

**AN OBSERVATIONAL STUDY COMPARING
THE FUNCTIONAL OUTCOME IN PATIENTS
WITH OPEN FRACTURES OF THE LOWER
LIMBS, WITH AND WITHOUT INFECTION
DURING THE COURSE OF TREATMENT**

**A DISSERTATION SUBMITTED IN PARTIAL FULFILLMENT OF THE
REQUIREMENT OF THE TAMIL NADU DR. M.G.R. MEDICAL UNIVERSITY,
CHENNAI, TAMIL NADU FOR THE DEGREE OF M.S ORTHOPAEDICS TO BE
HELD IN APRIL 2016**

ENDORSEMENT BY THE HEAD OF DEPARTMENT AND PRINCIPAL OF
INSTITUTION

This is to certify that this dissertation entitled “**AN OBSERVATIONAL STUDY
COMPARING THE FUNCTIONAL OUTCOME IN PATIENTS WITH OPEN
FRACTURES OF THE LOWER LIMBS, WITH AND WITHOUT INFECTION
DURING THE COURSE OF TREATMENT**” is a bonafide research work done by
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This is a dissertation submitted in partial fulfilment of the requirement of the Tamil Nadu Dr. M.G.R. medical university, chennai, tamil nadu for the degree of M.S orthopaedics to be held in april 2016

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Contents

ABSTRACT:.....	5
ACKNOWLEDGMENTS	7
INTRODUCTION.....	8
OBJECTIVES.....	10
LITERATURE REVIEW:.....	11
METHODS	29
INCLUSION CRITERIA	29
EXCLUSION CRITERIA	30
INSTRUMENTS:.....	31
STATISTICAL ANALYSIS	38
RESULTS:.....	39
CASE EXAMPLE 1.....	65
CASE EXAMPLE 2.....	68
CASE EXAMPLE 3.....	75
DISCUSSION.....	79
LIMITATIONS.....	83
CONCLUSION	84
ANNEXURES	85
REFERENCES:.....	100

ABSTRACT:

TITLE : AN OBSERVATIONAL STUDY COMPARING THE FUNCTIONAL OUTCOME IN PATIENTS WITH OPEN FRACTURES OF THE LOWER LIMBS, WITH AND WITHOUT INFECTION DURING THE COURSE OF TREATMENT

DEPARTMENT: ORTHOPAEDICS UNIT 1

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OBJECTIVES:

To assess the functional outcome of patients with open fractures, those infected and those not infected.

To profile patients undergoing treatment for open fractures under us.

METHODS:

32 patients with open fractures were studied. These were patients treated between January 2011 and December 2013 (3 year span). 32 patients were chosen out of which 12 were infected and 20 were not infected. Demographic data and profiling of these patients were tabulated. Functional outcomes were assessed using SF-36 and LEFS (Lower extremity function scores)

An Independent t test/Mann Whitney u test was used to see the difference of functional scores between the infected and non-infected persons.

RESULTS:

Functional outcome was better in the non infected category ($p < 0.001$) for both the SF 36 and LEFS scores. Other parameters studied did not show any statistically significant difference between the groups.

The study suggests that infection needs to be considered as an important factor in the functional outcome following open fractures. Hence prevention of the same could be considered important factor during treatment of open fractures.

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Above all, I would like to thank God.

I would like to thank my guide Dr Vinoo Mathew Cherian, my co – guide Dr Sandeep Albert.

I would like to thank all the patients who complied in answering the questionnaire and hence made this study possible.

I would like to thank Mrs Gowri who helped with the statistical analysis

I would like to thank the Orthopaedics out patient department staff and Medical records Staff at CMC Vellore for their assistance.

INTRODUCTION:

Open fractures are susceptible to infection as the internal structures are exposed to the outside environment. Infection adversely affects patients in variety of ways. This study seeks to answer the question if functional outcomes are varied with infection in such fractures.

In India road traffic accidents are common, and a growing bane with the rising population and urbanization. Ruikar et al reported statistics of road traffic accidents in India in 2013. Around 1 million people die around the world from road traffic accidents and close to 50 million sustain injuries, while non fatal, affect them and their activities of daily living. While developing countries like ours have not even half the total vehicles, over ninety percent of the deaths on roads occur in these countries.

Those frequently involved are those walking by the side of the road or attempting to cross them. Two wheelers are the other group of people on roads frequently involved in road traffic accidents.

Between 1970 to 2011, the total accidents increased over 4 times and close to 10 times increase in deaths. The injuries have increased three times for every 1,00,000 people.

Tamil Nadu had the highest number of accidents as per statistics of 2012 followed by Uttar Pradesh and Andhra Pradesh. The number of accidents in Tamil Nadu was 67,757.

According to Ruikar et al s survey Rural areas had more road traffic accidents and more fatalities as compared to the urban population. The age groups involved were mainly the bread winning group. Two wheeler and pedestrian accidents were most common.

Various causes were driving inebriated, indecision ,drivers who were tired and others who were novices to the art of driving. Others included the impetuous and perfunctory, those who refused to respect authority and traffic rules. Over 70% of road traffic accidents are attributed to the drivers fault in some way.

However, after all , the patient comes to us for treatment and when an open fracture is the result of perhaps, a momentary lapse of reason or fate, things get challenging for the patient, the relatives and the treating team.

Infection emerges as one of the nagging problems that persist in spite of first class treatment, state of the art care and compassion for each patient.

Does this infection substantially make a difference to the patient. We have sought to quantify the effect infection has on outcomes.

OBJECTIVES:

To assess the functional outcome in patients who underwent treatment for open lower limb fractures, under us.

The two groups assessed were those who had proven infection during the course of treatment and those who did not have infection.

To profile patients who underwent treatment for open fractures under us taking into account various demographic, orthopaedic and radiological parameters and analyzing them. However these are secondary outcomes.

LITERATURE REVIEW:

Fractures constitute a large part of the myriad conditions treated by the Orthopaedic surgeon. Fractures are breaks in bones which incapacitates the person. Fractures are characterized by many idiosyncrasies, some of which make more difference to how the bone heals than others.

Certain factors play an important role in the outcome of the injury. Various factors are the velocity of the injury, the injury to the soft tissue surrounding the bone, the time after which the doctor sees the patient following injury, whether or not the fracture is open or not.

Closed fractures have the advantage of having the injured bone and soft tissue covered by skin and this prevents contamination from the surroundings. This contamination includes farmyard waste, domestic waste and sewage. This complicates the fracture. In closed fractures the concept of infection does not come into play until there is a breach to the skin barrier, which can occur if over time, the fractured bones create internal pressure onto the skin and then create a wound or if there is surgical intervention to the same.

Open fractures are those injuries with the bare broken bone is in contact with the environment implying a break in skin and damage to the interposing soft tissue and neurovascular structures.

Closed fractures do not have this breach in barrier.

HISTORICAL PERSPECTIVE

Hippocrates advocated that the knife or fire can cure wounds. Ambrose Pare and others discovered, during the siege at Turin, that the hot oil used at that time, wasn't required to treat fractures.

Open fractures result in damage to soft tissue and these tissues being exposed to external environment. Some of these tissues eventually die or are dead at presentation.

Desault coined the term debridement and advocated removal of dead tissues to help in healing.

Open fractures are those with high energy most commonly and they increased dramatically during the world wars and with this brought a high mortality rate associated with them over 70%. Josep Trueta was a Catalan exile in the United Kingdom where he became a field doctor during world war 1. He concentrated on meticulous removal of dead tissue and then casting the injured legs. This was truly revolutionary with respect to how open fractures were being managed.

In World War 2, Penicillin was available. Though this was of cardinal benefit this did not mean they could be complacent about debridement. This is something surgeons realized as the years went by.

CLASSIFICATION OF OPEN FRACTURES:

With antibiotics, the mortality drastically decreased, and more limbs were salvaged.

Gustilo and Anderson studied 1025 long bone injuries both prospectively and retrospectively(1) finding out that although mortality had decreased infection of open fractures was now the new challenge.

Based on their new found data they devised a classification system for open fractures, severity being graded from Type 1 to Type 3.

Type I included those with a simple fracture pattern, low velocity with minimal damage to skin and underlying muscle/soft tissue and no blemish by way of road dirt, farmyard waste, sewage etc. Type II included those with larger wounds and a little more complex fracture pattern.

Type 3 included those with high velocity, complex fracture patterns, destroyed soft tissue and larger wounds.

For the Type 3 open fractures, the infection rates were 44 per cent in the retrospective study and 9 per cent in the prospective study.

Here in India , most of our open fractures stem from high energy motor vehicle accidents and owing to high contamination, most of our open fractures instantly figure in Type 3 of this classification.



Figure 1 – This shows a typical fracture seen in our patients with periosteal stripping and exposed bone with gross contamination.



Figure 2 shows a more benign looking injury, however the chances of skin and soft tissue cover become paramount while treating complex periarticular fractures



Figure 3 shows the wound per se to be small in size but the soft tissue contusion that can be appreciated surrounding the wound, is an important factor when considering infection.

Since the spectrum of these high energy injuries figuring in Type 3 ranges from simpler wounds to those that can be barely salvaged ,Gustilo further classified Type 3 fractures as follows(2)

	Wound	velocity	soft tissue	fracture pattern
A -	Usually >10 cm long	High	Severe with crushing	Usually comminuted; soft tissue coverage of bone possible
B -	Usually >10 cm long	High	Very severe loss of coverage; usually requires soft tissue reconstructive surgery	Bone coverage poor; variable, may be moderate to severe comminution
C -	Usually > 10 cm long	High	Very severe loss of coverage plus vascular injury requiring repair; may require soft tissue reconstructive surgery	Bone coverage poor; variable, may be moderate to severe comminution

THE PROBLEM OF INFECTION:

Various studies done at different times give us one dreaded complication, whatever be the surgery. This is the one complication that marks every study done on follow up of any procedure.

This complication is infection. Open fractures have rates of infection that are higher than that of closed fractures.

In Gustilo and Anderson's study all inclusive the infection rates were 5.24 percent in the retrospective analysis and 2.4 percent in the prospective analysis following change in protocol which included decreased time to surgery and standardized antibiotic cover.

Infection is taken to be a culture proven condition, wherein the microbiologists work with surgeons to provide a clear cut insight into the nature of the offending organism taken from the wound, the sensitivity of the organism with respect to antibiotics and the various special characteristics of these organisms which would prove useful while managing the deleterious effects of the same. We have taken this definition of infection to make things uniform among all patients.

This is of importance as these days the term "infection" can be used rather loosely without specification. It may imply pus discharge, serous or mixed sero-sanguinous wound discharge from the wound. It may imply there was redness and pain over the affected limb. Certain blood tests are done routinely which keep infection suspicion

high. Examples of such blood tests are ESR and CRP. These blood tests while being sensitive are not specific for infection.

Radiologic findings and bone scans are being used these days. The gold standard however remains to be cultures from the wound that is positive for organisms.

As per the infectious disease protocol, superficial cultures may not provide a reasonable representation of the milieu interior. Hence deep cultures are preferred.

These are those open fractures succumb to, during the course of treatment and during the breakdown of the same, *Staphylococcus aureus* emerged the prime culprit of the same.

Robinson et al showed that more than 80% of open fractures (Type 2 and Type 3) were already infected when they presented to hospital. This was proven by cultures taken from the wounds on patients arrival.(3) The outcomes of his study showed that it was essential that open fractures be taken care of with great diligence with radical debridement, 48 hour washouts if deemed essential and re culture of the wounds.

A number of studies were done to confirm the positive effect that antibiotics had on the outcome of open fractures . Gurusamy et al (4) dealt specifically with Methicillin resistant *Staphylococcus aureus* which is quite virulent and a growing bane with Hospital acquired infections.

Another recent study showed that only 18 percent of the infections had isolates of organisms cultured from the initial pre operative swabs as compared to the older study rate of 73 percent.

This shows a definite increase in nosocomial infection being the prime cause.

Saveli et al (5) and Gosselin et al (6) showed that antibiotic prophylaxis decreased infections in open fractures. Saveli again studied MRSA specifically(7) as staphylococcus emerges as the prime culprit.

Patzakis et al(8) showed that with antibiotic use infections decreased from around 14 % to 4.5 % and also that a single antibiotic may not be enough for Type 3 fractures(9).

At our centre all our open fractures are given crystalline penicillin, broad spectrum gram positive and gram negative cover intravenously when they are admitted in the accident and emergency department.

CHRONIC EFFECTS OF INFECTION:

Open fractures in spite of best treatment still pose a challenge. Now limb salvage being the order of the day, persistent infections and prolonged time to union are the challenges faced by surgeons today. Chronic osteomyelitis is the long term effect of infection and this is extremely difficult to treat. A condition best prevented to say the least. Treatment of chronic osteomyelitis requires debridement and for Cierny and Mader type 4 osteomyelitis , skeletal stabilization is required. This prolongs time of treatment, requires further admissions and expenditure.

One of the many manifestations of chronic infection of an open fracture is osteomyelitis which is usually encountered as a pus discharging sinus as shown in Figure 4



Figure 4 shows a patient with a united fracture on follow up with us with a persistent discharging sinus suggestive of chronic infection.

