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Original Article

Outcome of Locked Reamed Intramedullary Nail V/S K-Nail Plus Augmented Plating in Aseptic Distal Femur Non-Union

Syed Zain Abbas[1], Muhammad Waqas Azam[2], Shuja Uddin[3]*, Abdul Waqas[4], Junaid Khan[5], Sohaib Ilyas[5], Muhammad Kahlid Syed[6]

[1]Consultant Orthopedic, DHQ- Gujranwala- Pakistan.
[2]Consultant Orthopedic, DHQ- Johrabad- Sarghoda- Pakistan.
[3]Consultant Orthopedic, Lahore General Hospital, Lahore, Pakistan.
[4]Registrar, Orthopedic Unit 1, LGH- Lahore- Pakistan.
[5]PG, Orthopedic Surgery, LGH- Lahore- Pakistan.
[6]Professor of Orthopedic Surgery, LGH- Lahore- Pakistan.
Corresponding Author: Shuja Uddin, Consultant Orthopedic; Email: drshujauddin111@gmail.com

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ABSTRACT

Background: Aseptic nonunion of the distal femur presents a significant challenge in orthopedic surgery, affecting patient outcomes and healthcare systems. Traditional treatments include locked reamed intramedullary nailing (LRIN) and K-nail with augmented plating, with varied reported efficacies.

Objective: The study aimed to compare the outcomes of LRIN versus K-nail plus augmented plating in the treatment of aseptic nonunion of the distal femur, focusing on union rates, operative time, complications, and functional recovery.

Methods: In this prospective comparative study, 50 patients with aseptic nonunion of the distal femur were randomly assigned to undergo either LRIN (Group A) or K-nail plus augmented plating (Group B). The primary outcome measures included the modified Radiographic Union Score for Tibial fractures (mRUST) and rates of implant failure and infection. Secondary outcomes considered operative time and intraoperative blood loss. Statistical analysis was performed using SPSS version 25, with a p-value of less than 0.05 deemed significant.

Results: Group A exhibited higher mRUST scores at 12 weeks (4.84 vs. 4.16, p=0.010), 24 weeks (6.40 vs. 5.48, p<0.001), and 36 weeks (8.12 vs. 7.00, p<0.001). Nonunion rates at 36 weeks were lower in Group A (12% vs. 36%, p=0.047), with no significant differences in infection rates. Operative time was significantly longer for Group A (159.40±5.82 minutes) compared to Group B (123.96±6.20 minutes, p<0.001), but there was no significant difference in blood loss between the groups.

Conclusion: LRIN outperformed K-nail plus augmented plating in promoting bone union in aseptic nonunion of the distal femur, with a lower nonunion rate and higher mRUST scores, despite a longer operative time.

Keywords: Aseptic Nonunion, Distal Femur, Locked Reamed Intramedullary Nailing, K-nail Augmented Plating, Bone Union, Orthopedic Surgical Techniques, mRUST Scores, Implant Failure, Intraoperative Blood Loss, Operative Time.

INTRODUCTION

Long bone non-unions significantly impact patient quality of life and impose a substantial socioeconomic burden. These non-unions are often due to a combination of mechanical and biological factors, including inadequate immobilization, comminution, bone defects, low vascularity of fracture fragments, poor soft tissue coverage, and localized infection (1). The characteristics of the patient and the nature of the fracture play crucial roles in the development of non-unions. As surgical techniques and the development of implants have advanced, there has been a shift towards surgical intervention, providing reliable stability and enabling early mobilization. Nevertheless, non-unions in the diaphyseal regions of long bones like the tibia and femur remain challenging to treat (2).

Historically, intramedullary nailing has been the standard treatment for acute adult femur shaft fractures. Research by Luo et al. indicates that the nonunion or delayed union rates for femoral shaft fractures treated with intramedullary nailing are less than 2% (3). Various treatment options for femoral shaft nonunion or delayed union include exchange nailing for a larger size, augmentative plating alongside nailing, dynamization, bone grafting alone, and applying a compression plate following nail removal (2,3).

