

Original Research Article

Clinical outcomes of the intramedullary humerus nailing system in the treatment of humerus fractures

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ABSTRACT

Background: After femoral and tibia bone fractures, the humerus fracture is the third long bone fracture. The purpose of this study was to clinically evaluate the outcomes of treating humerus fractures with an KN-5H humerus nailing system. The fixation of humerus fracture especially shaft fractures from intramedullary humeral nail the clinical outcomes obtained from the retrospective study of humerus nailing system on humeral fracture is controversial feature in surgical technical research, follow-up factors, and implants.

Methods: In this retrospective study of KN-5H humerus nailing system (KN-5H intramedullary cannulated humerus nail, KN-5H reconstruction nail, cannulated and KN-5H reconstruction cannulated intramedullary humerus nail) manufactured by the Kaulmed Pvt. Ltd. is used. The total 26 patients from which 11 males and 15 females between the age group of 18-70 years with humerus fracture were taken. Patients didn't received conservative management. The fractures were categorized based on AO classification and Neer type. The post-operative clinical effectiveness was evaluated using the Radiological evaluation, VAS score and Functional ROM results.

Results: The mean follow-up period was 15 months (range 13 to 24 months). The mean time of union was 14 weeks (range 10 to 18 weeks) in 26 patients. No non-union occurred in any patients. Functional end results of shoulder and elbow were excellent in 92.3% patients, moderate 5.75% patients and poor in 1.95% patients. Postoperative complications included one superficial infection, 3 patients had nail impingement complain, one patient has shoulder stiffness and had pain in adduction. No implant related complication was reported.

Conclusions: The treatment of proximal and diaphysis humerus fracture is highly recommended using intramedullary humeral nailing due to lower post-operative complication with high union rate.

Keywords: Intramedullary nailing system, Humerus bone fracture, VAS score, IM nails, Plate osteosynthesis

INTRODUCTION

Humerus fractures occurrence accounts for 7-8% of all fractures.¹ Although fractures of humerus at different locations has different incidence. Proximal humerus fractures has the most occurrence which account for 5-6% of all fractures observed in accident and emergency departments and are more prevalent in the elderly particularly in the women.¹⁻³ The humerus fracture has >10% occurrence among children. The majority of humerus fractures among paediatric population, about

70% are distal humerus fracture (supracondylar fractures) while proximal humerus fractures accounts for 24% followed by diaphysis fracture of about 4%.⁵ Humerus shaft fractures has relatively low occurrence of 1.2% and shows bimodal distribution for men and women which means occurrence of such fractures are more frequent among young and old age population.^{1,6,7} On the other hand, the distal humerus fractures has very low incidences of 0.5% with prevalence of 5.8-8.3 cases/10⁵ of population.^{1,8} Moreover the incidences of humerus fractures also depends on the geographic location and

demographics of that region.^{2,7} In all of the studies associated with the epidemiology of humerus fracture, it is found that the female population has higher occurrence of such fractures and shows bimodal distribution for all fractures in humerus bone.

The main reason for the humerus fractures in younger population is the result of high energy trauma, while in elderly it is low energy trauma. The latter is the result of osteoporosis in the elderly population.⁹ The proximal and distal humerus fractures are predominantly found in the elderly population because of low energy trauma which are managed using operative or non-operative techniques whereas humerus shaft fractures are usually the result of high energy trauma.¹

