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Analysis of Delayed Fracture Healing following Unreamed Tibial Nailing

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To My Parents

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List of Abbreviations

ANOVA: Analysis of Variants

AO: Arbeitsgemeinschaft für Osteosynthesefragen

AP: Anteroposterior

ARDS: Adult Respiratory Distress Syndrome

ASIF: Association for the Study of Internal Fixation

ATLS: Advanced Trauma Life Support

BA: Bicycle accidents

BKA: Below Knee Amputation

CRP: C-reactive Protein

CT: Computerized Tomography

DLS: Distal locking Screws

DU: Delayed Union

DVT: Deep Venous Thrombosis

ESR: Erythrocyte Sedimentation Rate

FFLS: Fatigue Failure of the Locking Screws

FIG.: Figure

FU: Follow Up

ICBG: Iliac crest Bone Graft

ICU: Intensive Care Unit

ILN: Interlocking Nail

IM: Intramedullary

IMN: Intramedullary nail

IV: Intravenous

Kg: Kilograms

LC-DCP: low contact dynamic compression plate

LLD: Leg Length Discrepancy

MCA: Motor Cycle Accident

MM: Millimetres

MOF: Multiple Organ Failure

MU: Malunion

MVA: Motor Vehicle Accidents

n: Number

NB: Note bene

NSAID: Non-steroidal anti-inflammatory drugs

NU: Non-union

OA: Osteoarthritis

ORIF: Open Reduction and Internal Fixation

OTA: Orthopaedic Trauma Association

P: Proximal

PDS: Polydioxanone

PE: Pulmonary Embolism

PLS: Proximal locking screws

PM: Proximal-middle

PMVA: Pedestrian versus motor vehicle accident

RTN: Reamed Tibial Nail

ROM: Range of Motion

ST: Soft Tissue(s)

TAN: Titanium

US: Ultrasound

UTN: Unreamed Tibial Nail

1. Introduction

Despite significant advances in fracture care, the management of unstable fractures of the tibial shaft remains controversial (Watson, 1994). Such fractures are commonly associated with severe soft tissue injuries, which often lead to a high rate of complications, such as malunion, non-union, and infection (Ellis, 1958; Nicoll, 1964; Smith, 1974; Trafton, 1988; Rommens et al., 1989; Watson, 1994; Greitbauer et al., 1998; Bhandari et al., 2000; Gaebler et al., 2001). Significant advances have been made in the last century in the management of both open and closed tibial shaft fractures through a better understanding of the biologic respect for the soft tissues and biomechanical properties of the implants.

Intramedullary nailing has revolutionized the treatment of long bone fractures, and, in the past few decades, has gained universal acceptance. The case for this technique has been strengthened by the advent of interlocking techniques. The advantages of intramedullary fixation include early stable fixation, early joint mobilization, and preservation of the soft tissues at the fracture site. Many patients also have other major injuries, making early fracture fixation desirable for both nursing and rehabilitation management (Angliss et al., 1996). Over the years, shift has been made away from intramedullary devices that do not control axial deformation, such as unlocked centromedullary nails and Ender type devices, to interlocking nails. Locked intramedullary nailing currently is considered the treatment of choice for most types I, II, and IIIA open and closed tibial shaft fractures. It is especially useful for segmental and bilateral fractures. The ability to lock the nails proximally and distally provides control of length, alignment, and rotation in unstable fractures and permits stabilization of fractures located below the tibial tubercle or 3-4 cm proximal to the ankle joint.

Canal reaming allows the surgeon to insert larger diameter nails, which in virtue of their larger size provide better fracture stability (Fairbank et al., 1995) and more secure filling of the medullary canal. In addition, reaming has a “bone graft” effect. Furthermore, surgeons may be more comfortable allowing early weight bearing when stronger, better-fitting nails with larger locking bolts have been used for fixation (Alho et al., 1990).

Misgivings have however been expressed regarding the ill effects of intramedullary reaming with particular emphasis on the disruption of the endosteal blood supply with thermal injury to the bone (Rheinelander, 1974; Kessler et al., 1986; Klein et al., 1990, Whittle et. al, 1992; Grundnes and Reikeras, 1993). This is thought to compromise bone which is already partly devascularized and problems such as increased rates of non-union (Chapman, 1986;

Habernek et al., 1992), and infection (Smith, 1974; Bone and Johnson, 1986; Court-Brown et al., 1992; Jenny et al., 1994) compared with non-operative techniques have been reported.

The introduction of unreamed small diameter nails in the treatment of open and closed tibial fractures with severe soft tissue damage has reduced these complications. The absence of reaming minimises the trauma of nail insertion, thereby offering the theoretical advantages of less blood loss, decreased operative time, preservation of the endosteal blood supply which provides a favourable environment for early bone healing and less risk of infection, in addition to avoidance of some serious complications associated with reaming, both locally as compartment syndrome and systemically as fat embolism syndrome. The use of an unreamed nail is therefore particularly attractive in open fractures as it combines the advantages of intramedullary fixation in terms of maintenance of alignment and soft tissue management, with minimal damage to the blood supply. It facilitates patient compliance when compared with external fixation. Moreover, subsequent reamed exchange nailing remains an option.

Because of the success of small-diameter interlocking nails for open tibial fractures, several authors have developed series of closed fractures treated with different types of interlocking nails inserted without reaming and at some trauma centers, unreamed nailing has replaced reamed nailing and at others, external fixation (Tornetta et al., 1993; Krettek et al., 1994; Runkel et al., 1996). More recent studies, however, revealed that up to 48% of tibial fractures treated with small-diameter IM nails inserted without reaming require a secondary procedure to achieve union (Whittle et al., 1992; Bone et al., 1994; Riemer et al., 1995; Blachut et al., 1997). Other problems, such as early fatigue failure of locking nails and locking screws were reportedly increased by using small-diameter nails (Cole and Latta, 1992; Court-Brown et al., 1990; 1991; 1996; Watson, 1994; Whittle et al., 1995; Hutson et al., 1995; Keating et al., 1997; Blachut et al., 1997; Alberts et al., 1999; Gaebler et al., 1999). Unfortunately, most of the articles that have dealt with clinical results after unreamed nailing have included only a few dozen cases. The small numbers of patients in these studies has generally prevented evaluation of statistical significances of complications and outcome. An additional problem is the definition of unreamed nailing and small-diameter nails. Small-diameter nails and unreamed nails must be differentiated. Reaming is a technique. A nail of any diameter may be inserted without reaming if the medullary canal is larger than the nail diameter. Small-diameter nails are defined as nails with a diameter of 9 mm or less (Gaebler et al., 2001). The fact that most authors used different protocols and classifications and that certain complications were not even mentioned make a direct comparison of results nearly impossible.

Aim of the Work:

A continuing controversy in the management of long bone fractures is reaming of the medullary canal for intramedullary nailing. Small-diameter unreamed nails have opened a new perspective in the treatment of tibial fractures in polytrauma patients and also in those associated with severe soft tissue injury. Widespread use of such implants in closed fractures, however, has been associated with a reportedly increased complication rate.

The aim of this study is to evaluate the clinical results with the use of unreamed tibial nails in diaphyseal tibial fractures treated in our hospital, to determine the variable that influence fracture union following such procedures, as well as to offer recommendations that would increase the union rate, improve the overall outcome, and decrease the possible complications. The study was designed to address the following questions:

- Do certain patient demographics, injury factors, or fracture variables have a negative impact on fracture healing process or promote development of delayed or non-union?
- Does fracture site cortical contact affect healing of tibial shaft fractures?
- How could the locking pattern used in unreamed nails affect the treatment outcome?
- Which variables contribute to a complicated course or a less than favourable result?

2. Materials & Methods

2.1. Patient Population

In the time period between April 1991 and December 2002, 160 diaphyseal tibial fractures in 158 skeletally mature patients were treated operatively at the department of Trauma, Hand, and Reconstructive Surgery, University of Ulm, a Level I trauma center, using the AO Unreamed Tibial Nail (UTN®, Synthes GmbH, Umkirch, Germany).

The medical records and radiographs of all patients were reviewed to determine the demographic data, injury characteristics, intraoperative and postoperative complications, alignment, implant failures, and times to union . One alcoholic patient with polytrauma aggravated by acute necrotizing pancreatitis died from multiple organ failure (MOF) five weeks after trauma. Six cases were lost to follow up, and 8 had incomplete records or radiographs.

- ***Age and Sex Distribution:***

The study population included 105 men and 53 women (ratio 2:1), who ranged in age between 16 years and 89 years (average 39.5 years). The mean age for males was 37.6 years whereas the mean age for females was 43.4 years. The maximum incidence occurred between 31 and 40 years with 60% of cases occurring in patients before their fifth decade (Tables 1-2).

- ***Side Distribution:***

The study group included 82 patients treated by a UTN for a right tibial shaft fracture (52%), of them two had a contralateral fracture that was treated with a reamed tibial nail (RTN) in one case and by definitive external fixation in the other. In addition, 74 patients (47%) presented with a left tibial fracture, and two male patients (1%) had bilateral UTN-fixed fractures.

2.2. Fracture Classification

According to the fracture site, fractures in the current study were anatomically classified as involving either the proximal, the middle, or the distal thirds of the tibial shaft, junctions inbetween, or as segmental fractures. There were 4 proximal third fractures, 5 fractures involving the junction between the proximal and middle thirds, 37 midshaft fractures, 17 fractures involving the junction between the middle and distal thirds, and 84 distal shaft fractures. Thirteen segmental fractures were also treated, with the fracture lines solely involving the middle third in 2 cases, involving the proximal and middle thirds in 4, the middle and the distal thirds in 3, the proximal and the middle-distal junction in 2, the junctions between the proximal, middle, and distal thirds in 1, as well as all three thirds in an additional 4-level fracture (Table 3).

All fractures were classified using the AO/ASIF classification of long bone fractures proposed by Müller et al. (1990) and adopted by the adopted by the Orthopaedic Trauma Association (OTA). About half of the fractures (78 cases) were simple type A fractures (41 type-A1, 16 type-A2, and 21 type-A3), 65 wedge type B fractures (15 type-B1, 30 type-B2, and 20 type-B3), and 17 complex type C fractures (2 type C1, 13 type-C2, and 2 type-C3) (Tables 4-5; Fig. 1).

Fractures were also classified using Winquist et al. (1984) criteria, applied to tibial fractures by Henley (1989). There were 41 (25.6%) Winquist type-0 (no comminution), 47 (29.4%) type-I (minimal comminution), 32 (20%) type-II (larger comminution but with at least 50% cortical contact), 23 (14.4%) type-III (50%-100% of the circumference is comminuted), 4 (2.5%) type-IV (all cortical contact is lost), and 13 (8.1%) segmental fractures (Table 6; Fig. 2)

There were 115 closed (72%) and 45 open (28%) fractures. Soft tissue injury for closed fractures was classified according to the Tscherne and Gotzen classification (Table 7). There were 25 fractures without soft tissue injury, 52 fractures with grade I, 28 fractures with grade II, and 10 fractures with grade III closed soft tissue injury. Open fractures were classified according to the criteria of Gustilo and Anderson (1976) and Gustilo et al. classification (Table 8) as type I (21 fractures) type II (13 fractures), and type III (11 fractures) respectively (Table 9).

Table 1:

Age distribution of cases (in years)

≤20	21-30	31-40	41-50	51-60	61-70	71-80	>80	Total
19	41	36	18	22	13	7	2	158

Table 2:

Sex distribution of cases

Sex	**Males**	**Females**	**Total**
All patients of the Study	105	53	158
(Percentage)	(66.5%)	(33.5%)	(100%)

Table 3:

Fracture Sites

Proximal (P)	4 (2.5%)
Proximal/Middle (PM)	5 (3.1%)
Middle (M)	37 (23.1%)
Middle/Distal (MD)	17 (10.6%)
Distal (D)	84 (52.5%)
Segmental	13 (8.1%)
Total	**160**

Table 4:
AO classification of fractures according to the fracture sites.
(P: Proximal, PM: Proximal/Middle, M: Middle, MD: Middle/Distal, D: Distal)

Fractures	P	PM	M	MD	D	Segmental	Total
A	1	1	16	8	52	0	**78 (48.8%)**
B	2	3	19	9	32	0	**65 (40.6%)**
C	1	1	2	0	0	13	**17 (10.6%)**
Total	**4**	**5**	**37**	**17**	**84**	**13**	**78 (48.8%)**

Table 5:
AO/ASIF Classification of cases

Fracture Type	1	2	3	Total (%)
A	41	16	21	**78 (48.8%)**
B	15	30	20	**65 (40.6%)**
C	2	13	2	**17 (10.6%)**

Table 6:
Winquist Classification of Fractures

0	41 (25.6%)
I	47 (29.4%)
II	32 (20%)
III	23 (14.4%)
IV	4 (2.5%)
Segmental	13 (8.1%)
Total	**160**

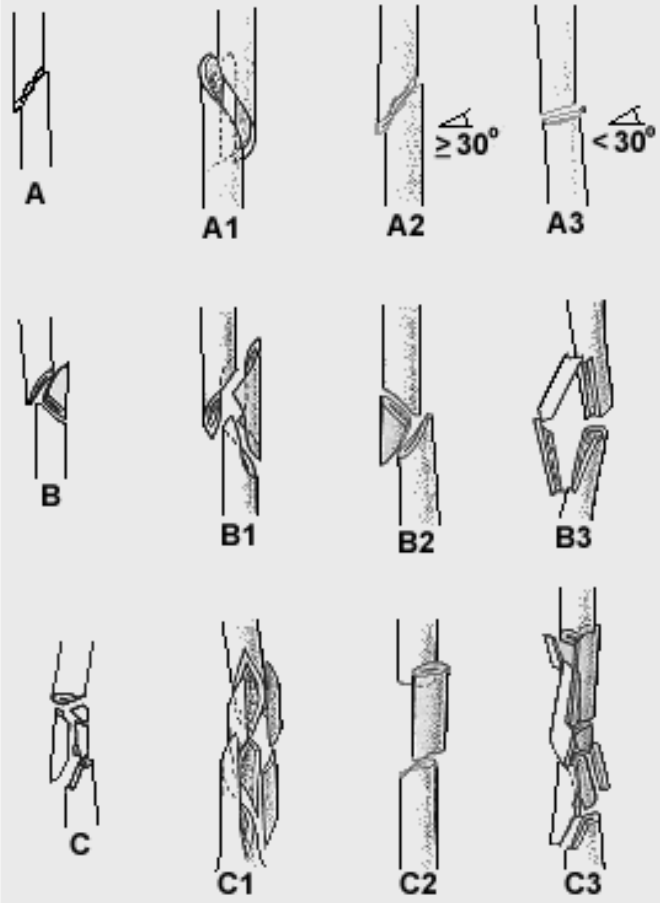


Figure 1: The AO/ASIF classification of long bone fractures (Müller et al., 1990).

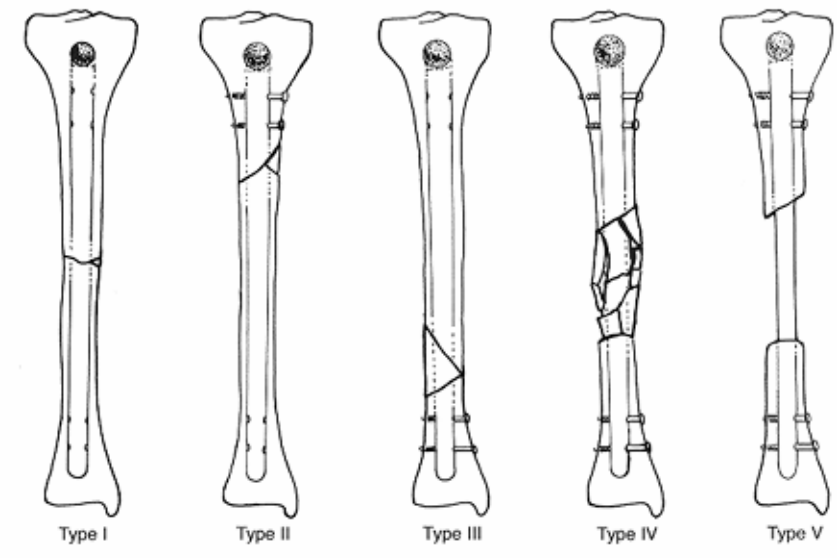


Figure 2: Winquist classification of fracture comminution (Henly, 1989).

Table 7:

Grading of soft-tissue injuries for closed fractures *(Tscherne and Gotzen, 1984).*

Grade 0	Little or no soft tissue injury.
Grade 1	Indirect, contusion from within, superficial abrasion.
Grade 2	Usually direct with deep contaminated abrasion or severe indirect with significant blistering and edema, local contusional damage to skin or muscle, impending compartment syndrome.
Grade 3	Usually direct with extensive contusion or crushing of skin; severe muscle damage, subcutaneous avulsion, decompensated compartment syndrome, or rupture of a major vessel.

Table 8:

Classification of open fractures *(Gustilo et al., 1984).*

Type I	An open fracture with a wound <1cm.
Type II	An open fracture with a laceration >1cm long without extensive soft tissue damage, flaps, or avulsions.
Type III	Either an open segmental fracture, an open wound with extensive soft tissue damage, or a traumatic amputation.
III-A	Adequate soft-tissue coverage of a fractured bone despite extensive soft tissue laceration or flaps, or a high-energy trauma irrespective of the size of the wound.
III-B	Extensive soft-tissue injury with periosteal stripping and bony exposure, usually associated with massive contamination.
III-C	Open fracture associated with arterial injury requiring repair.

Table 9:

Grading of soft-tissue injuries for closed & open fractures

Closed Fracture (Tscherne-Gotzen)					**Open Fracture (Gustilo-Anderson)**			**Total**
0	**1**	**2**	**3**		**I**	**II**	**III**	
25	**52**	**28**	**10**		**21**	**13**	**11**	**160**

2.3. Mechanism of Injury

In this study, the mechanism of injury was a result of a high-energy trauma in 100 patients (64%). Thirty cases (19%) were injured in a motor car accident, 28 (18%) had motor cycle accidents, 2 had bicycle accidents (1%), and 15 (10%) were pedestrians struck by motor vehicles, 2 of them had bilateral fractures. Work accidents were responsible for 15 fractures (10%), mostly because of a falling heavy object. Ten fractures (6%) were caused by high-energy falls from heights of at least 3 meters. Low-energy falls, trips, and twisting injuries accounted for 35 fractures (22%) in our series and was predominant in elderly osteoporotic patients specially females. Sports injuries caused fractures in 18 patients (11%), of them 10 had football injuries, and 8 had skiing, snowboarding, or on-line skating accidents. Direct trauma caused the remaining five fractures (3%) (Table 10).

Table 10:

The Type of Trauma

Type of Trauma	Patients (%)
▪ Minor falls, trips, and twisting injuries	35 (22%)
▪ Motor Vehicle Accidents (MVA)	30 (19%)
▪ Motor Cycle Accidents (MCA) & Bicycle accidents (BA)	30 (19%)
▪ Pedestrian struck by a motor vehicle (PMVA)	15 (10%)
▪ Work Accidents	15 (10%)
▪ Fall from a height	10 (6%)
▪ Sports Injuries	18 (11%)
▪ Direct trauma	5 (3%)
TOTAL	158 (100%)

2.4. Associated Injuries

From the 158 patients included in this study, 79 patients (50%) have additional injuries. Nearly half of them (35 cases) were victims of polytrauma. The most common associated trauma was a head injury occurring in 18 patients (the only associated trauma in 3 cases, with other injuries in 15 cases, and with facial bone fractures in 2 patients). Chest trauma with multiple rib fractures, haemo-, pneumo-, and haemopneumothorax, and lung contusion was present in 16 patients. Blunt abdominal trauma with a spectrum of injuries (liver tears, splenic rupture, pancreatic and renal contusion, and bowel injury) occurred in 10 patients. Eight patients had associated fractures of the spine. Lumbar fractures occurred in 5 patients (2 L1 Burst fractures, 2 L2 chance fractures, and one patient with L4-L5 fractures). One patient had a unstable thoracic spine fractures T5-7 with complete paraplegia, and 2 more had stable cervical spine fractures. Associated foot injuries (tarsal, metatarsal, and phalangeal fractures and dislocations) occurred in 11 patients. The commonest ipsilateral injury was an associated Volkmann's triangle fracture, mostly undisplaced or minimally displaced, associating 13 fractures. Bimalleolar or trimalleolar ankle fractures occurred in 5 patients in the ipsilateral side and in 4 patients in the contralateral side. Bilateral tibial shaft fractures were present in 4 patients, of them 2 were treated using bilateral UTNs, the contralateral side was treated by a reamed tibial nail (RTN) in one case, and by an external fixator in the fourth case. One patient had an ipsilateral lateral tibial plateau fracture with avulsed tibial spine, another had a contralateral plateau fracture, and a third had a contralateral subcondylar tibial fracture. Femoral shaft fractures occurred in 13 patients: 11 on the ipsilateral side, one in the contralateral side and one had bilateral femoral shaft fractures. Two patients had femoral neck fractures, 2 more had trochanteric fractures, 1 had ipsilateral hip dislocation, 4 patients had acetabular fractures, and 6 had associated pelvic fractures.

Fractures of the shoulder girdle occurred in 9 patients in this study, of them 2 had clavicular fractures, 3 had scapular fractures, and 4 had fractures of the proximal humerus. Humeral shaft fractures occurred in 4 patients. Seven patients had fractures and/or dislocations around the elbow. Olecranon fractures occurred in 2 patients. Forearm fractures involving both bones occurred in 4 cases whereas isolated fractures of the ulna occurred in 5 cases. Two more patients had associated distal radius fractures and 4 had associated hand injuries (Table 11).

Table 11:

The various associated injuries and their distribution

▪ Head Injury	18
▪ Chest Trauma	16
▪ Blunt abdominal Trauma	10
▪ Foot Trauma	11
▪ Ipsilateral Volkmann's triangle fracture	13
▪ Ankle Fractures (excl. Volkmann's triangle)	10
▪ Contralateral Tibial Shaft Fractures	4
▪ Tibial Condylar Fractures	3
▪ Knee Soft Tissue Injuries	5
▪ Patellar Fractures	2
▪ Femoral Fractures	13
▪ Pelvic, Hip & Acetabular Fractures & Dislocations	15
▪ Spine Fractures	8
▪ Shoulder Girdle Fractures	9
▪ Humerus Shaft Fractures	4
▪ Elbow Fractures & Dislocations	7
▪ Olecranon Fractures	2
▪ Both Bones Forearm Fractures	4
▪ Ulnar Fractures	5
▪ Distal Radius Fractures	2
▪ Hand Injuries	4

2.5. Preoperative Evaluation

Assessment of patients with diaphyseal tibial fractures follows the traditional methodological system for evaluation of all trauma patients. This includes an accurate history taking, proper physical examination, adequate imaging studies, and pertinent laboratory tests. As these injuries occur often in the context of the multiply injured individual, initial management is usually directed toward general patient stabilization following the principles of Advanced Trauma Life Support (ATLS). This effort should be undertaken prior to any definitive treatment of the tibial shaft fracture other than fracture splinting with a back slab, wound care, if any, and screening radiographs.

