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### Comparative study of clinical outcome in the “surgical management of open v/s closed tibial shaft fractures with intramedullary interlocking nailing” technique

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#### Abstract

**Background:** Tibia is the most usually fractured long bone. The present study has been taken to review the results of diaphyseal fractures of tibia both closed and open fractures. To evaluate the results of Interlocking intramedullary nailing in diaphyseal fracture of tibia in both open and closed fractures and associate them with fracture union, complications, range of movements and serum lactate levels.

**Methods:** This is a prospective study conducted on included 80 consenting patients of both sex and above 18yrs and below 60years with Gustilo's grade I and II, admitted in RRMCH with both open and closed fracture of tibia who met a predefined criteria. Following ethical clearance the study was initiated. On admission in the ward, detailed history was taken, severity of the injury, extent and type of the trauma to the tissues and detailed examination of the affected extremity was done. Ski grams were studied in detail so as to classify the fracture. The patient is usually followed up at 4 weeks, 8 weeks, and 12 weeks, 16 weeks, 20 weeks and 6 months.

**Results:** Tibial fractures were more commonly seen in males, 30-50 years. We found that Road Traffic Accident was the prime cause of Tibial fracture 62%. The dominant side was commonly involved, 55% the fracture was type I gustilo's grade. There was a direct relationship of the level of serum lactate with the grade of injury and an inverse relationship with the duration of healing and the complication rate.

**Conclusion:** In the present study we concluded that serum lactate positively co-relates with the severity of injury.

**Keywords:** Serum lactate, tibial shaft, intra medullary nailing, gustilo's grade

#### Introduction

Tibia is the most usually fractured long bone in the body with a yearly occurrence of tibial shaft fracture is 2 for every 1000 people [1]. Since tibia is the vast bone of the body and one of the main load bearing bones in bringing down furthest point of weight bearing in the body, fracture can cause delayed morbidity, broad disability, unless treatment is proper. Different systems are currently accessible for treatment of diaphyseal fractures of tibia where Orthopaedics specialist must know about the favourable circumstances, disservices and impediment of each to choose the correct treatment for every patient. The severity, area, level of comminution, age, patient social and financial requests may impact the strategy for treatment. The utilisation of non-agent treatment of tibial that are broadly dislodged or that are the after effect of high-velocity strengths is related with a high pervasiveness of malunion, firmness of the joint, and poor utilitarian result. Tibia has been posturing issues to the orthopedists the world over. With the expanding number of industrialisation, urbanisation and vehicles on street in India, complex injury cases caused by street car crashes have expanded dynamically. Tibial diaphyseal fracture are the commonest long bone fracture experienced by the vast majority of the Orthopaedics specialist's [2].

In a normal populace there are around 26 Tibial diaphyseal fractures for each 1 lakh populace for every year around the globe. Males are more ordinarily affected than females with male rate being around 41 for every lakh for every year and female rate around 12 for each 1 lakh for each year [3] There is a bimodal circulation of Tibial fractures with a prevalence of youthful males [4]. Since 33% of the tibial surface is subcutaneous all through the vast majority of its length, open fracture are more common in tibia than in some other major long bone [5].

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Promote progressively the blood supply of tibia is more shaky in its distal third than that of bone encased by overwhelming muscles.<sup>[6]</sup> The treatment of tibial shaft fractures in open and closed sort has constantly held specific enthusiasm for orthopaedic surgeons. Not just are they moderately normal yet they are frequently hard to treat.<sup>[7-10]</sup> Till now specialists had alternate treatment in the form of "V"nailing, "plates and screws" and external fixators yet these had their own particular disadvantages like delayed mobilisation, infection, delayed union, non-union, malunion and exceptionally unwieldy for patients.<sup>[7-10]</sup>

There are five standard reasons for tibial diaphyseal fractures; falls, sports wounds, coordinate blows or strikes, vehicular accidents and firearm shot injuries.<sup>[11-13]</sup> The essential factors in anticipation are Measure of starting uprooting, Level of comminution, Regardless of whether disease has created and the customary strategy utilised as a part of our facilities in India is towards closed tibial fractures is cast and immobilisation and for the full time of clinical and radiological recuperating. This outcomes in patients lying on bed without weight bearing for a long time prompting complications like joint stiffness, muscle decay, osteoporosis and delayed prostration and its reactions. The strategy for closed nailing without reaming took after by early ambulation and weight-bearing has positive points of interest over every single existing technique, essentially bring down complication rate and has various outcomes. Interlocking nailing has turned out to be the strategy for decision for treatment of these fractures. The intramedullary nailing under image intensifier satisfies the target of stable obsession with negligible tissue harm bringing about better and faster fracture unions.<sup>[14]</sup> The method for treating closed tibial shaft fractures and, during the last few years, also for treating open tibial shaft fractures. The use of intra medullary nailing in the treatment of tibial shaft fractures has the following advantages: closed reduction and preservation of the periosteal blood supply, the possibility of early mobilisation of the knee and ankle joint, the ease with which the limb can be observed postoperatively, a lower prevalence of wound infections, good biomechanical stability of the cortical bone, good possibility for bone union, and a faster recovery and return to work. One common complication after IM nailing of a tibial shaft fracture is anterior knee pain which may be an important handicap for the patient. The pain usually appears a few months after the nailing procedure. The incidence of anterior knee pain varies from 10% to 86% in different studies. The aetiology of anterior knee pain after IM nailing is multiple. Trauma-induced tissue damage, inappropriate methods of nailing, anatomical changes in the knee due to IM nailing, and the presence of the nail have been proposed. However, the exact aetiology of this common postoperative problem is still unknown.<sup>[15-17]</sup> the present study has been taken to review the results of diaphyseal fractures of tibia both closed and open treated with Intramedullary interlocking nailing.