The treatment of the humerus fractures depends on the patient's associated injury. The treatment includes conservative treatments, internal fixation through plate and IMN (Intramedullary nail) fixation and external fixator. The choice of the treatment associated with patient's injury. Majority of humerus fractures are treated non-operatively and usually recommended for stable, minimally displaced fractures or fractures with minimal articular surface involvement. Although, the treatment of proximal humerus fracture is debatable due to differences in the management of different types of fractures.¹⁰⁻¹⁴ The non-operative treatment complications includes osteonecrosis, nonunion, malunion, stiffness and rotator cuff dysfunction.¹² Due to the high occurrence of proximal humerus fractures in older patients with osteoporotic bone which prevent stable internal fixation, usually non operative treatment is preferred with some exceptions.^{15,16} The operative fixation of proximal humerus fractures is indicated for the complex fractures because of, high energy trauma in adults which includes fixation techniques from Nail, plate or arthroplasty.^{2,17} A study conducted by Xiaoqing et al shows that IMN nail for humerus shows better result as compare to plate fixation for the treatment of proximal humerus fractures, although plate fixation offer treatment of different type of fracture which lacks in the treatment from IMN.²¹ The operative treatment for humerus shaft fractures shows better functional results compared to non-operative treatment.¹⁸ As compared to the plate fixation in the humerus shaft fractures, use of IMN shows lower risk of infection, secondary radial nerve palsy and shorter operation duration.^{2,19} The distal humerus fracture are managed non-operatively or operatively using plate fixation.²⁰

In the case of operative treatment for humerus fractures there are wide variety of implants are available but to date there is no consensus method of reduction and fixation. Intramedullary nailing system was introduced to reproduce the success seen with the IMN technique in the lower extremities. The expected advantages of IM nails for humerus includes less soft tissue mutilation, closed reduction and periosteum-sparing stabilization in complex fractures. However, several complications were reported

which gets reduced due to advancement in design and technology which have led to better results.²²

The primary objective of this study to evaluate the performance of intramedullary humerus nailing system by assessing the functional and clinical assessment of patient who were treated using the intramedullary humerus nailing system manufactured by Kaulmed Pvt. Ltd., India. The system includes KN-5F Intramedullary cannulated humerus Nail, KN-5G reconstruction Nail, cannulated and KN-5H reconstruction cannulated intramedullary humerus nail along with other fixation screws and end caps as shown in Figure 1.

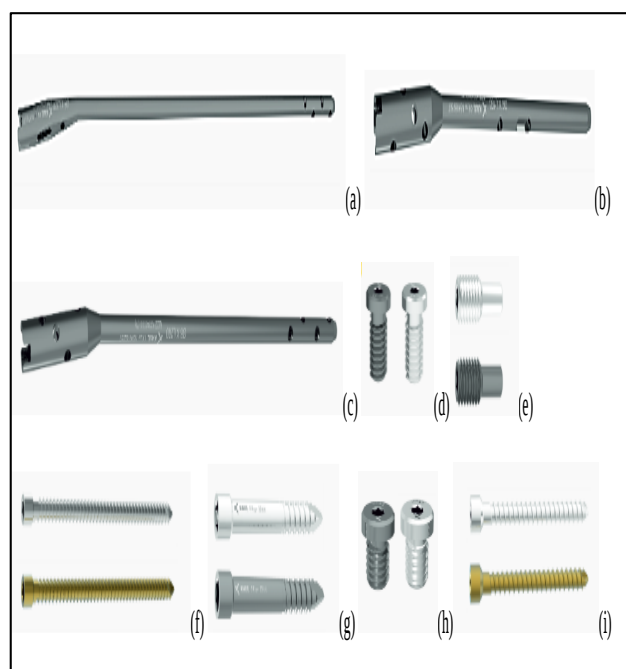


Figure 1 (A-I): Humerus nailing system-KN-5H intramedullary cannulated humerus nail, KN-5H reconstruction nail, cannulated, KN-5H reconstruction cannulated intramedullary humerus nail, end cap for KN-5H intramedullary humerus nail, compression screw for KN-5H intramedullary humerus nail, $\varnothing 4.5$ mm locking bolt, self-tapping, for KN-5 nail, $\varnothing 4.5$ mm proximal screw, end cap for KN-5H reconstruction cannulated intramedullary nail and $\varnothing 3.5$ mm locking bolt.

METHODS

A retrospective study of 26 patients with humerus fracture was carried out at Mesoamerican university, Quetzaltenango, Guatemala. Data was gathered from the patients treated with the KN-5H humerus nailing system during October 2021 to September 2022. Total 40 patient were screened who have humerus fracture and eligible for operative treatment. Out of which 26 patients are selected in a row who met the inclusion criteria. The data collected from the hospital includes age, gender, fracture type, Aetiology of injuries and post-operative visits assessment.

