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Original Article

Plate Fixation of Femoral Nonunion Over an Intramedullary Nail with Autogenous Bone Grafting

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ABSTRACT

Background: Intramedullary nailing are used to treat femoral shaft fractures with an accepted success rate. However, non-union still reported and represented a challenge.

Aim of the work: The current work was designed to document the rate and time needed for union after bone augmented by plate with nail retention in treatment of femoral shaft non-unions with nailing. In addition to recognize potential complications related to the treatment approach, and to report on the overall clinical outcomes.

Patients and methods: This trial included 27 patients with non-union, who were scheduled for plate augmentation for bone grafting with nail retention. A standard preoperative assessment was performed [history taking, clinical examination, laboratory and radiological evaluation]. Then under spinal anesthesia, surgery was performed. Postoperative clinical and radiological evaluation was performed on regular intervals for at least 6 months. Radiological and clinical outcome was recorded and any complications were documented.

Results: Data were collected for 27 patients [18 males and 9 females], their age ranged between 25 and 55 years. Most of the patient [66.7%] had a history of motor accident. The mean time of nonunion was 9.33 ± 3.258. Hypertrophic nonunion was recorded for 22 patients [81.48%]. The mean operative time was 67.296 ± 10.571 minutes, with a range of 55-95 minutes. The mean blood loss was 200 ± 120.135 ml. Complete union was achieved in 26 patients [96.3%] with mean union time of months [5.111 ± 3.332]. On the basis of Wu's score, the outcome was excellent for 10 patients and good outcome was recorded for 16 patients.

Conclusion: Using plate augmentation in addition to the iliac bone graft seems to be a safe and effective treatment approach for non-united femoral shaft fracture in patients treated previously by the interlocking nails. It is associated with a high success [union] rate and reasonable clinical results.

Keywords: Fixative Devices; Non-Union; Fractures; Femur; Intramedullary nailing; Augmentation.

INTRODUCTION

Femoral fractures are common and treatment options include direct fixation by closed reduction and intramedullary nailing for stabilization. It permits early ambulation with reduction of associated complications. Intramedullary nail [IMN] is a highly successful treatment approach with minimal rate of complications when appropriate patient selection was the rule. This permits IMN to be the standard of care treatment option for femoral fractures [1-4].

The non-union or incomplete healing is specifically associated with local pain or motion at the site of the fracture. Radiographically, it is defined as a failure of complete healing [union] within 6 months or lack of sufficient progression to healing within 3 months after fixation. This is characterized radiographically by sclerotic edges of the fracture, absence of the bone crossing the site of the fracture and persistence of fracture lines [5,6].

Risk factors for femoral shaft fracture non-union included biological, patient related and biomechanical factors. The biological factors include, but not limited to, damage of soft tissues, and marked bone injuries. Additionally, the patient related factors included comorbid chronic diseases [e.g., Diabetes mellitus among others] and smoking. The biomechanical factors attributed to fracture include fracture site [distal or proximal], the size of the nail, distraction of the fracture, comminution or implant-related leakage which led to rotational instability at the site of the fracture [7,8].

The ultimate goal of treatment options for nonunion is to provide osseous union. This can be achieved by stable reduction of the bone fragments and preservation of sufficient blood supply. The available treatment options for femoral shaft non-union after nailing include exchange reamed nailing, dynamization of static interlocking nails, removal of nails, using plate for fixation with or without graft, and removal of the nail with external fixation [9,10].

These are effective treatment options. However, these options have some limitations [e.g., probable failure, reduced mobility, and complications at the surgical site]. Previous studies reinforced the use of the reamed exchange nailing as the favorite treatment approach for non-union of diaphyseal femoral fractures. The rate of success reported to be 96% -100.0%. However, subsequent and more in-depth assessment of exchange nailing showed inferior results than that reported in earlier studies. This initiated the need for further investigation to determine the proper method for treatment of femoral shaft nonunion [11]. In addition, exchange nailing may not be the optimal choice treatment due to fracture location, stability, or morbidity of nailing removal [8,12].

So, using of augmentation plating with retained IMN is evolving as a practical care plan for treating nonunion of femoral shaft fractures [13,14].

THE AIM OF THE WORK

The current work was designed to recognize the rate of union and time to reach union after plate augmentation with bone grafting and nail retention in cases of femoral shaft non-unions with nailing. Also, to recognize the potential complications related to the treatment method, and to report on the overall clinical outcomes.