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Techniques such as nail dynamization, exchange nailing, augmentation plating, and bone transportation with external fixation are currently employed to address diaphyseal long bone non-unions. Exchange nailing, in particular, is favored for its biological and mechanical advantages, although studies have shown mixed results regarding its effectiveness, and the technique has its limitations (4).

Despite the proven efficacy of compression plating for humeral shaft non-unions (5), this method is rarely emphasized for tibial or femoral diaphyseal non-unions, particularly when complicated by infection and bone loss (6). This study was conceived to compare the outcomes of locked reamed intramedullary nail (LRIL) versus K-nail plus augmented plating in aseptic nonunion of the distal femur. A review of the literature suggested that the K-nail plus augmented plating approach might be more successful for treating nonunion of the distal femur than reamed nailing. Both techniques have been applied with almost equal efficacy in the few studies conducted on this topic. While some research supports reamed nailing, others advocate for the augmented plating with nailing approach. Historically, there has been limited research in this area, particularly a lack of local evidence from Pakistan (7-9).

The objective of this research was to compare the effectiveness of LRIL versus K-nail plus augmented plating in treating aseptic nonunion of the distal femur, specifically examining operative time, bony union, and infection rates. This study aims to provide evidence to determine which technique offers a more successful approach, with the goal of implementing the findings in local clinical settings to benefit the general population.

MATERIAL AND METHODS

This prospective comparative study was conducted in the Department of Orthopedic Surgery at Lahore General Hospital, Lahore, over a duration of 12 months following the approval of the study synopsis. Ethical approval for the study was granted by the PGMI/LGH Ethical Review Committee (ERC No. 00/86/22) on 7 January 2022. The sampling technique employed was non-probability convenience sampling.

Participants included in the study were aged between 20 and 60 years, of either gender, who presented with aseptic nonunion of the distal femur and had undergone previous surgical treatment. A total of 50 patients who met these inclusion criteria and provided informed consent were enrolled from the indoor ward. These patients were randomly assigned to two treatment groups using a random number table generated in Microsoft Excel by a computer operator (10).

Group A patients underwent surgery using the locked reamed intramedullary nail technique with bone graft through a lateral approach, while Group B underwent surgery using the K-Nail plus augmented plating technique, also through a lateral approach under spinal anesthesia. A single surgical team, assisted by the researcher, performed all surgical procedures (11).

Postoperative follow-up was conducted in the outpatient department at intervals of 6, 12, and 24 weeks, and at the final visit, during which patients were evaluated for bone union using the modified Radiographic Union Score for Tibial fractures (RUST) and for complications such as infection, based on the Southampton criteria, and for implant failure or persistent nonunion. All patient data were systematically collected through a specially designed proforma (2, 4, 7).

Data analysis was performed using SPSS version 25. Quantitative variables such as age, duration of previous surgery, operative time, and intraoperative blood loss were presented as means and standard deviations. Qualitative variables, including gender, anatomical side of the fracture, union status, and complications, were reported as frequencies and percentages. Statistical comparisons between the two groups were made using independent samples t-tests for mean operative time and intraoperative blood loss, and chi-square tests for union status and complications. Stratification of the data was done for age, gender, duration of previous surgery, and anatomical side. A p-value of less than 0.05 was considered statistically significant. The study adhered to the ethical standards of the Declaration of Helsinki regarding human research, ensuring that all participants were fully informed about the nature of the study and the procedures involved, and that they provided their consent before participation.

