The Outcome of Conservative Management of Tibial Shaft Fractures in Kenyatta National Hospital

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This is a dissertation in part fulfillment for the degree of Master in medicine surgery

DECLARATION

Student declaration

This dissertation is my original work and has not been presented for a degree in any university.

Signed Dr. Oburu G. Jagero, MD

University of Nairobi

Supervisor's declaration

This dissertation has been submitted for examination with my approval as the university professor

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DEDICATION

To my late father Mzee Hellekia Oburu Jagero who taught me the real value of life, "work" and to my first born baby Leckie Oburu both of who died while I was in this program

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OPERATIONAL DEFINATIONS

KNH	Kenyatta National Hospital the main public health institution and University hospital in Kenya
X-ray	Röntgenogram (radiographic image of the injured bone) taken by fluoroscopic machine
Check X ray	X-ray taken after manipulation and immobilization in cast
RTA	Road traffic accident
Non union	Fractures that failed to heal during the period of study.
Mal union	Fractures that healed with angulations, loss of acceptable alignment of fracture fragments, overlap or shortening.
AO/ASIF	Association for the study of internal fixation
MESS	Mangled extremity severity score
WBC	White blood cell count
AP	Anteroposterior
P value	Statistical probability of obtaining a result as extreme as a given data point assuming that the data point was the result of chance alone, this gives the measure of how much evidence there is against the null hypothesis.
Complicated union	Union of fracture that occurs with complications which include delayed union, angulations, un acceptable alignment, overlap of fracture fragments and limb shortening
Stable fracture	Hairline or incomplete fracture
Unstable fracture	complete fracture
Displaced fracture	Fracture with loss of alignment
IMLN	Intramedullary locking nail
IML	Intramedullary nail

ABSTRACT

INTRODUCTION

Tibial shaft fractures are the most common long bone fractures encountered all over the world, motor vehicles accident being the most common single cause. Closed reduction and cast immobilization has been regarded as the standard treatment for low energy tibial shaft fracture. This mode of treatment has proved to be generally successful and offers reliable healing without the risks seen in operative procedures. A subset of patients however have less than satisfactory outcome with this modality of treatment but literature remains ambiguous in identifying the fractures best managed operatively.

MATERIALS AND METHODS

A prospective study was conducted looking at the conservative management of tibial shaft fractures. Patients were recruited from casualty or in the wards and consents' were taken if they satisfied the inclusion criteria. Patients were recruited from April 2005 to December 2005 and followed up to June 2006. Patients were classified as per the dynamism of injury, severity of soft tissue damage, geographical location of the fracture, fracture geometry and Gustilo classification. The extent of alignment, angulations and limb shortening of the fracture were determined. A cast of plaster was applied and the patients were followed up over a period of six months with repeated check x-rays and re evaluation of alignment, angulations, limb length, callus formation and time to union.

RESULTS

One hundred and seventy patients with 178 fractures, 154 (90.6%) male and 16 (9.4%) female patients were recruited. There were 108 (60.7%) fractures followed up. Most of the injuries were sustained from RTA, 116 (65.2%) cases. There was a mean time to union of 15.85 weeks and a union range of 4 to 38 weeks. There was a rate of union by 20 weeks of 81.5%.

There was a non union rate of 7.4%, a mal-union rate of 17.6% and delayed union rate of 11.1%. The infection rate was 6.6%. The fracture geometry, alignment and angulations were the main causes of complications.

DISCUSSION

The mean time to union of 15.85 weeks and a union range of 4 to 38 weeks compares very well with the internationally reported outcome of tibial shaft fracture management therefore the outcome of our management is in conformity with reported data elsewhere. This result is further evidenced by the rate of union at 20 weeks of 81.5%.

The non union rate of 7.4 in our study is in conformity with internationally reported data. The mal-union rate of 17.6% and delayed union rate of 11.1% conform to the reported data. The infection rate of 6.6% compares well with reported results.

Simple fractures with < 25% alignment, fracture angulations > 7.5˚ or limb shortening more than 2cm after plaster cast immobilization are more likely to unite after 18 weeks compared to alignment > 25%, angulations < 7.5° or limb shortening < 2cm.

Simple fractures with < 25% alignment, fracture angulations > 7.5˚ or limb shortening more than 2cm are more prone to complications compared to fractures with > 25% alignment, < 7.5° angulations or < 2cm reduction in limb length. This can be the basis of determining which type of simple fractures require open management

Fracture alignment < 25% is an important prognostic indicator for complications and delayed union, hence patients who have this kind of alignment require open reduction and internal fixation.

Anteroposterior and lateral angulations > 7.5° are important prognostic indicators for complications, patients who have this kind of angulation require open reduction and internal fixation.

INTRODUCTION

Tibial shaft fractures are the most common long bone fractures encountered the world over, accounting for approximately 77,000 hospitalizations, 569,000 hospital days with average length of stay of 7.4 days and 825,000 office visits per year in the USA[5]. In the United Kingdom epidemiological data from Edinburgh suggest an incidence of two fractures per ten thousand people per year with motor vehicle accident being the most common single cause accounting for 50% of the cases[3].

The tibia is the most common site of long bone fractures due to the fact that it is superficially placed in the leg hence more easily exposed to traumatic injury[6]. A long period of convalescence is required even when the fracture and the healing period are not complicated due to the precarious blood supply to this bone [1, 2, 3, 4, 7]. In some cases the results of the management of these fractures are poor due to high rates of complications; mal-union, non-union, limb shortening, infections, compartment syndromes and peripheral nerve injury [7, 8, 9].

Closed reduction and cast immobilization have been regarded as the standard treatment for low energy tibial shaft fracture for many years [10, 11, 12]. This method has proved to be generally successful [13] and offers reliable healing without the risks seen in operative procedures [14]. However a subset of patients have less than satisfactory outcome with closed treatment but the literature remains ambiguous in identifying the fractures best managed operatively[14, 15].

A functional brace is a modification of the traditional long leg cast treatment [12]. Other reports of the use of early weight bearing claimed rates of union and functional success as high as 100% [16]. Loss of limb alignment is a frequent sequel of cast or brace treatment of tibial fractures. Yet no consensus exists on the long term consequences of mal-alignment or limits of acceptable deformity [28]. Some patients are conservatively managed with dynecast compost of ultra fine glass fibers. This has the advantage of reduced mobility of the fracture fragments [21].

Increasing familiarity with recent advances in fracture fixation technology and greater appreciation of their benefits has prompted many surgeons to become aggressive in their approach to closed tibial shaft fractures [14, 17]; many patients have been managed surgically. The surgical management includes dynamic compression plating, external fixation and intramedullary tibial nailing. Dynamic compression plates are capable of restoring limb alignment and permit adjacent joint motion but can be associated with considerable soft tissue morbidity [18] and limitation of early weight bearing [15]. External fixation which is less invasive hence more soft tissue friendly can also restore and maintain limb alignment; though this requires a very tolerant and compliant patient. Such a patient will need daily pin site wound care to avoid infections, serial management decisions all through the treatment and cast or brace immobilization after removal of external fixators [15]. Intramedullary nailing has also been recommended for both closed and open tibial shaft fractures but this has a very high risk of infection and compartment syndrome than other reduction and fixation devices [19, 20].

In Kenyatta National Hospital (KNH) many patients are initially managed with closed reduction and plaster cast immobilization, a check x-ray follows to asses the acceptability of the reduction and the patients are subsequently followed-up in the trauma clinic till complete healing is achieved. Patients who develop complications; nonunion, mal-union or mal-alignment are subjected to operative management. A study has not been conducted to determine the outcome of conservative management of tibial shaft fractures at KNH. There are no clear cut criteria of determining the tibial shaft fractures that would require conservative management and those who would require surgical fixation. A pilot study was conducted of the tibial shaft fractures managed in KNH between December 2003 and September 2004. Over this ten month period 384 patients with tibial shaft fractures were managed. This is a large number of cases which render appropriate management of such patients important.

A prospective study was conducted to determine the outcome of conservative management of tibial shaft fractures and to evaluate the indications for conservative management as opposed to the indications for operative management.

LITERATURE REVIEW

Surgical anatomy of the leg

The tibia is the weight bearing bone of the leg together with the fibula they form the skeleton of the leg. Grossly, it is composed of three surfaces; anteromedial, posterior and lateral separated by three borders; anterior, interosseus and medial. These give the tibia a triangular cross sectional area. The tibial diaphysis is divided into three equal parts the proximal, middle and distal thirds with the junction between the middle and the distal being the weakest region, hence most prone to fractures [(22)]. The medullary canal of the tibia is also triangular. Key anatomical landmarks of the tibia include the tibial tuberosity located proximally at the anterior border with the patellar ligament attached to its upper part.

The fibula is roughly triangular with medial, lateral and posterior surfaces, separated by the interosseus, anterior and posterior borders. The interosseus membrane joins the two interosseus borders and plays a big role in stabilizing the leg structures but also in the development of compartment syndrome due to its inelasticity [(23)].

There are four compartments of the lower limb separated by the crural fascia, these are the anterior, lateral, superficial and deep posterior compartments. The anterior compartment contains tibialis anterior, extensor hallucis longus and extensor digitorum longus together with peroneus tersus muscles are all involved in dorsiflexion of the foot and ankle joint. Near the ankle, the tendons of tibialis anterior and extensor hallucis longus are situated close to the tibia and are prone to injury during a fracture of the tibia at this point especially in high energy open fractures or by the abundant formation of callus during the healing of the same fractures [(24)].

The deep peroneal nerve and the vascular bundle is located between the tibialis anterior and extensor digitorum longus in the upper part and between the tibialis anterior and extensor hallucis longus in the lower part of the leg hence may be injured when these muscles are injured by high energy trauma.

The lateral compartment contains peronus longus and peronus brevis muscles which are principally planter flexors and inverters of the foot. The superficial peronial nerve and its vascular bundle run between these muscles and the extensor digitorum muscles. The posterior compartment is divided into two, the superficial and deep. The superficial posterior compartment contains the gastrocnemius, soleus, popliteus and plantaris muscles, all responsible for the flexion of the knee and the foot. The deep posterior compartment on the other hand contains tibialis posterior, flexor digitorum longus and flexor hallucis longus. Muscles which planter-flex the foot and toes. The tibialis posterior also inverts the foot. These muscles are supplied by the posterior tibial nerve, the peronial and posterior tibial arteries also run in these compartments, supplying the lateral compartment and posterior compartment respectively, while the anterior compartment is supplied by the anterior tibial artery that runs in its neurovascular bundle.

Blood supply to the tibial shaft are; the nutrient artery, derived from the posterior tibial artery and the periosteal vessels. The single nutrient artery enters the tibial shaft from the posterior proximal part of the middle third of the shaft. This artery is easily injured in midshaft displaced fractures through its long cortical foramen within the medullary canal and along its course both proximally and distally.

Classification of Tibial shaft fractures

Tibial shaft fractures are classified according to their location, configuration and severity of associated soft tissue injury. In terms of location, fractures of the shaft are divided into the proximal third, middle third and distal third fractures. Distal third fractures are reported to have a higher incidence of nonunion while proximal third fractures are more difficult to manage surgically with intramedullary tibial nail.

Tibial shaft fractures are also classified according to the fracture geometry into simple fractures and comminuted fractures. Simple fractures include transverse, short oblique and spiral fractures. Long oblique or spiral fractures are axially unstable and are better managed with intramedullary nails. Comminuted fractures are composed of comminuted and segmental.

Comminuted fractures are further subdivided into three categories based on the extent of comminution; group I have less than 25% of the cortical circumference comminuted while group II have comminution of between 25% and 50% of the cortical circumference yet group III have comminution of between 50% and 100% cortical circumference and group IV have a segmental combination. There is a group V which is fracture with loss of the segment [(25)]. The purpose of this classification is to determine the stability of the fracture after reduction especially with placement of the tibial nail. Group I fractures are stable after reduction; Group II fractures are axially stable but rotationally unstable however group III fractures are both axially and rotationally unstable [(25)].

Segmental fractures can further be classified as bifocal fractures of the tibia involving the ankle and tibial plateau, shaft and plateau or shaft and ankle. Bifocal fractures of the tibial shaft and plateau have a poor prognosis.

The severity of soft tissue injury is the most important factor in relation to incidences of (1) nonunion, (2) mal-union, (3) infection, and (4) residual stiffness of the knee and ankle joints. Soft tissue injury severity can initially be assessed through the initial bone displacement, the fracture configuration and the dynamism of injury i.e. high or low energy. Displacement more than one tibial diameter, presence of comminution or transverse fracture pattern imply high energy pattern of injury with extensive soft tissue injury. These high energy types of injury can be closed or open, a factor whose role is limited to the differences in the initial management but does not affect the long term management and the final results including complications. Low energy fractures are commonly associated to oblique and spiral fractures which in most cases are minimally displaced or not displaced at all.

There are many soft tissue injuries, closed and open tibial shaft fracture classifications by Western and Schering, Gustilo and Anderson, Teflon and AO/ASIF.

The severity of soft tissue injury has been described and graded by Öestern and Tscherne into Grades O, I, II, and III with respect to increasing severity [(26)]. This classification is used for both closed and open fractures with some modification.

The severity of soft tissue injury in open tibia fractures is also graded according to Gustilo and Anderson classification system which classify open Tibial fractures into five grades [(27)]

Teflon classification looks at the characteristics of the injury in relation the severity of the injury thus the modified tibial fracture classification; [(28)]

The mangled extremity severity score (MESS); is a predictor of outcome of management of mangled extremity. This score is extremely useful in very severe injuries where the decision is to be made on whether to salvage the limb or amputate. In studies so far conducted a MESS score of seven and above have 100% predictive value for amputation [(29)].

Another system of classification is the Association for the study of internal fixation (AO/ASIF) method which is a comprehensive and more advanced variant of the Gustilo Anderson system for tibial shaft fractures but which generally classifies long bone fractures in a more descriptive manner based on the pattern of the primary fracture and number of fracture fragments. This type of classification is generally only useful for Audit and research but less so for management purposes. AO/ASIF classification of tibial shaft fractures classifies the fractures into simple A; wedge B; and comminuted C. Each of these main groups has three sub groups which represents morphologic criteria representing direct and indirect impact. Group 1 fractures are produced by direct impact while group 2 and 3 by indirect impact e.g. bending. Simple fractures cause single cortical disruption in 90% of cases [30]. A wedge fracture with butterfly fragment is in group 2 while comminuted fractures are in group 3 [30].

Management of Tibial Shaft Fractures

The treatment modality of tibial shaft fractures can be grossly grouped into two conservative and surgical. Conservative management is further sub-divided into cast management and functional brace management [31]. Surgical management techniques are divided into intramedullary nailing, plating and external fixation. The intramedullary nailing can be open or closed. In the 1960s the concept of early weight bearing was introduced and achieved widespread acceptance [32]. Subsequently a combination of early weight bearing and functional bracing was introduced proposing that controlled movement of the fracture site improved osteogenesis [25, 31, 33].

The difficulty in establishing indications criteria for conservative or surgical management of closed tibial shaft fractures is because most surgeons emphasize only the incidence of union or time for bone healing as the indicator of successful treatment [28]. Morbidity during treatment and ultimate limb function also merit consideration before the optimal treatment for a particular fracture is established [28].

The criteria for non operative treatment of tibial shaft fractures, has been predicted on the fact that these fractures can be effectively managed by closed cast or functional brace immobilization [10, 14 15, 16, 19, 28]. In his analysis of the treatment of 705 tibial fractures Nicoll [10] found that closed treatment achieved overwhelmingly favorable results. Surgery was therefore justifiable only if it could reduce the incidence of deformity, joint stiffness and delayed or non union [10].

Although conservative treatment of closed tibial shaft fractures usually produce acceptable results , reported complication rates of up to 66% [21] support the need for comprehensive criteria with which the surgeon can select the patients who would benefit from surgical treatment while re emphasizing that any criterion must be individualized to reflect the needs or function of each patient. The indications for invasive treatment of closed tibial shaft fractures include [28]-:

- Fracture characteristics that retard or inhibit fracture healing
- Fracture instability likely to result in significant deformity
- Associated factors that limit the patients function or recovery
- Cost

Successful fracture union in the tibia entails [12];

- Patients ability to bear weight painlessly
- Absence of clinically detectable motion at the fracture site
- Visible bridging callus across the fracture on a plain x-ray

The temporal distinction between delayed union and non union is not very clearly defined. Usually delayed union is designated at 4 to 6 months (16 to 24 weeks) after injury while frank non union is established between 8 to12 months (32 to 52 weeks) [12, 18]

The excellent union rates reported with conservative management of closed tibial shaft fractures appear to be highly dependent on the patient's ability to initiate early weight bearing (cyclic loading) on the fractured limb [28]. Consequently surgical stabilization should be considered for all unstable fractures in which early weight bearing is not possible [28].

However, various standards have been proposed by numerous authors as guidelines for acceptable alignment. Depending on the parameters used to define acceptable alignment, 4% to 42% of the tibiae can be considered mal-aligned [34]. Most publications average at between 5 and 10° for acceptable alignment in all plains.

The indication for non-operative management of tibial shaft fractures include, minimal soft tissue injury, type 0 and 1[26]. Stable fracture pattern are defined by coronal angulation of less than 5 °, sagital angulation's of less than 10 °, rotation less than 5 ° and shortening of less than 10mm, the ability to bear weight in a cast or functional brace [25].

Other goals considered by the surgeons apart from avoiding factors that could cause disabilities are simple management of the cases, early weight bearing, early knee and ankle range of motion, cost effectiveness and early return to work.

In conclusion the indications for non operative management of tibial shaft fractures include minimal soft tissue injury, type 0 and 1 [26]. Stable fracture patterns are defined by coronal angulation of less than 5°, sagital angulation of less than 10°, rotation less than 5° and shortening of less than 10mm together with the ability to bear weight in a cast or functional brace [25].

Not all patients with closed tibial shaft fractures are guaranteed a satisfactory result [28]. In a review of 27 fractures managed conservatively Wadell [21] found that there was lost reduction in 9 fractures, 5 required cast wedging and 3 were treated with late internal fixation. Limb deformity especially in the unstable fracture is often unavoidable [35]. Approximately 22% of patients with acceptable results after closed reduction had more than 5° angulation [12]. At issue is the extent of residual deformity that is considered excessive [35]. Fracture instability has been found to affect acceptable alignment. Closed reduction is very difficult to maintain with initial displacement of more than 50% of the tibial width and with distal third fractures [13].

Regardless of the variability of union in the majority of closed tibial shaft fractures treated with cast or bracing, the potential for compromised healing should be recorgnised early in order to promptly consider early surgical intervention [28]

The fracture characteristics most likely to indicate the need for early operative intervention because they may have inhibitory effect on fracture healing are [10, 13];

- significant instability of the healing limb
- excessive comminution
- excessive initial fracture displacement

The functional outcome of the patient with closed tibial shaft fracture is probably the most important consideration made when deciding the best mode of treatment for a particular fracture. Unfortunately tibial fractures occur predominantly in the young, healthy and economically productive patient population [10, 11, 34,]. Orthopedic surgeons do not agree on how much deviation from anatomic alignment is acceptable for a good functional outcome.

Complications of conservative fracture management

Complications attributable to tibial shaft fracture may be related to qualities of the fracture or to the management of the fracture [24]. Severe comminution defined as loss of 50% or more of cortical circumferential continuity, often reflects the extent of energy or trauma sustained by the bone and soft tissue and can further increase the risk of delayed or non union [19]. In one study major earlier axial loading [40]. The crucial factors among the higher risk fracture patterns include the degree of fracture obliquity, the presence of spiral pattern and the extent of fracture comminution [10, 13, 35, 36]. Another reliable factor of instability is the initial fracture displacement of 50% or more of bone width. In a review of 192 spiral fractures with lateral displacement of more than 50% of tibial width, it was found that reduction was maintained in only 18% [13].

Table I Sampling of widely variable limb alignment standards deemed acceptable in Literature [28]

Study	Varus	Valgus	Anterior or Posterior	Rotational	Shortening
Bone and Johnson [21]	-	5°	-	15 - 20°	10mm
Bostman [41]	5°	5°	-	-	10mm
Collins et al [19]	5°	5°	5 - 10°	-	10mm
Haines et al [13]	4°	4°	-	5°	13mm
Jehnsen et al [16]	8°	8°	15°	-	20mm
Johner and Wruhs [20]	5°	5°	10°	10°	-
Nicol [12]	10°	10°	10°	10°	20mm
Puno et al [40]	10°	10°	20°	-	20mm
Trafton [17]	5°	5°	10°	10°	15mm
Van der Werken & Martl [42]	-	-	-	15 - 20°	-

The degree of deformity that ultimately becomes functionally significant however is yet to be determined [43]. Another complication that is commonly encountered is angular mal-alignment that leads to residual limb deformity in the long term. Some authors report that a small degree of angular mal-alignment of the tibia can lead to premature ankle degeneration [41]. In the laboratory relatively minor angulation of the tibia in a rabbit study induced premature osteoarthritic changes of the knee [42]. The relevance of angular deformity may also be dependent on the level at which the tibia is fractured. In an in vitro study it was demonstrated that an angular deformity of 15% had little effect on ankle contact when it was located proximally or on midial tibia; in the distal tibia however the contact area in the tibiotala joint was reduced by as much as 42% [44]. Despite this laboratory evidence to the contrary other authors suggest that a correlation between deformity and poor functional outcome does not exist. In a retrospective review of tibial shaft fractures twenty years after injury Merchant and Dietz [45] found no post traumatic arthritis in the adjacent knee or ankle regardless of the residual deformity of either structure. In a review of 28 tibial shaft fractures with mean follow up of 8.2 years Puno et al [35] established a direct correlation between the extent of residual limb mal-alignment and clinical outcome in the ankle but not in the knee.

Compartment syndrome

The complications encountered in the early management of tibial shaft fractures include compartment syndrome this has an estimated incidence of 1 to 10% commonly seen in snuggly applied casts especially on injured and swollen soft tissue [21]. This arises when high pressures occur in a closed fascial space reducing capillary perfusion below a level necessary to sustain tissue viability. A significant delay has been noted in fracture union of patients who developed compartment syndrome [46].

Limb shortening

Limb shortening, a frequent sequel of closed treatment is as controversial as angulation with regards to the limits that are deemed acceptable [2]. Haines et al [11] suggested that only patients with more than 2cm of shortening require a lift. Johner and Wruhs [18] felt that shortening is only acceptable if less than 5mm yet Lindsey and Blair [28] felt that acceptable leg length discrepancy is variable and is dependent on the individual patient's functional expectations or demands but designated 1cm of shortening. Sarmiento et al [12] found that regardless of the degree of shortening deemed acceptable, there was no difference between the amount of shortening on the initial and final x-rays on 80% of the cases. They concluded that if initial shortening is significant, acute treatment should be operative in the absence of other mitigating factors. Literature suggests that anywhere between 0.5 and 2.0cm of limb shortening is acceptable [11, 18]. Limb shortening of 2.5cm or more have obvious cosmetic and gait disadvantages but the long term consequences are still controversial. It has been postulated that significant length discrepancy may potentate the development of low back pain [47]

Partial initial stability of the limb in the presence of an intact fibula may also inhibit fracture healing. Traitz [37] reported altered fracture union in 26% of adult patients with closed tibial fractures but intact fibulae who were treated with cast immobilization. Since 61% of the patients experienced one or more complications during the treatment, it was theorized that intact fibula prohibited axial loading of the tibia thereby depriving the fracture site of weight bearing [37].

