A study to compare the rate of union of operatively treated Vs the non-operatively treated closed tibial diaphyseal fracture

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Abstract:

Fractures of the tibia are important for two reasons. The first is that they are common; the second that they are controversial – and anything that is both common and controversial must be important". By reason of its superficial location, the tibial shaft represents the most common site of long-bone fractures. A long period of convalescence is inherent even to an uncomplicated healing course of this notorious fracture. Both conservative and surgical techniques have been introduced in an effort to speed time to union while minimizing the occurrence of complications such as residual deformity, consolidation problems, refracture, infection, compartment syndrome, peripheral nerve injuries, anterior knee pain, joint stiffness and vascular complications. The purpose of this study was to observe any changes in the rate of union in fracture of Tibia comparing both methods and to evaluate optimal method of treatment of these fractures.

Keywords: Rate of Union, Operative, non-operative, Closed Tibial, Diaphyseal, Fracture

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Introduction:

Nicoll [1] (1964), has stated, "Fractures of the tibia are important for two reasons. The first is that they are common; the second that they are controversial – and anything that is both common and controversial must be important". By reason of its superficial location, the tibial shaft represents the most common site of long-bone fractures (Leach 2 1975). A long period of convalescence is inherent even to an uncomplicated healing course of this notorious fracture. Both conservative and surgical techniques have been introduced in an effort to speed time to union while minimizing the occurrence of complications such as residual deformity, consolidation problems, refracture, infection, compartment syndrome, peripheral nerve injuries, anterior knee pain, joint stiffness and vascular complications. Less severe fractures generally do well without surgery; more severe fractures usually require it. The question is not whether tibial fractures should be treated operatively or conservatively, but rather which tibial fractures should be treated by what method. The indications for operative and non-operative treatment of the tibial shaft fractures continue to be redefined. Non-operative treatment commonly advocated in the

past, is now generally reserved for closed, stable, isolated, minimally displaced fractures caused by low energy trauma and some stable low-velocity gunshot fractures. Operative treatment is indicated for most tibial fractures caused by high-energy trauma, in which the fractures are usually unstable, comminuted and associated with varying degrees of soft tissue trauma. Much controversy associated with treatment of tibial fractures is the result of proponents of a given therapy failing to specify clearly enough, the characteristics of patients for whom they use it. An increasingly higher expectation by the patient and society for improved functional outcome from treatment [2] Quotes from two of the Doyens of Orthopaedics fraternity will enlighten the dilemma. "Management of fracture tibia requires the widest experience, greatest wisdom and the best of clinical judgement in order to choose the most appropriate treatment for a particular pattern of injury". - Watson and Jones[3] "We still have long way to go before the best method of treating a fracture of the shaft of tibia can be stated with finality". - Sir John Charnley [4] With the increasing use of closed interlocking nailing for fractures of the Tibia, nonoperative techniques are becoming rare. The optimal method of treatment of these injuries remains debatable. The purpose of this study was to observe any changes in the rate of union in fracture of Tibia comparing both methods and to evaluate optimal method of treatment of these fractures.

Aims and Objectives:

To compare the rate of union of operatively treated (ILN) and non-operatively (CR) treated closed tibial diaphyseal Fractures.

Materials and Methods:

STUDY DESIGN: Prospective comparative study

STUDY SUBJECTS: Hospital Based Study, 30 in each group patient who are admitted under Orthopaedics department satisfying inclusion and exclusion criteria were included in the study.

INCLUSION CRITERIA:

1. The inclusion criteria is patients with isolated, Closed Tibial diaphyseal fractures situated within 4 cm distal to tibial tuberosity and 4 cm proximal to the ankle joint.
2. Age >18

EXCLUSION CRITERIA:

1. Associated fractures of same limb or opposite limb
2. The patients with other major injuries, which can Influence the final functional result
   a. Those with open growth plates,
   b. Those with compound fractures.
   c. Fractures with bone loss & severely comminuted Fractures.
   d. Pathological fractures
3. Patients unfit for surgery (declared unfit by anaesthetist on medical reasons)

SAMPLE SIZE: 30 in each group

SAMPLE SIZE ESTIMATION: A power analysis using the G power computer program (Faul et al, 2007) indicated that a total sample of 28 in each group would be needed to have large effect (d=.80) with 90% power using a t test with alpha at.05.[5]

STUDY PERIOD: 6 months

STUDY SETTING: Department of Orthopedics, S.M.B.T Institute of medical sciences and Research Institute.