After achieving haemodynamic stability, the patients' personal information were taken, and inquiries were made regarding the time, place, type, and mechanism of trauma. It is important to ascertain whether low- or high-energy forces have caused the fracture. Elapsed time is especially important for vascular injuries, compartment syndromes, and open wounds. Certain locales (e.g., barnyards and swamps) are notorious for the presence of virulent microorganisms. The amount of energy involved in causing the injury is perhaps the major determinant of its severity.

Pain, inability of unrestricted weight bearing, and deformity are the hallmarks of a tibial fracture. Pain is the major symptom and is almost always severe and well localized to the fracture site. When the fracture is relatively stable with little displacement or soft-tissue injury, pain may subside if the leg is immobilized; however, motion of the fracture fragments causes a marked increase in pain. Severe, unremitting pain may indicate muscle ischemia. Occasionally a nerve will be caught in fracture fragments so that a particular lancinating pain may be produced by movement of the limb. Absence of sensation can be caused by nerve injury, progressive ischemia, or both. Deformity is usually obvious, giving insight to the fracture pattern.

Baseline medical information were not neglected. Previous injuries to the part and any persisting disability were documented. Exercise tolerance helps identify preexisting limb ischaemia. Activity level, both recreational and occupational, may help set functional goals or suggest an injury resulting from overuse. Any complicating general illness as diabetes mellitus, or conditions such as smoking, alcoholism, or drug abuse were also documented. General medical status includes identification of any allergies to medication, the current or recent use of any medication, known medical problems and previous operations, personal or family history of bleeding disorders, and problems with anesthesia or with frequent or poorly healing fractures.

Patients then underwent a thorough physical and radiographic evaluation to assess fully their injuries. The skin and soft tissues around the fracture were carefully examined for abrasions, bruises, contusions, and lacerations that may delay nailing procedures or interfere with the use of internal fixation hardware. Care was taken to recognize the presence of an impending open fracture. In this case, the fracture must be reduced as soon as possible to prevent further soft tissue compromise, necrosis, and subsequent fracture contamination.

Because the tibia is subcutaneous for the majority of its length, deformity (angulation, shortening, or malrotation) is usually identified readily both visually and by palpation. Local swelling occurs rapidly from bleeding and soft-tissue reaction. Palpation allows localization of tenderness. It may reveal a soft boggy swelling (haematoma) or a degloved area. The leg should not be tested for crepitus, but this is often noted when splints are applied. Fracture stability is one of the first assessments required during examination. An obvious deformity or shortening confirms mechanical instability. Undisplaced fractures may be tested by careful varus or valgus stress testing. Associated fibular fractures may give insight into the degree of initial displacement and also potential for instability.

Impaired perfusion of the injured limb is revealed by skin pallor, coolness, absence of venous and capillary filling, and above all by the absence or significant diminution of palpable pulses. Swelling may indicate venous obstruction or, if rapidly developing, may be the result of arterial hemorrhage. A thrill or bruit suggests an arteriovenous fistula. Proximal tibial fractures may injure the anterior tibial artery as it pierces the interosseous membrane. Crushing injuries may take several days to fully declare their picture. Compartment syndrome is heralded by a tense swelling, an inordinate pain at rest, pain with passive muscle stretch, and hypo- or anesthesia of the skin supplied by nerves in the compartment. An elevated compartment pressure is diagnostic with 30 mm Hg is the threshold indication for fasciotomy. Neurological function, both motor and sensory, for peroneal and tibial nerves must be thoroughly assessed. Paralysis and loss of sensation may be due to ischemia; which must always be excluded specifically whenever neurological abnormalities are found in association.

Because several fractures were the result of high-energy trauma, a high index of suspicion was always kept for other injuries e.g. cranial, thoracic, and abdominal injuries. Ipsilateral hip, femur, knee, ankle, and foot injuries may require treatment modifications and portend a worse patient prognosis.

Anteroposterior (AP) and lateral radiographs of the whole tibia from knee to ankle were obtained in all cases. Traction views in displaced and comminuted fractures and comparison views of the contralateral leg were also helpful in preoperative planning as well as to rule out the presence of an associated, perhaps less obvious, fracture. Oblique views, plateau views, and mortise views were done in individual cases.

Radiography of the spine was considered when injury was the result of a fall, when spinal cord injury is suspected, or when the patient is unconscious. Radiographs of the pelvis and femur may be required in associated injuries. Biplanar tomography and/or CT scan were done in comminuted fractures to delineate fracture extent and were found helpful in assessing union.

2.6. Timing of Surgery

The timing of surgery was variable depending on the magnitude of injury. The vast majority of fractures (119 fractures) were operated within few hours from trauma. Delay occurred in about a quarter of cases (41 fractures) and ranged between one day up to 158 days (average delay, 18.7 days). Twenty patients had a delay of one week or less, 11 were operated between 1-3 weeks, and 10 had their UTNs inserted after 3 weeks. The cause of delay was mostly a concomitant high-grade soft tissue injury.

Twenty patients (21 legs) had a compartment syndrome at presentation and needed urgent fasciotomy. Two more developed a compartment syndrome after nailing and were decompressed. All open fractures were treated with immediate irrigation and debridement. If needed, wounds were re-debrided every 48 hours, commonly with active drainage using vacuum seal and temporary skin replacement with polyvinyl-alcohol foam (Coldex®) until secondary closure was possible or definitive coverage was obtained. Skin stretching was done in two patients to allow secondary skin closure. A split-thickness (Thiersch) skin graft was used for closure of traumatic or fasciotomy wounds in 10 patients, of them one patient with a grade II open segmental tibial fracture needed, in addition, a free latissimus dorsi flap for anterior tibial coverage. Two patients required fasciocutaneous flaps.

Twenty-four patients had preliminary stabilization using external fixation frames. These were 15 open and 9 closed fractures with a variable degree of soft tissue injury (2 GI, 4 GII, and 3 GIII). The average period of external fixation was 29 days. Two cases were managed by calcaneal traction and four by above knee casts 1-8 days before nailing. Cases with head injury were treated after achieving a stable conscious level. Associated fractures were usually fixed in the same setting.

2.7. Surgical Technique

- **Set-Up:**

All procedures were done in a standard operation room without laminar flow. The surgical technique for UTN insertion involves positioning the patient supine under general (endotracheal) or regional (spinal or epidural) anesthesia on a radiolucent operating table with biplanar fluoroscopic control. The image intensifier was positioned to allow AP and lateral X-rays to be taken along the full length of the tibia. Traction was not required.

The lower limb up to the midthigh was sterilely prepped and draped into the surgical field The foot is left partly exposed to control rotation and evaluate the circulation throughout the surgical procedure. A tourniquet was not used. The ipsilateral iliac crest was prepared when primary grafting was needed. A bump was put under the ipsilateral hip while the contalateral limb was often depressed downwards to make biplanar fluoroscopic control easier. The knee of the injured leg was flexed 70°–90°. A knee support was sometimes used to facilitate reduction and subsequent stabilisation of the reduced fracture.

A second generation cephalosporin (e.g. Cefuroxime) was given intravenously as a pre-operative single-dose antibiotic prophylaxis with the induction of anaesthesia in all cases. This was continued in patients with grade-I or II open fractures until wound closure. Patients with grade-III open fractures were given a cephalosporin and an aminoglycoside. Penicillin was added for the severely contaminated wounds. Most wounds were debrided every forty-eight hours, mostly with vacuum sealing until wound closure or until definitive coverage was obtained. Efforts were made to obtain definitive coverage of the wound within 7-10 days.

- **Reduction:**

Fracture reposition in all but one case was done using closed reduction with manual longitudinal traction and manipulation. Reduction was sometimes helped by the percutaneous use of a reduction forceps, a large distractor, or a previously applied external fixator.

In one case with proximal third fracture, Open reduction was done through extending the proximal incision for nail insertion and a PDS cord passed through drill holes in the proximal and distal fragments was used to maintain fracture reduction. In two patients with early malreduction, also of a proximal fracture, open reduction and plate fixation was done after 2 and 3.5 weeks respectively to correct malalignment and add stability.

• The Unreamed Tibial Nail:

The Unreamed Tibial Nail (UTN®, Synthes GmbH, Umkirch, Germany) is a solid non-cannulated nail designed by the AO/ASIF group (Fig. 3). This structure ensures adequate nail strength even for very small diameters and avoidance of a dead space that may favour infection in patients with high-grade closed or open soft tissue injury. In the proximal third, the cross-section is square-shaped whereas in the middle and distal thirds it is semicircular with the edges on the dorsal side to follow the triangular cross-section of the tibial shaft, and thereby implantation of a 1 mm thicker triangular nail, in contrast to a rounded nail, can be done. At the junction between the proximal and middle thirds, the implant is convex (11°) on the dorsal surface. The lower end of the nail is tapered, flattened and rounded. This reduces the risk of perforation of the dorsal cortex during nail insertion. The upper end of the nail has a slanted edge. This reduces the risk of patellar ligament irritation. The implant was first provided in a diameter of 8 or 9 mm, was 300-375 mm long and was graded in 15 mm intervals with two proximal and two distal locking holes located in the coronal plane. These holes are used for small self-tapping locking bolts with 3.9 mm thread and 3.2 mm core diameter.

To enhance locking fixation in proximal and distal shaft fractures, the nail has been modified to allow the insertion of a third diagonal proximal locking bolt in a 45° oblique plane (to minimize the risk of vascular injury with direct AP screws) in anterolateral to posteromedial or anteromedial to posterolateral direction and a third distal locking screw in the AP plane. One proximal hole was replaced by a longitudinal slot to allow dynamic locking while retaining rotational stability. The bolt in this hole is allowed to move by up to 8 mm distally. The Herzog bent became 9 degrees. A third diameter of 10 mm was introduced with 4.9 mm locking screws and more nail lengths became available from 255 mm with 15 mm increments to 360 mm then in 20 mm increments till 420 mm. Titanium nails (UTN TAN®) are now available.

In the current study, The Old UTN design was used in the first 12 cases. The most common nail diameter used was the 9 mm UTN, used in 78 fractures (48.8%). The 8-mm UTN was used in 63 fractures (39.4%) while the 10-mm nail was used in only 19 patients (11.8%). Nail lengths ranged between 255 mm and 420 mm. The nail length most frequently utilized was 360 mm (*n:* 36), followed by 330 mm (*n:* 30), 345 mm (*n:* 27), 315 mm (*n:* 24), 38 mm (*n:* 18), 285 (*n:* 10), 300 mm (*n:* 9), 27 mm and 40 mm (*n:* 2 nails each), and finally 255 mm and 42 mm (*n:* 1 nail each).

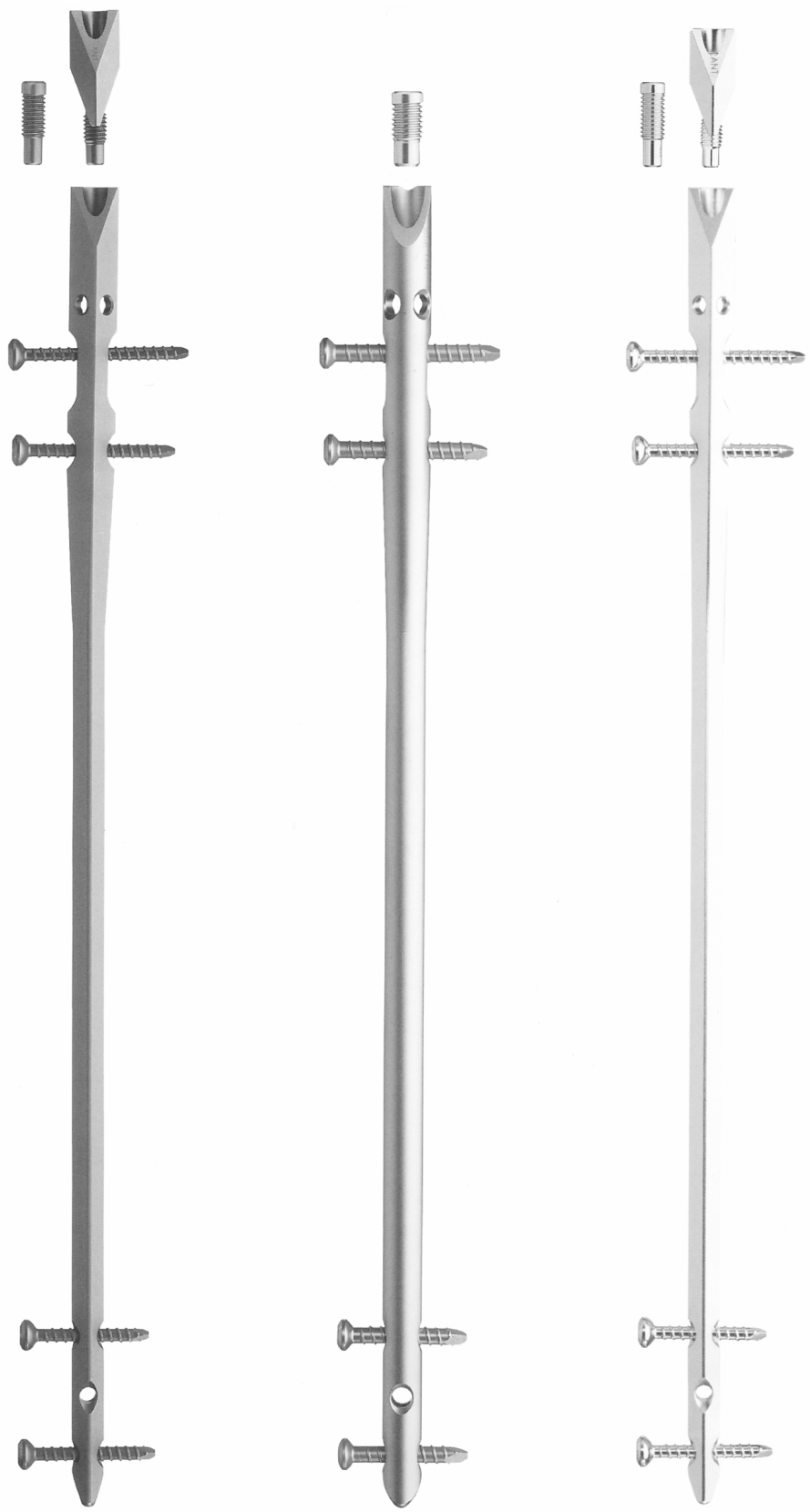


Figure 3: The AO/ASIF Unreamed Tibial Nail (UTN®).

The required nail length and diameter may be determined using several techniques either before or after disinfection of the injured leg. Clinical measurement of the intact leg length from the medial joint line to the medial malleolus or radiographs of the intact contralateral tibia can be used in this regard after appropriate subtractions. Intraoperatively, the use of the Radiographic Ruler for UTN under fluoroscopy can suggest the exact nail length and the diameter needed. The possibility of immediate or subsequent dynamization must be taken into account when determining nail length and a correspondingly shorter nail chosen.

A small midline infrapatellar skin incision was used for nail insertion. Deep dissection used either a transligamental midline approach (as done in most cases) or a parapatellar medial approach. The nail insertion point is slightly distal to the tibial plateau, slightly lateral, and exactly in line with the proximal anterior tibial margin. The centering pin is mounted in the universal chuck with T-handle and screwed in at a 9° angle to the tibial shaft axis for approximately 8–10 cm. The position is checked in two planes fluoroscopically. The protection sleeve and the cutter for the UTN are pushed over the centering pin to open the medullary canal over 8–10 cm; then the centering pin, the cutter and the protection sleeve are removed. The insertion handle is mounted onto the nail and secured with the solid connecting screw. The inserter/extractor is screwed onto the connecting screw.

The nail is inserted up to the bend with gentle rotary movements. Further insertion follows by hand but without rotating the nail. Under image intensifier, the passage of the nail tip through the fracture line is checked. Gentle blows using the slotted hammer was usually needed until the proximal end has sunk 1–5 mm into the bone. Throughout surgery, the adequacy of the mechanical axis so as leg rotation have been checked continually.

Locking of the UTN was performed from the medial side. Proximal locking was done through stab incisions using the aiming arm mount on the insertion handle. The round holes at both ends of the UTN are provided for static locking and ensure both rotational and axial stability. In principle, a bolt should also be inserted into the dynamic locking hole to leave open the possibility of secondary dynamization. Distal locking is preferably carried out first, enabling the use of the back-strike technique for interfragmentary compression and to prevent fracture diastasis. The nail must have been inserted to the sufficient depth beforehand. Distal locking was almost always done with the “free-hand technique” with a radiolucent drive. A 3.2 mm Drill bit was used for 3.9 mm bolts (UTN diameter 8 and 9) whereas a 4.0 mm drill bit was used for 4.9 mm bolts (UTN 10).

Finally, the appropriate end cap for the nail size is inserted to prevent tissue ingrowth and thus facilitate later nail removal (Fig. 4).

Static locking was used in 143 nails (89%) whereas primary dynamic nail insertion was used in the remaining 17 fractures (11%). The commonest mode for static locking of nails inserted in this study was using 4 coronally-oriented locking screws, two in each end. This was done in 100 cases (62.5%). In one of them, an additional third distal locking screw was added to augment locking 18 days after nail insertion. Other variations of static locking using 4 locking screws include the use of 3 screws in the coronal plane (2 proximal and 1 distal) and one distal AP screw (in 6 cases), 3 in the coronal plane (2 proximal and 1 distal) and 1 proximal oblique (45°) screw (in 3 nails), 2 coronally-oriented screws with 1 proximal oblique screw and 1 distal AP screw (in 2 cases), and finally using only one proximal oblique screw and 3 distal locking screws (in one case).

Five screws (2 proximal and 3 distal) were used to statically lock 29 UTNs; in only one of them, the proximal oblique hole was used for static locking. Nail locking using three screws inserted in a static mode was done in only 2 nails with 1 oblique proximal screw and 2 distal transverse screws in one UTN of the old design and using 2 proximal transverse screws and only one distal locking screw in the other.

Primary dynamic mode of locking uses the proximal dynamic slot as the only site of proximal locking. Distal locking was done using the 2 coronally-oriented screw holes in 11 nails, 1 coronal and one AP hole in one nail, all three holes in 3 nails, and only coronal hole in two nails.

- **Fibular Osteosynthesis:**

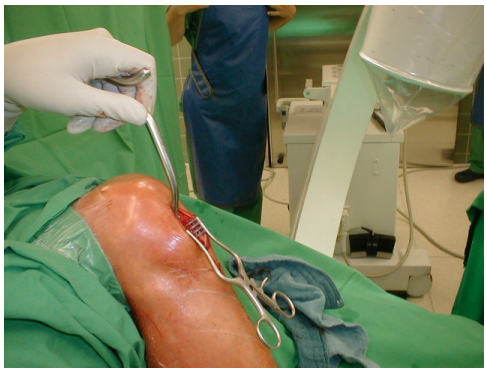
Seventeen out of the 160 fractures involved in this study were associated with an intact fibula (10.6%). Of the 143 cases with fractures of both leg bones, plate ORIF of the fibula was performed through a lateral or a posterolateral incision in 12 cases (8%). These included 9 distal third tibial fractures, two segmental fractures in which selective plating of the distal fracture level was done, and 1 B3 midshaft tibial fracture.

- **Minimal internal fixation:**

One or two percutaneously inserted 4-mm cancellous lag screws were used to fix associated fractures of the Volkmann's triangle in 13 cases (Fig. 5). In three more patients, percutaneous fixation of a concomitant medial malleolar fracture was done simultaneous with screws or screw/K-wire combinations.



a) Patient set-up.



b) Opening the medulla by a curved awl.



c) Inserting the guide wire (C-arm control).



d) Nail insertion.



e) Proximal Locking.



f) Distal locking.



g) Insertion of the end cap.

Figure 4: The Surgical technique for the Unreamed Tibial Nail.

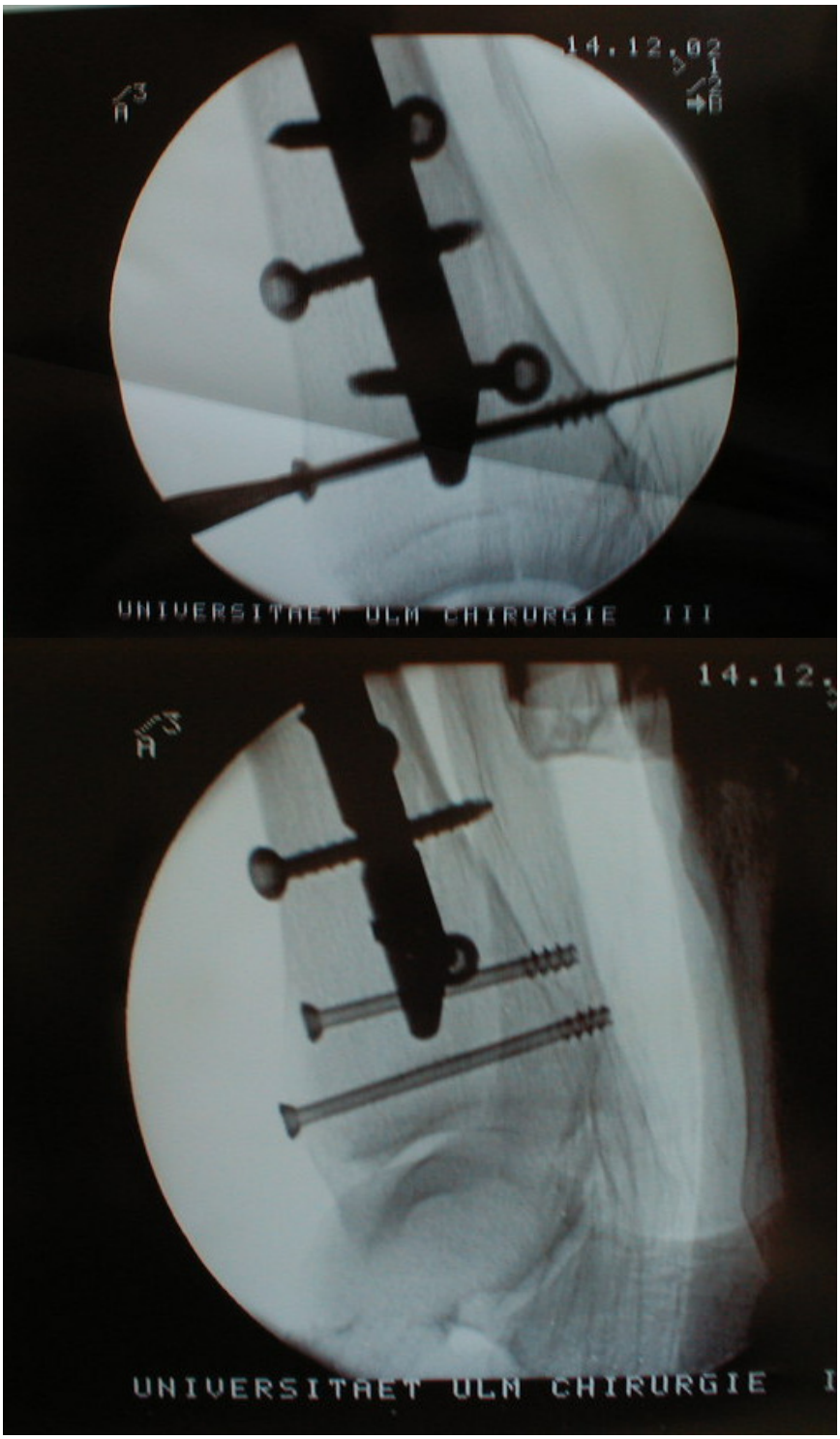


Figure 5: Percutaneous screw fixation of an associated Volkmann's triangle fracture.