RESULTS

The study comprised a cohort of 50 individuals who had previously undergone surgical intervention for aseptic nonunion of the distal femur. The average age among participants was 43.52 years, with a standard deviation of 11.58. The age distribution was bimodal, with 42.0% (21 individuals) falling within the 20-40 year age bracket, while the majority, 58.0% (29 individuals), were between 41-60 years (Table 1). Gender-wise, the sample skewed male, consisting of 66.0% (33 individuals), with females representing the remaining 34.0% (17 individuals). Weight distribution indicated that 48.0% (24 individuals) were of normal weight, 30.0% (15 individuals) were overweight, and 22.0% (11 individuals) were classified as obese. The lateral side affected by the nonunion was nearly evenly split, albeit with a slight predominance of right-sided nonunions at 54.0% (27 individuals), compared to left-sided at 46.0% (23 individuals). The duration from the previous surgery averaged 8.90 months with a standard deviation of 2.77

months; most cases, 90.0% (45 individuals), had undergone previous surgery within 12 months, while a smaller fraction, 10.0% (5 individuals), had surgery over 12 months prior (Table 1).

The comparative analysis of mRUST scores between the two study groups revealed distinct trends over time. At the 6-week mark, mRUST scores were similar between the LRIN group (mean of 2.64 with a standard deviation of 0.907) and the K-nail plus Augmented Plating group (mean of 2.52 with a standard deviation of 0.963), with a p-value of 0.652, indicating no statistical significance. By the 12-week follow-up, a divergence emerged with the LRIN group exhibiting a mean mRUST score of 4.84 (standard deviation of 0.688), significantly higher than the 4.16 mean score (standard deviation of 1.068) of the K-nail plus Augmented Plating group, denoted by a p-value of 0.010. The discrepancy widened further at the 24-week follow-up, where the LRIN group achieved a mean of 6.40 (standard deviation of 0.707) compared to the K-nail group's mean of 5.48 (standard deviation of 1.005), with a p-value below 0.001. This pattern persisted through the 36-week assessment, with the LRIN group's mean mRUST score climbing to 8.12 (standard deviation of 0.526), notably surpassing the K-nail group's mean of 7.00 (standard deviation of 1.155), and a p-value still below 0.001, all indicating statistically significant differences favoring the LRIN technique (Table 2).

Table 1: Baseline Characteristics of Study Sample (n=50)

Characteristic	Total (n=50)	Detail
Age (years)	43.52 ± 11.58	
- 20-40 Years	21 (42.0%)	
- 41-60 Years	29 (58.0%)	
Gender		
- Male	33 (66.0%)	
- Female	17 (34.0%)	
Weight		
- Normal	24 (48.0%)	
- Overweight	15 (30.0%)	
- Obese	11 (22.0%)	
Lateral Side		
- Right	27 (54.0%)	
- Left	23 (46.0%)	
Duration from Previous Surgery (months)	8.90 ± 2.77	
- ≤12 months	45 (90.0%)	
- >12 months	5 (10.0%)	

Table 2: Comparison of mRUST Scores between the Study Groups

Timepoint	Group	N	Mean	Std. Deviation	p-value
6 Weeks	LRIN	25	2.64	0.907	0.652
	K-nail plus Augmented Plating	25	2.52	0.963	
12 Weeks	LRIN	25	4.84	0.688	0.010
	K-nail plus Augmented Plating	25	4.16	1.068	
24 Weeks	LRIN	25	6.40	0.707	0.000
	K-nail plus Augmented Plating	25	5.48	1.005	
36 Weeks	LRIN	25	8.12	0.526	0.000
	K-nail plus Augmented Plating	25	7.00	1.155	

Table 3: Comparison of Non-union and Implant Failure between the Study Groups

Timepoint	Outcome	LRIN (n=25)	K-nail plus Augmented Plating (n=25)	p-value
6 Weeks	Non-Union	7 (28.0%)	13 (52.0%)	0.074
	No Non-Union	18 (72.0%)	12 (48.0%)	
12 Weeks	Non-Union	5 (20.0%)	10 (40.0%)	0.123
	No Non-Union	20 (80.0%)	15 (60.0%)	
24 Weeks	Non-Union	4 (16.0%)	9 (36.0%)	0.107