PATIENTS AND METHODS

This observational descriptive study was held at the Department of Orthopedic outpatient clinic, Al-Azhar University Hospital, New Damietta. It was completed from April 2023 to April 2024. We were able to collect data of for a convenient sample of 27 patients. We **included** patients of both genders, adults [18 years or older], who had non-united femoral shaft fractures with intramedullary interlocking nailing [nonunion defined as no healing sings by radiography after 6 months] provided that, all types of non-union are aseptic [atrophic or hypertrophic]. On the other side, we **excluded** patients who were unfit for surgery, those showed healing sings on radiographs, those with septic non-union or who had wound complications.

Preoperatively, and at admission, all patients were thoroughly assessed by history taking, clinical examination [to assess mobility at fracture site, the skin around the fracture, presence of any leg length discrepancy and to check the presence of any infection]. In addition, routine laboratory workup was performed [included CBC, ESR, CRP, PT, PTT, INR, AST, ALT, RBS and Creatinine, and in some cases HBA1c, s. albumin and creatinine clearance was performed]. Finally, radiological examination in the form of two views [anteroposterior and lateral views] of plain radiography was performed for each affected femur. In addition, the ipsilateral knee and hip were imaged for comparison [Figure 1]. Preoperative computed tomography [CT] examination was performed to assess the union site, and intraoperative C-arm was used to confirm non-union [Figure 2].

Figure [1]: Preoperative x-ray image of non-union site.

Figure [2]: Intraoperative c-arm image of non-union site.

We used several criteria for non-union to standardize the data collection. These criteria included nonunion associated with sepsis or no [septic or aseptic], the type of nonunion and its anatomical site. First, non-union was defined as [1] persistent pain at the site of the fracture for at least 6 months after the primary treatment surgery; [2] absent bridging callus at the end of the sixth month, provided that, it affects three out of 4 cortices, or [3] absent radiographic signs of progressive healing in a row, for at least three months.

Nonunion was classified as either hypertrophic or atrophic, according to the criteria proposed by Weber and Brunner. A fracture line that lasts longer than expected and has varied quantities of callus surrounding the fracture site on radiographic examination is referred to as hypertrophic nonunion. Conversely, atrophic nonunion was defined as increasing sclerosis of the fracture edges and persistent fracture lines that did not show any callus on radiographic inspection and lasted past the anticipated period of union.

The study did not include patients with femoral shaft septic nonunion. Intraoperative biopsy taken from the non-united ends of the femoral shaft was used to diagnose septic nonunion. For every nonunion during surgery, three sets of tissue biopsies were performed; patients were added to the research if all of the results show no signs of bacterial development.

Ethical aspects: each patient signed an informed completely autonomous consent for participation in the study. The surgical intervention, its potential complications were fully explained for the patient before signing the consent.

Preoperative preparations:

A standard protocol was used for all patients after admission. It consisted of 1] proper analgesia taking into considerations the hepatic and renal functions, 2] mobilization in bed to prevent bed sores, 3] prophylaxis against deep vein thrombosis [DVT] & pulmonary embolism by using low molecular weight heparin [40 IU subcutaneous] which was stopped exclusively 12-24 hours before surgery, 4] correction of any fluid and electrolytes imbalance after laboratory investigations by the aid of internal medicine consultations, 5] proper control of blood sugar in diabetic patients by the use of short acting insulin [regular insulin] with detection of regular random blood sugar level every 8 hours, 6] cardiology consultation to cardiac patient to assess their cardiac condition and their fitness for surgery, 7] control of any other co morbidities especially chest infection and urinary tract infection and finally 8] anesthesia consultation to determine patient fitness for surgery.

Operative management [figure 3, a-i]:

The spinal anesthesia was used as the anesthetic approach for all patients. This was performed while the patient put in the supine position [Figure 3a]. After proper incision and lateral approach in relation to the femur, the vastus lateralis was elevated to expose the site of non-union. The non-united site was then debrided with curettage as a refresh method. A drill with thin osteotome was used to create thin layers by decortication on the different edges of the bone [posterior, lateral and anterior edges]. The ipsilateral iliac crest was used to obtain an autogenouse graft, which was placed at the site of nonunion.

