ORIGINAL ARTICLE

Feasibility and value of non-locking retrograde nail vs. locking retrograde nail in fixation of distal third femoral shaft fractures: radiographic, bone densitometry and clinical outcome assessments

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ABSTRACT

Aim Distal femoral shaft fractures are characterized by increasing incidence and complexity and are still considered a challenging problem. No consensus on best surgical option has been achieved. The aim of this study is to investigate mineral bone densitometry, radiographic and clinical outcomes of locking retrograde intramedullary nailing (LRN) and non-locking retrograde intramedullary nailing (NLRN) regarding surgical treatment of distal femoral shaft fractures in adults based on the hypothesis that there is no statistical difference among the results of both surgical options.

Methods Retrospective study: 30 patients divided into 2 groups (Group 1 LRN, Group 2 NLRN). Average age was 42.67±18.32 for Group 1 and 44.27±15.11 for Group 2 (range of age 18-65 for both groups). Gender ratio (male:female) was 2.75 (11:4) for both groups. AO Classification, Non Union Scoring System (NUSS) and Radiographic Union Score Hip (RUSH), Visual Analogic Score (VAS), Dexa scans, plain radiographs were used. Evaluation endpoint: 12 months after surgery.

Results No statistical difference was obtained in terms of surgery time, transfusions or wound healing. There were similar results regarding average time of bone healing, RUSH scores, VAS, regression between RUSH and VAS, average correlation clinical-radiographic results and patients outcomes. Only one patient of LRN group had reduction of mineral bone densitometry values.

Conclusion No statistical difference in terms of radiographic, bone densitometry and clinical outcomes among LNR and NLNR for the treatment of distal femur fractures was found. The presence of no statistical difference regarding radiological findings is the main factor supporting our hypothesis given their strong objectivity.

Key words: bone minerals, femoral, fractures, radiology, retrograde nail

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INTRODUCTION

Distal femoral fractures currently make about 4–6% of all femur fractures. The incidence and complexity are increasing due to the increasing rate of high-energy trauma, particularly in young patients (1). There is a number of reasons for which these fractures remain a challenging problem. Among those are high complication rates, relatively high morbidity and mortality, non-union, delayed union, duration of rehabilitation, duration of surgery, blood loss and the impact of quality of life. Surgical treatment goals are to restore axial alignment, anatomic reduction of the joint surface and minimize joint stiffness by allowing early mobilization, all of those with minimal soft tissue disruption (2).

Several conservative and surgical strategies have been studied with various and controversial results. Studies have shown that internal fixation devices provide superior outcomes as compared to closed methods by providing good stability that subsequently allows early mobilization (3,4). In particular, intramedullary nails (anterograde and retrograde) have shown to be particularly successful, with a reduction in surgical blood loss, operating time and hospitalization. Other surgical options include the use of locking plates, cannulated screws, external fixation, blade plates, or distal femoral replacement (3,4). Recent studies opened the possibility of proximal non-locking retrograde nail to fix distal third femoral shaft fractures (4). This could potentially become one of the frequently used surgical techniques, but there have been neither specific studies performed yet nor has the comparison with other techniques been reported. Therefore, we still do not clearly know its potentials, indications and results. Also, there are no studies that compare the results of locking retrograde nailing and non-locking retrograde nailing in the treatment of distal femur fractures (5-7).

This study aims to investigate and compare results in terms of radiographic, mineral bone densitometry and clinical outcomes of locking retrograde intramedullary nailing (RLN) and non-locking retrograde intramedullary nailing (NRLN) used to fix distal third femoral shaft fractures in young adults based on the hypothesis that there is no statistical difference with regard to these results.

PATIENTS AND METHODS

Patients and study design

From January 2015 to December 2017, 72 patients with sustained distal third femoral shaft were admitted, treated and followed up at 3 linked specialist trauma centres. Out of these 72 patients, 30 patients who sustained a distal third femoral shaft fracture were included in the study. These 30 patients were divided into two groups: Group 1- treated with locking retrograde intramedullary nailing (RLN), Group 2 - treated with non-locking retrograde intramedullary nailing (NRLN).

Inclusion criteria were the patients who sustained a distal third femoral fracture in the settime frame admitted and treated at any of the 3 trauma centres linked, pre-trauma conditions and absence of local or systemic disease able to affect the surgical treatment or their comorbidity and mortality, fitness to undergo surgery established by an anaesthetic team, availability for a 12-month postoperative clinical and radiological follow up. Exclusion criteria included haematological or oncological patients, presence of acute or chronic infections; 3.2 type of fracture according to the AO Classification System (8), age under 18 or over 65 for males, age over 50 for females or early menopause patients, bone metabolism disorders, rheumatologic diseases, polytrauma, no previous injury on ipsilateral lower leg.

All fractures were classified according to the AO classification (8) (Table 1).