### Materials and Methods

This is a prospective comparative interventional study conducted on 80 consenting patients of both sex and above 18yrs and below 60years with compound tibial fractures or closed fractures fracture of the tibial shaft Gustilo's grade I and II between December 2015 to November 2016, admitted in the orthopaedic wards of Rajarajeshwari medical college with both open and closed fracture of tibia who met a predefined criteria.

### Inclusion criteria

1. Closed tibial diaphyseal fractures.
2. Open diaphyseal fractures of tibia, Type I, Type II as classified by Gustilo-Anderson grading.
3. Diaphyseal fractures in the age group of 18-60yrs.
4. Segmental and comminuted diaphyseal fractures of tibia.

### Exclusion criteria

1. Open diaphyseal fracture of tibia Type IIIA, B and C
2. Tibial fracture with intra articular extensions.
3. Presence of excessive narrow medullary canal.
4. Aseptic non-unions.
5. Malunions
6. Pathological fractures
7. Patients medically unfit for surgery.

The study was initiated after obtaining ethical clearance from the institutions ethical clearance committee.

### Methodology of the study

Ethical clearance from the institutions ethical clearance committee was sought first after which the study was initiated. The predesigned proforma was made available in the orthopaedic wards, emergency wards, the post-operative wards. The management of the injury was based on the following protocol.

### Initial management and resuscitation

The patient was received in the emergency and his vital parameters were recorded & monitored. Associated limb, chest, abdomen and head injury were ruled out. An intravenous line was established, tetanus prophylaxis and I/V cephalosporin antibiotics was given, fluid replacement started and haemorrhage from the wound was controlled by pressure bandage. The wound over the fracture site was cleaned and dressed and a groin to toes slab was applied by simply aligning the bone. Other wounds, if any, were taken care of appropriately. The patient once settled from the acute injury, was shifted to the orthopaedic ward.

### Preoperative assessment and planning

On admission in the ward, detailed history was taken, noting made and severity of the injury, extent and type of the trauma to the tissues and detailed examination of the affected extremity. Skiagrams were studied in detail so as to classify the fracture.

### Implants and instrument

A complete set of IL-nails from 28-38cm length available in 7, 8, 9 and 10 mm diameter. An osteotome, hammer and Periosteum elevator. A diamond - tip bone awl and a V – nail. An aluminium tissue protector, a nail extractor, Hand/Power drill and drill bits of 3.2mm, Depth gauge, bone tap and 4.5 mm cortical screw set Hexagonal tipped screw driver, tourniquets, Image intensifier television (IITV), Flexible Reamer, guide wire.

### Description of IL-Nail

A specially constructed IL-nail was used for the purpose in all cases. IL-nail is a hollow, metallic modified clover-leaf nail having a D-shaped platform at its proximal end (head) and a proximal locking hole. It has proximal bent of 20° in antero posterior direction to compensate for the proximal Herzog's curve within the medullary canal. The nail has a slot along its whole length on the posterior direction which facilitates unreamed nail insertion. About 2.5cm above the tip of the nail

is a distal locking hold in the anteroposterior direction. A suitable length of the nail is chosen by measuring from the tibial tuberosity to the base of the medial malleolus on the unaffected side. The diameter of the nail is decided according to the size of medullary canal on the X-ray or by reaming.

**Operative procedure**

All cases were operated within 7 days of the injury. All cases were done in the orthopaedic operation theatre. Close intramedullary nailing was done without opening the fracture site and with or without reaming.

**Operative technique used in our hospital and in our study**

In the operation theatre, under anaesthesia, under all aseptic precaution, painting and draping done. Then a tourniquet is applied and a pad is placed under the proximal part of the thigh. A 3" long incision is marked on the antero medial aspect of the tibial tuberosity. The periosteum is incised along the skin incision. The knee is flexed to more than 90°. A quadrangular flap of bone with its proximal base intact is made just medial to the tibial tuberosity in the anterior tibial cortex with the help of an osteotome. The lid of the bone so formed is returned so as to form a sort of a hood for the head of the IL-nail to about the underneath it. Keeping the knee flexed, with the help of a curved awl, the window is tunneled to the medullary canal. A V-nail is used to further smoothen the passage, if need to be. Reaming is done after inserting guide wire by flexible reamer. The IL nail is introduced over guide wire with its eye anteriorly and the slot kept posteriorly. The fracture is close reduced under IITV and the nail is negotiated into the distal fragment with the gentle taps of the hammer over the nail head, keeping the nail dead parallel to the axis of the limb. Impaction may be done, if needed, by padded gentle strokes over the heel. The distal locking of the nail is done as under IITV using the free hand technique. An appropriate length of 4.5mm cortical screw is used for locking. After suturing the periosteum with vicryl, skin closure is done. Compression bandage is applied and the tourniquet is removed and GT slab applied. The average operating time for close nailing was 45 minutes and 15 minutes for locking under IITV. Cephalosporin antibiotics are continued till suture removal.

