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Clinical Outcome of Complex Non-unions Using the Linear Rail System

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Authors' contributions

This work was carried out in collaboration between all authors. Author DDM designed the study, performed the statistical analysis, wrote the protocol and wrote the first draft of the manuscript. Authors JOD, MNS and NI managed the analyses of the study and reviewed the intellectual content. Authors WTY and DGM managed the literature searches and reviewed the intellectual content. All authors read and approved the final manuscript.

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ABSTRACT

Background: Complex non-union is considered to be one of the most challenging orthopedic situations to manage and the choice in such patients may be between limb salvage using limb reconstruction systems and amputation.
Aim: To share our experience on the functional and radiological outcomes and complications of complex nonunion of femur and tibia treated with the linear rail system.
Study Design: This is a 5-year retrospective study with prospective data collection.
Place and Duration of Study: Department of clinical services, National Orthopaedic Hospital, Dala- Kano, Nigeria between January 2009 and December 2014.
Results: A total of 92 patients were included of whom 72(78.3%) were males and 20(21.7%) were females. The mean age was 31.2±14.2 years and age range was 16-71years. There were

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61(66.3%) tibial nonunion and 31(33.7%) femoral nonunion. The commonest complication encountered was pin tract infection in 40 (42.6%). The clinical outcome revealed that 52(57%) of patients had excellent bone result, 27(29.3%) had good bone result and 55(60.0%) had excellent functional result, 23(25.0%) had good functional result.

Conclusion: This study revealed that majority of patients had satisfactory functional outcome with minimal complications following application of linear rail system. However, this is a long and arduous process requiring meticulous surgical technique, proper follow up, rehabilitation and patient compliance. Being a specialized surgery requiring multidisciplinary care, its use should be confined to specialist centers for optimum outcome.

Keywords: Linear rail system; complex non-union; tibia non-union; femoral non- union.

1. INTRODUCTION

Incidence of open fractures of long bones are increasing due to the increase in road traffic accidents (RTA) leading to increased incidence of complex non-union [1]. Complex nonunion is defined as an established nonunion (of at least 6 months) with one or more of the following criteria: (a) infection at the site of nonunion; (b) a bone defect of more than 4 cm (defect non-union); (c) an attempt to achieve union that failed to heal after at least one supplementary intervention, for example, bone grafting or exchange nailing [2].

These patients are usually operated upon several times for stabilization (and healing) or to eradicate infection, which in turn produces scarring of the soft tissues and devitalization of any surviving bone. They present with indolent infection, which is almost always associated with deformity, limb length discrepancy, joint stiffness, disuse osteoporosis and soft tissue atrophy [2, 3]. As a result, it is considered to be one of the most complex and challenging orthopedic situations to manage [2-4]. The choice in such patients may be between limb salvage using limb reconstruction systems and amputation [1,5].

Different treatment modalities have been used in the past; including extensive debridement and local soft tissue flaps, antibiotic beads, cancellous bone grafts, fibular strut graft and vascularised fibular grafts with internal or external stabilization. These procedures are usually staged requiring one or more procedures with prolonged recovery period. Variable success rate have been reported, however, majority have been unable to adequately accomplish treatment goals which include solid bony union, eradication of infection and restoration of limb length with maximum functional use of extremity [2-5].

The linear rail system (LRS) [6] is particularly valuable, is able to offer one stage procedure to accomplish treatment goals. It relies on the principle of tension stress which allows the use of compression, distraction forces, to achieve bone transport, lengthening, fracture healing and angular deformity correction [5-8].

The aim of this study is to share our experience on the functional and radiological outcome and complication of complex nonunion of femur and tibia treated with the linear rail system.

2. PATIENTS AND METHODS

This is a 5 year retrospective study with prospective data collection conducted in National Orthopaedic Hospital) Dala, Kano-Nigeria between January, 2009 and December, 2014. All patients with clinically and radiographic diagnosis of complex non-union involving the femur and the tibia who were treated with linear rail system were studied.

Clinical data were recorded on a standardized profoma. Ethical clearance was obtained and patients were informed that their treatment protocol would not be altered and the anonymously gathered data would be used for research and publication and could opt out of the study whenever they choose. Ninety two patients who met the criteria for complex nonunion were included in the study. Patients presenting with complex nonunion due to congenital disorders, pathological fractures, children less than 17 years and those with incomplete data were excluded from the study. The variables studied include; demographic, limbs affected, limb length discrepancy, length of bone defect, complications and functional outcome.

