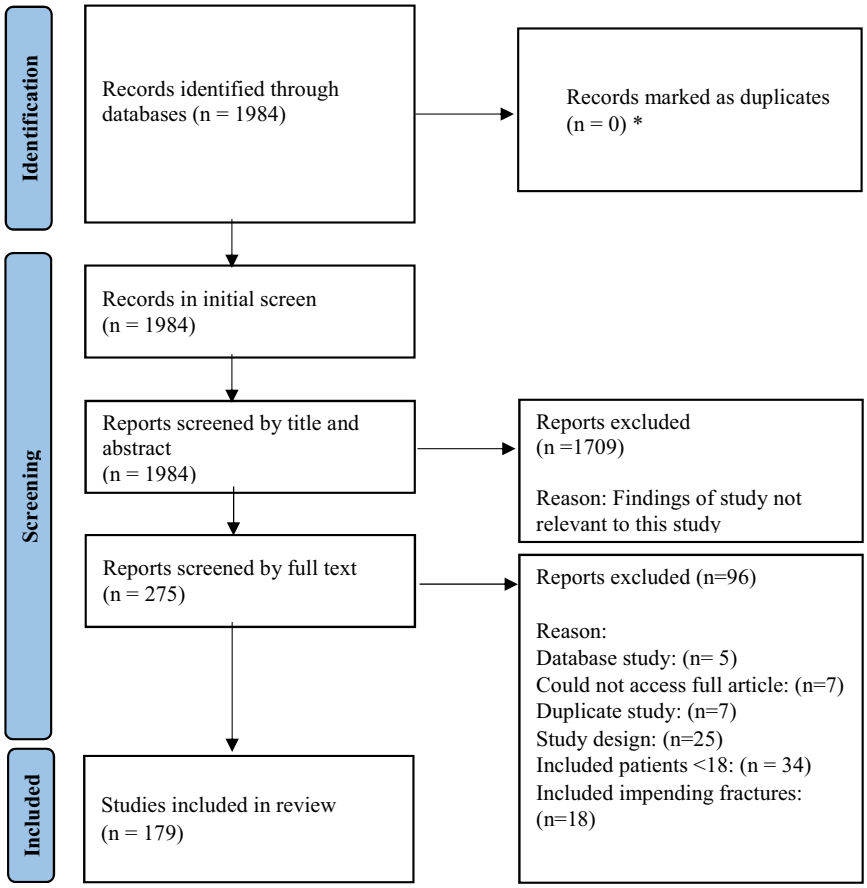

Figure 1 Prisma flow diagram.

complications (7.5%) and hardware complications (7.2%) were the most prevalent complications. Notably, nonunion accounted for the highest rate among fracture complications (2.8%), while screw migration was the most common hardware complications (3.6%). Reoperations were conducted in 6.8% of cases, predominantly for hardware removal or replacement (5.0%). Complication rate decreased by year of fracture with an R^2 of 0.0694. A comprehensive breakdown of complications are shown in Table II, and a visual representation of complication rate by year is displayed in Figure 2.

Pain

The mean VAS pain score was recorded at final follow-up. For all fracture types the mean VAS pain score was 1.6 (range = 0.2-3.9) with 788 patients reporting at a mean follow-up of 15.5 months (range = 9.2-72 months). The VAS pain score was highest in the humeral shaft group at an average of 1.85 (range = 0.2-2.3) with 189 patients reporting, at a mean follow-up time of 12.0 months (range = 10-35.6). Amongst proximal humerus fractures the average VAS pain score was 1.49 (range = 0.38-3.9) with 535 patients at a mean follow-up time of 16.5 months (range = 12.0-65.1 months). Other fractures reported an average VAS pain score of 1.02 amongst 64 patients.

Table I Summary of study characteristics and patient demographics

No. of studies	179
Patients (shoulders)	8160 (7984)
LOE	
IV	77
III	46
II	17
I	9
MQOE	58.3
% female	60.7
Age (yr)	55.2*
Follow-up (mo)	16.6*

LOE, level of evidence; *MQOE*, Methodological Quality of Evidence.
* Mean.