Fracture location has also been found to affect the likelihood of maintaining limb alignment with closed methods. Fractures of proximal or distal aspects of the tibia are especially difficult to immobilize even when the cast extends to incorporate the adjacent joints. Unfortunately most tibial shaft fractures occur in the distal third of the bone [34], and angulation's can be extremely difficult to control at this level [19].

Delayed union and nonunion

Despite acceptable union rates for cast or brace treatment of closed tibial shaft fractures, delayed union or frank non union continue to occur in certain situations [10, 14, 37]. In literature delayed union is designated at 16 to 30 weeks after tibial shaft fracture [10, 18, 55, 56]. Lack of standard assessment criteria for closed tibial shaft fractures [34] has made meaningful comparison between closed treatment and internal fixation difficult.

Joint stiffness

Sarmiento et al [12] modified the traditional long leg cast treatment by application of functional brace at approximately four weeks while encouraging active limb weight bearing and adequate joint motion to enhance healing and minimize functional compromise. This produced faster union with less knee or ankle joint stiffness [12].

Prolonged knee or ankle immobilization is usually essential for adequate conservative management but this result in to joints stiffness. Even in early weight bearing, residual joint stiffness has been reported in 20 – 30% of the patients [12, 21].

Infection

The most notable advantage of conservative treatment of tibial shaft fractures is the negligible incidence of deep infections [2, 48]. The risk of deep infection in closed and grade I open tibial shaft fractures is given at 0 to 3.2% [2, 4, 21].

In addition to these structural factors, a number of other relative factors that should be considered in order to choose between closed or open reduction as the optimal treatment for a particular closed and Gustilo I and II open tibial shaft fractures include; the pathologic nature of the injury e.g. presence of neoplastic conditions, osteoporosis, chronic diseases, nutritional status, age and a multiplicity of injuries to other organs and systems. All these should be evaluated as part of the decision making process [28].

Justification of the Study

The lower limbs play very important functional roles; stability, upright posture, and walking and other movements. The tibial shaft fracture is the most common long bone fracture encountered all over the world. A study has not been conducted to determine the outcome of conservative management of tibial shaft fractures at KNH. There are no clear cut criteria of determining the tibial shaft fractures that would require conservative management and those who would require surgical fixation see table IV. A pilot retrospective study was conducted of the tibial shaft fractures managed in KNH between December 2003 and September 2004. Over this ten month period 384 patients with tibial shaft fractures were managed averaging about 39 fractures per month. This is a large number of cases which render appropriate management of such patients important. The aim of this study was to evaluate the outcome of conservative management and determine the indications for conservative management of low and moderate energy tibial shaft fractures. This would form the basis upon which other studies can be formulated and can as well be important information in policy formulation.

Study Objectives

Broad Objective

To evaluate the outcome of conservative management of simple and compound Gustilo I and II tibial shaft fractures in KNH

Specific Objective

1. To document the mechanism and the extent of injury sustained by patients who suffer tibial shaft fractures.

2. To evaluate the complications encountered in the management of these fractures.

3. To determine the indications for conservative management of simple and compound Gustilo I and II tibial shaft fractures

4. To determine the critical extent of initial fracture alignment beyond which plaster cast immobilization can not adequately reduce and stabilize a tibial shaft fracture

The null hypothesis for this study is that there is no critical extent of fracture displacement beyond which conservative management is inappropriate.

METHODOLOGY

Inclusion and Exclusion criteria in the study

Inclusion criteria

- Patients presenting with simple and Gustilo I and II compound fractures were recruited into the study.

- Male and female patients aged from sixteen to fifty years seen at KNH during the period of recruitment.

- Fresh trauma cases presented at KNH within forty-eight hours of injury.

- The fracture that were located at least five centimeters from the joints

- Patients who gave informed consent to join the study

Exclusion criteria

- Patients aged below 16 years and above 50 years

- Patient who presented with Gustilo III A, B or C fractures

- Patients who presented to KNH more than 48 hours from the time of injury

- Fractures located within 5 cm from the knee and ankle joints

- Patients who declined to give consent

Period of study

The study was carried out for a period of fourteen months; eight months recruitment and six months follow up, from April 2005 to June 2006. This is because a pilot study had been conducted earlier which showed that in a six to eight month period, it was possible to recruit enough patients. The follow up period was taken as the mean of delayed union which was 24 weeks.

Recruitment procedure

The patients were recruited into the study from casualty (accident and emergency) department KNH if they were not admitted but met the inclusion criteria, the study concepts were explained and consent was taken. Patients requiring admission for further management were recruited either in casualty or in the orthopaedic wards. Patients admitted in Amenity wards were recruited provided they met the inclusion criteria.

Sample Size

To determine the sample size we used the formula assuming that the population is infinite thus

$$n = \frac{z^2.p.q}{e^2}$$

Where n is the size of the sample, z is the standard variance at a given confidence level determined from the table of area under normal distribution curve. For our study the level of confidence is 95% therefore z is 1.96. p is the sample proportion of defectives in the population i.e. average number of mal-unions from previously conducted studies varying between 4% and 12% for our case 8% = 0.08 and q is 1-p which is 0.92. e is the acceptable error in this is 7.5/180 = 0.0417

$$n = \frac{1.96^2 \text{ x } 0.08 \text{ x } 0.92}{0.0417^2} = 162.6 \quad = 163$$

Therefore the sample size was 163 patients

Once recruited the patients were divided into one of the groups A or B, managed by the surgical registrar and the orthopaedic technician respectively. This management involved reduction and plaster cast immobilization only. The injury was classified according to the dynamic of injury into RTA, fall from height, assault, gun shot and others. The injury was also classified by the Gustilo classification of the fracture. All the data on these parameters were recorded in the study questionnaire provided. A full length tibial X-rays in anteroposterior and lateral views were requested and fracture further classified according geographical location into proximal third, mid shaft or distal third fractures. The fracture was also classified according to the geometry into transverse, short oblique, spiral, comminuted or segmental.

The extent of limb shortening and fracture displacement were determined from these initial X-rays. The limb shortening was determined by taking the full length measurement from the tibial tuberosity to the medial malleolus on the injured and the normal tibia and comparing the two lengths. The extent of fracture displacement were determined by measuring the displacement length in both the sagital and coronal planes, a goniometer was used for this; measuring both the anteroposterior and transverse angulations and using the Pythagoras theorem where if coronal displacement was a, and sagital displacement was b then; c which was the total displacement was $= \sqrt{(a^2 + b^2)}$. The fracture alignment was then determined by subtracting c from 1 such that the alignment was $1\text{-}c \times 100\%$ (24).

If the fracture was closed, the patient was managed in casualty by immobilization in plaster of Paris by the technician or surgical registrar as per the group category if the registrar was available. When the registrar was not available, the fracture was managed by the technician. These patients were subjected to manipulation, reduction and immobilization in plaster cast (plaster of Paris) under pethidine 50mg intramuscular stat dose and diazepam 10mg intravenous stat dose. Patients with compound fractures required general anesthesia or spinal blocks. The irrigation and surgical toilet was performed before reduction and casting and a window created for wound dressing.

Reduction Procedures

To achieve reduction these patients were placed supine on the table with their fractured leg dangling free on the side with the arm rest as support of the thigh [50]. An assistant applied traction to maintain reduction as the operator, the surgical registrar or the orthopedic technician applied the plaster cast. The plaster applied was a long leg cast. Where an assistant was not available, a muslin was wrapped around the ankle of the fractured limb and a bucket of water attached to the Muslin[50]. This procedure was performed by the surgical registrar or the orthopedic technician depending on the category of the patient, group A or B and the availability of the registrar. Even those patients taken to theatre for surgical toilet were manipulated according to the category where they fell.

Those patients with an initial level of displacement of above 100% of the radius would have required an image intensifier but this facility was not available for the study. Patients with compound fractures received flucloxacillin penicillin (a broad spectrum antibiotic) 500mg per oral six hourly for a period of 5 days.

Once the fractures were managed by immobilization in long leg plaster cast, a check X-ray was ordered within 2 days of manipulation. The fracture site was re-assessed for alignment, angulations and limb shortening by measurement on check X-ray.

The fracture angulations in AP and lateral views were measured using a goniometer. The angulations were measured in degree based on the calibration of the goniometer that was used were considered in multiples of 2.5° up to maximum number of degrees of angulations that could be recorded. Angulations of more than 7.5° in either AP or lateral view were considered unacceptable and the patient was required to undergo re-manipulation. An alignment less than 25% that is minimal apposition was considered unacceptable and the patients' fractures were required to undergo a repeat manipulation. Limb length shortening of more than 2cm was also considered un-acceptable and the patient was required to undergo repeat manipulation. The repeat manipulations were performed by the initial fracture manager. After repeat manipulation a repeat check X-ray was done and alignment, angulations and limb shortening were again assessed.

The patients were assessed each time they came for clinic follow up. The appointments were at 2 days, one week, 6, 12, 18 and 24 weeks. During the follow up of patients, if there was fracture mal-alignment or angulations that were considered unacceptable, the patient was referred back to the plaster room for re-manipulation. This fact was recorded and post re-manipulation X-ray done and the results re-analysed. If these results were still not acceptable then the patient was admitted to undergo open reduction and internal fixation in theatre under general anesthesia or spinal block. Patients who had worn out casts were also referred to the plaster room for cast replacement. Casts that did not wear out during the period were never changed.

The patients with compound fractures were assessed for infection after 2 days by investigating the WBC count. Tightness of the plaster causing leg compression was assessed at this time. The patients were reviewed again after one week. At this time another check X-ray was done. A repeat WBC count was also analysed, tightness or looseness of the plaster, alignment, angulations and limb shortening were re-assessed.

At six weeks; besides the above data, the check X-ray was also assessed for callus formation. The same parameters were again checked at 12 and at 18 weeks. However, few patients came back for the follow-ups on these scheduled follow up appointments.

At any visit if there was radiological evidence of callus formation, then the plaster of Paris was removed and fracture site checked clinically for union. The time to union was considered as the time at which the patients could bear full weight on the affected limb without feeling pain or discomfort or fracture site mobility.

The complications such as wound infection and compartment syndrome were looked for, recorded and immediately managed.

Limb shortening of 2 cm or above determined from radiological measurement of limb fracture overlap. Later after removal of cast clinical measurement of limb length was done bilaterally from tibial tuberosity to the lateral maleolus. The limb lengths were compared and recorded. The patients admitted for surgical reduction if the limb length discrepancy was more than 2 cm. Angulations of $>7.5°$ in either AP or lateral X-ray views, and alignment of $\leq 25\%$ if found within a month of injury were scheduled for re-manipulation which included recasting and cast wedging, however the results were recorded for analysis. Patients discovered after this period were managed by open reduction.

Late complications such as a delayed union that is union occurring after 20 weeks, another complication that was assessed was non union, which was considered as union not occurring beyond 24 weeks. The patients who developed complications were referred to the ward for internal fixation.

Statistical Analysis

To describe the data; the mean, mode, median and range were reported for continuous variables. Percentages were used for categorized variables. Pearson chi square test was used for determination of the P value for the continuous variable. Fisher's exact test was the determination of the P value of the categorized data. The variables used were the Patients age, Dynamic of injury, geographical location of the fracture, the fracture geometry, alignment and angulations. The P value was determined at 95% confidence interval of the difference between the groups for continuous variables and the percentage and its 95% confidence interval for categorical variable. A confidence interval of 95% was considered appropriate and a P value of 0.05 was considered significant. The collected data was statistically analysed with SPSS for windows program version 14.0.

Ethical considerations

Permission to carry out the study was obtained from the ethical and research committee of Kenyatta National Hospital. Consent was sought and received from all patients who participated, for patients below 18 years consent was taken from the parent or guardian. All information was treated with utmost confidence.

LIMITATINS OF THE STUDY

- Not all the patients however managed to come back for follow up and some of those who came back lacked the finances even to do a check X-ray.

- Records on intact fibula should have been taken and analyzed as studies [25, 37] show that intact fibula affects the rate of union and the complications. However the same studies contradict each other in their results. Our study being none randomized would have just added to this controversy without giving appropriate answers.

- Nutrition and Smoking are some of the environmental factors that influence the rate of union and the complications in outcome of tibial shaft fracture management. However these variables were not kept constant in this study

- An image intensifier was not available for the intra operative determination of alignment of displaced fractures

- Joint stiffness and pain and other subjective parameters were not assessed. These were considered to be subjective hence difficult to analyse.

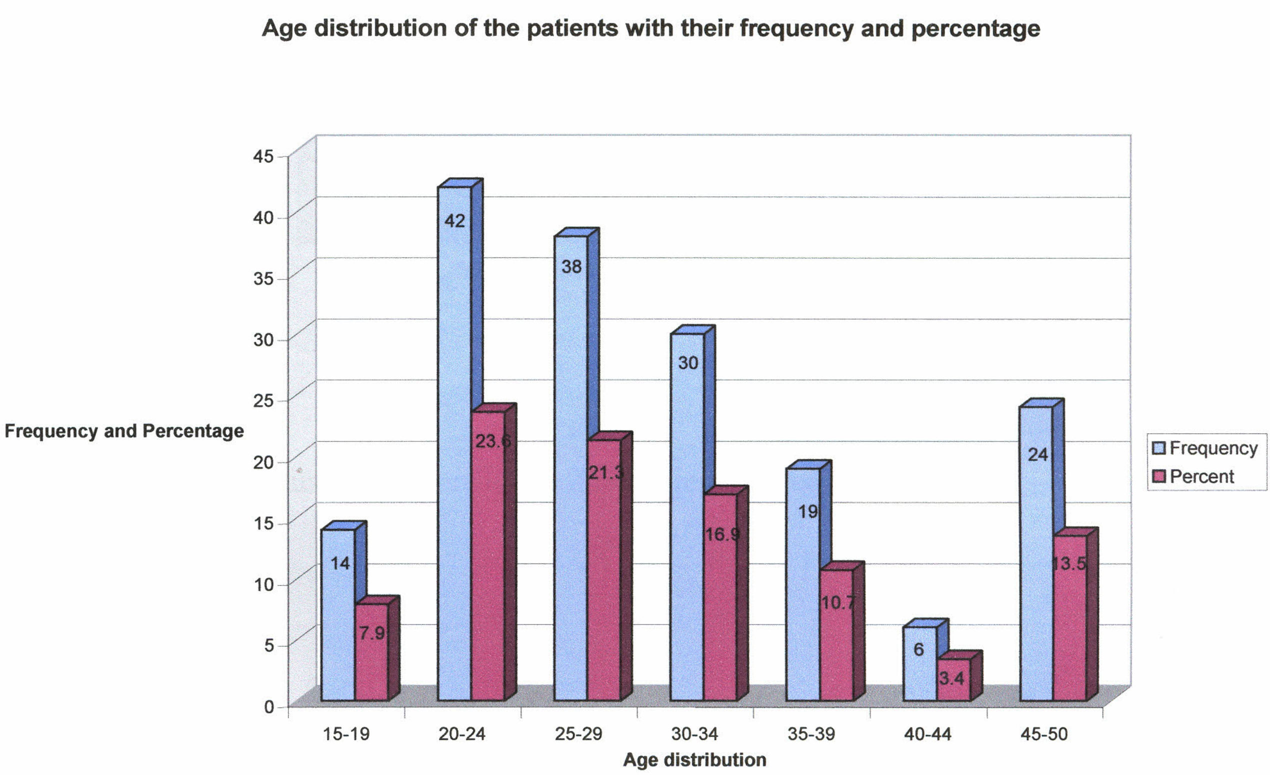
THE RESULTS

170 patients were enrolled into the study. There were 178 tibial shaft fractures recruited into the study between April 2005 and December 2005. Eight of these patients had bilateral tibial shaft fractures both of which were managed conservatively.

There were 154 (90.5%) male and 16 (9.5%) female patients. All the eight bilateral tibial shaft fractures belonged to the male patients giving a total of 162 fractures.

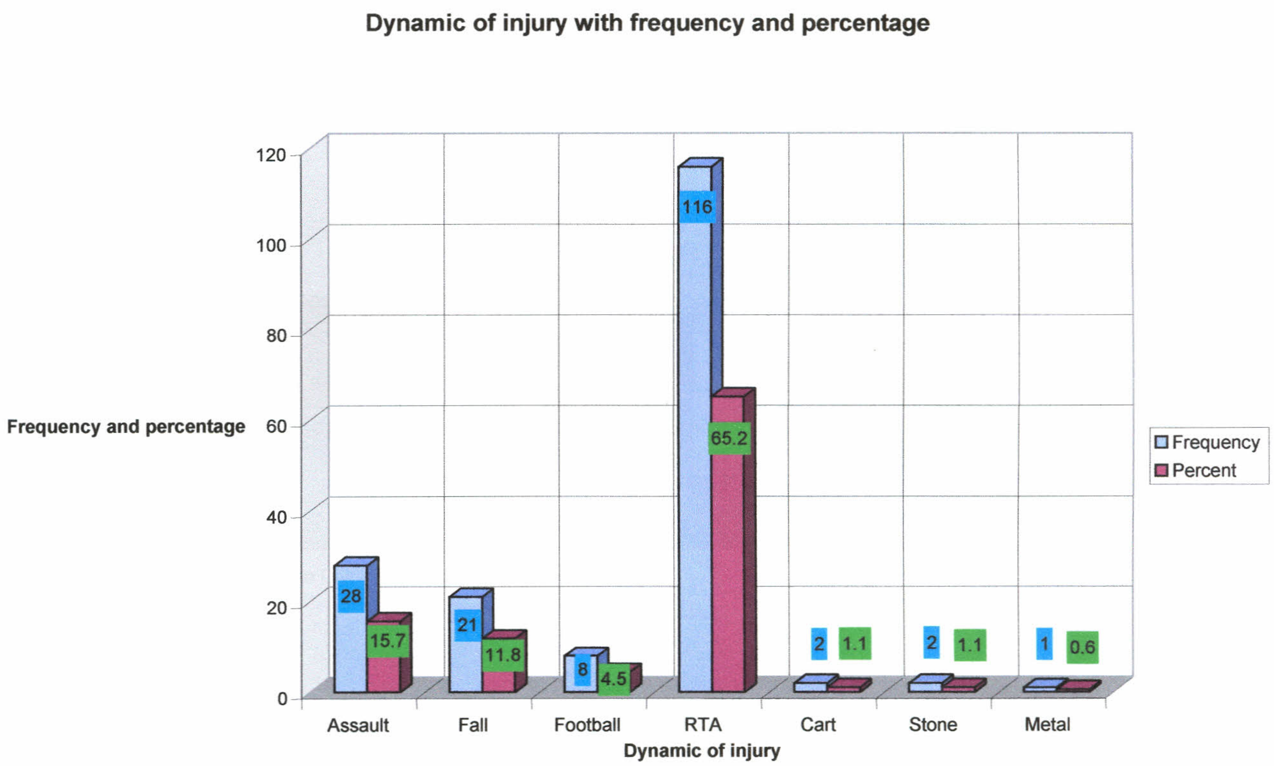
Of the 178 tibial shaft fractures managed and followed up during this period, only 108 (60.7%) were followed up to union or non union. 70 (39.2%) patients' fractures were lost to follow-up. The results were analysed with reference to the end points of complications and time to union.

Figure I



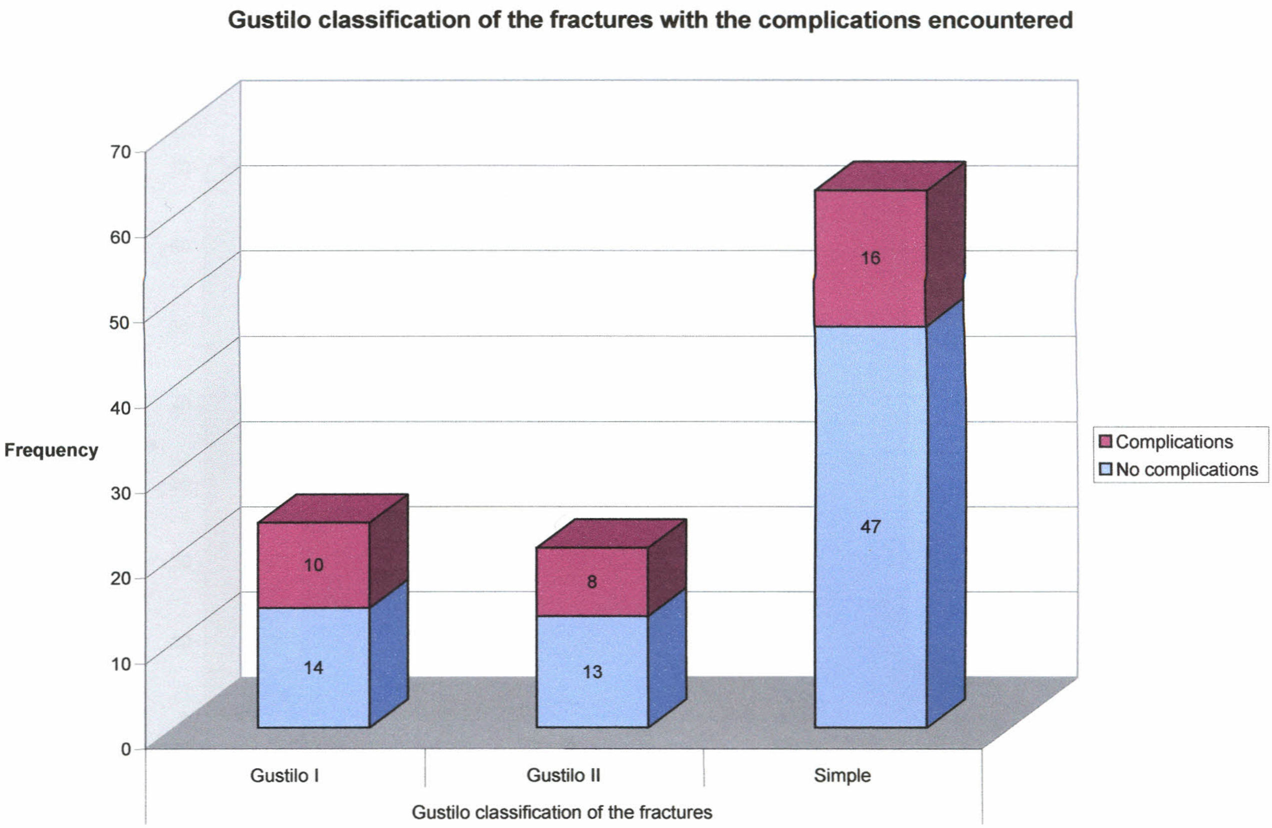
Ages of 5 adults could not be determined. The 20 to 29 year age group sustained 80 (46.2%) of the fractures but if this age group is adjusted to 20-34 years then 110 fractures accounting for 63.6% were sustained by the group.