TREATMENT OF OPEN FRACTURES:

Treatment for open fractures follows the principles of adequate removal of dead tissue (debridement), skeletal stabilization and antibiotics. Studies have shown various methods of management of open fractures some which have proven to be useful in decreasing infection. These methods have been frequently used at our centre. Negative pressure therapy and antibiotic bead cement placement are two of the techniques suggested complementing debridement, irrigation, antibiotics and skeletal fixation in a rigid fashion. (10)

Skeletal stabilization can be by way of external or internal fixation and in either one or more stages. External fixation can be converted to an internal fixation when the wound heals. Some close the wound primarily as opposed to others who leave the initial wound open. This aspect of treatment has been an area of debate. Delayed wound closure can be carried out by way of secondary suturing, skin grafting, local rotation flaps and free flap cover.

Thorough and radical debridement with soft tissue cover using local or free flaps composed of muscle have been advocated in the primary setting . (11)

If there is bone loss bone grafting has been recommended. (12)

In all of these schools of thought, debridement remains cardinal (13)(14)(15).

Recent studies, like the one from Ganga hospital Coimbatore (16) have shown that a radical approach viz. debridement, early fixation and flap coverage give good results.

Gopal et al also showed the same (17) where functional outcome using the SF 36 score (18) has been evaluated.

Anxiety and depression have been found to characterize post operative period in patients with open fractures. (19) However this has not been further delineated to various parameters. Anxiety and emotional disturbances are taken into account when functional scoring is done.

While day to day relationship with patients tells us that a patient is never happy when the doctor gives them a diagnosis of persistent infection, the documentation has not been clearly established by standardized instruments.

Apart from emotional disturbances pain and functional status are evaluated using these instruments.



Figure 5 shows an open fracture on external fixator, post flap cover. However , there is a persistent sinus although the major part of the wound has healed.



Figure 6 shows another of our study patients with a persistent sinus post skeletal stabilization and soft tissue cover.

Figures 5 and 6 show that although the wounds may have settled and the soft tissue cover over the bone is good, with time, a sinus can form and persist. This is again modified and affected by various host factors. Comorbid illnesses definitely worsen chances of recovery.

However, comorbid illnesses may not be present, as in most of our patients. Most of our patients are young , active males.

Even then, infection in spite of adequate soft tissue cover and debridement can persist and this poses perpetual problems for the patient and further impediments to progress.

In the present era an ideal outcome would be 3-6 months for the patient to be back to a pre injury functional level with near normal outcome scores.

Most patients do not achieve this satisfactory functional outcome despite union and absence of infection. Does culture proven infection during the course of treatment predispose to a worse outcome as compared to patients without infection? This is a question we have sought to answer while also collecting information on the profile of organisms grown from deep tissue cultures during the course of treatment.

METHODS:

This study was carried out in the Department of orthopaedics unit 1 in Christian medical college and hospital, Vellore, Tamil Nadu. Patients admitted under us over a three year span (1st January 2011 to 31st December 2013) were studied in a retrospective fashion after obtaining consents for the same. The study was passed and approved by our institutional review board following which the study was carried out.

The patients were selected as per the following inclusion criteria:

INCLUSION CRITERIA

- 1) Fresh open fracture sustained, presenting to our emergency department
- 2) Lower limb only(including femur and both bones leg)
- 3) Those who have undergone treatment here at CMC and on regular follow up at the fracture clinic in the department of Orthopaedics unit 1 injured between January 2011 to December 2013
- 4) Local patients within the limits of Tamil Nadu and Andhra Pradesh states.

The following exclusion criteria were considered while carrying out the study.

EXCLUSION CRITERIA

- 1) Those who have other major limb injuries, head injury, abdominal or thoracic injuries.
- 2) Those who have two or more AO classified regions of the lower limb fractured for example both femur and both bones leg fracture.
- 3) Those not on regular follow up with us
- 4) Those partly treated
- 5) Crush injuries of the foot and ankle.
- 6) Mangled limbs treated with amputation
- 7) Clinical Infection but culture negative (eg pin tract infections)
- 8) Those not from Tamil Nadu or Andhra Pradesh

Following assessment of patients in the 3 year period, 32 patients were selected as eligible for the study. Out of these 32 patients 20 of them had sustained open fractures which were not infected clinically and 12 patients had sustained open fractures with culture proven infection taken from the wound during debridement. Those patients who had clinical infection but had sterile wound cultures were excluded from the study.

A profiling of these 32 patients was done and the following data were taken into account;










Age of the patient, sex, region of the fracture with its appropriate AO classification, the Gustilo Anderson grade of the open fracture, the number of surgeries done and the different surgical procedures done, time taken for the fracture to unite radiologically and in the case of the 12 patients who had infected open fractures, the specific organism cultured.

INSTRUMENTS:



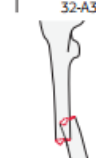

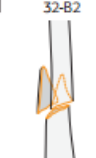




We have used the SF-36 score along with a lower extremity function scale (LEFS)(20) for our study. We have classified fractures using the Gustilo Anderson classification to describe the severity of open injury and the Muller's classification of fractures by the AO Swiss group(21)

Muller's AO classification – Femur










31 proximal (defined by a line passing transversely through the lower end of the lesser trochanter)

31-A1	31-A2	31-A3	31-B1	31-B2	31-B3	31-C1	31-C2	31-C3
								
31-A extraarticular fracture, trochanteric area 31-A1 pertrochanteric simple 31-A2 pertrochanteric multifragmentary 31-A3 intertrochanteric			31-B extraarticular fracture, neck 31-B1 subcapital, with slight displacement 31-B2 transcervical 31-B3 subcapital, displaced, nonimpacted			31-C articular fracture, head 31-C1 split (Pipkin) 31-C2 with depression 31-C3 with neck fracture		

32 diaphyseal

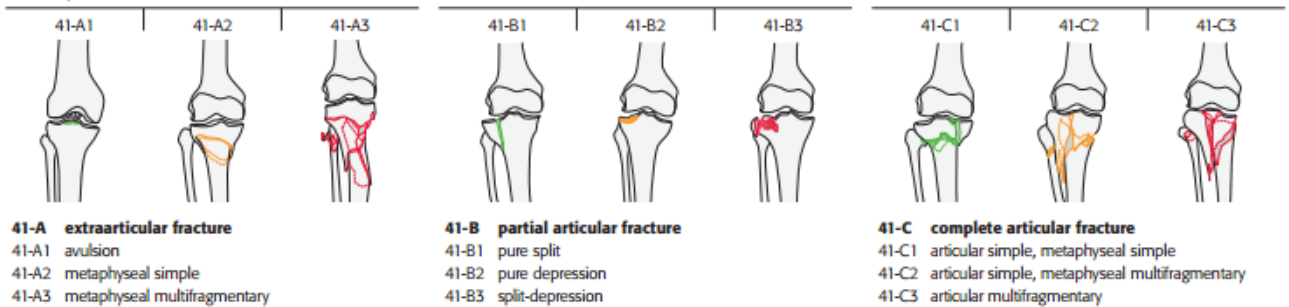
32-A1	32-A2	32-A3	32-B1	32-B2	32-B3	32-C1	32-C2	32-C3
								
32-A simple fracture 32-A1 spiral 32-A2 oblique ($\geq 30^\circ$) 32-A3 transverse ($< 30^\circ$) 32-A(1-3).1 = subtrochanteric fracture			32-B wedge fracture 32-B1 spiral wedge 32-B2 bending wedge 32-B3 fragmented wedge 32-B(1-3).1 = subtrochanteric fracture			32-C complex fracture 32-C1 spiral 32-C2 segmental 32-C3 irregular 32-C(1-3).1 = subtrochanteric fracture		

33 distal

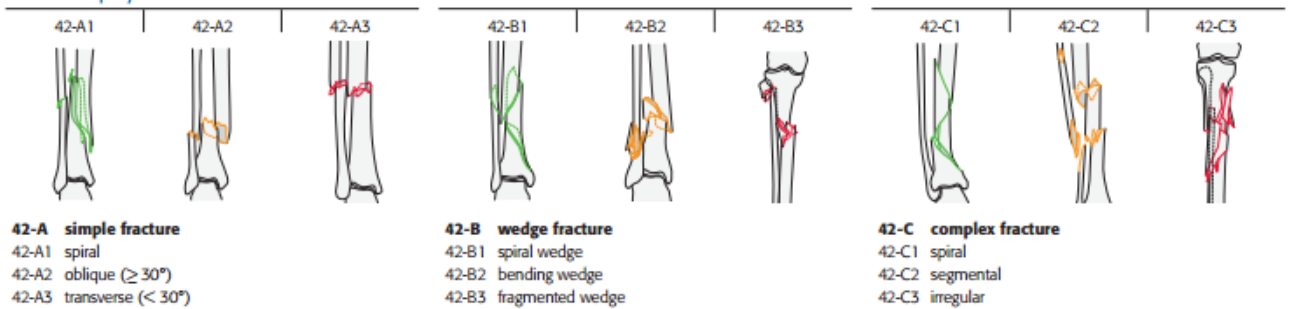
33-A1	33-A2	33-A3	33-B1	33-B2	33-B3	33-C1	33-C2	33-C3
								
33-A extraarticular fracture 33-A1 simple 33-A2 metaphyseal wedge and/or fragmented wedge 33-A3 metaphyseal complex			33-B partial articular fracture 33-B1 lateral condyle, sagittal 33-B2 medial condyle, sagittal 33-B3 coronal			33-C complete articular fracture 33-C1 articular simple, metaphyseal simple 33-C2 articular simple, metaphyseal multifragmentary 33-C3 articular multifragmentary		

Muller's AO classification – Leg

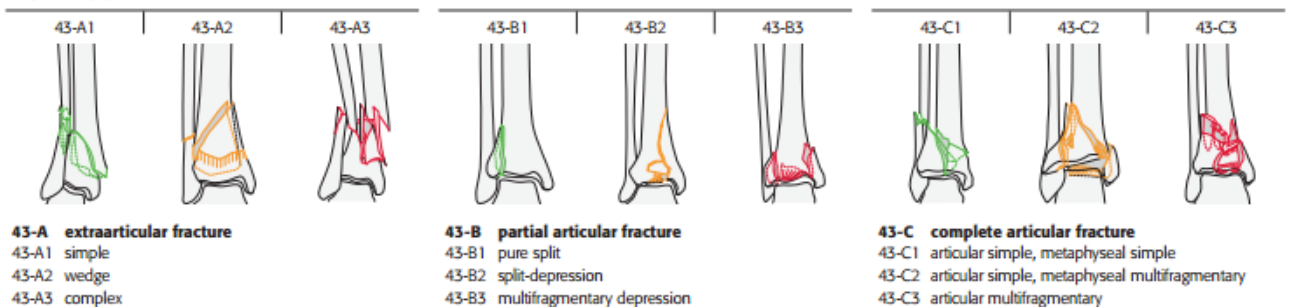
41 proximal



42 diaphyseal



43 distal



They were assessed with two functional scores, the lower extremity function score and the SF 36 scores.

The scores used were subjective wherein the patient was asked a standard set of questions which were then tabulated. In the Lower extremity function score a few questions were modified to suit our population keeping the idea behind the question unadulterated.

The clinically significant numbers for the SF36 scores were as follows.

Clinically significant changes being :

12 points for PF,

23 points for RP,

15 points for BP,

18 points for GH,

16 points for VT,

26 points for SF,

28 points for RE,

24 points for MH subscales

Where Physical functioning (PF), role physical (RP), bodily pain (BP), general health (GH), vitality (VT), social functioning (SF), role emotional (RE), and mental health (MH).(22)

Clinically significant changes, all the 8 components of SF-36 taken into account , is 20, from a baseline of 55 for open fractures derived from similar previous studies.

Using the following formula with a power of 90, the sample size, to be clinically significant is 49 in each arm. (22)(21)

$$n = \frac{2\{Z_{1-\alpha/2}+Z_{\beta/2}\}^2 \times \sigma^2}{\delta^2}$$

$$n = \frac{2\{1.96+0.84\}^2 \times 30^2}{20^2} = 49$$

However as this study was based on a 3 year time period (1st January 2011 to 31st December 2013) the number of patients were **20 in the non infected arm and 12 in the infected arm who satisfied the inclusion criteria.**

The data was tabulated and was analyzed (kindly refer to Appendix for instruments used)

Lower Extremity Functional Scale (LEFS)

The Lower Extremity Functional Scale (LEFS) is a questionnaire containing 20 questions about a person's ability to perform everyday tasks. The LEFS can be used by clinicians as a measure of patients' initial function, ongoing progress and outcome, as well as to set functional goals.

The LEFS can be used to evaluate the functional impairment of a patient with a disorder of one or both lower extremities. It can be used to monitor the patient over time and to evaluate the effectiveness of an intervention.

The columns on the scale are summed to get a total score. The maximum score is 80.

Interpretation:

The lower the score the greater the disability.

The minimal detectable change is 9 scale points.

The minimal clinically important difference is 9 scale points.

$\% \text{ of maximal function} = (\text{LEFS score}) / 80 * 100$

Performance:

The potential error at a given point in time was +/- 5.3 scale points.

Test-retest reliability was 0.94.

Construct reliability was determined by comparison with the SF-36. The scale was found to be reliable with a sensitivity to change superior to the SF-36.

This scoring was carried out similar to SF-36 scoring , where the questions are asked by the investigator to the patient and the patients responses were filled up by the investigator

(Few questions have been changed to suit our target population – Questions like getting in and out of a car has been replaced with using public transport)

STATISTICAL ANALYSIS

Description of continuous data was provided using mean along with standard deviations, and the categorical data was given using frequencies along with the percentages. An Independent t test/Mann Whitney u test was used to see the difference of functional scores between the infected and non-infected persons. A multiple linear regression was done to analyse the adjusted effect of gender, months to union and other variables.

