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The Study of "Infected Non-Union Tibia Treated With Ilizarov External Fixator as A Bone Transport Unit"

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Abstract:
Background*: An inherent risk in the treatment of open fractures is the occurrence of Infection, Bone loss, Loss of Soft tissue coverage, and Non-union. The rate of infection ranges from 5% for type 1,10% for type 2 fractures and 18-38% for type IIIa-c fracture[01,02,03]. Immediate internal fixation adds insult to devascularisation and mixed infection. Multiple failed surgeries lead to Infection, fibrosis, shortening, Deformity. Multiple operative attempts at Non-union will exhaust bone graft donor sites. The bony gap results initially from an acute traumatic bone loss at the site of the injury, later from repeated debridements. Persistent infection at the Non-union site decreases the chance of wound healing and fracture union. Prolonged bed rest postoperatively leads to osteopenia with delay in resuming work leading to social isolation. Orthopaedic surgeon needs skills in Bone transport techniques, limb lengthening, and deformity correction. They must have the goal of repeated debridement. Challenges include chronic infection, sclerotic bone ends, Joint stiffness, Bone gaps, complex deformities, and shortening. We conducted a study to assess the efficacy of Ilizarov external fixator as bone transporting unit to treat infected nonunion tibia.*
Materials and Methods*: In this prospective study,15 patients were(only males and no female patients) included from inpatients admitted in the Department of Orthopaedic ward, Government general hospital, Kakinada, and were followed for a period of 23 months from January 2018 to November 2019 with infected Non-union tibia aged between 22-45years were selected with a mean age of 42.5 years.*
Results*: All of our patients are moderately built and nourished. Fourteen cases achieved good bone union, one case still awaiting for union and consolidation. The duration of treatment ranged from 13 weeks to 72 weeks, with a mean duration of 42.5 weeks. 14 Cases needed bifocal osteogenesis, and only one case required trifocal osteogenesis. · The length of the bone defect was ranged from 1.5 to 5 cm, and mean defect was four cms. Fourteen patients have returned to their work. The mean bone transport time was 2.27 months. The mean time to union was 6.28 months. The mean healing index time was 1.11month/cm of regenerate formation. There was no realignment of the ring in any case. There were no mortality rates in the present study · There were no amputations in the present study.In all the cases, The Ilizarov ring removed after consolidation without any sedation and anaesthesia (spinal and general).*
Conclusion:*Adequate Debridement is the critical stone for successful treatment[06,07,08]. It allows weight-bearing during the treatment period preventing bone osteoporosis. Bone grafting is not necessary in all cases. It allows for simultaneous deformity correction and associated limb shortening. There is no limit for the size of bone defect for distraction osteogenesis. But if the established principles strictly followed, then the* ***Ilizarov ring fixation and distraction osteogenesis is the safest, most straightforward, most economical, and effective method for the management of segmental extended bone defects due to a variety of causes.***
Key Word*:Non Union : Bone Loss : Ilizarov External Fixator : Infection*

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I. Introduction

Non-union is the failure of fracture to unite. A fracture with non-union resembles a fibrous joint, namely pseudoarthrosis. The diagnosis made when there is no attempt at union at fracture site even after 6-8 months. Non-union is a morbid complication of a fracture and may occur when the fragments move too much, has less blood supply, or gets infected. Infected nonunion of the tibia causes significant challenges for complete resolution and functional restoration. Infected non-union is easy to diagnose but difficult to treat. Superimposed infection is chronic, debilitating, and resistant to treatment. Also, Bones are osteoporotic, deformed, sclerotic, and nonreactive with fibrosis at the non-union site. They are challenging to treat. There are significant gaps to fill at the non-union site and remediable surgeries to equalize limb length[04.]Sometimes united fibula prevents the union of the tibia. Post-operative Stiffness of the knee and ankle creates functional handicaps. The Prolonged treatment causes psychological, social, and economic hardships. Infected tibia non-union usually have bony

defects antero-medially, which results in Varus and Recurvatum deformity. Excision is not compulsory for sclerotic bone ends, which might unite with sustained compression. Creating short oblique bone ends and telescoping both ends results in compression and union of the fracture site. A multidisciplinary team is required for treatment[05.]