Figure II



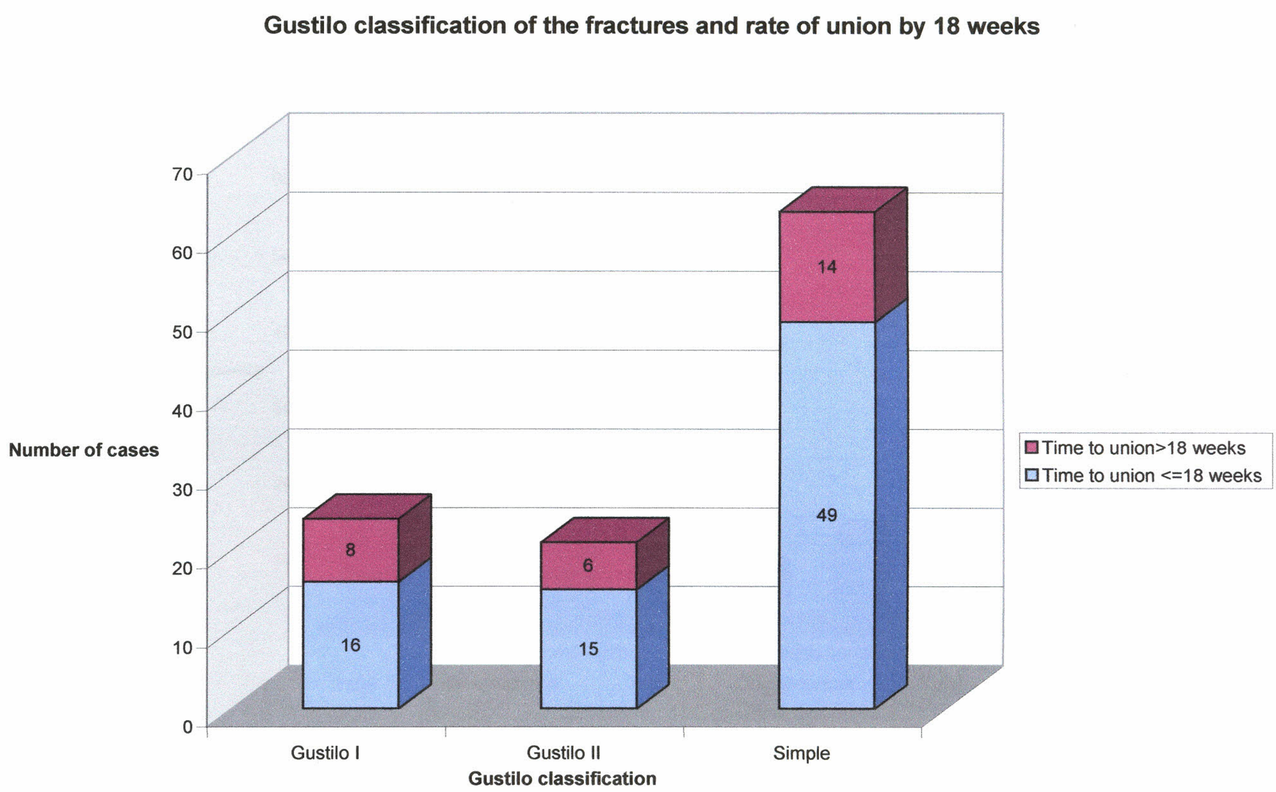
There was no firearm cause of fracture hence it is not represented in the table.

Figure III



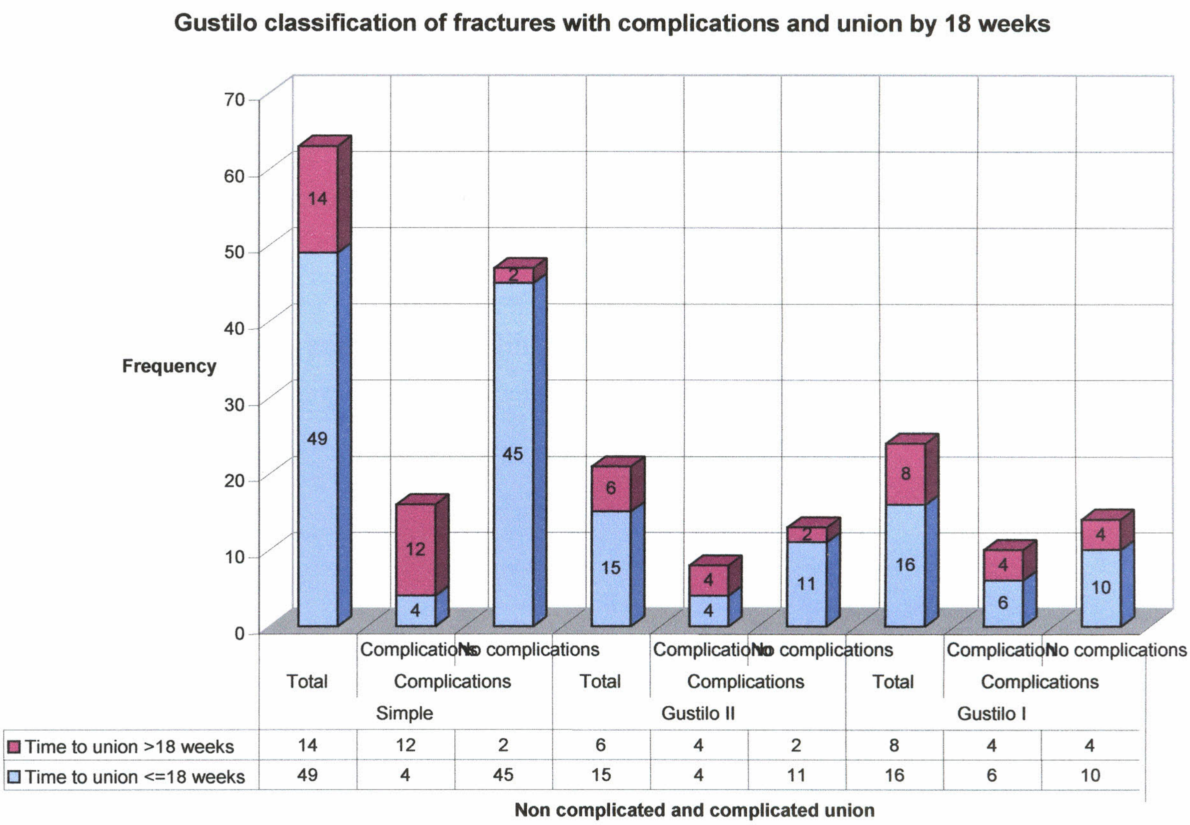
There were 24 Gustilo I fractures followed up and 10 {41.67%} of these developed complications. Of the 21 Gustilo II fractures followed up, 8 {38.1%} developed complications. Only 16 of 63 i.e. 23.4% of the simple fractures followed up developed complications.

Figure IV



Considering the rate of union, 16 of 24 that is 66.7% of Gustilo I fractures united by 18 weeks. Of the 21 Gustilo II fractures, 15 {71.4%} united by 18 weeks and 49 {77.8%} of 63 simple fractures united by 18 weeks.

Figure V



	Simple Total	Simple Complications	Simple No complications	Gustilo II Total	Gustilo II Complications	Gustilo II No complications	Gustilo I Total	Gustilo I Complications	Gustilo I No complications
Time to union >18 weeks	14	12	2	6	4	2	8	4	4
Time to union <=18 weeks	49	4	45	15	4	11	16	6	10

The fractures were analysed according to their Gustilo classification in relation to union rate by 18 weeks and rate of complications. The complicated fractures had a lower rate of union by 18 weeks compared to the non complicated fractures. Simple fractures that became complicated had 4 of 16 uniting by 18 weeks.

These results were not statistically significant for time to union. However the results were statistically very strongly significant for simple fractures that developed complications; i.e. they were more likely to unite after 18 weeks than fractures that did not develop complications P value of 0.00 Fishers exact test. The same test on Gustilo I and II compound fractures were not statistically significant p value of 0.673 and 0.146 respectively.

The complication rate was 39/108 = 36.1%. Looked at from geographical position of the fracture was thus distributed.

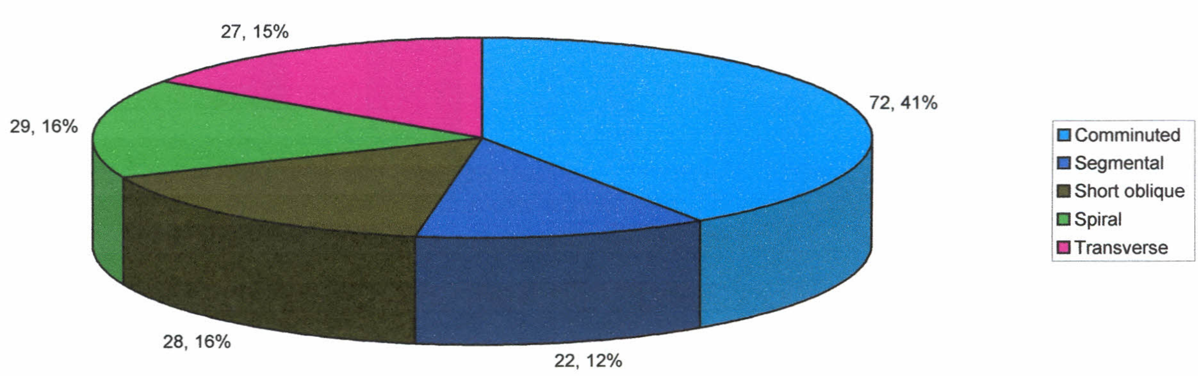
Proximal shaft fractures were 18 i.e. 16.7% of the 108 patients who were followed to union. Eight of these patients had complications i.e. 44.4%.

The mid shaft fractures were 35 i.e. 32% of patients followed up to union, of these 35 fractures, twelve had complications i.e. 34.3%

The distal third fractures were 50 (46.3%) of the patients followed up to union ten (20%) of these fractures had complications.

The pie chart of the fracture analysis according to the geometry of bone injury of the 178 fractures recruited into the study

Figure VI



The geometry of bone injury was analysed together with complications that arose and union by 18 weeks in the 108 patients' who were followed up and the results are shown in the histogram below

Figure VII

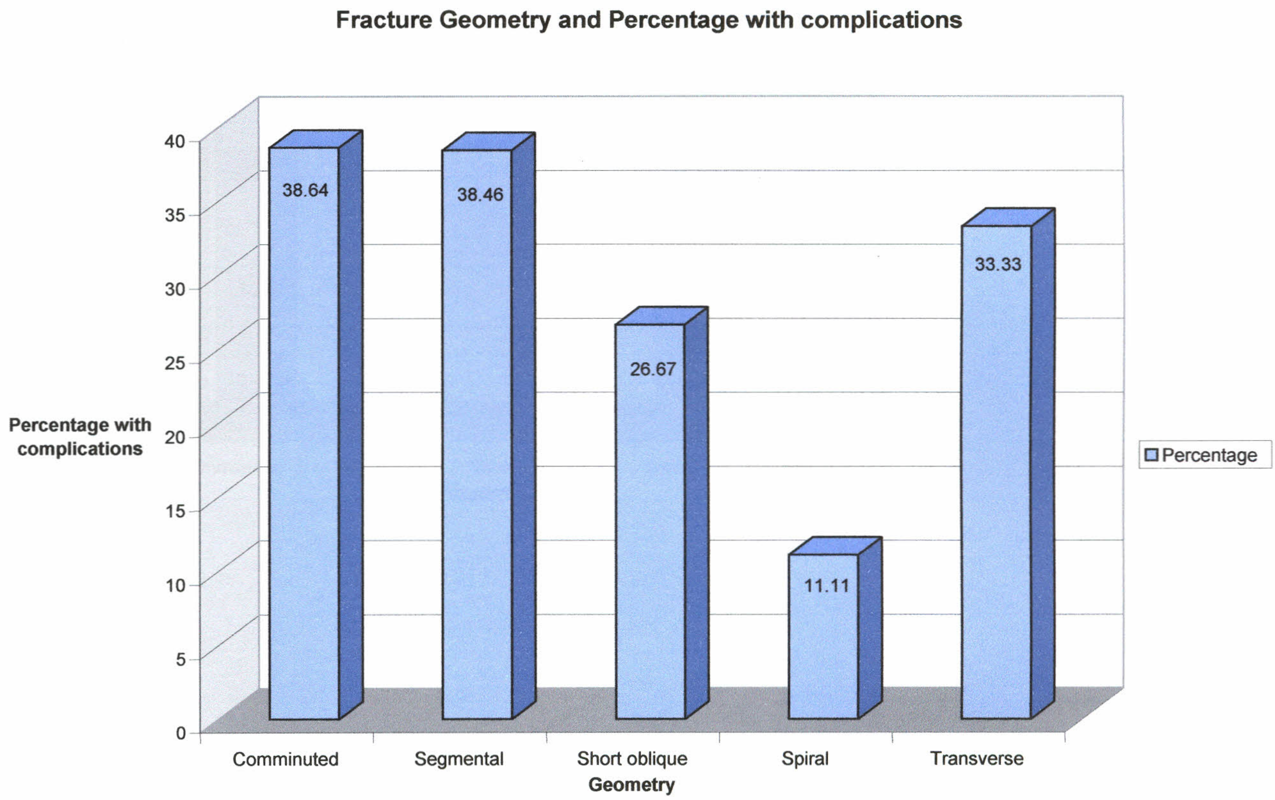


Figure VIII

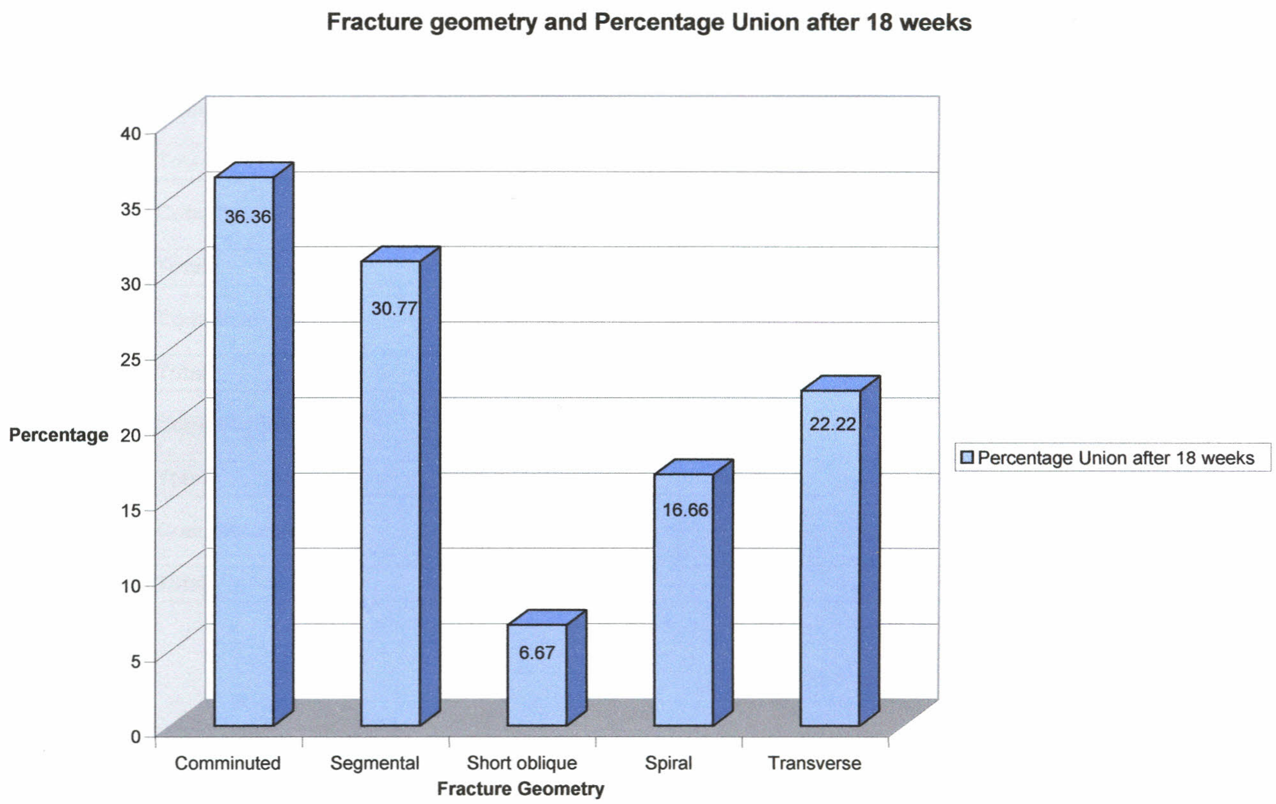

Fracture geometry and Percentage Union after 18 weeks
Percentage
40
35
30
25
20
15
10
5
0
36.36
30.77
6.67
16.66
22.22
Comminuted
Segmental
Short oblique
Spiral
Transverse
Fracture Geometry
Percentage Union after 18 weeks

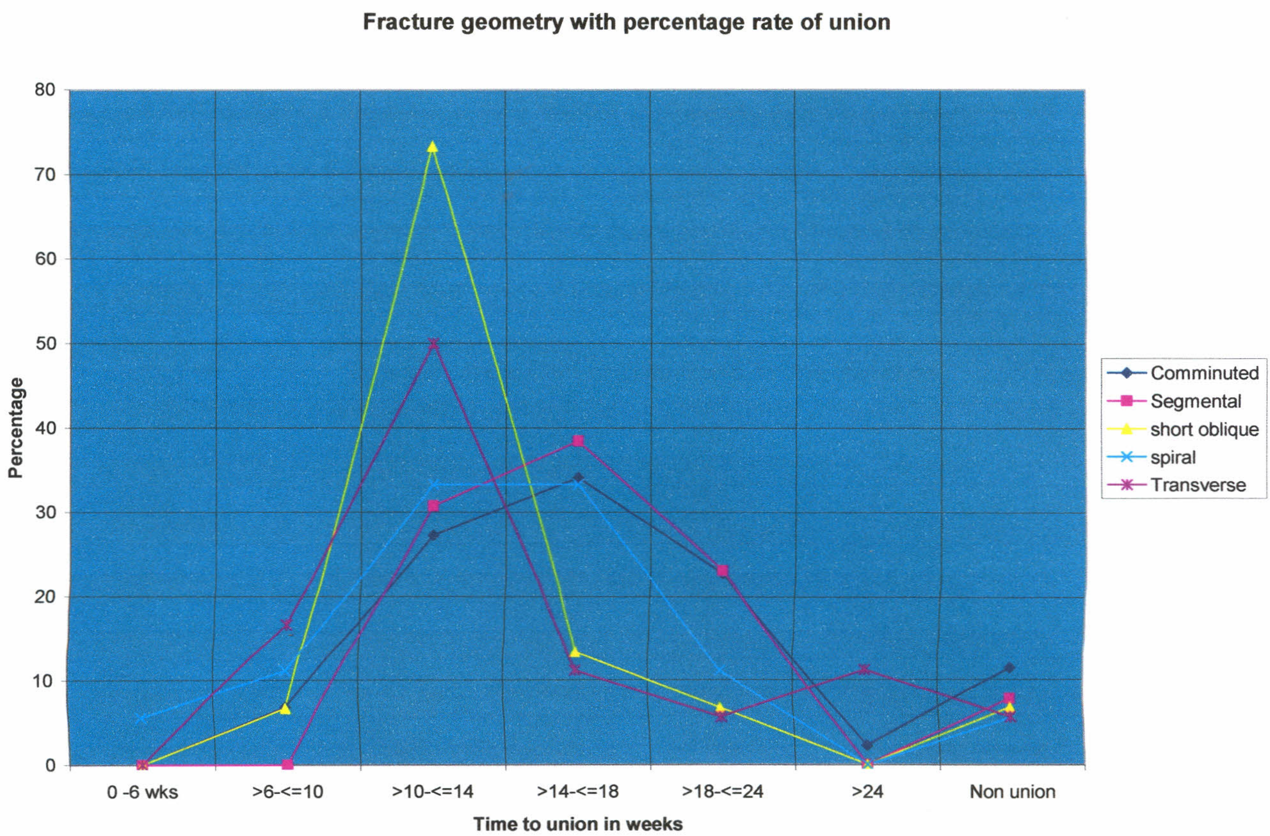
Table II ***Table of fracture geometry and rate of union before or after 18 weeks***

Fracture Geometry			Time to union < = 18 weeks	Time to union > 18 weeks	Total
Comminuted	Complications	No complications	22	5	27
		Complications	6	11	17
	Total		28	16	44
Segmental	Complications	No complications	7	1	8
		Complications	2	3	5
	Total		9	4	13
Short oblique	Complications	No complications	11	0	11
		Complications	3	1	4
	Total		14	1	15
Spiral	Complications	No complications	14	2	16
		Complications	1	1	2
	Total		15	3	18
Transverse	Complications	No complications	12	0	12
		Complications	2	4	6
	Total		14	4	18

61% of patients with comminuted fractures, 53% with short oblique, 62% with spiral, 66.7% of patients with transverse fractures and 59% with segmental fractures respectively were followed up.

Based on these results segmental and comminuted fractures followed by transverse had the highest complication rate. However this result was not statistically significant.

Figure IX



Of the 44 comminuted fractures only 39 fractures united. At 18 weeks 28 (72%) of the 39 fractures had united. Five fractures never united during the period of study.

Of the 13 segmented fractures nine had united by 18 weeks, 3 had union after 18 weeks and one did not unite during the period of study.

Of the 18 transverse fractures, 14 (78%) had union by 18 weeks, 3 united after 18 weeks while one never united during the period of study.

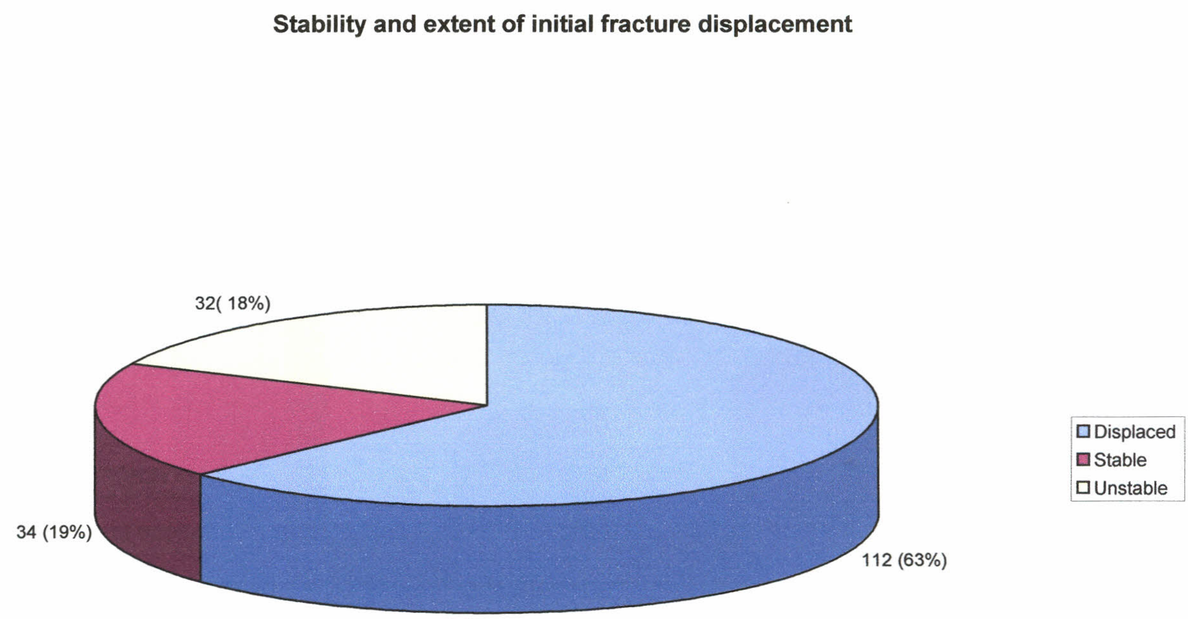
Of the 18 spiral fractures that were followed up 16 (89%) had union by 18 weeks and all united by 24 weeks.