Once the patient was admitted to the hospital, all information was recorded in the proforma prepared for this study. They were periodically observed during their hospital stay details of plaster cast (CR), surgery and post-operative period was recorded and were discharged with advice to come to the outpatient department regularly. Follow up finding was recorded in the follow up chart of Performa. Patients were followed for minimum 12 month after surgery. In both groups, initially radiographic and clinical examination was done weekly during the first 4 weeks until stability of fracture confirmed. Then they followed every 4 weekly for the 6 month and at 12 month.

OBSERVATION

Table 1: Number of patient

Number Of Patients	
ILN	29 (50.9%)
CR	28 (49.1%)
TOTAL	57 (100%)

There are 57 patients who were included in the study were grouped into **ILN** group, which consisted of 29 patients treated with intramedullary interlocking nailing. & the **CR** group, consisting 28 patients treated conservatively.

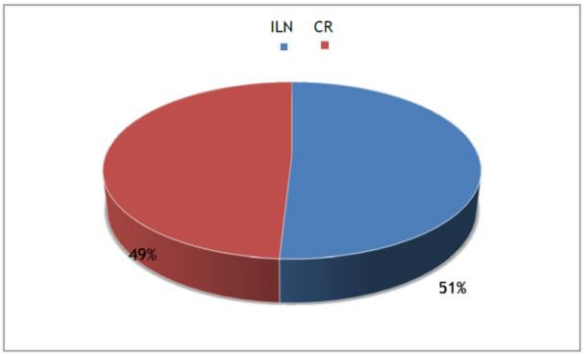

Figure 1: Number of patient in each group

Sex Distribution

Table 2: Sex Distribution

Sex Distribution			
SEX	**ILN**	**CR**	**TOTAL**
MALE	24 (82.75%)	23 (82.14%)	47 (82.46%)
FEMALE	5 (17.25%)	5 (17.86%)	10 (17.54%)
TOTAL	29(100%)	28(100%)	57 (100%)

There were 47 male (24 in ILN & 23 in CR) and 10 female (5 in ILN & 5 in CL) patients.

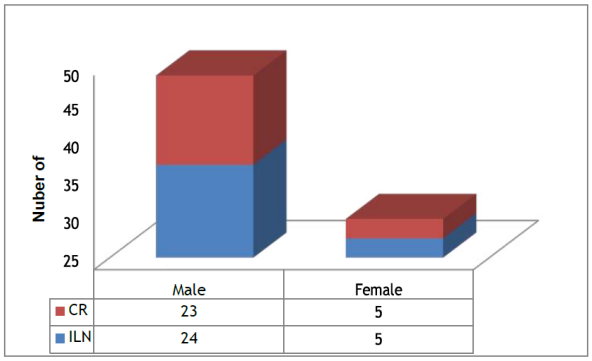

Figure 2: Sex Distribution

Age distribution

Table 3: Age distribution

Groups	Age Distribution						Total
	<20	20-29	30-39	40-49	50-59	60-69	
ILN	3	9	8	5	3	1	29 (50.88%)
CR	1	4	12	9	2	0	28(49.12 %)
Total	4	13	20	14	5	1	57(100%)
$\chi^2 = 6.05$ p= 0.31ns							

The mean age of the patients in the ILN group was 33.45 years and in the CR group it was 36.29 years, the difference being not significant statistically, $p > 0.05$

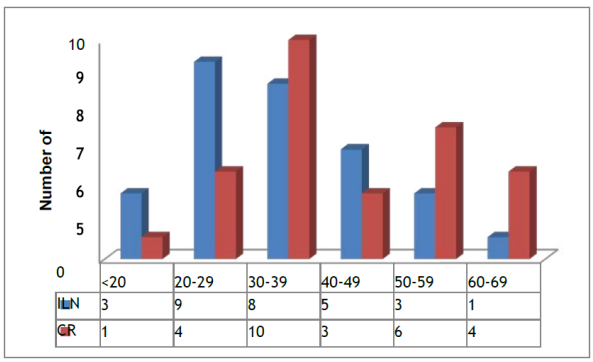

Figure 3: Age distribution

Mode of Injury

Table 4: Mode of Injury

Groups	Mode of Injury			Total
	RTA	FALL	ASSAULT	
ILN	22(75.86%)	7(24.14%)	0(0%)	29(100%)
CR	16(57.14%)	11(39.28%)	1(3.57%)	28(100%)
Total	38 (66.66%)	18 (31.57%)	1 (1.75%)	57(100%)
χ^2 = 2.82 p= 0.24 ns				

The mode of injury was direct trauma/ assault in 1, fall in 18 & RTA in 38. There were 38 (22 in ILN, 16 in CR) high velocity injuries [6] and 19(ILN – 7, CR – 11) low velocity injuries.