Proximal humerus fractures

In the cohort of 3211 patients treated with IMN for proximal humerus fractures, a total complication rate of 23.6%

Table II Total complications

Complications	No. of patients	%
Fracture complications	598	7.5
Nonunion	221	2.8
Malunion	161	2.0
Avascular necrosis	136	1.7
Delayed union	54	0.7
Iatrogenic fracture	26	0.3
Hardware complications	574	7.2
Screw migration	287	3.6
Nail migration	180	2.3
Other hardware issues	61	0.8
Broken nail	32	0.4
Broken screw	14	0.2
Soft tissue complications	144	1.8
Shoulder impingement	71	0.9
Rotator cuff injury	60	0.8
Adhesive capsulitis	8	0.1
Heterotopic ossification	5	0.1
Neurovascular complications	124	1.6
Radial nerve	98	1.2
Complex regional pain syndrome	15	0.2
Arterial injury	7	0.1
Posterior interosseous nerve	2	0.0
Axillary nerve	1	0.0
Brachial plexus	1	0.0
Infection	65	0.8
Superficial infection	35	0.4
Deep infection	18	0.2
Unspecified infection	12	0.2
Revisions	544	6.8
Hardware removal or replacement	398	5.0
Other	97	1.2
Conversion to arthroplasty	49	0.6
Visual analog scale (VAS)	788	1.6

was observed. The most frequent complications were hardware issues (11.2%) and fracture complications (9.1%). The overall revision rate stood at 9.4%, with hardware removal or replacement (4.6%) being the predominant reason. Complication rates varied among Neer classification categories, with 4-part fractures (52.9%) exhibiting the highest complication rates, followed by 3-part (24.2%) and 2-part fractures (14.0%). VAS was reported in 535 patients with a mean score of 1.5 and a mean follow-up time of 16.5 months. Proximal humerus complications and revisions are shown in Table III.

Humeral shaft fractures

In the cohort of 2854 patients treated with IMN for humeral shaft fractures, the total complication rate was 20.8%. Fracture complications (7.0%) and hardware complications (3.7%) were the most common complications. The overall revision rate was 9.9%, primarily for hardware removal or replacement (7.2%). VAS was recorded in 189 patients, with a mean score of 1.9 and a mean follow-up time of 12 months. Humeral shaft fracture complications and revisions are shown in Table IV.

Open fractures

In the cohort of 30 patients treated with IMN for open fractures, the total complication rate was 36.7%. Infection (30.0%) and fracture problems (6.7%) were most prevalent. Open fracture complications are shown in Table V.

Pathological fractures

In the cohort of 251 patients treated with IMN for pathological fractures, the total complication rate was 8.0%. Hardware complications (3.2%) and soft-tissue complications (1.6%) were the most common. Pathological fracture complications are shown in Table VI.

Discussion

The most important finding from this study was that IMN of humerus fractures demonstrated a subjectively moderate complication rate; yet a low revision rate. However, when comparing different fracture types, complication rates were highly variable with open fractures and 4-part proximal humerus fractures having the highest complication rate. Lastly, the mean VAS pain at the final follow-up was relatively low for all patients when considered as a single cohort and when stratified by fracture type.

This study demonstrated a subjectively moderate rate of complications among patients undergoing IMN of humerus fractures, most attributed to fracture complications, specifically nonunion. The majority of nonunions were reported in studies focusing on humeral shaft fractures. Previous literature has suggested that nonunion after IMN is largely due to technical errors, such as lack of or inadequate reaming, the use of small diameter or unlocked nails, and failure to eliminate fracture gap resulting in insufficient stability.[24,32,123,200] Lopiz et al[123] reported 1 nonunion in 110 patients when utilizing reaming, the widest possible nail diameter, and a third-generation straight IMN with an improved locking mechanism compared to earlier generations, suggesting that modifications of surgical technique and selection of the appropriate nail type and size may improve union rates.