Conventional plate of "broad dynamic compression [DCP] type or a plate with anatomical lock was used in fixation of the lateral surface of the femur. Screws of a uni-cortical type were used or conventional screws were placed around the nail. DCP were used to induce axial dynamic compression at the site of non-union by the use of eccentric placed screw. We noticed that, any slight motion at the fracture site was disappeared completely after the fixation of the plate. We used plates with 8-12 holes, according to appropriate length for each patient. To improve outcome, some adjunct measures were used. These include medical consultation if required, proper nutrition and smoking cessation. The preoperative optimization of the patient was considered a priority.

Figure [3a]: Patient in supine position with sterilization of wound site.

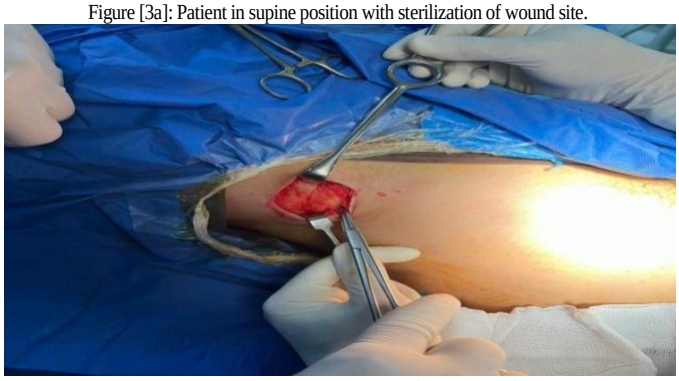

Figure [3b]: Incision over iliac bone for taking graft.

Figure [3c]: Sterilization and opening the old incision site.

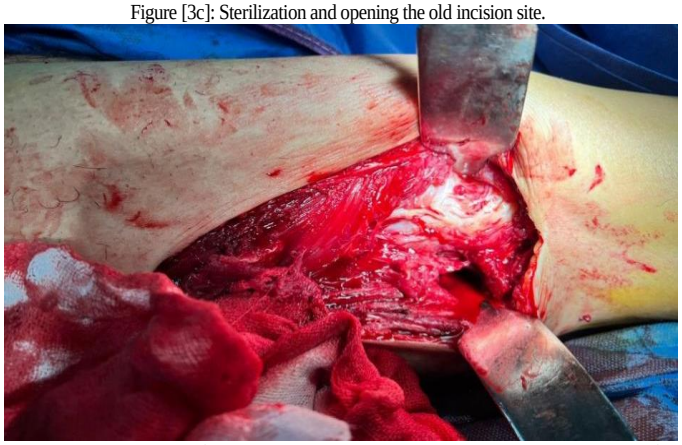

Figure [3d]: Opening the fracture site [skin, subcutaneous, ilio-tibial tract and elevation of vastus lateralis muscle].

Figure [3e]: The graft collected from one of the included patients.

Figure [3f]: Graft in pieces.

