# A COMPARATIVE STUDY ON MANAGEMENT OF INFECTED GAP NONUNION WITH MASQUELET-2-STAGED INDUCED MEMBRANE TECHNIQUE VERSUS CONVENTIONAL DISTRACTION OSTEOSYNTHESIS

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**ABSTRACT**

**BACKGROUND**
Management of segmental long bone defects is a challenging task. Attempting limb reconstruction in the presence of significant bone loss usually involves surgery, which is technically difficult, time-consuming, physically and psychologically demanding for the patient, and with no guarantee of a satisfactory outcome. Amputation, external fixators, vascularised fibular grafts, acute limb shortening, and various quantities of allograft and autograft have historically been the mainstays of treatment. For the past 4 decades, Vascularised Fibular Grafting (VFG) and distraction osteosynthesis with ring external factor (Ilizarov technique) stood the test of time to become standard techniques for the management of large long bone defects. More recently, Masquelet described the use of a cement spacer placed within the osseous void followed by staged bone grafting within the induced biomembrane formed around the spacer as a potential treatment strategy to manage these large defects. The main aim of the study is to compare the efficacy of the two philosophically different methods, conventional distraction osteosynthesis, and Masquelet technique in the management of tibial bone defect incurred due to traumatic bone loss, traumatic fractures complicated by infection, and chronic osteomyelitis of tibia.

**METHOD**
Prospective observational study on male and female patients admitted in the Department of Orthopaedics in our tertiary level hospital from November 2012 to September 2014. All patients who have tibial bone defect incurred due to traumatic bone loss, traumatic fractures complicated by infection, and chronic osteomyelitis of tibia are included in the study. Children of age less than 5 years and elderly patients of age more than 85 years are excluded from the present study. Patients with tibial bone defects resulting from injury or surgical intervention are selected into the study and assigned either group D or group M. The patients in group D (n=15) are treated by conventional distraction osteosynthesis while the patients in the group M (n=10) are treated by Masquelet's technique. Patient demographics, radiological bone union rates, time taken to achieve bone union, and infection rates and their statistical significances are compared to come to a scientific conclusion.

**RESULTS**
The study was done over a period of 2 years (November 2012 to September 2014). During this period, we observed 25 cases of tibial bone defects, which were managed by either distraction osteogenesis (Group D:15 cases) or Masquelet technique (Group M:10 cases). In our study, the mean age of group D and group M were 40.9 years (SD±9.89) and 37.8 years (9.13) respectively. In the present study, most of the patients belong to male gender in either groups (8 in group M and 13 in group D). Female gender has 2 patients in either group. In the present study, we observed trauma with infection (46.66%) and trauma (40%) were common aetiological causes for tibial bone defects. There was no significant difference in defect size between the two groups (p=0.889). There was no significant difference between the union rates between the two groups (p=0.358). There was a statistically significant lower duration of union time in group D (p=0.045).There was no statistically significant difference in postoperative infections between the two groups (p=0.175). In group D, two different techniques were done (Compression distraction technique and bone transport technique). On comparing the union rates in both subgroups in group D, there was no statistically significant difference (p=1.0). There was a statistically significant strongly positive correlation between tibial bone defect size and time taken for union in group D, which was not so in group M.

**CONCLUSION**
Masquelet two-stage technique for management of defect nonunions is a relatively newer technique with its own share of technical difficulty and disadvantages. This technique requires a lot of improvisation to improve the outcome. This technique can be an efficient alternative to cumbersome conventional techniques of treating defect nonunions.

**KEYWORDS**
Masquelet, Induced membrane, Distraction osteosynthesis, Defect, Defect nonunion, Nonunion.

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**INTRODUCTION:** Management of segmental long bone defects is a challenging task. Large segmental defects of long bones comprise a complex pathology resulting from a variety of aetiologies.[1] Defect of long bone like tibia is associated with tackling the problems like infection, shortening, deformity, soft tissue loss, and joint contracture.[2,3,4,5,6,7,8,9,10,11,12,13,14,15] The prolonged, painful, and uncertain treatment is usually beset with a range of consequences for the patient varying from the psychological to the socioeconomic problems.[1] Attempting limb reconstruction in the presence of significant bone loss usually involves surgery, which is technically difficult, time-consuming, physically, and psychologically demanding for the patient and with no guarantee of a satisfactory outcome. The function of the salvaged limb may be disappointing due to residual pain, joint stiffness, and neurovascular deficit. The patient may require a secondary amputation due to refractory infection or nonunion.[16]