The study is approved by the institutional ethics committee.

Inclusion criteria

Male or female participants who were at least 18 years old and had recently suffered a proximal humerus and humerus shaft fractures due to an injury between 12 to 72 hours before pre-operative investigation were included in the research. The patients included in the study have suffered from the fractures that are amendable from the humerus nailing system. The patients with minimum follow-up period of twelve months are included in the study.

Exclusion criteria

Patient age greater than 80 years; compounded fracture; Proximal humerus and shaft fractures along with fracture in other limbs, pathological fracture; Subjects who had problems with alcohol abuse, those who were detained or were in the process of being detained, those who had an infection at the site of the operation, patients who had any active local infections, those who had an allergy to the metal, ASA grade greater than II, open fractures (Gustilo-Anderson IIIa and IIIb) and patients who had problems with neuromuscular diseases were also excluded from this study.

Treatment

The patients with traumatic cases of proximal humerus and humerus shaft fracture were assessed whether operative management is required or not. The assessment was based on the radiograph taken during emergency treatment. The patients who required open reduction and fixation with intramedullary nail were then admitted and planned for surgery.

The surgery was performed based on the AO principles of fracture management that includes Anatomic reduction followed by stable fixation, early, active mobilization and preservation of blood supply. The surgery was carried out using a tibia plate made of titanium alloy (Ti-6Al-4V) or stainless steel (316LRM) manufactured by Kaulmed private limited in Sonapat, Haryana, India. The surgical approach followed for intramedullary humerus nailing fixation is based on the technique provided by Kaulmed Pvt. Ltd. The method of approach can be referenced from review article by Balkar et al.² Post-operative immobilization period is for 6-7 weeks in an abduction pillow sling, though immediate wrist, hand, elbow and passive shoulder ROM is permitted. Physiotherapy exercise includes pendulum exercise which can be done after surgery while actively-assisted and full ROM exercise begins after 4-8 week depending on fracture healing. Sutures are typically removed after 4-6 weeks. The full weight bearing can be done after the twelve weeks.

Statistical analysis

All statistical analyses performed using Minitab. Results are reported as means $\pm$ SD for continuous variables and number (%) for nominal variables. Endpoints summarized using descriptive statistics (Mean, median SD, minimum, maximum). For normal distribution, parametric tests will be applied; otherwise, equivalent non-parametric tests will be applied for analysis. For normally distributed data, intra group at various follow-up using paired t test using statistical software. $P \leq 0.05$ to be considered as statistically significant.

RESULTS

From 26 patients who were selected as part of the retrospective clinical study to evaluate the performance of Intramedullary humerus nail, 11 were men and 15 were female (Table 1). The Female patients were more vulnerable in the study. The youngest patient in our series was 20 years and the oldest 69 years. The patient's average age was 43.8 years, as indicated in (Table 1). In adults the primary cause of proximal tibia accidents includes vehicle accidents, fall from height and sport injury whereas in elderly (age > 65) the primary cause includes low energy trauma that includes fall different activities (Table 2). According to the AO/OTA classification and Neer classification, fractures in the humerus bone were classified in this study into the following categories: 11A2-A3 (2-part fracture), 11B1 (3-part fracture), 11C1-C3 (4-part fracture), 12 A/B/C (shaft fractures); 5 patients had 11A type fractures, 4 patients had 11C type fracture, 2 patients had 11C type fracture and rest 15 patients has diaphysis or shaft fracture (Table 3). Patient with soft tissue injury also given in the Table 3. The mean follow-up period was 15 months (Range 13-24 months).

Table 1: Demographic data.

Demographics	Percentage (%)
Sample size	26 (100)
Mean age (years)	43.8 (20-69)
Range	Youngest: 20 years, oldest: 69 years
Male	11 (42.3)
Female	15 (67.7)
Adults	22 (84.6)
Elderly	4 (15.4)

Table 2: Aetiology.