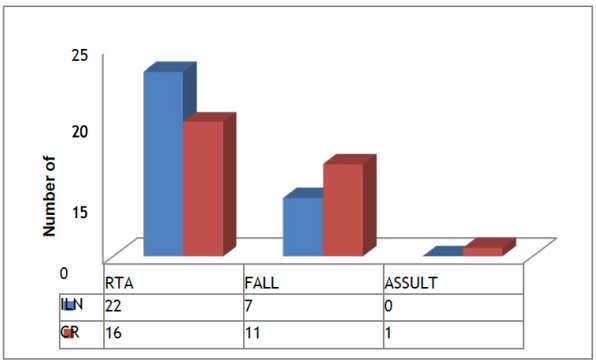

Figure 4: Mode of Injury

Fracture type according to classification

Table 5: Type of Fracture

	ILN	CR	Total
A1	1 (3.448%)	6 (21.429%)	7 (12.281%)
A2	8 (27.586%)	5 (17.86%)	13 (22.807%)
A3	6 (20.69%)	7 (25%)	13 (22.807%)
B1	5 (17.241%)	3 (10.714%)	8 (14.035%)
B2	5 (17.241%)	1 (3.571%)	6 (10.53%)
B3	4 (13.793%)	6 (21.429%)	10 (17.544%)
Total	29 (100%)	28 (100%)	57 (100%)
χ^2 = 7.892 p= 0.16 ns			

ILN group had 15 patients with Type-A (A_1 – 1, A_2 – 8, A_3 - 6) fractures and 14 with Type- B (B_1 - 5, B_2 – 5, B_3 – 4) fractures. In the CR group 18 patients had Type –A (A_1 -6, A_2 -5, A_3 – 7) fractures and 10 had Type – B (B_1-3, B_2 – 1, B_3 - 6) fractures.

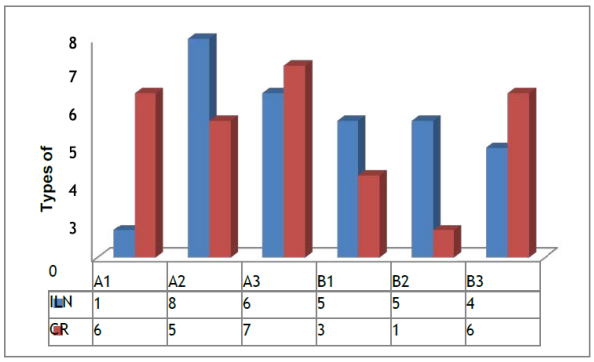

Figure 5: Type of Fracture

Site of Fracture

Table 6: shows the Site of Fracture

Group	Site of Fracture					Total
	Proximal	Proximal/ mid	Middle	Mid/Distal	Distal	
ILN	0 (0%)	6 (20.69%)	18 (62.07%)	1 (3.45%)	4 (13.79%)	29 (100%)
CR	2 (7.14%)	3 (10.71%)	15 (53.57%)	7 (25%)	1 (3.58%)	28 (100%)
Total	2	9	33	8	5	57
χ^2 = 9.56 p= 0.49 s						

The site of fracture of tibia shaft was proximal 1st and proximal/ mid 2nd junction in 11 patients, middle 3rd and mid/distal 4th junction in 41 patients and distal 5th in 5 patients. Comparison of the involvement of fracture in different sites in both groups was not significant (p= 0.49s).

