

# A Prospective Observational Study on Efficacy of Ilizarov External Fixation in Infected Non-Union Tibial Fractures

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## ABSTRACT

### BACKGROUND

Open fractures and fractures caused by high-energy trauma are likely to get infected and result in non-union. Infected non-union of long bones is a problem in developing countries like India. Ilizarov external fixator was employed to correct all the complications associated with non-union such as bone gap, infection, shortening, and deformities. Stable fixation, corticotomy and bone transport was employed to reduce or eliminate infection at the same time achieving bone union and correction of limb length discrepancy. Our study assesses the efficacy and safety of Ilizarov external fixation in patients with infected non-union tibial fractures.

### METHODS

A series of 30 patients with infected non-union of tibia were treated with Ilizarov external fixation in Yashoda super speciality hospital and regularly followed-up between May 2014 and April 2016 (2 years). Bony and functional results were estimated and correlated with existing studies.

### RESULTS

Out of thirty patients treated, bony results were excellent in 17 patients, good in 8 patients, fair in 4 patients and poor in 1 patient. Functional results were excellent in 17 patients, good in 5 patients, fair in 5 patients, and poor in 3 patients. Average duration of the fixator period was 8.1 months (min - 3 months, max - 14 months). Average length of regenerate was 3.64 cm (min - 2 cm, max - 6 cm). Average lengthening index in the study was 2.09 months / cm. Our study in all 4 categories of Association for the Study and Application of Methods of Ilizarov (ASAMI) criteria had approached Dror Paley's Bony results and functional results.

### CONCLUSIONS

In our study results have been encouraging in addressing all the complex problems by Ilizarov principle. Ilizarov external fixator system is the best device to treat infected non-union of tibia. Distal third of tibia is more prone for infection and non-union. Corticotomy or bone grafting is required for augmentation of the healing process. Almost all patients had varying degrees of oedema and pin track infections. Infection was controlled in all the cases and bony union was achieved, no patient had persistence of non-union and infection at the end of 2 years.

### KEYWORDS

Ilizarov External Ring Fixator, Infected Non-Union, ASAMI Criteria, Bony Results, Functional Results, Bony Union

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**BACKGROUND**

Infected non-union has been defined as a state of failure of union and persistent infection at the fracture site for 6 to 8 months.<sup>1,2</sup> Open fractures and fractures caused by high-energy trauma are likely to get infected and develop non-union. Tibia is a subcutaneous bone, and it is the most common weight bearing bone for open comminuted fracture and infected nonunion.<sup>3,4</sup> The prevalence of non-union of closed tibial shaft fractures is 2.5 % and increases 5 - 7 fold for open fractures with gross contamination and extensive soft-tissue damage.<sup>5</sup>

Infected non-union of tibia per se is a challenging problem to the orthopaedic surgeons. Bone union is not obtained until the infection has been eradicated,<sup>6</sup> Amputation is one of the risks of infected non-union and so the Ilizarov method can minimise this potential outcome.<sup>6,7,8</sup> Different modalities of treatment such as extensive debridement and local soft tissue rotational flaps, packing the defect with antibiotic impregnated beads, Papineau – type open cancellous bone grafting, tibiofibular synostosis, cancellous allograft in fibrin sealant mixed with antibiotics and or free micro vascular soft tissue and bone transplants<sup>9</sup> are also used routinely. Prof. Ilizarov’s famous quote “infection burns in fire of regeneration” speaks of the infection, hither to very difficult to control, that almost literally gets burnt out due to the increased blood supply (fire) due to the regenerate.

The Ilizarov method relies on distraction osteogenesis and is used not only for segmental defects, but also to correct complex malalignment with minimal surgery.<sup>10</sup> Ilizarov external fixation address all the complications like non-union, bone gap, infection, shortening, and deformities, but it can cause a variety of problems like pain, swelling of the limb, infection at the site of pins, neurovascular injuries, contractures of the soft tissues, delayed union and non-union, osteoporosis of the lengthened bone, angular deformity or pathological fracture, psychological problems etc. Infected non-union of tibia is a problem in developing country like India. WE wanted to study the efficacy and safety of Ilizarov external fixation in the treatment of infected non-union of tibial fractures and to document various complications associated with Ilizarov external fixation.