Patients were initially managed by implant removal and thorough debridement. The nonunion sites were freshened and fixed with the linear rail system (LRS) under suitable anesthesia using standard procedure [Fig. 2]. Broad spectrum antibiotics were commenced with 3rd generation cephalosporin or

cephalosporin and clindamycin in case of infected nonunion. All procedures were carried out by consultant orthopaedic surgeons or under their direct supervision by senior registrars. All cases were discussed and treated by a multidisciplinary team of orthopaedic and plastic surgeons, radiologist, specialist nurse and physiotherapist. Acute docking and metaphyseal or diaphyseal corticotomy for limb lengthening was done where the defect was ≤ 6 cm in the femur and ≤4 cm in the tibia following compression at the fracture site. Bone transport was done when the bone defect was ≥7 cm for the femur and ≥ 5 cm for the tibia or when the fibula was intact [Fig. 2]. Accelerated docking and limb lengthening was done when the defect exceeded 10 cm. Bifocal corticotomy was not done in any of the patients.

Fig. 1. Anteroposterior and lateral radiograph showing infected osteosynthesis with complex non-union of the femur

Following a variable latent phase of 7-10 days in the post-operative period, the corticotomy site was distracted at the rate of 1 mm/day, in four increments of 0.25 cm 6 hourly. Patients were discharged on being familiar with distraction process to outpatient department for follow-up at 6, 12 and 24 weeks and at completion of distraction. Patients were educated about pin tract care; regular dressing, cleaning of external fixator and compression-distraction. At each follow up appointment, problems of pin tract infection, loosening of pins, bolts, clamps were addressed. Plain radiographs were taken at each follow-up appointment.

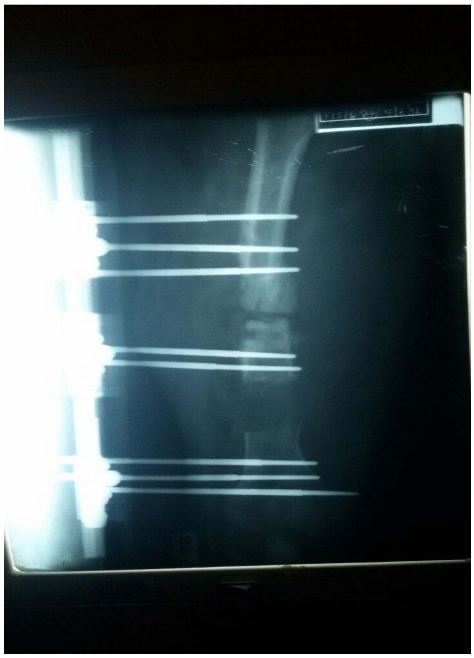

Fig. 2. Anteroposterior and lateral radiograph following removal of implant, thorough debridement, LRS application and methaphyseal corticotomy

Distraction phase was completed when limb length equalization was achieved or bone defect bridged in case of bone transport [Fig. 3]. The LRS clamps are tightened and patient is permitted to partial weight bearing with bilateral axillary crutches in the consolidation phase until corticalization of the regenerate and healing at the fracture site is achieved. LRS was maintained till clinical and radiological sign of union was obtained (at least three out of four cortices united or 3 cortices in 2 views seen) [9]. The LRS device is then removed and the limb protected with POP cast for 3-4 weeks prior to full weight bearing.

Patients were follow-up 4-6 months and assessed for gait, limb-length discrepancy and range of movement of the adjacent joints. Where patient was lost to follow up, contacts were made via phone calls to assess the Functional outcomes using the Association for the Study and Application of Methods of Ilizarov (ASAMI) criteria described by Paley et al. [10] (Tables 1 & 2).