Tibial bone defects are caused by traumatic and non-traumatic aetiologies. Gustilo-Anderson grade III fractures maybe associated with bone loss. The tibia being a subcutaneous bone is the most commonly involved weight bearing bone for open comminuted fracture and infected nonunion.[17,18] These injuries typically occur in young male individuals with high velocity traumatic open injuries with soft tissue loss and usually fall under Gustilo-Anderson grade III. Surgical interventions in the treatment of osteomyelitis, bone tumour, and congenital pseudoarthrosis invariably lead to large bone defects. Large defects of the tibia are more often caused by low-to-high speed injuries resulting in exposed comminuted fractures than by resection of bone tumours, osteomyelitis, or pseudoarthrosis.

Amputation, external fixators, vascularised fibular grafts, acute limb shortening, and various quantities of allograft and autograft have historically been the mainstays of treatment. Small bone defects (i.e., less than critically-sized defects), in favourable conditions, the bone gap can be managed by direct bone graft or bone substitutes. But, management of critically-sized defects and larger defects, (generally 4-5 cm and above) in association with different favourable or unfavourable variables, calls for specialised surgical interventions accordingly as direct bone grafting will lead to partial resorption of the graft, and weakness of the reconstructed segment. For the past 4 decades, Vascular Fibular Grafting (VFG) and Distraction osteosynthesis with ring external factor (Ilizarov technique) stood the test of time to become standard techniques for the management of large long bone defects. Recently, the use of osteoinductive substances such as recombinant bone morphogenic proteins (rBMP) and osteoconductive scaffolds such as calcium phosphate have found use in the treatment of these clinical situations. More recently, Masquelet described the use of a cement spacer placed within the osseous void followed by staged bone grafting within the induced biomembrane formed around the spacer as a potential treatment strategy to manage these large defects.

Every procedure has got its own advantages and disadvantages. To our knowledge, there is no study till now undertaken to compare the standard time tested and conventional distraction osteogenesis with a novel procedure like Masquelet technique. The purpose of this study is to compare the results of conventional distraction osteosynthesis and Masquelet's technique for the first time. This is, to our knowledge, the first time, the 2 procedures are compared. The main aim of the study is to compare the efficacy of the two philosophically different methods, conventional distraction osteosynthesis and Masquelet technique in the management of tibial bone defect incurred due to traumatic bone loss, traumatic fractures complicated by infection, and chronic osteomyelitis of tibia.

**MATERIALS AND METHODS:** Prospective observational study on male and female patients admitted in the Department of Orthopaedics in our tertiary level hospital from November 2012 to September 2014. All patients who have tibial bone defect incurred due to traumatic bone loss, traumatic fractures complicated by infection, and chronic osteomyelitis of tibia are included in the study. Children of age less than 5 years and elderly patients of age more than 85 years are excluded from the present study.

Patients with tibial bone defects resulting from injury or surgical intervention are selected into the study and assigned either group D or group M. The patients in group D (n=15) are treated by conventional distraction osteosynthesis while the patients in the group M (n=10) are treated by Masquelet's technique. Patient demographics, radiological bone union rates, time taken to achieve bone union, and infection rates and their statistical significances are compared to come to a scientific conclusion.

The present study was carried after obtaining ethical approval from the Institutional Ethics Committee (IEC) of this institute.

Patient data from both group D and group M was collected and later tabulated in Microsoft office excel chart. The continuous variables like age, bone defect size, time taken for union were expressed in mean with standard deviations, range, maximum, and minimum values. The data was analysed by Student's T-test. The categorical variables like sex, age wise distribution, aetiological cause of the bone defects, types of implant used, union rates, and infectious complication were expressed in percentages and analysed by Chi-square test. Correlation statistics between defect size and time taken for the union was done. All statistical analysis was done by using MS Office 2010, SPSS (Statistical Packages for Social Sciences) 17 software. P value of $<0.05$ was considered as statistically significant.

