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Treatment of Low-energy Tibial Shaft Fractures

Plaster Cast Versus Reamed Intramedullary Nailing

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ACADEMIC DISSERTATION
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To Marja, Jenni, Hanna, Jussi and Tiuku-Mari

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1. LIST OF ORIGINAL PUBLICATIONS

This dissertation is based on the following studies, referred to in the text by their Roman numerals I-IV.

I Toivanen JAK, Hirvonen M, Auvinen O, Honkonen SE, Järvinen TLN, Koivisto A-M and Järvinen M (2000): Cast treatment and intramedullary locking nailing for simple and spiral wedge tibial shaft fractures- a cost benefit analysis. Ann Chir Gyn 89: 138-142

II Toivanen JAK, Kyrö A, Heiskanen T, Koivisto A-M, Mattila P and Järvinen MJ (2000): Which displaced spiral tibial shaft fractures can be managed conservatively? Int Orthop 24: 151-154

III Toivanen JAK, Honkonen SE, Koivisto A-M and Järvinen MJ (2001): Treatment of low-energy tibial shaft fractures: plaster cast compared with intramedullary nailing. Int Orthop 25: 110-113

IV Toivanen JAK, Väistö O, Kannus P, Honkonen S, Latvala K, and Järvinen MJ: Anterior knee pain after intramedullary nailing of fractures of the tibial shaft: A prospective randomized study comparing two different nail-insertion techniques (submitted for publication)

2. ABBREVIATIONS

AO/ASIF	Arbeitsgemeinschaft für Osteosynthesefragen/ Association for the Study of Internal Fixation
AP	Anteroposterior
CI	Confidence interval
D_C	Coronal displacement
D_S	Sagittal displacement
D_T	True initial displacement
FIM	Finnish Mark
IM	Intramedullary
IMLN	Intramedullary locking nail
ROM	Range of motion
RR	Risk ratio
SD	Standard deviation
TM	Trade mark
SPSS	Statistical package for social sciences
USD	United States Dollar
VAS	Visual analogue scale

3. INTRODUCTION

Nicoll (1964) has stated, "Fractures of the tibia are important for two reasons. The first is that they are common; the second that they are controversial - and anything that is both common and controversial must be important".

By reason of its superficial location, the tibial shaft represents the most common site of long-bone fractures (Leach 1975). A long period of convalescence is inherent even to an uncomplicated healing course of this notorious fracture (Sarmiento et al. 1989, Court-Brown et al. 1990, Hooper et al. 1991, Alho et al. 1992, Bone et al. 1997, Downing et al. 1997). Both conservative and surgical techniques have been introduced in an effort to speed time to union while minimizing the occurrence of complications such as residual deformity, consolidation problems, refracture, infection, compartment syndrome, peripheral nerve injuries, anterior knee pain, joint stiffness and vascular complications.

Closed reduction and cast immobilization have been regarded as the standard treatment for low-energy tibial shaft fractures (Charnley 1963, Nicoll 1964, Haines et al. 1984, Sarmiento et al. 1984). However, during recent years many reports have shown that immobilization in a plaster cast cannot guarantee sufficient stability for all low-energy fractures (Böstman 1986, Hooper et al. 1991, Bone et al. 1997, Karladani et al. 2000). Along with more developed intramedullary (IM) nails and increased familiarity with nailing techniques, the intramedullary locking nail (IMLN) mode has gained numerous advocates in the treatment of both closed and open tibial shaft fractures (Alho et al. 1990, Court-Brown et al. 1990, Gad et al. 1990, Court-Brown et al. 1991, Hooper et al. 1991, Alho et al. 1992, Bone et al. 1997, Karladani et al. 2000, Keating et al. 2000). Many authors have drawn attention to anterior knee pain after IM nailing, which have been shown to affect over one half of IM- nail patients (Court-Brown et al. 1990, Koval et al. 1991, Orfaly et al. 1995, Court-Brown et al. 1997, Keating et al. 1997, Devitt et al. 1998, Hernigou et al. 2000, Karladani et al. 2000).

This present study was undertaken to compare the clinical, radiological and economic outcomes of plaster-cast treatment of low-energy tibial shaft fractures with those of IMLN treatment and to identify tibial shaft fractures eligible for plaster -cast treatment. A further aim was to establich whether it is possible to reduce anterior knee pain by means of paratendinous approach instead of that through the patellar tendon ligament.

4. REVIEW OF THE LITERATURE

4.1. Anatomy of the lower leg

The tibia is the weight-bearing bone of the leg. Its gross section is triangular, comprising anteromedial, lateral and posterior surfaces. The anterior border, the medial border and the interosseus border separate these surfaces. The diaphysis of the tibia has been defined as the area between proximal and distal segments, which in turn, have been described as the area defined by a square whose sides are the same as the widest part of the epiphysis (Müller et al. 1990).

The diaphysis of the tibia is usually divided into proximal, middle and distal thirds. The junction of the middle and distal thirds is the weakest region of the tibia (Martens et al. 1981). Open fractures of the tibia are common, since there are no traversing muscle tendon units on its anteromedial portion. The medullary canal of the tibia is also triangular in gross section. The tibial tuberosity is located at the anterior border of its upper section and the patellar ligament is attached to upper portion of tibial tuberosity.

The fibula is roughly triangular in cross-section. It constitutes medial, lateral and posterior surfaces, which are separated by anterior border, interosseal border and posterior border.

The interosseal membrane extends between the interosseus borders of the tibia and fibula and plays an important role as a stabilizing structure in the leg (Charnley 1963, Sarmiento et al. 1974).

Deep extensions of the crural fasciae separate four compartments of the lower leg. The anterior compartment contains the tibialis anterior, extensor hallucis longus, extensor digitorum longus and peroneus tertius muscles. This compartment is primarily responsible for dorsiflexion of the foot and ankle. Near the ankle the tendons of the tibialis anterior muscle and extensor hallucis longus muscle are close to the tibia and may be injured by an open fracture or by a prominent callus formation occurring during fracture healing. The deep peroneal nerve descends between the tibialis anterior and extensor digitorum muscles at the upper portion of the leg and is located between the tibialis anterior and extensor hallucis longus muscles in the lower part of the leg.

The lateral compartment contains the peroneus brevis and peroneus longus muscles, which serve primarily as plantarflexors and evertors of the foot. The superficial peroneal nerve runs between the peroneus muscles and the extensor digitorum muscle.

The superficial posterior compartment contains the gastrocnemius, the soleus, the popliteus and the plantaris muscles. The muscles of this compartment are responsible for flexion of the knee and the foot.

The deep posterior compartment contains the tibialis posterior, the flexor digitorum longus and flexor hallucis longus muscles. These muscles are involved in plantarflexion of the foot and toes. The tibialis posterior muscle also inverts the foot. The posterior tibial nerve is the major neurological structure in this compartment. The peroneal and posterior tibial arteries belong likewise to this compartment. The structures of the deep posterior compartment are seldom damaged in low-energy injuries to the tibial shaft.

The blood supply to the tibial shaft is derived from the nutrient artery and the periosteal vessels. The single nutrient artery arises from the posterior tibial artery (Rhinelander 1974). It enters the tibial shaft on its posterior surface in the proximal portion of the middle third of the shaft. This artery is easily injured by displacement of a fracture through its long cortical foramen. Within the medullary canal, it courses proximally and distally. A displaced fracture of the diaphysis is thus likely to devascularize the shaft downstream from the nutrient artery. Approximately one third of the blood supply to the tibial shaft comes from periosteal vessels (Rhinelander 1987).