**Objectives**

1. To assess bony results and functional results based on the Association for the Study and Application of Methods of Ilizarov criteria and to compare the results in our study with the existing ones.
2. To measure the average duration of external fixator period, average length of regenerate and Average Lengthening Index in our study.
3. To look for various complications that might arise due to Ilizarov external fixation during the course of our study.

**METHODS**

Our study is a prospective observational study conducted in Yashoda super speciality hospital, Hyderabad, Telangana (IEC no – ECR / 49 / Inst / AP / 2013 / RR - 16), between May 2014 and April 2016 (2 years). Patients between age group of 20 - 65 yrs., who had sustained injury (open / closed) to his / her leg, fulfilling inclusion and exclusion criteria, treated previously (outside hospital / in our hospital), presented at a later date with clinical and radiological signs of infection and non-union of tibia at fracture site, were selected as subjects for the study. The sample size of our study was 30 patients with infected non-union of tibia, estimated using nMaster 2.0 software based on the study done by Dr. Dror Paley et al.<sup>11</sup> A written informed consent was obtained at the time of admission. All the patients were treated operatively with debridement and Ilizarov external fixation and all the patients had regular follow-up visits to our out-patient department for the entire duration of treatment. Results of our study were compared using ASAMI criteria (Table 1) with that of existing ones.

<b>Bony Results</b>	<b>Excellent</b>	Union, no infection, deformity < 7°, limb length discrepancy < 2.5 cms
	<b>Good</b>	Union +, any of the two – absence of infection / deformity < 7°, LLD < 2.5 cms
	<b>Fair</b>	Union +, any one of – absence of infection / deformity < 7°, LLD < 2.5 cms
	<b>Poor</b>	Non-union / refracture / union + infection +, deformity > 7°, LLD > 2.5 cms
<b>Functional Results</b>	<b>Excellent</b>	Active, no limp, loss of < 15° knee Ext, < 15° ankle dorsiflex, no RSD, minimal pain.
	<b>Good</b>	Active, any one or two of – limp, stiffness, RSD, significant pain
	<b>Fair</b>	Active, three or all of – limp, stiffness, RSD, significant pain
	<b>Poor</b>	Inactive (unemployed / inability to return to activities of daily living), amputation.

**Table 1. ASAMI Criteria**

**Inclusion Criteria**

1. Patients with infected non-union of tibia fractures treated by Ilizarov method in our hospital.
2. Both male and female patients between age group of 20 to 65 years and with regular post-operative follow up throughout the study.

**Exclusion Criteria**

Patients with severe damage of the tibial nerve; peripheral vascular disease, psychiatric disorders, including senile dementia; and anticipated poor cooperation by the patient.

**Study Procedure**

Detailed history regarding the mode of injury, previous treatment history, time since the first insult and course of disease progression was recorded. After thorough general physical examination, local examination and documentation of events such as period of non-union and infection, amount of shortening, previous interventions if any, decision was made to treat with Ilizarov method. Ilizarov ring, wires and model frame were shown to the patients. They were also explained regarding the need for multiple