**RESULTS:** The study was done over a period of 2 years (November 2012 to Sept 2014). During this period, we observed 25 cases of tibial bone defects, which were managed by either distraction osteogenesis (Group D:15 cases) or Masquelet technique (Group M:10 cases).

In our study, the mean age of group D and group M were 40.9 years (SD±9.89) and 37.8 years (9.13) respectively. There was no significant difference in mean ages between group D and Group M (p=0.45).

In the present study, most of the patients belong to male gender in either groups (8 in group M and 13 in group D). Female gender has 2 patients in either group. There is no significant difference in gender distribution between the both groups. (p=1). The total number of male patients was 84% (n=21) and female patients was 16% (n=4).

The incidence of tibial bone defects was found to be more in male patients.

In the present study, we observed trauma with infection (46.66%) and trauma (40%) were common aetiological causes for tibial bone defects in group D. In group M, trauma (50%) and trauma with infection (40%) were common aetiological factors. There was no significant difference between the two groups. (p=0.881)

In the present study, Ilizarov frame, Limb Reconstruction System (LRS), and Locking Compression Plate (LCP) were used as the implants. In group D, Ilizarov frame 73.33% (n=11) and LRS 26% (n=4) were used. In group M, in 50% of cases Ilizarov frame, in 20% of cases LRS, and in 30% of cases LCP were used. There was no significant difference between the two groups (p=0.077).

The mean defect size in group D was 5.4 cm (±1.45) with maximum defect size being 10 cm and minimum defect size was 3 cm. In group M, the mean defect size was 5.5 cm (±1.85) with maximum and minimum defect sizes being 8 cm and 3 cm respectively. There was no significant difference in defect size between the two groups (p=0.889).

In the present study, the 86.66% (13/15) of cases achieved union in group D where as it is 70% (7/10) in group M. There was no significant difference between the union rates between the two groups (p=0.358).

Considering bone union cases, we calculated the mean union time in days. In group D, the mean union time was 250.76 days (SD±67.24) in 13 cases and in group M it was 361.71 days (SD±114.63) in 7 cases. There was a statistically significant lower duration of union time in group D (p=0.045).

In the group D, there was 13.33% (2/15) cases show postoperative infection where as it was 40% (4/10) in group M. There was no statistically significant difference in postoperative infections between the two groups (p=0.175). In group D, two different techniques were done (Compression distraction technique and bone transport technique). On comparing the union rates in both subgroups in group D, there was no statistically significant difference (p=1.0).

There was a statistically significant strongly positive correlation between tibial bone defect size and time taken for union in group D (r=0.788; p <0.0001).

There was no significant correlation between tibial bone defect size and time taken for union in group M (r=0.005; p=0.879).

**DISCUSSION:** Management of gap nonunions has always been a daunting task. They are usually compounded by the soft tissue problems, infection, or financial constraints. Many authors have tried different methods in the management of this unsolved problem with varying success rates. The time honoured management techniques are simple bone grafting, vascularised fibular grafting, posterolateral bone grafting, and distraction osteosynthesis.

As this is the first time that the comparison between conventional distraction and Masquelet technique are being compared, there is no previous similar study to directly compare the present study's results with. So, in the present study, previous studies on distraction osteogenesis and studies on Masquelet technique are separately compared with group D and group M respectively and inferences are drawn.

In the present study, 10 patients were managed by Masquelet's technique. Out of 10 patients, 7 cases achieved bone union. The union rate of the present study was 70%, which is lower than the previous other studies. Only iliac bone autografts were used, but no allograft or bone graft substitutes were used in this study.