2.8. Postoperative Protocol

Intravenous antibiotics were continued in patients with open fractures until wound closure. Analgesics and NSAID injections were usually needed in the first few days postoperatively. Prophylactic anticoagulation was ensued when associated injuries prevented early ambulation. Drains were removed on the second postoperative day and sutures were removed after 8-10 days .

All immediate postoperative x-rays were examined for the amount of postoperative fracture site gap from distraction, displaced butterfly fragments, or comminution after nailing. Distraction was measured in millimetres and described as none (full fracture site compression), minimal (less than 1 mm), mild (1-3 mm), moderate (3-5 mm), and severe (>5mm), cases with defects secondary to displaced fragments or comminution with mild or no distraction, and cases with significant distraction and comminution.

The quality of reduction was assessed using the final intraoperative or initial postoperative radiographs. Serial follow-up radiographs were made thereafter and were evaluated for secondary fracture displacement, mechanical axis deviation, loss of fixation, septic loosening, implant failure, fracture union, and the development of malunion or nonunion.

Early joint motion of the knee and ankle was allowed immediately in the early postoperative phase. Weight bearing was individualized according to the fracture pattern, the locking mode used, and the presence and type of associated injuries. Patients with type A fractures and stable injuries were allowed early ambulation with toe touch up to 20-kg partial weight-bearing following nail insertion. Weight-bearing was advanced as tolerated, until the patient can bear full weight. Patients with marked comminution were kept non-weight bearing for 4-6 weeks; may be longer, followed by incremental progression to full weight bearing by 8 to 12 weeks. Associated injuries, at occasions, necessitated prolonged non-weight-bearing.

Dynamization:

From the 17 dynamic nails, 2 nails were additionally dynamized by removing distal locking screws to fasten union. One nail was removed after 16 days because of a suspicion of infection.

From the 143 statically-locked nails, 61 nails were not dynamized, operative dynamization by removal of the static proximal locking screw in 26 nails and by removal

of both proximal screws in 2 more nails. Dynamization by removal of distal locking screws was done in 12 cases. In two of them, screw removal was done primarily to relieve pain. In two more cases, nails were already dynamic as shown before.

Autodynamization (secondary spontaneous dynamization) through fatigue failure of the locking screws (FFLS) occurred in 32 cases. Failure of only the static proximal locking screw occurred in 16 cases after an average of 16 weeks (range 5-39 weeks). No information regarding dynamization were available in the remaining 10 patients (1 died, 5 lost to follow-up, 4 with incomplete follow-up).

Only one 4.9 mm screw from 19 UTNs with a 10mm diameter failed. Six nails were dynamized during treatment (4 proximally, 2 distally) whereas the rest continued fixation without dynamization.

The time to dynamization (surgical or spontaneous) was recorded in weeks. Dynamization within 10 weeks of nail implantation was done in 29 fractures, dynamization between 10 and 20 weeks in 29 more patients, and late dynamization after 20 weeks was recorded in 16 cases.

Nail removal:

Nails were removed after clinical and radiographic evidence of fracture union. The hazards of early nail removal include malunion, mostly drifting into varus, nonunion, and refracture. Nail removal was effected at an average of 19.75 months (range 16 days to 10 years). Nails were removed early (before union) in cases of a suspected or definite infection (3 patients), fracture malreduction (3 patients), and nail breakage (1 patient). Five of these fractures were then treated by definitive external fixation and two with plate ORIF with iliac crest bone graft (ICBG). Few patients had their nails left in situ after full union. Most of them were elderly with associated comorbidity not justifying removal of asymptomatic implants.

2.9. Statistical Analysis

Fracture union was the major concern in this study. Statistical analysis was done for the mean time to union and the complication rate regarding all injury variables using the SAS system. Tests that are able to detect such an association assume that the continuous, dependent variable (time to union) is normally distributed. This was not the case here, therefore a log-transformation was applied to the variable time to union in order to make its distribution more similar to a normal distribution. All further analyses use the variable log (time to union) as a continuous, nearly normally distributed, dependent variable.

As a first step, one-way analysis of variance (one-way ANOVA) was conducted for each single factor at a significance level of 30%. All variables that showed to have a substantial influence at that significance level were included in the following multi-factorial ANOVA, i.e. an ANOVA with more than one factor as an independent variable. A backward selection was then applied with a significance level of 10% and, when appropriate, 5%.

The p-value produced by the ANOVA only says that the variable may have a substantial effect on the time to union, but it does not say which levels of the factors are significantly different. A Tukey test was applied to detect differences among the levels of a factor. The Tukey test detects differences among levels, with the descriptive statistic one can say if the time to union is substantially longer for patients, who are in that level of the factor compared to patients categorized in another level of the factor.

To detect which factors may be related to complications like delayed or non-union, fracture malalignment, FFLS, or infection, a dichotomous dependent variable with the two levels: normal union and complicated union was used. A possible relationship of each factor with the complication was first analyzed, therefore a chi-square test or, if the cell counts were small, a Fisher's exact test was carried out. The apriori significance level was set to 30%. Next, a multiple logistic regression was conducted including all variables that were significant by the 30% level. A backward selection was applied with a significance level of 10% and, when appropriate, 5% and the odds ratios were estimated.

3. Results

One hundred and fifty-eight patients with one hundred and sixty tibial shaft fractures treated using the AO unreamed tibial nail were included in this study. There were 105 men and 53 women with a mean age of 39.5 years. Fractures were classified using the AO classification into 78 type A fractures (41 type-A1, 16 type-A2, and 21 type-A3), 65 type B fractures (15 type-B1, 30 type-B2, and 20 type-B3), and 17 type C fractures (2 type C1, 13 type-C2, and 2 type-C3). Fracture comminution was classified using Winquist criteria into 41 type-0 (26.2%), 47 type-I (29.4%), 32 type-II (19.4), 23 type-III (14.4%), 4 type-IV (2.5%), and 13 (8.1%) segmental fractures. There were 115 closed (72%) and 45 open (28%) fractures. There were 4 proximal third fractures, 5 fractures involving the junction between the proximal and middle thirds, 37 midshaft fractures, 17 fractures involving the junction between the middle and distal thirds, and 84 distal shaft fractures in addition to 13 segmental fractures. High-energy trauma was responsible for 64% of fractures. Seventy nine patients had associated injuries and about 25% were victims of polytrauma.

The vast majority of fractures (119 fractures) were operated within few hours from trauma. Delay ranged between one day up to 158 days (average delay, 18.7 days). Twenty-four patients had preliminary stabilization using external fixation frames (average duration, 29 days). Two cases were managed by calcaneal traction and four were put in above knee casts for 1-8 days before nailing. Closed manipulative reduction was done in all but one case. Plate ORIF of the fibula was performed in 12 out of 143 cases with associated fibular fractures. Minimal internal fixation using 4-mm cancellous lag screws was done to fix associated fractures of the Volkmann's triangle in 13 cases and medial malleolar fractures in 3 patients.

Static locking was used in 143 nails (89%) whereas primary dynamic nail insertion was used in the remaining 17 fractures (11%). Sixty-one statically-locked nails were not dynamized. Operative dynamization by removal of the locking screws was done in 40 nails. Autodynamization through fatigue failure of the locking screws occurred in 32 fractures. No information regarding dynamization were available in the remaining 10 patients.

One alcoholic patient with polytrauma aggravated by acute necrotizing pancreatitis died from multiple organ failure 5 weeks after trauma. Six cases were lost to follow up, and 8 had incomplete records or radiographs.

3.1. Fracture Union

Union was defined as the ability of the patient to bear full weight without support on the injured leg, if other injuries allowed, with no appreciable fracture site pain or tenderness, together with the presence of mature callus bridging the fracture in at least three of four cortices seen in the anteroposterior and lateral radiographs.

Delayed union (DU) was defined as lack of solid clinical and radiographic fracture union at 26 weeks, whereas non-union (NU) was defined as failure of a fracture to heal within 39 weeks with persistence of pain at the fracture site.

All cases with complete follow up were finally united (Fig. 6-8). The average time to union was 24.3 weeks (range, 11-134 weeks).

Thirty-six fractures (23.5%) had a delayed or non-union, of them one had an early UTN removal so as non-union occurred with external fixation treatment. Additional surgical procedures to promote union, apart from dynamization, were done in only 9 cases (6%).

Among patients with delayed or non-union, 29 cases were males and 7 were females (4:1). High-energy trauma (traffic and work accidents and high-energy falls) was responsible for 28 cases (78%): MVA, MCA, BA, and PMVA: 19; work accidents: 6; fall from a height: 2; minor falls: 4; sports: 3; and direct trauma: 1. Distal third tibial fractures were seen in 17 cases, middle third fractures in 7 cases, middle-distal junction fractures in 5, proximal-middle junction fractures in 2 and lastly proximal tibial fracture in one case. As regards fracture patterns, nearly 60% of cases with DU/NU had type B fractures (2 B1, 9 B2, and 10 B3). Simple type A fractures were seen in 8 cases (3 A1, 2 A2, and 3 A3), and complex type C fractures in 7 cases (1 C1, 4 C2, and 2 C3). Twenty patients had significant fracture comminution (12 Winquist III, 4 Winquist IV) or segmental fractures (*n:* 4) whereas the rest had more than 50% cortical contact (4 Winquist 0, 5 Winquist I, and 7 Winquist II).

All but 8 cases had associated high-grade soft tissue injuries (78%): 8 Tscherne GII-III closed soft tissue injury and 18 open fractures. Twenty cases had concomitant injuries (55%).

Twenty-five fractures were nailed within hours of injury. The rest were operated after a mean delay of 34 days (range, 3-158 days). The post-operative fracture site distraction was graded as minimal in 5 cases, mild in 3, moderate in 4, and severe in 3. A gap secondary to comminution was seen in 9 cases and to comminution and distraction in 4 cases. No gap was seen in only one fracture.

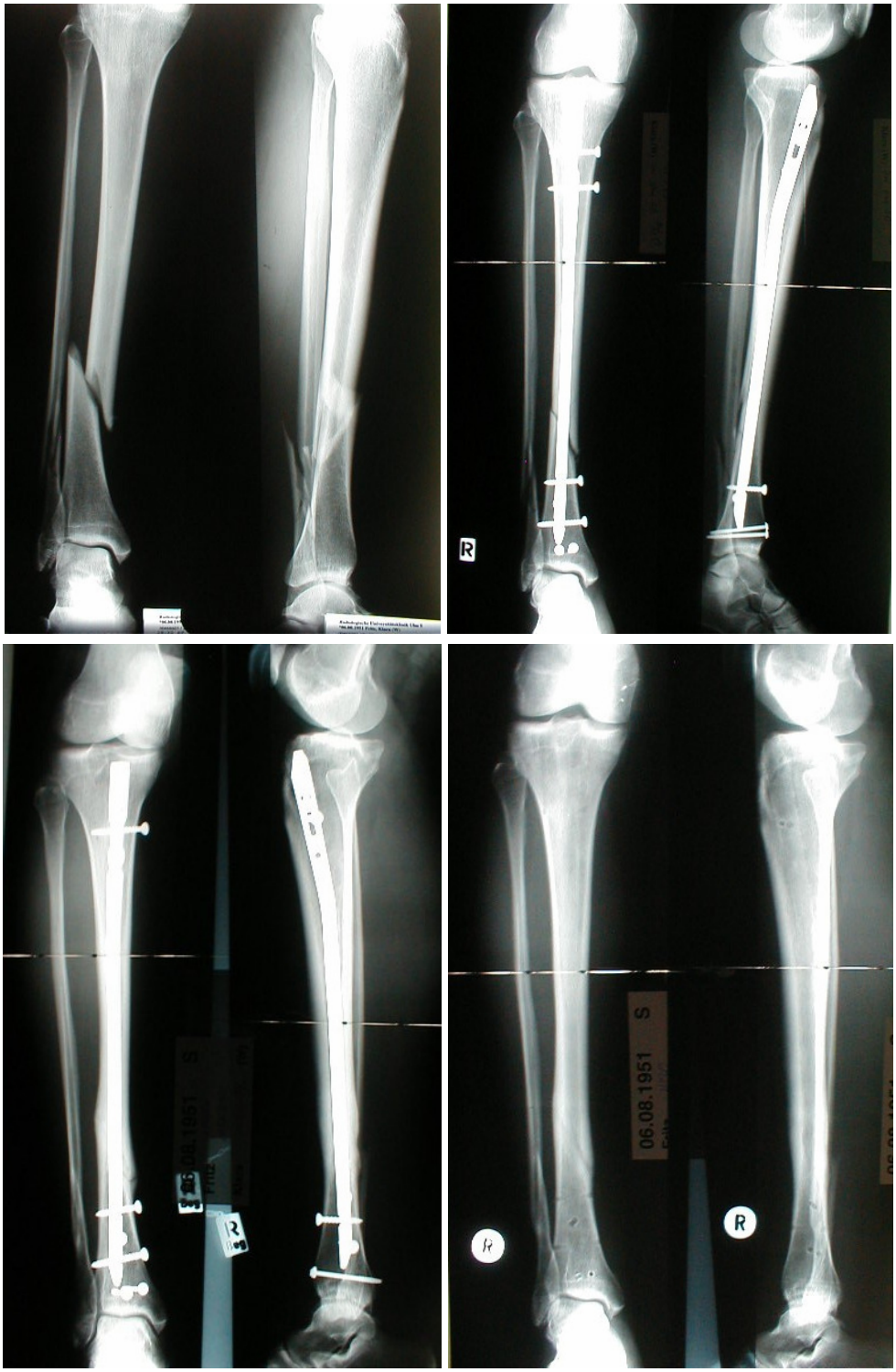


Figure 6: Type A1 distal tibial fracture treated by an unreamed tibial nail with percutaneous screw fixation of the Volkmann's triangle. Full union occurred after dynamization.

Delayed Union:

As for cases with DU, six patients united without intervention (3 of them had already dynamic nails), six united after dynamization by surgical removal of the locking screws, five united after spontaneous dynamization through FFLS, one united after ICBG performed 10 weeks after nailing and needed later nail dynamization for full union, one united with US treatment, and in the last patient an exchange reamed nailing was done to treat delayed union associated with a 17° external rotation deformity.

Non-union:

Sixteen patients (Fifteen when excluding the case of early UTN removal) had nonunion. No intervention was done for three of them (2 because of paralysis and one because of bleeding tendency). All three cases united (one after spontaneous dynamization with FFLS).

Three fractures united after dynamization, 2 more needed ambulatory low-intensity pulsed ultrasound treatment for union. One patient had a nonunion despite early bone grafting (10 days after fracture). Dynamization after 19 weeks was done and the fracture united after 40 weeks with shock wave treatment.

Three nonunions were treated with fracture site revision and secondary ICBG. Fibulectomy was performed simultaneously in two cases and plate ORIF was added in one case.

Exchange reamed tibial nailing (RTN) was done in two cases. One united uneventfully while in the other patient infection developed and the RTN had to be removed. The fracture united in a Sarmiento brace after 134 weeks.

One patient who was initially treated with UTN, that was removed early because of suspicion of infection, continued treatment with definitive external fixation. Non-union developed despite fixator dynamization and US treatment. Pin tract infection necessitated frame removal and the fracture later united in a Sarmiento brace.

An alcoholic patient broke his nail due to extreme non-compliance. External fixation using an Ilizarov frame was done after nail removal but had later to be removed because of pin tract infection. Plate ORIF was performed 6 weeks after frame removal but resulted in an infected NU, necessitating a below knee amputation (BKA) 14.5 months after the fracture (Table 12).



Figure 7: A segmental tibial fracture went into non-union. Union occurred after failure of all 3 static locking screws. Final result with good motion of the ankle and knee joints

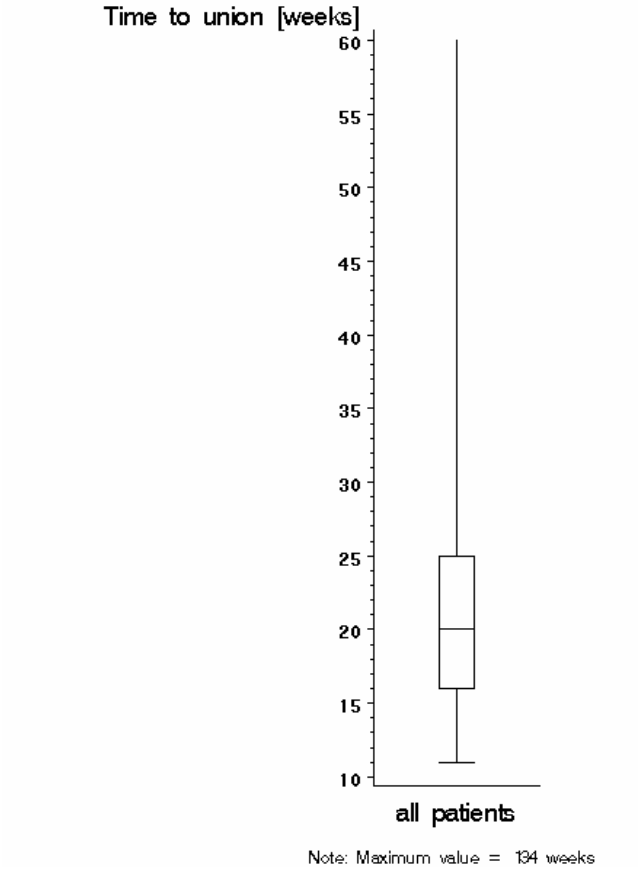


Figure 8: Time to fracture union in this study.
(Min: 11 weeks, Max.: 134 weeks, Median: 20 weeks).

Table 12:
Secondary procedures performed to achieve Union

Treatment	Delayed Union	Non-union
None	6	2
Dynamization	6	3
Fatigue failure of the locking screws	5	1
Ultrasound / Shock wave	1	3
Iliac crest bone graft (±Fibulectomy &/or Plate fixation)	1	3
Reamed nailing	1	2
Amputation	-	1
External Fixation / Brace	-	1
Total	20	16

3.2. Variables affecting fracture union

3.2.1. Patient factors:

Age:

The patient cohort in the current study was divided into 2 groups. Patients 40 years old or younger (n: 96) had an average time to union of 23.7 weeks (range, 11-110 weeks). Patients older than 40 years (n: 62) had a mean time to union of 25.3 weeks (range 12-134 weeks). There were 11 cases of DU (11.7%) and 10 cases of NU (10.6%) in the first group as compared to 9 cases of DU (16%) and 6 cases of NU (11.5%) in the second group (Table 13).

Sex:

The time to union in female patients included in this series ranged from 13 to 60 weeks, with an average of 19.7 weeks. Five cases (10%) of delayed union and two (4%) non-unions (both in high-energy accidents) were identified. The mean time to union in male patients was 26.5 weeks (range, 11-134 weeks). Fifteen cases of delayed union (14.6%) and 14 non-unions (13.6%) occurred (Table 14).

3.2.2. Trauma factors:

Mechanism of Trauma:

Collectively, low-energy mechanisms (minor falls, sport injuries, and low-energy direct trauma) had a mean time to union of 19.7 weeks with a combined DU/NU rate of 15% (6 delayed unions and 2 nonunions). On the other hand, high-energy injuries (high-energy falls, work, and traffic accidents) had a mean time to union of 27 weeks with a combined DU/NU rate of about 30% (14 cases each). The difference was statistically significant (p=0.005).

Minor falls, trips, and twisting injuries occurred in 35 patients in this study. The average time to union in these cases was 19.5 weeks (range 12-37 weeks). One patient with an open B2 (Winquist III) fracture had an infected non-union after nail breakage and failed attempts at external and internal fixation due to absolute non-compliance and was amputated. Three patients had delayed union and three had a malunion (9.3%).

Five patients had fractures from direct leg trauma. These fractures united after 11- 32 weeks (mean, 20 weeks). One case of delayed union and one malunion were identified.

Fractures from sports injuries (*n:* 18) united after a mean time of 20 weeks (range, 12-58 weeks). There were two cases of delayed union (11%) and one non-unions (5.5%).

High-energy falls and traffic accidents (MVA, MCA, PMVA, and BA) had an average time to union of 26 weeks (range, 13-110 weeks). Complications included 9 delayed unions (11%), 13 non-unions (16%), 10 malunions (12%), and 3 deep infections (3.6%).

Work and industrial accidents were mostly high injury injuries caused by falling trees or heavy weights or machine injuries. The mean time to union after such accidents was 32 weeks (16-134 weeks). One third of the patients had a delayed union (*n:* 5) and one patient had a non-union (combined DU/NU rate of 40%). There were also one case of deep infection and one torsional malunion (Table 15, Fig. 9).

Associated injuries:

Half of the patients included in this study had no associated injuries. Fractures in these patients united after an average of 21.5 weeks (range, 11-58 weeks). There were 13 delayed unions and 3 non-unions. In contrast, patients with associated injuries (*n:* 79 cases) united after an average time of 29.8 weeks (range, 12-134 weeks) with 13 non-unions, 7 delayed unions, one death, and one above knee amputation. Patients with polytrauma had a mean time to union of 26.3 weeks. The patient who died early after injury and the case of below knee amputation belong to this group (Table 16).

3.2.3. Personality of the fracture :

Fracture Site:

Fractures of the proximal third of the tibia (n: 4) united after an average of 21 weeks (range, 16-26 weeks). One case had a delayed union and one a malunion. Junctional fractures between the proximal and middle thirds of the shaft (n: 5) united after an average time of 27 weeks (range, 16-54 weeks). Complications included a case of delayed union, one non-union, one malunion, early malreduction, and superficial soft-tissue infection (Table 17).

Midshaft diaphyseal tibial fractures constituted 23% of fractures included in this series. Three cases were lost to follow-up. The rest (*n:* 34) united after an average time of 23.5 weeks (range, 13-57 weeks) with 3 cases of delayed union (9%) and 4 non-unions (12%).

Fracture involving the transition between the middle and distal thirds were separately analyzed. The time to union of such fractures ranged from 13 to 32 weeks (mean 21.5 weeks). There was 3 cases of delayed union (18%) and 2 non-unions including one amputation (12%).

Table 13:
The relation between patient's Age & Fracture Union

	Union	Delayed Union	Non-union
Age ≤ 40 years	23.7 weeks	11 (11.7%)	10 (10.6%)
Age > 40 years	25.3 weeks	9 (16%)	6 (11.5%)

Table 14:
The relation between patient's Sex & Fracture Union

	Union	Delayed Union	Non-union
Males	26.5 weeks	15 (14.6%)	14 (13.6%)
Females	19.7 weeks	5 (10%)	2 (4%)

Table 15:
Fracture union according to the mechanism of Injury

	Union	Delayed Union	Non-union
Low-energy falls	19.5 weeks	3 (9%)	1 (3%)
Sports injuries	20 weeks	2 (11%)	1 (5.5%)
Direct trauma	20 weeks	1 (20%)	-
High-energy Falls, Traffic accidents	26 weeks	9 (11%)	13 (16%)
Work accidents	32 weeks	5 (33%)	1 (7%)

Table 16:
The effect of associated injuries on Fracture Union

	Union	Delayed Union	Non-union
Isolated fractures	21.5 weeks	13 (17%)	3 (4%)
Associated Injuries	30 weeks	7 (9%)	13 (17%)

Distal third fractures were seen in more than half of the study patients. From the 84 fractures recorded, 3 cases were lost to FU. Mean time to union in this group was 25 weeks (range, 11-134 weeks) with 10 cases of delayed union (12.3%) and 7 non-unions (8.6%).