Following this the following results were obtained.

RESULTS:

Following statistical analysis the following results were obtained. Baseline characteristics were considered. They are given below, followed by the primary result which is the functional outcomes based on the SF 36 and LEFS scores.

Following this secondary outcomes are displayed.

AGE IN YEARS :

Given below are tables showing the age distribution of patients in our study.

INFECTED OPEN FRACTURES (N = 12)

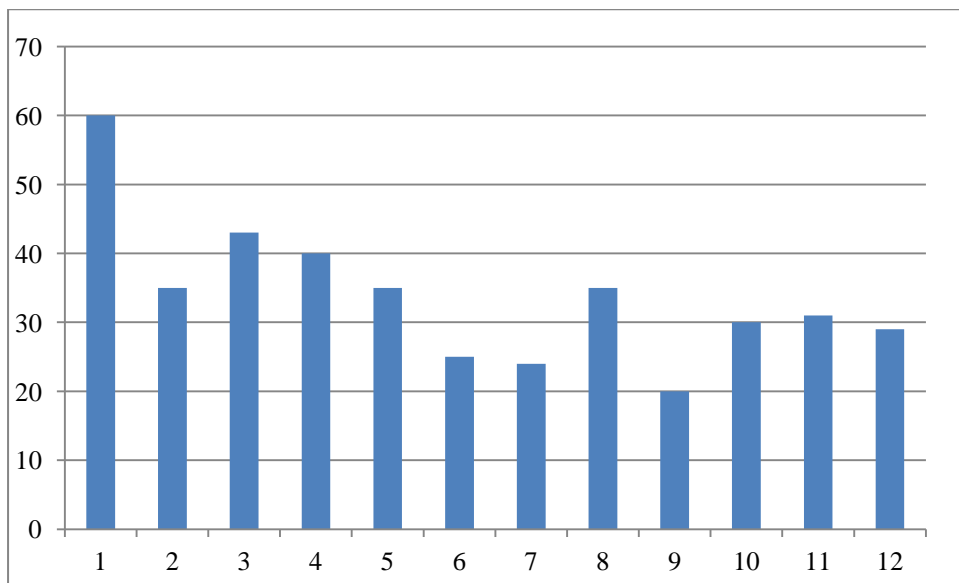


Figure 7: Age distribution in the 12 infected fractures y axis = age in years

NON INFECTED CATEGORY – n = 20

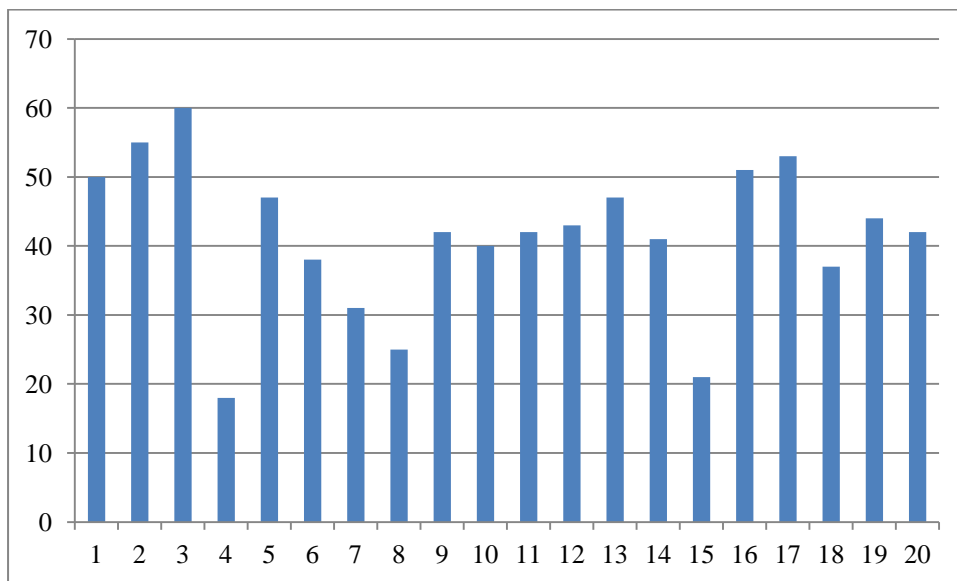


Figure 8: Age distribution in the 20 non-infected fractures y axis = age in years

On comparing the age distribution between the groups, the age was found to be higher among the patients in the non infected group as shown below.

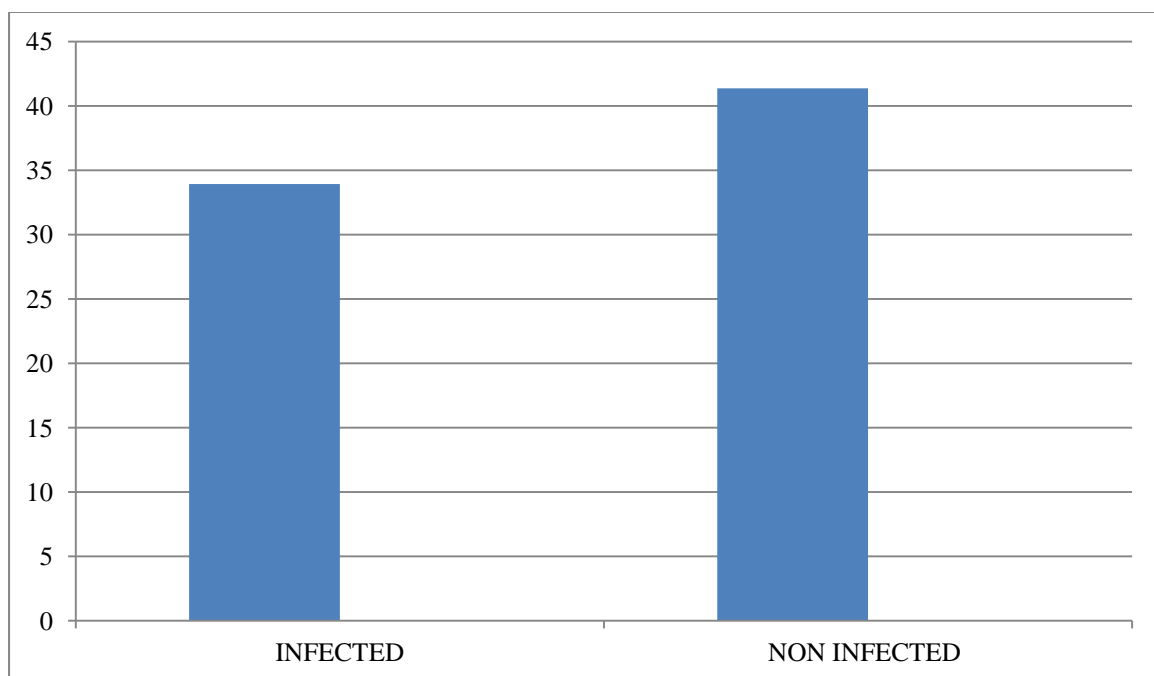


Figure 9: A comparative graph of age between the two groups (y axis – age in years)

SEX

31 out of 32 patients studied were males and 1 was female. This shows the men being involved in high energy vehicle collisions leading to open fractures as compared to the women. This is shown in the graph below.

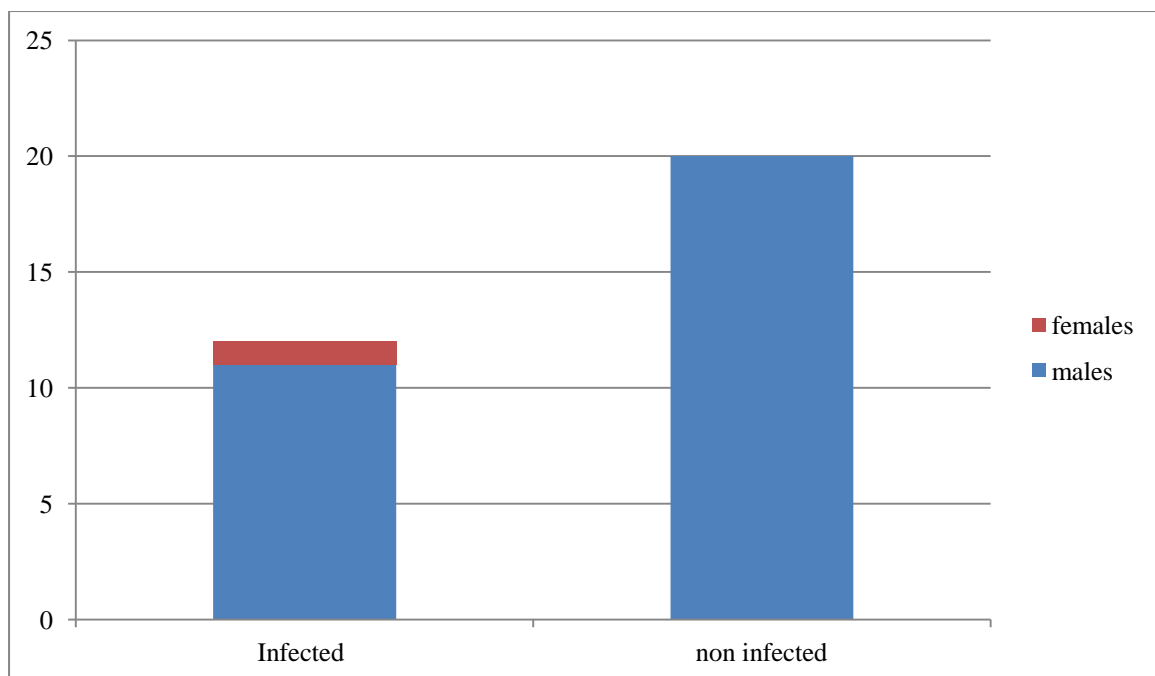


Figure 10 : Distribution of sex

DISTRIBUTION OF ETIOLOGY OF THE FRACTURES STUDIED:

OVERALL :

Total number – 32

Road traffic accidents – 31

Fall from height – 1

Out of all the fractures studied only 1 was not a road traffic accident. This reiterates the frequency of road traffic accidents.