AIM OF THE STUDY: The Aim is to achieve union in Infected Nonunion Tibia by Dynamic Circular Ilizarov External Fixator.

OBJECTIVES:

1) Eradication of infection by Debridement of infected nonviable bony edges followed by Parenteral antibiotics according to culture sensitivity reports & local application of Antibiotic cement and gel foam.
2) Filling the bone gap & achieving union by Bone transportation.
3) To evaluate the functional outcome of the limb by ASAMI SCORING.

II. Materials And Methods:

In this prospective study,15 patients were(only males and no female patients) included from inpatients admitted in the Department of Orthopaedic ward, Government general hospital, Kakinada, and were followed for a period of 23 months from January 2018 to November 2019 with infected Non-union tibia aged between 22-45years were selected with a mean age of 42.5 years.

INCLUSION CRITERIA :

1) Age group between 20-45 years.
2) Infected non-union.
3) Only male patients were selected.
4) Bone gap more than 1.5cm & less than 10cm.

EXCLUSION CRITERIA :

1) All acute compound fractures.
2) Pathological fractures.
3) Presence of comorbidities like Diabetes associated Neuropathy complications, chronic kidney diseases, chronic lung disease, HIV patients.
4) Non-cooperative and non-willing patients.
5) Pseudoarthrosis tibia

III. Methodology:

My study is a prospective study. A total of 15 Patients were included from inpatients admitted in the Department of Orthopaedic ward, Government general hospital, Kakinada, and were followed for a period of 23 months from January 2018 to November 2019 with infected Non-union tibia aged between 22-45years were selected with a mean age of 42.5 years. ESR, CRP, Total count, Differential count monitored the infection, confirmed by growth conducted positive bacterial cultures. In all the selected patient's definitive surgeries done for primary open trauma developed due to Road traffic accidents resulting in infected Non-union, which has made them chosen for the presentstudy. All the Selected patients had a history of a variety of compound type 1,2,3 injuries with Primary(First) surgeries done include Interlocking tibia done for 8 cases, External fixator done for 4 cases, Plating done for 3 cases. Due to the development of complications like Non-union, Infective discharge with sero-purulent discharge, skin, Subcutaneous tissue necrosis with bone exposure patients were planned for the Ilizarov ring fixator unit application with adequate DEBRIDEMENT for dead and necrotic bone, necrosed slough and soft tissues.

BONE GAP AND OSTEOSYNTHESIS:

POST TRAUMA BONE LOSS	Mean 1-2cm
POST DEBRIDEMENT BONE LOSS	Mean 2-8cm

TYPE OF OSTEOSYNTHESIS	NUMBER OF PATIENTS	PERCENTAGE
BIFOCAL OSTEOSYNTHESIS	14	93.3%
TRIIFOCAL OSTEOSYNTHESIS	1	6.6%

The following surgical procedures done before application of the Ilizarov ring fixator include:

a) Interlocking nailing - 8 cases.
b) Compression plating - 3 cases.
c) External fixator - 4 cases.

d) Skin flap -1 case.
e) Bone cement application in 4 cases.

The following methods did during ring fixator appliance include:
a) Biopsy done in all cases for culture and antibiotic sensitivity.
b) Debridement done in all cases that is the keystone for the removal of the infection.
c) Fibular osteotomy in one case.
d) Bone grafting done in delayed consolidation of regenerate-Two cases.
e) Pin exchange-3 cases.
f) Recorticotomy- Three cases.

Corticotomy was done during ring application in 10 cases and delayed in others due to a prolonged surgical period. The latency period after corticotomy was between 7 to 10 days, with a mean time of 8.5 days. The site of corticotomy varied in different patients according to the non-union site and Debridement site.

RATE OF DISTRACTION:
The Rate of distraction was 1mm per day (0.25mm / 4 times per day) in most of the cases. During transport in a few cases, the rate is slowed down to 1/2mm per day to form proper regenerate.

POST-OP REHABILITATION PROTOCOL:
Started from the Post-operative day 1 include:

I. Daily Pin tract care.
II. Patients are advised to do daily active and passive foot dorsiflexion exercises to prevent the Equinus contracture of the foot. (Asking the patient to tie a roller band to foot).
III. Active knee and Ankle ROM
IV. Quadriceps Isometric exercises.
V. Walker aided, guarded weight-bearing[10,11] started on day two if pain allows, which is the main advantage of the Ilizarov ring fixator.