Table 1. Objective assessment using bone results of Association for the Study and Application of the Methods of Ilizarov (ASAMI) scoring system

	Bone results
Excellent	Union, no infection, deformity < 7°, limb-length discrepancy < 2.5 cm
Good	Union + any two of the following: absence of infection, < 7° deformity and limb- length inequality of < 2.5 cm
Fair	Union + only one of the following: absence of infection, deformity < 7° and limb- length inequality < 2.5 cm
Poor	Nonunion/re-fracture/union + infection + deformity > 7° + limb-length inequality > 2.5 cm

Table 2. Objective assessment using functional result of Association for the Study and Application of the Methods of Ilizarov (ASAMI) scoring system

	Functional results
Excellent	Active: no limp, minimum stiffness (loss of < 15° knee extension/< 15° dorsiflexion of ankle), no reflex sympathetic dystrophy (RSD), insignificant pain
Good	Active, with one or two of the following: limp, stiffness, RSD, significant pain
Fair	Active, with three or all of the following: limp, stiffness, RSD, significant pain
Poor	Inactive (unemployment or inability to return to daily activities because of Injury)
Failures	Amputation

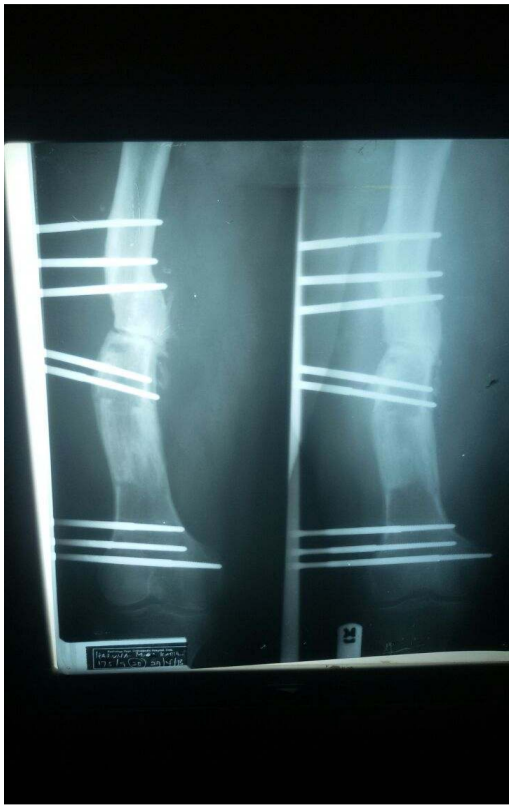

Fig. 3. Anteroposterior and lateral radiograph following completion of distraction phase of bone transport union at docking site and corticalization of regenerate

The data was analysed for frequencies of various variables. Statistical program for social science (SPSS) version 21 and Microsoft excel was used to analyse the data.

3. RESULTS

A total of 92 patients were treated for femoral and tibial Nonunion at our institution during the study period of whom 72(78.3%) were males and 20(21.7%) were females with a male: female ratio of 3.6:1. The mean age was 31.2±14.2 years and range was 18-71 years. The mechanism of in injury in majority of the cases was vehicular accident 51(55.4%) followed by motorcycle accident 29(31.5%) and gunshot injury 6 (6.5%). Other mechanisms of injury such as assault and industrial accidents constitute 5(5.4%) only [Table 3].

There were 61(66.3%) tibia nonunion and 31(33.7%) femoral nonunion. Majority 70(76.1%) were infected non unions and 22(23.9%) were non infected non unions. The mean limb length discrepancy was 5.9±3.3 cm. The mean duration of latent phase was 8.8±3.5 days, the mean duration of distraction phase was 10±13 weeks, while the mean duration of consolidation phase was 8.0±8.7 months. The mean total duration of device in situ before removal was 13.6±6.2 months. The consolidation distraction index was 3.2 and the healing index was 1.78 months/cm [Tables 4].

The commonest complication encountered was pin tract infection in 40 (42.6%) followed by revision surgeries in 9(9.6%) patients, chronic osteomyelitis in 3(3.2%) persistent pin tract infection 3(3.3%), infection requiring changing of frame 1(1.1%), refracture1 (1.1%), and poor regenerate in 1 (1.1%) patient [Fig. 4].