OVERALL ETIOLOGY OF FRACTURES

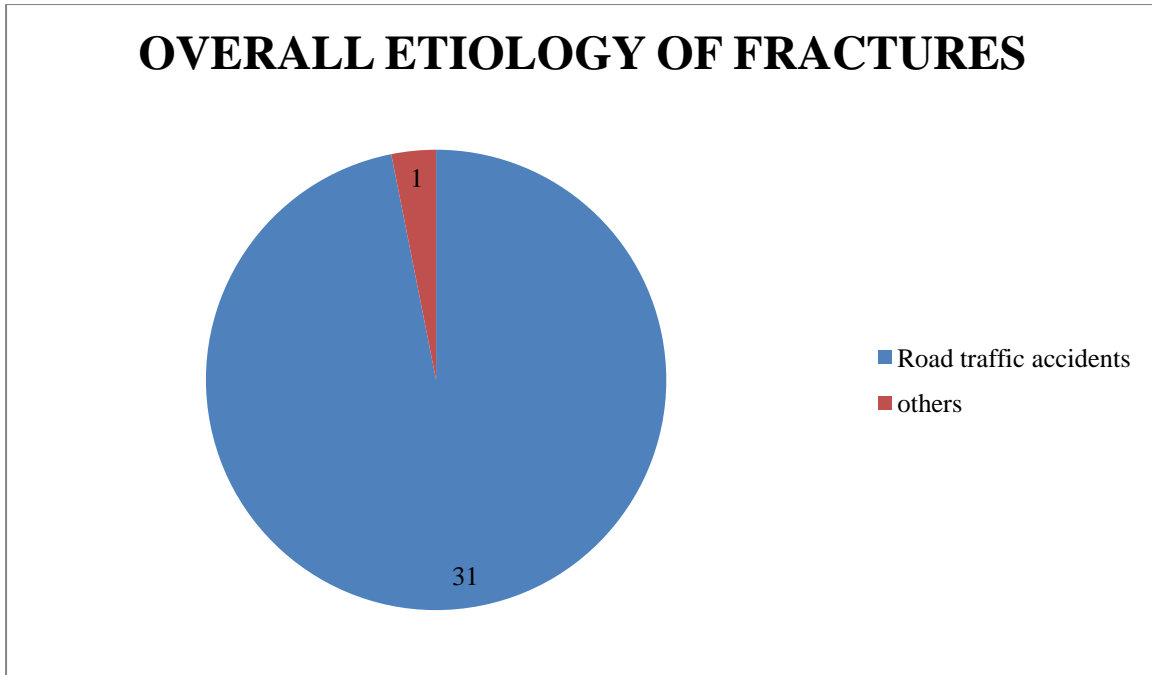


Figure 11 shows the overall etiology of fractures studied

DISTRIBUTION OF ROAD TRAFFIC ACCIDENTS - OVERALL

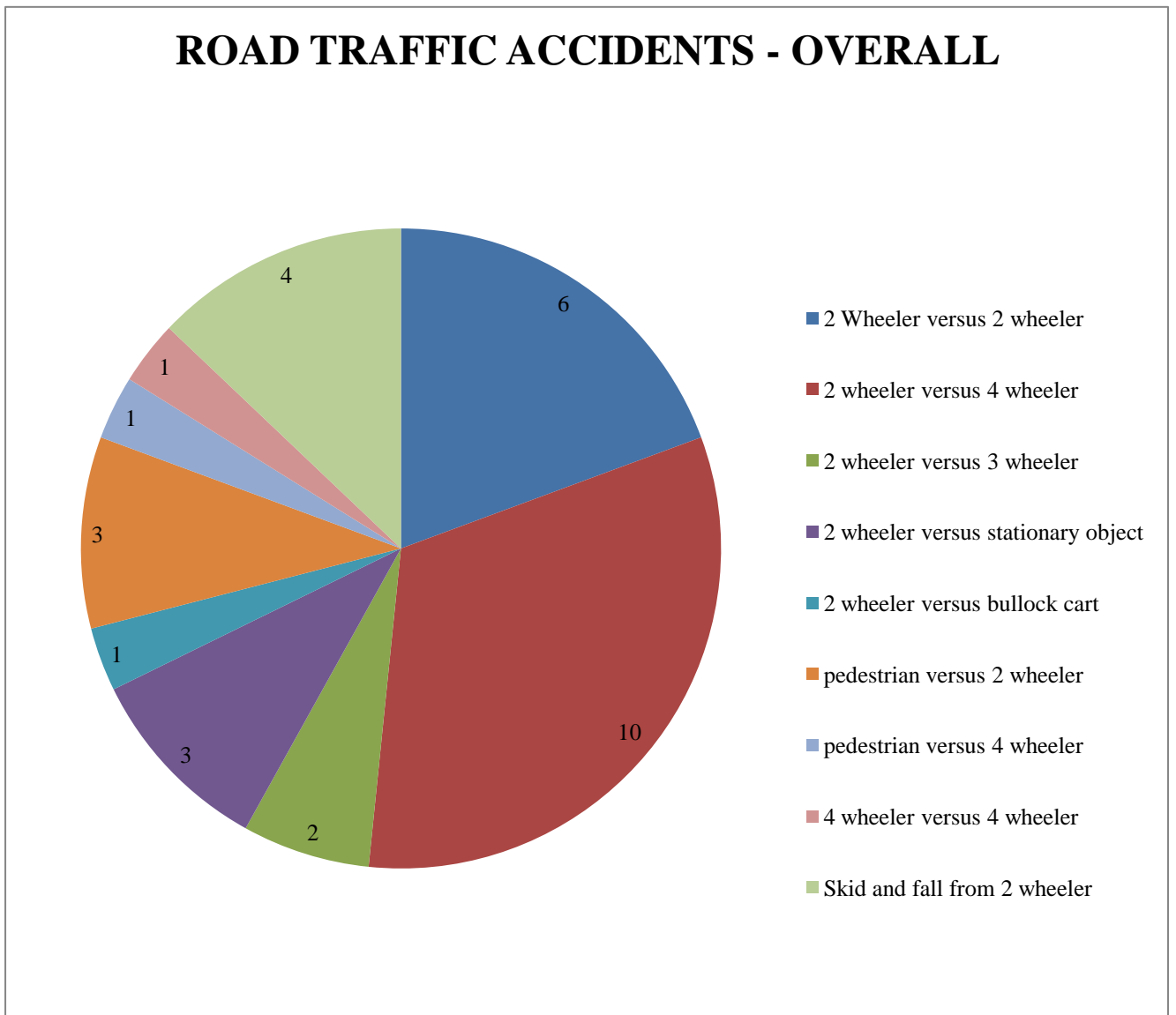


Figure 12 shows the overall road traffic accident etiology of fractures

INFECTED CATEGORY:

Total - 12

Road traffic accidents – 12

DISTRIBUTION OF ROAD TRAFFIC ACCIDENTS:

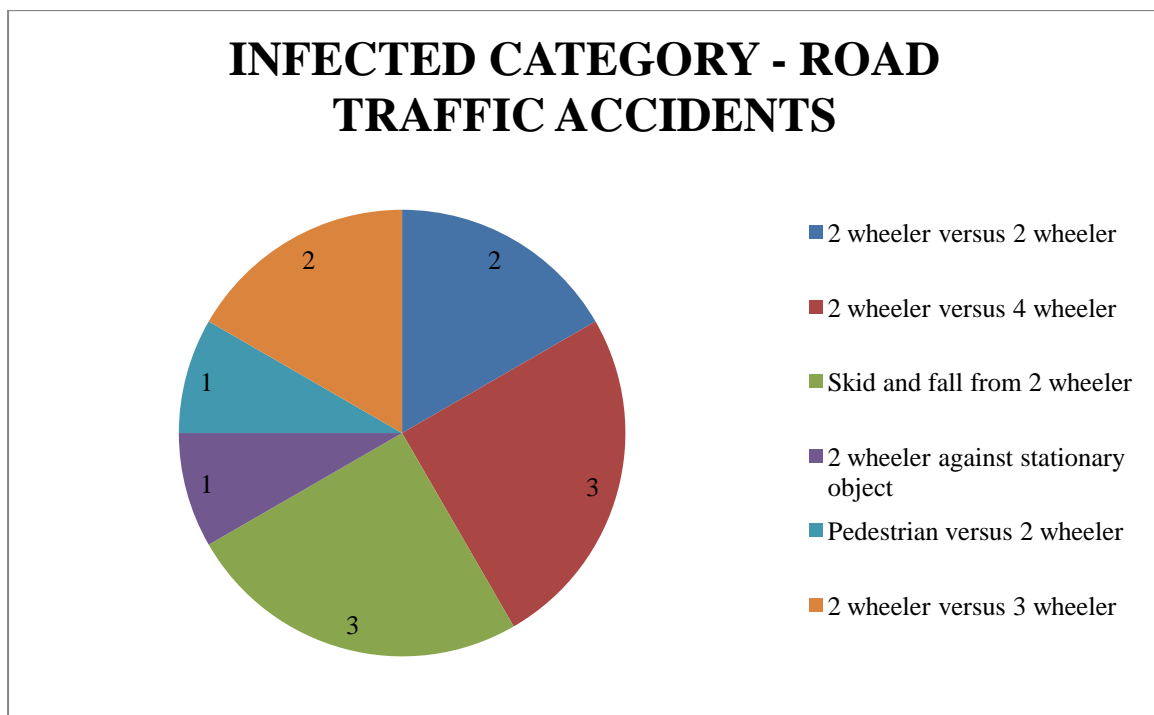


Figure 13 shows the distribution of road traffic accidents among the infected fractures

DISTRIBUTION OF ETIOLOGY IN NON INFECTED CATEGORY:

Total - 20

Road traffic accidents – 19

Fall from height – 1

Out of the 19 road traffic accidents 2 wheeler accidents were the highest. 4 wheelers were hardly involved. Pedestrians crossing the road or hit by the sidewalk were also present among them.

DISTRIBUTION OF ROAD TRAFFIC ACCIDENTS IN NON INFECTED:

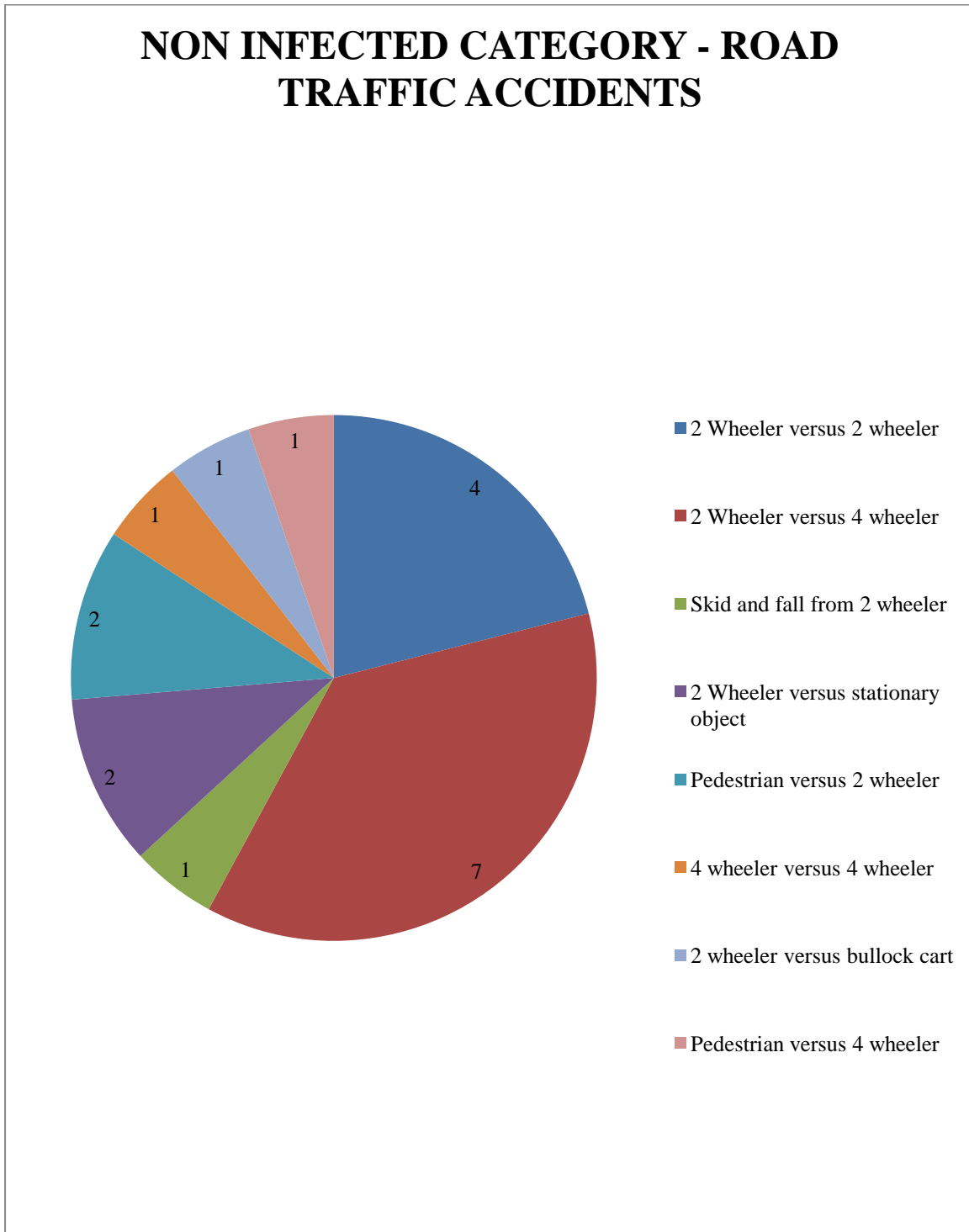


Figure 13

PRIMARY OUTCOME MEASURED (FUNCTIONAL OUTCOME):

COMPARISON OF SF36 AND LEFS SCORE

AMONG INFECTED AND NON-INFECTED

Score	not infected	infected	p-value
SF36	74.85	51.33	<0.001
LEFS	54.85	35.08	<0.001

Table 1 – Functional outcome scores

The p-value which is <0.05 , reveals that there is a significant difference in mean score SF36 and LEFS among infected group and non-infected group

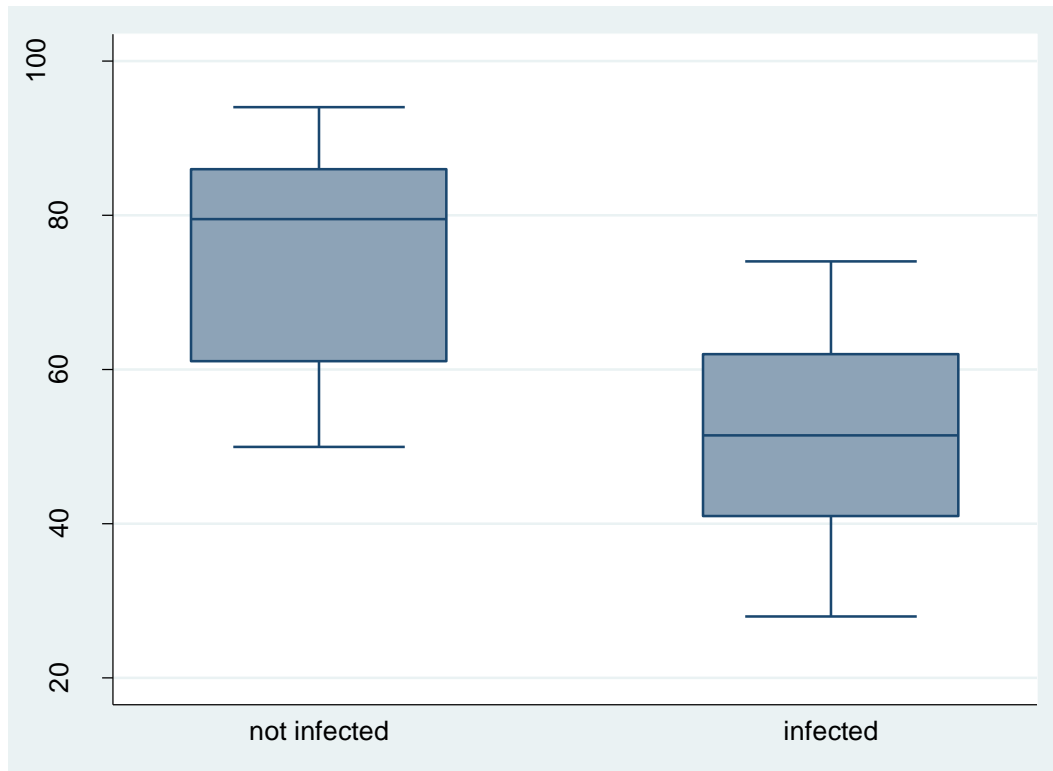


Figure 14 : Box plot showing the difference in sf36 score among infected and non-infected

Box plot shows the distribution of sf 36 score among infected and non infected group where the infected group have a low sf 36 score compared to the non infected

Note: the centre dark line in box shows the median and the two extended line shows the variability in data. The variability in scores is more or less similar in both the group. But the median shift can be clearly seen

Sf36

domains	Non infected	infected
PF	73	40
RP	60	27.08
RE	80.05	72.33
VT	72.75	57.92
MH	70.2	57.67
BP	81.5	50.17
GH	75.1	57.46

Table 2

Where:

Physical functioning (PF),

role physical (RP),

bodily pain (BP),

general health (GH),

vitality (VT),

role emotional (RE),

mental health (MH)

LEFS RESULTS

Below shows the box plot for the Lower extremity function score.