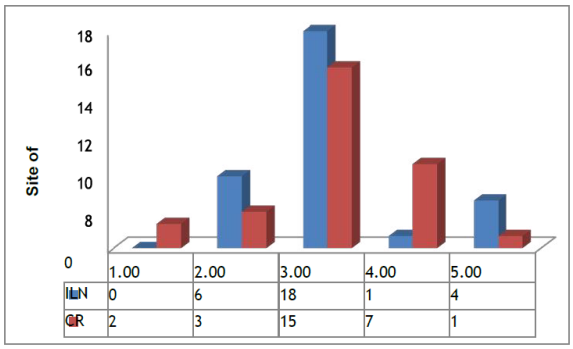

Figure 6: Site of Fracture

Time for treatment from injury

Table 7: Time Taken For Definitive Treatment (In Days)

Time Taken For Definitive Treatment (In Days)				
	No. of cases	Mean	Std. Deviation	t
ILN	29(50.88%)	6.72(53.42%)	2.03(45.011%)	1.44
CR	28(49.12%)	5.86(46.581%)	2.48(54.99%)	p= 0.15 ns
Total	57(100%)	12.58	4.51	

The mean time from the injury to the definitive treatment was almost similar in both the groups (ILN and CR). There was no statistical significant found in the comparison of mean values (p>0.05)

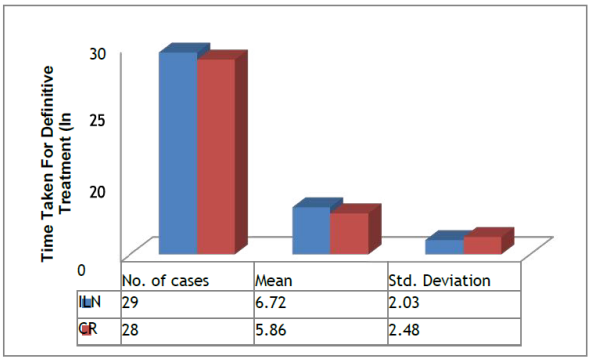

Figure 7: Time Taken For Definitive Treatment (In Days)

Time to PWB

Table 8: Time to Partial Weight Bearing (In Wks.)

Time to PWB (In Wks.)			
GROUP	Mean	Std. Deviation	t
ILN	8.90	1.68	8.50
CR	12.96	1.93	p= 0.00

Partial weight bearing was begun at a mean of 8.90 weeks (SD 1.7) in ILN group and by 12.96 weeks (SD 1.93) in CR group, the difference being highly significant statistically p<0.001

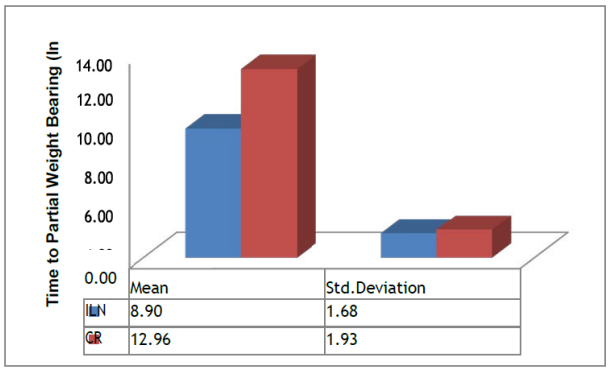

Figure 8: Time to Partial Weight Bearing (In Wks.)

Time to FWB

Table 9: Time to Full Weight Bearing (In Wks.)

Time to FWB (In Wks.)			
GROUP	Mean	Std. Deviation	t
ILN	14.17	1.60	9.37
CR	19.50	2.58	p=0.00 vhs

Time-to-Full weight bearing was 14.17 weeks (SD 1.60) in ILN group and 19.50 weeks (SD 2.7) in the CR group. There was a significant difference observed between ILN and CR groups p<0.001

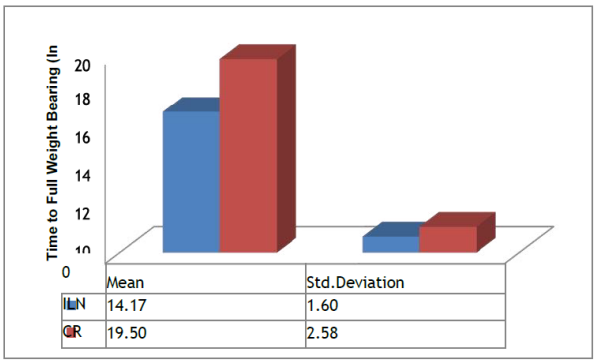

Figure 9: Time to Full Weight Bearing (In Wks.)