RADIOLOGICAL EVALUATION:
Regular clinical and radiological evaluation was done monthly after the start of distraction to know for adequate regenerate formation.

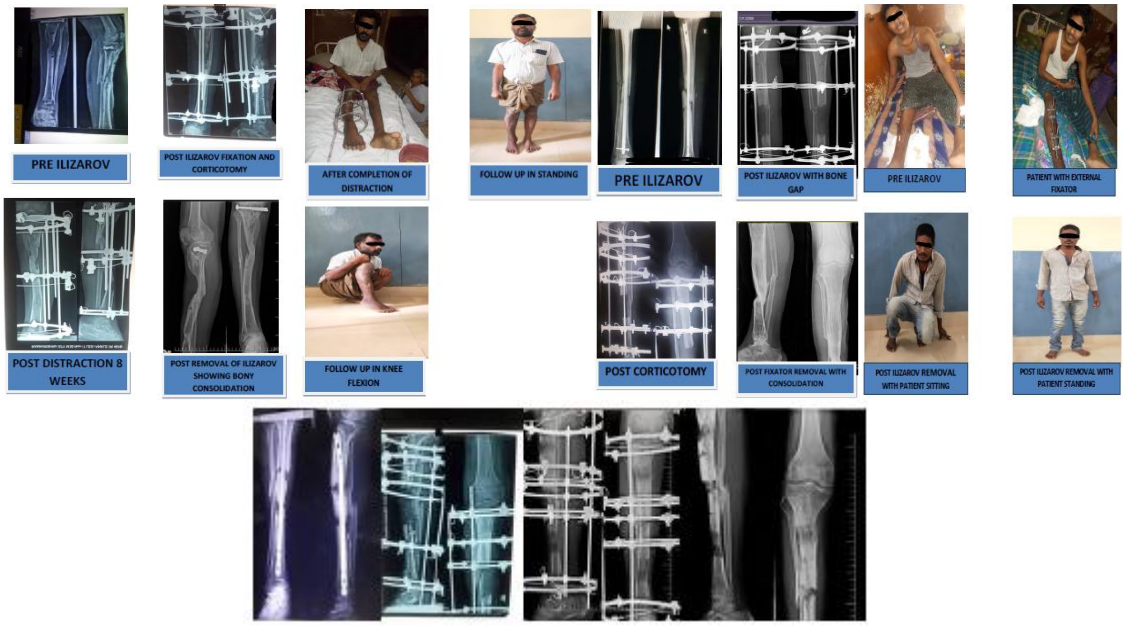
FIXATOR REMOVAL:
1) After a proper formation and consolidation of regenerate, Fixator removed.
2) Radiological consolidation of at least three cortices on orthogonal views.

IV. Results:

We had a total of 15 patients in the study. No patients were lost to follow up. There were only males and no female patients. Their ages ranged between 20-45years with a mean age of 42.5 years. The majority of injuries were due to RTA. Most of the wounds were open, including type III (4 cases) followed by type II (9 cases) and type I(1 case).

- The various bacteria cultured include staphylococcus aureus(MRSA)- 7(55.4%), MSSA- 3(20%), Escherichia coli- 2(13%),pseudomonas aeruginosa -2(13%), Klebsiella-1(6%).
- All of our patients are moderately built and nourished.
- Fourteen cases achieved good bone union, one case still awaiting for union and consolidation.
- The duration of treatment ranged from 13 weeks to 72 weeks, with a mean duration of 42.5 weeks.
- 14 Cases needed bifocal osteogenesis, and only one case required trifocal osteogenesis.
- The length of the bone defect was ranged from 1.5 to 5 cm, and mean defect was four cms.
- One Case developed Equinus contracture deformity.
- Two patients developed knee and ankle stiffness, respectively.
- Distraction rate slowed down in two cases due to poor regenerate formation.
- Local Antibiotic injections are given in four patients with Pin tract infections despite regular Pin tract care.
- Three patients developed failure of corticotomy due to incomplete corticotomy in two cases,
- Early callus formation in one case.
- All patients had some pain at one time or the other so managed with Opioid analgesics.
- Fourteen patients have returned to their work.
- The mean bone transport time was 2.27 months.
- The mean time to union was 6.28 months.
- The mean healing index time was 1.11month/cm of regenerate formation.