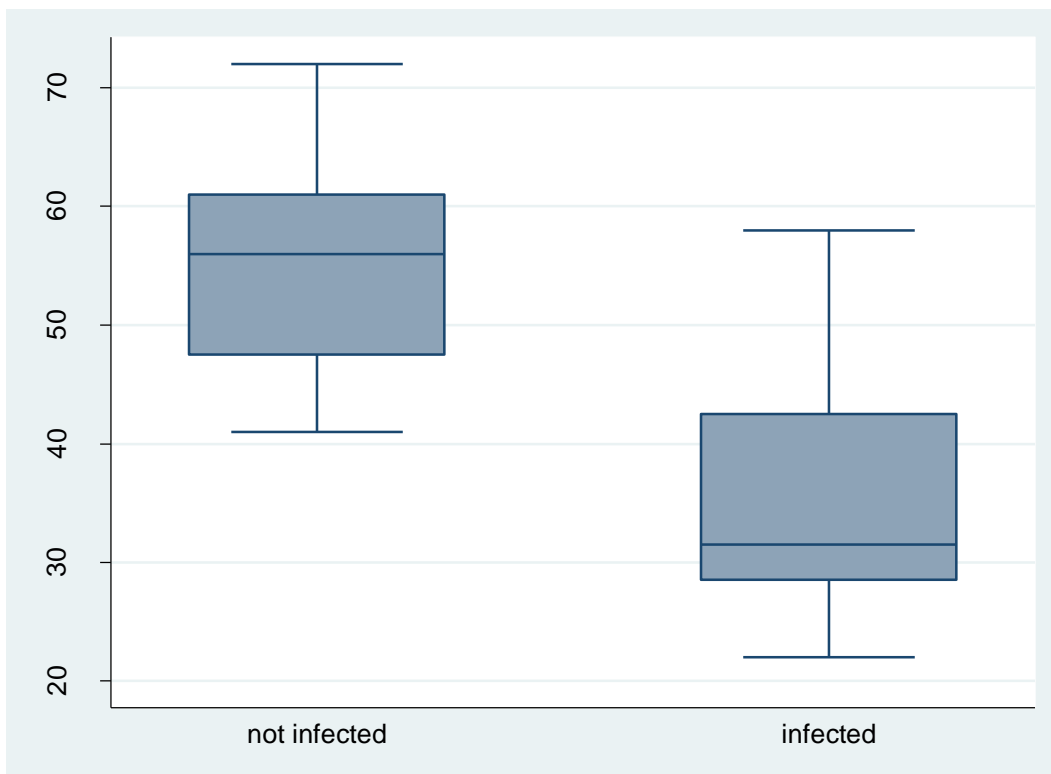


Figure 15 : Box plot showing LEFS score distribution

CLASSIFICATION BASED ON GUSTILO ANDERSON TYPE –

The classification used as stated previously was the Gustilo Anderson classification of which Type 1 and 2 were not present among the patients studied. This again confirms the high energy nature of road traffic accidents that present to a trauma surgeon these days.

Types 3A, 3B and 3C were distributed in the pattern as shown in figure 4.

Although this shows that there was a greater percentage of type 3A open fractures in the non infected category, this was not found to be statistically significant (p value = 0.496)

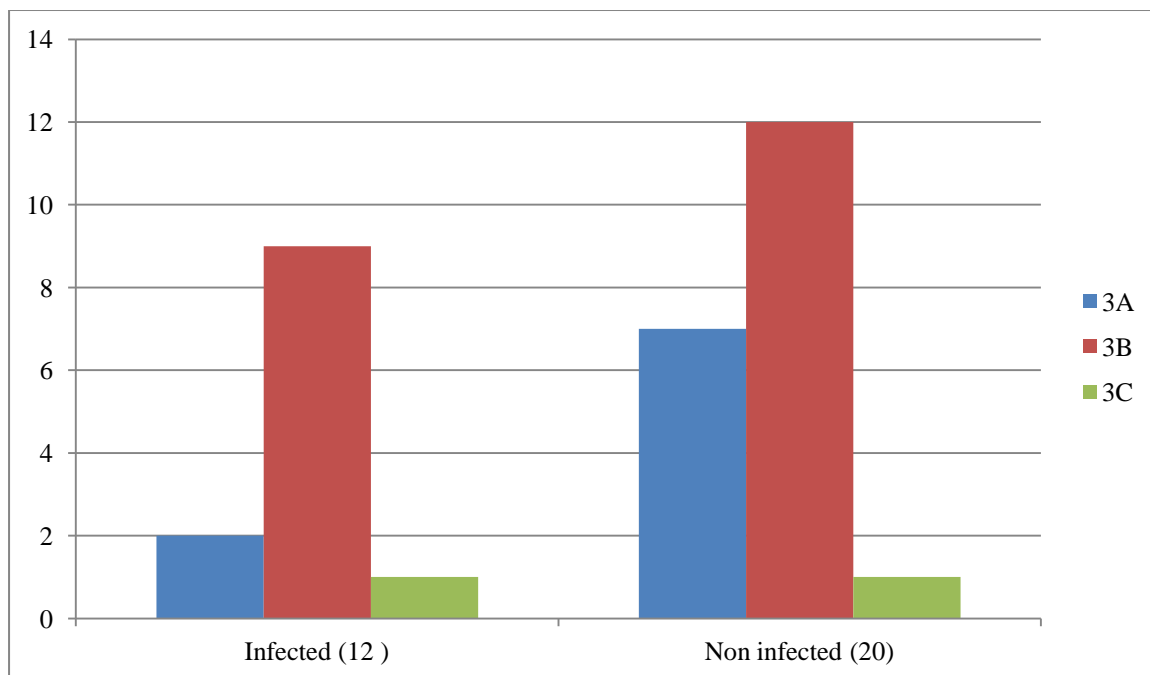


Figure 16: This shows a comparative graph between the groups with respect to the various types of open fracture distribution.

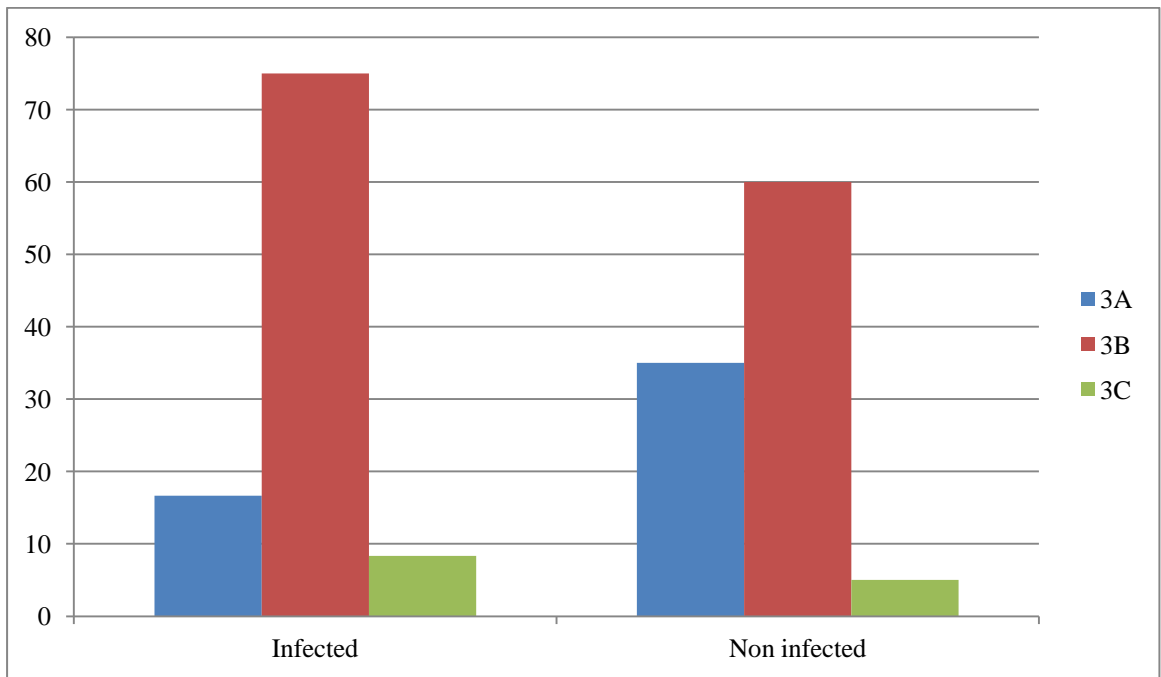


Figure 17: Percentage distribution of types of fractures in both groups.

BASED ON THE FRACTURED BONES INVOLVED:

As our study assessed functional outcome in lower limb open fractures, fractures of the femur and of both bone leg were included in both groups as shown in figure 6.

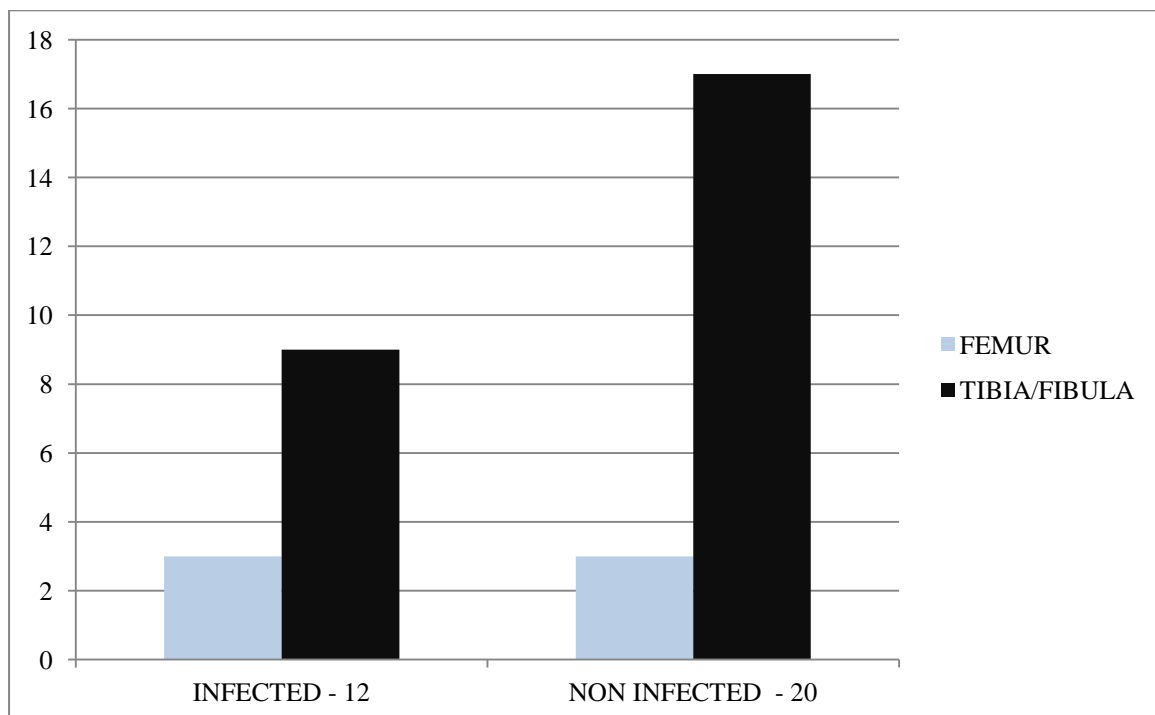


Figure 18: Fracture location distribution

BASED ON THE AO SYSTEM OF FRACTURE CLASSIFICATION:

The AO system of classification was used to classify the fracture patterns of those included in our study.

INFECTED FEMUR FRACTURES:

The three infected femur fractures were of high comminution (C3 pattern) one in the shaft and two in the distal femur.