Time to Full Range of Movements

Table 10: Full ROM of Knee & Ankle

Group Statistics					
TREAT GRP		N	Mean	Std.Deviation	t
Knee	ILN	29	2.37	0.62	37.26
	CR	28	18.21	2.20	p= 0.00vhs
Ankle	ILN	29	2.28	0.70	29.28
	CR	28	20.54	3.28	p= 0.00vhs

Full range of both knee joint and ankle joint movements were achieved much early in the ILN group (2.37 wks & 2.28 wks) than in the CR group (18.21 wks & 20.54 wks), where the movements were not possible because of the cast.

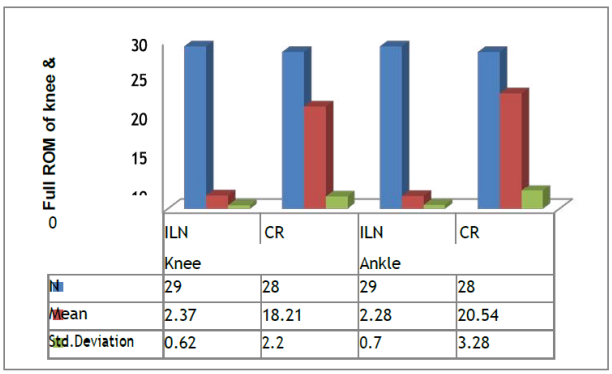

Figure 10: Full ROM of knee & Ankle

Table 11: Rate of Union

Rate of Union			
GROUP	**Mean(wks)**	**Std. Deviation**	**t**
ILN	20.48	3.61	5.43
CR	26.07	4.15	p=0.00 vhs

The rate of union in both ILN and CR groups were noted based on the clinical and Radiological assessment. Clinical assessment includes painless weight bearing and no movement at fracture site. Rate of union based on Radiological assessment includes minimum of 3 of 4 cortices united on antero-posteroir and lateral radiograph.[6]

The mean time to union of bone for the ILN group was 20.48 weeks (SD 3.61), compared to 26.07 weeks (SD 4.15) for the CR group. There was a very high significance observed statistically in the mean values p<0.001.

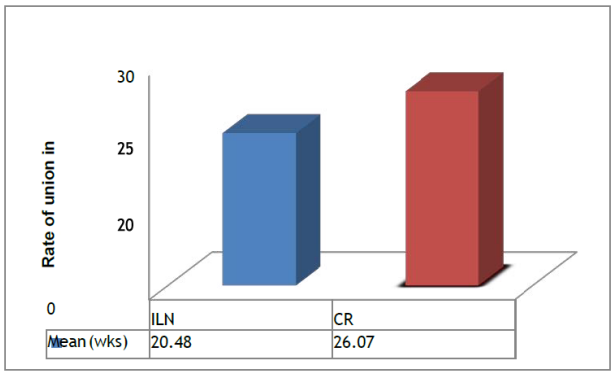

Figure 11: Rate of Union

Discussion:

Tibial shaft fracture is one of the most commonly fractured long bone in the body.[13] Isolated closed tibial shaft fractures conventionally have been treated with closed manipulative reduction and an above-the knee plaster of pairs (POP) cast, followed by conversion to a patellar tendon-bearing cast or a functional cast-brace at about 1 month.[7, 8] An intact fibula was a relative contraindication to functional cast-brace because of increased risk of developing angular deformity. Sarmiento et al had 30 years of experience with the treatment of tibial shaft fractures with a functional cast-brace, and to our knowledge, the results of their study were excellent—the best reported in the literature. However, their results have not been reproduced by other researchers.[9, 10] Therefore prompt and appropriate treatment is essential to curtail prolonged morbidity and disability. Due to the advancement of technology, various techniques are proposed for the management of tibial shaft fracture. However, it is quite difficult to compare the treatment results of intramedullary nailing and cast or functional brace. This is because of difficulty in selecting comparable groups. To make such comparison, both groups must contain comparable fractures

in terms of age, sex, site of fracture, type of fracture etc. As displaced, unstable fractures cannot be treated with a cast or brace alone, which means that they should be excluded from this group. Hence in this study all fractures that were included were suitable equally to for plaster cast treatment and intramedullary nailing so as to obtain comparable groups of conservatively and operatively treated fractures.

In present study total 60 patients were included, out of which 3 patient lost follow up, hence 57 patients only assessed for study. 29 were in ILN group and 28 were in CR group.