Historically, antegrade IMN has been associated with shoulder impingement, due to proximally prominent screw or nail placement, and rotator cuff injury, as this technique requires entry through the rotator cuff. Hardware complications were prevalent in the literature, including screw and nail migration. However, the mean VAS pain score was relatively low across the total patient cohort and when

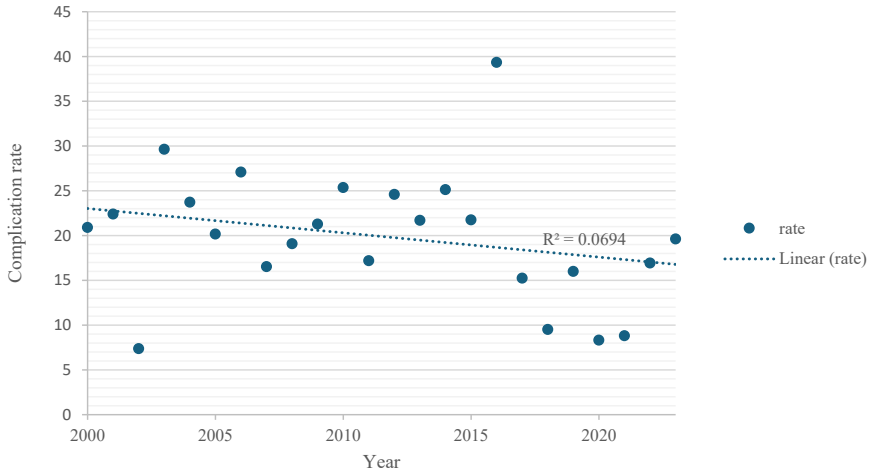

Figure 2 Complication rate by year.

Table III Complications by Neer type

Complications	All PHF % (N)	2-part % (N)	3-part % (N)	4-part % (N)	*P* value for 2-4 part
Fracture complications	9.1 (293)	4.3 (17)	0.1 (30)	26.9 (32)	.1
Hardware complications	11.2 (359)	3.1 (12)	9.0 (19)	11.8 (14)	.21
Soft tissue complications	1.0 (32)	2.8 (11)	0.5 (1)	31.1 (5)	**.01**
Neurovascular complications	1.5 (49)	2.8 (11)	0.5 (1)	9.2 (11)	**.02**
Infection	0.8 (24)	1.0 (4)	0.0 (0)	0.8 (1)	.07
Total complications	23.6 (757)	14.0 (55)	24.2 (51)	52.9 (63)	-
Revisions	9.4 (302)	7.1 (28)	4.3 (9)	13.4 (16)	-

PHF, proximal humerus fracture.
$P < .05$ are indicated in bold.

analyzed by fracture type. Additionally, shoulder impingement and rotator cuff injury were reported in only a minority of patients and all but 2 of these patients were treated with antegrade nailing, when surgical technique was specified. Retrograde nailing has been proposed as a potential method to mitigate shoulder impingement and rotator cuff injury; however, it is not without risks, such as elbow joint stiffness and iatrogenic fracture.[7,154] When comparing retrograde vs. antegrade IMN, Cheng et al[28] found that an antegrade approach resulted in increased limitation of shoulder elevation and a prolonged recovery for shoulder function. However, with appropriate patient selection and experienced surgical technique, both treatments can achieve optimal results.

Furthermore, prior research has suggested that the use of newer generation nails may reduce complication rates.[17,121,123] Lopiz et al[121] found a 39% reduction in rotator cuff injury when comparing a newer, straight nail to an older, curved design. This difference was attributed to the fact that the straight nail facilitates a more medial entry point, thus avoiding rotator cuff tendon insertion violation and minimizing shoulder pain. Boileau et al[17] echoed this perspective, emphasizing a nail entry point posterior and medial to the bicipital groove, with exact placement determined by displacement of the humeral head. Similarly, Saltzman et al[166] showed through anatomic and radiographic analyses that the optimal insertion point for IMN placement through the rotator interval is situated on the medial side of the lateral third of the humeral head on anteroposterior view and on the posterior side of the anterior third of the humeral head on lateral view. The majority of studies in this review did not specify nail type used. However, our review suggests a decreasing trend in complications over time, possibly reflecting the increasing adoption of newer generation nails and modified surgical techniques in recent studies, although this trend was relatively weak.