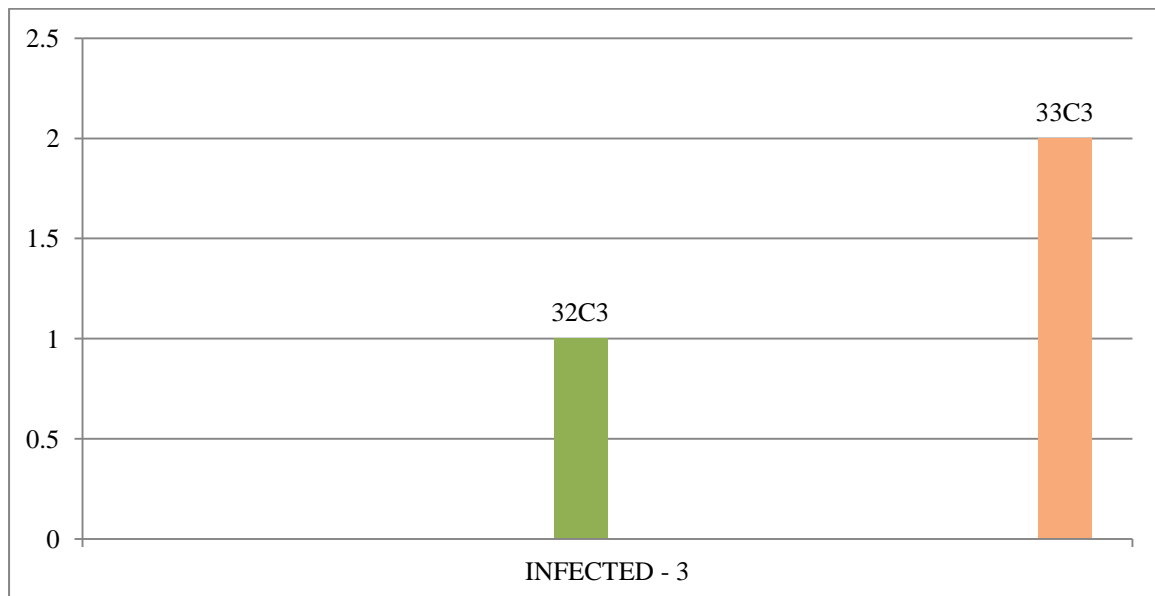


Figure 19 – Fracture pattern distribution in infected open femur

NON INFECTED FEMUR FRACTURES:

Two of the non infected femur fractures were of high comminution at the distal femur and one was a simpler fracture of the shaft of femur.

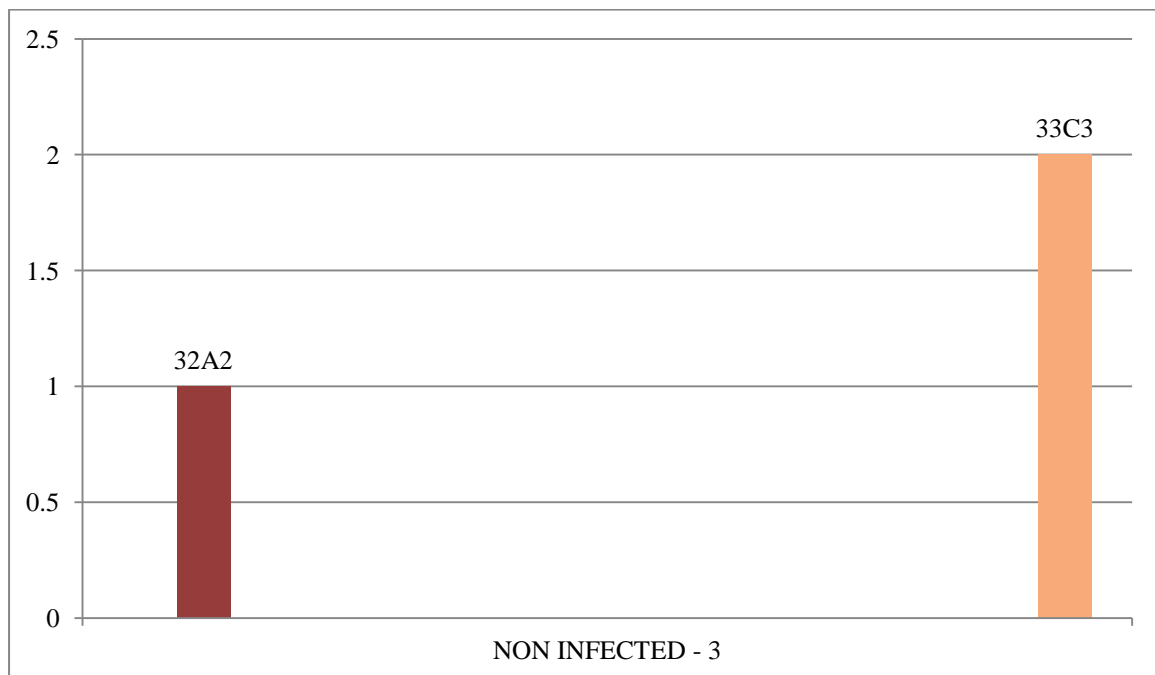


Figure 20 : Graph showing AO classification distribution among non infected femur fractures

OPEN BOTH BONE LEG FRACTURES: AO CLASSIFICATION

CLASSIFICATION NON INFECTED INFECTED TOTAL

41A1	1	0	1
41C2	1	0	1
41C3	1	0	1
42A2	2	1	3
42A3	2	3	5
42B1	2	0	2
42B2	0	1	1
42B3	3	3	6
42C3	3	1	4
43C2	2	0	2

Table 3 : Showing the overall distribution of fractures based on AO classification

INFECTED BOTH BONE LEG FRACTURES:

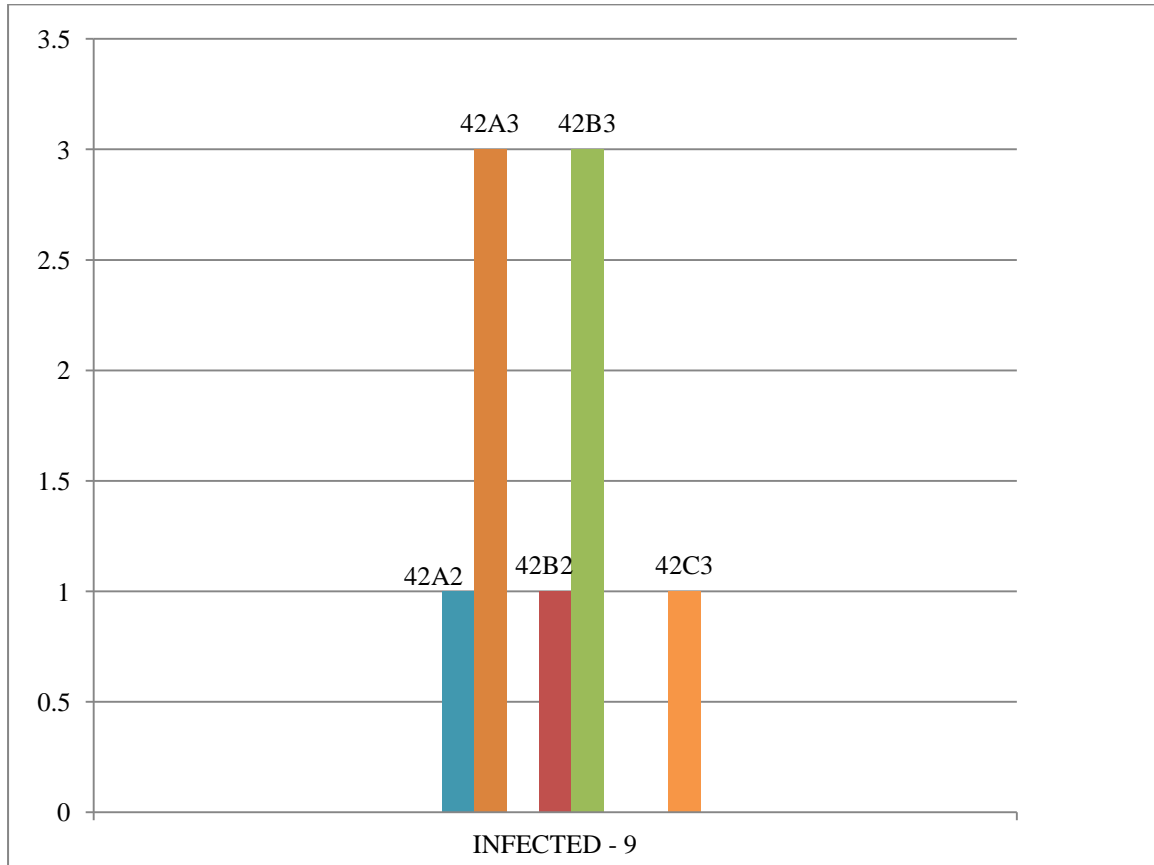


Figure 21 : showing distribution of infected both bone leg fractures

NON INFECTED BOTH BONE OPEN LEG FRACTURES:

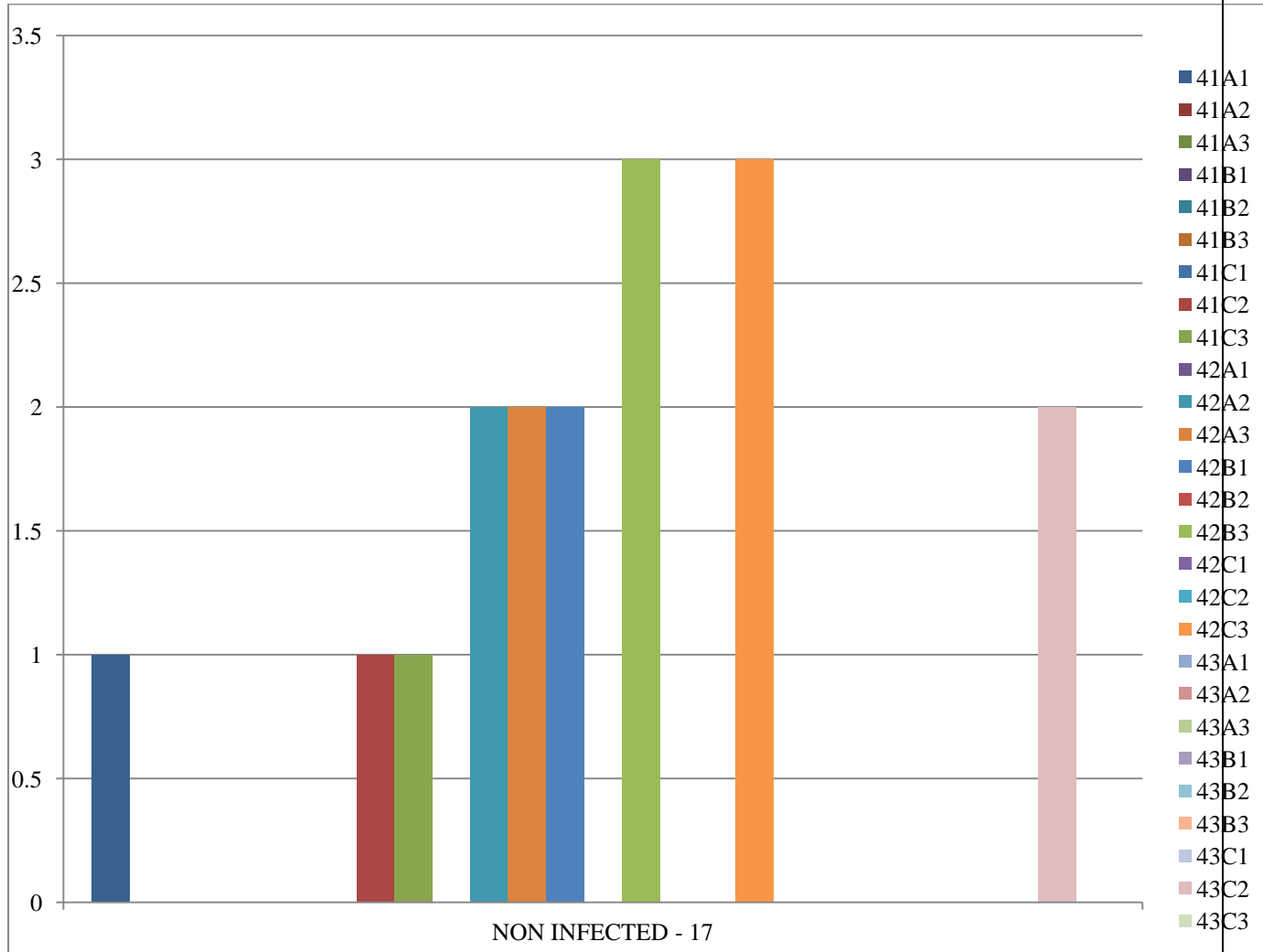


Figure 22 showing distribution of non - infected both bone leg fractures

SURGICAL INTERVENTION :

At our hospital, we keep debridement and skeletal stabilization indispensable. If the contamination and wound did not allow primary internal fixation, an initial external fixation with debridement was carried out which was followed by internal fixation at a later stage. Certain patients, although on follow up, could not be regular owing to various personal pressures and may not have had an ideal, smooth transition from one of treatment to the other. However, union was achieved.

Few patients required revision surgeries and few required bone grafting, bone marrow injections as adjuncts to fixation especially in those who had delayed union.

Shown below in Table 4 is the number of surgeries undertaken in both groups. Those

In the infected category required a third surgery in 25 % of patients.

Those in the non infected required only a single surgery in 65 % of patients.

Number of surgeries (In percentage)

	One surgery	Two surgeries	Three surgeries
Infected (n = 12)	41.6	33.3	25
Non infected (n = 20)	65	35	0

[Table 4]

MONTHS TO UNION

The mean months to union was not significant with the infected 12 patients uniting in a mean of 8 months and the 20 non infected patients uniting in a mean of 7.10 months.