4.2. Epidemiology of tibial shaft fractures

In 1999 a total of 1422 patients were treated for tibial shaft fractures in hospitals in Finland (National Research and Development Centre for Welfare and Health)

(Table 1). Of these, 256 patients were less than 15 years old. In the Finnish population tibial shaft fractures occur most frequently in the age group 50 to 54 years (Fig. 1). About sixty per cent of patients sustaining tibial shaft fractures were males. In other societies tibial shaft fractures also occur predominantly in young, healthy and economically active patient population (Nicoll 1964, Haines et al. 1984, Bridgman and Baird 1993). Court-Brown and McBirnie (1995) found in an epidemiological study in the United Kingdom that 77% of tibial fractures were closed and 54% involved only minor soft-tissue injury. A simple fall, falling on stairs, a fall from a height, sporting injury, direct blow or assault, and road-traffic accident were the main causative factors in these injuries. Further, they reported that road accidents and sporting injuries have proved to be most common reason for tibial shaft fractures among the young population and simple falls among the elderly. Based on a material of 1000 patients sustaining tibial shaft fractures, Sarmiento and colleagues (1995) made the following observation: Spiral fractures, distal third fractures and low-energy fractures were more common in women than in men and transverse fractures, middle third fractures and high-energy fractures occurred more often in men than in women.

Table 1. Patients of fifteen years or over treated in hospitals in Finland for tibial shaft fracture during 1999

	n	Hospitalization days	Completed treatment periods	Hospitalization days of completed treatment periods	Mean number of Hospitalization days
Male	695	8023	956	7642	7.9
Female	471	8338	627	10379	16.6
Total	1166	16361	1583	18021	12.3

According to the National Research and Development Centre for Welfare and Health.

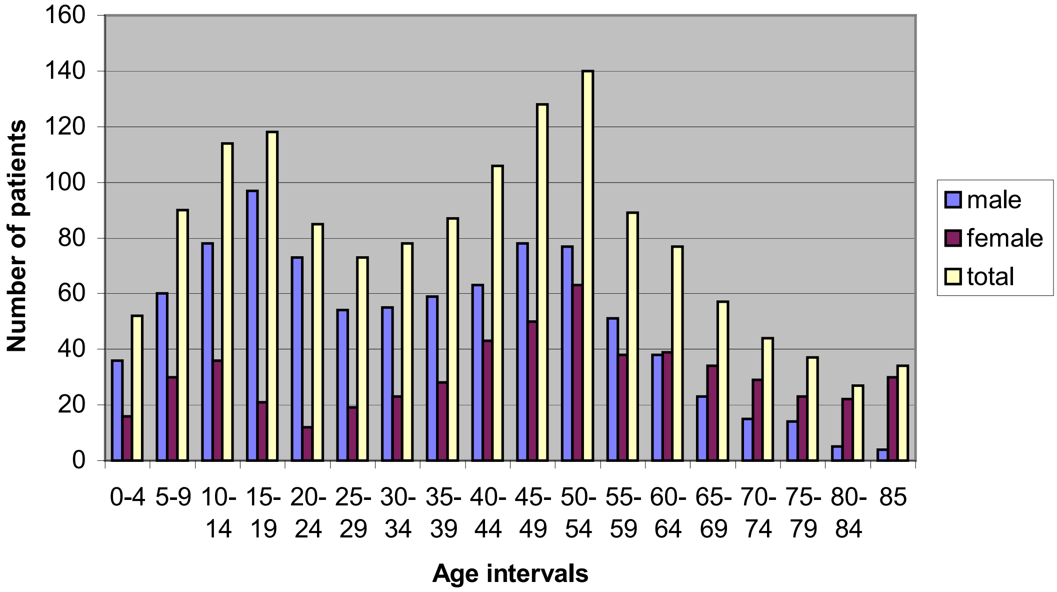

Figure 1. Distribution of patients sustaining tibial shaft fracture over different age groups treated in hospitals in Finland in 1999.

4.3. Classification of tibial shaft fractures

The classification of the extent and type of the fracture and its associated soft-tissue injuries facilitates determination of optimal treatment. Classification also allows the surgeon to monitor his results and to compare them with those of other surgeons. It also provides a basis for the evaluation of new treatment modalities.

4.3.1. Classification of soft-tissue injury

Tscherne (1984) developed a four-grade system of classifying closed fractures; Grade C0 injuries result from indirect forces and cause negligible soft-tissue damage, Grade C1 fractures are closed fractures caused by low- or moderate-energy mechanism and involve superficial abrasions or contusions, Grade C2 are closed fractures with significant muscle contusion and possibly also deep contaminated skin abrasions. Grade C3 fractures are accompanied by extensive contusion and crushing of skin or destruction of muscle.

Open tibial shaft fractures are generally classified on the three-grade scale published by Gustilio and Anderson (1976). According to this classification Type I fractures are those with a minimal puncture wound less than 1 cm caused by a spike of bone. Type II fractures involve a wound larger than 1 cm but no extensive avulsion or crushing of soft tissue. Type III open fractures had extensive soft tissue injury. Gustilo and Anderson (1976) reported that prognoses of grades I and II fractures are significantly better than those of grade III. Subsequently, Gustilo and colleagues (1984) divided Group III into three subgroups according to severity of wound. Those fractures which after adequate debridement have sufficient soft tissue coverage belong to Group IIIA. Group IIIB have more extensive soft-tissue damage and after debridement muscle flap coverage is necessary. All open fractures, which are associated with an arterial injury which must be repaired for limb salvage fall into Group IIIC. Due to the subjective nature of the Gustilo-Anderson system it has been criticized as having low interobserver agreement (Horn and Retting 1993, Brumback and Jones 1994). Brumback and Jones (1994) found approximately 60% agreement on the grading of individual fractures from videotape. The consensus was better in the case of the most severe or most minor extremes.

4.3.2. Classification of skeletal injury

The classification developed by the AO/ASIF group (Arbeitsgemeinschaft für Osteosynthesefragen/ Association for the Study of Internal Fixation) is that generally used to assess a configuration of the fracture (Müller et al. 1990) (Appendix 1). This classification divides fractures as simple (A), wedge (B), and comminuted (C). Each of these has main group have three subgroups which represents morphologic criteria reflecting direct and indirect impact. Group 1 include fractures produced by indirect impact (torsion). Groups 2 and 3 comprise fractures produced mainly by direct impact (bending). Simple fractures have two fragments characterized by a single cortical disruption involving at least 90% of the circumference of the bone. Wedge fractures have a butterfly fragment and there is always contact with main fragments after reduction. Comminuted fractures are more complex, without contact of the main fragments after reduction. In an evaluation of 400 fractures of the tibial and fibular shaft, Müller and colleagues (1990) noted that severity of fracture pattern increased from A to C types and from subgroups 1 to 3, with the exception of B1 fractures. The prognosis of B1 fractures was second best after A1-type fractures.

The AO classification does not take account of the severity of soft-tissue injury. However, Court-Brown and McBirnie (1995) found that there is a reasonable correlation between the AO classification and both Tscherne and Gustilo-Anderson classifications.

4.3.3. Classification according to the energy of injury

Low-energy tibial shaft fractures are caused either by indirect stress or by direct violence. Typical mechanisms of injury here are slipping or stumbling at ground level, falling from a height less than three metres, sporting or bicycle accidents where a motor vehicle is not involved (Önnerfält 1978). High-energy fractures are those sustained in road traffic accidents and falling from a height more than three meters (Önnerfält 1978).

4.4. Treatment

The cyclic nature of fracture treatment is clearly seen in the management of tibial shaft fractures. According to Watson-Jones (1943) " If immobized long enough, all fractures will eventually heal". He recommended anatomic reduction and absolute immobilization in a long-leg cast until bony union has been achieved. At the beginning of last century surgical techniques were also increasingly recommended for the treatment of tibial and femoral shaft fractures. Hey Groves (1922) introduced IM nailing of long bones, which approach was popularized by Küntscher (1940), who performed the first known IM nailing on a Finnish patient on August 25th 1942 in Kemi, while completing his military service during World War II (Lindholm 1980). However, indiscriminate use of open procedures and lack of powerful antibiotics frequently led to severe complications such as deep infections, and this provoked criticism of the surgical approach. In the 1960s Dehne and colleagues (1961) introduced the concept of early weight-bearing and subsequently Sarmiento (1967) introduced a combination of early weight-bearing and functional brace treatment. He and his coworkers heed that controlled movement at the fracture site is conducive of osteogenesis (Sarmiento et al. 1980, Latta et al. 1980). They achieved impressive results using functional principles in the treatment of tibial shaft fractures. Apparently the learning curve for functional treatment is relatively long because other authors have not been able to reproduce as good results as Sarmiento (Alho et al. 1992).