Despite the moderate complication rate, this study observed a low revision rate. The difference in complication and revision rate is likely due to many of the reported complications not requiring a revision surgery. Literature reporting on revision rates following IMN has been

Table IV Humeral shaft fractures

Complications	No. of patients	%
Fracture complications	199	7.0
Hardware complications	106	3.7
Soft tissue complications	131	4.6
Neurovascular complications	133	4.7
Infection	24	0.8
Total complications	593	20.8
Revisions	283	9.9

Table V Open fractures

Complications	No. of patients	%
Fracture complications	2	6.7
Infection	9	30.0
Total complications	11	36.7

Table VI Pathological fractures

Complications	No. of patients	%
Fracture complications	2	0.8
Hardware complications	8	3.2
Soft tissue complications	4	1.6
Neurovascular complications	3	1.2
Infection	3	1.2
Total complications	20	8.0

inconsistent, with some studies reporting rates comparable to other surgical treatments, while others suggest higher revision rates after IMN.[14,86,126,195] Given the variability in complications and revisions, it is important for future research to identify specific risk factors contributing to increased complications following IMN of humerus fractures.

Moreover, a wide variation in complication rates was noted based on fracture type, with open fractures exhibiting the highest complication rate, primarily due to infection, a common postoperative complication for open fractures irrespective of treatment. Nevertheless, IMN has been reported to have a lower infection rate compared to alternative treatments like plate fixation.[13,69,86] Additionally, there was a higher complication rate reported in proximal humerus fractures, particularly in the case of 4-part proximal humerus fractures. Willasuchus et al[196] reported that 4-part fractures led to more than twice the complications experienced by patients with 2- and 3-part fractures. In the current study, most of these complications were related to avascular necrosis, which in 4-part fractures were twice that of 3-part fractures and nearly 4 times that of 2-part fractures.

Complications were least frequent among humeral shaft and pathological fractures. Consistent with prior literature, IMN has demonstrated satisfactory results in treating these specific types of fractures.[29,86,154] Given the varying risk of complications depending upon fracture type, there is a need for future studies to evaluate postoperative complications by fracture type. While IMN may be an effective treatment option for pathological and humeral shaft fractures, its efficacy may be less pronounced for proximal humerus fractures, especially 4-part fractures. Therefore, it is essential to identify these differences to provide appropriate counseling to patients regarding the risk of complications based upon fracture type and complexity.

Previous literature has raised concerns about the rate of complications following IMN as compared to plate fixation.[201] However, more recent analyses have demonstrated that both techniques yield comparable functional outcomes and complication rates.[171,172,200] Nevertheless, IMN is associated with lower infection rate and shorter operative time and time to union.[86,171] Therefore, when selecting the best treatment, it is important to consider surgeon preference and patient-specific variables, such as age. IMN may benefit elderly patients due to its minimally invasive nature, reduced infection risk, and shorter operative duration.

Limitations

This study has several limitations. The majority of studies were retrospective or nonrandomized prospective studies, and as such, their inherent limitations are applicable to the analysis. Additionally, many studies investigated multiple types of proximal humerus fractures but failed to separate outcomes by type. Therefore, these studies could not be included in final analysis of complication rate by proximal humerus fracture type, ultimately limiting the analysis. Similarly, the final VAS pain score was reported in only 23 out of the 179 included studies, further limiting evaluation of pain after IMN of humerus fractures. Furthermore, it was not possible to analyze the complication rate by specific implant or generation of nail, and thus, year of publication was used instead to show trends over time.

Conclusion

Overall, there was a moderate rate of complications but low rate of revision following IMN of humerus fractures. Open fractures and 4-part proximal humerus fractures had the highest complication rates.

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