Stafford et al[19] in their study (n=19) reported 89.5% union rate. In their study, Reamer Irrigator Aspirator System (RIA System) was used to harvest Reamer Irrigator Aspiration Autograft from femur. Evidence exists to show that levels of many growth factors (fibroblast growth factor-alpha, platelet-derived growth factor, insulin-like growth factor-1, TGF-Beta1, and BMP-2) in femoral cancellous bone are present in higher concentrations than they are in iliac crest and platelet preparations.[20] Wideman and co-authors also found that RIA reamings had increased osteogenic elements compared with iliac crest.[21]

Derek J. Donegan et al. [22] (n=6), reported a union rate of (83.3%). In their study, Derek J. Donegan et al. used a non-standardised grafting technique that was determined by the individual defect size, patient profile, and senior author's discretion. They used combinations of iliac crest bone graft, reamed femoral cancellous autograft, free fibular allograft, recombinant BMP, platelet rich concentrate preparations, demineralised bone matrix allograft to fill the residual defects.

Schottle et al[23] (n=6) reported a union rate of (83.3%). In their study, they used mostly autograft, but augmented with allograft when needed. Uzel et al[24] (n=1) and Woon et al[25] (n=2) reported union in all the cases though the significance was minimal considering the number of cases in each case report. Karger et al[26] (n=61) in their retrospective study reported a union rate of 86%.

In the present study, the low quantity of autograft and non-availability of allograft or bone graft substitutes was a limiting factor while addressing large bone defects.

The previous studies used non-standardised grafting technique where they used different components in different proportions with varying bone union rates. Further research and clinical series will hopefully elucidate the grafting components necessary to optimize healing in these patients.

In the present study, of the 15 patients in the distraction osteogenesis group, 13 patients showed union. The union rate of the distraction osteogenesis study group in the present study was 86.7%.

Saleh and Rees et al[8] reported a study comparing bone transport and bifocal compression and distraction. They concluded that the compression-distraction group had a shorter treatment time and lower rate of complication.

Studies by Hans P. Granhed et al,[27] M.A. EL Rosasy et al,[28] C. Sen et al,[29] Yusuf Ozturkmen et al,[30] in which compression and distraction was used showed 100% union rates to which the union rate of the present study group D (86.7%) is not comparable.

The union rate of the study group D is comparable to the union rates of studies done by Chaddha et al[31] (91.6%) and Hiranyakumar Seenappaetal[32] (83.3%) in which bone transport has been done.

In the present study, autograft was not used in the first operation as done by M.A. El. Rosasy et al[28] in their study.

Though, the individual rates of union in the both procedures done in the present study were subpar when compared to the mean union rates of the other studies, the difference in the union rates is maintained.

The study shows that the union rates of Masquelet technique are lower when compared to union rates of distraction osteogenesis.

Being a new technique, further studies to gain more knowledge of the biological aspects is needed and there is more space for the refinement and standardization of the Masquelet technique.

The mean time to union in the present study was calculated from the time since the first stage of Masquelet technique to bone union in case of Masquelet study group and the time since the fixator application to the time to bone union in case of distraction osteogenesis group.

In the Masquelet study group (n=10), mean time to union was 11.9 months with a mean defect size being 5.5 cm. In distraction osteogenesis study group (n=15), mean time to union was 8.07 months with a mean defect size of 5.4 cm. There is a statistically significant difference noted in the time to union between the two study groups. (P=0.045). When the above results were analysed, it was found that the time to union in group D was significantly lower when compared to that of group M.

It was found that the time to union in group D was significantly correlating with the size of the tibial bone defect, whereas in group M, there was no such correlation. C. Karger et al[23] in their retrospective study on Masquelet technique reported that the time until union was not influenced by the size of the bone defect, the present study observed the same in the group M study group.

In the present study, 4 cases (40%) of the Masquelet group (n=10) were infected at the defect site while in 2 cases (13.33%) of the distraction osteogenesis group (n=15) were infected showing increased rate of infection in the Masquelet study group. But, there is no statistically significant difference noted in the infection rates between the two study groups. (p=0.175).

The infections in the Masquelet group were lately presented after the second stage. Of the four infected cases, in one case, union was achieved with the eradication of infection with antibiotic administration. Remaining 3 cases went into nonunion.

In one of the non-united cases, there was persistent discharge and infection after the second stage. It was found to be due to a piece of bone cement, which was missed in the second stage operation. This highlights the importance of the meticulous and complete removal of the bone cement spacer kept in the first stage of the procedure.

Derek J. Donegan et al,[22] Stafford et al, and Schottle et al[23] reported lesser infection rates than the present study infection rate.