**Post-operative regimen**

The limb is kept elevated at all times and active toe movements are encouraged. The patient is watched for excessive swelling, pain and distal circulation. The first dressing is done after 5 days of the operation. If suture line is clean, suture removal done after 10 to 12 days under full asepsis. The compression bandage and GT slab is removed a crepe bandage is applied from knee to the ankle. Active knee and ankle mobilisation is started immediately after the dressing. Partial weight bearing with 2 axillary crutches started. Gait training on the parallel bars if possible, can also be done review after 1 month. Advice regarding full weight-bearing is given on the basis of pain and the stability of the fracture fixation.

**Follow-up and evaluation**

The patient is usually followed up at 4 weeks, 8 weeks, and 12 weeks, 16 weeks, 20 weeks and 6 months. Check X-rays are taken at every visit and patient is assessed clinically for

fracture union. The results are assessed on the basis of; Pain and mobility at fracture site, clinical and radiological fracture union, range of movements at knee and ankle, complete weight bearing and return to work.

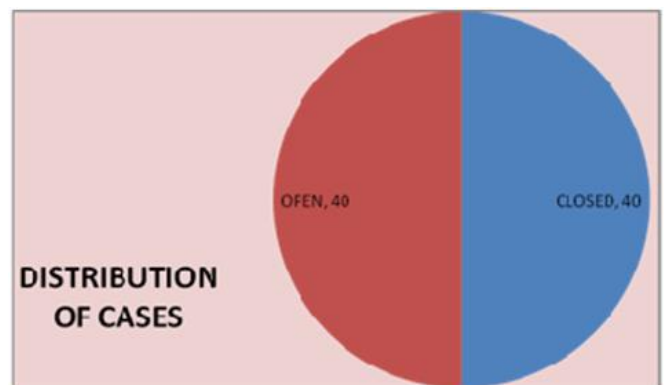
**Sample size and estimation**

The sample size is 40 cases of closed tibia shaft fractures and 40 cases of open tibia cases of type 1 and type 2 according to Gustilo & Anderson grading of open injuries, and is calculated based on previous studies as well as approximate availability of number of cases from December 2015 to November 2016 duration satisfying inclusion and exclusion criteria.

**Results:** This was a prospective comparative interventional study that was conducted during the time period between December 2015 to November 2016 which included 80 consenting patients of both sex and above 18yrs with compound Tibial fractures or closed fractures of the Tibial shaft. The results were as follows.

**Table 1:** Distribution of Cases

DISTRIBUTION OF CASES	CLOSED	OPEN	TOTAL
FREQUENCY	40	40	80
PERCENTAGE	50	50	100

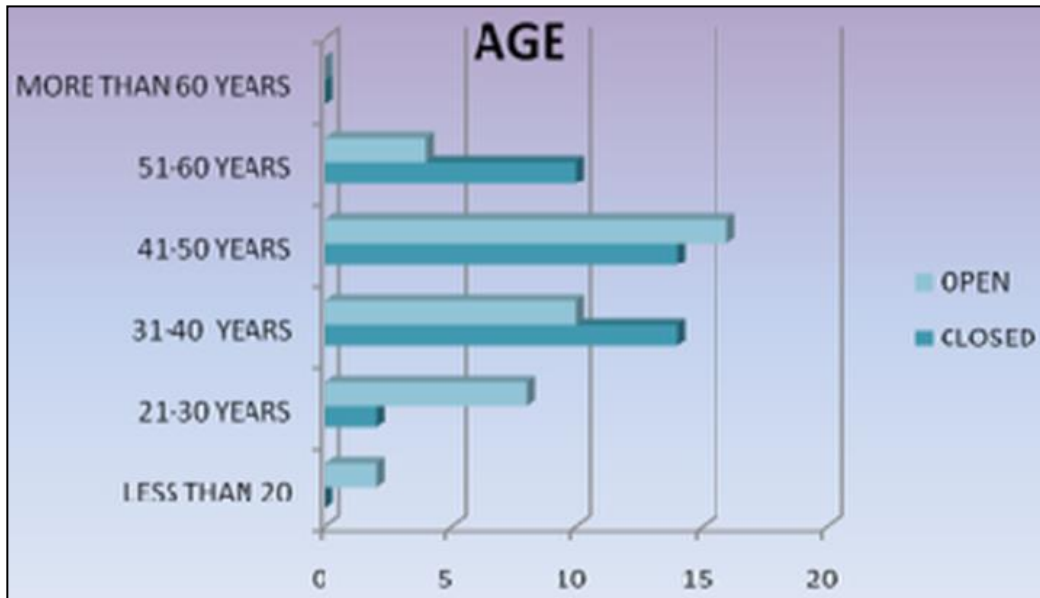


**Graph 1:** Distribution of Cases

In the present study we had a total of 80 cases of tibial fractures, 40 cases of open and 40 cases of closed tibial fracture.