The Küntscher nail was effective in controlling bending and displacement, whereas rotational stability was not guaranteed with this equipment. Further, alignment of the fracture of the distal third of the tibial shaft was difficult to control by this means. However, with a new generation of IM nails with interlocking bolts introduced in the late 1970s, rotational stability and prevention of shortening were also attained (Klemm and Schellmann 1976, Kempf et al. 1978). With the advent of interlocking capacity and better familiarity with the technique of IMLN treatment the approach has come to constitute a viable treatment alternative along with conservative treatment in the management of low-energy tibial shaft fractures. However, it is self-evident that there is no panacea in the treatment of this notorious fracture. Thus the physician responsible for the treatment of tibial shaft fractures must be familiar with both conservative and surgical managements. Finally, the personality of each fracture as well as the patient's personality must be considered. The universal problem of finance in the health care system has obliged the physician to take account of the economic consequences in choosing between different treatment options.

In regard to soft-tissue injury, low-energy tibial shaft fractures are usually eligible for plaster cast treatment started immediately after injury (Sarmiento 1995). Fractures involving more severe soft-tissue injury must be treated either by means of IMLN or by an external fixation device.

One of the advances of closed reamed IMLN treatment is that the fracture site is not exposed, minimizing additional disruption of the periosteal blood supply (Rhinelander 1974). In addition, the use of interlocking bolts to stabilize the fracture fragments on the nail has made it possible to commence unprotected weight-bearing before radiological signs of consolidation are visible (Court-Brown et al. 1991).

4.4.1. Outcome of the treatment of tibial shaft fractures

Many authors have found that the functional outcome after IM nailing of tibial shaft fracture is better compared with plaster cast treatment (Alho et al. 1992, Bone et al. 1997, Karladani et al. 2000). Prolonged joint immobilization in a long-leg cast seems to result in difficulties in resuming everyday activities (Slätis and Rokkanen 1967, Digby et al. 1983, Hooper et al. 1991, Alho et al. 1992, Bone et al. 1997, Downing et al. 1997, Kyrö et al. 1991, Karladani et al. 2000). There are few studies comparing the outcomes of conservative and IMLN treatments (Table 2).

Table 2. Studies where conservative and IMLN treatment have been compared

Author	Study type	Treatment modality	Number of fractures	Energy of trauma Low/High	Deep infection	Malunion	Delayed union	Non-union
Karladani et al. 2000	Prospective	Unreamed IMLN	27	21/6	0%	4%	22%	4%
Karladani et al. 2000	Prospective	Cast	12	8/4	0%	25%	66%	0%
Templeton et al. 2000	Retrospective	Reamed and unreamed IMLN	12	12 /0	2%	0%	41%*	
Templeton et al. 2000	Retrospective	Cast	44	44 /0	0%	9%	7%*	
Bone et al. 1997	Retrospective	Reamed IMN+IMLN	47	Not defined	0%	2%	Not defined	2%
Bone et al. 1997	Retrospective	Cast	52	Not defined	0%	>27%	Not defined	10%
Alho et al. 1990	Prospective	IMLN	43	21/22	7%	Not defined	2%	0%
Alho et al. 1990	Prospective	Functional brace	35	22/13	3%	Not defined	14%	6%

*delayed/non-union requiring surgery

4.4.2. Reamed versus unreamed intramedullary nailing

Formerly, a 12-mm diameter interlocking nail was required to achieve adequate nail strength and reaming of the intramedullary canal was necessary to permit insertion of these large-diameter implants. Recently, many studies have examined the various biological effects of intramedullary reaming and insertion of tight-fitting implants. Klein and colleagues (1990) note in their canine study that use of an unreamed nail causes a 15 to 30% reduction in cortical blood supply, whereas reaming leads to 45 to 85% reduction. In contrast, Reichert and colleagues (1995) suggested that reaming has a beneficial effect on fracture healing. Using intact sheep tibiae and labeled microspheres they demonstrated that IM induces a six-fold increase in the periosteal circulation. However, overall circulation did not rise, indicating that the increased periosteal circulation compensated for the decrease in intramedullary circulation. Laboratory studies indicate that after insertion of small-diameter nails without reaming there is more rapid revascularization of the intramedullary blood supply, which may lead to earlier union compared with reamed nailing. Avoiding reaming may also involve fewer embolic phenomena, which are thought to be important in patients with associated pulmonary injuries. Further, reaming disrupts the intramedullary blood flow, and the insertion of a tight-fitting nail delays revascularization of the endosteal canal. On the other hand, reaming has been found to cause a compensatory increase in extraosseus blood flow which may benefit callus formation, and ultimately union (Slätis and Rokkanen 1967, Schemitch et al. 1994). The latter group compared the effects of reamed and unreamed IMLN on blood flow in the intramedullary callus and early strength of union in a sheep tibial model (Schemitch et al. 1994). Their study demonstrated that perfusion of the callus and early strength of union is similar following IMLN with or without reaming. Thus even though there is a large body of laboratory data suggesting that intramedullary reaming has harmful effects, it is not clear whether these findings are clinically relevant. Court-Brown and colleagues (1996) undertook a prospective study comparing reamed and unreamed nails in the treatment of closed tibial shaft fractures. Their results indicate that fractures treated with reamed nails united more rapidly and needed less secondary surgery than those treated with unreamed nails. Furthermore, higher incidences of screw breakage and malunion were associated with unreamed nails. The writers suggested abandoning unreamed nails in the treatment of closed tibial shaft fractures.

4.4.3. Fracture healing in plaster cast and intramedullary nail treatment

According to the literature the average healing time for tibial shaft fractures is difficult to establish, since no adequate definition of fracture healing has been agreed upon. Groups under Oni (1988) and Hooper (1991) regarded a fracture as healed when painless weight-bearing was possible without external support. Sarmiento and colleagues' (1995) suggest as criteria for healing of a fracture peripheral callus bridging of the fracture site, no motion or tenderness at the site, and pain-free full weight-bearing on the injured extremity. Both plaster-cast treatment and treatment with IMLN allow callus formation, which can be verified from radiographs (Sarmiento et al. 1977, Mc Kibbin 1978). However, some authors have found both clinical and radiological assessment of fracture healing to be subjective and unreliable (Hammer et al. 1985, Richardson et al. 1994).

The status of the soft tissues has been observed largely to determine the duration of the time to union. Sarmiento and colleagues (1989) observed that time to union in cases of 539 closed fracture was 17.4 weeks, 78 open-grade I fractures took 18.3 weeks, 97 open-grade II fractures 24.7 weeks, and 34 open-grade III fractures 25.3 weeks on average. They advised combining closed and open grade-I fractures in the same category reporting time to union. Court-Brown and colleagues (1990) noted that the mean time to union in 114 closed fractures was 16.9 weeks and that of 11 open grade I was 15.1 weeks. In addition, they observed that the mean time to union of 16 closed C0 fractures was 12.5 weeks, 59 C1 fractures 16.2 weeks, 30 C2 fractures 18.7 weeks, and 9 C3 fractures 23.7 weeks.

Based on analyses of 160 closed tibial shaft fractures, Puno and colleagues (1986) reported average times to union of 15.3 and 9.1 weeks in conservative treatment and IM nail treatment, respectively. The corresponding figures 41 open grade-I and -II fractures were 23.5 and 15.2 weeks.