**CONCLUSION:** It has been found that the infection presented in this group lately after the second stage of Masquelet technique. The infection rate of the present study was comparable to the infection rate of the study by Apard et al. who reported an infection rate of 41.7%. They also reported late infection.

The late infection in the present study might be because of infection in the first stage due to the presence of antibiotic eluting bone cement spacer in the defect and its persistence after the second stage.

Masquelet et al recommended using a bone cement spacer without antibiotic and a per os antibiotic prophylaxis limited to 7 days, so that an infection related to insufficient debridement would not be masked. It seems that the quality of initial debridement, although difficult to quantify is the main factor of prognosis.

| | **Distraction Osteogenesis** | **Masquelet technique** | **P value** |
|---|---|---|---|
| Mean age (Years) | 40.9(±9.89) | 37.8(±9.13) | 0.45 |
| Gender (Male/female) | 13/2 | 8/2 | 1 |
| Mean defect size (cm) | 5.4(±1.45) | 5.5(±1.85) | 0.889 |
| Nonunion/Union achieved | 2/13 | 3/7 | 0.358 |
| Mean union time | 250.76 (±67.24) | 361.71 (±114.63) | 0.045 |
| Infection (+ve/-ve) | 2/13 | 4/6 | 0.175 |

***Table 1: Comparison of Distraction Osteogenesis and Masquelet Technique Study Groups***

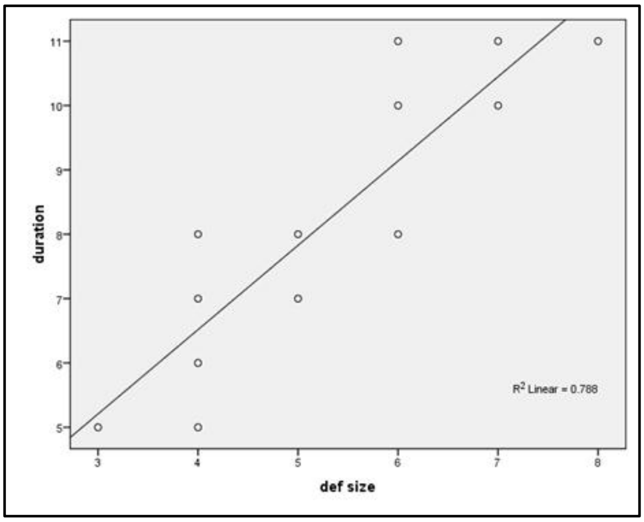



***Chart 1: Correlation Between Duration and Bone Defect Size in Group D***

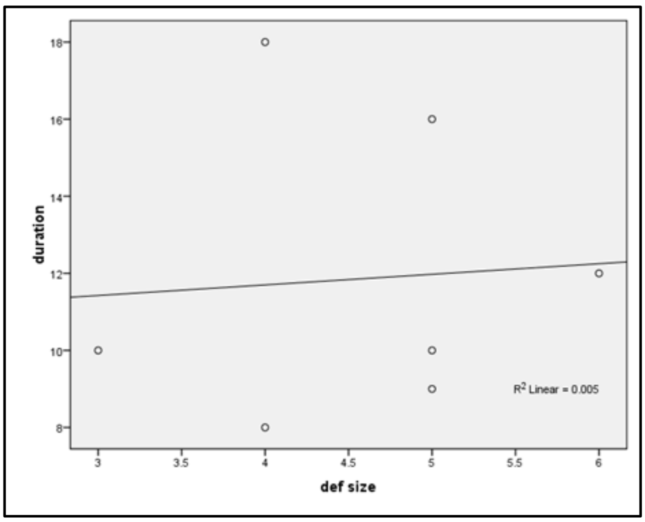
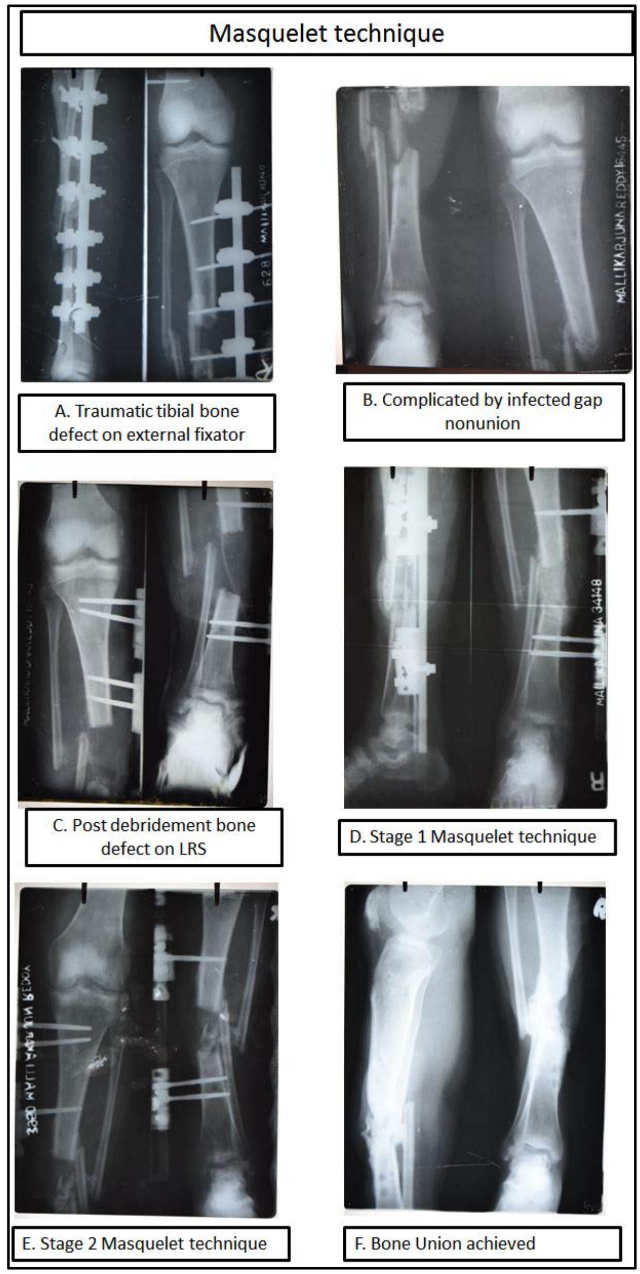
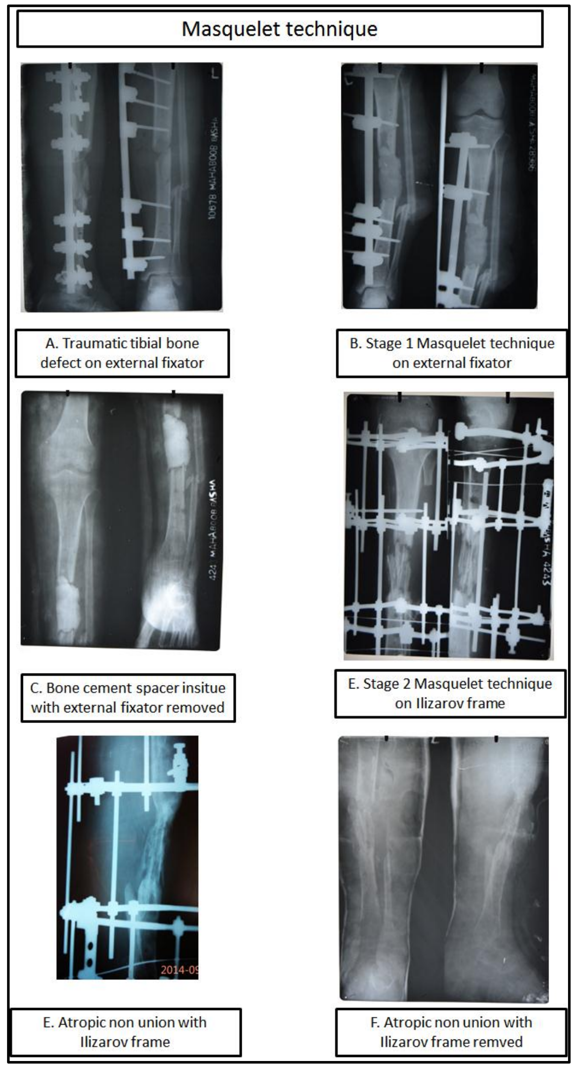
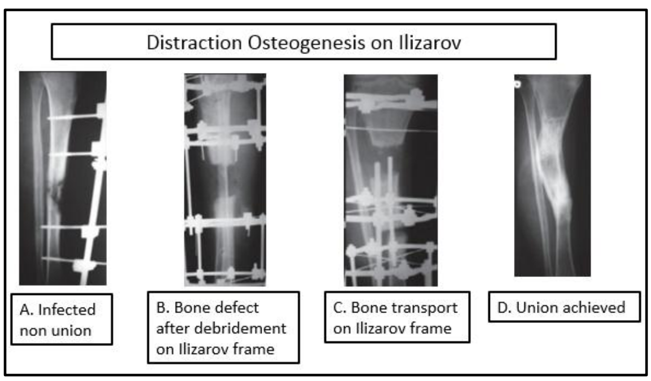