**Table 2:** Age

AGE	CLOSED	OPEN	TOTAL	PERCENTAGE
LESS THAN 20	0	2	2	2
21-30 YEARS	2	8	10	12
31-40 YEARS	14	10	24	30
41-50 YEARS	14	16	30	38
51-60 YEARS	10	4	14	18
60 YEARS >	0	0	0	0
TOTAL	40	40		100



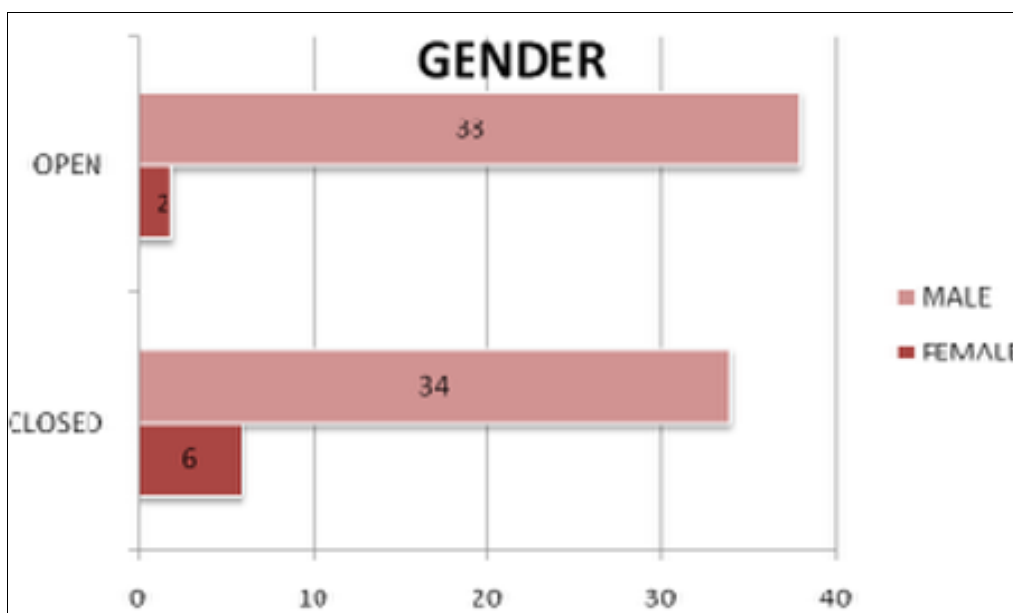
Graph 2: Age

On evaluation of the demographic data 30-50 years constituted 68% of the study subjects indicating that the active working population was commonly involved in the

fractures of the tibia. Between the two groups there was no statistical difference with a p value less than 0.05.

Table 3: Gender

Gender	C l o s e d		O p e n		Total	Percent
	Frequency	Percent	Frequency	Percent		
FEMALE	6	15	2	5	8	90
MALE	34	85	38	95	72	10
Total	40	100	40	100	80	100



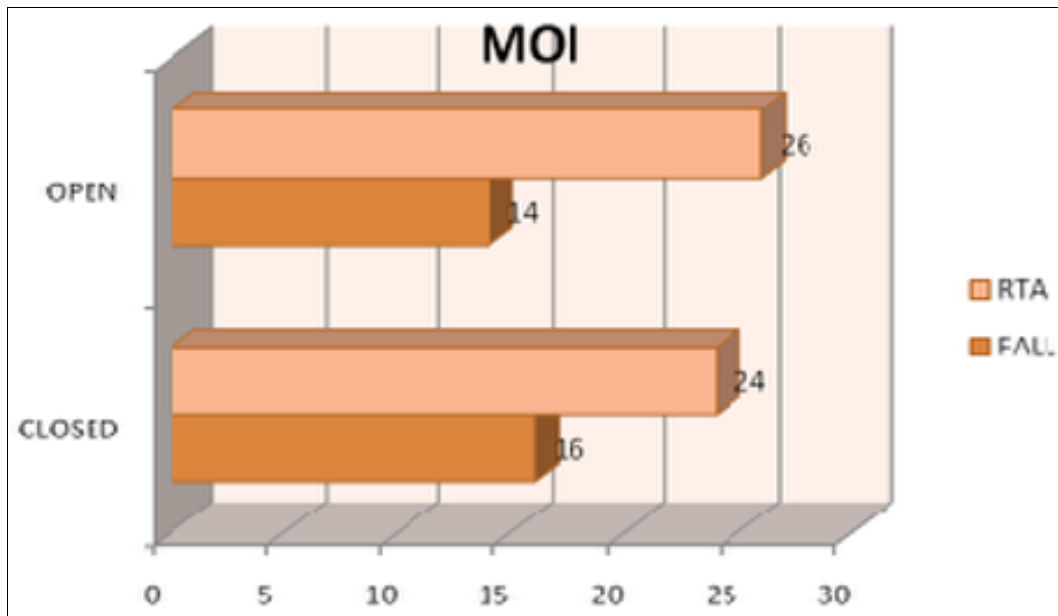
Graph 3: Gender

On evaluation of the demographic data tibial fractures were more commonly seen in males. Between the two groups there

was no statistical difference with a p value less than 0.05.

**Table 4:** Mechanism of Injury

MOI	C l o s e d Frequency	Closed Percent	O p e n Frequency	O p e n Percent	T o t a l Frequency	T o t a l Percent
FALL	16	40	14	35	30	63
RTA	24	60	26	65	50	37
TOTAL	40	100	40	100	80	100