The fracture pattern and the level of the fracture have also been considered prognostic factors when discussing times to union. In a study of 780 tibial shaft fractures treated with functional braces, Sarmiento and colleagues (1989) noted that transverse fractures consolidated in 14.9 and oblique fractures in 14.6 weeks, while spiral and segmental fractures required approximately 17 weeks to heal. Time to union of fractures in proximal third of the tibia was 18.3 weeks, in the middle third 16.6 weeks, and in the distal third 16.4 weeks.

Inconsistent reports have been published regarding the effect of the trauma energy on fracture healing. Oni and colleagues (1988) found that high-energy trauma is the predominant factor associated with compromised consolidation. On the other hand, Sarmiento and colleagues (1989) found that in any fracture group low-energy fractures united in similar fashion to fractures caused by high energy.

4.4.4. Role of initial displacement as an indicator for surgical intervention

Nicoll (1964) coined the term "personality of the fracture", by which the eventual outcome of any given fracture could be predicted. The major factors affecting the outcome were the amount of soft-tissue damage, the magnitude of initial displacement, the degree of comminution, and the presence or absence of infection. Subsequently, other authors have established the important role of initial displacement as a factor predictive of successful treatment of a tibial shaft fracture (van der Linden and Larsson 1979, Böstman 1986, Sarmiento et al. 1989, Ferrandez et al. 1991, Sarmiento et al. 1995). Haines and colleagues (1984) found in a prospective series that the mean time to union of tibial shaft fractures with up to half diameter initial displacement was 18.5 weeks and in those with more than half diameter initial displacement 25.6 weeks. Böstman (1986) noted that the overall rate of successful retention of fracture position after primary closed reduction was 42%. Other investigators have questioned the significance of the initial displacement in the treatment of tibial shaft fractures (Johnson and Pope 1977, Johner and Wruhs 1983). They assume that fracture displacement immediately after injury is not equivalent to that seen on radiographs at an emergency department.

4.4.5. Complications

Complication attributable to tibial shaft fracture may be related to qualities of the fracture itself or to management of the fracture. Waddell and Reardon (1983) reported that only 12 out of 36 patients with tibial shaft fractures escaped completely, with no complication compromising the final result. Comparison of the results of treatment of tibial shaft fractures is difficult in that the characterization of injury severity and patients is inadequate and unstandardized.

4.4.5.1. Malunion

One of the most important requirements of any treatment modality for tibial shaft fracture is that it can retain fracture fragments in an acceptable alignment throughout the course of the treatment. Crucial factors underlying risk of loss of acceptable reduction are fracture obliquity, the presence of a spiral pattern, the extent of fracture comminution, and the magnitude of the initial displacement (Nicoll 1964, Digby et al. 1983, Böstman 1986, Puno et al. 1986, Ferrandez et al.1991). Also an intact fibula has been considered the cause of excessive varus deformity (Hooper et al. 1981, Teitz et al. 1980, den Outer et al. 1990, Sarmiento 2000). However, definition of the maximum degree of angulation and shortening acceptable in the treatment of a tibial shaft fracture and still compatible with good long-term function and avoidance of osteoarthritis remains controversial (Table 3). The most common guidelines for the acceptable position of a tibial shaft fracture are 5 degrees or less of angulation in coronal plane, 10 degrees or less of angulation in sagittal plane, and shortening no more than 10 mm (Slätis and Rokkanen 1967, Böstman and Hänninen 1982, Johner and Wruhs 1983, Harley et al. 1986, Kettelkamp et al. 1988, Kristensen et al. 1989, Merchant and Dietz 1989). Angulation is more significant, in terms of its effect on ankle loading, at more distal fracture sites (Wagner et al. 1984, Tarr et al. 1985, Puno et al. 1991, Tetsworth and Paley 1994). Kettelkamp and colleagues (1988) reported that after 30 years' follow-up the increased force on either medial or lateral tibial plateau due to the malunion was strongly associated with the presence of a varus or valgus deformity at the knee. Some authors have found that malalignment predisposes adjacent joints to osteoarthritic changes (Goodman et al. 1991, Puno et al. 1991, McKellop et al. 1994, van der Schoot et al. 1996). Kristensen and colleagues (1989) found no arthrosis of the ankle 20 years after a malaligned tibial shaft fracture. Merchant and Dietz (1989) assessed radiographs in respect of osteoarthritic changes in patients sustaining tibial shaft fracture 29 years previously and reported that 10- to 15-degree angular deformities were well tolerated. Gofton (1985) proposed that leg length disparity may be the causative factor underlying low back pain. Olerud (1985) reported that varus angulation may be more poorly tolerated because of the limited ability of the hind-part of the foot to compensate this deformity.

Loss of acceptable alignment has been noted to be the most frequent drawback in conservative management. Malunion rates have been reported to vary between 25 and 50 % in plaster-cast treated patients (Slätis and Rokkanen 1967, van der Linden and Larson 1979, Böstman and Hänninen 1982, Waddell and Reardon 1983, Haines et al. 1984, Sarmiento et al. 1984, Böstman 1986, den Outer et al. 1990). In connection with conservative treatment fracture location has been noted to correlate with final varus deformity with increased final varus in proximal fractures (Sarmiento et al. 1995).

Malunion rates have been reported to be 0 to 3% after IMLN treatment of tibial shaft fractures (Bone et al. 1986, Puno et al. 1986, Court-Brown et al. 1990, Alho et al. 1990). The use of IMLN for fractures of the proximal third tibial shaft have been observed to be problematic because they do not appear to respond as favorably to intramedullary nailing as do fractures in the distal 2/3 of the tibia (Freedman and Johnson 1995, Lang et al. 1995). Valgus, apex anterior angulation, and residual displacement at the fracture site are common after nailing of these kinds of fractures. Surgical errors in medialized nail entry point and a posteriorly and laterally directed nail insertion angle contribute to malalignment. Plate fixation or external fixation has been recommended for the treatment of proximal third fractures of the tibial shaft (Lang et al. 1995).

Table 3. Limb alignment standards deemed acceptable in the literature

Study	Varus	Valgus	Anterior or posterior	Rotation	Shortening
Nicoll (1964)	10^0	10^0	10^0	10^0	20 mm
Slätis and Rokkanen (1967)	5^0	5^0	10^0	10^0	10 mm
Jensen et al. (1977)	8^0	8^0	15^0	…	20 mm
Johner and Wruhs (1983)	5^0	5^0	10^0	10^0	…
Haines et al. (1984)	4^0	4^0	…	5^0	13 mm
Puno et al. (1986)	10^0	10^0	20^0	…	20 mm
Böstman (1986)	5^0	5^0	…	…	10 mm
Trafton (1988)	5^0	5^0	10^0	10^0	15 mm
Merchant and Dietz (1989)	5^0	5^0	10^0	...	...
Collins et al. (1990)	5^0	5^0	5^0-10^0	…	10 mm

4.4.5.2. Delayed union and nonunion

In the literature, delayed union is designated at 16 to 30 weeks after tibial shaft fracture (Table 4.). According to the most frequently used criterion for delayed union consolidation must be considered to be delayed if no clinical or radiological signs of bony union are seen at 20 weeks after injury (Table 4). The predictive factors for compromised fracture healing are excessive comminution and excessive initial displacement, and open wound (Nicoll 1964, Böstman 1986, Dickson et al. 1994). Conflicting views have been reported as to the role of an intact fibula in the development of a delayed union (Charnley 1963, Teitz et al. 1980, Hooper et al. 1981, Sarmiento et al. 1989).