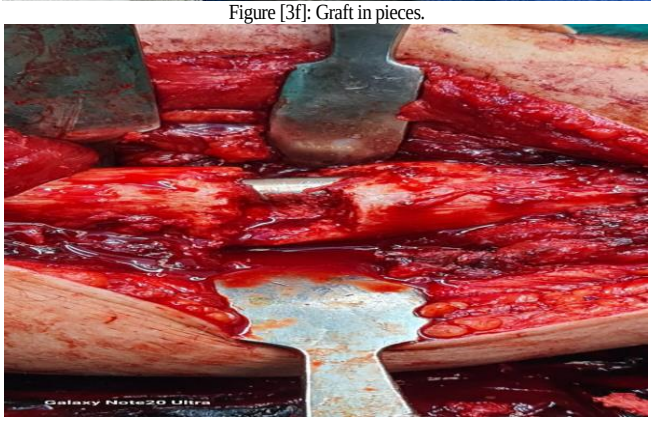

Figure [3g]: The nonunion site

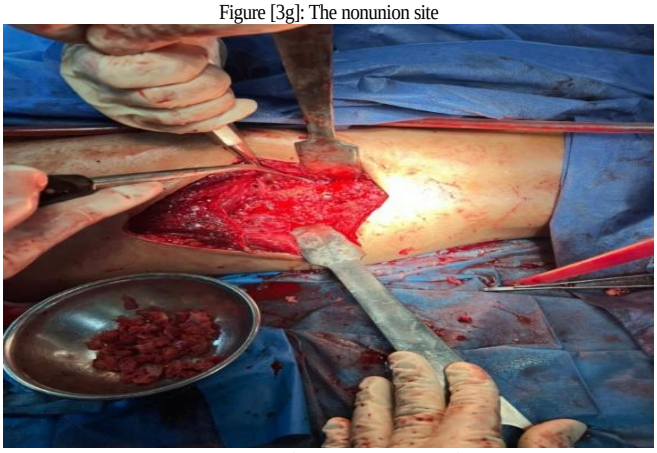

Figure [3h]: Putting graft pieces in non-united fracture site

Figure [3i]: Fixation of fracture site by locked Plate

Direct Postoperative management approaches

After surgery, all patients were transferred to the internal ward, with application of the following procedures: 1] administration of broad spectrum antibiotic [cefotaxime third generation cephalosporin] through intravenous route, repeated for 3 days before the shift to oral route [amoxicillin-clavulanic acid], 2] use of low molecular weight heparin [LMWH] [40 IU enoxaparin] subcutaneously, started 12-24 hours after surgery and continued for 14 days to protect against thromboembolic events [e.g., deep venous thrombosis [DVT] and pulmonary embolism [PE]], 3] determination of postoperative hemoglobin, 4] mobilization was started one to three days after surgery to promote active movement of the hips. The knee movement was permitted when tolerated, 4] discharge on oral broad spectrum antibiotic extended for 10 days and low LMWH for the total duration of 14 days.

Clinical and radiological Follow-up:

In the outpatient clinic, all follow up visits were performed as follow: 1] Two weeks after surgery, the wound was re-examined and the sutures were removed. 2]. Six weeks after surgery, x-ray was done and the mobilization was encouraged. 3]. Three months after surgery, x-ray was re-performed to examine the union process. In addition, the ability of weight bearing was evaluated and the range of motion [ROM] was examined and results were recorded. 4] Sixth months after surgery, another x-ray was performed to re-check for union and presence of any complications. The non-union was determined by the formation of callus with resolution of the persistent fracture lines. Wu criteria [15] were used for assessment of the healing. Any changes in the position of the implant and the extent of fracture union were noted in follow up x-rays.

Statistical analysis:

The recorded data was anonymized [by coding], then coded data was fed to the statistical package of social science software program, version 21 [IBM®SPSS®, Armonk, USA] and was submitted to statistical analysis. Data was summarized by the mean for central tendency, SD [Standard deviation for dispersion], for quantitative variables. On the same time, numbers [relative frequencies] and percentages were used to represent qualitative variable

RESULTS

Demographic parameters

In the current work, 27 patients with confirmed diagnosis of femoral fracture nonunion were included. The mean age was 39.44 ± 9.936 [range between 25 and 55 years old]. Of them, 18 patients were males [66.7%] and 9 were females [33.3%]. The commonest comorbid condition [potential risk factor] was smoking [37.0%], followed by hypertension [29.6%], then diabetes mellitus [11.1%] and finally cardiovascular disease [7.4%] [Table 1]. Table [2] presented the trauma and fracture characteristics. Most of the patient [66.7%] had a history of motor accident, while only 9 patients [33.3%] had a fall from height history. Regarding the type of the fractures, only 3 patients had open injuries [11.1%], while 24 patients [88.9%] had closed injuries. Sixteen patients [59.3%] had infra-isthmic fracture, while 7 patients [25.9%] had isthmic fracture, and 4 patients [14.8%] had supra-isthmic fracture.

Regarding the interval between trauma and first [original] surgery, the majority of included patients [81.48%] underwent surgery in the first week of injury. The mean operative time was 67.296 ± 10.571 minutes, with a range of 55-95 minutes. The average blood loss was 200 ± 120.135. The mean time of nonunion among the included patients was 9.33 ± 3.258. Hypertrophic nonunion was the most common nonunion pattern 22 patients [81.48%], followed by atrophic nonunion in only 5 patients [18.52%] [Table 2].

Clinical outcome [Table 3]: Complete union was achieved in 26 patients [96.3%] with mean union time of months [5.111 ± 3.332]. According to Wu's scoring system, the excellent outcome was recorded for 10 patients and good outcome was recorded for 16 patients.