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Timepoint	Outcome	LRIN (n=25)	K-nail plus Augmented Plating (n=25)	p-value
	No Non-Union	21 (84.0%)	16 (64.0%)	
36 Weeks	Non-Union	3 (12.0%)	9 (36.0%)	0.047
	No Non-Union	22 (88.0%)	16 (64.0%)	
6 Weeks	Implant Failure	1 (4.0%)	2 (8.0%)	1.000
	No Implant Failure	24 (96.0%)	23 (92.0%)	
12 Weeks	Implant Failure	1 (4.0%)	3 (12.0%)	0.609
	No Implant Failure	24 (96.0%)	22 (88.0%)	
24 Weeks	Implant Failure	1 (4.0%)	3 (12.0%)	0.609
	No Implant Failure	24 (96.0%)	22 (88.0%)	
36 Weeks	Implant Failure	1 (4.0%)	3 (12.0%)	0.609
	No Implant Failure	24 (96.0%)	22 (88.0%)	

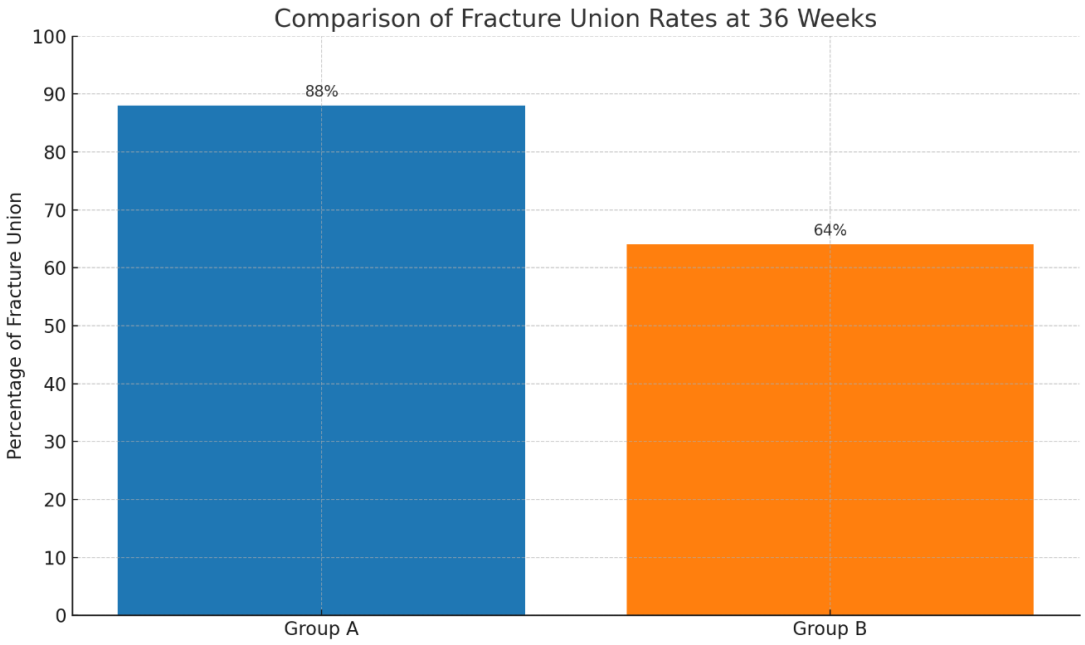

Figure 1 Comparison of Fracture Union Rates

The analysis of non-union rates at each timepoint provided further insight. At 6 weeks, the LRIN group presented a non-union rate of 28.0% (7 individuals) as opposed to the K-nail group's 52.0% (13 individuals), yielding a p-value of 0.074. While this difference was not statistically significant, a trend seemed to favor the LRIN approach. The trend continued at 12 weeks with the LRIN group reporting a non-union rate of 20.0% (5 individuals) compared to 40.0% (10 individuals) in the K-nail group (p-value of 0.123), and at 24 weeks with rates of 16.0% (4 individuals) versus 36.0% (9 individuals) respectively, with a p-value of 0.107. However, by the 36-week endpoint, the LRIN group's non-union rate of 12.0% (3 individuals) was significantly lower than the 36.0% (9 individuals) observed in the K-nail group (p-value of 0.047) (Table 3).