Table 4. Time criteria for delayed union used in different studies

Study	Delayed union (weeks)
Nicoll (1964)	20
Johner and Wruhs (1983)	16
Oni and colleagues (1988)	20
den Outer and colleagues (1990)	20
Sarmiento (2000)	30
Templeton and colleagues (2000)	16

There is considerable diversity in definitions of time criteria for nonunion of tibial shaft fractures. Nicoll (1964) defines nonunion as a condition in which, in the opinion of surgeon, the fracture would not unite with further conservative treatment. According to Brighton (1981), nonunion is manifest when a demonstrable reparative process had ceased without bony continuity being restored. Also many chronological definitions for nonunion have been presented. Some authors have defined nonunion as a lack of consolidation at nine months after injury (Müller et al. 1979, Basset et al. 1982). Many authors have considered nonunion as a stage where no signs of union can seen at six months and there is no further progression in the consolidation process during three consecutive months (Nicoll 1964, Rosenthal et al. 1977, Goulet and Bray 1988, Helfet et al. 1992).

Delayed unions and nonunions in mixed series of conservatively treated closed and open tibial shaft fractures are reported to occur in 9 to 15% (Nicoll 1964, Puno et al. 1986, Alho et al. 1990, Bone et al. 1997, Downing et al. 1997).

4.4.5.3. Refracture

The optimal strength of the tubular bone is not restored until one year after a fracture of a long bone in an adult (Frankel and Burstein 1968). Refracture can arise by two different mechanisms. It may occur at the site where the fracture is healing with callus or it can develop secondarily after internal fixation (Köbler and Schipke 1972, Fisher and Hamblen 1978). Böstman (1983) reported an overall incidence of refractures of 2% and an incidence of 6% among torsional fractures. For torsional fractures of the tibial shaft the following factors have been associated with increased frequency of refractures: repeated closed reductions; fracture of the fibula at a different level from that of the tibia, and marked initial displacement. When all these factors were present simultaneously, the incidence was 18% (Böstman 1983).

4.4.5.4. Infection

Based on the literature, the most notable advantage of conservative treatment of tibial shaft fractures is the negligible incidence of deep infections (Jensen et al. 1977, van der Linden and Larson 1979, Böstman and Hänninen 1982, Hooper et al. 1991). The most severe complication associated with intramedullary nailing is deep infection, which may even lead to limb amputation. The risk of deep infection in closed and grade I open tibial shaft fractures is given as 0- to 3.2 % (Maatz 1983, Waddell and Reardon 1983, Alho et al. 1990, Hooper et al. 1991, Court-Brown et al. 1992, Bone et al. 1997). Bone and Johnson (1986) found that the major complication in their series of 112 IM nailed fractures was deep infection. In the seven patients with postoperative deep infection the complication was associated with opening of the fracture site.

4.4.5.5. Compartment syndrome

Compartment syndrome may constitute a be the complication of closed or open tibial shaft fracture, or in some cases intracompartmental pressure may be elevated after surgical procedure or during plaster cast treatment (Garfin et al. 1981, McQueen et al. 1990).

The syndrome arises when high pressure occurs within a closed fascial space, reducing capillary perfusion below a level necessary to maintain tissue viability. When associated with a tibial shaft fracture it may be produced by hemorrhage, sarcomere swelling following direct trauma or subsequent ischemia, interstitial edema resulting from increased capillary permeability, or a combination of all three factors (Matsen 1975a). The compartment syndrome may occur in approximately 10 % of patients after tibial shaft fracture (Rorabeck and Macnab 1976, Alho et al. 1990, Court-Brown et al. 1990, McQueen et al. 1990, Williams et al. 1995, Bone et al. 1997, Karladani et al. 2000, Templeton et al. 2000). Debate prevails as to the role of intramedullary nailing in the pathogenesis of the syndrome. In the light of many studies it seems clear that very high transient compartment pressures may occur during traction and reaming (McQueen et al. 1990, Breitfuss et al. 1991, Moed and Strom 1991). However, McQueen and colleagues (1990) studied the compartment pressure in 67 patients treated with IM nail and observed that the elevated pressure during reamed nailing did not necessarily lead to manifestation of compartment syndrome. On the other hand, Breitfuss and colleagues (1991) stated that this syndrome is a phenomenon inherent in IM nailing. A tight plaster cast may likewise precipitate the development of compartment syndrome (Garfin et al. 1981). Untreated posterior compartment syndrome can cause claw-toe deformity, which has been reported to occur in 2 % of patients sustaining tibial shaft fracture (Matsen 1975b, Abdel-Salam et al. 1991). Karlström and colleagues (1975) found cavus foot deformity in association with tibial shaft fracture. Typically talocrural and subtalar mobility was limited in those patients with this complication. They concluded that the typical short cavus foot is due to fibrous contracture of the muscles in the deep posterior compartment caused by vascular damage, swelling in the deep posterior compartment, or severe muscle laceration. Court-Brown and McQueen (1987) noted a significant delay in fracture union among patients with compartment syndrome.

4.4.5.6. Peripheral nerve injury

Direct impact to the lower leg may cause injury to the peripheral nerves concomitant with the tibial fracture (Mino and Hughes 1984). Transient peroneal nerve palsy has been described to affect up to 9 % of patients after IM nailing (Bintcliffe et al. 1984, Collins et al. 1990, Willams et al. 1995). The incidence of nerve lesions after intramedullary nailing has been reported to vary between 0 and 30% (Puno et al. 1986, Alho et al. 1990, Court-Brown et al. 1990, Koval et al. 1991, Hooper et al. 1991). Iatrogenic sural and saphenous nerve lesions have also been described in association with insertion of distal locking bolts (Court-Brown et al. 1990). Persistent common peroneal nerve lesion or lesion of its division have been observed to affect up to 6% of IM-nail patients (Koval et al. 1991, Williams et al. 1995). However, common peroneal nerve palsy has been found to occur in 10 % of patients already prior to intramedullary nailing (Williams et al. 1995). In plaster cast treatment avoidance of pressure indentations over the proximal fibula will prevent the development of peroneal nerve palsy.

4.4.5.7. Anterior knee pain

Anterior knee pain is the most common complication following IM nailing of a tibial shaft fracture (Alho et al. 1990, Court-Brown et al. 1990, Orfaly et al. 1995, Court-Brown et al. 1997, Keating et al. 1997, Karladani et al. 2000). Typically the pain begins several months after the nailing procedure (Keating et al. 1997). In a series of 169 patients Court-Brown and colleagues (1997) reported that anterior knee pain occurred in 56.2 % of IM cases and there was significant functional impairment in 92% of patients experiencing pain when kneeling, 60%, when squatting, 57% when running, and 34% having pain even at rest. The pain was mild in 68% of patients, moderate in 22%, and severe in 9%. Keating and colleagues (1997) reported that in 46% of cases the IM nail had to be removed because of anterior knee pain. Court-Brown and colleagues (1997) for their part reported complete resolution of pain after IM nail removal in 27% of patients, marked improvement in 69%, and worsening in 3%. One year after IM nail removal, Orfaly and colleagues (1995) reported complete resolution of pain in 44%, partial resolution in 34% and no resolution in 20% of patients

The reason for this pain remains unclear. Court-Brown and colleagues (1997) observed that the only distinguishing feature between patients with or without anterior knee pain was that those experiencing pain were significantly younger. Orfaly and colleagues (1995) found that when a paratendinous incision had been used, 51% of patients suffered anterior knee pain. On the other hand, when IM nail insertion was through the patellar tendon 78% developed subsequent anterior knee pain. Keating and colleagues (1997) noted that anterior knee pain occurred in 77% and 50% when paratendinous and transtendinous incision was used, respectively. Court-Brown and colleagues (1997) found no higher incidence of anterior knee pain among patients operated by using transtendinous approach compared with those operated using paratendinous incision. None of the above studies demonstrated an association between knee pain and nail prominence in relation to the anterior cortex or tibial plateau. Devitt and colleagues (1998) performed a cadaveric study and found that contact pressure in the patellofemoral articulation increased after nailing regardless the mode of incision. Hernigou and Cohen (2000) found that in some cases the source of the anterior knee pain was damage to the menisci or unrecognized articular perforation. Tornetta and colleagues (1999) studied the safe zone for the IM nail and found that the risk of damage to the intra-articular structures of the knee is possible when reamed nails were used. They concluded that the safest starting-point for nailing should be slightly lateral to the center of the tibial tubercle.