Complications among the included patients [Table 3]: Two patients expressed limitation of movement, another two showed bleeding, one showed nonunion, one showed fat embolism, one showed mal-alignment, and one had irritation of the overlying soft tissue. In addition, an infected postoperative hematoma was recorded for one patient at distal femoral incision. It was treated by surgical debridement, use of antibiotics [intravenous and oral antibiotics for 12 weeks]. No other complications were recorded for the same patient and the fracture went on to complete union.

Case Presentation:

A male patient, 33 years old, mechanic, smoker with history of RTA and fixation of femur by [ILN] 11 months ago presented to the outpatient clinic complaining of severe pain, and inability of weight bearing of his left lower limb. On clinical examination, he had severe tenderness and edema on middle third of his left thigh. Radiological examination revealed non-united old fracture of middle third of the left femur. The patient was admitted to orthopedic surgery department in Al-Azhar university hospital – Damietta and was prepared for the surgical intervention. Preoperative X-ray and CT were done and revealed non-united old fracture of the middle third of left femur bone due to failure of the [ILN] to make stable fixation of the femur. After complete preparation of the patient for surgery, the patient entered the operative theatre, opening the old incision site, with excellent exploration of the fracture site to make sure that there's not any source of infection, fixation the old fracture site by locked plate with auto-graft from iliac bone, drain was left, and wound was closed. Postoperative x-rays were done. After 2-3 days when the drain became empty, drain was removed and the patient was discharged with follow up card containing the proper medication for his condition. The patient had follow up in outpatient clinic after 2 weeks of the operation until 6 months with signs of improvement and complete union of the old fracture site with no postoperative complications. Figure 4 illustrated the case.

Table [1]: Socio-Personal data and comorbid conditions [potential risk factors] among study group

Variables		Values [n=27]
Age [years]	Mean±SD	39.44 ± 9.936
	Min. – Max.	25- 55
Gender [n,%]	Male	18 [66.7%]
	Female	9 [33.3%]
Comorbid conditions [n,%]	Hypertension	8 [29.6%]
	Cardiovascular disease	2 [7.4%]
	Diabetes Mellitus	3 [11.1%]
	Smoking	10 [37%]

Table [2]: Trauma, fracture characteristics of the studied patients

Variables		Values [n=27]
Mode of trauma	Motor car accident	18 [66.7%]
	Falling from height	9 [33.3%]
Type of fracture	Open	3 [11.1%]
	Closed	24 [88.7%]
Fracture site	Isthmic	7[25.9%]
	Infra-isthmic	16 [59.3%]
	Supra-isthmic	4 [14.8%]
Interval from injury to surgery [n,%]	Within one week	22 [81.48]
	After one week	5 [18.52%]
Operative time [min]	Mean±SD	67.296 ± 10.571
Intraoperative blood loss [ml]	Mean±SD	200 ± 120.135
Non – union time [months]	Mean±SD	9.33 ± 3.258
Type of non-union [n,%]	Hypertrophic	22 [81.48]
	Atrophic	5 [18.52%]

Table [3]: Clinical outcome among the studied patients:

Variables		N= 26
Time to union[m]	Mean±SD	5.111±3.332
Clinical outcome [n,%]	Excellent	10 [38.46%]
	Good	16 [61.54%]
Complications [n,%]	Limitation of movement	2 [7.4%]
	Non-union	1 [3.7%]
	Bleeding	2 [7.4%]
	Fat embolism	1 [3.7%]
	Mal-alignment	1 [3.7%]
	Irritation of the overlying soft tissue	1 [3.7%]

Figure [4a]: Figure [4a]: Preoperative x-ray of case 1.

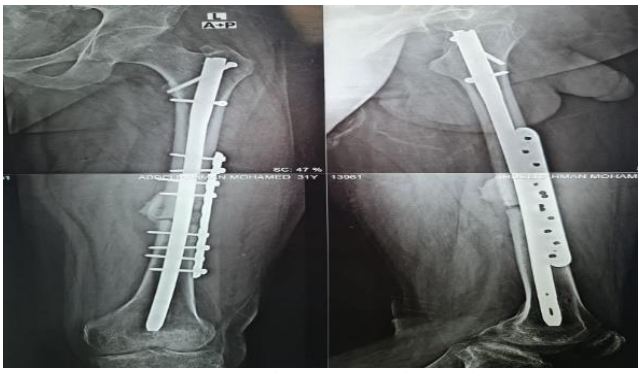

Figure [4b]: Postoperative follow up X-ray of case 1 after 1 month.