Table 3. Showing demographic variables, mechanisms of injury, number of previous surgeries and type of non-union

Variables		Frequency	Percent
Age(years)	31±14.2		
Sex	Male	72	78.7
	Female	20	21.3
Long bone affected	Tibia	61	66.3
	Femur	31	33.7
Side	Left	56	60.9
	Right	36	39.1
Mechanism of injury	Vehicular Accident	51	55.4
	Motorcycle Accident	29	31.5
	Gunshot Injury	7	7.6
	Others	5	5.5
Type of Non-union	Infected non union	70	76.1
	Non infected non union	22	23.9

Table 4. Showing details of treatment

Variables	Mean	Std. error of mean	Std. deviation
limb length discrepancy (LLD) (cm)	5.88	.370	3.333
Length of Bone Defect (cm)	6.87	.612	3.819
Duration of Latent Phase(days)	8.83	.395	3.469
Duration of distraction phase(weeks)	10.02	1.865	13.575
Duration of Consolidation Phase(months)	8.00	1.293	8.671
Duration of Hospital Stay (weeks)	4.91	.299	2.776
Total Duration of Device before Removal (months)	13.57	.874	6.239
Consolidation distraction index = 3.2			
Healing index = 1.78/cm			

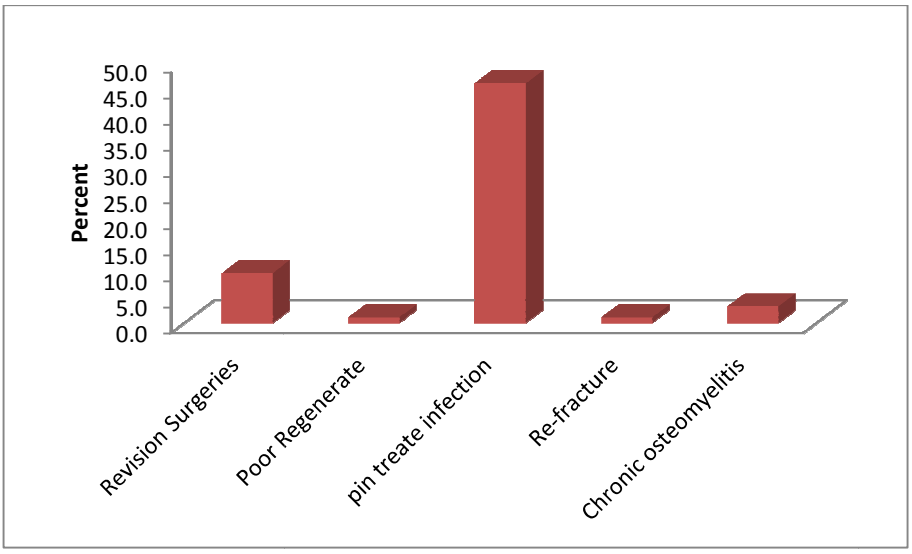

Fig. 4. Bar chart showing complications of treatment

The outcome according to the ASMI scoring system revealed that 52(57%) of patients scored had excellent bone result, 27(29.3%) had good bone result, 12(13.0%) had fair bone result and 1(1.0%) patient had poor bone result. While 55(60.0%) had excellent functional result, 23(25.0%) had good functional result, 7(7.6%) had fair functional result and 7(7.6%) had poor functional result [Fig. 5 & Table 5].

4. DISCUSSION

In this study mean age of patients with complex nonunion was 31.2±14.2 years with male predominance 72(78.3%). This is similar to previous study by Hiranya et al. [1] Mahantesh et al. [5] and Ashraf et al. [11] who found complex non-union most common in the third decade with male predominance, Road traffic accident (RTA) was the predominant mechanism of injury 70 (74.5%) [Vehicular accident 41(43.6%) and motorcycle accident 29(30.9%)] was most common mechanism of injury [Table 3]. This is in keeping with previous studies by Harinya et al [1], Mahantesh et al. [5] and Ashraf et al. [11] where RTA was the commonest mechanism of injury. This is probably because people of this age group are more adventurous and more prone to open fractures of long bones secondary to high velocity trauma [12,13].