operative interventions such as debridement, augmentation of healing by bone grafting / bone marrow infiltration, corticotomy, change of wires / pins etc. Thorough preoperative evaluation and pre anesthetic check-up was done. Pre construct of Ilizarov frame was made one day prior to surgery and was sterilized. Antibiotics were stopped two days prior to surgery for obtaining intraoperative cultures. Patient was placed in supine position with sterile draped sandbags to position the limb on radiolucent operating table, for easy ring assembling under c-arm guidance. Standard Ilizarov technique was followed in wire passing and frame construction. Wires were passed with power drill slowly with start stop technique to prevent thermal necrosis of bone surrounding the wire. Wire were positioned at an angle of 45 - 60 degrees, positioned exactly over the ring. Sinus tracks were excised, and non-union site was opened and debrided thoroughly, sequestrectomy performed till Paprika sign / punctuate bony bleed was seen from freshened bony ends. Intraoperative cultures were obtained and sent for Gram staining, Ziehl-Neelsen (ZN) staining, bacterial culture, antibiotic sensitivity and histopathological examination. Intra operative broad-spectrum antibiotics were administered. Olive and K wires of 1.5 / 1.8 mm were passed in the safe zones and pre-constructed Ilizarov frame was fixed to the wires with the help of wire fixation bolts and tensioned to 120 kg. Further stability was achieved with drop wires placed away from ring and tensioned to a maximum of 90 Kg and half pins were inserted in safe zones. The ring construct is placed over the limb in the correct way so that the limb is ideally in the middle of the ring in its whole length. It is placed / held with 2 finger breadth anteriorly and 3 finger breadth posteriorly. Finer adjustment of the Ilizarov rings with respect to its exact placement over the limb was done. The first and the last rings are then fixed to the limb with an Ilizarov wire. This will position the entire Ilizarov construct ideally and hence, these two transverse Ilizarov wires are known as "Reference wires". The rest of the Ilizarov wire and half pins are inserted and fixed as planned till a stable Ilizarov external fixator is applied to the limb. Other surgeries like implant removal, excision of infected non-union, fibular osteotomy or partial fibular excision and corticotomy are done as and when required during our study. Corticotomy was done using a corticotome and it was performed 6 - 7 cms distal to knee joint. Postoperative epidural analgesia continued for next 48 hrs. Patients were given appropriate IV / oral antibiotics as per bacterial culture and antibiotic sensitivity reports and advised to continue for next 6 - 8 weeks. The pin tracts were cleaned and dressed in Betadine or saline solution regularly. Pin tract infection were graded according to Dahl's classification and treated accordingly. Patients treated with monofocal osteosynthesis were advised to compress non-union site. They were shown how to achieve desired compression / distraction by marking the direction of turn and marking one of the six sides of nut and explained that one turn will give a compression / distraction of 1 mm depending on the direction of turn. Patients treated with bifocal osteosynthesis were advised for compression at non-union site and controlled distraction at corticotomy site

after 7 - 10 days of surgery @ rate of 1 mm per day (four intervals of 0.25 mm) Weekly x-rays were taken and observed for uniform opening of corticotomy site and nature of regenerate. Distraction rate was manipulated accordingly. The regenerate is classified radiologically, and distraction rate is adjusted accordingly. Early maturing regenerate was distracted, and poor regenerate was distracted at a slower rate. Distraction continued till adequate length of regenerate is formed and stopped once radiological maturation of regenerate was achieved and waited for consolidation of regenerate. Regular physiotherapy was given to prevent knee and ankle stiffness. Correcting leg length discrepancy with shoe raise was done to prevent secondary deformities like fixed pelvic obliquity / adduction or abduction deformity, contralateral hip and knee fixed flexion deformity, ipsilateral ankle equinus and spine deformities. Frame dynamisation test was employed to dynamize the frame before removal after complete consolidation of regenerate. When at least three of the four cortices show neo-corticalisation, the non-union site was labelled united and removed under local anaesthesia in operation theatre. And above knee pop slab was applied for 2 weeks, followed by functional cast bracing and full weight bearing. Functional bracing was removed after 4 - 6 weeks.

At each follow-up, progression of events was documented in patients record book, study proforma and tabulated in MS Excel sheet and results were analysed at the end of study.

## RESULTS

In our study, 30 patients with 30 limb segments were studied and results were tabulated in Master chart. Out of whom 26 were males and 4 were females. In our study minimum age was 21 years and maximum age was 63 years with a mean age of 35.56 years. Majority of them were between 20 - 30 years (12 patients) followed by 31 - 40 years (9 patients), 41 - 50 years (5 patients), 51 - 60 years (3 patients), > 60 years (1 patient). All cases in our study sustained high velocity injury due to road traffic accidents. We had 18 patients (60 %) with Type III compound injury, 5 patients (16.67 %) with Type II, 3 patients (10 %) with Type I compound injury and 4 patients (13.34 %) with closed injury. With the severity of trauma, the infection chances raised significantly in our study. AO-fixator was performed previously in 17 patients, nailing was performed in 8 patients and plating was done in 5 patients. Most common site of non-union was distal 1 / 3rd in 15 patients (50 %), followed by middle 1 / 3rd in 12 patients (40 %) and proximal 1 / 3rd in 3 patients (10 %). Average duration of non-union in preoperative period was 9.8 months (min - 2 months, max - 64 months) and monofocal osteosynthesis was done in 19 patients. Bifocal osteosynthesis was done in 11 patients. Tibia had a pre-operative shortening ranging between 1 - 8 cm with an average of 2.83 cm (1.63 cm in monofocal group and 4.9 cm in bifocal group). Bone marrow infiltration was done in 50 % (15 patients), bone grafting in 20 % (6 patients), no