All patients were informed in a clear and comprehensive way of the procedure (see Operative Surgical Technique) and other possible surgical and conservative alternatives. Patients were treated according to the ethical standards of the Helsinki Declaration and were invited to read, understand, and sign the informed consent form.

Methods

We retrospectively used the Non-Union Scoring System (NUSS) (Table1) (9) to study bone healing on x-rays. The criteria to evaluate the patient groups' bone healing included 2 readers using the RUSH (Radiographic Union Score for Hip) score provided by Chiavaras et al. (10,11) and derived from the RUST (Radiographic Union Scale in Tibial Fractures) scoring system. The RUSH provides four component scores: cortical bridging, cortical disappearance, trabecular consolidation and trabecular disappearance. Each component can be scored from 1 to 3. Similarly, two trabecular indices were scored from1 to 3, each based on consolidation for one of the indices, and fracture line disappearance for the other. The overall RUSH score therefore ranged from a minimum of 10 to a maximum of 30.

Pain visual analogic score (VAS) was collected the same day when the X-rays were taken (12).

We studied mineral bone densitometry of the top part of the femur by performing DEXA Scans for all patients (13). The femoral alignment was measured using plain radiographs (two projections, AP and lateral views) and correlated with clinical outcomes.

The evaluation endpoint was set at 12 months after surgery.

Group 1 Surgical Technique (RLN). After checking for associated fractures (e.g. fracture of the ipsilateral femoral neck), alignment, knee stability and limb length, patients were positioned supine on the radiolucent table. Routine prep and draping with a sterile bump under the knee were made. The anterior transtendinous approach to the knee was used with the knee kept in about 30 degrees of flexion to avoid the action of the gastrocnemius from moving the distal fragment (incision from inferior pole of patella and tenotomy). Self-retainers, suction of synovial fluid and accurate haemostasis were performed to improve visualization. A guide wire was then inserted from the centre of the intercondylar notch to the distal metaphysis under fluoroscopy check, followed by the reamer. These were then removed and replaced by a ball tip guide wire in the femoral canal that was pushed into the distal aspect of the fracture. Pulling traction was then applied at the 30 degree angle to achieve good fracture reduction. The guide wire was subsequently pushed through the fracture site and 3 cm proximal to the lesser trochanter under fluoroscopy check. A ruler was used to decide the nail length and reaming of the canal was performed. A nail 1.5 mm inferior to the size of the last reamer was used then inserted through the guide wire and pushed past the fracture site till there was a fluoroscopy confirmation of good positioning. Distal interlocking screws (as indicated) were positioned (most distal first) using bicortical drilling and fluoroscopy. The same process was performed for the proximal interlocking screws (most proximal first, 34 or 36 mm screws). Confirmation of final good metalwork position and no rotation of the distal femur was obtained with fluoroscopy (AP and lateral radiographs) with knee extension and 90 degree of bending. Good range of motion of both knee and hip, limb length and rotation were checked. Appropriate irrigation and haemostasis were assured throughout the entire procedure. Closure in layers (starting with patellar tendon and paratenon) was performed and surgical dressing applied.

Group 2 Surgical Technique (NRLN). This procedure was performed identically to the one described for the RLN Group (including positioning, equipment, fluoroscopy, surgical steps, irrigation, haemostasis and closure) with the only exception that the proximal locking was not performed.

During the pre-operative stage, an X-ray of the healthy contralateral limb was taken in order to decide the correct length of the nail to be used. All patients took the same rehabilitation program protocol. This included early passive and assisted knee mobilization (on first or second post-op day as pain allowed) and foot pump exercises; all patients had a post-op X-ray check of the operated limb and achieved progressive weight bearing, based on stability of the fracture on the X-ray and clinical conditions. A personalized physiotherapy program was then continued with the aim to achieve early full weight bearing and full ROMs, always considering the post-op stability of the fracture and subjective individual aspects of the patients.

Statistical analysis

Descriptive statistics were used to summarize the characteristics of the study group and subgroups, including means and standard deviations of all continuous variables. The t-test was used to compare continuous outcomes. The Fisher exact test (in these groups were smaller than 10 patients) were used to compare categorical variables. The statistical significance was defined as p<0.05. Pearson correlation coefficient (r) was used to compare the predictive score of outcomes and quality of life. Mean age (and its standard deviations) of the patients was rounded at the closest year. The predictive score of outcomes and quality of life and their standard deviations were approximated at the first decimal, while Pearson correlation coefficient (r) was approximated at the second decimal. The reliability and validity of the correlation between functional outcomes and bone healing were determined by the Cohen's kappa (k).

RESULTS

The mean of follow-up was 16.24 (±0.44; range 12–24) months for LNR and 15.97 (±0.38; range 12–24) months for NLRN (p>0.05) (Table.1).