- There was no realignment of the ring in any case.
- There were no mortality rates in the present study ·
- There were no amputations in the present study.
- In all the cases, The Ilizarov ring removed after consolidation without any sedation and anaesthesia (spinal and general).



SCORING: The results evaluated as per ASAMI scoring & Dror Paley assessment criteria[12.]The results divided into bony and functional outcomes.

For bone results: Criteria included were: *Union, Infection, Deformity, Limb length discrepancy.*

In the present study, six patients have excellent bone results; four patients have good criteria, Four patients have fair criteria, and one patient has poor criteria. In my study, all the cases except one achieved union. One case though united, still having persistent sinus. Two cases had a shortening of less than<2cms.

For functional results: Criteria included were: Significant limp, Equinus, Ankle rigidity, Soft tissue dystrophy, Pain, & inactivity.

An excellent result indicates active individual with none of the above criteria. A good result shows an active individual with one or two of the above criteria. A fair result means an active individual with 3 or 4 of the above criteria. An inactive individual was considered as a poor result regardless of other criteria. In the present study, functional criteria were excellent in 5 cases, Good in 7cases, fair in 2 cases, Poor in one case.

Functional results including limp due to equinus contracture, Continuous serosanguinous discharge, Previous futile surgeries.

The Scoring Questionnaire for ankle status was the AOFAS[09](American Foot and Ankle Hindfoot Scale). In this, a higher score reflects better pain control and good function.

a) The average pain score was 30/40.
b) The average function score was 30/50, and
c) The mean alignment score was 7/10.

Overall the average total score was 70/100.

COMPLICATIONS:

Various problems encountered include are:

1) Ankle stiffness in 2 cases, probably due to lack of proper rehabilitation.
2) Knee stiffness in 2 cases and was managed with proper physiotherapy.
3) Pin tract infections in 9 cases and were cured with local antiseptic care (local instillation of antibiotics) and daily dressings.
4) Pin Loosening in 3 cases, so removed and later repinning done after control of infection.
5) Poor regenerate formation in one case due to rapid distraction rate.
6) Recorticotomy, in three cases, has done due to incomplete breakage and Improper technique.
7) Repeat debridement done at the non-union site because of discharge.
8) Bone grafting done in two cases at the Non-union site.

AUTHORS	SUBJECT STUDIED	BONY RESULTS %(E,G,F,P)	FUNCTIONAL RESULTS %(E,G,F,P)	No. of patients RETURN TO WORK
Dendrinos et al.	Infective tibia nonunion	50, 28, 4, 18	26, 41, 15, 18	82
Maini et al.	Infective nonunion	70, 10, 0, 20	27, 40, 10, 23	77
Patil et al.	Infective femoral and tibial nonunion	42, 34,10, 14	44, 44, 6, 6	22
Madhusudhan et al.	Infective tibia non-union	22,36.4,22,18.4	5.5,22.2,33.3,38.8	10
Present study	Infective nonunion	40,26.6,26.6,6.6	33.3,46.6,13.3,6.6	14

9) Ankle equinus contracture developed in one case, which was left untreated as the patient managed to walk with it.
10) Valgus deformity, in one case, modified with a shoe raise.
11) Delayed consolidation of regenerate site and Non-union site noted in one patient.

V. Discussion

We employed the Prof.Gavril Abramovich Ilizarov's technique, a Russian doctor, in our patients with infected tibia non-union cases, and had favorable outcome results. The legendary surgeon Ilizarov pioneered the method in 1951. Since then, it has earned the status of being the gold standard for the treatment of difficult non-unions of long bones, including tibia. The technique entails inserting fine wires percutaneously, tensioning them adequately, and attaching to the rings of the rigid circular frame. Hence compression, bone distraction, bone histogenesis, bone lengthening, and deformity correction are all possible to achieve simultaneously. The fixator is strong and stable, thus allowing ambulation and full weight-bearing.