grafting was required in 30 % (9 patients). No lengthening was aimed in monofocal osteosynthesis, so patients had a residual average shortening similar to that of pre-operative value, that is 1.63 cm. Corticotomy with lengthening was aimed in bifocal osteosynthesis, so residual shortening came down from an average of 4.9 cm to 1.27 cm at the end of study. The total average residual shortening in all the 30 patients after treatment with Ilizarov fixation was 1.5 cm. The average duration of Ilizarov external fixator period in our study was 8.1 months (min – 3 months, max – 14 months). Monofocal fixation period was 8.63 months. Bifocal fixation period was 7.18 months. No lengthening was aimed in monofocal osteosynthesis. Average length of the regenerate in bifocal osteosynthesis was 3.64 cm (min – 2 cm, max – 6 cm). Lengthening index is defined in months in the apparatus i.e. fixator period / the length gained. In our study, the average lengthening index was 2.09 months / cm.

Out of thirty patients in our study, bony results were excellent in 17, good in 8, fair in 4, poor in 1. Functional results were excellent in 17, good in 5, fair in 5, poor in 3 (Table 2).

ASAMI Criteria	Bony Results	Functional Results
Excellent	17 (56.67 %)	17 (56.67 %)
Good	8 (26.67 %)	5 (16.67 %)
Fair	4 (13.33 %)	5 (16.67 %)
Poor	1 (3.33 %)	3 (10 %)

**Table 2. ASAMI Results of Our Study**

**Complications**

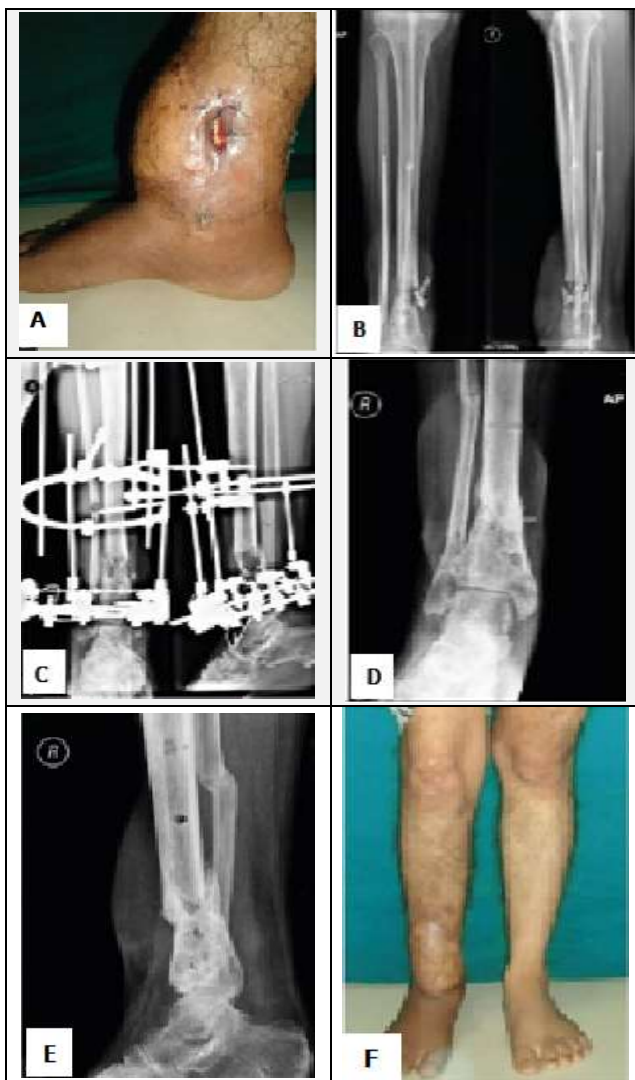
All the patients tolerated Ilizarov fixator well during the course of our study. Five cases had permanent ankle stiffness and subtalar joint stiffness. All patients had varying degrees of oedema, pain and pin tract infection. Delayed appearance of regenerate was seen in 5 patients and poor regenerate in 3 patients. Infection needing change of wires / pin / rings was seen in 5 patients and wire breakage in 2 patients. Significant shortening (> 2.5 cm), significant deformity (> 70 of angulation) was seen in one patient each. Equinus deformity of ankle was seen in 5 patients.