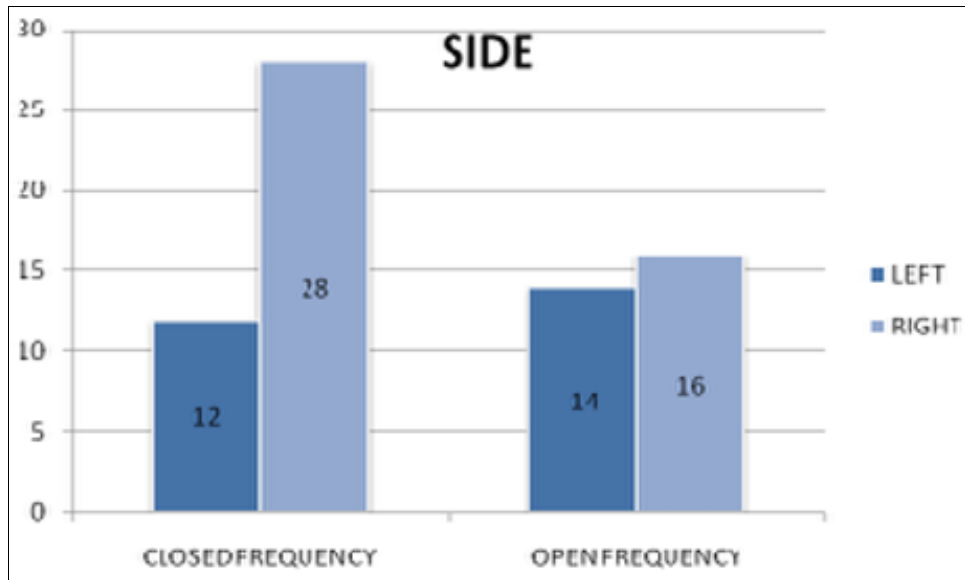
**Graph 4:** Mechanism of Injury

On evaluation of the mechanism of injury we found that road traffic accidents was the prime cause of tibial fracture that was responsible for 63% (50 cases) of all fractures evaluated.

Between the two groups there was no statistical difference with a p value less than 0.05.

**Table 5:** Side of Injury

SIDE	C L O S E D FREQUENCY	O P E N FREQUENCY	TOTAL	O P E N PERCENT	CLOSED PERCENT
LEFT	12	14	26	35	30
RIGHT	28	16	44	65	70
TOTAL	40	40	80	100	100



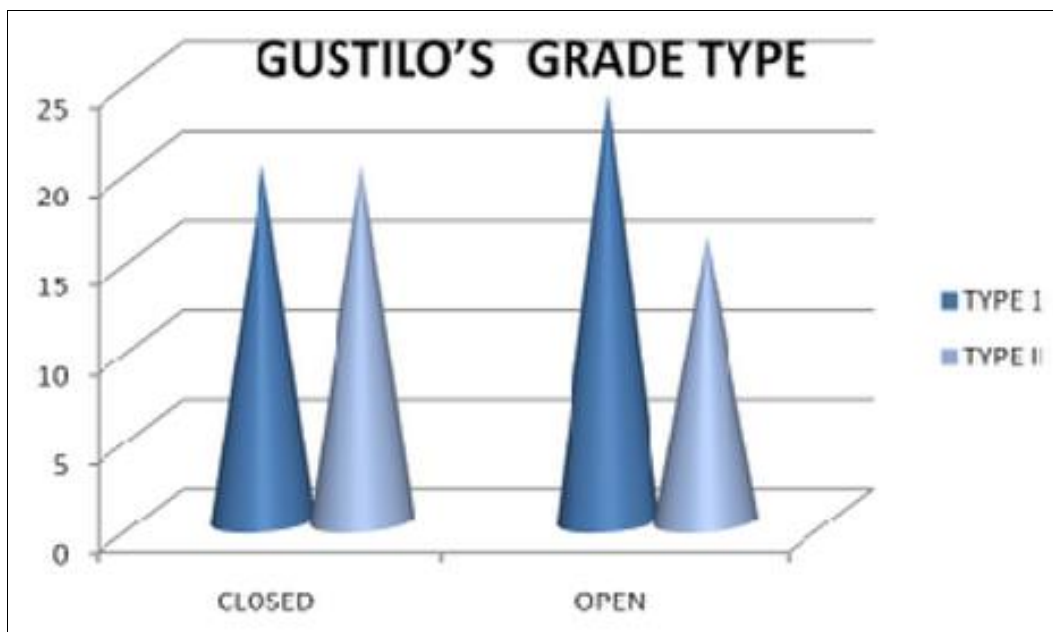
Graph 5: Side OF Injury

In both the groups the dominant side was commonly involved, all the cases in our study 4 were left and 36 were right dominant, 68% (27cases) were right sided in our study.

Though between the groups there was no statistical significance.

Table 6: Gustilo’s Grade Type

GUSTILO’S GRADE TYPE	C L O S E D FREQUENCY	O P E N FREQUENCY	TOTAL	O P E N PERCENT	C L O S E D PERCENT
TYPE I	20	24	44	60	50
TYPE II	20	16	36	40	50
TOTAL	40	40	80	100	100