Tension stress effect is the fundamental mechanism of the Ilizarov technique. A mode of segmental bone transport achieved after performing a corticotomy in the metaphysis, followed by gradual bone distraction. Ilizarov techniques employ three methods. These include compression osteosynthesis, bone transport, and acute compression/ lengthening — the compression osteosynthesis mainly used for small defects. The acute compression and lengthening technique are usually considered appropriate for 4-5 cm defects to avoid soft tissue stacking and any neurovascular compromise, which can adversely affect the fracture healing. The published literature has reported on the successful management of some exceptionally more significant size defects in this regard.The other commonly used Ilizarov technique is bone transport, which is equally useful for both small as well as very large skeletal defects.

Particular	*Drorpaley et al.*	*Present study*
No. of cases	25	15
Age	19-62years	20-45 years
Size of defect	Mean 6.2cm	Mean 4cm
Assc.deformity	13	2
LLD	19(2-12cm)	3(1.5-2cm)
Bone grafting	None	Two
Union	All patients	14
Meantime for healing	13.6 months	6.28months
Limp	5	4
Equinus	2	1
Neurovascular complications	0	0
Pain	2	4
Amputations	0	0
Total		

Cattaneo R. Et al[13] found the application of Ilizarov fixator to infected diaphyseal segmental non-unions were very encouraging. They used both internal transport and 78 compression–distraction technique. In the present study, only the external transport technique used with excellent results.

Hosny G. Sharoky MS[14] treated 11 patients with segmental defects of tibia and Non-union with compression and distraction technique only. No additional procedures used in any of their patients. In the present study, Secondary methods like bone grafting, an extension of fixator in the form of foot assembly.

Song H.R. et al.[15,] recommended bone grafting at the docking site to shorten the duration of treatment, prevent re-fracture and non-union in 27 tibia bone defect cases.In the present study, only two cases needed bone grafting.

RING, DAVID MD et al. studied the treatment of infected non-union tibia fractures using the technique of Ilizarov and compared with autogenous cancellous bone graft application under a well-vascularized soft tissue envelope. There were ten patients in the Ilizarov group and seventeen in the bone graft group. Twenty-six patients had a functional limb, and one patient (Ilizarov group) ultimately required a below-knee amputation.

J.Mahaluxmiwala et al.[16] recommend acute docking (shortening) followed by lengthening in segmental bone defects less than 6 cm as this method has the advantage of shorter duration of treatment and minimal additional procedures needed for the bony union. In the present study, This method was not attempted.

Yokoyama K. et al.17 attempted to show the differences between callus distraction and free vascularized fibular grafting. They found that both the functional outcomes and the cost between the two groups did not significantly differ other than the need of vascular surgeons for free fibular graft technique. Even though the defect 79 sizes are varied, the present study has not attempted free fibular graft in any of the cases. A lot of these patients experience difficulty in the longevity of treatment and referral.

DISADVANTAGES OF THE PRESENT STUDY:

01- Less number of patients.
02- Multiple surgeons intervention.
03- Long term follow up.
04- A technical failure in one patient.

VI. Conclusion:

In the present-day of orthopedic practice, Large segmental bone defects of long bones with or without limb shortening can be treated with either the Ilizarov Bone transport unit or Dynamic axial fixator system. Of these two, Ilizarov bone transport unit is cheap, least economical, Less invasive, Easily available, Steep learning curve, Easily learnable procedure, Good stability for immediate rehabilitation compared to dynamic axial fixator system but it is more cumbersome, Bulky apparatus, Futile technique, Requires patient compliance for long term treatment with some preventable complications like Pin tract Infections with effect of loosening of pins, Stiffness of nearby joints Prevented by regular active joint range of movements. The neurovascular complication is an avoidable morbid complication with the careful pinning of k-wires.

- Adequate Debridement is the critical stone for successful treatment.
- It allows weight-bearing during the treatment period preventing bone osteoporosis.
- Bone grafting is not necessary in all cases.
- It allows for simultaneous deformity correction and associated limb shortening.

There is no limit for the size of bone defect for distraction osteogenesis. But if the established principles strictly followed, then the Ilizarov ring fixation and distraction osteogenesis is the safest, most straightforward, most economical, and effective method for the management of segmental extended bone defects due to a variety of causes. Though it is a long-lasting and poor compliant treatment, Results are good with minimal infection compared to other alternatives. Treatment of infected Non-union with the Ilizarov apparatus is a better alternative to Amputation.

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