Segmental tibial fractures occurred in 13 patients. One of them died after 5 weeks as a sequela of his polytrauma. The remaining 12 patients united after a mean time of 27.6 weeks (range, 14-53 weeks). One-third of fractures had either a delayed or non-union (two cases each). It is to be noted that from these twelve fractures, early malreduction needed addition of a proximal plate in one case and nail removal and external fixation treatment in the other.

Fracture Classification:

The fracture pattern according to the AO classification was an influential parameter at a significance level of 10% (p=0.043). Complex type C fractures took a significantly longer time to unite than simple type A fractures. No significant difference exists between type A and B or between type B and C fractures. The detailed results are shown (Table 18, Fig. 10):

Type A fractures:

Simple Type A fractures united after an average time of 20.65 weeks (range, 11-60 weeks). Five delayed unions (7.5%) and 3 nonunions (4.5%) were identified in this group.

- ***A1 fractures:***

From the 41 A1 fractures, 2 cases were lost to FU and one reclassified as B1 fracture after an iatrogenic comminution. The mean time to union for those fractures was 20 weeks (range, 12-60 weeks). There was two cases of delayed union (5%) and one non-union (2.5%).

- ***A2 fractures:***

One patient in this group was lost to FU, 4 were reclassified after intraoperative fractures into 3 B2 and 1 B3 fractures. The remaining 11 cases showed 2 cases of delayed union (18%) but no non-unions. The mean time to union was 21 weeks (range, 14-38 weeks).

- ***A3 fractures:***

One patient was lost to FU, one fracture was reclassified after intraoperative fracture as a B3 fracture. Of the remaining 19 cases, 1 patient had delayed union (5%) and two had non-union (10.5%). The average time to union was 21 weeks (range, 11-58 weeks).

Type B fractures:

AO type B (wedge) fractures had a mean time to union of 27 weeks (range, 13-134 weeks). Delayed or non-union occurred in 30% of cases (10 fractures each).

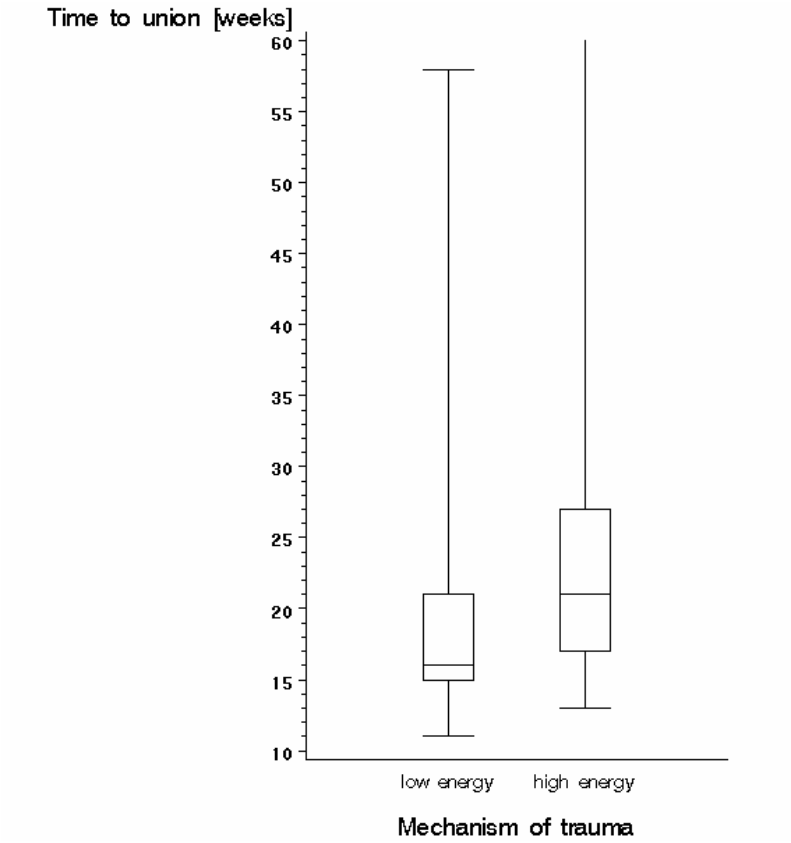


Figure 9: Time to union according to the mechanism of injury (max. value 134 weeks).

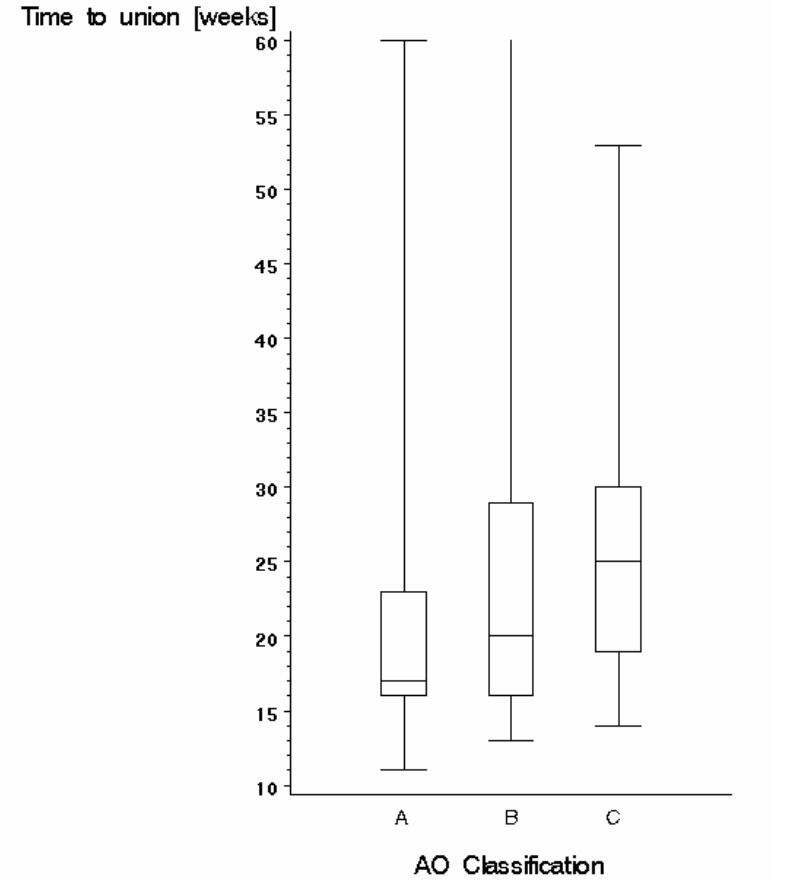


Figure 10: Time to union according to the fracture pattern (max. value 134 weeks).

Table 17:
Fracture union according to the fracture site

	Union	Delayed Union	Non-union
Proximal	21 weeks	1 (25%)	-
Proximal/Middle	27 weeks	1 (20%)	1 (20%)
Middle	23.5 weeks	3 (9%)	4 (12%)
Distal/Middle	21.5 weeks	3 (18%)	2 (12%)
Distal	25 weeks	10 (12%)	7 (9%)
Segmental	27.6 weeks	2 (17%)	2 (17%)

Table 18:
Fracture union according to AO Classification

	Union	Delayed Union	Non-union
A1	20 weeks	2 (5%)	1 (2.5%)
A2	21 weeks	2 (18%)	-
A3	21 weeks	1 (5%)	2 (10.5%)
B1	19.3 weeks	2 (13%)	-
B2	28.3 weeks	3 (10%)	6 (20.7%)
B3	31 weeks	5 (21%)	5 (21%)
C1	22.5 weeks	1 (50%)	-
C2	27.6 weeks	2 (17%)	2 (17%)
C3	26.5 weeks	2 (100%)	-

- ***B1 fractures:***

The average time to union was 19.3 weeks (range, 13-33 weeks). One patient was lost to follow-up. Two patients had delayed union (13%) but no non-union.

- ***B2 fractures:***

One patient was lost to FU. Two fractures were reclassified as B3 and not included here whereas 3 A2 fractures reclassified as B2 were added (one lost to FU, one developed non-union, and one united after 21weeks). Three patients had delayed union (10%) and 6 had non-union (20.7%), of them one had a below-the-knee amputation for an infected non-union). The DU/NU rate was 26.5%. The mean time to union was 28.3 weeks (range, 13-134 weeks).

- ***B3 fractures:***

In addition to 20 B3 fractures, 4 more fractures were reclassified as B3 after intraoperative comminution. Five patients had delayed union and five more a non-union (21% each). The mean time to union was 31 weeks (range, 14-110 weeks).

Type C Fractures:

Multifragmentary Type C fractures united after a mean time of 26.7 weeks (range, 18-53 weeks). One polytrauma patient died shortly after Injury. Delayed union occurred in 5 out of 16 patients (31%) whereas non-union complicated 2 more fractures (12.5%).

- ***C1 fractures:***

One out of the two C1 fractures included in this study had a delayed union (27 weeks) while the other united fully after 18 weeks.

- ***C2 fractures:***

From the 13 cases of C2 tibial fractures treated in this series, one patient with polytrauma died early after nailing. The rest united after an average time of 27.6 weeks (range, 14-53 weeks). There were 2 cases of delayed union and 2 more with a non-union (17% each).

- ***C3 fractures:***

Both C3 fractures included in this study had a delayed union. The average time to union was 26.5 weeks.

Fracture Comminution:

Minimal or no comminution (0-I) was seen in 55% of fractures, whereas 25% had marked comminution (III or IV) or where segmental. Progressive increase in the DU/NU rate was seen with transition from grade 0 to IV comminution (Table 19, Fig. 11). Statistical analysis at a 10% significance level showed that marked and segmental comminution were associated with a substantially longer time to union than when more than 50% of the cortical circumference was intact (p=0.05). The odds for having a DU/NU were 6.5 times more with the former (high comminution) than the latter at a significance level of 5% (p=0.0003).

Winquist 0 fractures:

Three cases were lost to FU. Two patients were reclassified into Winquist I and II fractures following intraoperative fractures. The rest united after an average of 20.25 weeks (range 12-60 weeks). There were two cases of delayed union and two nonunions (5.5% each).

Winquist I fractures:

There were 47 Winquist I fractures, of them 2 were lost to FU. Four fractures were reclassified into Winquist II and one into Winquist VI fractures. The mean time to union was 23.15 weeks (range 12-134 weeks). There were three cases of delayed union (7.5%) and two non-unions (5%). Both non-unions were in patients with high-grade soft tissue injury (C-II and O-III injuries) and both had delayed dynamization.

Winquist II fractures:

Included in this class were 32 fractures in addition to 5 more cases from iatrogenic comminution (one Winquist 0 and 4 Winquist II fractures). One patient was lost to follow-up. The rest united between 13 weeks and 66 weeks (average 23 weeks). There were 4 cases of delayed union (11.7%) as well as 3 non-unions (8.3%).

Winquist III fractures:

Twenty-four cases were classified as Winquist III fractures after nailing. Six cases had delayed union and six had non-union (25% each). The mean time to union was 32 weeks (range 17-110 weeks) and one patient with a an infected non-union was amputated.

Winquist VI fractures:

The average time to union in this fracture class was 27.6 weeks (range 18-40 weeks). Three out of five cases had delayed union (60%) and one had a non-union (20%).

Segmental fractures:

The mean time to union for the 12 cases of segmental tibial fractures followed up until union was 27.6 weeks (range, 14-53 weeks). One-third of fractures had either a delayed or non-union.

3.2.4. Soft tissue injury:

Fifty-two percent of the fractures included in this study were associated with a high-grade soft tissue injury (open fractures or G II-III closed fractures). The degree of soft tissue injury was a decisive factor in fracture healing. There was a steady rise in the time needed for union and the DU/NU rate with the increased severity of the associated soft tissue injury (Table 20, Fig. 12).

Patients with no associated soft tissue injury united after an average time of 18.65 weeks with only one case of delayed union (4%) and no non-union.

From the 90 patients with closed soft tissue injury, 3 cases were lost to follow up whereas the rest united after a mean time of 22 weeks (range, 11-58 weeks). Twelve cases of DU (15.38%) and 5 NU (6.4%) were seen. Further analysis using the Tscherne and Götzen classification revealed that patients with G-I closed soft tissue injury united after an average of 21.2 weeks with 7 cases of delayed union and 2 non-unions (18.75% DU/NU rate). Patients with G-II closed soft tissue injury united after an average of 22.2 weeks with 5 cases of delayed union and 1 non-union (22.5% DU/NU rate). Patients with G-III closed soft tissue injury united after an average of 27.8 weeks with 2 cases of NU (20% non-union rate).

Open tibial shaft fractures were present in 45 patients in this study. The average time to union for the whole group was 31 weeks (range 12-134 weeks). There were 7 cases of DU (15.5%), 11 non-unions and one amputation (24.5%). Patients with Gustilo I open fractures united after an average of 24.6 weeks with 2 cases of delayed union (10%) and 4 non-unions including one amputation (20%). Patients with Gustilo II open fractures united after an average of 30.6 weeks with 1 case of delayed union and 3 non-unions (30.7% DU/NU rate). Patients with Gustilo III open fractures united after an average of 44.4 weeks with 4 cases of delayed union and 4 non-union (72% DU/NU rate).

With a significance level of 10%, the degree of soft tissue injury substantially affected the healing process ($p=0.02$). Grade III open tibial fractures had a significantly longer time to union than grade I and II open and closed fractures. No significant difference, however, exists between grade III closed and grade III open injuries.

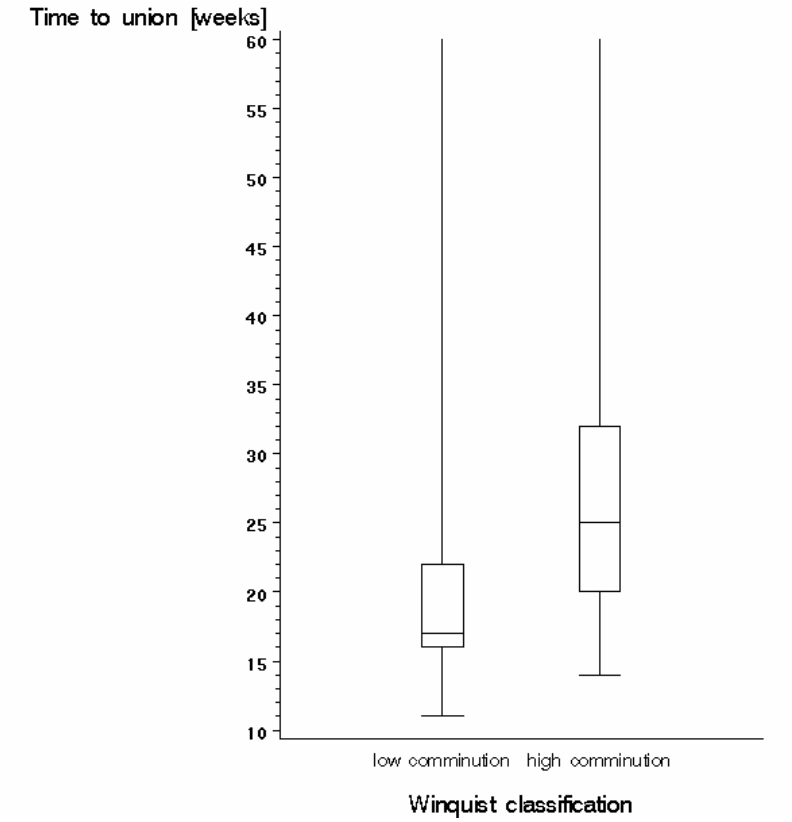


Figure 11: Time to union according to the degree of comminution (low comminution: >50% intact cortex, high comminution: >50% cortical comminution or segmental fracture).

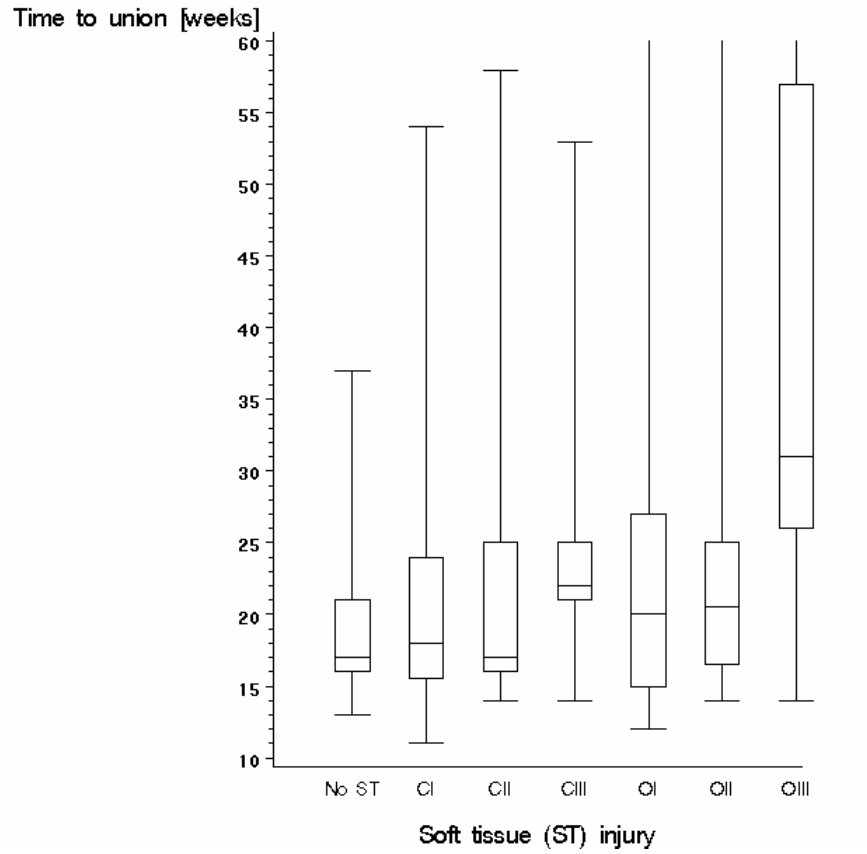


Figure 12: Time to union according to the degree of soft tissue injury (C: closed, O: Open).

Table 19:
Fracture union according to Comminution
(Winquist et al., 1984)

Winquist Classification	Union	Delayed Union	Non-union
0	20 weeks	2 (5.5%)	2 (5.5%)
I	23 weeks	3 (7.5%)	2 (5%)
II	23 weeks	4 (12%)	3 (8%)
III	32 weeks	6 (25%)	6 (25%)
IV	27.6 weeks	3 (60%)	1 (20%)
Segmental	27.6 weeks	2 (17%)	2 (17%)

Table 20:
Fracture union according to Soft Tissue Injury

Fractures	Union	Delayed Union	Non-union
G-0	18.6 weeks	1 (4%)	-
G-I	21 weeks	7 (14.5%)	2 (4%)
G-II	22 weeks	5 (18.5%)	1 (4%)
G-III	28 weeks	-	2 (20%)
O-I	24.6 weeks	2 (10%)	4 (20%)
O-II	30.6 weeks	3 (23%)	1 (7.7%)
O-III	44.4 weeks	4 (36%)	4 (36%)

3.2.5. Timing of Surgery:

Fractures treated within hours of the injury united after an average time of 24 weeks. Cases operated upon after 24 hours had a mean union time of 25 weeks. Fractures nailed after a delay of less than one week, however, had a longer time to union (mean 28.5 weeks). This may be due to the lack of preliminary stabilization in most of these cases (as opposed to a higher rate of temporary external fixation if delay was one week or longer).

3.2.6. Surgical & Technical factors:

Nail Diameter:

Sixty-three fractures were treated with an 8-mm UTN. One patient died soon after nailing. Union occurred after a mean time of 23 weeks (range 12-57 weeks). There were 8 cases of DU (13%), 5 NU (8%), and combined DU/NU rate is 21% (Table 21). Malreduction occurred in 4 patients (6.4%) and malunion in 6 cases (9.6%). Fatigue failure of the locking bolts occurred in 16 nails (26%) and iatrogenic fractures occurred in 4 patients (6.4%).

The 9-mm UTN was used in 78 fractures. Five patients were lost to FU. The average time to union was 26 weeks (range, 12-134 weeks). There were 7 cases of DU (9.5%) and 9 NU (12.5%); combined DU/NU rate is about 22%. Early malreduction occurred in 4 patients (5.5%) and 8 fractures ended up in a malunion (11%). Fatigue failure occurred in the locking bolts in 26 nails (36%). Iatrogenic fractures occurred during insertion of 6 nails (8%).

The application of a 10-mm UTN was done in 19 patients. One patient broke his nail due to extreme non-compliance. He was later amputated for an infected non-union. Three patients had delayed union (16.6%). The mean time to union was 19.7 weeks (range, 13-37 weeks). Only one screw failed in a grade II open C3 (Winquist IV) proximal tibial fracture. Malunion occurred in 2 fractures: one was a C2 fractures that united in 12 degrees of valgus, and the other had a varus collapse and recurvatum after septic loosening and backing out of the distal locking screws. Additional comminution through nail insertion occurred in one case.

Fracture Site Gap:

As shown before, 8 cases had incomplete follow-up, 6 cases lost to FU, 1 patient died, and 1 nail was removed early. For the rest (*n:* 144), 21 fractures had no distraction, 21 had minimal distraction ($\leq$1mm), 38 had mild distraction (1-3 mm), 19 had moderate distraction (3-5 mm), and 5 had severe distraction (>5mm). Fragment displacement or comminution without distraction was seen in 35 cases and comminution with distraction in 5 more cases.

None:

Twenty-one fractures had fracture site compression with no distraction seen in the postoperative radiographs. The average time to union for these fractures was 17 weeks (range, 11-29 weeks). Only one case of delayed union was seen, where actually nailing was done after 4 months of external fixation and the fracture united 2 months later (Table 22, Fig. 13).

Minimal distraction:

The average time to union for fractures in this group was 26.7 weeks (range 14-134 weeks). There was 3 cases of delayed union (14%) and 2 (9.5%) non-unions. Both cases of non-union where in fractures with high-grade ST injury (C-II and O-III). When both fractures were excluded, the mean time to union drops to 19.5 weeks.

Mild distraction:

Fractures nailed in mild distraction united after an average time of 19.7 weeks (range, 14-33 weeks). Three cases of delayed union were identified but no non-union.

Moderate distraction:

A mean time of 25 weeks was required for union in such fractures after nailing (range, 13-53 weeks). Two cases of delayed union and 3 non-unions were seen in this group.

Severe Distraction:

Five patients had a fracture site distraction of more than 5 mm after nailing. In a sixth patient with a segmental fracture, plate ORIF was added to correct malalignment and supplement fixation of the proximal fracture after 24 days with a minimal gap remaining. The rest united after an average time of 29.5 weeks (range 14-60 weeks) with 2 cases of delayed union and 1 non-unions.

Comminution without distraction:

Thirty-five patients had fracture site comminution with minimal or no distraction. The average time to union in these cases was 29 weeks (range, 13-110 weeks). Seven cases of delayed union (20%) and 7 non-union (20%) were found in this group.

Comminution with distraction:

Five patients had combined fracture comminution and distraction. All but one case had a delayed or non-union (two cases each). One patient with infected non-union was amputated later on. The average time to union was 34.25 weeks (range, 20-60 weeks).