Of the 15 short oblique fractures that were followed up 14 (93%) had united by 18 weeks. One did not unite during the period of study.

These results were statistically significant by Fishers exact test P value 0.003 and 0.005 for comminuted and segmental fractures respectively. The comminuted and segmental fractures had a significant number of cases uniting after 18 weeks or not at all.

The pie chart below shows the results of analysis of fracture stability, instability or displacement for the 178 fractures recruited into the study.

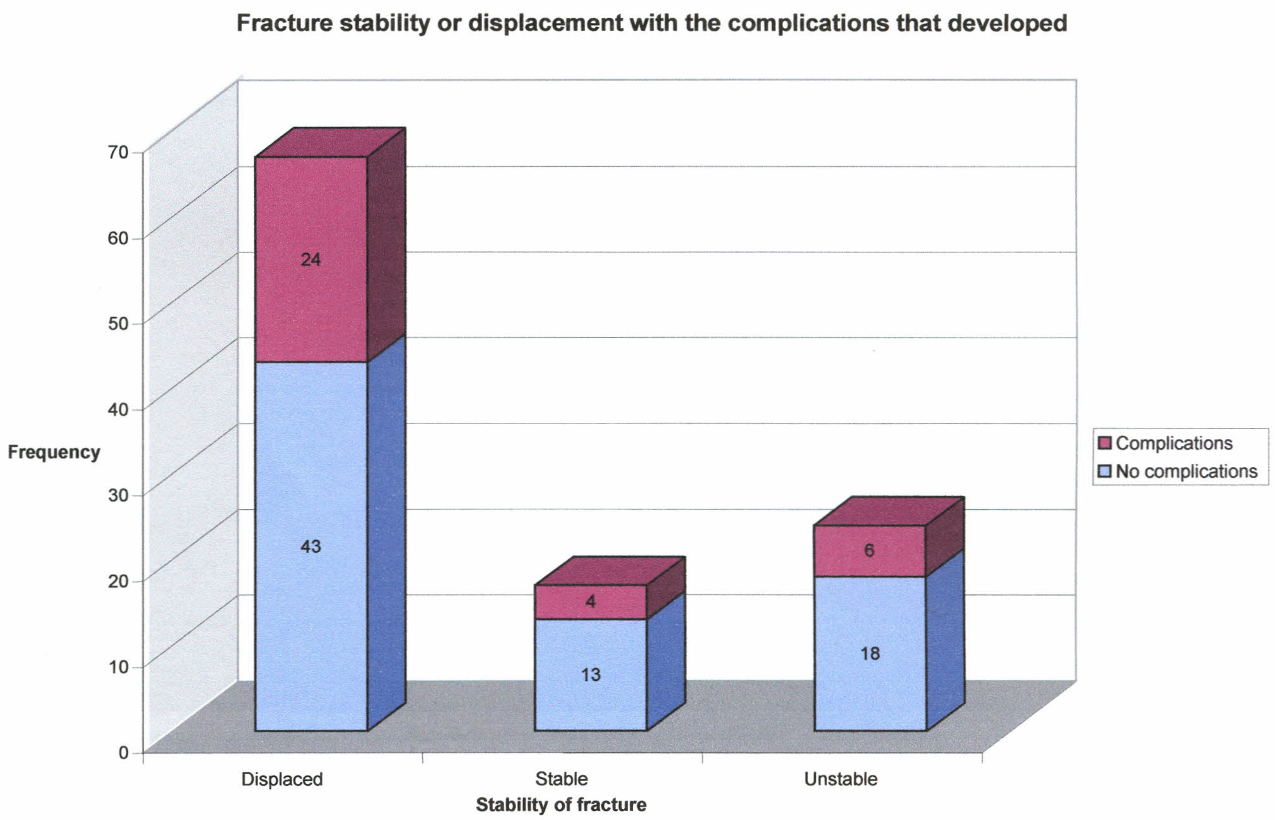
Figure X



Of the 178 fractures entered into the study 112 were displaced, 32 were unstable {complete} but not displaced and 34 were stable {incomplete or hairline} fractures.

Below is the Histogram indicating the fracture stability and the complications that developed as seen in the 108 fractures that were followed up.

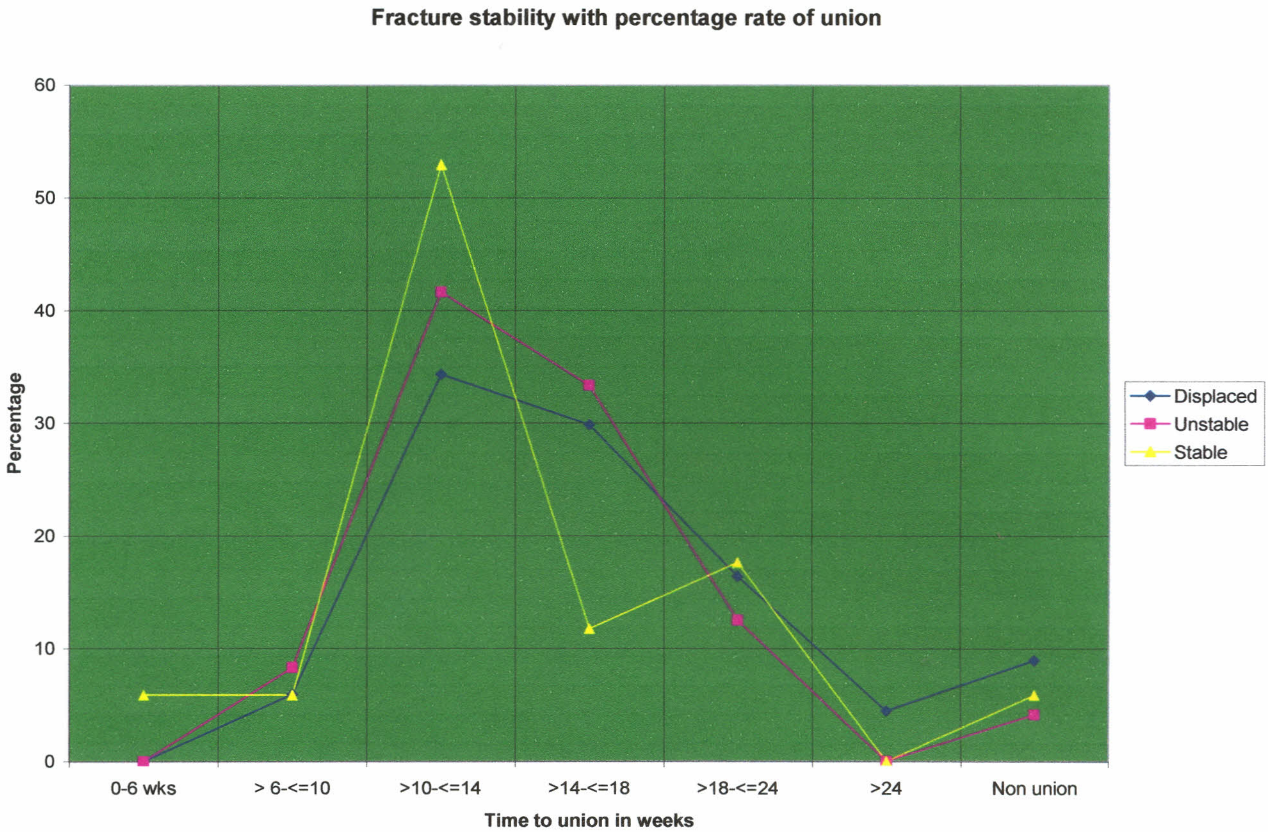
Figure XI



This gives a complication rate of 35.8% for the displaced fractures, 23.53% for the stable fractures and 25% for the unstable fractures.

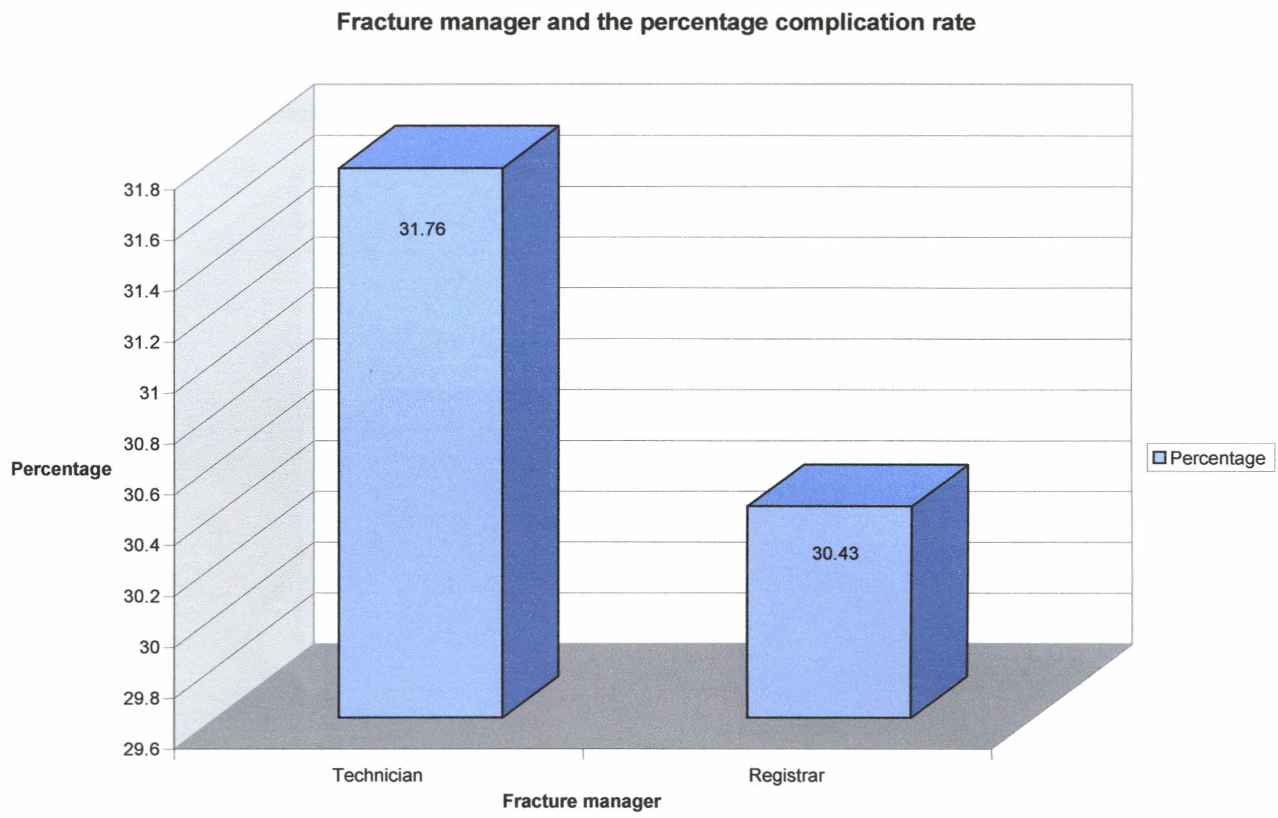
The line graph shown bellow gives the fracture stability with relevant rate of union for the 108 fractures followed up. These results were not statistically significant.

__Figure XII__



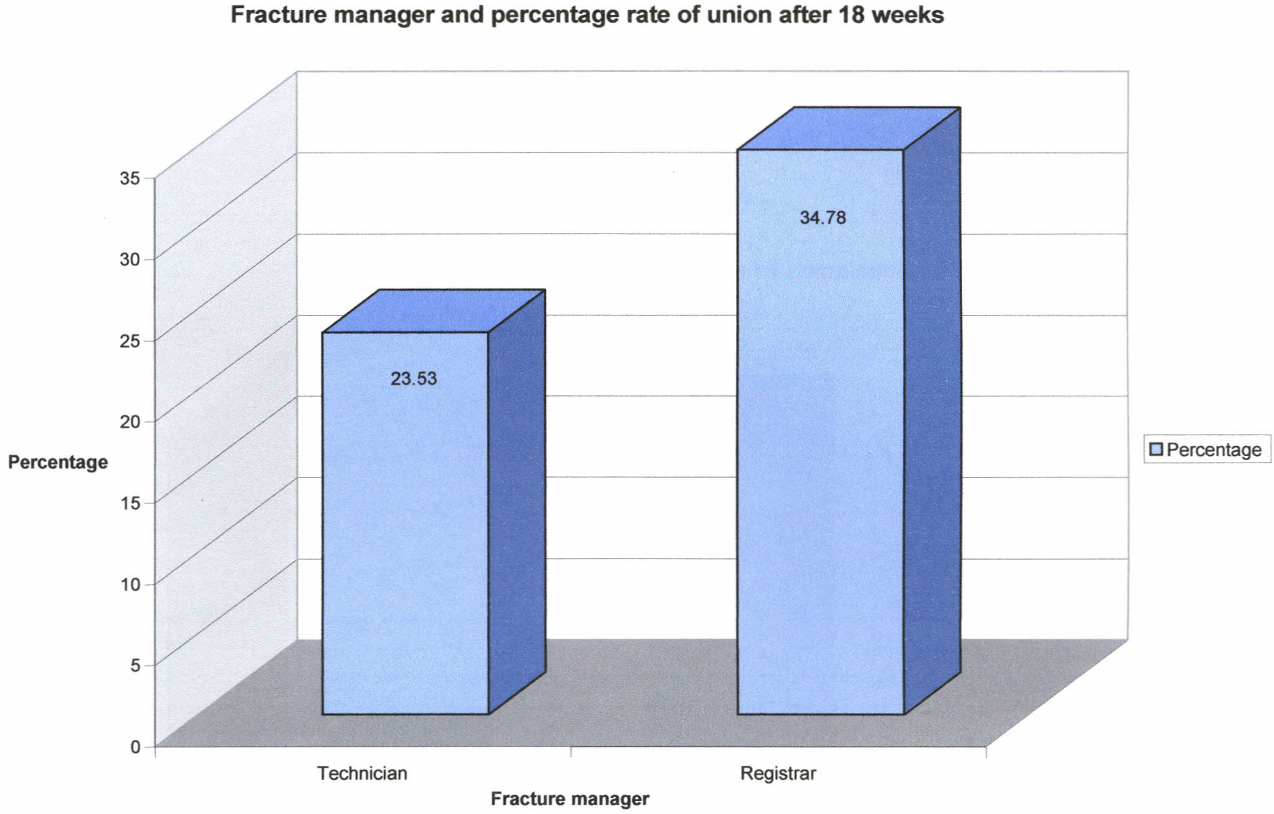
Looked at in terms of the fracture manager in relation to complication of the fracture; of 178 patients 134 were managed by orthopaedic technicians while 44 were managed by surgical registrar. Only 23 (52%) of the 44 patients were followed up and 7 (30%) of these had complications. 85 (63%) of the 134 fractures whose plaster of Paris was applied by the technician were followed up and 27 (32%) of them developed complications.

Figure XIII



Fracture manager and the percentage complication rate
31.8
31.6
31.4
31.2
31
30.8
30.6
30.4
30.2
30
29.8
29.6
Percentage
31.76
30.43
Technician
Registrar
Fracture manager
Percentage

Figure XIV

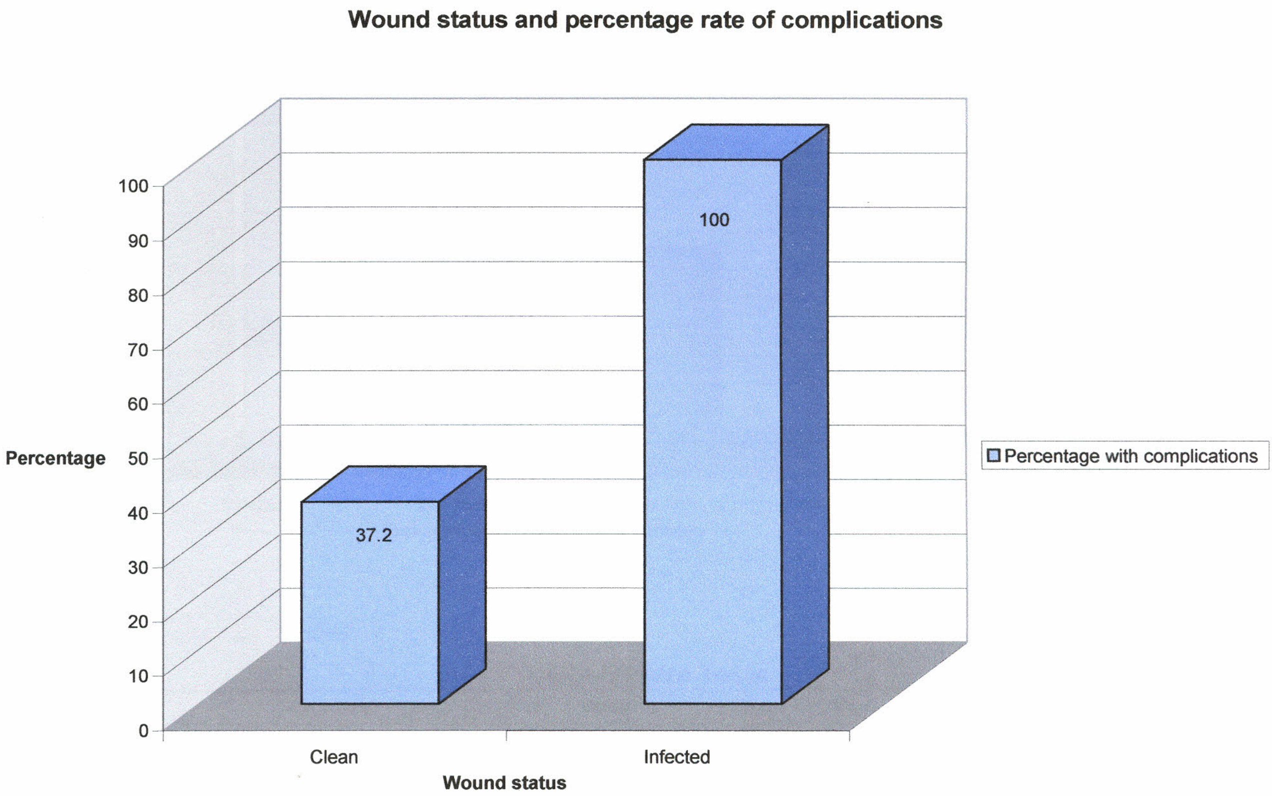


These results translate into union rate of 82.3% by week 18 for fractures managed by technicians compared to 71% for fractures managed by surgical registrars. Considered at 24 weeks the union rate of fractures managed by technicians is 97% while for those managed by registrar is 95%.These results were not statistically significant.

There were 76 open fractures that were subjected to surgical toilette and wound closure before applications of plaster of Paris. 5 (6.6%) of these developed wound infections, none of these patients was taken back for repeat surgical toilet.

The histogram below shows the correlation between the complications encountered and the infection rate of the 45 patients with infection who were followed up.

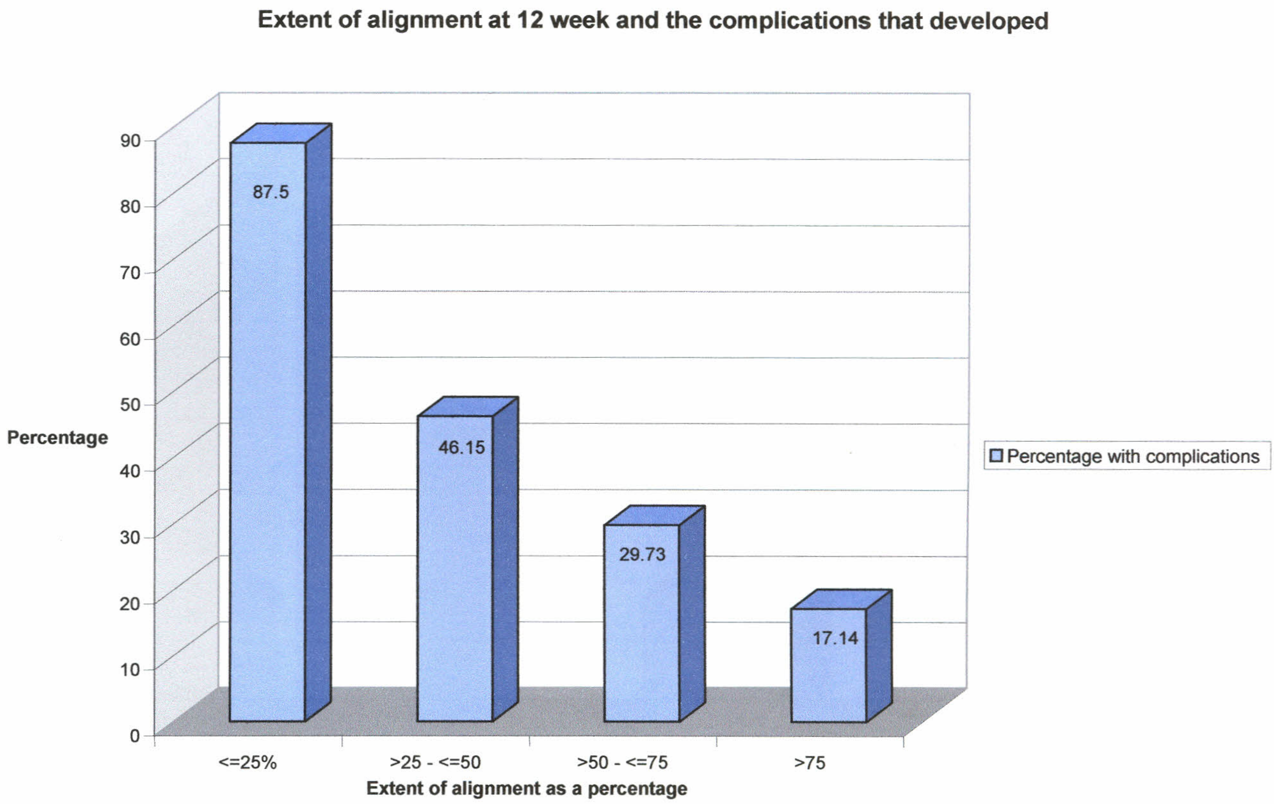
Figure XV



It is important to note that there were only two fractures that were followed up among the infected fractures however they had union with complications

The bar graph below shows the extent of fracture alignment at 12 weeks and the complication that developed of the 94 fractures that were followed up.