Fracture cause	Percentage (%)
Adults (22)	
Motor vehicle accidents	12 (54.5)
Slip and fall	8 (36.7)
Other (sports, etc.)	2 (8.8)
Elderly (4)	
Motor vehicle accidents	1 (25)
Slip and fall	3 (75)

Table 3: Injury description.

Variables	N
AO fracture type	
11 A2-A3 (2-part fracture)	5
11 B1 (3-part fracture)	4
11 C1-C3 (4-part fracture)	2
12 A/B/C	15
Soft tissue injury	
Gustilo-Anderson I	6
Gustilo-Anderson II	3
Gustilo-Anderson III	1
Closed fracture	16
Side of fracture	
Left	15
Right	11

Out of 26 patients, 19 were classified as ASA I (a normal healthy patient) and 7 as ASA II (a patient with a mild systemic disease). At each follow up, radiological evaluation was performed to assess bone union progress. Meantime taken for full bone union was 14 weeks with a range of 10-18 weeks. No patient had delayed union and non-union. At each follow up, functional assessment was performed using ROM of shoulder and elbow and clinical assessment was performed from pain evaluation using VAS scale and measuring complication rate.

Functional assessment

The overall functional assessment was excellent in 92.3% patients, moderate in 5.75% patient and poor result in 1.95% patients (Table 5).

Table 4: Grading of functional assessment.

Grades	ROM of shoulder and elbow
Excellent	<10° loss of ROM in any direction
Moderate	10°-30° loss of ROM in any direction
Poor	>30° loss of ROM in any direction

Table 5: Result of functional assessment.

Grades	Shoulder, n (%)	Elbow, n (%)
Excellent	23 (88.5)	25 (96.1)
Moderate	2 (7.7)	1 (3.8)
Poor	1 (3.8)	0 (0.1)

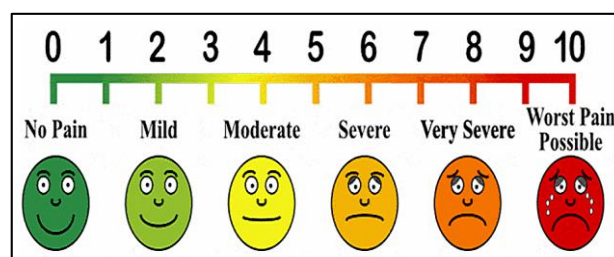
Clinical assessment

Pain was recorded for each patient at their respective visits through VAS score (Figure 2), the average pain scale at 3 week was 5.4, 3.4 in 16-week and 1.2 in 24 weeks. The pain due to implant impingement was 1.2 after 12 months.

Complications

There were no pre- or intra-operative complication noted. The post-operative complication includes superficial

infection in 1 patient, 3 patients had nail impingement, 1 patient had shoulder stiffness and had pain in adduction. No non-union and mal-union was observed in the patient assessment. No Implant related complication was reported.

**Figure 2: VAS scale.**

DISCUSSION

The non-operative approach or conservative management is the preferable treatment method in simple fracture but takes longer duration to heal and return of patient to daily activities. Moreover, the conservative approach does not produce effective result in case of complex fracture of proximal humerus and shaft. Due to this, operative stabilization is preferred by both the patients and surgeon. The operative approach provides patient with rapid relief of symptoms and restoration of Joints.

For the operative approach, intramedullary nail and locking plate fixation have been the main choice of internal fixation in the case of proximal humerus fracture and humeral shaft fracture. The decision for the use of which internal fixation device is a debatable issue. The bio-mechanical comparative study by Edward et al shows locking plates has advantage over IM nails in bending and torsional resistance while similar study by Kitson shows nail is superior to plate in terms of axial, torsional and bending load.^{23,24} Plate osteosynthesis has yielded high success rate but requires extensive dissection with the risk of radial nerve damage and refracture after implant removal. Advantages of intramedullary nailing have made it the choice of surgical treatment, but the use of unlocked flexible nails has been complicated by poor rotational stability and slipping of the nails causing joint irritation.²⁵ Locked nailing overcomes these deficiencies, and results in satisfactory therapeutic outcome. It has been considered the treatment of choice in humeral shaft fractures in the recent past.²⁶