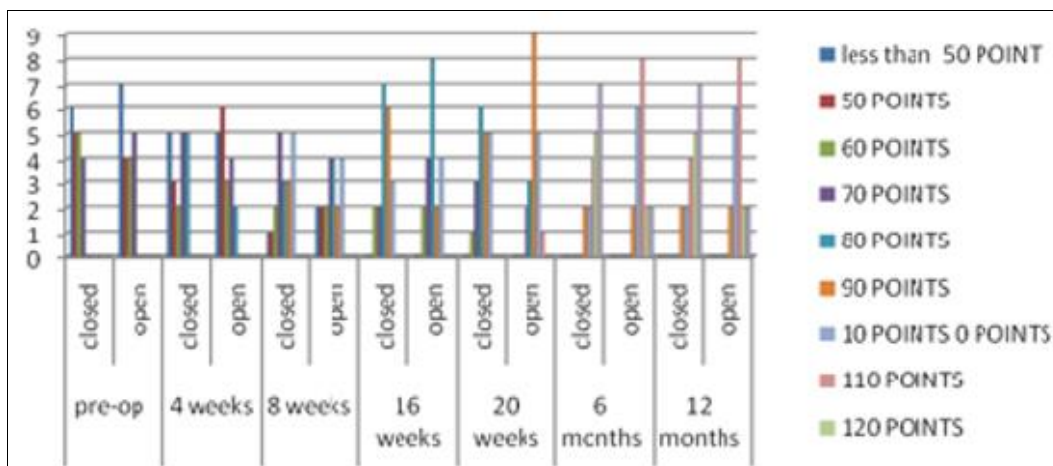
Graph 6: Gustilo’s Grade Type

In most cases that is 55% the fracture was type I Gustilo’s Grade. Between the two groups there was no statistical

difference with a p value less than 0.05.

**Table 7:** Range of movements in the two groups over time

ROM	pre-op		4 weeks		8 weeks		16 weeks		20 weeks		6 months		1	2
	closed	open	closed	open	closed	open	closed	open	closed	open	closed	open	closed	open
< 50	12	14	10	10	2	4	0	0	0	0	0	0	0	0
50	10	8	6	12	2	4	0	0	0	0	0	0	0	0
60	10	8	4	6	4	4	4	4	2	0	0	0	0	0
70	8	10	10	8	10	8	4	16	6	4	0	0	0	0
80	0	0	10	4	6	8	14	8	12	6	0	0	0	0
90	0	0	0	0	6	4	12	4	10	18	4	4	4	4
100	0	0	0	0	10	8	6	8	10	10	4	24	8	12
110	0	0	0	0	0	0	0	0	0	2	8	8	4	16
120	0	0	0	0	0	0	0	0	0	0	10	2	10	4
130	0	0	0	0	0	0	0	0	0	0	14	2	14	4



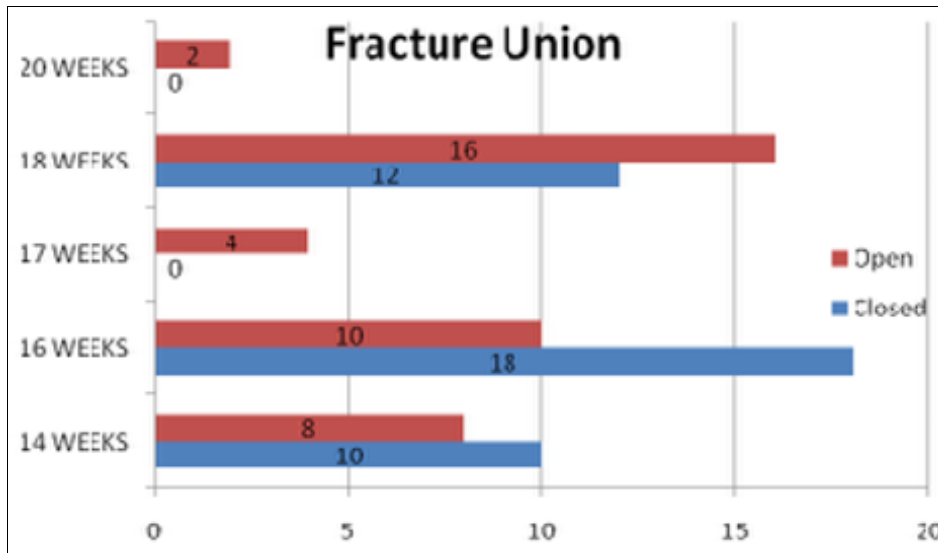
**Graph 7:** Range of movements in the two groups over time

The above graph and table show the improvements in the range of movements in the two groups over time. The improvement was better in the closed group as compared to

the open group this was statistically significant at all times with a p value 0.0001.

**Table 8:** Fracture union

Fracture Union	Closed Frequency	Closed Percent	Open Frequency	Open Percent
14 WEEKS	10	25	8	20
16 WEEKS	18	45	10	25
17 WEEKS	0	0	4	10
18 WEEKS	12	30	16	40
20 WEEKS	0	0	2	5
Total	40	100	40	100



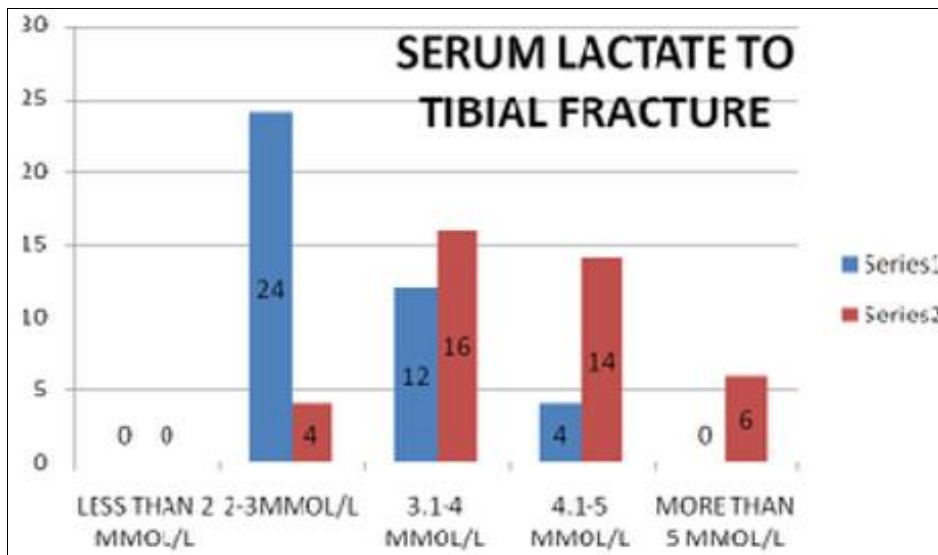
Graph 8: Fracture Union

At 16 weeks 45% of open and 65% of closed fractures were healed at 20 weeks in both groups. All the fractures that

healed after 16 weeks had higher lactate levels within their groups.