ORGANISMS CULTURED IN THE 12 INFECTED WOUNDS:

Escherichia coli – 3

Enterobacter – 4

Enterococcus – 1

Methicillin resistant *staphylococcus aureus* – 3

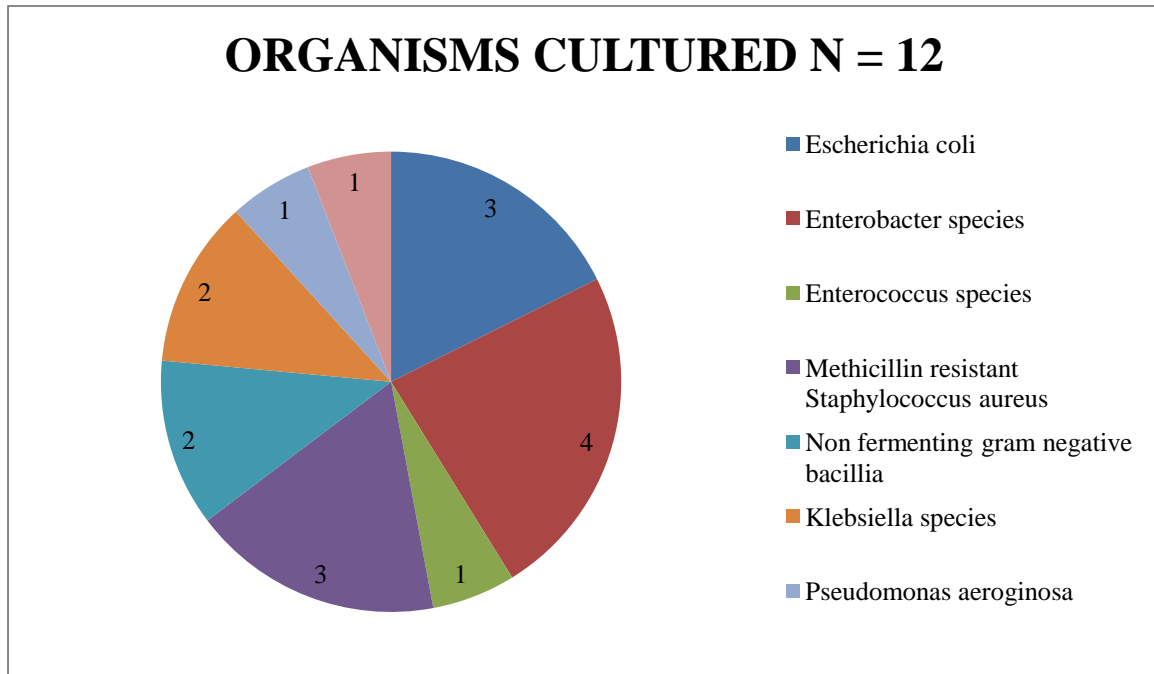
Non fermenting gram negative bacilli – 2

Klebsiella species – 2

Pseudomonas aeruginosa – 1

Coagulase negative *Staphylococcus aureus* -1

GRAPH SHOWING DISTRIBUTION OF CULTURED ORGANISMS



CASE EXAMPLE 1

We discuss a 42 year old gentleman who sustained an open Gustilo – Anderson Type 3b fracture distal femur , AO class 33C3 (Figure – 7)



Figure 7 – Open distal femur C3 fracture

He underwent debridement and plating of the same with a lateral locked plate.

(Figure 8)



Figure 8 – Immediate post operative Xray showing distal femur fixation

He persisted to have infection following this and although his fracture had united within 9 months his infection continued to trouble him.

In spite of union achieved as shown in Figure 10, his functional score was only 36 (SF – 36) and 33 (Lower extremity function score)



Figure 9 – This united distal femur fracture however required debridement and implant exit to treat the persistent infection.

CASE EXAMPLE 2

We discuss another gentleman, who sustained an open fracture to the leg, while riding a 2 wheeler, hit against another 2 wheeler. He sustained an open fracture. The fracture pattern was AO class 42 A3 and there were 4 small wounds over the fracture site.

Figure 10 shows the initial Xray



Figure 10 – pre operative

Debridement and orthofix placement was done as shown in Figure 11



Figure 11 – immediate post operative x ray

As the fracture did not unite, debridement and Ilizarov fixator was applied as shown in Figure 13



Figure 13 shows an Ilizarov fixator placed for an infected delayed union

On the Ilizarov frame the patient was made to weight bear, regular dressings were done for the infection that was intermittent yet persistent.



Figure 14 shows the fracture has united , however sequestrum and a sinus persists.

This persistent infection needed to be addressed as it did not settle with antibiotics.

A thorough debridement was done which required much bone and tissue to be removed.



Figure 15 shows the anteroposterior view following debridement and sequestrectomy.

This chronic osteomyelitis was type 4 (Cierny and Mader staging)



Figure 16 shows the post debridement lateral view of the leg.

As this chronic osteomyelitis required radical debridement, skeletal stabilization was required. An Ilizarov fixator had to be applied again as shown below.



Figure 17 shows the reapplied Ilizarov circular fixator to stabilize post debridement leg.

This case can be said as an extreme case of recalcitrant infection. While this is not the case with every patient with infection, it gives us a picture of how long and tedious the road is, once infection sets in.

This gentleman had the lowest SF 36 score and one of the lower LEFS scores.

CASE EXAMPLE 3

We discuss the third case example, a gentleman who sustained a road traffic accident and similar fracture pattern as discussed in case example 2. (AO 42 A3). It was a type 3b open fracture.

The initial xrays are shown below in figure 18



Figure 18 – anteroposterior view of the initial fracture

An initial debridement and primary intramedullary interlocked nailing was done.

The immediate post operative Xrays are shown in Figure 19 below



He went on to unite as shown below.



His functional outcome was the best among all those studied. He had no infection.

He had returned back to work and he was almost near normal. In fact he had said he felt there was no difference at all pre injury and post injury.

Apart from work, he felt his social and family life had also regained its full vigour.

His SF 36 score was the highest and LEFS scores among the highest.

DISCUSSION:

The word “infection” leaves a trail of apprehension and fear in the minds of the common man.

Infection usually manifests itself by way of persistent pus discharge or chronic discharging sinus.

We discuss 12 patients who had open fractures which had culture proven infection during their treatment and another 20 patients who had open fractures but with no culture proven infection.

Profiling of patients were done and analyzed.

As per the national survey and studies like the one by Ruikar et al (23), the bread winning population was most affected by road traffic accidents. We found similar results among our patients.

There were 31 males out of the 32 patients studied. This again goes in line with the national survey which showed women were only 15% of all those involved in road traffic accidents. Male to female ratio was higher than this in our study.

Both the groups involved patients with a higher Gustilo Anderson type that is, type 3 injuries . In fact, all patients were type 3 open injuries. The sub class showed a slightly higher type 3b in the infected category however this was not significant.

Both groups had a wide variety of distribution of fracture patterns, the more comminuted, complex patterns being more frequent.

While most of the other parameters studied did not yield statistically significant differences in the infected and non infected groups of open fractures, functional outcome proved to be significantly different.

Although we had not matched the two groups studied, this helps us to see a similarity between the groups, their parameters being not significantly different.

The various causes of disgruntlement and general dissatisfaction among the patients were due to persistent pain and persistent pus discharge which required regular dressings even after 1 year of treatment.

Pain seemed to be an important cause of decreased functional outcome (bodily pain). Physical functioning seemed to be decreased which implied that their activities of daily living were significantly hindered and for most patients going back to work was hindered by fractures. This parameter was found to be more especially, in the infected fracture group.

There was also social stigmata to be considered especially in the infected group as the presence of a bandage signifies a persistent wound or ulcer which , among friends and family was found to be an impediment to conversation and pleasant relations.

Infection that persisted in the form of a non healing ulcer or sinus gave off an unpleasant , idiosyncratic smell which was another factor that the patients complained off in the infected group.

In spite of the decreased functional outcome owing to emotional reasons, our population included breadwinners of the families so the social and emotional aspect, while being important, was not as cardinal as getting back to their jobs and putting food on the table.

The vicious spiral downwards following an injury of this kind starts with money spent on hospital bills and loss of pay. But if , for whatever reason, there is delay in this process of getting the patient back to his feet and working, there is more damage done.

Debt, family problems and dependence on others , to name a few, plague homes where the breadwinner is victim to an open fracture. Infection, for various reasons, prolonged this time to getting back to productive life. Hence, functional outcome, measured by the SF-36 score involved a major role played by a decreased physical functioning and physical role component.

Few patients in the infected group had a prolonged time to union and this affected their functional outcome. However, as there was no significant difference between the time to union among the groups, this may not have proved confounding.

On the other hand, since this prolonged time to union was probably due to persistent infection, this too is part of the worse outcome that follows an infection in an open fracture.

As the infection persisted, these patients required frequent visits to the hospital, this involved money and time which was a cause for dissatisfaction.

Incidentally, it was also found that the infected group had hospital bills twice that of the non infected group.

Hence, although one particular reason cannot be pointed out, there remains significant reasons why the patients in the infected group of open fractures have a worse functional outcome.

As a by product of this study we found that the organisms cultured from the wounds intraoperatively belonged to a group of organisms that have been shown to be an upcoming and growing threat in various situations.

This group of organisms go by the acronym of ESKAPE implying *Enterococcus faecium*, *Staphylococcus aureus*, *Klebsiella pneumoniae*, *Acinetobacter baumannii*, *Pseudomonas aeruginosa* and *Enterobacter* species.

The profile of organisms included all of the above apart from *Acinetobacter*.

Patzakis et al, Berman et al , Braun et al ,Dellinger et al ,Carsenti-Etesse et al have carried out various studies to look into the various organisms over the decades specific to wound infections (surgical site infections). In all of these studies *Staphylococcus aureus* proved to be the main culprit.

In our study 4 out of 17 organisms were *Staphylococcus aureus* out of which 3 were methicillin resistant *Staphylococcus aureus*.

Gram negative bacteria are increasingly prevalent and wound infections are no different.

LIMITATIONS:

As this was a retrospective study with smaller numbers for sample size, the significance could be difficult to comment on.

The heterogenous nature of the groups with femur and both bone leg fractures compiled together gives an blurred picture of specific results .

Even if the investigator was blinded , on asking various questions to the patients, the presence of infection could not be avoided as the patients would invariably complain about pus discharge from the leg which hindered them from various activities. Thus blinding was not possible in a true sense

All patients may not have got cultures taken intraoperatively hence the lower incidence of infection.

CONCLUSION:

At the outset, this study shows us that infection is definitely an important factor to consider while treating open fractures. In developing countries, the chances of sustaining an open fracture with higher contamination is more hence the chances of infection.

Treatment initially with thorough debridement, skeletal stabilization and antibiotics with meticulous methods are important.

Considering infection causes a worse functional outcome, it is important to take utmost care to prevent it. Functional outcome is a valid reason for this serious approach to infection, apart from potential spread of infection, especially in the immunocompromised hosts.

Hence, prevention of infection should be one of the goals while treating open fractures.

ANNEXURES

This questionnaire was dictated to the patient in either Tamil, Telugu or English as per their respective choices and was be filled up by the investigator.

Patient Name:

SSN#: _____ Date:

Person helping to complete this form:

1. In general, would you say your health is:

- Excellent
- Very good
- Good
- Fair
- Poor

2. Compared to one year ago, how would you rate your health in general now?

- Much better now than a year ago
- Somewhat better now than a year ago
- About the same as one year ago
- Somewhat worse now than one year ago
- Much worse now than one year ago

3. The following items are about activities you might do during a typical day. Does your health now limit you in these

activities? If so, how much?

a. Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports.

- Yes, limited a lot.
- Yes, limited a little.
- No, not limited at all.

4b. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf?

- Yes, limited a lot.
- Yes, limited a little.
- No, not limited at all.

5c. Lifting or carrying groceries.

- Yes, limited a lot.
- Yes, limited a little.
- No, not limited at all.

6d. Climbing several flights of stairs.

- Yes, limited a lot.
- Yes, limited a little.
- No, not limited at all.

7e. Climbing one flight of stairs.

- Yes, limited a lot.
- Yes, limited a little.
- No, not limited at all.

8f. Bending, kneeling or stooping.

- Yes, limited a lot.
- Yes, limited a little.
- No, not limited at all.

9g. Walking more than one mile.

- Yes, limited a lot.
- Yes, limited a little.
- No, not limited at all.

10h. Walking several blocks.

- Yes, limited a lot.
- Yes, limited a little.
- No, not limited at all.

11i. Walking one block.

- Yes, limited a lot.

Yes, limited a little.

No, not limited at all.

12j. Bathing or dressing yourself.

Yes, limited a lot.

Yes, limited a little.

No, not limited at all.

13/4. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

a. Cut down the amount of time you spent on work or other activities?

Yes

No

14b. Accomplished less than you would like?

Yes

No

15c. Were limited in the kind of work or other activities

Yes

No

16d. Had difficulty performing the work or other activities (for example, it took extra time)

Yes

No

17/5. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

a. Cut down the amount of time you spent on work or other activities?

Yes

No

18b. Accomplished less than you would like

Yes

No

19c. Didn't do work or other activities as carefully as usual

Yes

No

20/6. During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbours, or groups?

Not at all

Slightly

Moderately

Quite a bit

Extremely

21/7. How much bodily pain have you had during the past 4 weeks?