Table 21:
Relation between Nail Diameter and Fracture Union

UTN® diameter	Union	Delayed Union	Non-union
8 mm	23 weeks	8 (13%)	5 (8%)
9 mm	26 weeks	7 (9.5%)	9 (12.5%)
10 mm	19.7 weeks	3 (16.5%)	1 (5.5%)

Table 22:
Fracture union according to Fracture site Gap

Gap	Union	Delayed Union	Non-union
None	17 weeks	1 (5%)	-
Minimal (<1 mm)	26.7 weeks	3 (14%)	2 (9.5%)
Mild	19.7 weeks	3 (8%)	-
Moderate	25 weeks	2 (10.5%)	3 (16%)
Severe	29.5 weeks	2 (40%)	1 (20%)
Comminution	29 weeks	7 (20%)	7 (20%)
Comminution + Distraction	34.3 weeks	2 (40%)	2 (40%)

Statistical analysis showed that gaps at the fracture sites were a statistically significant parameter affecting the time of union (p=0.01). At a 10% significance level, it also influenced the DU/NU rate (p=0.06). The odds for having a delayed or non-union were 1.6 times more with distraction of 1-3 mm, 6 times more with distraction more than 3 mm, and 9 times more with gaps from comminution with or without distraction respectively.

Dynamization:

The delay in dynamization was the most influential parameter in the development of DU/NU (p=0.0001). The odds for having a delayed or non-union in tibial shaft fractures rise from 2 to 4 times when dynamization is performed after 10-20 weeks of nailing. Nails dynamized after 20 weeks are 52.5 times at risk of having a DU/NU.

- **No dynamization:**

Sixty fractures were not dynamized neither surgically nor spontaneously till nail removal. These cases were mostly axially stable fractures with early progressive union, however 3 cases of DU (5%) and 3 more NU (5%) were directly caused by this static locking. The mean time to union was 19.7 weeks with a range of 12-66 weeks (Table 23, Fig. 14).

- **Dynamic nails:**

Two out of 17 dynamically locked nails were additionally dynamized after 12.5 weeks and 25 weeks respectively to enhance union (one for delayed union) and not included here. One nail was removed because of a suspected infection. One patient was lost to follow-up. The 13 remaining nails resulted in fracture union after an average of 21.5 weeks (range, 12-38 weeks). There were four cases of delayed union (31%) but no non-unions.

- **Dynamization within 10 weeks:**

Nail dynamization within 10 weeks after fracture fixation resulted in an average time of union of 23 weeks (range, 13-60 weeks). Four non-unions (14%) were seen in this group including one A3 fracture, two O-III B2 fractures, and one segmental fracture (the mean union time drops to 17.7 weeks if these 4 cases were excluded).

- **Dynamization between 10-20 weeks:**

Dynamization (surgical or spontaneous) occurring between 10 and 20 weeks postoperatively resulted in fracture union after a mean time of 24.3 weeks (range, 14-50 weeks). This was associated with 5 cases (17%) of delayed union and 3 non-unions (10%).

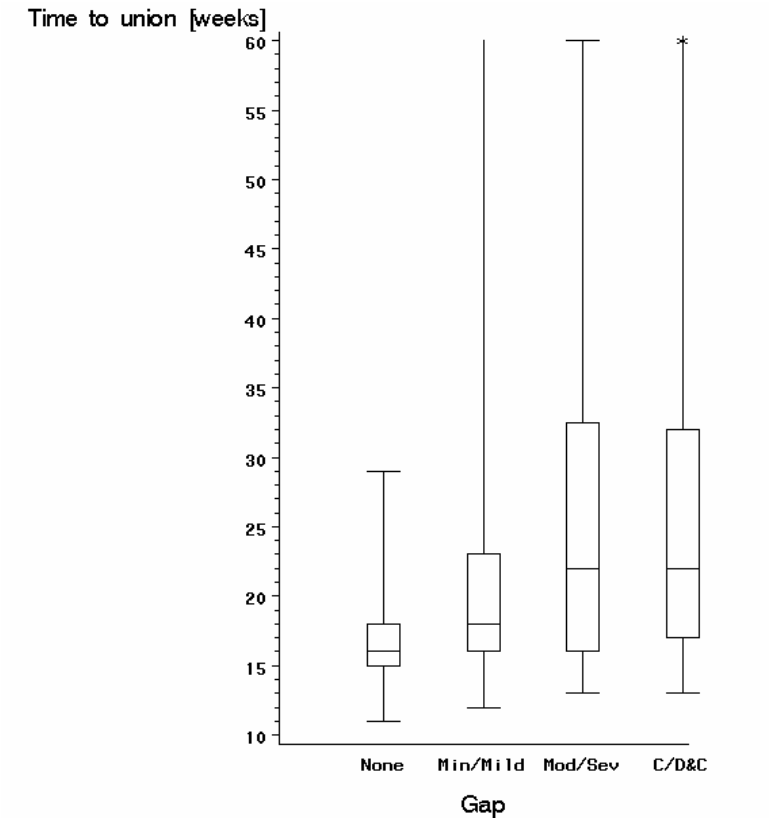


Figure 13: Fracture distraction and time to union (None: No distraction, Min: minimal distraction (≤1mm), Mild: 1-3 mm distraction, Mod: moderate distraction (3-5 mm), Sev: severe distraction (>5mm), C: comminution, C&D: comminution with distraction).

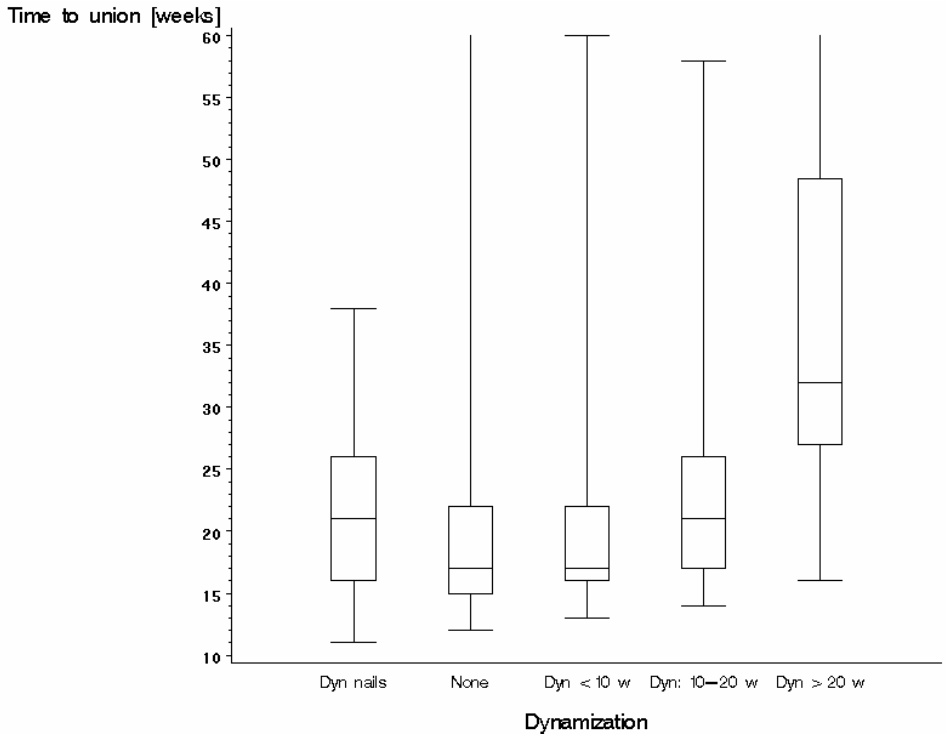


Figure 14: Fracture union according to nail dynamization (Dyn: Dynamization, w: weeks).

- **Dynamization after 20 weeks:**

Fractures that were dynamized after 20 weeks, whether surgically or through screw failures had an average union time of 42 weeks (range, 16-134 weeks). There was a 75% combined rate of DU/NU in this group (7 delayed unions and 5 non-unions).

Fibular Osteosynthesis:

Seventeen fractures (10.6%) in this study were associated with an intact fibula. All but three cases were caused by traffic accidents. Ten fractures were type A, six type B and one type C fractures. Ten fractures had either minimal or no comminution (Winquist 0-I fractures) but more than half of the fractures were associated with either open or high-grade closed soft tissue injury. The average time to union in these cases was 19.4 weeks (range,12-44 weeks). One case had a delayed union and another had a non-union (6% each), whereas the rest united uneventfully. On the other hand, fibular plating, done in 12 out of the 143 cases with fractures of both leg bones, was associated with a mean time to union 25.2 weeks (range, 14-46 weeks). All patients in the plated group were victims of high-energy injuries. Half of them had either open or high-grade closed soft tissue injury. Five fractures were classified as type A fractures, 6 as type B, and one as a C2 fracture but half of these fractures had moderate to marked comminution (Winquist II-III) or were segmental fractures. One patient was lost to follow up, delayed union occurred in about one third of the patients (4 cases), non-union occurred in one patient (DU/NU rate of 45%).

Patients with associated fibular fractures that were not plated had an average time to union of 24.9 weeks (range 11-134 weeks) with 15 delayed unions and 14 non-unions. These data show no significant difference in the time to union between cases with and cases without plating of an associated fibular fracture. The incidence of delayed union, however, was higher with fibular plating. Both groups united after a mean time of about 25 weeks, which is 5.5 weeks longer than the mean time needed for union of isolated tibial fractures (Table 24).

Table 23:
Relation between Nail Dynamization and Fracture Union

Dynamization	Union	Delayed Union	Non-union
No dynamization	19.7 weeks	3 (5%)	3 (5%)
Dynamic nails	21.5 weeks	4 (31%)	-
Dynamization ≤ 10 w	23 weeks	-	4 (14%)
Dynamization 10-20 w	24.3 weeks	5 (17%)	3 (10%)
Dynamization ≥ 20 w	42 weeks	7 (44%)	5 (31%)

Table 24:
Relation between Fracture Union and Fibular Fracture/Plating

Fibular fracture/ORIF	Union	Delayed Union	Non-union
No/No	19.4 weeks	1 (6%)	1 (6%)
Yes/Yes	25.2 weeks	4 (36%)	1 (9%)
Yes/No	24.9 weeks	15 (10%)	14 (9%)

3.3. Complications

Complications are local or systemic perioperative or intraoperative problems or difficulties not resolved after treatment or emerged after treatment (Paley, 1990). A major complication was defined by Wyrsch et al. (1996) as an infection that necessitated operative treatment, wound breakdown that necessitated a soft-tissue coverage, a neurovascular injury, fixation failure, malunion, non-union, or amputation.

3.3.1. General complications:

An alcoholic polytrauma patient with chronic obstructive pulmonary disease, a contralateral central hip fracture-dislocation, a pelvic fracture with retroperitoneal hematoma, blunt abdominal trauma with colonic contusion, and pancreatic haematoma with necrotising pancreatitis exacerbating a preexisting chronic alcoholic pancreatitis developed a septic shock. The case was rapidly complicated by multiple organ failure and the patient died 5 weeks after trauma.

Another polytrauma patient with a grade II open fracture developed adult respiratory distress syndrome (ARDS) and was admitted to the ICU and had a tracheostomy. Few days later he developed fever, leucocytosis, and circulatory failure. Wound revision was done and despite revealing no infection, the UTN was removed 16 days after insertion with IM reaming and external fixation. In a third polytrauma case, a postoperative septic shock was suspected without abnormal wound behavior. Wound revision was done, proved no infection, and the patient recovered fully with IV antibiotics.

Two patients with MVA and C3 fractures developed deep venous thrombosis (DVT) while in external fixation before UTN insertion. A third patient with bilateral tibial fractures developed an acute pulmonary embolism (PE) 20 days after trauma for which a pulmonary embolectomy was done. The patient developed a hypoxic brain damage with residual spastic tetraparesis, dementia, bradydiadocokinesia, and delayed and NU.

3.3.2. Early technical complications:

Intraoperative completion or displacement of a wedge fragment or comminution during nail insertion occurred in 13 cases. Six fractures united uneventfully, three had a DU, three developed NU, and one developed progressive valgus up to 10 degrees necessitating UTN removal and LC-DCP Plate ORIF of distal tibia and fibula. An incomplete cortical fissure fracture developed while inserting the first DLS but with no effect on stability.

Six nails in five patients where considered shorter than necessary. One had delayed union despite a dynamically locked nail and another ended in malunion due to a varus collapse of 8 degrees after FFLS of the second PLS. Two screws where considered either too long or too short respectively. One proximal locking screw was mal-inserted outside its hole. One drill bit was broken inside the static proximal hole and was left in place with proximal locking using the diagonal and the dynamic proximal holes. An incompletely inserted (protruding) proximal cap was seen in one nail without adverse effects.

Mild proximal nail migration occurred in a case with a short nail and a short first PLS after FFLS of second PLS 11 weeks after fracture with varus collapse and eventual malunion.

Distal nail migration and ankle joint penetration occurred in a patient with septic implant loosening and backed-out fourth DLS (removed) in a nail that was formerly dynamized by removing both PLSs. The nail was removed and an Ilizarov ring fixator applied after medullary reaming.

3.3.3. Malreduction:

Two patients were nailed in excessive external rotation. Revision was done 8-14 days later with new distal locking and the fractures united in normal alignment. One patient was nailed in 23º of internal rotation and had an early attempt of surgical correction but with resultant 18º external rotation malunion. Early nail removal and external fixation was done (6 weeks after nailing) in one patient with a segmental fracture and a complex malalignment with 5º distal recurvatum and 5º proximal valgus partially corrected in the distal fracture but with lateral translation. Another patient with a segmental fracture was nailed in 10º valgus, 14º procurvatum, 20º external rotation, together with posterolateral translation of the proximal fracture. Open reduction and dynamic relocking were done after 24 days with additional medial plate fixation of the proximal fracture using a 5-hole narrow LC-DCP.

Plate ORIF was also done in 2 more B3 distal tibial fractures with progressive valgus malalignment (10º), one after 11 weeks with full deformity correction and another after 20 weeks with residual valgus malunion. Another elderly patient with a distal tibial fracture nailed in 8º of valgus malalignment was lost to follow up.

Two patients with junctional fractures between the proximal and middle thirds of the tibia needed early intervention to correct postoperative malalignment: one with a C1 fracture and 8º of procurvatum was corrected after 8 days with proximal relocking and Poller screw insertion and one with a B3 fracture nailed in marked lateral translation of the distal fragment was treated with supplementary ORIF using a 6-hole 4.5 LC-DCP 2 weeks after nailing.

3.3.4. Compartment Syndrome:

The development of compartment syndrome after nailing occurred in only two patients. One had an anterior tibial compartment syndrome 12 hours after UTN with sensory abnormality in the first web space. The second was a patient with bleeding tendency (von Willebrand disease) and developed an acute compartment syndrome in the same night of fixation with peroneal nerve palsy despite preoperative desmopressin (Minirin®) treatment. Both cases undergone urgent perifibular fasciotomy.

N.B. Twenty-one fractures with impending or established compartment syndrome at presentation were also urgently decompressed.

3.3.5. Neurological injury:

Ten patients suffered neurological sequelae following their injuries. Temporary anterior tibial hyposthesia occurred in three patients. Peroneal nerve palsy occurred in 5 patients: four with distal tibial fractures with variable degrees of soft tissue injury (C-I, C-II and O-I) and recovered with expectant treatment and as a result of a compartment syndrome in a patient with bleeding tendency and recovered after fasciotomy. Superficial peroneal nerve injury occurred in a patient with O-III tibial fracture due to injury in a revolving machine with persistent sensory abnormalities. Persistent tibial nerve injury occurred in one patient and necessitated neurolysis after 1 year. Finally one patient developed a Baker's cyst with intermittent compression of the tibial and peroneal nerves. The patient refused surgery.

3.3.6. Wound problems:

Early aseptic wound complications including dehiscence, edge necrosis, and haematoma formation occurred in seven patients (4%). Most cases responded to local treatment. Some patients needed repeated vacuum sealing and wound coverage using a meshed Thiersch graft.

3.3.7. Infection:

Superficial infection (wound or soft tissue infection superficial to the deep fascia without muscle or bone involvement and with stable implant) occurred in 4 cases. All of which responded to local wound care and antibiotic treatment.

Deep infection, defined as a culture positive infection of the tissues around bone with or without osteomyelitis, occurred in five patients, all having fractures of the distal tibia (two open). In three cases, infection followed UTN implantation. Two of them had septic loosening and backed-out DLS and treated by nail removal, IM reaming, and external fixation (Fig. 15).



Figure 15: Deep infection with septic loosening of the distal locking screws. Nail removal, medullary reaming, and external fixation were done. Union occurred in varus.

.

The third was an alcoholic patient with a type III open fracture that united without additional intervention but with chronic osteomyelitis, malalignment, and 1cm shortening. Ten years later, he presented with a refracture after a quarrel. Closed reduction and external fixation were done.

Two patients ended with malunion. In the remaining two patients, infection developed after a revision reamed tibial nailing (RTN) in one and after Ilizarov external fixation and pin tract infection in the other. The former united after nail removal, reaming, and Sarmiento bracing whereas the latter had a below knee amputation.

3.3.8. Nail breakage:

Only one nail have been broken (4 months after insertion) in an alcoholic patient with an open B2 (Winquist III) fracture due to absolute non-compliance and early full weight bearing long before union. An Ilizarov external fixator was applied after nail removal and had later to be removed due to pin tract infection. Plate ORIF was performed 6 weeks later but resulted in an infected non-union, necessitating a BKA 14.5 months after the fracture.

3.3.9. Fatigue failure of the locking screws (FFLS):

The most common complication by far in this study was fatigue failure of the locking screws that occurred in 43 cases (30%). A total of 68 locking screws were either broken or excessively bent. In 25 cases, only one screw failed, the static proximal locking screw was the failed screw in 14 of them, the last DLS in 7, the proximal DLS in 3, and the first PLS (in the oblique hole) in one case. In 11 cases, 2 screws per nail failed, these were mostly both DLS in 7 patients, and in the remaining 7 cases, all three screws in static holes had failed. All failed screws, except one, were 3.9 mm locking screws (Fig. 16). Some screw found only to be slightly bent on X-ray were actually broken when they were surgically removed. Nail diameter was the only statistically significant parameter in this complication ($P<0.05$). The odds for having a FFLS were 6 times and 11.5 times higher for 8-mm and 9-mm UTN respectively as compared to the 10-mm UTN. The highest rate of FFLS occurred in proximal (50%) and transitional fractures (PM: 40%; MD: 35%), whereas the lowest rate occurred in midshaft fractures (20.5%). More than half of the cases and 51% of the failed screws occurred in distal third diaphyseal fractures. The incidence of FFLS in the latter was 30%. In segmental fractures, 3 cases had failed screws (27%).

No difference in weight-bearing protocol existed between fractures with and fractures without screw failure. Screw failure allows secondary spontaneous dynamization of static nails (autodynamization). Loss of reduction and proximal nail migration occurred in only one

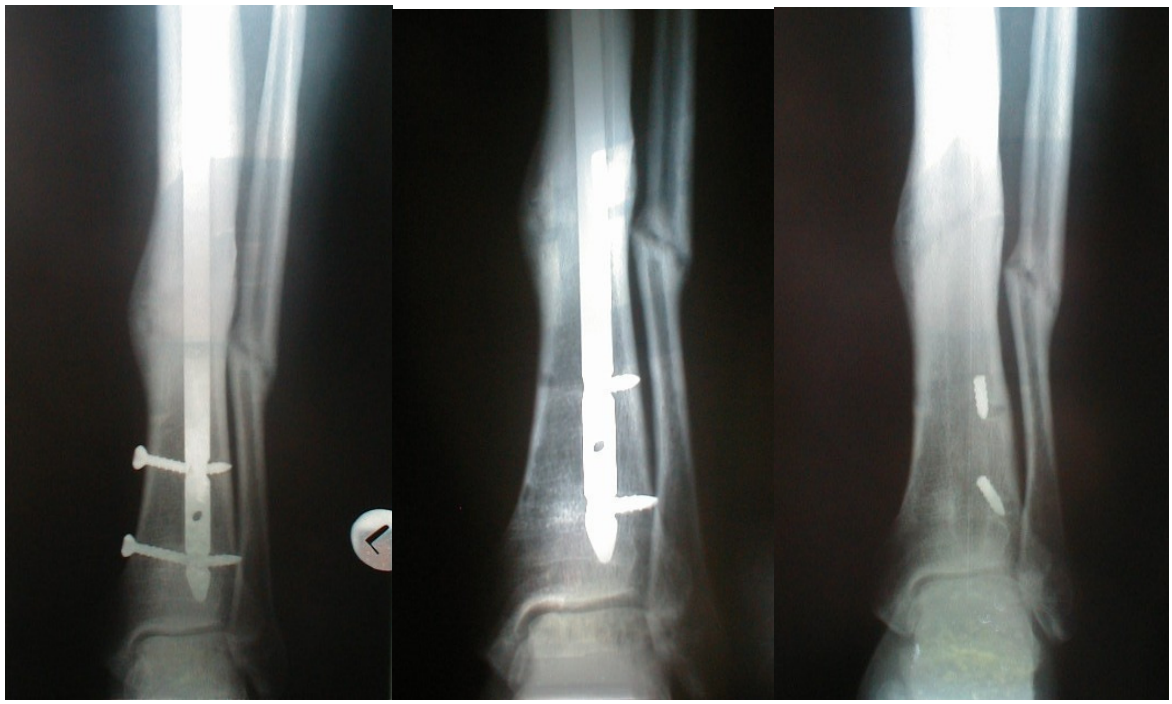


Figure 16: Fatigue failure of the distal locking screws with partial screw removal.

patient who had in addition a short nail and a short first PLS after FFLS second PLS 11 weeks after fracture. Union occurred in varus angulation of 8 degrees. Although, difficult, broken screws were usually removed fully at the time of nail removal through percutaneous incisions on the contralateral side after pushing the remaining part with a strong K-wire.

3.3.10. Malunion:

Malunion (MU) was used to describe any fracture healed in more than 5º of angulation in the frontal plane (varus/valgus), more than 10º of angulation in the sagittal plane (procurvatum/recurvatum), torsional deformity more than 10º, or shortening more than 1 cm.

In the current series, malunion occurred in 16 cases (10%). These were 9 distal, 3 middle, 3 mid-distal, and one segmental fractures. Valgus malunion occurred in 6 patients and ranged between 6 and 12 degrees (mean 10.7 degrees), of them one had additional leg length discrepancy (LLD) with 1.5 cm tibial shortening.

Three patients had a varus malunion: one as a result of varus collapse after fatigue failure of the second (static) PLS and proximal nail migration and united in 8º of varus; another had a final malunion of of 9º varus and 8º recurvatum after nail removal and external fixation due to infection with backing out of the DLS and loss of reduction; and a third patient had an early complex malalignment of 10º varus, 10º recurvatum, and 20º external rotation. Corrective osteotomy with reamed tibial nailing was done after 16 weeks and the patient had a final varus malunion of 6 degrees.

Torsional malunion (assessed clinically as well as radiographically using CT scans or navigated US measurement) occurred in 7 patients, all had external rotation deformity ranging between 15 and 24 degrees (range 19º). One of these patients had an early postoperative internal rotation of 23 degrees that was overcorrected 17 days postoperatively into 18 degrees of external torsional deformity but had no complaints. Corrective osteotomy and fixation with a RTN was also done for another patient with torsional deformity and DU resulting in union in sound alignment (Fig. 17). No other patients were operated upon because they were either asymptomtic or they refused corrective procedures.