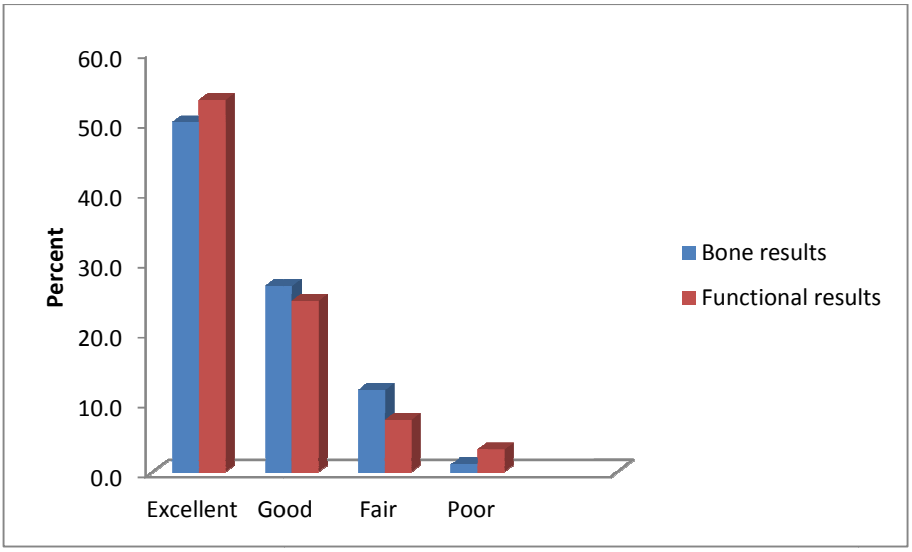

Fig. 5. Composite bar chart showing comparism of bone results and functional results

Table 5. Showing comparism of present results with previous studies

Results		Present study	Hiranya et al. [1]	Hashmi et al. [18]	Patil et al. [2]	Rose et al. [17]
		No(%)	No(%)	No(%)	No(%)	No(%)
Bone						
	Excellent	52(57)	22(79)	67(61)	17(41)	1(17)
	Good	27(29)	03(11)	38(35)	14(34)	3(60)
	Fair	12(13)	-	04(3)	4(10)	1(17)
	Poor	1(1)	03(10)	-	6(15)	1(17)
Functional						
	Excellent	55(60)	11(40)	46(42)	14(39)	1(17)
	Good	23(25)	14(50)	55(50)	14(39)	3(60)
	Fair	7(8)	-	04(3)	2(5)	-
	Poor	7(8)	-	-	2(5)	2(33)
	Failure		3(10)	05(5)	2(6)	-

This study showed that tibia 61(66.3%) was the more commonly predisposed to complex nonunion and majority 64 (68.1%) were infected non unions [Table 3]. This is in keeping with previous studies by Harinya et al. [1] which reported tibia as most commonly involved (54.0%) in complex nonunion and Mahantesh et al. [5] who reported 100% of infected non unions involving the tibia. The likely cause for this is that one-third of tibia being entirely subcutaneous on its anteromedial border is more prone to open fractures with associated devitalized bone and soft tissue envelope which leads to decreased contributors to fracture healing and increased susceptibility to infection. This limits options for stabilization with consequent high rate of complex non-union [1-3,5].

Complications may occur during treatment most commonly during the distraction phase; hence, the surgeon has to be constantly on the lookout. The rate of major complications (excluding pin tract infections) in this study was 19.6%. This is in keeping with Dahl et al. [8] who reported between 13%- 33% of major complications following distraction osteogenesis and they stated that the complication rates appears to relate to the severity of the deformity, rather than the device used and observed that there was a significant decrease in complications as experience was gained [8].

The commonest complication encountered in this study was pin tract infection in 40 (42.6%) [Fig. 4]. Previous studies reported by Hiranya et al. [1] reported 78% pin tract infection. Mahantash et al [5] and Marko et al. [14] also reported pin tract infection as the commonest complication in their studies. Majority (90.0%) of pin tract infection in this study were Checketts-Otterburn grade 1 and 2 [15] which resolved with improved pin site care with povidone iodine and oral antibiotic therapy according to sensitivity pattern. Four patients (10.0%) had Checketts-Otterburn grade 3 [15] in tract tract infection which required revision surgeries to reposition the screws. No major pin tract infection (Checketts-Otterburn grade 4-6) [15] requiring abandoning of LRS was encountered in this study. Pin tract infection remains a clinically challenging problem. It is advocated that standardised pin site protocols that encompass an understanding of external fixator biomechanics and meticulous surgical technique during pin insertion, postoperative pin site care, tightening of all bolts to ensure rigidity of construct, avoidance of weight bearing during latent phase and distraction phase could limit the incidence of major infections and treatment failures [15].

Chronic osteomyelitis was observed in 3(3.2%) patients. Harinya et al. [1] reported 6% chronic osteomyelitis in their study. Extensive debridement is advocated prior to application of the linear rail system to minimize this complication. Any tissue of doubtful viability should be removed during debridement. This should be followed by antibiotic therapy with good bone penetration.