In this study, we have evaluated post-operative results of the intramedullary humerus nail used the patient with proximal humerus fracture and humeral shaft fracture. Out of 26 patients selected in the study, 11 were men and 15 were women and mean age is 43.8 years, which confirms the epidemiology data as shown in study by Charles et al.¹ The aetiology data suggests that a younger population is more prone to having humerus fractures due to driving two-wheelers and indulgence in more physical activities like sports, while older population is likely to have such injuries primarily due to fall. The data correlates with

epidemiology study by Tytherleigh et al.⁶ The majority of patients that are selected for the study are adults and suffered humerus fracture due to high energy trauma while some elderly patients included had humerus fracture injuries due to low energy trauma. The majority of humerus fractures are shaft fractures followed by proximal humerus fractures while distal humerus fractures injuries are not the part of the study. This data does not correlate with the results shown in the study by Charles et al, this is due to fact this study is for intramedullary humerus nail which is primarily recommended for the shaft fractures.¹

The post-operatively results show no major complication which require re-intervention or re-surgery. There was no delayed union and non-union. The results in this study aligns with the results from the meta-analysis by Xiaoquig et al.²¹ The benefits of using IM nail is proximal and shaft fractures of humerus are less intra-operative blood loss, operation duration, fracture healing time, post-operative complication and post-operative complication which show significant results as compare to locking plate osteosynthesis.²⁷ The IM Nails also show better function and clinical results in terms of radiographic evaluation, ROM, VAS and complication rates in this study. Potential deleterious effects of antegrade humeral nailing on shoulder function have been debated the most. This can be due to impingement of proximal nail tip or proximal locking screw due to adhesive capsulitis or due to rotator cuff tears. In most of the studies with antegrade nailing, 80-95% of patients regained their normal shoulder function.²² In the study by Ozturkmen et al excellent therapeutic outcome was reported in 80% patient while it was moderate in 13%, and poor in 8% patients.²⁸ In our study, 92.3% patients had excellent shoulder function with near normal range of motion of shoulder while 5.75% had moderately good shoulder function. These patients had impingement of the proximal end of the nail. One patient had severe shoulder stiffness with significant restriction of shoulder motion.

Early mobilization of elbow and shoulder is critical in attaining full ROM post-operatively in patient having humerus fracture. The movements and the functional ability of the shoulder depend on the patient's adherence to rehabilitation program and early intensive physiotherapy hastened the recovery of shoulder function.

Closed intramedullary nailing with an interlocking nail is a safe and reliable method of treating humeral shaft fractures. Among available surgical modalities, closed nailing is the least invasive surgical technique and has the least chance of post-operative infection. It reduces the duration of the hospital stay. Complications like non-union can be avoided by intraoperative compression and avoiding distraction at fracture site. Certain technical aspects like burying the proximal nail end at the entry portal are essential in avoiding impingement and to gain better shoulder function.

In the current study, a humerus fracture is treated with an intramedullary nailing device created and produced by Kaulmed private limited, India. Our study's limited sample size and retrospective methodology were its main drawbacks. Despite these limitations, the results were in line with what we had anticipated before the clinical trial ever started. Although the primary clinical outcome in the current trial was pain, the data indicate that pain can be reduced with good results in a shorter amount of time. No significant complications such as mal-unions, non-union, or deep infection was found.

CONCLUSION

Closed intramedullary nailing is an excellent, least invasive surgical option available to manage humeral shaft fractures with early fracture consolidation and better union rates. It decreases the hospital stay, provides early rehabilitation and reduces morbidity. It is ideal in patients with poly-trauma and osteoporosis. Early intensive physiotherapy hastens the recovery of shoulder function.

The current retrospective case series, demonstrates the effectiveness of KN-5H humerus nailing system as treatment with a high percentage of union without any clinical, functional and bio-mechanical complications.

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Conflict of interest: None declared

Ethical approval: The study was approved by the institutional ethics committee

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