Figure XVI



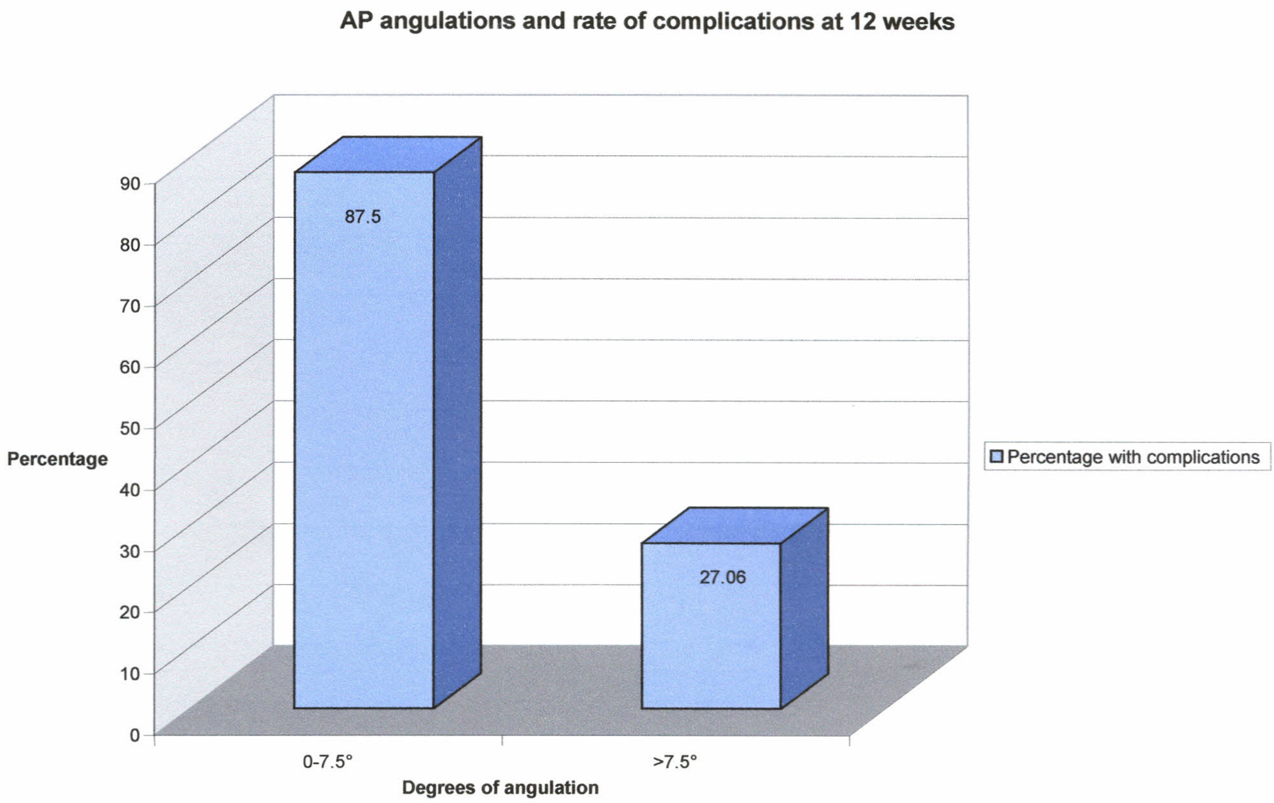
Chi-Square Tests

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	16.088(a)	3	0.0
Likelihood Ratio	15.88	3	0.0
Linear-by-Linear Association	14.44	1	
N of Valid Cases	93		

These results demonstrate that an important contributor to complications is alignment of 25% or less.

The Bar graph below shows the results of the analysis of fractures in terms of AP angulations and the complication rate

Figure XVII



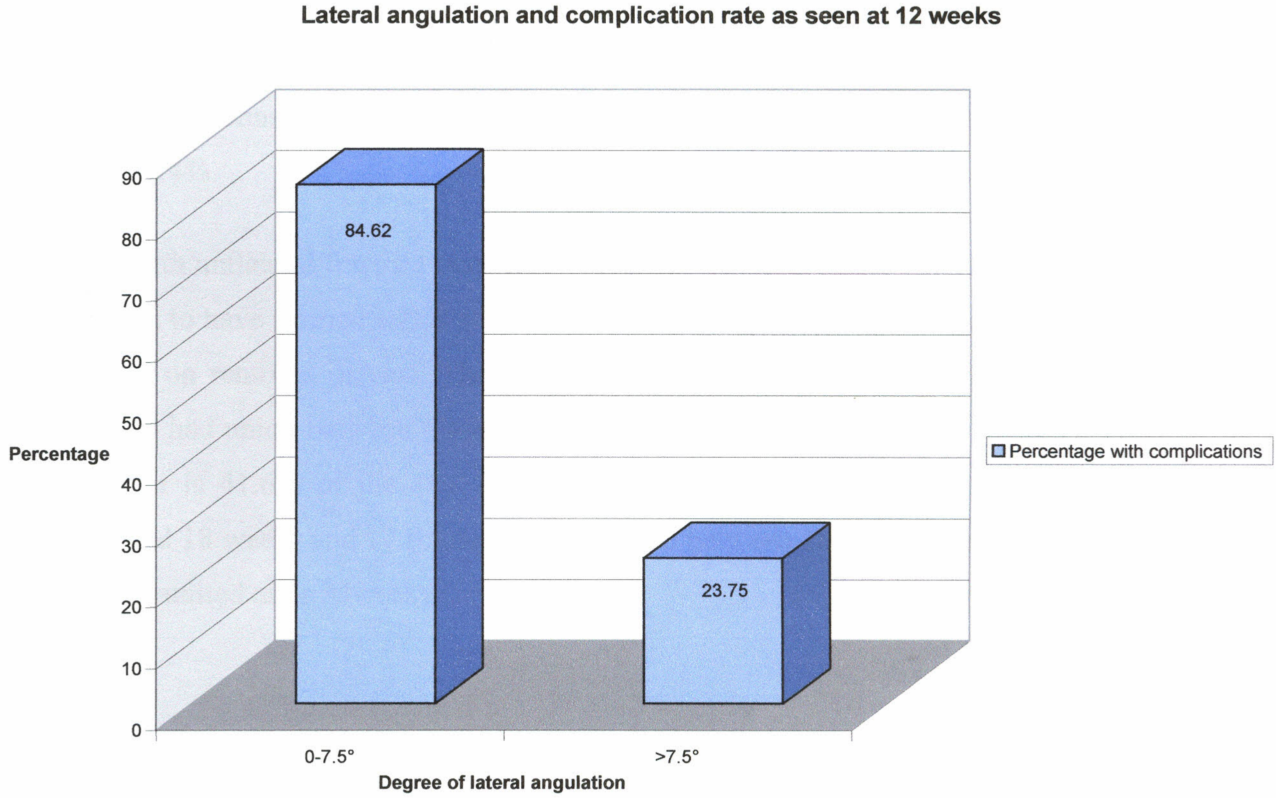
Chi-Square Tests

	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-side
Pearson Chi-Square	12.224(b)	1	0		
Continuity Correction(a)	9.614	1	0.002		
Likelihood Ratio	11.675	1	0.001		
Fisher's Exact Test				0.001	0.0
Linear-by-Linear Association	12.092	1	0.001		
N of Valid Cases	93				

This shows that fractures with AP angulations of > 7.5° are more prone to healing with complications than fractures with AP angulations < 7.5°.

The histogram below shows the lateral angulations of the 93 fractures analysed at 12 weeks and the complications that developed

Figure XVIII



Chi-Square Tests

	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-side
Pearson Chi-Square	18.958(b)	1	0		
Continuity Correction(a)	16.275	1	0		
Likelihood Ratio	18.085	1	0		
Fisher's Exact Test				0	
Linear-by-Linear Association	18.754	1	0		
N of Valid Cases	93				

This shows that fractures with lateral angulations of > 7.5° are more prone to healing with complications than fractures with lateral angulations < 7.5°.

Time to union

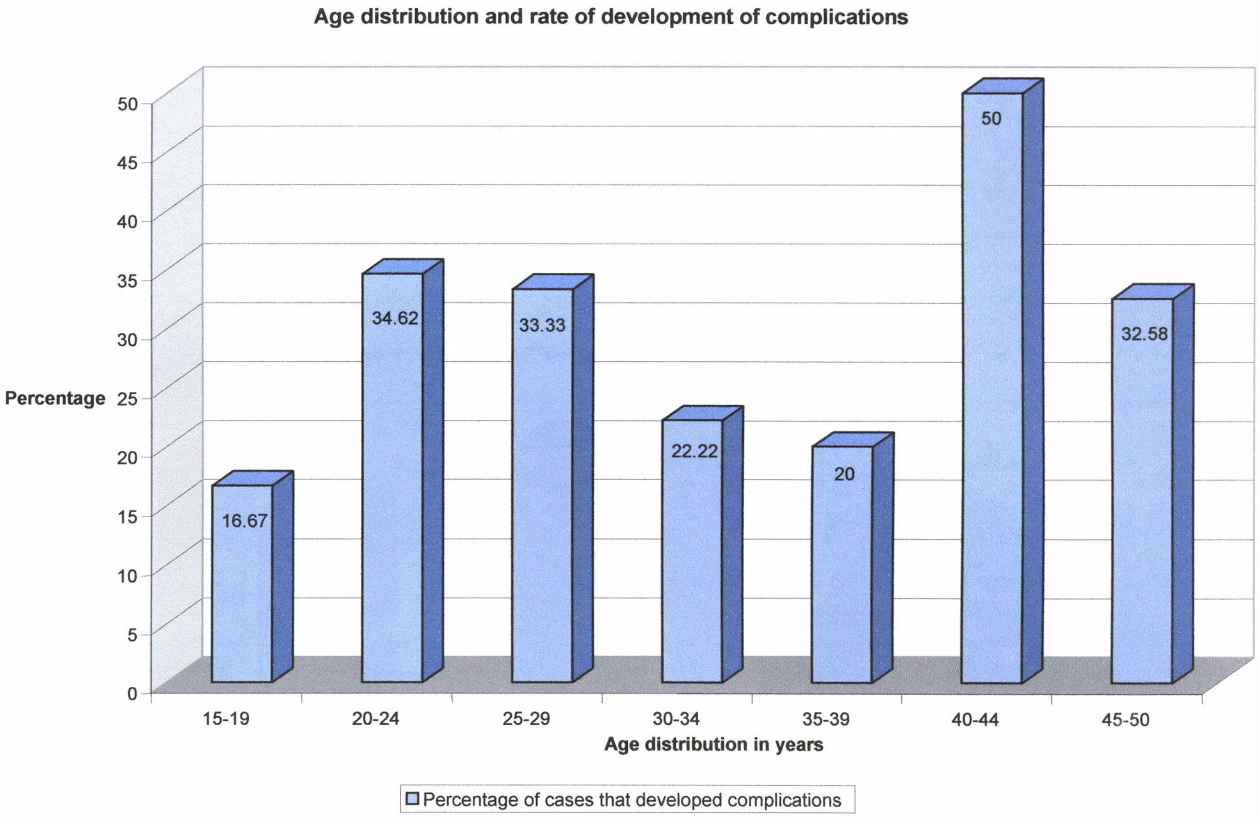
The mean time to union was 15.85 weeks for the 101 fractures that united. The earliest union was at 4 weeks while the latest fracture to unite was at 38 weeks. The median time to union was at 15 weeks and the mode was at 14 weeks.

80 of 108 fractures united by week 18 while 88 fractures were united by 20 weeks, i.e. 81.5%; delayed union was considered above 20 weeks. There was a delayed union rate of 11.1 % and a non union rate of 7.4%.

One patient with unilateral fracture united by 4 weeks, this was a stable spiral hairline fracture which was confirmed to have formed callus at four weeks and the patient was able to fully bear weight with no tenderness on removal of cast. The patient was a 24 year old male who suffered from a fall. Seven patients had union between 6 and 10 weeks, i.e. 7%, 42 fractures were united between 10 and 14 weeks, that is 41.6% of the 101 fractures that went up to union yet 30 fractures had union between 14 and 18 weeks and 17 fractures were united between 18 and 24 weeks i.e. 17% and only 3 fractures (3%) united after 24weeks.

Effect of age distribution on the rate of complications

Figure XIX

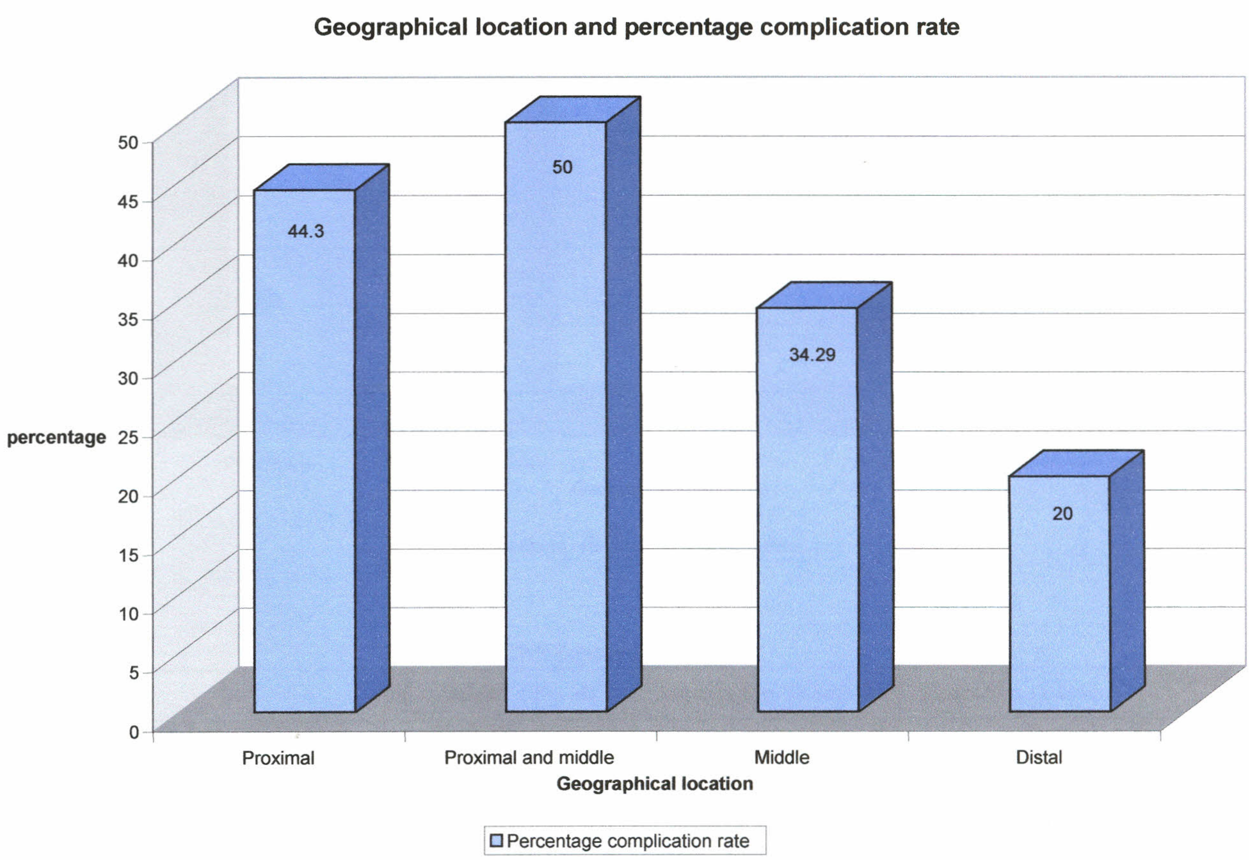


According to these results the age distribution did not have any influence on the rate of complications that developed and the age distribution does not influence the rate of union by 18 weeks.

Effect of Geographical location of fracture on Complication rate

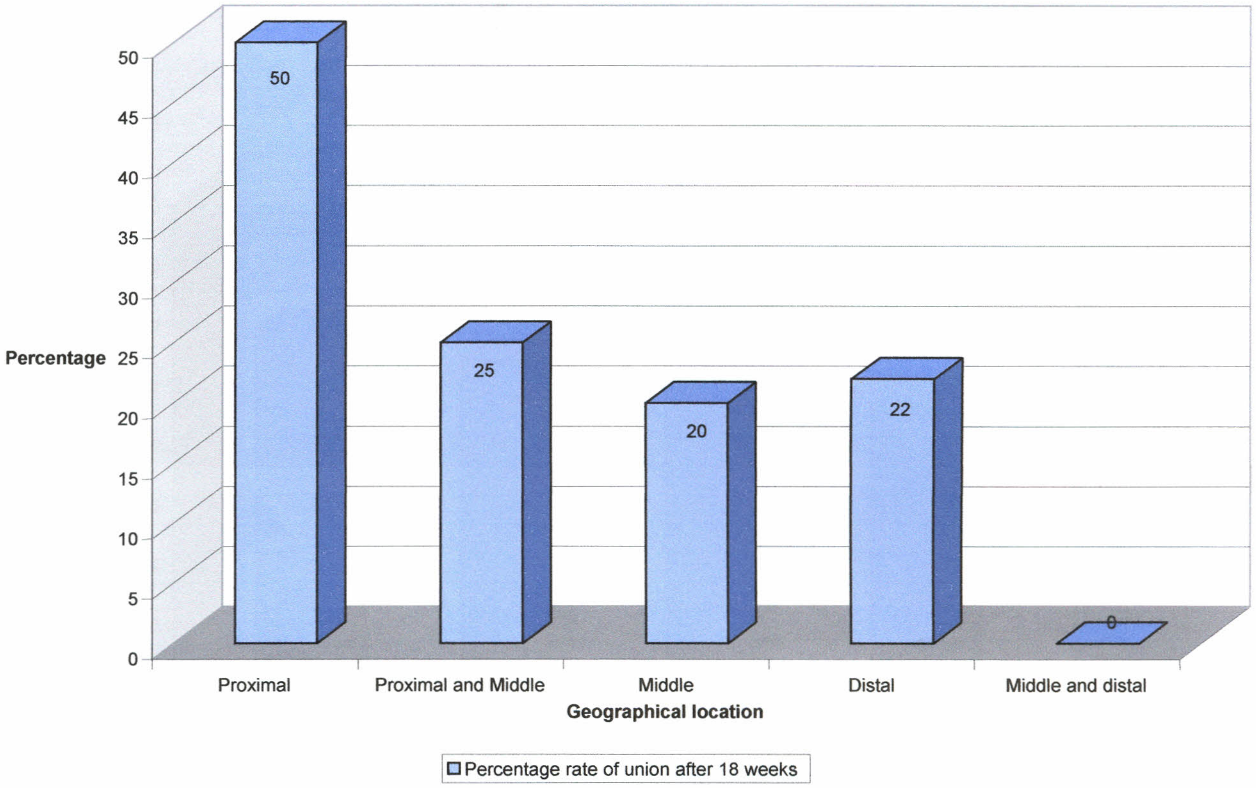
The time to union was analysed in relation to the geographical location of the fracture and the complications encountered. The histogram below shows the geographical location of the fractures in relation to the complications and union before or after 18 weeks

<u>Figure XX</u>



Effect of Geographical location of fracture on rate of union

Figure XXI



Chi-Square Tests

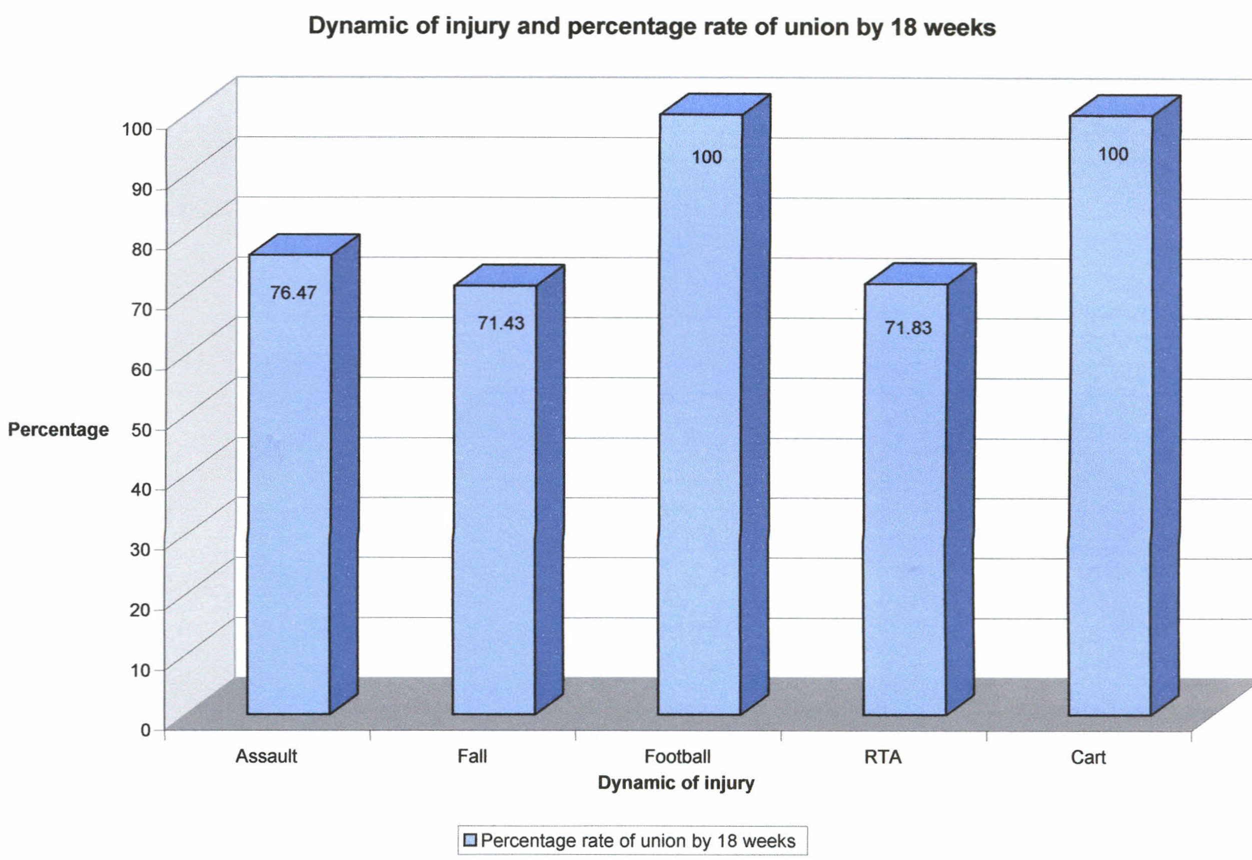
cation of cture		Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
stal	Pearson Chi-Square	16.783(c)	1	0		
	Continuity Correction(a)	13.469	1	0		
	Likelihood Ratio	14.467	1	0		
	Fisher's Exact Test				0	0
	Linear-by-Linear Association	16.448	1	0		
	N of Valid Cases	50				
ddle	Pearson Chi-Square	10.272(d)	1	0.001		
	Continuity Correction(a)	7.617	1	0.006		
	Likelihood Ratio	10.166	1	0.001		
	Fisher's Exact Test				0.003	0.003
	Linear-by-Linear Association	9.978	1	0.002		
	N of Valid Cases	35				

The results for the rate of union by 18 weeks for complicated proximal shaft fractures compared to uncomplicated fractures did not show statistical significance.

Effect of the dynamic of injury on the rate of union

The dynamic of injury was analysed in relation to time union and complications for the fractures that were followed up. The histogram below gives the results of this analysis.