Statistical analysis, at a significance level of 10%, showed that the most influential parameters in having a malalignment were the injury mechanism ($p=0.055$) and more importantly the degree of fracture comminution ($p=0.004$). The odds for having a malaligned fracture were 13 times in high energy falls as compared to minor falls and 5 times in patients with high comminution (Winquist III, IV, and segmental fractures) as compared to patients with more than 50% cortical contact (Winquist 0, I, and II).

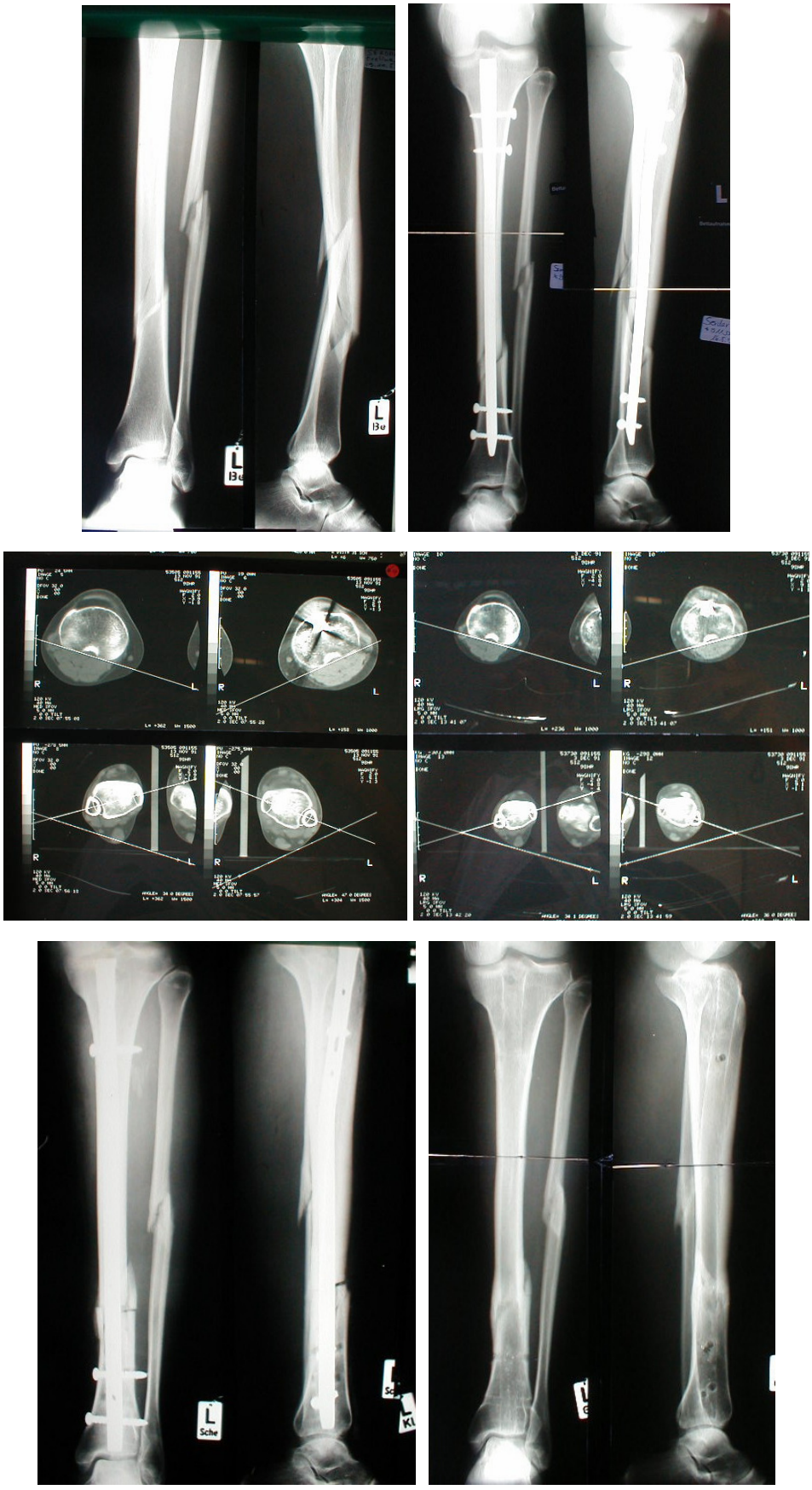


Figure 17: Torsional deformity after unreamed nailing treated by a corrective osteotomy with and a Reamed Tibial Nail. Pre- and then postoperative CT scans are shown.

3.3.11. Fibular non-union:

Two patients had isolated fibular nonunion without symptomatology or functional disability. Two more had both fibular and tibial nonunions, one following fibulectomy done to promote union and was treated with fibular plating to correct ankle valgus. A fifth patient had a torsional fibular malunion with shortening.

3.3.12. Tibiofibular synostosis:

Cross-union between the tibia and fibula occurred in 6 patients. The commonest cause was a same level fracture of both bones. This was further augmented in one case by the presence of a too long proximal locking screw close to the proximal fracture line, acting as a scaffold for bony bridge inbetween the two bones (Fig. 18).

The site of synostosis was proximal in one patient, midshaft in another, at the junction between the middle and distal thirds of the leg in a third case, and distal in the remaining three cases. This was a radiological finding and no patient developed disability, hence no treatment was needed.

3.3.13. Knee problems:

Six patients had a mild limitation of knee motion with a flexion range between 90 and 110 degrees. One polytrauma patient had knee stiffness secondary to patellar nonunion and was treated with arthroscopic lysis of adhesions. Another elderly patient had advanced knee osteoarthritis (OA). A third developed a recurrent Baker cyst with intermittent functional limitation and neurological compression.

One patient complained of a persistent anterior knee pain. Knee arthroscopy was done and revealed a hypertrophied Hoffa's fat pad with an infrapatellar plica that were resected.

3.3.14. Ankle and foot problems:

One patient had an early equinus contracture later corrected by physiotherapy. Five patients had persistent mild limitation of ankle motion (mainly dorsiflexion), of them an elderly patient had an anterior ankle impingement with adherent gastrocnemius muscle. He was managed by arthroscopic excision of the osteophyte and lysis of the adhesions tethering the gastocnemius. The same patient had a mild limitation of knee motion as well. Rare complications included a hammer big toe, a Morton's metatarsalgia, and a persistent ankle instability.

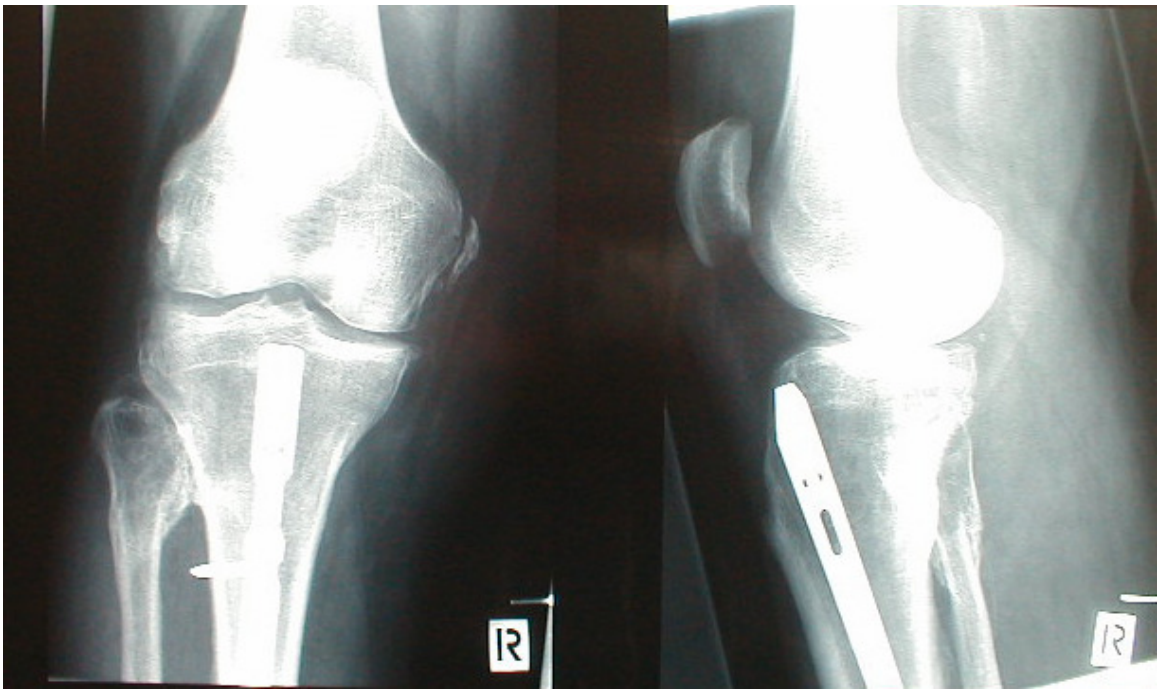


Figure 18: Proximal tibiofibular synostosis.

4. Discussion

Fractures of the tibial diaphysis constitute a spectrum of injuries that result in a loss of the normal unrestricted load-bearing capacity of the leg. This spectrum includes fatigue-type injuries, stable minimally displaced fractures from low-energy trauma, as well as extreme energy-absorbing injuries that result in the loss of soft-tissue envelope continuity, neurologic dysfunction, vascular insufficiency, and loss of bone.

Few topics in fracture care are as controversial as that of the treatment of fractures of the tibial shaft (Watson, 1994). Significant advances have been made in the last century in the management of both open and closed tibial shaft fractures. Five distinct philosophies of treatment have evolved, with ardent supporters of each. Closed reduction with cast or brace immobilization, external fixation, open reduction with internal fixation, and intramedullary nailing techniques are the four major treatment groups; the fifth is the biologic approach to the open tibial fracture, encompassing principles of radical debridement, antibiotic treatment, early wound coverage with plastic surgical techniques, and early bone grafting combined with one of the other four options for bony stabilization (Russel, 1996).

Fractures of bones have been capable of healing ever since the evolution of bone as a tissue in reptiles, amphibians, birds, and mammals (Chapmann, 1998). Humans probably first tried to influence fracture healing by inserting objects into the medullary canal in the sixteenth century. In the nineteenth century, European surgeons recognized the potential advantages of intramedullary fixation. Bircher and König of Germany described the use of metal pegs. Lambotte of Belgium first used metallic nails. According to Peltier, it was Hey-Groves of England during World War 1, Rush and Rush in the United States during the 1930s, and Küntscher in Germany during the l930s, who ushered in the era of modern intramedullary nailing as it is known today. Küntscher developed his V-shaped and cloverleaf nails in the 1930s. In 1940, he reported good results in the treatment of diaphyseal tibial fractures using closed intramedullary nailing. but it was not until the 1970s that rigid intramedullary nailing became a widely accepted treatment for tibial shaft fractures. Herzog modified the straight Küntscher nail to accommodate the eccentric proximal portal.

Zucman and Maurer (1969) treated 136 open tibial fractures using unreamed straight Küntscher nails with an 8% infection rate. However, only 15% of their open fractures were severe. Their incidence of aseptic non-union was 0.7% and they had no fracture malunions. Merle d'Aubigne et al. (1974) reported a 6.6% incidence of infection in 256 open tibial

fractures. Their incidence of non-union in open fractures group was only 2.4%. Both authors emphasized the importance of a long-leg cast and delayed weight bearing for 1 month in stable fractures and longer in comminuted fractures.

In the 1950s, Lottes developed a rigid triflanged intramedullary nail that could be inserted without reaming using either an open or closed technique. Lottes reviewed tibial fractures treated with his nail and reported infections in only 0.9% of 330 closed fractures. The infection rate was 7.3% following nailing of open unifocal tibial fractures and 6.3% in open segmental fractures. He reported 2.3% nonunion in his series. Sedlin and Zitner (1985) reported healing of 63 closed and types I and II open fractures treated with the Lottes nail. Other studies confirmed the safety and efficacy of treating all grades of open, axially stable fractures with unreamed Lottes nails.

With earlier designs of nonreamed noninterlocking nails, application was limited to short oblique and transverse isthmic fractures without comminution. Rotational control was poor, necessitating a long-leg cast. Therefore these nails fell soon into disrepute. This is because many tibial fractures either occur at the junction of the middle and distal thirds of the bone or are spiral or comminuted. The invention of interlocking intramedullary nails allowed surgeons to combine the advantages of closed tibial nailing with the avoidance of post-operative casts, therefore widening the scope of indications for intramedullary fixation. Modney is credited with designing the first interlocking nail. Küntscher also designed an interlocking nail (the detensor nail), and this was modified by Klemm and Schellman and later by Kempf and Grosse and others. These pioneers developed the techniques and implants that formed the basis for several designs and techniques now in use by Russell and Taylor, the AO/ASIF, and the Uniflex and Alta systems (Christian, 1998).

Studies published in the 1970s and 1980s by Hamza et al. and by Bone and Johnson reported unacceptably high infection rates (13.6% to 33%) in small series of open tibial fractures treated with reamed nailing. These reports led to the conclusion that medullary reaming is contraindicated in open tibial fractures, especially Gustilo types II and III. Studies of open tibial fractures treated with unreamed Ender pins and Lottes nails during the same time period reported infection rates of 6% to 7%. Animal experiments by Klein et al. (1990) and Schemitsch et al. (1994) demonstrated that cortical reaming disturbs the blood flow in the early weeks after trauma, possibly increasing susceptibility to infection. In rare instances reaming may be associated with disastrous complications. Leunig and Hertel (1996) reported three occurrences of thermal necrosis of bone and soft tissue resulting in infection in patients

with narrow canals in whom reaming was performed with a tourniquet inflated. Concerns have also been exhibited regarding an increased incidence of compartment syndrome with reamed nailing. Wenda et al. (1988), measuring IM pressures intraoperatively, found values between 420-1,510 mm Hg with reaming procedures, as compared with 40-70 mm Hg in cases where solid nails were used without reaming. These factors led to the development of small-diameter interlocking nails suitable for unreamed insertion. By preservation of the endosteal blood supply, unreamed nails provide a favourable environment for early bone healing and less risk of infection. Runkel et al. (1994) showed using fluorescence microscopy a more extensive and earlier formation of callus after unreamed tibial nailing. At 4 weeks postoperatively, the remodelled periosteal bone surface was 1.6 times that after the reamed procedure. Histological investigations showed that bone healing was faster after unreamed nailing and there was a reduced loss of vitality. This is of particular clinical relevance in treatment of fractures with severe soft tissue injury and of open and comminuted fractures.

Systemic changes, apart from other effects of reaming, have to be considered. These include pulmonary embolization, temperature-related changes of the coagulation system and humeral, neural, and inflammatory reactions, among others. Although controversy still exists regarding its clinical significance, embolization of fat and other marrow elements into the general circulation following medullary reaming has been seen experimentally in animals (Manning et al., 1983; Sturmer, 1993) and later on demonstrated in humans as well by transesophageal echocardiography and other measures (Wenda et al., 1988, 1989; Pell et al., 1993; Pape et al., 1996). An acute rise of the ESR and CRP values together with temperature elevation was noticed following reamed intramedullary nailing by Garnavos et al. (2002). The development of post-traumatic pulmonary failure (including ARDS) following early femoral nailing in the multiply injured patient is associated with the reaming process. The passage of thrombi into the pulmonary circulation after reaming has been demonstrated in studies focusing on this topic. Pape et al. (1996) observed a significant impairment of oxygenation in multiply injured patients treated with reamed nailing. Kröpfl et al. (1997) echoed these conclusions. Intramedullary nailing appears to be a particular insult to the patient's pulmonary system, especially in cases of polytrauma, since the lungs are very sensitive to any additional stress in the period immediately following trauma.

The above findings had led to a renewed interest in unreamed nailing techniques as the treatment of choice in open fractures and fractures in polytrauma patients. Several new designs of unreamed interlocking intramedullary nails have emerged and a several reports have been published on their clinical success.

In a prospective study, beginning in 1989, surgeons in Hannover started treating tibial shaft fractures using a solid unreamed tibial nail (UTN) developed by the AO/ASIF group. This nail was initially designed as a temporary implant. They reported their first 33 cases with second or third degree soft tissue damage in 1991 (Krettek et al., 1991). In 1993, 43 cases with at least 6 months of follow up were reviewed. Fracture healing occurred with a mean of about 22 weeks. Although malalignment was a concern, none of the patients had an osteomyelitis, concluding that the unreamed tibial nail is a viable alternative in the treatment of tibial shaft fractures with severe open or closed soft tissue damage (Haas et al., 1993).

Whittle et al.(1992) treated 50 open tibial shaft fractures (3 type I, 13 type II, and 34 type III) with debridement and unreamed tibial nails. Most of the fractures were the result of high-energy trauma. The average follow-up was 12 months. Forty-eight (96%) of the 50 fractures united at an average of 7 months; there were no malunions. There were 4 infections (8%), all at the sites of grade-III fractures. All resolved with no chronic osteomyelitis.

Melcher et al. (1993) treated 20 fractures of the tibial shaft with the new, solid AO unreamed tibial nail (UTN). There were 13 open fractures, while four of the seven closed fractures had severe soft tissue injuries. There were nine fractures classified as complex or type C according to the AO classification. In all, 12 fractures (five of them open) were stabilized primarily by unreamed nailing, whereas the first eight (open) fractures of the series were fixed initially by an external fixator and then nailed after 14 days. No intraoperative complications occurred, and no major soft tissue problems or infections were observed. The functional results were generally good; however, fracture healing appeared to be delayed in six cases. One patient had a further operation because of non-union. The authors concluded that the UTN seems to be a reliable and safe treatment for fractures with severe soft tissue injuries as an alternative to external fixation and that, in contrary to initial assumptions, it can be used as a definitive implant with no need for further stabilization in the majority of cases.

Riemer et al. (1995) used a nonreamed nailing technique in polytrauma patients. Weight bearing was delayed because of the concern for implant failure and frequently owing to their associated injuries. Reoperation rates were 33% for closed or type I and II fractures compared with 46% for type III fractures. Among closed type I and II, static versus dynamic nailing times to union were 36 versus 25 weeks ($P < 0.01$), and the reoperation rates were 44% versus 13% ($P < 0.04$). Static locked fractures required a 48% reoperation rate versus 12% for dynamic locked fractures. Titanium alloy nails had a 2% failure rate versus 25% for

stainless steel nails ($P < 0.01$). This study reflects the complex interplay between weight-bearing protocols, different implant designs, and materials.

Anglis et al. (1996) advocated unreamed nailing of tibial fractures in multiply injured patients. In their preliminary report detailing the first 60 consecutive fractures with a minimum three month follow-up, 56 fractures united at a mean of 21 weeks. Four non-unions, one deep infection occurred in open fractures. The major complication identified was fatigue failure of the locking bolts. Bonatus et al. (1997) analysed 72 fractures in 71 patients treated with unreamed nails. Forty nine fractures united within 6 months and all fractures ultimately healed within 12 months of injury. Deep infection occurred in only 3 factures (4%). Based on their results, the authors supported the use of nonreamed locking nailing in Types I, II, IIA, and IIIB open fractures of the tibial shaft.

The successful use of unreamed nailing in patients with open tibial fractures has led some investigators to recommend this technique for closed fractures as well. Potential advantages of unreamed nailing over the reamed technique include shorter operative time, less blood loss, and less disruption of the endosteal blood supply in patients with severe closed soft tissue injuries. Krettek et al. (1995) popularized closed interlocking nailing without reaming in Tscherne type 2 and 3 closed tibial fractures. In a prospective study, 21 closed tibial shaft fractures with severe soft-tissue trauma (grades 2 and 3) were treated with a nonreamed nail. The mean follow-up was 29 months. All fractures healed in an average time of 23 weeks. However, 3 patients required a bone graft, and in 3 patients fixation was revised (29% secondary surgery rate). One infection occurred after an exchange reamed nailing.

Conversely, Gregory and Sanders (1995), after analysis of 47 closed unstable tibial fractures treated with interlocked intramedullary nailing inserted in a nonreamed manner, have adopted the technique as the treatment of choice for the closed, unstable tibial shaft fracture in polytrauma patients but found no advantage over reamed nailing for isolated, closed, unstable tibial fractures. They encouraged early full weight bearing in a brace as soon as the patient's condition allowed. Fractures without cortical continuity were allowed protected weight bearing. Eighty-seven percent of patients healed within 26 weeks (mean of 16 weeks). The screw failure rate was 15% but required reoperation in only one case. Similarly, Duwelius et al. (1995) recommended unreamed nailing of closed fractures with severe soft tissue injuries and reamed nailing of those without significant soft tissue injury.

Court-Brown et al. (1996), in a randomized, prospective trial, compared reamed and unreamed nail insertion in 50 Tscherne type I closed tibial fractures. They found that reamed

nailing resulted in a shorter time to union and reduced the need for additional surgery. They recommended reamed tibial nailing for all Tscherne type I closed tibial diaphyseal fractures. Blachut et al. (1997) also reported a randomized, prospective study comparing 73 fractures treated with reamed nailing to 64 fractures treated with unreamed nailing. There were no significant differences in infection (0% for reamed, 1.6% for unreamed), nail failure (1.4% reamed, 0% unreamed), malunion (4.1% reamed, 3.2% unreamed), or fracture union (95% reamed, 89% unreamed), although there was a trend toward improved union with reamed nailing. Significantly more screws failed in unreamed (16%) than in reamed (2.7%) nailings.

Problems with delayed union and hardware failure with the smaller implants used in unreamed nailing have led some investigators to return to the use of reamed nailing in open tibial fractures. Using perioperative antibiotics and modern techniques of wound closure, Court-Brown et al. (1992) reported infection in 1.8% of type I, 3.8% of type II, and 9.5% of type III open tibial fractures (5.15% in type IIIA and 12.5% in type IIIB) treated with reamed nailing. These results are similar to those obtained with unreamed locked tibial nails. Bhandari et al. (2001) published a meta-analysis of the published data concerning open tibial fractures treated by both reamed and unreamed nailing. Their results have identified compelling evidence that unreamed nails reduced the incidence of reoperations, superficial infections and malunions, when compared with external fixators. They showed that the difference between reamed and unreamed nails is inversely related to the degree of soft-tissue injury associated with the fracture. Thus, analysis of the results of closed tibial fractures associated with relatively little soft-tissue injury shows that reaming confers considerable advantages whereas in fractures associated with major soft-tissue damage no advantage can be demonstrated.

Two prospective randomized studies comparing reamed and unreamed nailing in the treatment of open tibial fractures were presented in the last decade. Keating et al. (1997) undertook a study of 91 patients with 94 open tibial diaphyseal fractures. Analysis showed no clinically important differences between the groups with regard to the technical aspects of the procedure or the role of early post-operative complications. Their later results illustrated no difference in the time to union between the reamed and unreamed groups (mean time to union was 30 weeks for reamed nailing and 29 weeks for unreamed nailing) Similarly, there was no difference in the incidence of infection, non- or malunion and no difference in the functional outcome between the groups. The only difference related to the incidence of cross screw failure in the unreamed group which was 29% compared with 9% in the reamed group. They concluded that reaming did not confer any advantage in the treatment of open tibial fractures.