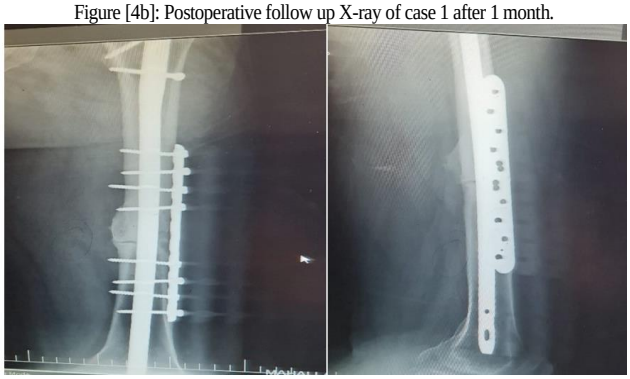

Figure [4c]: Postoperative follow up X-ray of case 1 after 3 months.

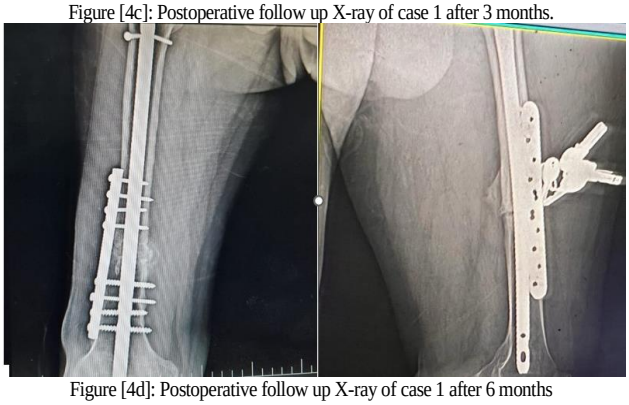

Figure [4d]: Postoperative follow up X-ray of case 1 after 6 months

DISCUSSION

Intramedullary nailing is extensively used in treatment of fractures of the femoral shaft, with higher percentage of union rate. Non-united femoral fractures were managed by exchange nailing as the method of choice. Plate augmentation is associated with better outcome and low rate of complications than exchange nailing along **[16].**

In this series, the plate augmentation with iliac bone graft was used with preservation of the nail for all patients. The union rate was recorded for 26 patients, representing 96.3% of the study sample. It needs an average 5.1 months to be completed [the average time for union was 2–12 months]. The excellent results were reported for 10 patients and good results were reported for 16 patients. These results are comparable to previous studies using the same approach [plate augmentation with bone graft]. For instance, a retrospective study included 40 patients with non-united femoral shaft after management by an interlocking intramedullary nailing, **Jhunjhunwala and Dhawale [17]** recorded a union for 97.5% of patients using augmentation approach. The authors added autogenous iliac bone graft in 24 patients with nonunion and 9 patients treated by nail exchange with larger size nails. However, the selection criteria were not described, may be due to the retrospective nature of the study. **Chiang *et al.* [18],** in another study, reported results for 30 patients, who were treated by plate augmentation with nail preservation. The union was recorded for 29 patients [96.7%]. The biologic augmentation was achieved by autogenous bone graft or bone morphogenetic protein [for selected patients with atrophic nonunion]. However, the indications for the use of bone morphogenetic protein were not clear. The nonunion type treated in their study were atrophic, oligotrophic and hypertrophic nonunion for 7, 18 and 5 patients successively. Furthermore, **Vaishya *et al.* [19]** reported comparable results in the study for 16 patients with non-union of the femoral shaft fractures after fixation by interlocking nails. Patients with non-union of atrophic type were also had an autologous cortico-cancellous bone graft, with no additional inter-fragmentary compression at the non-union site to achieve bone healing.