4.4.5.8. Joint stiffness

After plaster cast treatment 22 to 30 % of patients have been found to suffer stiffness of the ankle (Nicoll 1964, Jahna 1977, Önnerfelt 1978, Digby et al. 1983, Haines et al. 1984, Sarmiento et al. 1984, Merchant and Dietz 1989, Alho et al. 1992). However, authors have been divided as to whether the severity of the initial injury or immobilization is responsible for this stiffness (Nicoll 1964, Karlstrom and Olerud 1974). Haines and colleagues (1984) noted that the average time in a plaster cast in 30 cases with stiffness was 24 weeks as compared to 19.4 weeks in patients without stiffness.

4.4.5.9. Deep venous thromboses

Deep venous thromboses have been reported to occur in 1% of conservatively treated patients (Jensen et al. 1977, Böstman and Hänninen 1982). Among surgically treated patients deep venous thrombosis is found to be between 0 and 6% (Böstman and Hänninen 1982, Johner and Wruhs 1983).

4.5. Costs attributable to tibial shaft fracture

Costs attributable to the injury can be evaluated from a number of viewpoints: the patient, the medical care delivery system and the society at large, which covers social security payments and lost wages as well as treatment. Overall costs of the injury can be divided into direct costs, which can be specified as treatment, hospitalization and outpatient costs. Indirect costs are those incurred because of lost production if the individual is away from work. Sarmiento and colleagues (1985) reported that IM nailing costs were USD 6811 compared to USD 2781 with functional braces. However, their calculations evaluated only direct costs and omitted indirect costs. There is only one report comparing the overall costs attributable to plaster cast treatment and IM nailing of tibial shaft fractures. Downing and colleagues (1996) compared the costs associated either with plaster cast treatment or intramedullary nailing of AO-type A, B1, B2 tibial shaft fractures. They found in their retrospective study that the mean costs per cast-treated patient were £ 218 (approximately FIM 2100) higher those in cases treated with intamedullary nail, which was not a significant difference, and that indirect costs constituted 77% and 43% in the plaster cast and IM nail group, respectively (Downing et al. 1996).

Reports concerning the average duration of hospitalization in plaster cast-treated patients gives figures varying between 8 and 30 days (van der Linden and Larson 1979, Kay et al. 1986, Hooper et al. 1991, Downing and colleagues 1996). Time in hospital following IM nail treatment was reported to be between 7.1 and 11.7 days (Court-Brown et al. 1990, Hooper et al. 1991, Downing et al. 1996). Hooper and colleagues (1991) reported that the mean numbers of out-patient appointments for plaster and IM nail patients were 7.04 and 4.35, respectively. Corresponding figures in the study by Downing and colleagues (1996) were 7.4 and 6.1. Sick leave after plastering has been reported to be from 23 to 26 weeks and after IM nailing 12 to 22 weeks (Haines et al. 1984, Puno et al. 1986, Court-Brown et al. 1991, Hooper et al. 1991, Downing et al. 1997). Bhandari and colleagues (1999) found that surgical delay results in longer postoperative hospital stays, greater complication rates and increased total cost to the health care system.

5. AIMS OF THE PRESENT STUDY

The aims of the present study were:

1. to compare the cost implications of plaster immobilization with those attributable to IMLN treatment of low-energy tibial shaft fractures.

2. to establish the critical extent of true initial displacement after which plaster cast immobilization cannot sufficiently stabilize a tibial shaft fracture.

3. to compare the final results of cast treatment and intramedullary nailing of low-energy tibial shaft fractures .

4. to assess whether it is possible to reduce anterior knee pain after IMLN treatment using paratendinous instead of transtendinous incision.

6. PATIENTS AND METHODS

The material for studies I, II, and III comprised 217 low-energy tibial shaft fractures. Of these, 181 patients were treated at Tampere University Hospital and 36 in study II at the Central Hospital of Central Finland (Table 5). Study IV involved of 50 patients treated at Tampere University Hospital (Table 5).

Table 5. Characteristics of studies I, II, III, and IV

	Study I	Study II	Study III	Study IV
Number of patients	77	131	87	50
Study period	1991-1995	1990-1995	1991-1995	1996-1998
Study design	Retrospective	Retrospective	Retrospective	Prospective, randomized
Study location	Tampere University Hospital	Tampere University Hospital Central Hospital of Central Finland	Tampere University Hospital	Tampere University Hospital

6.1. Definitions

A fracture was considered suitable for IMLN treatment when located at least 6 cm from the tibial plate and at least 6 cm from the tibio-talar joint. To the location of the foci of the fractures, the anatomical region of the diaphysis was divided into three areas. The fracture was considered to be located in the region where the center of the fracture was located. Healing time was defined as time from injury to the point when painless weight-bearing was possible without external support (Oni et al. 1988, Hooper et al. 1991). Delayed union was defined as little or no radiographic evidence of union at 20 weeks after injury, with instability at the fracture site necessitating a change in treatment (Nicoll 1964, Oni et al. 1988, den Outer et al. 1990). Nonunion was the stage where no consolidation was found at six months after injury (Nicoll 1964, Rosenthal et al. 1977, Goulet and Bray 1988, Helfet et al. 1992).

The following criteria for acceptable residual deformity were used: varus or valgus malalignment did not exceed 5 degrees, ante-/recurvature did not exceed 10 degrees and shortening was no more than 10 mm, and there was no clinically measurable rotational malalignment (Slätis and Rokkanen 1967). Deep infection was only noted as such if resulted in osteitis or fistula formation. Superficial infections which healed uneventfully are not reported. Initial treatment refers the treatment commenced within the first 3 days after injury.

6.2. Inclusion criteria

In studies I, II, and III, all fractures had to be amenable equally to for plaster cast treatment and intramedullary nailing. Inclusion criteria in the original studies I, II, and III differed slightly from each other (Table 6).

Table 6. Inclusion criteria in different studies

	Study I	Study II	Study III	Study IV
Patients age ≥ 15 years	x	x	x	x
Only low-energy fractures	x	x	x	
AO-type A1, B1 only		x		
AO-type A1, A2, A3, B1	x		x	
Closed or open grade I wound	x	x	x	
Concomitant fibula fracture	x	x	x	
Suitable for plaster cast and IMLN treatment	x	x	x	
Location in middle or distal third of the shaft	x	x	x	
All patients employed	x			

6.3. Treatment protocol and technical details

A traction table and spinal or general anesthesia were used for reduction before application of plaster cast. Closed IM nailing was performed with the patient lying supine, with the knee on the affected side flexed to at least 90^0. Slight traction was maintained using an os calcis pin. A longitudinal skin incision was made midway between the joint line and the tibial tubercle. Reaming of the medullary canal prior to nail insertion was routinely performed. All nailed patients received routinely an intravenous cephalosporin antibiotic (1.5 g, Kerfurion™) at induction of anesthesia. Standard static locking was used routinely and locking bolts were predrilled using free-hand technique, with image intensifier.

Regardless of treatment selected patients were instructed to bear weight only with the weight of the lower leg during the first six weeks; subsequently they were encouraged to increase weight-bearing gradually so that full weight-bearing would be achieved at twelve weeks after injury. If a cast-treated fracture was sufficiently stable at six weeks the treatment was continued with a below-knee or patellar tendon-bearing cast. Plaster cast treatment was interrupted if no radiological or clinical signs of consolidation were found within 20 weeks after injury and reamed intramedullary nailing or bone grafting operation was undertaken. Static nailing was dynamized if the fracture line was clearly visible and no bridging callus was detected at 12 weeks from injury. During cast treatment no rereductions were performed in this patient material. If necessary, correction of excessive angulation was attempted by wedging of the cast.