The surgery lasted for an average of 52.8 (±15.6; range 25-76) minutes in LNR and 48.6 (±22.4; range 38 -83) minutes for NLRN (p>0.05) (Table 1).

The red blood cell international unit (RBCIU) of perioperative transfusion was on average 2.9 (±1.42; range 0-7) in LNR and 2.7 (±1.8; range 0-6) in NLRN (p>0.05).

In both groups, the patients demonstrated wound healing within 21 days. During the follow up no complications were noticed in both groups (Table 1).

The average time of bone healing was 142.4 (±15.7; 72 -168) days after the surgery in LNR and 140.8 (±13.9; 69 -172) days for NLRN (p>0.05). On average day of bone healing the RUSH was of 26.8 (±2.4; range 24.1-30) point in LNR and 26.3 (±2.8; range 23.9-30) in NLRN (p>0.05).

On average day of bone healing the VAS was of 2.3 (±0.7; range 0-4) point in LNR and 2.5(±0.7; range 0-4) in NLRN (p>0.05) (Table 1).

We found that on average day of bone healing the regression between RUSH and VAS scores showed p=0.059 in LNR and p= 0.066 in NLRN (p>0.05).

Only one LRN patient had a reduction of mineral bone densitometry of proximal (from normal to osteopenia) at the evaluation endpoint (Table 1).

The average correlation of clinical-radiographic results and patients' outcomes was high according Cohen κ: 0.859457333±0.085103467 for LNR while κ: 0.823026667±0.09557 for NLRN (Figure 1) (p>0.05).

Table1. Description of the patients with locked (LRN) and patients with non-locked retrograde intramedullary nailing (NRLN)

Characteristic	LRN	NLRN	p
Number of patients	15	15	>0.05
Average age (±standard deviation) (range) (years)	42.67 (±18.32) (18-65)	44.27 (±15.11) (18-65)	>0.05
Male: female ratio	2.75(11:4)	2.75(11:4)	>0.05
Previous type of accident (No, %)			
Fall from height	2(13.33)	2(13.33)	>0.05
Traffic accident	8(53.34)	8(53.34)	>0.05
Work accident	3 (20)	3 (20)	>0.05
Shooting	2 (13.33)	2 (13.33)	>0.05
Previous type of femoral shaft fractures according Arbeitsgemeinschaft für Osteosynthesefragen Classification (8) (No, %)			
A1	2 (13.33)	2 (13.33)	>0.05
A2	2 (13.33)	2 (13.33)	>0.05
A3	(6.67)	(6.67)	>0.05
B1	2 (13.33)	2 (13.33)	p>0.05
B2	(6.67)	(6.67)	p>0.05
B3	2 (13.33)	2 (13.33)	>0.05
C1	2 (13.33)	2 (13.33)	>0.05
C2	2 (13.33)	2 (13.33)	>0.05
C3	(6.67)	(6.67)	>0.05
Orthopaedic device used in the surgery for the osteosynthesis of the femoral shaft fracture	Locked retrograde intramedullary nail	Non locked retrograde intramedullary nail	Not calculated
Work occupation (No, %)			
Agricultural industry	3 (20)	3 (20)	>0.05
Industrial sector	9 (60)	9 (60)	>0.05
Tertiary industry	3 (20)	3 (20)	>0.05
Injured lower limb side			Not calculated
Right	6 (40)	6 (40)	
Left	9 (60)	9 (60)	
Average non union scoring system (SD) (range)	40.72 (±18.33) (21-65)	39.68 (±22.47) (21-65)	p>0.05

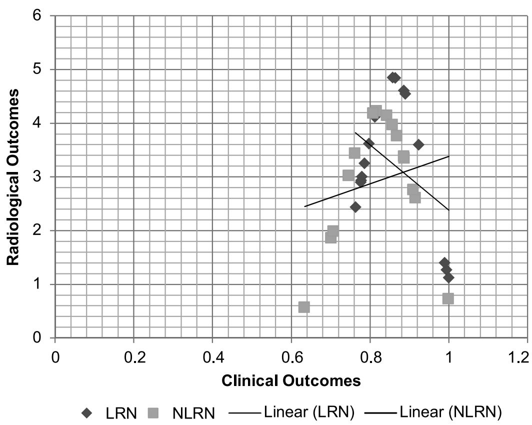

Figure 1. Comparison of the k's Cohen correlation (clinical outcomes/radiological outcome) between the LRN and NLRN groups at the12-month post-op follow up (p<0.05)

DISCUSSION

A sufficient stabilization usually requires surgical management in order to withstand static and dynamic forces applied to the femur (14,15). The traditional indications for the use of the nailing technique are the presence of an extra-articular fracture or a simple intra-articular fracture with little or no displacement (16). However, to the best of our knowledge, no studies have been performed to compare specifically locking retrograde intramedullary nailing to non-locking intramedullary nailing procedure for the treatment of distal third femoral fractures.