Figure XXII



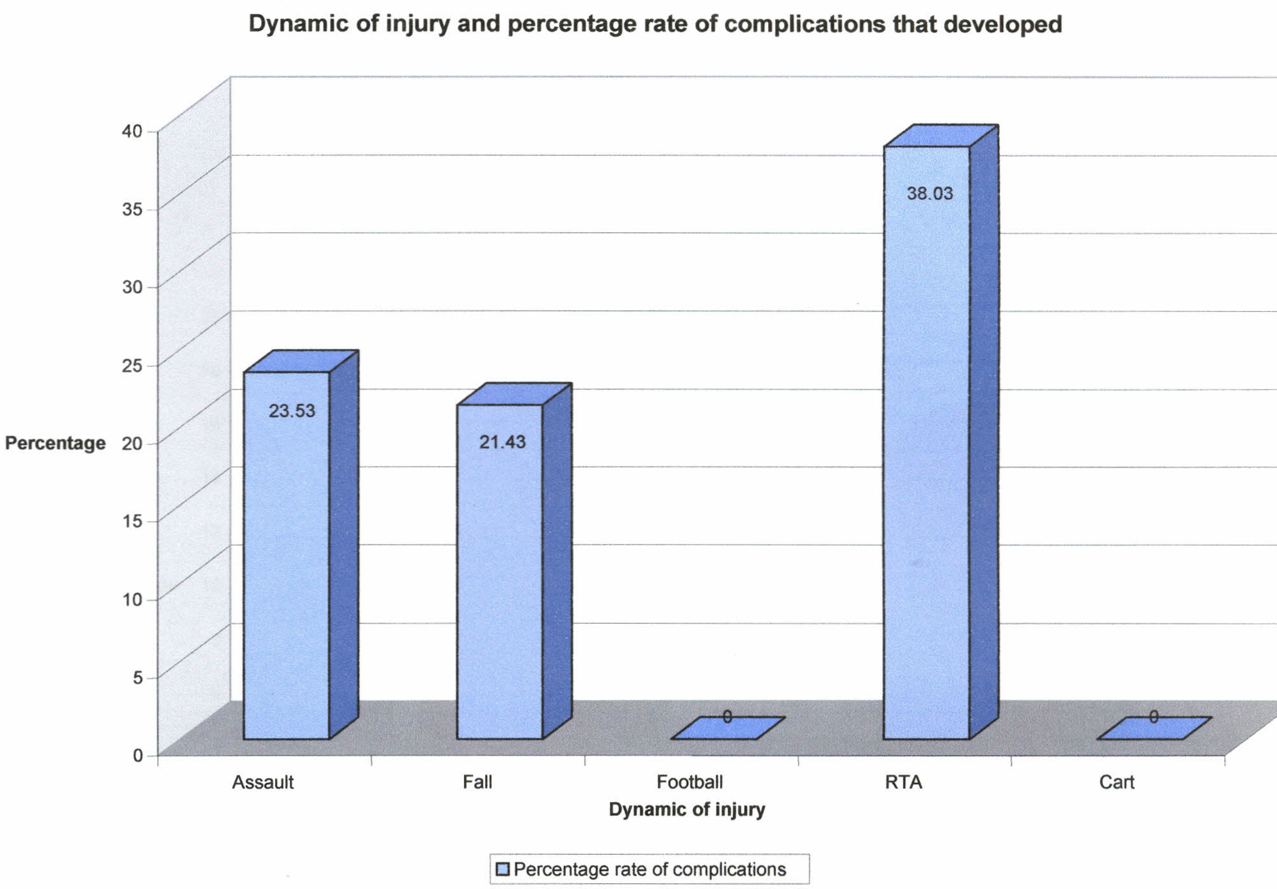
Chi-Square Tests

Dynamic		Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Si (1-sidec
Fall	Pearson Chi-Square	9.545(c)	1	0.002		
	Continuity Correction(a)	5.611	1	0.018		
	Likelihood Ratio	10.05	1	0.002		
	Fisher's Exact Test				0.011	0.C
	Linear-by-Linear Association	8.864	1	0.003		
	N of Valid Cases	14				
RTA	Pearson Chi-Square	16.150(e)	1	0		
	Continuity Correction(a)	14.039	1	0		
	Likelihood Ratio	16.173	1	0		
	Fisher's Exact Test				0	
	Linear-by-Linear Association	15.922	1	0		
	N of Valid Cases	71				

A significant proportion of complicated fractures caused by RTA or a fall united after 18 weeks or not at all.

Effect of the dynamic of injury on the complication rate

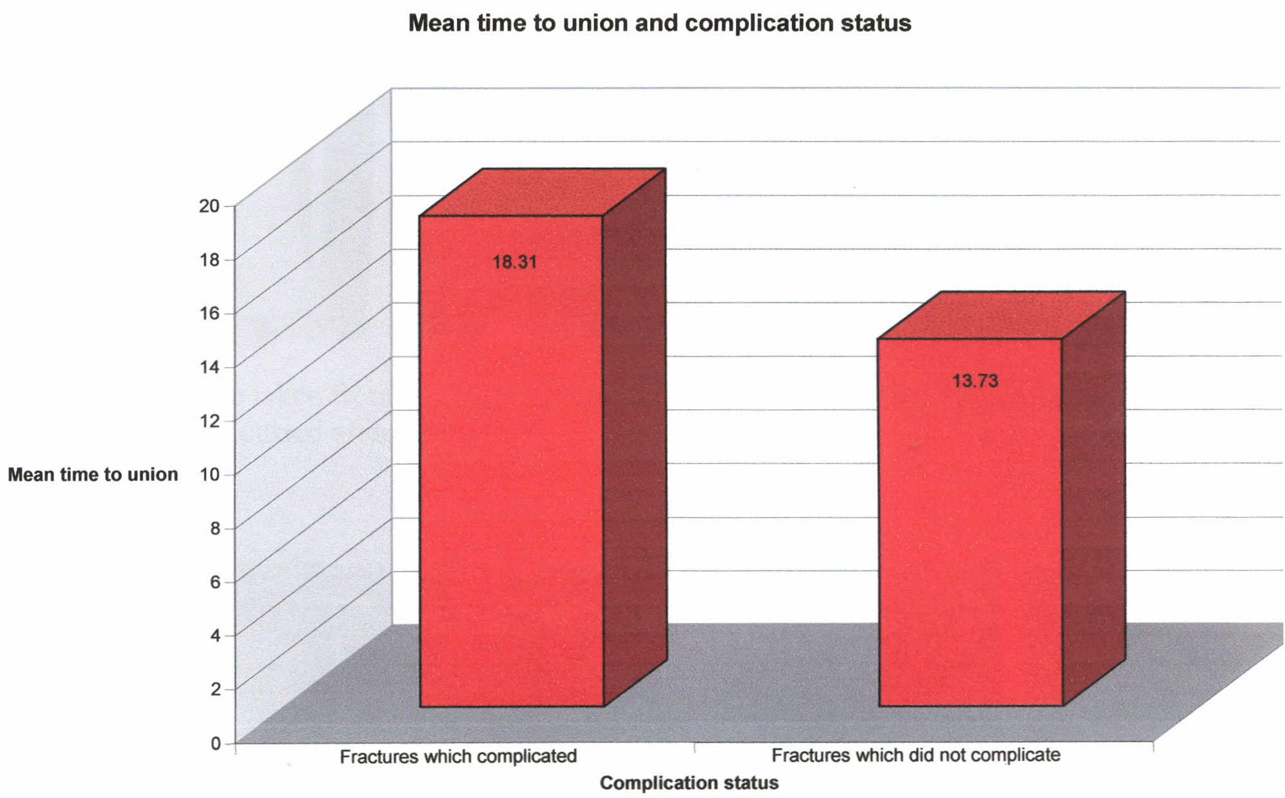
Figure XXIII



At 6 weeks 84 fractures were evaluated with check x-rays and 28 (33%) already had callus formation. At 12 weeks 94 fractures were evaluated and 81 (86%) already had callus formation. At 18 weeks 66 fractures were evaluated and 61 (92.4%) already had formed callus. There were 7 united fractures by 10 weeks while 28 fractures had formed callus by 6 weeks hence only 28.6% of these were considered to have union 4 weeks later. 81 of 94 fractures evaluated at 12 weeks had callus yet 50 fractures united between 10 and 16 weeks hence 61.7% of the fractures with callus at 12 weeks actually united within the 4 weeks period to 16 weeks, this figure rises to 55 (67.9%) one week later at 17 weeks. At 18 weeks 66 fractures were evaluated and 31 fractures (47%) united in the 4 week period from 18 to 22 weeks another 4 united 2 weeks later making a total of 53%. These results show that half to two thirds of the fractures with callus will unite within 4 weeks period of the callus formation.

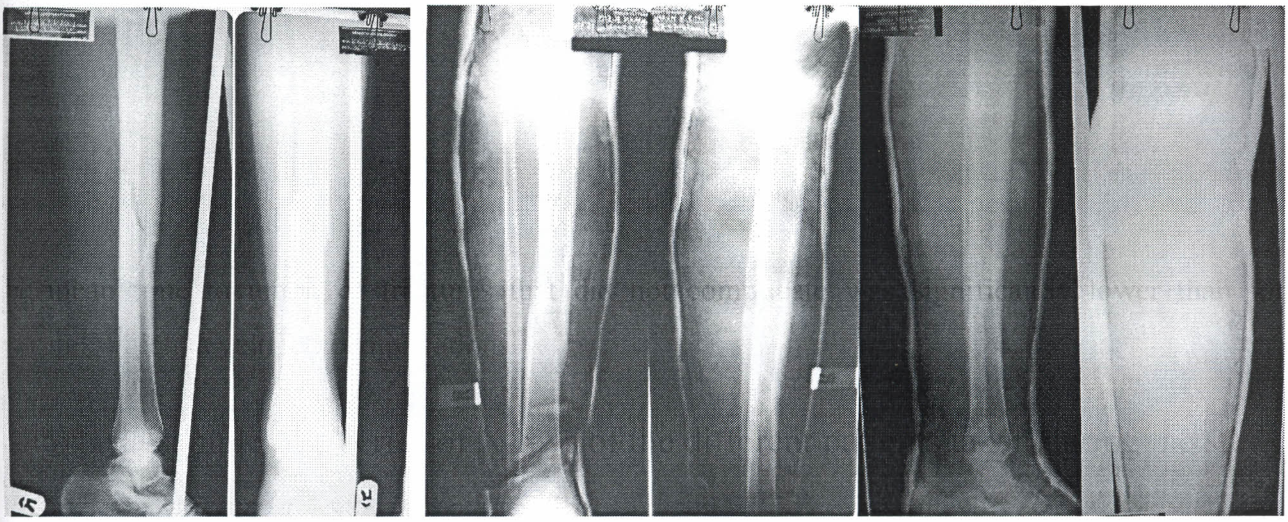
Effect of complications on the rate of union

Figure XXIV



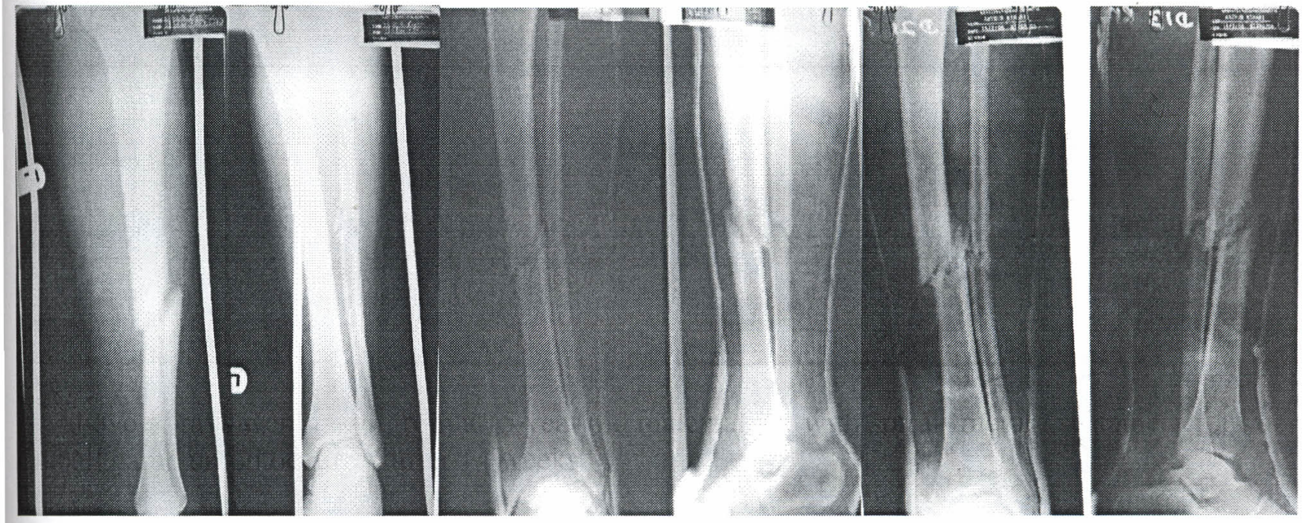
The mean time to union of fractures that did not complicate was significantly lower than for fractures which developed complications.

Below is a sample of a series of X-rays of the different patients taken during the study period. ***Picture a***



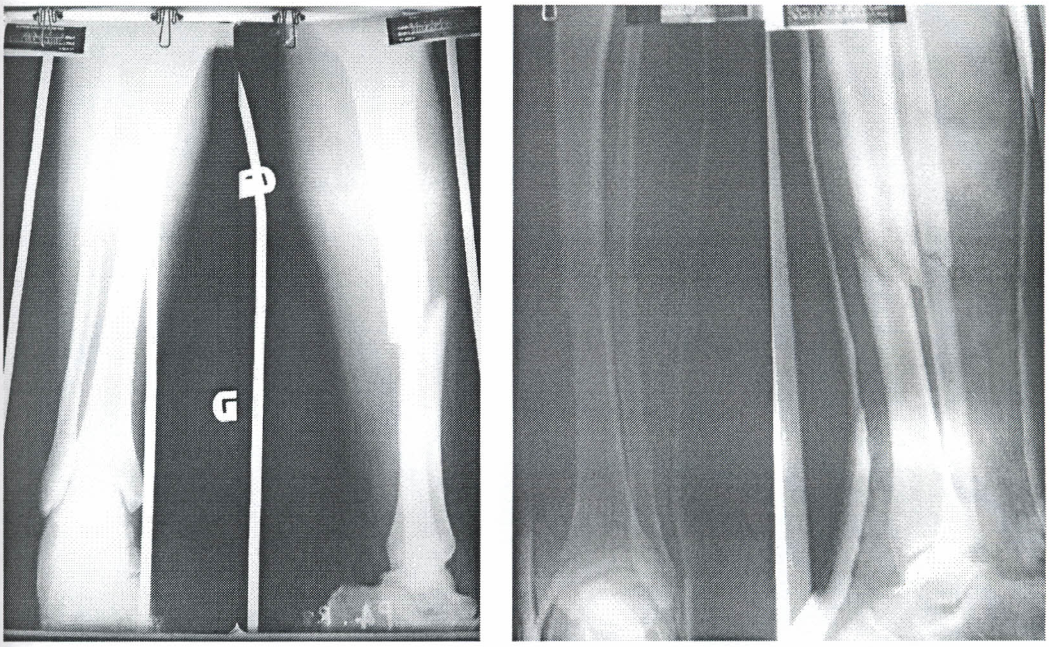
The above X-rays were taken from a 15 year old male patient with spiral fracture sustained from football game union occurred after 14 weeks.

Picture b



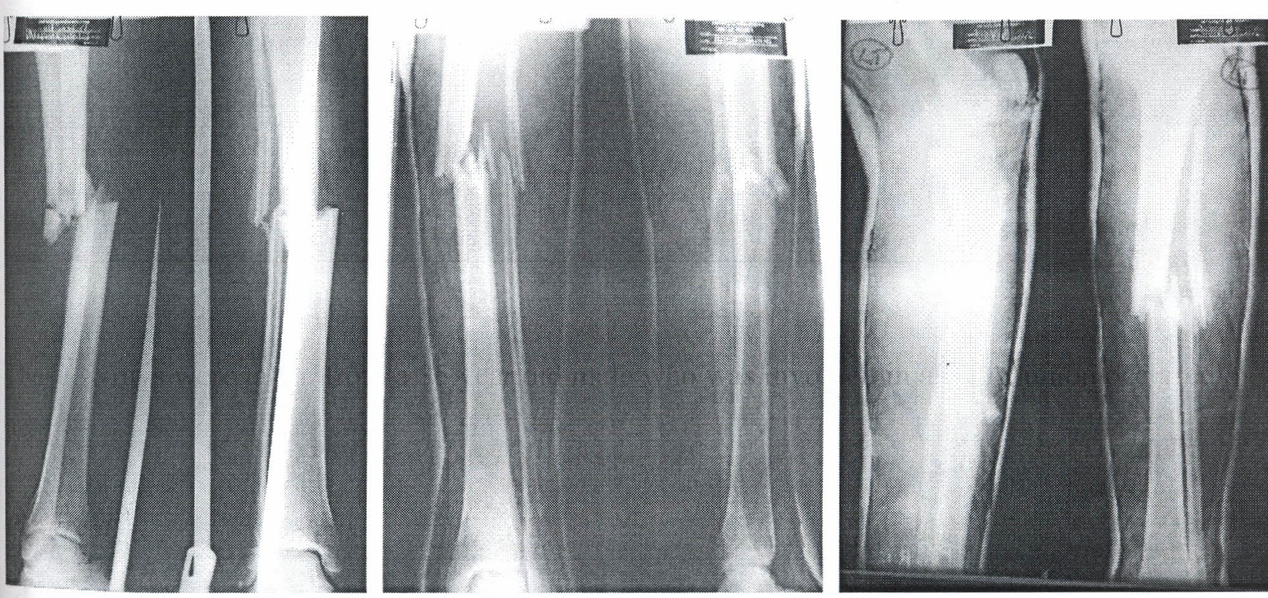
These X-rays were taken from a 24 year old male patient who was involved in a RTA union occurred after 14 weeks.

Picture c



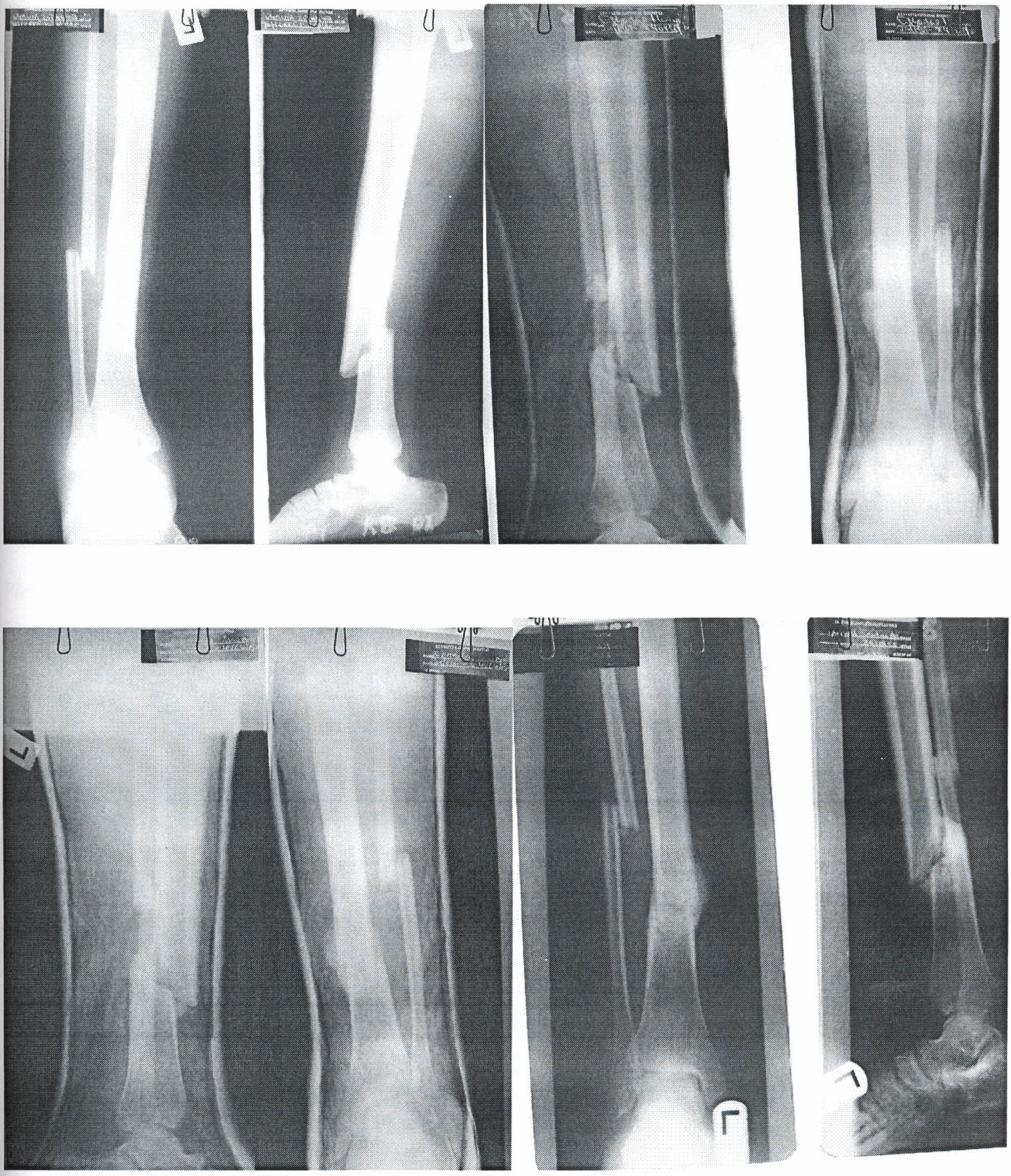
These X-rays were taken from a 35 year old male who was involved in a RTA, union occurred by 16 weeks

Picture d



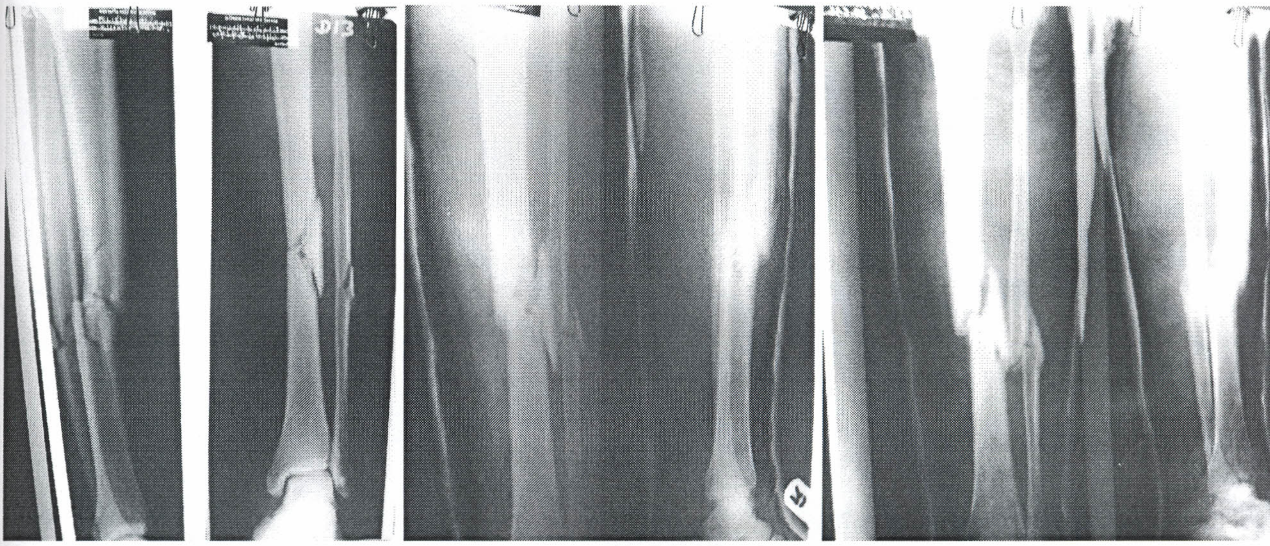
These X-rays were taken from a 23 year old male patient who was involved in a RTA sustaining comminuted fracture; union did not occur during the period of study.