6.4. Cost accounting

For cost accounting the overall costs were divided into direct and indirect. Direct costs were extracted from the Tampere University Hospital patient-related accounting system and were divided into treatment costs (use of the operation department, instruments, plaster casts, nails and bolts), hospitalization costs and outpatient costs. Social insurance payments for the nursing staff and doctors as well as the overhead and material costs were taken into account in calculations of direct costs.

Indirect costs consisted in Workers' Compensation and Social Insurance costs evaluated on the basis of average earnings in Finland in 1995 (FIM 338 per day) (Statistics Finland, Statistical Yearbook 1997). The costs of social insurance were 33%

(FIM 109 per day) of the salary (Statistics Finland, Prices and wages review 1995). The number of sick leave days was obtained from the case notes and in most cases confirmed during additional follow-up visits.

6.5. Measurement of initial displacement

True initial displacement was assessed from the first radiographs (Fig. 2) (Böstman 1986). To validate our measurement method we analysed its intra- and interobserver reliability.

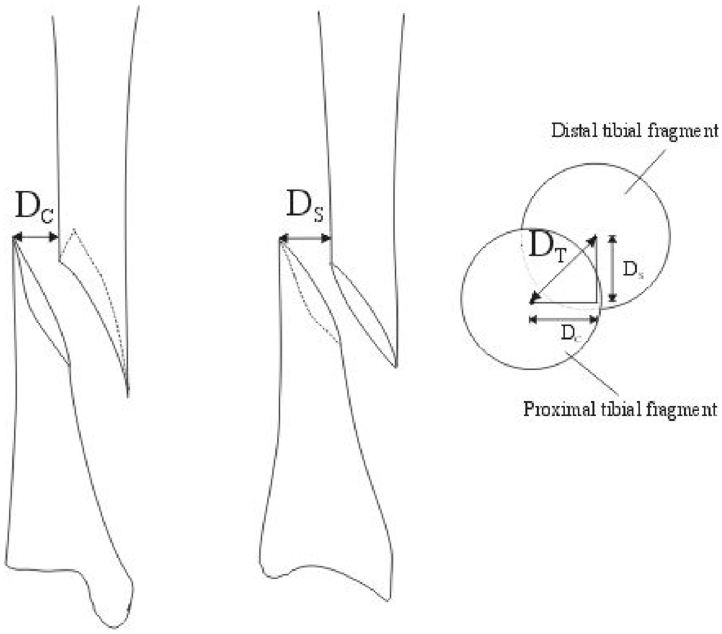

Fig 2. True initial displacement was calculated as follows: $D_T = \sqrt{D_C^2 + D_S^2}$, coronal ($D_C$) and sagittal ($D_S$) displacement measured on anterioposterior and lateral X-rays, respectively.

6.6. Measurement of residual deformities and joint movements

Angular deformities were measured on the radiographs, and rotational deformities clinically, with the patient lying in prone position and knees flexed. Shortening was measured either by comparing the radiographs of the injured leg with those of the contralateral leg or solely on the basis of radiographs obtained of the injured leg. Knee and ankle motions were measured using a goniometer.

6.7. Study I

The aim of this study was to compare the relative costs of treating simple displaced tibial shaft fractures in a plaster cast or with intramedullary locking nail. Twenty-six patients whose fracture was initially immobilized in a plaster cast formed the plaster cast group and 51 whose fracture was treated with an IMLN formed the IMLN group. All fractures were displaced and required closed reduction under anesthesia before immobilization either in plaster cast or by application of IMLN.

The patients were monitored until clinical and radiological assurance of fracture healing was obtained. In addition, 65 (84%) of the patients attended a further examination on an average of 33 (range, 18-73) months after the injury.

6.8. Study II

The aim of the study was to establish a threshold for the initial displacement of a spiral tibial shaft fracture beyond which its retention in an acceptable position cannot be guaranteed by plaster immobilization. The X-rays and records of 101 patients whose fracture was initially displaced less than 50% of the diameter of the tibial shaft were analyzed. All the fractures were caused by low trauma energy.

The treatment was considered to be successful if the following criteria were fulfilled: (1) the fracture was maintained in plaster and managed nonsurgically throughout its course; (2) varus or valgus malalignment did not exceed 5 degrees, ante-/recurvature did not exceed 10 degrees and shortening was no more than 10 mm; (3) and there was no clinically measurable rotational malalignment.

To determine the critical extent of displacement above which the risk of lost retention or development of malunion increased, the true initial displacements were classified into pairs of categories using cut-off points of 10, 20, 30 and 40 % of the diaphyseal diameter. Comparison was then made of the proportions of failed treatments (inability to retain the fragments in an acceptable position or consolidation of the fragments in an unacceptable position) between each of these pairs. The risk of failure and its 95%CI were also calculated.

6.9. Study III

The purpose of this study was to compare clinical outcome of cast treatment and intramedullary nailing of low-energy tibial shaft fractures. Out of 181 patients 28 patients whose cast treatment was converted to another within 20 weeks from injury were excluded from this study, as were 29 alcohol abusers, 10 diabetics, 9 mentally retarded patients and 3 rheumatoid patients. Fifteen patients were lost to follow-up (2 died of unrelated causes, and 13 refused to attend for review). The material thus comprised 87 patients, all of whom were reviewed at the outpatient clinic. The follow-up time was at least 24 months.

After examining the present material it proved possible to match 25 fractures treated with plaster cast to 25 treated with IMLN. The criteria which were used in forming the matched pairs were sex and age +/- 15 years.

AP and lateral radiographs were used to determine the location, comminution, fracture configuration, malunion and nonunion. At the review visit, radiographs were taken of both legs, both knee and ankle joint being visible.

Criteria for an acceptable knee and ankle joint restriction of range of movement (ROM) were 20 % and 25 % compared to the contralateral side, respectively. Final results were assessed according to the system introduced by Johner and Wruhs (1983), which takes into account functional, radiological, clinical and subjective outcome (Appendix 2.).

6.10. Study IV

This aim of this study was to assess whether the prevalence or the intensity of anterior knee pain following intramedullary nailing of the tibial shaft fracture is reduced by using a paratendinous incision for the nail entry portal. Fifty patients whose isolated tibial shaft fractures were treated using reamed IMLN (Grosse-Kempf-nail, Howmedica) entered the trial. After the decision to treat the patient with an IMLN randomization into two study groups was accomplished by sealed envelopes: twenty-five patients were operated on using the patellar tendon splitting incision (transtendinous group) and twenty-five using paratendinous incision (paratendinous group) (Fig. 3.).

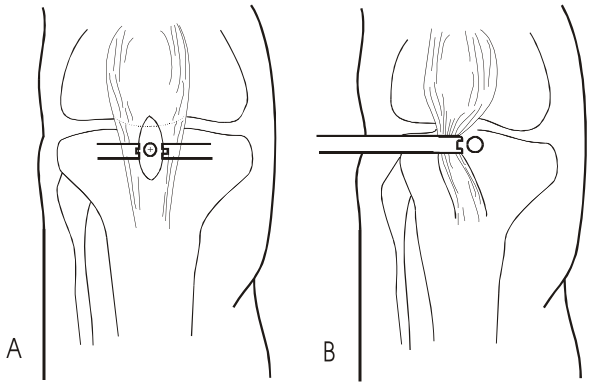

Fig.3. Entry points used in transtendinous
(A) and paratendinous (B) study groups.

In both groups one patient was excluded from the study because the IMLN had to be removed in the early phase of treatment due to deep infection. Both fractures were caused by high-energy violence. One patient in both groups died of causes not related to the tibial shaft fracture. In addition, four patients could not be traced for the follow-up examination (two in both groups), thus leaving twenty-one patients for both study groups.