Retrograde intramedullary nailing has historically been used more widely and has been shown to provide better surgical revision and mal-union rates compared to other techniques (17). Markmilleret al. (18) did not report improved results for any particular implant for identical indications. However, it seems that with appropriate application the use of retrograde nails is suitable for all fractures of the distal third of the femoral shaft including highly instable bicondylar fractures without damage to the soft tissues or to the knee joint (19). Given this uncertainty about specific indications and related results, it seems that high quality results are more dependent upon the surgical technique and experience of the surgeon than on the selection of implant. High powered randomized multicentre studies are needed in order to achieve higher level of evidence regarding surgical options in order to treat distal femoral fractures (1,20).

Locking and non-locking nails have been used to treat distal femoral fractures (20,21). There is not just a lack of high level evidence among different surgical options in the literature, but also a lack of studies regarding indications and results of locking vs non-locking nailing procedures. We have therefore planned our study as a retrospective group control study (15 patients forming each of the 2 groups) including patients treated at 3 linked trauma centres. We compared radiographic, bone densitometry and clinical outcomes of the two groups.

We did not find any significant difference in terms of duration of surgery, despite the mean duration of LNR surgery exhibiting a higher value, neither could we find a significant statistical difference regarding the RBC IU of perioperative transfusion. Again, similar results were obtained regarding bone healing timing: no statistical difference was noted among the groups, with average time of bone healing; similarly, RUSH scores were noted not to be very dissimilar. These results support the hypothesis that good fracture healing is achieved with both surgical techniques and that bony healing is not negatively affected by any of the two procedures.

At the time of bone fracture healing, similar VAS scores were obtained in both groups keeping in line with our hypothesis that the two studied procedures allow similar results. Linking RUSH and VAS scores, we found that the regression between RUSH and VAS scores showed the p value of 0.059 in LNR and the value of 0.066 in NLRN (at the time of bone healing). More strength and significance to our results is given by Cohen K values for the average correlation of clinical-radiographic results and patients' outcomes.

Correlating clinical outcomes with radiographic outcomes we could not find any statistical difference among the two aspects at the 12-month post-op follow up. We considered this similarity as a further strong factor highlighting the absence of significant statistical differences among the two studied surgical procedures. This is further supported by the fact that significant difference in terms of bone densitometry was not found in the two groups following evaluation of Dexa scans results. Only one patient of the LRN was found to have a reduction of mineral bone densitometry values at the evaluation endpoint.

We believe that the obtained radiological results (good and relatively early bone healing shown on post-op X-rays and absence of reduction of mineral bone densitometry in almost all patients with similar results among the two groups) are strong, objective and undebatable findings able to support our hypothesis. In fact, clinical and functional results could be biased by subjective factors linked to the patients (age, gender, comorbidities, compliance to rehabilitation, personal goals). Different radiological findings are only marginally influenced by the same subjective factors, and the homogeneity of the obtained radiological results seems to be able to provide quite solid information supporting our theory and aim of the study.

We believe that our results could be relevant for the orthopaedic surgeons dealing with distal femur fractures by providing an interesting tip that the use of LNR or NLNR could not significantly affect neither clinical nor functional or radiological results. This means that decisions must be taken respecting the traditional indications and considering the experience and consensus of the surgical team (and multidisciplinary team when necessary: for example patients with significant comorbidities, polytrauma patients or high risk of mortality following surgery).

Differently from other situations, when the surgical procedure is chosen not just according to the most appropriate indications but also taking into account comorbidities and subjective aspects (such as pre-injury mobility status, goals, rehabilitation, etc.). The study results suggested the useful technical tip (applicable to all cases that are treated with a retrograde nailing procedure after a distal femur fracture) that using locking or non-locking screws is not going to affect significantly any aspect of the results (2).

We advocate for the need for a more powered study and bigger cohorts in order to definitively validate (or eventually reject) our hypothesis. More objective and/or subjective outcomes may be also studied in adjunct to the available ones in order to have a wider scenario and stronger results. In fact, the paucity and variable results currently present in the literature do not allow generalization and definitive validation of our results. Furthermore, few studies have shown different results and even statistical differences among the two techniques (21).

In conclusion, no statistical difference was obtained in terms of radiographic, bone densitometry and clinical outcomes among LNR and NLNR for the treatment of distal femur fractures. Both techniques provide good subjective and objective results. We believe that the presence of no statistical difference regarding the radiological findings is the main factor supporting our hypothesis, given its strong objectivity. For a definitive validation of our hypothesis we advocate for the need for a more powered study with bigger cohorts and possibly more both subjective and objectives measurements.

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TRANSPARENCY DECLARATION

Competing interests: None to declare.

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