Not at all

Slightly

Moderately

Quite a bit

Extremely

22/8. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

Not at all

Slightly

Moderately

Quite a bit

Extremely

23/9. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question,

please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.

a. did you feel full of pep?

- All of the time
- Most of the time
- A good bit of the time
- Some of the time
- A little of the time
- None of the time

24b. have you been a very nervous person?

- All of the time
- Most of the time
- A good bit of the time
- Some of the time
- A little of the time
- None of the time

25c. have you felt so down in the dumps nothing could cheer you up?

- All of the time
- Most of the time
- A good bit of the time
- Some of the time
- A little of the time
- None of the time

26d. have you felt calm and peaceful?

- All of the time

- Most of the time
- A good bit of the time
- Some of the time
- A little of the time
- None of the time

27e. did you have a lot of energy?

- All of the time
- Most of the time
- A good bit of the time
- Some of the time
- A little of the time
- None of the time

28f. have you felt downhearted and blue?

- All of the time
- Most of the time
- A good bit of the time
- Some of the time
- A little of the time
- None of the time

29g. did you feel worn out?

- All of the time

- Most of the time
- A good bit of the time
- Some of the time
- A little of the time
- None of the time

30h. have you been a happy person?

- All of the time
- Most of the time
- A good bit of the time
- Some of the time
- A little of the time
- None of the time

31i. did you feel tired?

- All of the time
- Most of the time
- A good bit of the time
- Some of the time
- A little of the time
- None of the time

32/10. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc.)?

- All of the time

- Most of the time
- Some of the time
- A little of the time
- None of the time

33/11. How TRUE or FALSE is each of the following statements for you?

a. I seem to get sick a little easier than other people

- Definitely true
- Mostly true
- Don't know
- Mostly false
- Definitely false

34b. I am as healthy as anybody I know

- Definitely true
- Mostly true
- Don't know
- Mostly false
- Definitely false

35c. I expect my health to get worse

- Definitely true
- Mostly true
- Don't know
- Mostly false
- Definitely false

36d. My health is excellent

- Definitely true
- Mostly true
- Don't know
- Mostly false
- Definitely false

Lower Extremity Functional Scale (LEFS)

Source: Binkley JM, Stratford PW, Lott SA, Riddle DL. The Lower Extremity Functional Scale (LEFS): scale development, measurement properties, and clinical application. North American Orthopaedic Rehabilitation Research Network. *Phys Ther.* 1999 Apr;79(4):371-83.

The Lower Extremity Functional Scale (LEFS) is a questionnaire containing 20 questions about a person's ability to perform everyday tasks. The LEFS can be used by clinicians as a measure of patients' initial function, ongoing progress and outcome, as well as to set functional goals.

The LEFS can be used to evaluate the functional impairment of a patient with a disorder of one or both lower extremities. It can be used to monitor the patient over time and to evaluate the effectiveness of an intervention.

The columns on the scale are summed to get a total score. The maximum score is 80.

Interpretation:

The lower the score the greater the disability.

The minimal detectable change is 9 scale points.

The minimal clinically important difference is 9 scale points.

$\% \text{ of maximal function} = (\text{LEFS score}) / 80 * 100$

Performance:

The potential error at a given point in time was +/- 5.3 scale points.

Test-retest reliability was 0.94.

Construct reliability was determined by comparison with the SF-36. The scale was found to be reliable with a sensitivity to change superior to the SF-36.

This scoring was carried out similar to SF-36 scoring , where the questions are asked by the investigator to the patient and the patients responses were filled up by the investigator

(Few questions have been changed to suit our target population – Questions like getting in and out of a car has been replaced with using public transport)

Today, do you or would you have any difficulty at all with: Activities	Extreme difficulty or unable to perform activity	Quite a bit of difficulty	Moderate difficulty	A little bit of difficulty	No difficulty
1. Any of your usual work, housework or school activities.	0	1	2	3	4
2. Your usual hobbies, recreational or sporting activities.	0	1	2	3	4
3. Taking a bath.	0	1	2	3	4
4. Walking between rooms.	0	1	2	3	4
5. Getting onto a bicycle	0	1	2	3	4
6. Squatting.	0	1	2	3	4
7. Lifting an object, like a bag of groceries from the floor.	0	1	2	3	4
8. Performing light	0	1	2	3	4

activities around your home.						
9. Performing heavy activities around your home.	0	1	2	3	4	
10. Using public transport	0	1	2	3	4	
11. Walking 300 metres.	0	1	2	3	4	
12. Walking 1 and half km.	0	1	2	3	4	
13. Going up or down 10 stairs (about 1 flight of stairs).	0	1	2	3	4	
14. Standing for 1 hour.	0	1	2	3	4	
15. Sitting for 1 hour.	0	1	2	3	4	
16. Running on even ground.	0	1	2	3	4	
17. Running on uneven ground.	0	1	2	3	4	
18. Getting off a bicycle	0	1	2	3	4	

19. Hopping.	0	1	2	3	4
20. Rolling over in bed.	0	1	2	3	4
Column Totals:	0	1	2	3	4

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Assignment Inbox: The Tamil Nadu Dr.M.G.R.Medical Uty 2014-15 Examinations				
	Info	Dates	Similarity	
TNMGRMU EXAMINATIONS		Start 01-Sep-2014 11:27AM Due 30-Oct-2015 11:59PM Post 30-Oct-2015 12:00AM	8%	Resubmit View

NAME	HOSP NO	AGE	mode	SEX	OPEN	REGION	SITE OF #	CLASSIFICATION	NO OF SX	UNION	LEFS	INFECTION	PF	RP	RE	VT	MH	SF	BP	GH	SF36 TOTAL	
Alamelu	069644F	60	pedestrian versus 2 wheeler	F	IIIA	4	2	A2	1N	3	32	E COLI	60	75	100	50	52	50	75	38	62	
Chitrasenan	064018F	35	2 wheeler versus 4 wheeler	M	IIIB	4	2	A3	1O	14	47	E COLI ENTERO PSEUDO MONAS	80	25	67	75	76	75	75	67	67	
Elumalai	630918F	43	skid and fall	M	IIIB	4	2	B3	1O	5	58	KLEBSIELLA	55	75	67	50	56	62.5	75	54	62	
Ezhilarasan	999012D	40	2 wheeler versus tree	M	IIIB	3	3	C3	3PPP	9	33	ENTERO BACTERIA	30	0	67	45	36	38	25	46	36	
Gandhi	671591F	35	skid and fall	M	IIIB	4	2	B3	3O	5	29	ENTERO BACTERIA	15	50	100	50	60	38	38	63	52	
Gopinath	474242F	25	2 wheeler versus 4 wheeler	M	IIIB	4	2	B3	3EFI	8	28	MRSA , NFGNB	15	15	0	100	55	64	38	25	54	44
Hareesh	675331f	24	2 wheeler versus 2 wheeler	M	IIIC	4	2	C3	2EI	6	40	NFGNB	60	0	67	80	76	75	38	67	58	
Kuppan	995380D	35	2 wheeler versus 3 wheeler	M	IIIB	3	3	C3	2EI	11	22	Enterococcus	30	0	67	55	60	25	25	46	38	
Loganathan	651896F	20	2 wheeler versus 3 wheeler	M	IIIB	4	2	A3	2OI	9	29	KLEBSIELLA then MRSA	35	0	33	50	44	63	63	63	44	
Loganathan	347525F	30	2 wheeler versus 2 wheeler	M	IIIB	4	2	A3	2OI	14	27	MRSA	20	0	0	45	40	25	50	46	28	
Vijay	716349F	31	skid and fall	M	IIIB	4	2	B2	1O	5	45	ECOLI, ENTEROBACTER	50	100	100	70	64	50	75	79	74	
Vinoth Kumar	651620F	29	2 wheeler versus 4 wheeler	M	IIIA	3	2	C3	1N	7	31	Coag negative staph	30	0	100	70	64	38	38	67	51	

OPEN 3A = 1 3B = 2
GENDER M = 1 F = 2
CLASS A1 = 1 A2 = 2
B1 = 4 B2 = 5
C1 = 7 C2 = 8
SITE 1 = PROXIM 2 = MIDSHAFT
REGION 3 = FEMUR 4 = LEG

3C = 3
A3 = 3
B3 = 6
C3 = 9
3 = DISTAL

OTHER SURGO = ORTHO P = PLATING

I = ILIZ N = NAW = WASL = LCP E = EXFIX BP = BG + PLATING

L

NAME	HOSP NUM	mode	AGE	SEX	OPEN	REGION	SITE OF #	CLASSIFICATION	NO OF SX	UNION	LEFS	PF	RP	RE	VT	MH	SF	BP	GH	SF36 TOT/	
Ch B	713507F	4 wheeler versus 4 wheeler	50	M	III A	3	2	A2	1N	4	52		55	0	33	55	72	75	38	75	50
Da	962628D	2 wheeler versus 2 wheeler	55	M	III A	4	2	C3	1I	8	56		80	50	100	85	84	100	75	63	80
Go	140738F	2 wheeler versus bullock cart	60	M	III A	4	1	C3	1I	4	57		75	100	100	65	56	100	88	92	84
Ga	092448F	skid and fall	18	M	III A	4	2	A2	1N	5	66		90	100	100	80	64	88	88	83	87
Im A	835142D	2 wheeler versus 4 wheeler	47	M	IIIB	4	1	C2	2EP	12	61		85	75	100	80	56	100	100	92	86
Jag K	309577F	2 wheeler versus 2 wheeler	38	M	III A	4	2	C3	1N	5	60		85	75	100	80	56	100	100	92	86
Ja R	133150F	2 wheeler versus 2 wheeler	31	M	IIIC	4	1	A1	2EP	7	61		80	100	67	80	64	75	88	75	79
Ka	611544F	pedestrian versus 2 wheeler	25	M	IIIB	4	2	B3	2EI	5	54		60	0	67	80	64	75	88	67	62
Kup	704647F	2 wheeler versus 4 wheeler	42	M	IIIB	4	2	A2	1N	5	56		90	100	67	80	64	88	88	75	81
Moy	394681F	fall from height	40	M	III A	4	3	C2	1E	5	69		95	100	100	80	80	88	88	75	88
Mu	039422F	2 wheeler versus stationary object	42	M	III A	4	2	A3	1E	6	72		95	100	100	80	80	100	88	83	91
Nov	119162F	2 wheeler versus 2 wheeler	43	M	IIIB	4	2	B1	1N	12	56		65	75	100	80	80	88	75	79	80
Pal	401304F	2 wheeler versus 4 wheeler	47	M	IIIB	4	2	B3	2EI	9	52		55	75	100	80	80	88	75	75	78
Pe	618600F	2 wheeler versus 4 wheeler	41	M	IIIB	4	2	C3	2EI	10	42		45	0	33	55	68	88	63	58	51
Pel V.	095242F	pedestrian versus 4 wheeler	21	M	IIIB	4	2	B1	1O	8	43		45	0	33	60	68	75	63	58	50
Pra	213484F	2 wheeler versus 4 wheeler	51	M	IIIB	3	3	C3	2PP	12	47		65	50	67	70	76	88	100	71	73
Ra	657856F	2 wheeler vs stationary object	53	M	IIIB	3	3	C3	1P	8	41		65	0	67	65	72	75	75	63	60
Rav	983573D	2 wheeler versus 4 wheeler	37	M	IIIB	4	3	C2	2EP	6	41		65	0	67	60	68	75	75	63	59
Rud	222694F	pedestrian versus 2 wheeler	44	M	IIIB	4	2	B3	1E	6	48		70	100	100	60	68	88	75	67	78
Si	119588F	2 wheeler versus 4 wheeler	42	M	IIIB	4	2	A3	1N	5	63		95	100	100	80	84	100	100	96	94

AL





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Additional Vice Principal (Research)

July 29, 2014

Dr. Vinay Timothy Kuruvilla
PG Registrar
Department of Orthopaedics
Christian Medical College
Vellore 632 004

Sub: **Fluid Research Grant Project:**
An observational study comparing the functional outcome in patients with open fractures of the lower limbs, with and without infection during their course of treatment.
Dr. Vinay Timothy Kuruvilla, PG Registrar, Dr. Vinoo Mathew Cherian, Dr. Sandeep Albert, Orthopaedics unit 1, CMC Vellore

Ref: IRB Min No: 8890 [OBSERVE] dated 09.06.2014

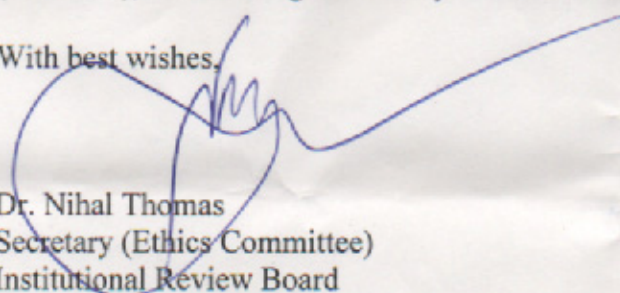
Dear Dr. Vinay Timothy Kuruvilla,

I enclose the following documents:-

1. Institutional Review Board approval
2. Agreement

Could you please sign the agreement and send it to Dr. Nihal Thomas, Addl. Vice Principal (Research), so that the grant money can be released.

With best wishes,


Dr. Nihal Thomas
Secretary (Ethics Committee)
Institutional Review Board

CC: Dr. Vinoo Mathew Cherian, Department of Orthopaedics, CMC