Picture e



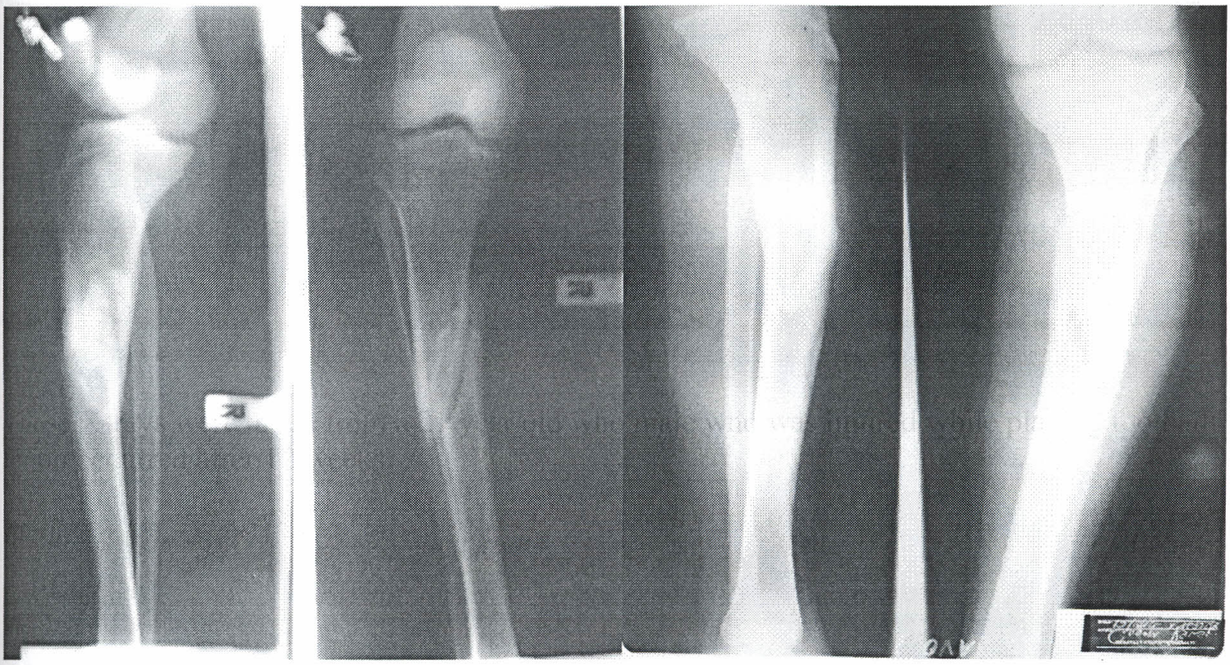
These X-rays were taken from a 23 year old male patient who was involved in a RTA, union occurred after 15 weeks.

Picture f



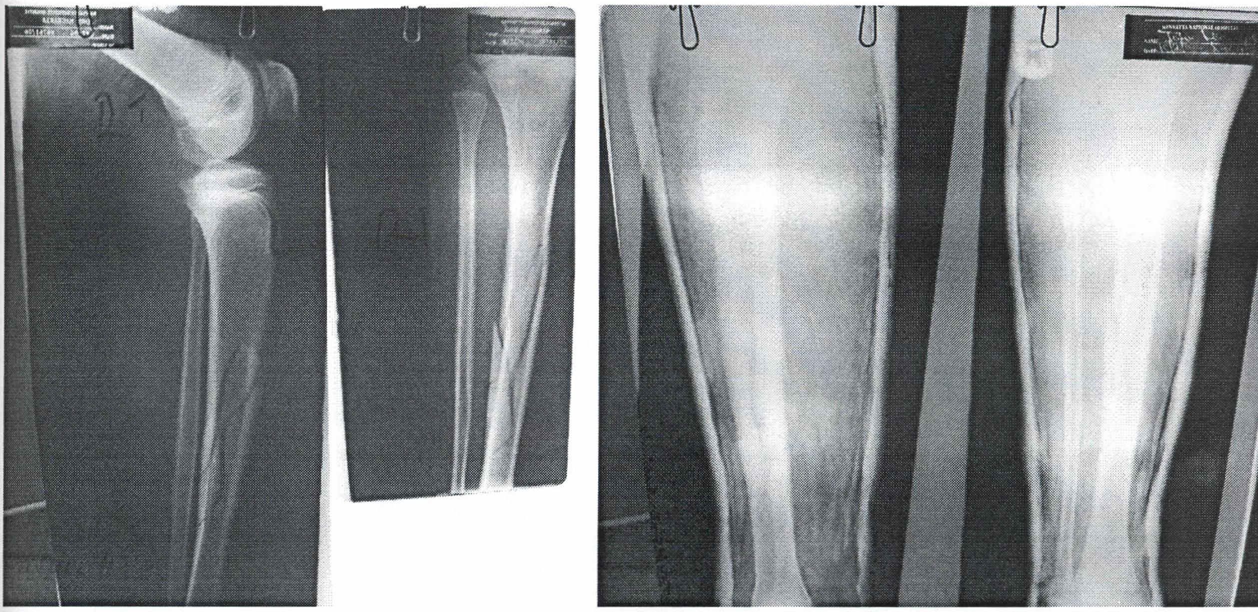
These X-rays were taken from a 21 year old who male who was injured while playing football; union occurred after 12 weeks.

Picture g



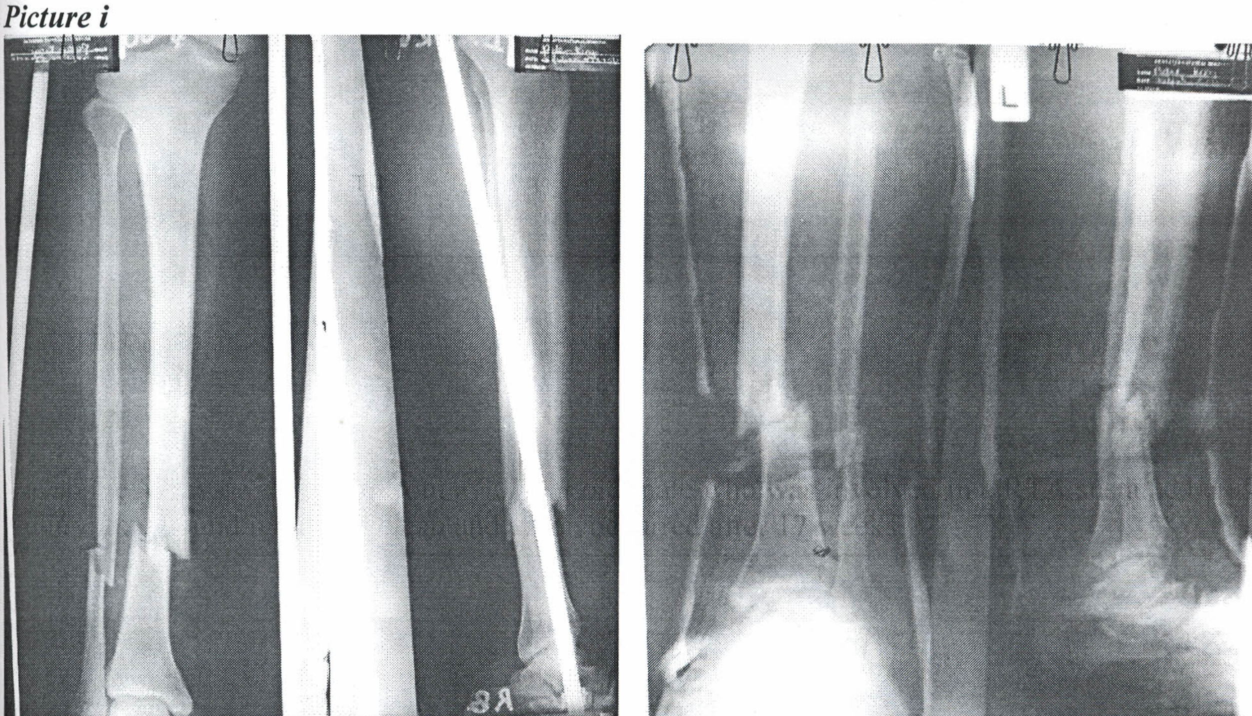
These X-rays were taken from a 23 year old male who was assaulted, had Gustilo I injury. Plaster cast had been applied however the patient had rotational mal alignment and the cast was removed and the patient admitted for open reduction and internal fixation

Picture h



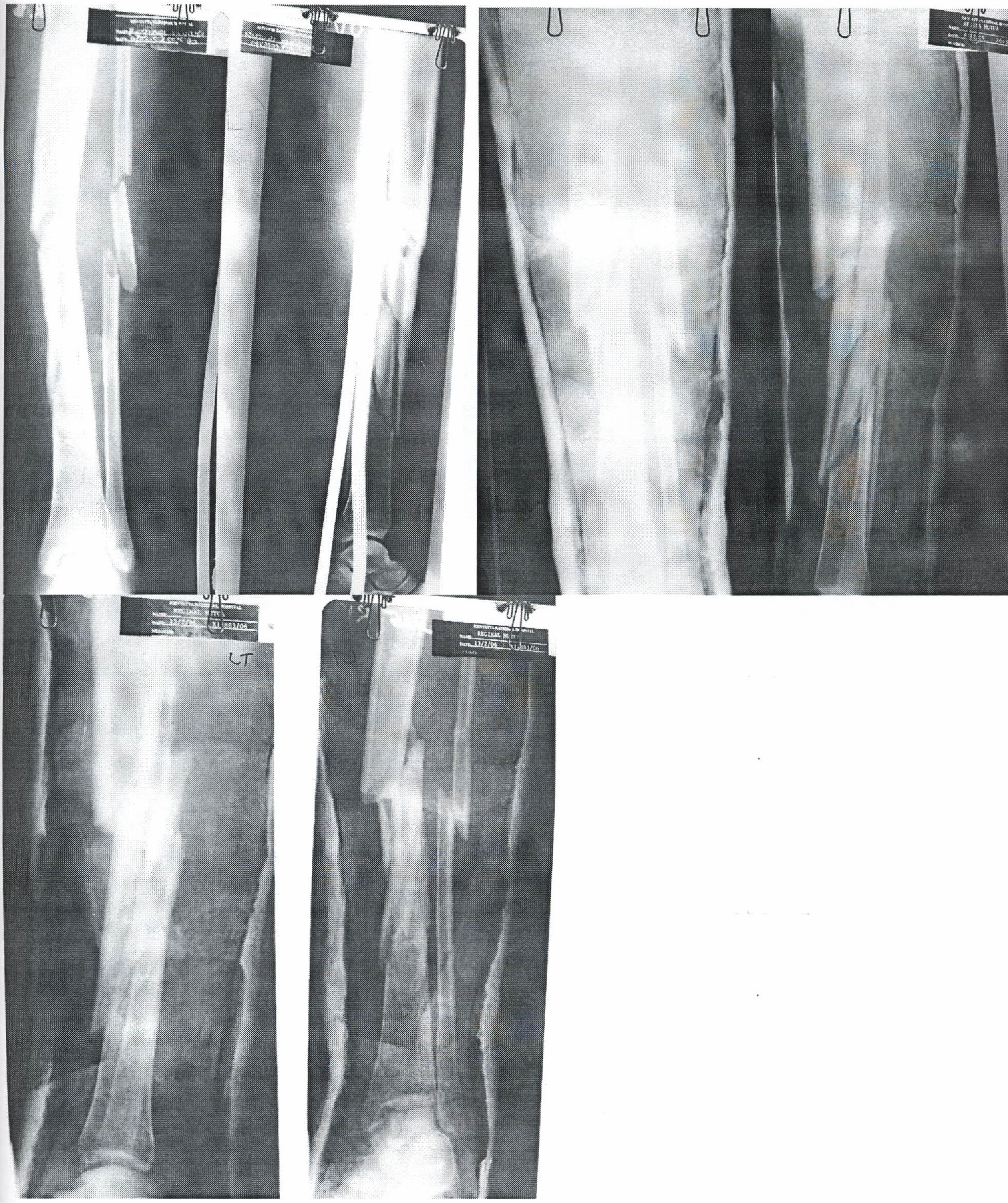
The above X-rays were taken from a 30 year old male who was involved in a RTA sustained Gustilo I injury; the wound remained clean and union occurred after 17 weeks.

Picture i



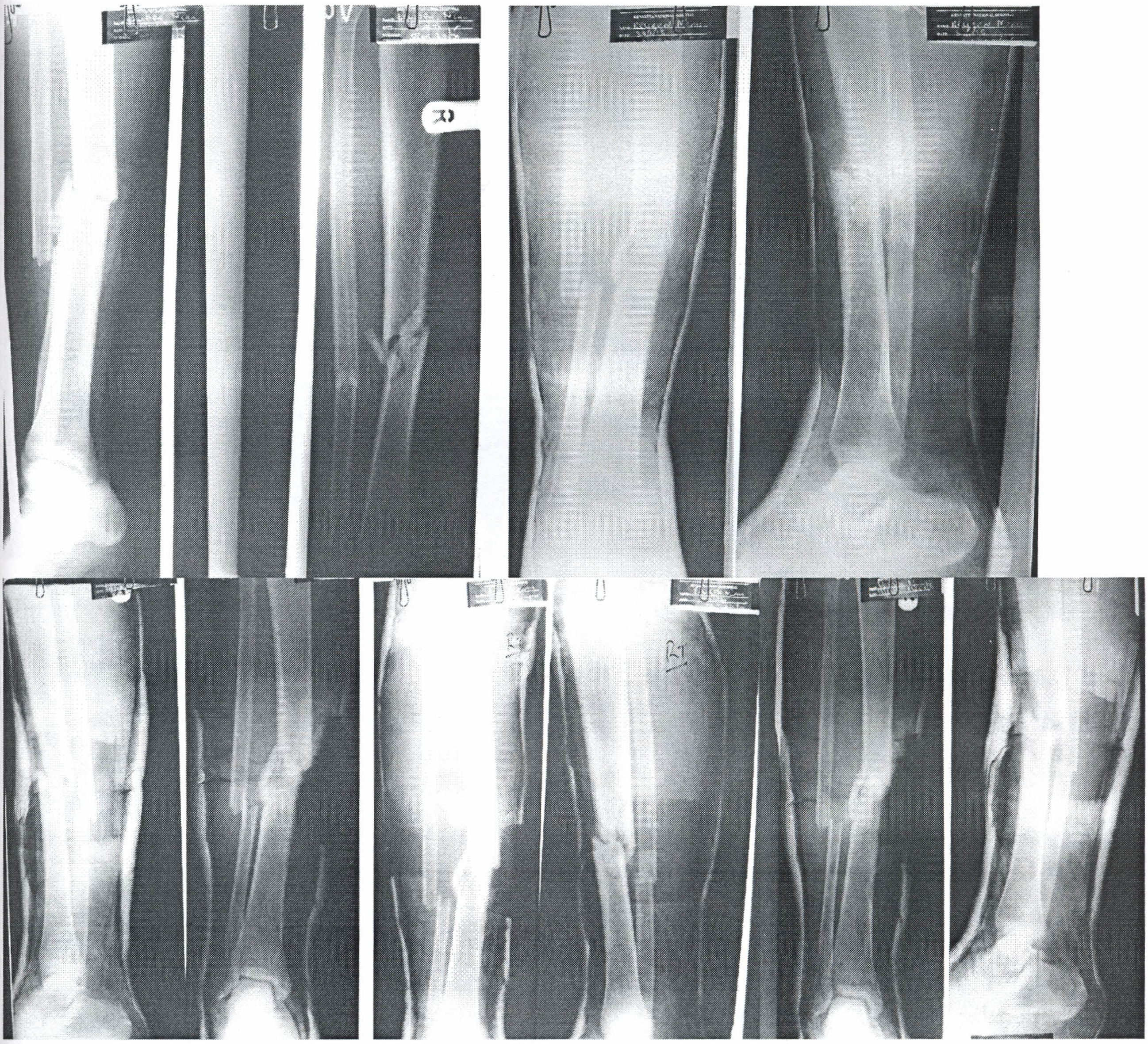
These X-rays were taken from a 32 year old male victim of RTA who suffered Gustilo II injury, the wound was never infected and union occurred by 13 weeks.

Picture j



These X-rays were taken from a 36 year old female who was involved in an RTA sustained Gustilo II type of injury however the wound remained clean; union occurred after 14 weeks.

Picture k



These X-rays were taken from a 45 year old male involved in a RTA who sustained Gustilo I injury though the wound remained clean. Due to poor alignment and angulation a wedge was created on the cast with minimal improvement and union occurred at 19 weeks

DISCUSSION

The indication for non-operative management of tibial shaft fractures include, minimal soft tissue injury, type 0 and 1[57]. Stable fracture pattern are defined by coronal angulation of less than 5 °, sagital angulation's of less than 10 °, rotation less than 5 ° and shortening of less than 10mm, the ability to bear weight in a cast or functional brace [15].

90.5% of our patients were male, this compares relatively well with other studies 81.8% [19], 78% [1] and 81.3% [50] male patients.

There was a follow up rate of 60.7% which compares well with Sarmiento 1989 study on functional brace management of tibial shaft fractures in which the follow up rate of patients was (63%) [1]. Though the actual loss to follow up in the Sarmiento study was only 17% with the other 14% not included in the study due to late presentation. The loss of follow up in our study can be attributed to financial reasons and low energy type of injury. It is possible that most of the patients lost to follow up did not have complications and could have altered the results in favor of the simple and Gustilo I injuries.

The majority of the tibial fractures occurred in the 20 to 35 year age group accounting for 65 of the 108 patients followed up which makes 60% of the patients. Forty five percent of these fractures occurred in the 20 to 30 year age group. The 20 to 30 year age group and the 40 to 50 year age groups had the greatest complication rate of above thirty two percent. The fact that the greater part of the fractures were caused by RTA is an indication that the younger more active people travel more or are easier to be found by the roadside hence more prone to accidents.

The dynamic of injury in our study showed that 65.2% of the fractures were caused by RTA, 15.7% assault, 11.8% fall and 4.5% football.

In our study the dynamic of injury was shown to have relevance on the rate of fracture complication with RTA the more likely to cause complications at 38%, assault was related to 23% complication and fall 21%. The fractures sustained from football all healed with no complications. This could be explained by the amount of energy involved in sustaining these fractures. Non complicated RTA fracture had 88.6% union by 18 weeks compared to 44% for complicated fractures. Non complicated assault had 84.6% union by 18 weeks compared to 50% while fall had 91% compared to 0%. These results were significant for RTA and fall P values of 0.00 and 0.011 respectively. Assault with a P value of 0.219 was not significant. Efforts to reduce road accidents and increase road safety and security can go along way in lowering the incidence of fractures especially those sustained through RTA. RTA per se is a significant prognostic indicator for delayed union and complications

Court Brown [(50)] had a distribution of 31.2% RTA, 36% sport with 89% of them due to football that is 32% of the total, 28% fall and 4.8% assault. Yet Bone and Johnson [(19)] had 75% of the fractures caused by RTA, fall and other miscellaneous causes cased 24% and gun shot 1%. This indicates that the causes of these fractures are the same.

Evaluating the fractures according to the geographical distribution; 16.7% were proximal third fractures, 32% middle third and 46% distal third fractures. The geographical distribution pattern of the fractures in this study showed that 50% of the proximal third, 80% of the middle third and 76% of the distal third fractures were united by 18 weeks. The geographical location of the fractures had effect on the complication with proximal third fractures having a higher 44.3% rate, middle third fractures had a rate of 34% and distal third fractures with a lower complication rate of 20%. Of more significance was the rate of union by 18 weeks for complicated fractures and non complicated fractures. The uncomplicated proximal third fractures had union rate of 70% by 18 weeks yet the complicated fractures only had a rate of 37.5%. The uncomplicated middle third fractured had a rate of 95.6% at 18 weeks while the complicated fractures had a rate of 50%. The distal fractures had a rate of union at 18 weeks of 90% if not complicated and 42% if complicated. The P value for distal third fractures for complication and time to union was 0.00; while for middle third fractures were 0.003 Fishers exact test. These results were very significant and show that the geographical location of the fracture influence the rate of complications which influence the rate of union. In literature reports, time to union of proximal third fractures was 18.3 weeks, middle third was 16.6 weeks and distal third was 16.4 weeks. There has been some inconsistency in the report regarding the amount of energy and effect on trauma healing [(1)].

The geographical location of the fracture also contributed to non union with mid shaft fractures being the more prone to non union 11.4% against 5.6% for proximal and 6% for distal third. Fracture of the tibia with intact fibulae have been implicated as a major risk factor for an increased rate of non union and angular mal alignment according to other studies [53] however this variable was unfortunately not evaluated in our study. These results compare well with the 11% proximal third, 43% middle third and 44% distal third fractures in the Sarmiento study [1]. The geographical distribution pattern of the fractures in this series compare well with other reported results in literature [11, 12, 24, 48].

Looked at in terms of geometry 41% were comminuted compared to 31% in the Sarmiento study, 16% were short oblique against 27%, 16% were spiral fractures compared to 20%, 15% were transverse compared to 19% while 12% were segmental compared to 3% in the Sarmiento study [1]. These results compare well apart from segmental and short oblique fractures which have significant variation.

Of the short oblique fractures 93% united by 18 weeks, 89% of the spiral and 78% of transverse fractures also united by 18 weeks. On the contrary 72% of the comminuted fractures and 69% of the segmental fractures had union by 18 weeks. The complication rate was quite high for comminuted fractures 17 of 44 (38%), segmental fractures 5 of 13 (38.5%) and transverse fractures 6 of 18 (33.3%). The complication rate for the short oblique fractures was 26% and 11% for the spiral fractures. These are probably due to the higher energy needed to cause these fractures compared to the energy employed to cause short oblique and spiral fractures.

Twenty-two of 27 (81.4%) comminuted fractures united by 18 weeks with no complications. Only 5 of 27 comminuted fractures united after 18 weeks without complications. Of the 17 comminuted fractures which developed complication 6 (35%) had union by 18 weeks and 11(67%) had union after 18 weeks P value of 0.003 Fishers exact test. For segmental fractures the P value was 0.005 with 12 uncomplicated fractures all uniting by 18 weeks while for the six complicated fractures only two united by 18 weeks, the other four had union after 18 weeks. These results show that the comminuted and segmental fractures had a significant number of cases uniting after 18 weeks or not at all. The same analysis was not significant for transverse, short oblique and spiral fractures. The fracture geometry is a variable which had direct relevance on complication and time to union. In a study with functional braces, it was found that transverse fractures took 14.9 weeks to unite, oblique fractures took 14.6 weeks to unite, spiral fractures and segmental fractures took 17 weeks to unite.