More recently, Finkemeier et al. (2000), published results of prospective, randomized study of 94 unstable tibial shaft fractures. They illustrated the benefit of reaming in closed tibial fractures but, like Keating et al., they failed to show any significant difference in time to union or number of additional procedures required to obtain union in open fractures. Allowing for the fact that they excluded Gustilo type IIIb fractures their infection rates were comparable to other series. These and other studies appear to indicate that fracture and soft tissue characteristics are more important in determining fracture outcome than the choice of treatment, and reamed nailing is recommended for most closed unstable tibial shaft fractures.

In the largest retrospective multicenter study ever reported, Gaebler et al. (2001) analyzed the rates and odds ratios for complications in 467 closed and open tibial fractures stabilized by small diameter nails in four level-I trauma centers. There were 52 proximal, 219 midshaft, and 196 distal fractures. Breakdown into different AO/OTA groups showed 135 Type A fractures, 216 Type B fractures, and 116 Type C fractures. Two hundred sixty-five were closed fractures and 202 were open fractures. Analysis showed five (1.1 percent) deep infections (with a 5.4 percent rate of deep infections in Gustilo Grade III open fractures), forty-three delayed unions (9.2 percent), and twelve (2.6 percent) nonunions. Compartment syndromes occurred in sixty-two cases (13.3 percent), screw fatigue in forty-seven cases (10 percent), and fatigue failure of the tibial nail in three cases (0.6 percent). They concluded that fracture distraction of more than 3 mm should not be tolerated when stabilizing tibial fractures with unreamed, small-diameter nails as this increases the odds of having a delayed union by twelve times ($p < 0.001$) and a nonunion by four times ($p = 0.057$). There was a significant increase of complications in the group of Grade III open fractures ($p < 0.001$), AO/OTA Type C fractures ($p = 0.002$), and to a lesser extent in distal fractures. However, the rate of severe complications resulting in major morbidity was low. Analysis of this multicenter study supports reports documenting low incidences of infection, nonunion, and malunion in open fractures of the tibial shaft.

The current study is one of the largest series reported from one center on the use of the AO/ASIF Unreamed Tibial Nail (UTN) in treatment of closed and open tibial shaft fractures. The major outcome measurement (dependent variable) of this study was the time to union regarding all injury variables. Although accurate determination of the time to union is difficult specially in noncompliant patients with prolonged follow up intervals and, in several studies, was not clearly identified or union was reported at four, six, and twelve months, and so on; we were able to do this in 145 of our 160 fractures.

Mean time to union in this study was about 24 weeks. This agrees favourably to other reports with use of unreamed nails by Haas et al. (22 weeks), Haddad et al. (22 weeks), Angliss et al. (21 weeks excluding 4 cases of NU), Krettek et al. (23 weeks in severe closed fractures) and Whittle et al. (28 weeks in open fractures). Although this time is somewhat longer than the mean time reported by Greitbauer et al. (1998), using Howmedica's 7.5-mm Solid Tibial nail (15 weeks) and Boenisch et al. (1996) using Russel Taylor and AO unreamed nails (18.5 weeks), this time was clearly shorter than that reported by Wiss and Stetson (1995) using reamed nailing who obtained fracture union after an average time of 28 weeks in their closed fractures and 39 weeks in open fractures and by Singer and Kellam (1995) where 42 of their 43 fractures treated with unreamed nails united after a mean of 6.1 months.

The definition of delayed and non-union is not fixed in the various reports seen. Some authors regard any tibial fracture that heals without intervention as healed uneventfully. Court-Brown (2003) defined non-union as present if the fracture did not unite without exchange nailing or bone grafting whereas Blachut et al. (1997) defined it if serial radiographs made over a period of at least 3 months, showed no progression toward healing. Greitbauer et al. (1998) defined delayed union as failure of fracture healing within 12 weeks and non-union as failure of fracture healing within 6 months whereas Duwelius et al. (1995) defined delayed union as after 6 months and non-union after 1 year. Bonatus et al. (1997) defined delayed union as failure of fracture healing within 6 months and non-union as lack of progressive healing on sequential radiographs taken at least 6 weeks apart in a fracture older than 6 months, or a fracture older than six months requiring operative intervention to achieve union. Wiss and Stetson (1995) defined delayed union as failed radiological consolidation by the end of the sixth month. A non-union was defined as fracture site pain without radiographic healing 9 months after nailing.

Because of the different protocols in various trauma centres regarding routine dynamization or the indication and timing of bone grafting or exchange nailing, it is preferred to define delayed and non-union on basis of the time required to union whether the patient needed intervention or not. The last definition was adopted but in terms of weeks. Any fracture that failed to unite within 26 weeks was defined as having a delayed union and any healing that needed more than 39 weeks was defined as a non-union. With this definition, we had a delayed union rate of 13.7% and a non-union rate of 10.3% (combined DU/NU of 24%). Bonatus et al. (1997) reported a delayed union rate of 15% and 17% non-union. Melcher et al. (1993) had 6 DU and 1 NU in their preliminary experience with 20 fractures whereas Whittle et al. (1995) reported rates of DU/NU by our definition in at least 50% of their cases.

Additional procedures to promote union, apart from dynamization, were needed in 9 cases (6%). Early nail removal or additional fixation or grafting because of malreduction, a suspected infection, or comminution in 9 more cases. This rate seems better than that reported in similar series by Bone et al. (1994), Sanders et al. (1993), Riemer et al. (1995), Whittle et al. (1995), Singer and Kellam (1995), and Steggemann et al. (1995) where secondary surgery to achieve union was needed in 32% to 48% of cases, commonly with multiple procedures.

As with most series dealing with diaphyseal tibial fractures, male predominance and a high incidence in younger age groups was also identified in this series. The third decade showed the highest incidence of fractures and the number of fractures in males was double that in female patients. The predominance of traffic, work, and sports injuries in this study offers an explanation. Age had no significant influence on fracture healing apart from a slightly higher rate of delayed union in patients older than 40 years. This was not statistically significant. Sex, on the other hand, was an important determinant. Fractures in female patients needed only ¾ of the time needed for fractures in male patients to unite. They also had half the DU/NU rate seen in male patients. This can be due to the fact that many fractures in females were caused by low energy trauma mechanisms like minor falls and stumbles.

Fractures of the tibial diaphysis constitute a spectrum of injuries that result in a loss of the normal unrestricted load-bearing capacity of the leg. This spectrum includes fatigue-type (stress) injuries, stable minimally displaced fractures from low-energy trauma, as well as extreme energy-absorbing injuries that result in the loss of soft-tissue envelope continuity, neurologic dysfunction, vascular insufficiency, and loss of bone.

Since ancient Egyptian times, many authors have emphasized that tibial fractures are not all alike, and that prognosis varies with the severity of the injury. The importance of an open wound extending to the fracture site was recorded in the Edwin Smith papyrus. Hamilton emphasized the prognostic significance of comminution. Not until the end of the nineteenth century, when radiography was applied to the diagnosis and treatment of fractures, could fracture configuration and displacement be used for classifying fracture severity. In 1964, Nicoll referred to the so-called "personality of the fracture." He recognized the degree and severity of the initial displacement, the severity of the damage to the soft-tissue envelope, the amount of comminution at the site of the fracture, and the presence of infection as factors that determine a poor outcome. More recently, Trafton (1988) described severe soft-tissue injury, involvement of the articular surface, complete initial displacement of the fracture, comminution of more than half of the circumference of the bone, and a transverse

orientation of the fracture as indications of an unstable fracture, which tend to preclude non-operative treatment.

Tibial fractures have many causes, ranging from twisting forces to severe injuries like being crushed between 2 automobile bumpers. Severity can be graded in several ways. It is essential to distinguish between high- and low-energy transfer. The damage associated with a severe soft-tissue injury to an extremity is the result of a high-energy impact between an object and the limb. On contacting the object, the limb absorbs energy and then releases it in an explosion that comminutes bone and creates a soft-tissue shock wave. This shock wave strips the periosteum. If the shock wave is substantial, it will tear apart the skin, creating an open fracture as well as a momentary vacuum that sucks adjacent foreign material into the depths of the limb. Additionally, loss of skeletal stability may cause stretching, tearing, or laceration of the neurovascular bundle with obvious sequelae, including compartment syndrome (Sanders et al., 1995).

Oni et al. (1988) noted that the only major clinical factor associated with a delayed union was a high-energy injury. There was a much higher prevalence of delayed healing with this type of injury than with fractures caused by a low-energy mechanism. The average time to union was approximately 20 weeks for the stable fractures that had been caused by a low-energy mechanism and more than 30 weeks for the unstable fractures that had been caused by a high-energy mechanism ($0.02 > p > 0.01$).

Corroborating the results in these studies, the time to union in the current series was directly proportional to the energy imparted to the tibia during injury. The shortest time was recorded in patients with minor falls (19.5 weeks) and the longest was seen in work accidents. Low energy mechanisms (minor falls, sport injuries, and low-energy direct trauma) had a mean time to union of 19.7 weeks with a combined DU/NU rate of 15%. On the other hand, high energy injuries (high-energy falls, work, and traffic accidents) had a mean time to union of 27 weeks and almost double the DU/NU rate (30%). The difference was statistically significant ($p=0.005$).

Unstable high-energy fractures are usually associated with injuries of multiple organ systems or are in conjunction with multiple fractures. In this series, the presence of associated injuries prolonged the healing time and increased the rate of non-union not only because of delay in weight bearing with associated lower extremity injuries but also because of the high-energy trauma associated.

Bauer et al. (1962) and Edwards (1965) noted that the type of trauma (direct or high-energy versus indirect or low-energy) had a significant effect on the outcome and related this to the extent of soft tissue damage. They suggested that the prognosis in fractures of the shaft of the tibia was related more to the severity of soft tissue damage than to the bone injury. In the current study, high-energy soft tissue injuries were present in all but 8 DU/NU cases. Fractures with no ST injury had a mean time to union of 18.6 weeks with only one case of DU (4%). Fractures with closed ST injury were associated with 22% rate of DU/NU. This rate is doubled in open fractures (40% DU/NU). Similarly, Greitbauer et al. (1998) noted that their mean union time of 15 weeks was prolonged to 27 weeks in Grade IIIA open fractures and to 21 weeks in Grade IIIB open fractures, for an average of 23 weeks for all Grade III open fractures ($p = 0.02$). The authors concluded that fracture union appeared to be mainly a function of soft tissue injury. Gaebler et al. (2001), in their multicenter study, had the highest rate of DU in grade III open fractures (23%), compared with closed (4.5%), OI (6.2%), and OII fractures (10%). We have had the same observations where the time to union and the rate of DU/NU were progressively increasing as the magnitude of ST injury increases , with type III open fractures having statistically longer time to union than all other classes. Similar findings were also shown in other reports by Singer and Kellam (1995), Boenish et al. (1996), Angliss et al. (1996), and Whittle et al. (1995).

Johner and Wruhs (1983) found that the most important factor in prognosis was the fracture pattern, with nonspiral, bending fractures having the worst prognosis. Spiral fractures seem to be associated with less soft-tissue injury because they are caused by indirect forces, whereas bending fractures involve crushing injury of varying degrees to the soft tissues, compromising the biologic repair capability of the fracture. Experimental studies by Oni et al. (1989) have validated this hypothesis. By manually producing rabbit tibial fractures and assessing soft-tissue damage visually and radiographically, they noted that transverse fractures produced circumferential laceration of the periosteum and complete transection of the marrow. Spiral fractures, however, produced longitudinal periosteal laceration and incomplete marrow damage. They also demonstrated in perfusion studies that collateral channels may feed trunks of the nutrient artery, even though the artery is lacerated by fracture.

In this study, the fracture pattern, classified using to the AO/ASIF system, statistically influenced the healing time. Complex type C fractures took significantly longer time to unite than simple type A fractures. The results of most clinical series support these findings. Boenisch et al. (1996) noted that the simpler fractures of type A and B took 17.6 and 17.4 weeks to unite. Complex type C fractures took a mean of 33.6 weeks. Gaebler et al. (2001)

found a significant increase in DU in type C fractures (16%), compared with type A (7%) and type B (6%). Angliss et al. (1996) had all their type A fractures united at a mean of 17.7 weeks. Non-union occurred in 3 type B and 1 type C fractures with the mean time to union for the rest of cases of 26.3 and 19.7 weeks respectively. The mean time to union in Greitbauer et al. (1998) study was 12, 13, and 22 weeks for Type A, B, and C fractures respectively. AO type C fractures, when open, resulted in delayed union. Combined with soft tissue Grade II injury, time to union was 24 weeks, with Grade IIIA 32 weeks, and Grade IIIB 40 weeks on average. The only exception was Singer and Kellam (1995) report who noted a longer time to union for simple type A (29 weeks) than type B or type C fractures (25 and 28 weeks respectively). This was not statistically significant.

According to Winquist et al. (1984), comminution ranges from none to total circumferential involvement. In the current study, comminution affected significantly the time to union ($p=0.05$). It had also increased the risk of DU/NU as well as fracture malalignment and malrotation. The odds to experience DU/NU were more than 6.5 times higher if comminution more than half the cortical circumference was present. Fracture malalignment risk was 5 times higher with such comminution. Bone et al. (1994) also noted a relationship between fracture comminution and the need for secondary procedures. In their study, all 7 non-comminuted fractures healed without an additional procedure; however, 13 (59%) of 22 comminuted fractures needed an additional procedure to achieve solid union ($p < 0.001$).

Fractures of the tibia most commonly occur in the distal 2/3 of the bone (Nicoll, 1964; Sarmiento et al., 1989). Involvement of the proximal third is relatively uncommon, with an incidence ranging from 5% to 11% in most large series (Nicoll, 1964; Bone and Johnson, 1986; Sarmiento et al., 1989; Court-Brown et al., 1990; Freedman and Johnson, 1995). In this series, fractures of the proximal third and proximal-middle junctional fractures constituted 5.6% of all fractures. Some segmental fractures also had their upper level in the proximal tibia. Although not statistically significant in this study, mostly because of this small sample size, a prolonged time to union with a DU/NU developing in 3 out of 8 cases are worrisome. Midshaft and distal tibial fractures had nearly similar times to union and DU/NU rates (21%). Mid -distal junctional and segmental fractures, on the other hand, had a higher rate of DU/NU (30% and 34% respectively). A longer time to union in proximal fractures was also noted in several series. A mean time to union of 26.8 weeks was reported by Boenisch et al. (1996) in their proximal third fractures, in comparison to 17.8 and 17.9 in middle and distal third fractures. Greitbauer et al. (1998) noted that the time to union was significantly longer statistically in AO Type C complex tibial fractures, especially when they

were located at the proximal third of the tibia or when there was an intermediate segmental fragment (Type C2). All their proximal and segmental fractures, regardless of fracture type and soft tissue injury, averaged 22 weeks to union. When combined with open injuries, proximal third fractures and segmental fractures showed delayed union up to 40 weeks;

Fractures of the proximal tibia are also notorious for malalignment following IM nailing because of the large size discrepancy between the tibial nail and the wide tibial metaphysis. Anatomic reduction is not always possible using the nail despite choosing an appropriate path. In contrast to mid and distal tibial and isthmic femoral fractures, an IMN will not necessarily reduce proximal tibial fractures. Valgus, antecurvatum, and residual fracture site displacement are common. Surgical errors of a medialized nail entry point and a posteriorly and laterally directed nail insertion angle contributed to malalignment. More than one third of proximal and proximal-middle junctional fractures had an early malalignment or an established malunion. Similarly, 2 more segmental fractures were reoperated early because of malreduction of their proximal fractures.

Lang et al. (1995) treated 32 extraarticular fractures of the proximal third of the tibia with locked intramedullary nails including 27 unreamed nails. Thirty fractures eventually healed; however, secondary procedures were needed in about 1/3 of the cases to achieve union. Angular malalignment of more than 5 degrees was seen in 84%, a displacement of one or more centimetres in 59% of fractures, and loss of fixation in 25%, most often associated with a single proximal locking screw. Based on their findings, the authors have limited the use of IMN for proximal third tibial shaft fractures and consider alternate forms of fixation. In their biomechanical study, Henley et al. (1993) found that medial to lateral screws in one plane can allow the nail to slide on the screws. Apex anterior angulation or anterior displacement can be caused by a portal that starts too distally or is directed too posteriorly. They also found that a nail with a proximal bend that is at or below the fracture site can cause anterior translation of the proximal fragment when the nail wedges against the cortex. Locking the nail proximally with the knee flexed causes extension of the proximal fragment due to the pull of the patellar tendon. In a roentgenographic analysis of 133 tibial nailings, Freedman and Johnson (1995) found that 58% of proximal-third fractures were malaligned as compared with 7% of middle-third fractures and 8% of distal-third fractures. Eighty-three percent of the malaligned fractures were either segmental or comminuted, and there was no difference between reamed and unreamed insertion. Refinements in technique, including more precise placement of the entry portal, the use of some form of supplemental fixation such as blocking screws, unicortical plates, and two-pin medial external fixation have greatly reduced

the frequency of this complication. Ricci et al. (2001) reported 12 proximal-third tibial fractures treated with locked intramedullary nailing and blocking screws. Malunion occurred in only one patient, but a lateral blocking screw to control valgus had not been used.

Distal tibial fractures are often highly unstable and accompanied with a high rate of malunion and other problems (Whittle et al., 1992; Hutson et al., 1995; Strecker et al., 1996). Additional means of stabilization, such as Poller screws and fibular plates, were therefore suggested in these cases. Apart from biological reasons, clinical problems reported for distal fractures may be due to the less favourable mechanical conditions in unreamed nailing. In their biomechanical study, Duda et al. (2001), reported that unreamed nailing of distal tibial defects results in extremely low axial and high shear strain between the fragments. They concluded that the treatment of distal tibial shaft fractures with unreamed nailing without additional fragment contact or without stabilizing the fibula should be carefully reconsidered. In a study by the AO Clinical and Documentation center in Davos, the treatment of tibial shaft fractures in Swiss clinics from 1994 to 1997 was analysed in detail. In a total of 94 cases treated by unreamed nailing, 17 showed delayed fracture healing. In 10 cases, simple fractures were located within the distal third of the bone and had to undergo revision surgery. All 10 fractures showed simple fracture patterns and were without accompanying severe soft tissue damage or other complication circumstances (Goldhahn et al., 2000). These complications give rise to doubt about the applicability of the general concept of favourable biological conditions (e.g. minimal invasive, intramedullary blood supply preserved due to no reaming) if appropriate mechanical stability is missing.

The current study confirmed the high rate of complications accompanying fractures of the distal tibia. Although not statistically significant, deep infection occurred solely in this area. Half of the cases with early malreduction and three-fourths with established malunion were distal third or mid-distal junctional fractures. The rate of malalignment was clearly higher in such fractures (17% each) than in midshaft diaphyseal fractures (6%). The rate of screw failure was about 10% more in distal than middle third fractures (30% and 20.5% respectively). The time to union, however, and the rate of DU/MU was nearly the same in distal and midshaft fractures. This compares favourably to reports by Boenisch et al. (1996), Bonatus et al. (1997) and Greitbauer et al. (1998), among others. Unreamed nailing seem to offer an acceptable treatment alternative in distal shaft fractures. Biomechanical complications, however, calls for product modification in such implants (Blachut et al., 1997; Gaebler et al., 2001).

It is important not to ignore an associated fibular fracture, as it may provide helpful opportunities for reconstructing a severely injured leg. Once fixed or healed, it may contribute to stability. It may be used as the basis of bypassing segmental defects in the tibia and also guides restoration of tibial alignment. The pattern of the associated fibular fracture indicates the degree of blunt trauma to the soft tissues and the energy imparted to the fracture. Severe comminution or tibiofibular diastasis indicate an unstable fracture with relative devascularization of the fracture fragments and the surrounding soft-tissue envelope, along with a tendency for a higher rate of delayed union, non-union, and malunion.

Some believe that the presence of an intact fibula makes an isolated tibia fracture more prone to complications, such as delayed union and non-union or varus deformity resulting from maintenance of length on the lateral side (Teitz et al., 1980). Oni et al. (1988) defied these reports stating that an intact fibula does not affect tibial fracture healing rates. In our point of view, an intact fibula actually signifies a low-energy stable fracture with a better outcome. The presence of an associated fibular fracture often indicates an unstable fracture as well as a high-energy mechanism of injury (Oni et al., 1988; Den Outer et al., 1990). It was clear in this study that isolated tibial fractures needed a shorter time to union (19.4 weeks in contrast to 25 weeks) and a lower rate of DU/NU (6% each) than cases with associated fibular fractures. Fibular plating, however, was associated with a higher risk of delayed union (36%) than in unplated fractures (10%). The rate of non-union was the same (9%).

Several recent reports have shown that, although tibial fractures may heal with 100% displacement, delayed and non-union are more common with this degree of displacement. Conversely, no distraction should be tolerated, because as little as 5 mm of distraction may increase healing time of the tibial fracture to 8-12 months (Ellis, 1958). In unreamed nails, however, Gaebler et al. (2001) showed that a fracture distraction of as little as 3 mm increased the odds of delayed union by 12 times ($p>0.001$) and the odds of having a nonunion by 4 times ($p=0.057$). Gaps at the fracture site were also considered responsible for delayed union by Wood et al. (1992). Duwelius et al. (1995) noted that fractures that were not adequately compressed had higher rates of delayed union (25% versus 18%) and non-union (25% versus 4%) than fractures compressed to within 2 mm. Krettek et al. also noted the necessity of eliminating gaps at the fracture site and describe a "backstrike" technique of distal locking first, backing up the nail and then proximal locking. Similar findings have been observed in the current study. Fracture site distraction was a statistically significant parameter affecting the time to union ($P=0.01$). Fractures with severe distraction (>5 mm), had nearly double the time to union than fractures with no gaps. The odds for having a delayed or non-union were

1.6 times with distraction of 1-3 mm, and 6 times with distraction more than 3 mm. Gaps from comminution with or without distraction were associated with 9 times risk of having a DU/NU. Combined distraction and comminution were associated with the longest time to union (34.3 weeks) and the highest rate of delayed and non-union (40% each). These results are supported by biomechanical studies done by several researchers. In their experimental studies, Augat et al. (1998) demonstrated that large osteotomy gaps resulted in poorer mechanical and histological qualities, and a less complete repair process. Increased size of the gap (from 1 to 6 mm) resulted in a significant reduction in the bending stiffness of the healed bones. Larger interfragmentary movements and strains (31 compared with 7%) stimulated larger callus formation for small gaps (1-2 mm) but not for larger gaps (approximately 6 mm) (Claes et al., 1997). Cortical contact significantly improves the stiffness of fixation constructs in axial and valgus/varus loading but not in torsion (Henley et al., 1993). Fixation that allows excessive shear movement significantly delayed the healing of diaphyseal osteotomies compared to healing under axial movement of the same magnitude (Augat et al., 2003).

Interlocking fixation is defined as dynamic, static, and double-locked. Dynamic fixation controls bending and rotational deformation but allows nearly full axial load transfer. Static fixation controls rotation, bending, and axial load and makes the implant a more load-bearing device with the potential for a reduced fatigue life. It is used in comminuted fractures. The double-locked mode controls bending, rotation, and some axial deformation, but because of capability of axial translation of the screw within the nail, some shortening is possible (Christian, 1998). While locking is advisable in reamed nailing, it is nearly mandatory in unreamed nailing, since the nails used are thinner and consequently, the unreamed nail-bone construct is less stable than reamed construct (Fairbank et al., 1995).