Age wise distribution showed that majority of the patients in both the groups were between 20 - 60 years, and the difference in the mean age was not statistically significant (p = 0.31). The mean age of the patients in the CR group was 36.29 years and in the ILN group it was

33.45 years. Hence the patients were comparable with regard to age. This is comparable to previous study conducted by **Maity et al in 2011**[6] and **Toivanen et al in 2001**.[11]

The majority of the patients were males (CR-82.14%, ILN-82.75%) in both the groups. In a study males constituted 70.58% and 82.35% in Conservative and operative groups respectively **Maity et al in 2011.** [6] In a study by **batta et al in 2012** [12] the male /female ratio was 31/3 and 28/6 in CR and ILN group respectively. Thus the sex distribution in present study is similar to that of earlier studies. In the present study the sex distribution was similar in both the groups and hence comparable.

When comparing the mode of injury in both the groups, fractures resulted from a RTA was 57.89% and from fall was 42.14%, and none of the patients had assaults in the ILN group. In the CR group, fractures resulted from a RTA was 38.89%, fall was 61.11%, and assault was 3.57%. The mode of fracture was similar in both the groups and hence comparable. In **Hooper et al in 1991** [13] series 45% of the fractures were the result of RTA. **Batta et al in 2012** [12] reported 80.9% of patients with RTA, **Maity et al in 2011** [28] reported 12/17 (76.47%) cases due to RTA, while **Soumya et al in 2014** [14] reported 52/68 (76.47%) due RTA, which are greater than results which were reported earlier **by Toivanen et al in 2001.**[11]

In the ILN group 15 (51.72%) patients had Type A (A1-1, A2-8, A3-6) fractures and 14 (48.28%) had Type B (B1-5, B2-5, B3-4) fractures.CR group had 18 (64.28%) patients with Type-A (A1-6, A2-5, A3-7) fractures and 10 (35.72%) patients with Type-B (B1-3, B1-2, B3-6).

Overall, both the groups were similar and do not differ statistically, hence were comparable, which was necessary criteria for this study. A study by **Toivanen et al in 2001** [11] showed Type A/ Type B ratio for ILN was 88/12 and for CR group it was 91/9.In **Maity et al in 2011**[6] series Type A/Type B ratio was 13/4 for surgical group and 12/5 for conservative group. In our series the anatomical location of the fracture was in the middle-third of the shaft of tibia in 18 (62.06%) and 15(53.57%) in ILN and CR group of patients respectively. This is comparable to **Batta et al in 2012** [12] series where 52.94% in surgical group and 41.17 in conservative group were middle – third fractures. Similarly **Maity et al in 2011** [6] showed 64.70% in surgical group and 58.82 in conservative group were middle – third fractures. In another study by **Soumya et al in 2014** [14] showed 14/68 (20.58%), 42/68 (61.76%), 12/68 (17.64%) number of patient as a proximal third/ middle third/ distal third respectively. The middle third fractures are common because of anatomical features of more rigidity of the bone and its subcutaneous nature makes it more vulnerable to the injuring force. In our study time from injury to definitive treatment was almost similar in both the groups, 7 days for ILN and 6 days for CR group. This delay for definitive treatment was due to soft tissue swelling, which prevented us to do definitive treatment early. In study by **Maity et al in 2011** [6] mean time of delay to definitive treatment was 5 days for intramedullary nailing group and no days for plaster group. In study by **Soumya et al in 2014** [14] the median time of delay of operation was 5 days for nailing group and for plaster group for (0-5) days. In the present series the partial weight bearing was possible by 8.90 weeks on an average in patients treated with ILN. Patients treated with cast were able to bare partial weight at a mean of 12.96 weeks. This difference was very highly significant statistically (p=0.00). In the present series the full weight bearing was possible by 14.17 weeks on an average in patients treated with ILN. Patients treated with cast were able to

bear full weight at a mean of 19.50 weeks. This difference was very highly significant statistically (p=0.00). In the present study, the full ROM was achieved much earlier in ILN group for both knee and ankle with 2.4 and 2.3 weeks respectively. However for the CR group it was 18.21 and 20.54 weeks. This study results were supportive of earlier study conducted **2012 by Batta et al** [12] **Hooper et al** [13] and **Alho et al** [15] reported early return of knee and ankle joints motion to normal or near normal range without any significant residual stiffness in patients treated with interlocking nail.

Conclusion:

Treatment of Closed Tibial shaft fractures with Intramedullary Interlocking nail provides faster healing and low incidence of severe complications.

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