Another study by **Hakeos *et al.* [20]** reported results of a retrospective review of seven patients [6 men, 1 woman, mean age 42.5 years]. They had diaphyseal non-union of the femoral shaft fractures. Initially, all patients received treatment by intramedullary nail fixation. They developed a symptomatic nonunion on the basis of radiographic and clinical criteria. Then, the nonunion was treated by operative debridement, plate fixation with autogenous bone graft with preservation of the intramedullary nail. All patients showed a radiographic evidence of fracture consolidation within an average of 17.9 months [12–26 months]. The immediate weight bearing was permitted, with reduced pain and improved function. Six patients showed absent pain at the fracture site with ambulation. But one patient had discomfort at the site of the distal femoral compression plate. Free [independent] ambulation was recorded for 6 patients and none of studied patients needed additional surgery to remove implant or manipulation of bone graft.

Similarly, a study done by **Mohamed *et al.* [21]** assessed the union rate and recorded the time required for union after plate augmentation with bone grafting without nail removal in treatment of non-united femoral shaft fractures. Twenty patients were included, all had atrophic nonunion of the femoral shaft fractures initially fixed by intramedullary nailing. They showed that, the union [consolidation] was achieved for all treated subjects within a mean time of [4.9 months [range 3 to 8 months] that all of the included patients achieved bony union at an average time of 4.9 months [3–8 months]. The outcome was excellent in 12 patients and good in 8 subjects, according to Wu's scoring system and no complications were recorded. Moreover, **Uliana *et al.* [22],** reported comparable results. They included 22 patients with aseptic femoral shaft nonunion after treatment by intramedullary nail. They were treated by plate augmentation with a retained nail. The location of non-united fractures was supra-isthmic, isthmic, infra-isthmic in one, 12, and 9 subjects respectively. Nailing was ante grade for 11 subjects and retrograde for 11 patients, and reaming was done for 12 subjects. The fractures were treated by open fixation for 8 subjects. Bone union was recorded for 19 patients after plate augmentation. The average follow up time was 23.5 months [range 12- 51 months]. The outcome was excellent and good for all subjects, with no breakage of screw or plate and no infection was reported.

Another study by **Mittal *et al.* [23]** conducted on 21 subjects, 18 had non-union with intact implant and 3 had broken nail. The lateral femoral approach was used to reach the site of non-union, and fixation was performed by 4.5 hole LCP or distal femoral locking compression plate according to the fracture site. Decortication and bone grafting was performed for 18 subjects, while nail exchange was performed for 3 subjects with broken nails. All non-unions were reunited without development of any complications, and all patients regained normal walk.

In the current work, we not recording any complications, except infection in one patient. These results are comparable to those reported in previous studies [22- 24]. Other studies reported wound infection in one patient in each study. The infections were non-serious and successfully treated by conservative measures [17-19]. These studies confirmed the safety of treatment approach. Some studies used clinical scoring systems to evaluate the clinical outcome [22- 24], while others depended only on the radiological signs of healing **[17-19].** In the current work, Wu scoring system was used to evaluate the results, and accordingly, there were excellent and good outcome in 10 and 16 subjects, respectively. A published study by **Uliana *et al.*** used the same scoring system and reported comparable results **[22]**.

Exchange nailing was considered as the treatment approach of choice for the nonunion of the non-united femoral shaft fractures. However, it may be challenging, due to the broken locking screws, broken nails, and heterotopic calcification at the entry. In addition to technical and surgical problems, especially in referred patients without full data **[16].** Furthermore, the failure rate of exchange nailing is higher in long bone non-united fractures associated with comminution or bone defects. The use of large size nail is not applicable when the largest diameters nails were used previously **[21].**

Most investigators have advocated the use of autogenous iliac crest cortico-cancellous bone grafts regardless of the defect size. Its value has been highlighted previously when applied for atrophic or hypertrophic non-unions **[18]. Jhunjhunwala and Dhawale [17]** used bone chips from hypertrophic callus for vascular non-unions to reduce possible complications developed in relation to the iliac crest donor site. They recommended exchange nailing for thin, short and broken nails. However, we recommend the use of associated exchange nailing only in the presence of a fixed angular deformity preventing the correction by the intramedullary nail. In this specific situation, we recommend other treatment approaches.

Conclusion: Plate augmentation with the use of iliac bone graft and preservation of previous nail, is an effective and safe treatment approach for non-united femoral shaft fracture previously treated by interlocking nails. It offers a high union rate and good clinical results. However, due the limitation of small number of patients, future studies are recommended to further validate the results.

Disclosure: none

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