Considering the Gustilo classification, closed fractures formed 58% of the 108 followed up while 42% were open of which 22% were Gustilo I and 20% Gustilo II injuries. In our study simple fractures had lower complication rate of 25% compared to compound fractures; Gustilo I with a complication rate of 41.7% and Gustilo II fractures with a complication rate of 38%. 95.7% of the uncomplicated simple fractures united by 18 weeks while only 25% of the complicated simple fractures united by 18 weeks. This was a highly significant result P value of 0.00 Fishers exact test. 71.4% of the uncomplicated and 60% of the complicated Gustilo I united by 18 weeks and 84.6% of the un complicated and 50% of the complicated Gustilo II fractures had union by 18 weeks. These results were not statistically significant P value of 0.439 and 0.115 for Gustilo I and II respectively.

In a 1989 study (1) of patients with tibial shaft fractures there were 69% closed, 10% Gustilo I and 12.5% Gustilo II. Of 539 patients with closed tibial shaft fractures, union occurred averagely after 17.4 weeks. Of the 78 patients with Gustilo and Anderson Grade I open tibial shaft fractures union occurred after 18.3 weeks. In 97 patients with open Grade II fracture union occurred after 24.7 weeks. Gustilo therefore, recommended combining Grade I and closed tibial shaft fractures in the same management categories (1). In another study of 1990 the mean time to union was found to be 16.9 weeks for 114 closed tibial shaft fractures and 15.1 weeks for 11 Gustilo grade I open tibial shaft fractures. More significant the mean time to union of 16 Schering type 0 closed tibial shaft fracture was 12.5 weeks, 59 patients with Schering type 1 averaged 16.2 weeks while 30 patients with type 2 averaged 18.7 weeks(7). Puno et al (35) reported an average of 15.3 weeks time to union for a plaster cast. The corresponding figures for 41 Grade I and II Gustilo and Anderson Fractures was 15.2 and 23.5 weeks respectively.

The majority of fractures sustained 63% were displaced, another 18% were clinically and radiologically unstable but not displaced while 19% were stable. The displaced fractures had the greatest complication rate of 35.8% while unstable and stable fractures had complication rates of 25% and 23.53% respectively. Displaced fractures had 77% union by 18 weeks, 92% union by 24 weeks and 95% union over the whole follow up period. Unstable fractures had 87% union by 18 weeks and 100% union by 24 weeks while stable fractures had 81% union by 18 weeks and 100% union by 24weeks. In this study the fracture displacement was a major contributor to non union with a P value of 0.001 Pearson chi square. These results show that displaced fractures are more likely to heal with complications whereas there is not much difference in complication rate between the stable and unstable fractures. Union still occurs in displaced fractures however with complications, it takes longer time.

The infection rate in this study was 6.6% compared to reported rates ranging from 0% through 1.6 [(52)] to 6% with an average of about 4% [(1)]. Litternberg [(57)] in a meta-analysis study on closed tibial shaft fractures found median value of both deep and superficial infection of 0% with a range from 0% to 4% for superficial and 0% to 2% for deep infections. However it is important to note that none of these patients had deep infection even though the follow up period was short.

Fractures with alignment of 25% or less developed complications at a rate of 87.5%, fractures with 25 to 50% alignment developed complications at a rate of 46%. The complication rate was 30% and 17% for alignments of 50 to 75% and over 75% respectively. These results were statistically significant with a P value of 0.001 showing that alignment of 25% or less is an important contributor to complications.

The fractures with AP and Lateral angulations of above 7.5° developed complications at a rate of 87.5% and 84.6% respectively. The fractures with AP and Lateral angulations of 7.5° and below developed complications at a rate of 27% and 24% respectively. These results were statistically significant with P values of 0.001 and 0.00 respectively, showing that fractures with AP and Lateral angulations of above 7.5° are more prone to healing with complications than angulations of less than 7.5°.

The mean time to union of 15.85 weeks with a healing range of 4 to 38 weeks in this study compares very well with reported data. More significantly in this study the mean time to union for non complicated fractures was 13.73 weeks while the mean time to union for complicated fractures was 18.31 weeks. The union rate was 71.4% at 18 weeks and 81.5% at 20 weeks of the fractures analysed. In this study comminuted and segmental fractures took the longest time to unite with 72% and 78% respectively uniting by 18 weeks. A review of literature shows union times of 15.3 weeks [(50)] to 19.4 weeks [(51)] with a healing range of 6 to 40 weeks [(1)] following plaster cast treatment. Litternberg et al [(57)] had a median union by 20 weeks of 84.7% and a range of 56-100% in his meta-analysis of 6 different groups and a total of 664 patients. They [(57)] showed a median time to union of

14.7 weeks with a range of 12 to 18 weeks. Hooper [2] had a union rate of 76% union by 20 weeks for conservatively managed patients.

These show that there is not much difference between the outcome in our set up and in other areas of the world. The time to union is fundamentally influenced by the personality of the fracture especially fracture geometry; segmental or comminuted fractures, initial displacement of the fracture; alignment, lateral and AP angulations and extent of damage of the soft tissue.

Studies indicate that the initial degree of displacement of the fractures is the predictive value of the degree of final deformity after treatment. The factors that were in one way or the other related with union are comminuted and segmental fracture pattern which was associated with a longer time to union. In this study the high energy trauma fractures depicted by RTA, comminuted and segmental fractures and displacement contributed to the rate of union.

Other studies have had conflicting results on the relevance of level of energy on rate of union. In one study it was shown that there was no difference between low and high-energy trauma. However, in another study the high-energy trauma was a predominant consideration. The initial displacement was also found to play a big role with the time to union of tibial shaft fractures in displacement of only half diameter taking place after 18.5 weeks and those more than half diameter initial displacements taking up to 25.6 weeks [11, 12, 24, 48].

The complication rate was quite high with 39 of 108, 36% having complications which included 8 (7.4%) non unions during the period of study, 19 (17.6%) mal unions, 10 (9.26%) delayed unions, 4 (3.7%) limb shortenings more than 2 cm and two (1.85%) rotational mal alignments. However, for the analysis of the results; the 19 mal unions, the 10 delayed unions, 4 limb shortenings, 2 rotational mal alignments and the 8 non unions were lumped together as complications.

The non union rate of 7.4% in this study falls close to the reported average non union rate of 8% [10, 14] and within a reported range of 6 to 12% [1, 35, 52] however Haines[11] grafted 18.6% of closed fractures at 16 weeks. The geographical distribution of the fractures and displacement were contributors to delayed union. Litternberg [57] found a median non union value of 1.1% with a range of 0 to 13%. The non union rate had been found to be dependent on the grade of open fracture [50], the severity of soft tissue injury [18], the mechanism of injury and degree of comminution [10].

Table III of Comparative Studies between Intramedullary locking nail and conservative casting of Tibial shaft fractures

thor	Study type	Treatment modality	No. of fractures	Energy L/H	Infection	Mal Union	Del. Union	Non Union
landani 0	Prospective	Unreamed IMLN	27	21/6	0%	4%	22%	4%
landani 0	Prospective	Cast	12	8/4	0%	25%	66%	0%
npleton 0	Retrospective	Reamed & Non reamed IMLN	12	12/0	2%	0%	41%	
npleton 0	Retrospective	Cast	44	44/0	0%	9%	7%	
e 1997	Retrospective	Reamed IMN & IMLN	47	Not defined	0%	2%	Not defined	2%
e 1997	Retrospective	Cast	52	Not defined	0%	27%	Not defined	10%
1990	Prospective	IMLN	43	21/12	7%	Not defined	2%	0%
1990	Prospective	Functional Brace	35	22/13	3%	Not defined	14%	6%

In this study the rate of mal union was 17.6%. Van der Warken et al [39] reported a malunion rate of as much as 50% while Haines [11] reported a rate of 25%, Sarmiento [12] reported a rate of 22% and Oni[52] reported a rate of 21%. After functional bracing Digby [36] reported a mal union rate of 10%.

Literature suggests that if the fracture does not meet criteria for acceptable alignment and more than one or two reductions are required to maintain acceptable alignment or if the fracture shortens more than 15mm non-operative treatment should be abandoned. This together with the possibility of using an image intensifier would seem to suggest that a trial of closed reduction can be done on closed fractures however if the post casing results are not acceptable then the patients can be converted to surgical management however the problem with this criteria is the time wasted and the costs involved which would skyrocket. The ideal would be to use the indications as provided in the first paragraph. It is important to note also that most of our patients who were recommended for change into surgical management did not undergo surgery either because they declined or for lack of theatre space hence ending up with mal union.

It is evident however, that there is no treatment modality that can be generalized to be the best for the low energy tibial shaft fractures. The universal problem of finance in the healthcare system also forces physicians to take account of economic consequences in making a choice between different modalities of treatment. Many of our conservatively managed patients were lost to follow up for economic reasons some of the patients could come to the clinic but were unable to do X-rays. In a health care provider where most patients cannot afford plaster cast and check X-ray let alone the intramedullary nail or the lock nail, many patients are managed conservatively and even then follow up is not easy. A number of patients report later with complications that would have been identified earlier and re manipulated with very satisfactory results.

In a study conduced by Bostman(13) overall rate of retention of fracture position after successful reduction was only 42%. Yet in other studies (18, 54) the significance of the whole concept of fracture displacement was questioned arguing that the displacement after injury is different from what is seen on the X-rays at emergency department. Complications of tibial shaft fractures can be attributed to the fracture personality or to the management of the fracture. Comparison of management of tibial shaft fracture has been difficult in that the characterization of the injury severity and patients is inadequate and cannot be standardized. In this study some of the fractures had a change in the level of coronal and lateral angulation and even fracture displacement this could be attributed to the dynamisation at the site of the fracture and instability of the fracture.

CONCLUSION

Fracture alignment < 25% is an important prognostic indicator for complications and delayed union P value of 0.001 Fishers exact test, hence patients who have this kind of alignment require open reduction and internal fixation.

Anteroposterior and lateral angulations are also important prognostic indicators for complications p value of 0.00 for lateral angulation and 0.001 for anteroposterior angulation >7.5° by Fishers exact test hence, patients who have this kind of angulation require open reduction and internal fixation.

Comminuted and segmental fractures take longer time to unite and have a greater complication rate. Such fractures require the evaluation of dynamic of injury, alignment, angulation, to asses for need for open reduction and internal fixation. Short oblique and spiral fractures take shorter time to unite and have a lower complication rate.

The geographical location of the fracture is an important prognostic indicator for union by 18 weeks. Complicated distal third fractures are likely to unite after 18 weeks while the non complicated fractures are likely to unite before 18 weeks. The middle third fractures are also more likely to unite by 18 weeks if not complicated and after 18 weeks if complicated. It would therefore be necessary to take this as one of the important variables to be considered when evaluating patients for appropriate management criteria

RECOMENDATIONS

1 The results of this study can be used to generate a protocol for conservative management of fractures of the tibial shaft. The fracture geometry; comminuted and segmental, alignment < 25% and angulations > 7.5° need reduction and internal fixation. Proximal third fractures also need to be subjected to internal fixation.

2. Understanding the economic implications of open management of tibial shaft fracture in our set up, it would appear necessary to use the results obtained from this study and subsequent studies to be guidelines on which patients require open reduction from the onset. This would reduce the costs of long term patient follow up, eventual operative management and complications.

3. A study needs to be done that looks at each of these variable separately to determine the most significant variables in predicting poor prognostic outcome of conservatively managed patients. A multi-centre randomized study with a longer period of follow up would also be appropriate to determine medium and long term complications associated with these fractures e.g.; joint stiffness and pain and functional characteristics of the limb.

4. More aggressive campaign needs to be put on road safety to reduce to the minimum RTA trauma since this is the main cause of complicated fractures in our set up.

5. To avoid high loss to follow up future studies should be well financed so that patients who can not afford investigations and finances for follow up would benefit from such financing.

REFERENCES

1. **Sarmiento, A., Gersten, L.M., Sobol, P.A., Shankwiler, J.A. and Vangsness, C.T.** Tibial shaft fractures treated with functional braces, experience with 780 fractures. J Bone and Joint Surgery. 1989; 71 – B: 602 – 609

2. **Hooper, G.J., Keddell, R.G. and Penny, I.D.** Conservative management or closed nailing for tibial shaft fractures, a randomised prospective trial. Journal of Bone & Joint Surgery 1991;79: 1336-41

3. **Alho, A., Benterud, J.G., Hogevold, H.E. and Ekeland, A.** Comparison of functional bracing and locked intramedullary nailing in treatment of displaced tibial shaft fractures. Clinical Orthopedic 1992; 277: 243-50

4. **Bone, L.B., Sucato, D., Stagemann, P.M. and Rohrbacher, B.J.** Displaced isolated fractures of tibial shaft treated with a cast or intramedullary nail, an outcome analysis of matched pairs of patients. Journal of Bone & Joint Surgery 1997; 79A: 1336 – 41

5. **Praemer, A., Furner, S. and Rice, D.P.** Musculoskeletal conditions in the United States. American Academy of Orthopaedic Surgeons 1992; Park Ridge, IL

6. **Leach, R.E. Fracture of the Tibia and Fibula. Rockwood, C.A. Jr and Green, D.P. (Eds).** Fractures, JB Lippincot Philadelphia 1975; vol. 2: pp 1593 – 1663.

7. **Court Brown C.M, Keating J.F and Mc. Queen M.M.** Infection after intramedullary nailing of the tibia. Incidence and protocol for the Management, J Bone and Joint Surgery 1992; 74 – B: 770 – 4

8. **Dawning, N.D., Griffin, D.R. and Davis, T.R.** A comparison of the relative costs of cast treatment and intramedullary nailing for tibial diaphysial fractures in the UK. Injury 1997; 28: 373 – 5

Project design

Appendix 1 Tibial shaft fracture study questionnaire

Patient name...................................... Age.......... Sex....

IP/OP No...................................... Study No...................

Dynamic of injury

RTA................. Fall from a height............... Gun shot...........

Assault........................ Others (specify)...........................

Fracture location

Proximal third............ Mid third............... Distal third..............

Type of injury

Simple fracture

Transverse.................. Short oblique.......................... Spiral................................

Comminuted...........

Compound fracture

Gustilo I compound fracture.............

Transverse.............. Short oblique............ Spiral......................

Comminuted............ Segmental.................

Gustilo II compound fracture....................

Transverse........ Short oblique......... Spiral......................

Comminuted.......... Segmental.............

X-ray results

Stable fracture..............

Unstable fracture..........

Fracture displaced.................. Fracture not displaced...................

Type of management

Plaster of Paris after blind manipulation by plaster technician...............................

Plaster of Paris after blind manipulation by a doctor (Registrar/ Consultant)...........................

Plaster of Paris after manipulation under Image Intensifier by a doctor (Registrar/ Consultant).................................

For compound fractures Gustilo I and II

Full Haemogramme and differential count

Surgical toilette and antibiotics before proceeding to the above management and fashioning a window for dressing of the wound

Post Plaster of Paris check x-ray results

After two days

Is the wound clean or infected Clean........... Infected...............

If infected, WBC results..................

Is repeat surgical debridement done Yes............ No...............

Check x-ray results

Alignment.............. Angulation in degrees $<7.5^{\circ}$......... $>7.5^{\circ}$.........

Is re manipulation necessary? Yes......... No.........

If the answer to the above is yes;

Is the Image intensifier necessary for re-manipulation? Yes……… No……..

Post re-manipulation results after check x-ray

Alignment.............. Angulation in degrees <7.5°......... >7.5°........

At one week

WBC results……Differential count Neut….. Lymp….. Mono…. Eosi….

Condition of the Plaster of Plaster of Paris

Tight…………….. Lose………………… Worn out………………

Normal……………

Is reapplication of Plaster necessary? Yes………… No…………..

Check x-ray results

Alignment.............. Angulation in degrees <7.5°......... >7.5°.........

At six weeks

Check x-ray results

Alignment.............. Angulation in degrees <7.5°......... >7.5°.........

Callus formation Yes............. No..........................

Limb shortening >2cm Yes............. No..........................

Is change in the management necessary? Yes…………… No……………..

At twelve weeks

Check x-ray results

Alignment………….. Angulation in degrees <7.5°…….. >7.5°……….

Callus formation Yes............. No..........................

Limb shortening >2cm Yes............. No..........................

Is the fracture united? Yes……….. No………………...

Is change in the management necessary? Yes…………… No……………..

At eighteen weeks

Check x-ray results

Alignment…………… Angulation in degrees <7.5°…….. >7.5°……….

Callus formation Yes............. No..........................

Limb shortening >2cm Yes............. No..........................

Is the fracture united? Yes……….. No………………...

Is change in the management necessary? Yes…………… No……………..

Appendix 2: The Estimated Financial cost of the Study

Plaster of Paris @ shs1000, quantity 200 Total 200,000

Plain x-rays 6, @ shs500 i.e. shs3000 per patient, Total 3000 x 150 = 450,000

Image intensifier @ shs3000, quantity 40 Total 120,000

Laboratory investigations @ shs500, quantity 200 Total 100,000

Stationery

Plain paper 10 rims @ shs500 total 5000

Photocopy 6 x 200 = 1200 x 2 = 2400

Computer and printer 45000

Book binding @ 700 x 5 = 3500

Statistician services 20000

Floppy disks and compact disks 1500

Total cost Shs 947, 400

Appendix 3 Patients consent to join the study

Letter of request for consent

Dear Patient,

I am Dr Oburu G. Jagero a surgical registrar. This is to inform you that we are conducting a study on fractures of the tibial shaft, the objective of this study is to determine if the way we currently manage these fractures is the best possible or if there are avenues for improvement in the fracture management. The other objective is to look at the distribution of gravity of these fractures and the possible most appropriate way of managing them conservatively.

We hope to enroll patients who accept to participate in this study in this study once recruited in the study you may be managed using any of the procedures either using the exact way in which we have always treated fracture patients i.e. placing a plaster after fracture reduction by the orthopedic technologist and then be followed up by the study team. Or the patient will be managed by reduction and plaster placement.

The benefits of this study to you individually is that there will be close follow up of your management and appropriate intervention should the need arise. To the community at large, this study could lead to a change in the policy on the treatment of these injuries.

Your participation in this study is voluntary and your refusal to participate will not alter in any way the treatment given to you. The purpose of this letter is to explain what the study involves and benefits to you as an individual and the community at large and to ask you to join the study so that we can try to improve the results of treatment of such injury in our community.

If you agree to participate in this study, I will kindly request you to endorse the attached form for the records. You are free to ask any questions touching on this study now or at any other time in the course of the study. You are also free to withdraw from the study at any time if you have reasons to. In case of any enquires on this study, you can contact the following

Dr Oburu G Jagero Tel. 0722-740103

Yours truly

Oburu Gilbert Jagero

Study coordinator.

Patients Consent form

I patient name………………………………………………… of P.O. Box …………..
Do hereby consent to join the study on conservative management of Tibial shaft fractures; I accept to be managed according to the modalities of the study; the nature, the relevant risks and benefits of which has been fully explained to me by Dr Oburu G. Jagero who is conducting the study. I therefore give informed consent.

Patients signature…………………………………..   Dated………………..
I have adequately explained to the above patient all the issues pertaining to the study and given the opportunity to ask any questions or clarifications.

Signed……………………………………….   Date…………………

Appendix3 Fomu linalo kamiliswa na wagonjwa walio kubali kutumiwa kwenye utafiti hili.
Mimi (Jina la mgojwa)………………………………………………….wa S.L.P……… Nimekubali kutumiwa katika masomo ya utafiti wa conservative management of Tibial shaft fractures. Nimekubali kutibiwa kulingana na tibabu inalo tumika kwenye utafiti ili. Nimekubali kutumiwa kwa utafiti hili licha ya mabaya ao mazuri yanayo weza kutokea kulingana na vile nimeelezewa na Daktari Oburu G. Jagero , ambaye anafanya utafiti hili. Kwa hivyo, nimekubali.

Sahihi la mgonjwa……………………………………………   *Tarehe………………*

Appendix 4

The Table IV below shows the Tscherne and Öestern classification of soft tissue injuries

Öestern and Tscherne classification of closed fractures	Öestern and Tscherne classification of open fractures
Grade O – Indirect injury with minimal soft tissue damage	Grade I – Low energy puncture wound with no skin contusion and negligible contamination
Grade I – Low to moderate energy with skin abrasion and contusions	Grade II – Moderate energy small wound with small skin contusion and moderate contamination
Grade II – High energy injury with muscle contusion and contaminated skin abrasions	Grade III – High energy large wound with extensive skin contusion and severe contamination
Grade III – High energy injury with degloving of the skin and at times associated with compartment syndrome or possibly arterial injury.	Grade IV – Incomplete amputation

Appendix 5

Table V below shows the Gustilo and Anderson classification of open fractures of the tibial shaft

Grade I	Laceration less than 1cm in length which is in most cases bone prick from the fracture segment. Clean wound with simple bone injury and minimal soft tissue injury.
Grade II	Laceration more than 1cm but less than 10cm that is not or moderately contaminated, moderate bone injury or some comminution and moderate soft tissue injury or some muscle crushing and will not require flaps
Grade III	Injuries: Segmental fractures, severely contaminated wounds (e.g. farmyard injuries), short gun wounds.
Grade IIIA	Laceration more than 10cm with adequate soft tissue coverage, high contamination severe bone injury with no periosteal striping
Grade IIIB	Grossly contaminated with severe bone trauma, soft tissue laceration of more than 10cm requiring local or free tissue grafting to obtain coverage

Appendix 6

Table VI Teflon modified tibial fracture classification Extent of injury

ury Characteristic	Minor	Moderate	Major
cture displacement	< 50%	> 50%	Tibia or fibula displacement
mminution	Minimal	0 – 1 Butterfly fragment	> 2 free fragments or segments
und grade			
sed	0	I	II or III
en	I	II	III or IV Tscherne IIIa – IIIc Gustilo Anderson
rgy	Low	Moderate	High
cture Pattern	Spiral	Oblique or Transverse	Transverse or fragmented

Appendix 7 mangled extremity severity score *Table VII*

Another system of classification is the Mangled Extremity Severity Score (MESS) based on the severity of skeletal and soft tissue injury, limb ischemia, shock, and patient's age.

Mangled Extremity Severity Score (MESS)	
Skeletal / Soft tissue injury	**Score**
Low energy (stab; simple fractures; Pistol gun shot wounds)	**1**
Medium energy (open or multiple fractures, dislocation)	**2**
High energy (high speed RTA or rifle gun shot wounds)	**3**
Very high energy (high speed trauma and gross contamination)	**4**
Limb Ischemia	
Pulse reduced or absent yet perfusion is normal	**1***
Pulse less, paresthesia, diminished capillary refill	**2***
Cool, paralyzed, insensate, numb	**3***
Shock	
	0
Systolic BP always >90mm	
	1
Transiently hypertensive	
	2
Persistent hypotension	
Age	
	0
Less than 30	
	1
30 to 50	
	2
Above 50	
* Score doubled for Ischemia of over 6 hours	