Implant failure rates remained consistently low in the LRIN group across all timepoints, with a 4.0% rate at each interval, whereas the K-nail group experienced higher rates of 8.0% at 6 weeks and 12.0% at subsequent 12-, 24-, and 36-week marks. Nonetheless, the differences did not reach statistical significance, reflected by p-values of 1.000 at 6 weeks and 0.609 at subsequent timepoints (Table 3). The lack of significant differences suggests that while implant failure was more common in the K-nail group, the occurrence was not statistically predictable from the data.

DISCUSSION

The discourse surrounding the treatment of aseptic nonunion of the distal femur remains an area of intense scrutiny within orthopedic surgery. As such, various surgical methods have been evaluated for efficacy, with a particular focus on Locked Reamed Intramedullary Nail (LRIN) and K-nail plus augmented plating (7,8). LRIN typically entails the insertion of a nail into the femur's medullary canal, which is then secured by screws, while the K-nail with augmented plating method involves stabilizing the K-Nail with additional plating (9). The comparative efficacies of these approaches have been previously explored, with studies revealing higher union rates in LRIN over K-nail plus augmented plating, though the differences often did not achieve statistical significance

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(10). Another investigation underscored this finding, noting a greater union rate for LRIN, accompanied by a reduced complication rate (11).

Despite these insights, the debate over the superior surgical approach persists, driven by the variability in patient-specific factors and surgeon preference. It is imperative to account for the nonunion's location and extent, patient comorbidities, and the operating surgeon's expertise when selecting the appropriate intervention. The need for further evidence, given the controversies presented in the literature, warranted the current investigation.

The demographic profile of the present study's participants aligned with previous research, with a mean age of 43.52±11.58 years, fitting within the broader age spectrum noted in other studies (10,12). It is recognized that patient age may influence treatment decisions and potentially impact the outcome. Moreover, the gender distribution in this cohort, with a predominance of male participants (66.0%), parallels the higher incidence of non-union in males reported in other studies, suggesting the possible influence of bone density, hormonal variations, and anatomical differences (13,14).

Obesity was a significant factor among the study subjects, reflecting the known association with increased surgical risks (18). This underscores the need for effective weight management in the pre- and postoperative stages. Additionally, a slight majority of the patients suffered from right-side nonunion, a finding whose implications require further exploration (54% versus 46%).

Delayed intervention has been associated with heightened non-union risks in femoral fractures, as noted by Cattaneo et al. (15). This aligns with other literature pointing to superior outcomes associated with intramedullary nailing over other methods such as plating (16-18). The application of the modified Radiographic Union Score for Tibial fractures (mRUST) as a measure of union status offered a consistent evaluative framework across the study duration (19-22).

The notable improvement in mRUST scores for the LRIN group across several time points suggests a correlation with more effective healing when compared to the K-nail plus augmented plating group. This finding is corroborated by other studies that favored intramedullary nailing for distal femur fractures or non-unions (15, 23, 24).

Conversely, the study's limitations, including its single-center nature and the relatively small sample size, restrict the broad applicability of its conclusions. A multicentric approach with a larger cohort would be more indicative of the general population. Moreover, consistency in the operative team minimized variance in surgical proficiency, representing both a strength and a limitation due to potential skill bias.

CONCLUSION

The findings from this study suggest that locked reamed intramedullary nailing is a more effective surgical intervention for the treatment of aseptic nonunion of the distal femur compared to the K-nail plus augmented plating approach, with higher rates of bone union, fewer complications, and more favorable outcomes overall. These results have significant implications for human healthcare, potentially guiding orthopedic surgeons towards more successful, cost-effective, and patient-centered approaches for managing this complex condition, thereby enhancing patient recovery experiences and reducing the healthcare system's burden.

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