Poor quality of regenerate was observed in 1(1.1%) patient. This may be attributed to inappropriate distraction protocol. Harinya et al. [1] in their study reported premature consolidation in 3.4% of cases. Following latency period, distraction of 1 mm per day (0.25 mm 6hourly hour) yields most optimal results. Distraction less than 0.5 mm / day may result in premature consolidation, whereas more than 2 mm per day over-extends the bone regeneration process [1,14-16]. The quality of regenerate may also be influenced by factors such as age, where children, young adults with higher growth potential yield superior results [1, 15,16]. As well as site of lengthening where metaphyseal lengthening leads to better osteogenesis than diaphyseal lengthening (larger cross-sectional area and increased vascularity. Furthermore, the metaphyseal region contains much more cancellous bone than the diaphyseal region and this type of bone has a much higher potential for osteogenesis [14-16]. Mangal et al. [16] in his study stated that if the radiographic appearance of the regenerate contains central radiolucency greater than 8 mm then the distraction may be too fast and conversely, if the central radiolucency is less than 2 mm then the distraction may be proceeding too slowly. Radiographs taken at the 4th postoperative week should reveal some callus formation. If callus is not seen, then distraction should be temporarily slowed or reversed. If premature consolidation is present, then consider increasing distraction to 1.25 mm per day [16].

Refracture rate in this study was 1.1%. Hiranya et al. [1] in their study reported 3% refracture rate. Refracture may occur at the docking site where soft tissue interposition may not allow for adequate healing or when docking site malalignment may not provide enough surface contact for adequate healing. This complication should be prevented by removal of soft tissue interposition, ensuring adequate contact,

compression and bone grafting may assist in this regard. Protected weight bearing until the regenerate is fully corticalized is also advocated to prevent refracture. A previous study by Mangal et al. [16] has shown that autologous Bone Marrow Grafting Combined with Demineralized Bone Matrix Improves Consolidation of Docking site after Distraction Osteogenesis. Mahantesh et al. [5] with his experience with twenty patients, advocated tibial lengthening over an intramedullary nail to protect against refracture and aid early rehabilitation.

The outcome according to the ASAMI scoring system [Table 1 & Table 2] revealed that majority of patients had satisfactory clinical outcome [52(57%) had excellent bone result, 27(29.3%) had good bone result and 55(60.0%) had excellent functional result, 23(25.0%) had good functional result (Fig. 5 & Table 5)]. This result is comparable to previous studies by Hiranya et al. [1], Hashimi et al. [5], Patil et al. [2] and Rose et al. [17]. In our study, the functional result was superior to bone result which is in keeping with the previous study by Rose et al. [17] but at variance with Hiranya et al. [1], Hasmi et al. [18] and Patil et al. [2] [Table 5]. This showed that although the bone might not be in perfect anatomical alignment, majority had satisfactory functional outcome. Functional outcome is also improved when application and rehabilitation is confined to specialist centers with multidisciplinary team of orthopaedic and plastic surgeons, radiologist, specialist nurse, microbiologist and physiotherapist.

In view of the prolonged duration of treatment, active involvement and participation of the patients is necessary for successful outcome. Patient should be involved in daily adjustment of the apparatus as well as pin tract care. Exercise of the limb and joints with the cooperation of the physiotherapist is advocated throughout the treatment period. Partial weight bearing should be commenced immediately following the distraction phase. These are considered essential part of this method of treatment.

Several limitations of this study were observed. Being a retrospective study design, only preexisting data could be analyzed and this may have given inferior level of evidence compared to prospective study. Standardization of distraction protocol and pin tract care was difficult in view of active patient involvement and participation. Where patient was lost to follow up, contacts were made via phone calls to assess the Functional outcomes which may have introduced bias to the outcome score.

5. CONCLUSION

This study showed that infected long bone nonunion constitutes a challenging orthopaedic condition requiring complex time consuming surgery. Satisfactory functional outcome was observed in majority of patients with minimal complications. However, this is a long and arduous process requiring meticulous surgical technique, proper follow up, rehabilitation and patient compliance. Being a specialized surgery requiring multidisciplinary care, its use should be confined to specialist centers for optimum outcome.

CONSENT

It is not applicable.

ETHICAL APPROVAL

It is not applicable.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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