Table 9: Serum lactate to tibial fracture evaluation

SERUM LACTATE	CLOSED	OPEN
LESS THAN 2 MMOL/L	0	0
2-3MMOL/L	24	4
3.1-4 MMOL/L	12	16
4.1-5 MMOL/L	4	14
MORE THAN 5 MMOL/L	0	6
TOTAL	40	40



Graph 9: Serum lactate to tibial fracture evaluation

Normal blood lactate concentration in unstressed patients is 0.5-1 mmol/L. Patients with critical illness can be considered to have normal lactate concentrations of less than 2 mmol/L. Hyperlactatemia is defined as a mild to moderate persistent increase in blood lactate concentration (2-4 mmol/L), in my study the mean lactate levels were higher in the open group than the closed group.

**Discussion:** The search for the best marker or set of markers for the diagnosis, prognosis and treatment of ‘at risk’ trauma patients is ongoing. Serial estimation of serum lactate values are thought to help predict morbidity and mortality in trauma victims. 71, 72 [18-19] Lactate production occurs in all tissues including skeletal muscles, brain, RBCs and kidneys even at baseline levels under normal healthy oxygen rich conditions.



73 [20] In normal human subjects, lactate is cleared rapidly, at a rate of about 320 milimoles per litre per hour, mostly by liver metabolism and by reconversion of lactate back to pyruvate. This helps keep basal arterial and venous lactate levels below one milimole per litre. In a scenario of inadequate tissue perfusion, anaerobic metabolism prevails whereby pyruvate is metabolised to lactate. 73 [20] Persistent lactic acidosis is associated with higher rates of respiratory failure, multiple system organ failure and death after severe trauma or polytrauma. 74-76 [21-23] The longer the lactate is elevated, the more a patient is likely to develop multiple organ dysfunctions and die. 77 [24] Lactate levels followed over time is more reliable than isolated values. venous lactate can predict mortality for hip fracture patients. 78 -80 [25-27] There are no studies done on the serial measurement of serum lactate levels in open and closed tibia fractures hence we conducted this pilot study.

### Demographic data

**Gender distribution:** Tibial fractures were more commonly seen in males. this is probably due to the fact that in a developing country like India especially in a south Indian set-up where the study was conducted most outdoor works are carried out by males, also vehicular accidents was the prime cause mostly at the late evening hours and night time. This also would have contributed to the fact showing a increased male preponderance Between the two groups there was no statistical difference with a p value less than 0.05 hence the two groups were comparable. Nicoll *et al.* [28] in their study showed that males were affected more than females.

**Age distribution in comparison to other studies:** 30-50 years constituted 68% of the study subjects indicating that the active working population was commonly involved in the fractures of the tibia. Between the two groups there was no statistical difference with a p value less than 0.05. Hence the two groups were comparable. Vallier, Heather *et al.* [29] in their study showed that in tibia shaft fractures the mean age was 38 years (Range, 18–95 years) which is comparable with our study. Nicoll. *et al.* [28] in their study showed that 40% healed by 9-12 weeks and 78% by 20 weeks.

### Clinical data

**Mechanism of Injury:** The mechanism of injury we found that road traffic accidents was the prime cause of tibial fracture that was responsible for 62% ((25 cases) of all fractures evaluated. Between the two groups there was no statistical difference with a p value less than 0.05. Hence the two groups were comparable. Whittle *et al.* [30] in their study showed that the fractures were the result of high-energy trauma, and 68 per cent of the fracture wounds.

**Side Involved:** In both the groups the dominant side was commonly involved, all the cases in our study 4 were left and 36 were right dominant, 68% (27cases) were right sided in

our study. Though between the groups there was no statistical significance. Between the sides dominant side was statistically involved more than the non-dominant the possible explanation is that the dominant the leg was put to the ground during the fall or RTA to get balance. Between the two groups there was no statistical difference with a p value less than 0.05. Hence the two groups were comparable

**Gustilo's Grade:** In most cases that are 55% the fracture was Type I Gustilo's Grade. Between the two groups there was no statistical difference with a p value less than 0.05. Hence the two groups were comparable. Wiss, Donald *et al.* [31] in their study showed that the fractures (20 Grade 1 fractures, 12 Grade 2 fractures, and 1 fracture from a gunshot wound). Whittle *et al.* [30] in their study showed that the fractures were grade III.

**Duration of healing:** At 16 weeks 45% of open and 65% of closed fractures were healed at 20 weeks in both groups. All the fractures that healed after 16 weeks had higher lactate levels within their groups.