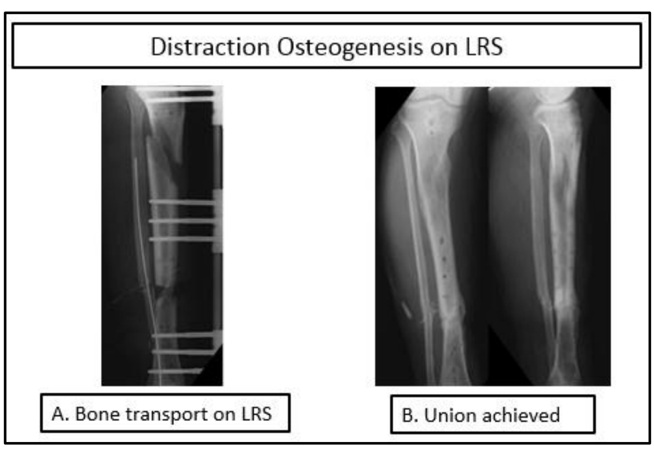

***Chart 2: Correlation Between Duration and Bone Defect Size in Group M***




Masquelet technique
A. Traumatic tibial bone defect
B. Stage 1 Masquelet technique on Ilizarov frame
C. Follow-up X ray after stage 2 Masquelet technique on Ilizarov frame
D. Bone Union achieved

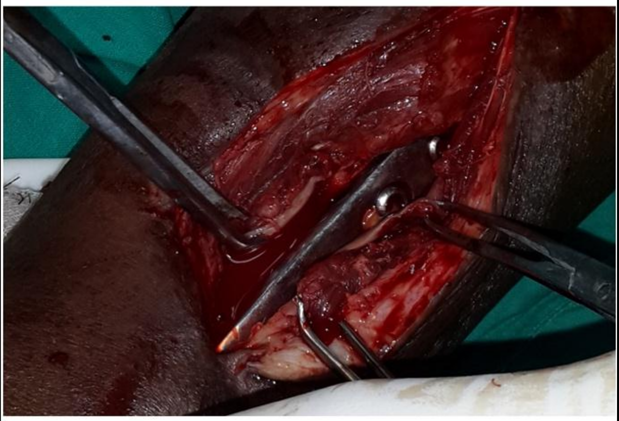

Masquelet technique
A. Traumatic tibial bone defect on external fixator
B. Stage 1 Masquelet technique on external fixator
C. Bone cement spacer insitue with external fixator removed
E. Stage 2 Masquelet technique on Ilizarov frame
E. Atropic non union with Ilizarov frame
F. Atropic non union with Ilizarov frame remved


Distraction Osteogenesis on Ilizarov
A. Infected non union
B. Bone defect after debridement on Ilizarov frame
C. Bone transport on Ilizarov frame
D. Union achieved


Distraction Osteogenesis on LRS
A. Bone transport on LRS
B. Union achieved

Intra operative photographs – Stage 2 Masquelet technique

A. Induced membrane with the bone defect filled with bone cement spacer



B. Induced membrane with the bone defect filled with bone cement removed

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