**DISCUSSION**

Ilizarov technique is based on the principles of tension-stress effect and distraction histogenesis. When a living tissue is distracted in a controlled way, it produces new tissue of the same kind called as regenerate. Ilizarov technique uses external fixation principles providing multiplanar stability. Ilizarov external fixation provides correction of all the complications associated with non-union, bone gap, infection, shortening, and deformities. Corticotomy, stable fixation and bone transport is employed. It reduced infection and at the same time achieved bone union and correction of limb length discrepancy.



**Case 1: A 27 yrs. old female patient had h / o road traffic accidents (RTA) 9 months ago, compound grade 2 fracture, mid shaft tibia, treated earlier with external fixator, came with pus discharging from sinus. We treated with debridement and Ilizarov fixation. Figure 1. A. External Fixator with Tibial Infection on Union. B, C, D. Ilizarov Ring Fixator Applied, Corticotomy and Distraction. E. Adequate Union and Consolidation at Fracture Site and Corticotomy Site Respectively. F – Squatting. G - Equalized Limb Length.**



**Case 2: A 38 yrs. old male patient sustained injury to right distal 1 / 3 tibia treated with free flap cover and external fixator, developed sinus track at fracture site. Treated with debridement and Ilizarov fixator at a later date. Union was achieved in 7 months. Figure 2. A. - Sinus Track at Fracture Site at the Flap Corner. B. - Sclerosing and Smoothing of Fractured Ends. C. - Debridement with Sinusotomy and Ilizarov Fixation. D., E. - Union Achieved in 7 Months. F. - Gross Appearance after Frame Removal.**

The average duration of non-union before Ilizarov fixator application in our study was observed to be 9.8 months, similar studies by ShahidKhan Azmat et al.<sup>12</sup> had 11.9 months, Sachin R Jain et al.<sup>13</sup> had 12 months. The average preoperative tibial shortening before Ilizarov frame application in our study was observed to be 2.83 cms, similar studies conducted by Sachin R Jain et al.<sup>13</sup> had 2.75 cm, ShahidKhan Azmat et al.<sup>12</sup> had 3.3 cms, David ring et al.<sup>11</sup> had 3.7 cms, Robert Cattaneo et al. had 4 cms, Harry L Tucker<sup>14</sup> had 3.1 cms. The average length of regenerate / length gain in tibia due to controlled distraction in our study was 3.64 cms, similar studies conducted by Sachin R Jain et al.<sup>13</sup> gained length of 2.56 cms, Dr. Dror Paley et al.<sup>15</sup> gained 5.6 cms. The average time duration of our patients in Ilizarov fixator was observed to be 8.1 months, similar study conducted by Sachin R Jain et al.<sup>13</sup> had a result of 8.6 months, Madhusudhan et al. had 8.6 months, Magdum et al.<sup>16</sup> took

10.2 months, Mehtab et al.<sup>17</sup> had 10.5 months, Dr Dror Paley et al. had a result of 10.1 months.



**Case 3: A 29 yrs. old male patient had compound fracture of middle 1 / 3 right tibia of 12 months duration treated with plain external fixator and developed non-union and had subclinical infection (intra-op cultures positive). 12 months old infected non-union with shortening of 3.5 cms. 5 months follow-up with complete consolidation of regenerate. Ilizarov frame was removed after 8<sup>th</sup> months. Figure 3. A. 12 Months Old Infected Non-Union with Shortening of 3.5 cms. B. 5 Months Follow-Up with Complete Consolidation of Regenerate.**

Study Group	Lengthening Index
Our study	2.09 months / cm
Sachin R Jain et al. <sup>13</sup>	1.98 months / cm
Madhusudhan et al.	1.57 months / cm
Magadam et al. <sup>16</sup>	1.02 months / cm
Mahaluxmivala et al. <sup>18</sup>	2.63 months / cm
Eduardo Gracia et al. <sup>20</sup>	1.02 months / cm
Dr Dror Paley et al.	1.2 months / cm