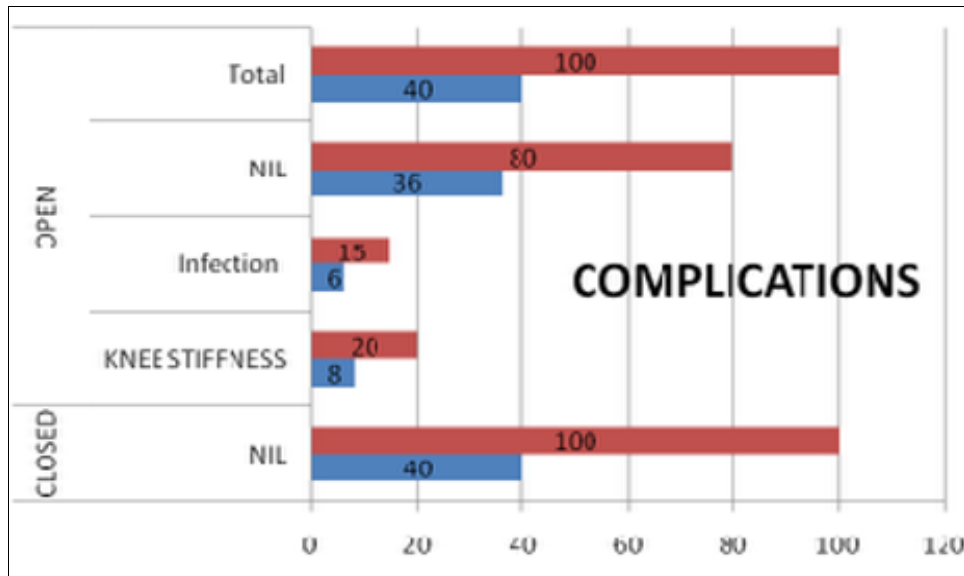
Finkemeier, Christopher A *et al.* [32] showed that higher percentage of closed fractures were healed at four months after reamed nail insertion compared with unreamed insertion ( $p = 0.040$ ), but there was not a difference at six and twelve months. Wiss, Donald fractures *et al.* [31] in their study showed that the time to fracture union averaged 28 weeks in closed fractures and 39 weeks in open fractures. Whittle *et al.* [30] in their study showed that the fractures forty-eight (96 per cent) of the fifty fractures united at an average of seven months; there were no malunions.

### Complications

We had only minor complications in the form of knee stiffness that needed physiotherapy which eventually improved with time. Infection was seen in 3 cases those with complications had a had higher lactate levels within their groups the improvement was better in the closed group as compared to the open group this was statistically significant at all times with a p value 0.0001.

**Table 10:** Complications

COMPLICATIONS		FREQUENCY	PERCENT
CLOSED	NIL	40	100
OPEN	KNEE STIFFNESS	8	20
	Infection	6	15
	NIL	36	80
	Total	40	100



Graph 10: Complications

Vallier, Heather *et al.* [29] in their study showed that eighty-three percent of infections occurred after open fracture ( $P < 0.001$ ). Four patients (7.1%) developed nonunion after nailing versus two (4.2%) after plating ( $P = 0.25$ ) with a trend for nonunion in patients who had distal fibula fixation (12% versus 4.1%,  $P = 0.09$ ). All non unions occurred after open fracture ( $P = 0.0007$ ); the primary union rate for closed fractures was 100%.

Wiss, Donald. *et al.* [31] in their study showed that 11 of the 14 delayed unions healed spontaneously, or after dynamization of statically locked nails. Seven fractures (5%) were not healed by 9 months and were classified as nonunion (2 closed, 5 open). All fractures required major additional procedures to obtain union. Infection developed in 13 fractures (10%). In closed fractures, there were 2 superficial (2%) and 3 deep (3%) infections; in open fractures there was 1 superficial (3%) and 7 deep (21%) infections.

Lamichhane *et al.* [18] had 7 tibia fractures (1 bilateral) 2 open and 5 closed they also found that the lactate levels were 3 and 3.5 for the open fractures and less than 3 for the closed fractures. On serial evaluation we found that the levels neared normal faster in the closed tibial fracture and thus concluded that the time needed to normalise lactate levels is a useful indicator in predicting prognosis. Significant lactic acidosis is present if blood lactate concentration rises more than five millimoles per litre and the blood pH falls less than 7.35. In our series, patients who had significant rise of serum lactate ( $>5$  millimoles/L) at admission had worse prognosis than whose lactate was mildly high. This is a small series of study we conclude that serum lactate can be a useful marker for identifying and monitoring resuscitation and treatment and prognosticating morbidity and mortality in the polytrauma or multi-trauma patient.

**Conclusion:** In the present study we concluded that Serum lactate positively co relates with the severity of injury and elevated serum lactate levels are a marker of prognosis as it has adverse outcomes. It is a marker for higher tissue injury. Indicator of hypoxia and change into anaerobic metabolism affecting the healing rate. Higher levels are associated with higher rate of infection.

### Recommendations

In today's era where litigation is taken as a rule, it mind that

to be borne mind that the treatment of any type of fracture has associated complication may be mild like joint stiffness or major like implant failure, we orthopaedicians need a marker to say the prognosis to the patient. Serum lactate though non specific yet signifies tissue injury and the stress that the body has sustained thus giving an indirect clue to the prognosis especially if it fails to normalise following therapy. Thus we recommend using lactate levels to evaluate the prognosis. Larger population based studies for longer duration is to be done to prove our results.

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