Static interlocking seems to abort fracture repair. In the femur, dynamization of statically locked nails is rarely necessary. In the tibia, however, dynamization of interlocking nails is necessary to avoid impairment of fracture healing (Bone et. al, 1994). It also decreases the risk of autodynamization through fatigue failure of the locking screws. Stegemann et al. (1995) recommended that statically locked small-diameter nails that are inserted without reaming should be either dynamized or bone-grafted at 6-8 weeks after injury to improve the rate of union in open fractures. Other authors have also advocated early nail dynamization in axially stable fracture (Kassman et al., 1992; Wood et al., 1992; Duwelius et al., 1995). Riemer et al. (1995) found that tibias treated with dynamic nails united in an average of 20 weeks, with 3 reoperations whereas tibias treated with static locked nails united in an average of 30 weeks, with 21 reoperations. Thomas et al. (1997) showed biomechanically that

unreamed dynamic nails were successful in increasing the compressive loading across the fracture site. Claes et al. (1995) studied the effect of dynamizing externally-fixed diaphyseal osteotomies on bone healing in comparison to rigid fixation of osteotomies having similar remaining gap sizes. Compared to the rigidly fixed osteotomies, the dynamized osteotomies showed significantly ($P < 0.05$) greater (+41%) callus formation and 45% greater tensile strength of the newly formed bone in the cortical osteotomy gap. It has been also shown that a certain amount of interfragmentary movement stimulates callus formation (Goodship and Kenwright, 1985) and healing rate (Kenwright et al., 1991). In the current study, delay in dynamization was the most influential parameter in the development of DU/NU ($p=0.0001$). The best time seems to be within 10 weeks following nailing. The odds for having a delayed or non-union in tibial fractures rise from 2 to 4 times when dynamization is done after 10-20 weeks of nailing. Nails dynamized after 20 weeks are 52.5 times at risk of having a DU/NU.

Technical complications (fracture of the drill bit, excessively short or long nails or locking screws) are common for all interlocked nailing systems (Klemm and Borner, 1986). Additional intraoperative fracture lines or fragment comminution were somewhat more frequent than in other reports on reamed nailing, with complicated healing in about half of the cases. The unreamed insertion of interlocking nails calls for a precise preoperative planning and a careful operative technique to decrease the risk of such avoidable complications.

Several studies reported compartment syndromes when both reaming and traction were used during the operation (Koval et al., 1991; Moed and Strom, 1991; Tischenko and Goodman, 1990; Anglen and Banovetz, 1994; Tornetta and Templeman, 1997) despite some evidence that canal reaming itself does not increase the risk of compartment syndrome (McQueen and Christie, 1990). The pressures studies of Tischenko and Goodman (1990) also indicate that there is a peak of pressure with reduction and sustained traction on an orthopaedic table. Only two cases in this study developed compartment syndrome after nailing, one with a bleeding tendency. All patients were positioned on an ordinary radiolucent operating table with the knee flexed to 90 degrees over a bolster. No traction was applied and the fracture was manipulated into position as the nail was passed. This seems a safer, quicker, and less traumatic technique than the use of a traction table.

Open fractures of the tibia have often been complicated by problems of malunion, non-union, and infection, compared with closed fractures, sometimes resulting in amputation, with a dramatic increase in grade III open fractures (Gustilo et al., 1984). An open fracture of the tibia differs from that of the femur in lack of an adequate muscular cuff, which usually

covers the site of the femoral fracture. The most severe tibial fractures are those caused by crushing injuries. These have complex highly comminuted or segmental patterns with extensive damage to the surrounding soft tissues. Sometimes the skin is minimally burst, suggesting the so-called “type I”. However, by definition, type I injuries consist of laceration of the skin envelop by a spike of bone produced in an indirect torsional injury. The term should not be used for injuries with different mechanisms or radiographic appearances.

Infection rates of up to 33% have been reported by Smith (1974) in a series of 18 open tibial fractures treated with reamed nails. Bone and Johnson (1986) reported infection in 2 of 8 grade II and III open tibial fractures treated with primary nailing with reaming. Hamza et al. (1971) evaluated 22 open tibial fractures with a nearly equal distribution of wounds, and they noted three infections (13.6%) in patients who had been managed with nailing with reaming. Wiss and Stetson (1995) reported a 21% occurrence of deep infection in 33 types I and II open tibial fractures treated with reamed nailing. These authors discouraged the use of reamed nails in open fractures even on delayed basis.

Using unreamed tibial nails, however, Greitbauer et al. (1998) had no infections in 70 cases (including 28 open fractures). Analysis of 202 open fractures by Gaebler et al. (2001) showed an infection rate of 2.5 % of all open fractures and an infection rate of 5.4% for OIII fractures. Only four infections (8%), all at the sites of O-III fractures, have been reported by Whittle et al. (1992), all resolved with no chronic osteomyelitis. The deep infection rate after UTN insertion in the current series (2%) compares favourably to the above mentioned reports. These low infection rates, compared with other methods of stabilization, show that unreamed nails are advantageous in the stabilization of tibial fractures with significant soft tissue injury.

Such favourable clinical results has been supported by several experimental studies. Less damage to the endosteal blood supply, less heat production, and a considerably less bone necrosis allows for a lower infection rate and regular fracture healing with such implants (Klein et al., 1990; Runkel et al., 1994). A loose-fitting nail did not affect cortical perfusion as did a tight-fitting nail and it allowed more complete cortical revascularization at 11 weeks post nailing (Hupel et al., 1998). Furthermore, the nail's solid form and its smooth surface may decrease the susceptibility to infection (Cordero et al., 1994). The susceptibility to experimentally-induced infection comparing solid with tubular nails in an animal model, has been studied by Melcher et al. (1994, 1995). The statistically significant results showed higher susceptibility to infection in the group treated by tubular nails when compared to the solid nail group. The dead space within the tubular nail is probably the main reason for the difference.

It has been recently argued that the decreased infection rate with unreamed techniques is owed to the advances in the operative care of open fractures with extensive soft-tissue debridement and coverage, methods of fixation, and broad-spectrum antibiotic coverage. Some recent reports have showed that a low infection rate between 5 and 10% and a reasonable outcome can be obtained with the use of reamed nails as well. These studies, showed clearly worse results, however, when only type IIIB open fractures are considered. Infection rates of up to 23% and a non-union rate of 70% are then found (Court-Brown et al., 1991; Keating et al., 1997; Finkemeier et al., 2000). On the other hand reports for the same open fractures subgroup revealed significantly better results with unreamed nailing. Infection rates around 6% and non-union between 0 and 17.6% (Tornetta et al., 1994; Schandelmaier et al., 1994). Using an external fixator as the means of skeletal stabilization, low rates of infection may be achieved in cases of open tibial fractures with severe soft tissue injuries and defects (Gustilo and Anderson, 1976). However, long recovery periods, delayed union, and pin tract infections may occur (Shepherd et al., 1998). Santoro et al. (1991) reported a prospective randomized study that directly compared stabilization with external fixation and nonreamed interlocked nails. They found a higher union rate, shorter time to union, and fewer malunions in their nail group. Tornetta et al. (1994) undertook the first study purely of Gustilo type IIIb fractures and compared unreamed nailing with external fixation. A shorter time to healing and a high patient tolerance was associated with unreamed nailing. Early fracture healing, less procedures to achieve union, a better fracture alignment, a higher ankle range of motion, and an overall better functional outcome with unreamed nails as compared with external fixation was also documented by Schandelmaier et al. (1994), Dervin (1996), Henley et al. (1998), and Alberts et al. (1999). Singer and Kellam (1995) noted that unreamed nails are more acceptable to the patients than external fixators and allow improved handling of the soft tissues in the acute phase and simplify the treatment of complications in the later phase. Local or free muscle flaps can be easily used to cover soft tissue defects with such fractures after unreamed nail insertion as well (Shepherd et al., 1998).

There are four components to fracture malunion: angulation, rotation, translation and shortening (Milner and Moran, 2003). Limb malalignment and shortening cause cosmetic deformities, gait abnormalities, and alter the loading biomechanics of the knee and ankle joints by decreasing the total area of contact pressure, which results in regions of increased pressure where the residual contact occurs. This increased pressure may cause increased shear stresses on the articular cartilage in the areas of high stress, which may result in the development of posttraumatic arthritis (Tarr et al., 1985; Ting et al., 1987). Malalignment has

been shown to accelerate the progression of established OA of the knee (Bilat et al., 1994) and may increase the risk of developing medial compartment OA (Milner and Moran, 2003). There is a significant association between lower limb malalignment after tibial fractures and ipsilateral subtalar stiffness as well (Milner et al., 2002).

Because of the body's ability to compensate for a deformity, it is difficult to establish definite guidelines for unacceptable deviations from the normal position. Anteroposterior angulation and external rotation deformities are more easily tolerated than opposite deformities (Cimino et al., 1990). However, there are data to indicate that, as the level of deformity approaches the distal third of the tibia, even a minor degree of malalignment can affect the ankle joint (Tarr et al., 1985; Ting et al., 1987). Up to 1 cm shortening is generally acceptable if alignment and rotation are restored. There is no consensus in the literature on what degree of MU is significant. Many authors have suggested arbitrarily values of 5°-10° as the limits of acceptable angulation. Nicoll (1964) stated that more than 10° angulation in any plane is unacceptable. Dehne et al. (1961), Sarmiento (1967), and Brown and Urban (1969) reported satisfactory function when angulation was less than 10°. Dietz and Merchant (1989, 1990) suggest that angular deformities of less than 10° to 15° are well tolerated over the long term follow up. MU was defined by Blachut et al. (1997) as any angulation more than 5°, more than 1cm of LLD or 15° of rotational malalignment. Wiss and Stetson (1995) defined malunion as shortening >1cm, angulation in any plane >7°, or malrotation >10°. Whittle et al. (1992), Bonatus et al. (1997), as well as Singer and Kellam (1995) defined malunion as varus or valgus angulation of more than 5°, anteroposterior angulation of more than 10°, or shortening of more than 1cm. Russell (1996) used the same definition but added rotational displacement of more than 10° whereas Trafton (1988) tolerated shortening up to 15 mm.

Using Russell's criteria, MU occurred in 16 patients in the current study (10%). The same rate was seen in the reports by Bonatus et al. (1997) and Boenisch et al. (1996) a slightly lower rate (5.6%) was noted by Henley et al. (1998). Although small-diameter nails are less able to obtain reduction by interference fit granted by larger diameter reamed nails, yet axial malalignment and limb length discrepancy are not peculiar for unreamed nailing procedures. The rates above correspond to those observed after conventional nails (Kuner et al., 1976). Keating et al. (1997) reported 6% malunion in their open fractures treated by reamed nailing. Furthermore, Freedmann and Johnson (1995) reported a 13% rate of malunion in reamed as comparted with 9% of their unreamed tibiae.

The main risk factor accounting to malalignment in this study was the degree of fracture comminution. The odds were 5 times higher with marked or segmental comminution than when more than 50% cortical contact was present. High-energy falls were 13 times more at risk of malalignment than low energy falls. Although not statistically significant, early malreduction or established malunion were also common in proximal and distal third fractures. Similar observations were made by other authors. All 3 malunited fractures reported by Whittle et al. (1995) were segmental fractures with malalignment occurring in the proximal fracture. Strecker et al. (1996) noted that spiral fractures of the distal tibia offer a critical tendency to secondary varus and torsional malalignment, particularly after unreamed nailing and consecutive shortening due to breakage of locking bolts. Greitbauer et al. (1998) reported 5 cases of antecurvatum in proximal shaft fractures (7%) as well as valgus deformity between 5-10 was recorded in 4 (6%) cases and recurvatum in 2 (3%) of distal fractures. Freedmann and Johnson (1995) reported a 12% rate of malunion, defined as 5 degrees angulatory deformity in any plane, after radiographic analysis of 133 cases of intramedullary nailing of the tibia . Malalignment was seen in 58% of proximal third fractures, 7% of middle third fractures, and 8% of distal third fractures. Of the malaligned fractures, 83% were either segmental or comminuted. Thirteen percent of the reamed tibiae were malaligned as compared with 9% of the unreamed tibiae. It seems that early bone grafting or exchange reamed nailing should be regarded when significant fracture comminution is present.

Rotational deformity seems to be commonly underestimated. In contrast to the reports by Boenisch et al. (1996), Greitbauer et al. (1998), and Gaebler et al. (2001), who found no rotational malunion in their cases, malrotation was seen in nearly half of malunion cases in this study. This is because rotational assessment was done in a considerable number of cases using CT scans or US measurement whereas it was evaluated clinically in other studies.

Hardware failure was recognised as the most frequent complication in this series. Fatigue of the locking screws is a common denominator in nearly all reports on using unreamed nails with rates ranging between in 6% and 41% whereas nail failure on the other hand was reported occurred in 0% to 6% of cases (Cole and Latta, 1992; Piccioni and Gaunche, 1992; Bone et al., 1994; Sanders et al., 1994; Riemer et al. 1995; Whittle et al., 1995; Singer and Kellam, 1995; Stegemann et al., 1995; Angliss et al., 1996; Kneifel and Buckley, 1996). An overall FFLS rate of 30% in the current study is quite comparable. Only one nail failed in an alcoholic noncompliant patient. Such low nail failure rates provide no significant indication that nail failure occur more often with unreamed implants. Small diameter nails seem stable enough to withstand the loads applied and can thereby be used as

definitive implants. However, The load is not carried by the compound system of nail and bone as in reamed nails, but is rather transmitted directly to the locking screws. As a consequence, screw failures will occur. Electron microscopy showed that bolt failure is caused by a fatigue process (Boenisch et al., 1996; Greitbauer et al, 1998).

Whittle et al. (1995) identified delayed union, degree of comminution, metaphyseal location, and dynamic locking of unstable fractures to contribute to hardware failure. Gaebler et al. (2001) reported a significant increase in screw breakage in grade III open fractures, an obvious increase in AO Type B and C fractures, and a higher failure rate with distal and midshaft fractures. Ruiz et al. (2000) associated implant failure with open fracture, severe comminution, smaller diameter nails, and distal third fractures. Several reports also indicate an increased incidence of mechanical failures in the unreamed nailing of distal tibial fractures (Whittle et al., 1992; Hutson et al., 1995; Kneifel and Buckley, 1996; Finkemeier et al., 2000) found that screw failure occurred much more commonly if one distal screw was used as compared to two distal locking screws (59% to 5%). Proximal screw failure occurred more often however with 2 distal screws. It was also common in heavy individuals, in tibias with wide medullary canals, and in the metaphyseal region, compared with the diaphyseal region.

In this study, the highest rate of FFLS occurred in proximal third and transitional fractures followed by distal third diaphyseal fractures. Nail diameter was the only statistically significant parameter in this complication ($p<0.05$). The odds for having a FFLS were about 6 times and 11.5 times higher for 8-mm and 9-mm UTN respectively as compared to the 10-mm UTN that uses 4.9 mm locking screws. The higher rate of screw failure in 9-mm versus 8-mm nails could be explained by the use of locking screws of longer length. Fractures fixed with the 10-mm nail also showed a shorter time to union and a lower rate of delayed or non-union or limb malalignment.

Although allows secondary dynamization, bolt failure is problematic at the time of implant removal or exchange nailing. In order to prevent screw failure, Kneifel and Buckley (1996) recommended non-weight bearing and screw removal as early as clinically indicated. They advised leaving screws ‘proud’ on both the near-side and far-side cortex to facilitate removal. Patients in this study were often allowed partial weight-bearing immediately postoperatively with gradual increase as tolerated. A better approach is to restrict full weight bearing till adequate callus is demonstrable or until dynamization. Early dynamization definitely shortens the time to union and can prevent a number of screw failures.

Conclusion

The use of unreamed tibial nails has shown excellent clinical results in several studies. Its use is easy with no associated technical difficulties. It does not require the use of a fracture table, and avoids the complications of pin traction. Interlocking nailing without reaming combines the most desirable features of interlocking nailing with reaming and of non-locking nailing without reaming. Length, alignment, and rotation are controlled, the soft tissues are easily accessible, and the endosteal blood supply is preserved. These factors should lower the rates of infection and malunion and expand the use of intramedullary nails to fractures near the metaphysis and to those with more severe comminution and soft-tissue injury.

The dramatic increase in the use of unreamed interlocking tibial nails is the result of reports documenting low incidences of infection, nonunion, and malunion in open fractures of the tibial shaft. These reports are supported by the results of this study, In this series of closed and open tibial diaphyseal fractures, there were remarkably few soft tissue complications with a very low deep infection rate. Intraoperative complications were comparable to that observed with other nailing techniques. Revision rates and times to union were lower than reported in similar series in the literature.

Patient characteristics had no statistically significant influence on fracture healing. The mechanism of injury, however, was influential in fracture union and patient outcome. High-energy fractures had a significantly longer time to union and a higher rate of delayed union, non-union, and malunion. There was a steady increase in the time required to union and the DU/NU rate with the increased severity of the associated soft tissue injury. Grade III open fractures showed the worst results in this regard.

Fracture comminution had a significantly high negative impact on fracture healing. AO type C fractures needed a substantially longer time to union than simple type A fractures. The odds for having a delayed or non-union were 6.5 times higher when more than 50% comminution of the cortex was present. The same applies for segmental fractures. Malunion was also common with such comminution (P=0.005).

The study findings cannot support the sole use of UTN in proximal tibial fractures. Proximal and transitional tibial fractures are at risk of developing postoperative malalignment, delayed and non-union. Indirect reduction techniques and plate and screw fixation with or without supplementary short-term external fixation may offer significant advantages in meta-diaphyseal transition fractures that are difficult to control with intramedullary nails.

It is mandatory to avoid fracture distraction of more than 3 mm when stabilizing tibial fractures with small-diameter nails with an unreamed technique. Fracture compression using the back hammering technique and careful reduction of displaced wedge fragments in order to eliminate large interfragmentary gaps at the fracture site is important.

Nail dynamization was the most significant variable influencing the time to union and affecting the development of delayed or non-union with unreamed tibial nails in this study. It is important to convert a statically locked (load bearing) nail to a dynamic (load sharing) nail within 10 weeks if the fracture length is stable. This can be done on an outpatient basis. Dynamization does potentially increase the fatigue life of the implant. It also increases the compression forces at the fracture site. Delay in dynamization more than 20 weeks after nailing had an odds ratio of 52.5 time for delayed and non-union.

The main risk factor accounting to malalignment in this study was the degree of fracture comminution. The odds were 5 times higher with marked or segmental comminution than when more than 50% cortical contact was present. High-energy falls were 13 times more at risk of malalignment than low energy falls. Although not statistically significant, early malreduction or persistent malalignment was common in proximal and distal third fractures. Torsional deformities should not be underestimated.

As an implant, the UTN is mechanically stable enough to be used for definitive fracture fixation. With patient compliance, no nail breakage is to be expected. This is not the case with the locking bolts and, without early dynamization, a high rate of FFLS has been reported. Despite allowing autodynamization and although secondary surgery is rarely necessary, bolt failure limits the surgeon’s ability to remove the implant. It is also an uncontrolled event. Careful patient mobilization and modification of the locking bolts would therefore appear to be desirable.

5. Summary

Intramedullary nailing has revolutionized the treatment of diaphyseal tibial fractures. A continuing controversy exists on the indications and boundary conditions for the use of unreamed nailing techniques. The goals of treating a tibial shaft fracture are to obtain a healed, well-aligned bone, pain-free weight-bearing, and functional range of motion of the knee and ankle joints. The best treatment should be determined by a thoughtful analysis of the fracture morphology, the amount of energy imparted, the mechanical characteristics of bone, and, most importantly, the status of the soft tissues. Often overlooked or underestimated are patient-related factors such as the age, activity, compliance, and pre-existing medical illness.

In order to determine the factors that affect tibial fracture union after such techniques and the variables that have a negative impact on the healing process or the complication rate, 158 patients with 160 tibial shaft fractures treated using the AO Unreamed Tibial Nail (UTN®) were retrospectively reviewed in this study. There were 105 men and 53 women with a mean age of 39.5 years. Fractures were classified using the AO classification into 78 type A fractures, 65 type B fractures, and 17 type C fractures. Fracture comminution was classified using Winquist criteria into 41 type-0, 47 type-I, 32 type-II, 23 type-III, 4 type-IV, and 13 segmental fractures. There were 115 closed and 45 open fractures. Nearly two-thirds of the fractures were caused by high-energy trauma. Half of the patients had associated injuries and about 25% were victims of polytrauma.

Fracture union occurred after a mean time of 24.3 weeks. There were 20 cases of delayed union and 16 non-unions, all united by the end of treatment. There were remarkably few soft tissue complications with a very low deep infection rate. Revision rates and malunion were lower than reported in similar series in the literature. Fatigue failure of the locking screws continues to be a major complication associated with the use of unreamed tibial nails.

The most important variables affecting fracture healing in this study were the mechanism of trauma ($p=0.005$), fracture site gap ($p=0.013$), and the time to dynamization ($p<0.0001$). In this regard, high-energy fractures, gaps from comminution with or without distraction, and fractures dynamized later than 20 weeks had a significantly slower rate of union. The fracture pattern, the degree of comminution, and the magnitude of soft tissue injury come next in importance (with a significance level of 10%).

Complex type C fractures, fractures with more than 50% cortical comminution, and grade III open fractures were associated with a longer time to union than simple type A fractures, fractures with more than 50% cortical contact, and grade I or II soft tissue injuries respectively. With a 10% significance level, the variables associated with a higher risk of delayed or non-union were the degree of comminution (p=0.056), fracture site gap (p=0.065), and most importantly, the time to dynamization (p=0.0002). The odds for having a delayed or a non-union were 6.5 times higher in patients with more than 50% cortical comminution. The risk for having a delayed or a non-union were 6 times higher with distraction more than 3 mm and 9 times with displaced fragments or comminution with or without distraction than with full compression respectively. Delay in dynamization for more than 20 weeks was associated with a 52.5 times risk for a complicated fracture healing.

Fracture comminution and high energy trauma were the main factors associated with a higher risk for malunion. The odds were 5 times more with high comminution and 13 times more with high-energy falls than with low comminution and low-energy-falls respectively. The risk of fatigue failure of the locking screws was highest for 3.9-mm screws used in 9-mm nails. Although not statistically significant, because of the small sample size, proximal tibial fractures showed a general tendency for a less than favorable outcome with unreamed nailing.

The results of the study compares favorably with most reports concerning the use of unreamed nails in diaphyseal tibial fractures. In order to avoid complications and improve the overall result, the following recommendations are offered:

- It is important to differentiate between low- and high-energy transfer and not to underestimate the severity of the associated soft tissue injury.
- Obtain fracture reduction before nailing and maintain it during nail insertion rather than relying on the nail itself for reduction.
- Fracture site compression, e.g. using the back hammering technique, and careful reposition of displaced fragments in order to eliminate large interfragmentary gaps.
- Early bone grafting or exchange nailing should be regarded in fractures with marked comminution to decrease the risk of fracture non-union or malunion.
- It is better to avoid using unreamed nails in stabilizing fractures of the proximal tibia or supplementing this fixation with plates or Poller screws to maintain alignment.
- Implant dynamization should be done within 10 weeks after nailing to improve fracture healing and avoid screw failure together with careful patient mobilization.

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