**Table 3. Comparison of Average Lengthening Index of Our Study with Similar Studies**

Bony Results	Excellent	Good	Fair	Poor
Our study	56.67 %	26.67 %	13.33 %	3.33 %
Dror Paley et al.	60.87 %	26.09 %	8.7 %	4.35 %
Sachin R Jain et al. <sup>11</sup>	59 %	27.3 %	9.1 %	4.6 %
Dendrinios et al.	50 %	29 %	3.6 %	17.4 %
Magadam et al. <sup>16</sup>	76 %	20 %	13.8 %	8.6 %
Rose et al. <sup>18</sup>	16.7 %	50 %	16.7 %	16.7 %
Madhusudhan et al.	22 %	36.34 %	22 %	18.18 %
LalitMaini et al. <sup>21</sup>	70 %	10 %	0 %	20 %

**Table 4. Comparison of ASAMI Bony and Functional Results of Our Study with Similar Studies**

Lengthening index is defined as months in the apparatus i.e. fixator period / the length gained. The average lengthening index in our study was observed to be close to the study of Sachin R Jain et al.<sup>13</sup> Mahaluxmivala et al.<sup>18</sup> Madhusudhan et al. Dr. Dror Paley et al. (Table 3).

The bony results in our study was observed to be similar to the study results of Dror Paley et al. Sachin R

Jain et al.<sup>13</sup> Farmanullah et al.<sup>19</sup> Dendrinios et al. The functional results in our study was observed to be similar to the study results of Dror Paley et al. Magadam et al.<sup>16</sup> Farmanullah et al.<sup>19</sup> Sachin R Jain et al.<sup>13</sup> (Table 4).

Functional Results	Excellent	Good	Fair	Poor
Our study	56.67 %	16.67 %	16.67 %	10 %
Dror Paley et al.	64 %	28 %	4 %	4 %
Sachin R Jain et al. <sup>13</sup>	68.2 %	9.1 %	9.1 %	13.7 %
Dendrinios et al.	25 %	39.2 %	14.13 %	21.5 %
Magadam et al. <sup>16</sup>	60 %	32 %	4 %	4 %
Farmanullah et al. <sup>19</sup>	56.9 %	31.1 %	6.9 %	5.1 %
Rose et al. <sup>18</sup>	16.7 %	50 %	0 %	33.3 %
Madhusudhan et al.	5.56 %	22.22 %	33.33 %	38.89 %
LalitMaini et al. <sup>21</sup>	26.7 %	40 %	10 %	28.3 %
Cattaneo et al.	75 %	0 %	22.7 %	3 %

**Table 5. Comparison of ASAMI Functional Results of Our Study with Similar Studies**

In our study, bony results were slightly better than the functional results. Excellent bony results do guarantee excellent functional results, but good bony results do not guarantee good functional results. Functional results are affected by many other factors like conditions of the muscles, vessels, joints, pin track care and patient's compliance to physiotherapy. On comparing our results with other similar studies conducted, the results are almost the same which shows that union was achieved at the non-union site in almost all patients by the end of the treatment. Almost all of our patients returned to their normal activities of daily living which was not possible before surgery.

## CONCLUSIONS

Infected non-union of tibia is common in developing countries like India, Ilizarov technique is effective in achieving bony union and in controlling infection. Infected non-union of tibia is associated with limb length discrepancy in the form of shortening, deformity, multiple discharging sinuses, osteomyelitis, bone loss due to necrosis and joint stiffness. Ilizarov technique is effective in treating all the complications associated with tibial infective non-union.

Thorough debridement and freshening the bony ends, removal of necrotic and sequestered bone is a key step in achieving bony union. Fibular osteotomy, corticotomy, bone grafting and bone marrow infiltration enhances bony union. Regular daily pin track dressings, follow-up visits along with uniformly applied compression at the fracture site and controlled distraction at corticotomy site, adequate tensioning of wires are recommended. Bone is labelled to be united once adequate regenerate and callus is evident radiologically, and in all cases, we recommend frame dynamization before removal. In infective state, implantation and in-situ internal fixation of fractured bony ends aggravate infection process by forming a biofilm, which acts as a barrier between organism and protective host immune system and also for antibiotic penetrance. Ilizarov technique employs principle of external fixator; so, complications related to internal fixation are better overcome with the Ilizarov external fixators. Early active physiotherapy and rehabilitation prevent joint stiffness,

improve bone strength, preserve range of movements, prevent secondary complications related to immobilisation like, deep vein thrombosis, pulmonary embolism, and depression. Ilizarov technique can be considered as a last stage procedure in grossly infected wounds which are at high risk for amputation.

Data sharing statement provided by the authors is available with the full text of this article at jebmh.com.

Financial or other competing interests: None.

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