During the study period IM nails were also routinely removed from asymptomatic patients approximately one and half years after the nailing and using the same entry point as at nail insertion.

A single physician performed a blinded re-examination of the forty-two patients at the outpatient clinic approximately one and half years (mean 1.7 $\pm$ 0.3 years) after nail removal.

The patients assessed anterior knee pain during rest, walking, running, squatting, kneeling, stepping up stairs, and down stairs by a 100-mm visual analogue scale (VAS). Subjective assessment of impairment caused by the anterior knee pain was made using a 100-mm impairment scale.

Combined subjective and functional knee evaluations were made with standardized scoring scales as described by Lysholm and Gillquist (1982) and Tegner and associates (1988). The Iowa Knees Score (Merchant and Dietz 1989) questionnaire was also filled in.

Four additional functional tests were undertaken. A 0-3 point scale was used to evaluate ability to perform one-leg jumping, duck-walking, 25-repetition full-squat and ability to be on knees. Scores obtained from the above-mentioned parameters were summarized for final comparison.

Isokinetic quadriceps strength testing was performed using the Cybex system (Cybex 6000, Division of Lumex, Inc., New York, 11779). The quadriceps and hamstring torque were measured, first at a low speed of 60^0/s with five maximal repetitions and after a 30-second rest at a medium speed of 180^0/s with five maximal repetitions. The repetition during which the maximal peak torque was produced was also recorded.

From the postoperative lateral plain radiograph the extent of the nail protrusion and nail-plateau distance were determined.

6.11. Statistical analysis

To describe the data, means and standard deviations or medians and lower and upper quartiles or range were reported for continuous variables. For categorized variables, percentages were used. In comparison of the costs attributable to plaster cast treatment and intramedullary nailing medians (range) were also reported. A CI of 95% was used as appropriate. Differences between the two treatments (study I and study III), successful and failed treatments (study II), and prevalence and intensity of anterior knee pain and disability when paratendinous and transtendinous incision was used (study IV) were tested using the Mann-Whitney U-test for continuous variables and Fisher's exact test for categorized variables. In matched materials (study III), differences between treatment groups were compared using Wilcoxon´s test for continuous variables and McNemar's test for categorized variables.

To test whether the differences in overall costs between the treatment groups could be explained by factors other than the initial treatment, linear regression analysis was performed (Study I). In view of the slightly skewed distribution of the overall costs variable, logarithmic transformation was performed. Predictors used were the initial treatment, age, fracture location, gender and compoundness. In study II the risk of unsuccessful treatment and its confidence interval according to the initial displacement was calculated. In study IV 95% confidence interval (CI) of the differences between the groups are reported for continuous variables. For categorized variables, percentages, and the risk ratio (RR) and its 95% CI, are reported.

Logistic regression analysis was used to establish whether initial displacement was an independent risk factor for successful/unsuccessful treatment. Initial displacement, gender, age, fracture pattern and fracture site were included in the logistic regression analysis.

A power analysis was performed in study IV. Applying less than 5% probability of a type-I error ($p<0.05$) and a power of 80% (type-II error, 0.20), a sample size of thirty patients (fifteen patients per group) was necessary to detect a 50% overall success rate difference between the groups. In evaluation of both intra- and interobserver errors (study II) the maximal error, the measurement error and the 95 % confidence interval of the error were calculated. The statistical analyses were carried out using the SPSS for Windows programme (Version 8.0-10.0; SPSS Inc.). Throughout the study, a p value of <0.05 was considered significant.

7. RESULTS

7.1. Cost of plaster-cast treatment versus costs of intramedullary nailing of tibial shaft fractures (Study I)

In respect of age, work profile, fracture configuration, fracture location and wound no statistically significant differences were found. There were no cases of deep infection or compartment syndrome in either group. Two transient peroneal nerve palsies and one deep venous thrombosis occurred in the IMLN group. In 6 (23%) patients in the plaster cast group problems with consolidation were noted, and thus, four bone grafting operations and one IM nailing were performed. None of the patients in the IMLN group had problems with consolidation, and no infection or compartment syndrome was found. The costs incurred by lost productivity constituted of 81 % and 67% in the plaster cast group and in the IMLN group, respectively. There were six patients in the plaster cast group and one in the IMLN group whose sick leave was more than 300 days (Table 7). Numbers of hospitalization days and outpatient visits as well as duration of sick leave are presented in Table 8.

Table 7. Characteristics of the patients and fractures whose sick leave exceeded 300 days

								Secondary intervention	
Patient	Sick leave	Sex	Age	Initial treatment	Configuration	Wound	Complication	Operation	Time from Injury (weeks)
1	390	M	27	plaster cast	A1	closed	no	IMLN	13
2	350	F	48	IMLN	A1	open gr I	no		
3	337	M	38	plaster cast	A1	closed	refracture	bone grafting	28
4	330	F	44	plaster cast	A1	closed	no	bone grafting	15
5	326	F	57	plaster cast	A1	closed	no		
6	320	F	50	plaster cast	A1	closed	no		
7	314	M	32	plaster cast	A3	closed	delayed union	bone grafting	21

Table 8. Mean and median hospitalization days, outpatient visits and duration of sick leave associated with plaster cast and IMLN treatment

	Plaster cast group (n=26)				Intramedullary nail group (n=51)			
	Mean	SD	Median	Q1,Q3*	Mean	SD	Median	Q1,Q3*
Hospitalization days	8.0	3.7	7.0	5.0, 11.3	7.4	3.8	7.0	5.0, 8.0
Number of outpatient visits	7.7	2.3	2.3	6.0, 9.0	5.0	2.0	5.0	4.0, 6.0
Sick leave period (days)	218	80	211	145.0, 281.0	124	57	105	90.0, 141.0

*Lower (Q1) and upper (Q3) quartiles

Direct costs per patient were FIM 22 919 ± FIM 9 079 (median FIM 19 484) and FIM 26 952 ± FIM 5 943 (median FIM 25 496), and overall costs per patient FIM 120 485 ± FIM 41 124 (median FIM 115 785) and FIM 82 223 ± FIM 27 161 (median FIM 71 902) in plaster cast and intramedullary locking nailing groups, respectively.

The linear regression analysis indicated that the treatment modality used was the only predictor of total costs of treatment.

7.2. Critical initial displacement of spiral tibial shaft fracture treated in plaster cast (Study II)

The material of 131 spiral tibial shaft fractures comprised 81 (62 %) male and 50 (38 %) female patients. Their median age was 43 years (range, 16-87 years). There were seven (5 %) grade I open fractures.

The median true initial displacement of the fractures was 33% (range, 14-50 %) of the diaphyseal diameter. Twenty-four fractures (18%) had to be operated because of unacceptable position of the fracture. The common denominator for all these fractures was that the true initial displacement was between 30 % and 50% of the diameter of the tibial diaphysis. The median time interval from injury to operation was seven days (range, 2-49 days).

Twenty-five fractures (19 %) treated with plaster cast were found to have consolidated in an unacceptable position. Shortening exceeding 10 mm was the most common type of malunion. Three fractures showed shortening exceeding 20 mm. There were three cases with valgus angulation exceeding 10 degrees, one of them exceeding 20 degrees. Seven fractures evinced more than one deformity at the fracture site.

The risk of treatment failure was statistically significantly higher when the initial displacement exceeded 30 % or 40 % as against 30 % or less of the diameter of the diaphysis, respectively ($p = 0.035$; RR = 2.18, 95%CI = 1.05 to 4.53). Plaster cast treatments failed in 28 % when the true initial displacement was 30% or less and in 46 % when the true initial displacement was more than 30 %.

The only variable which differed significantly between successfully and unsuccessfully treated patients was the median magnitude of the true initial displacement. When logistic regression analysis was used for each displacement cut-off point, neither gender, open/closed fracture ratio, patient's age nor the site of the fracture had any significant predictive value in considering success of treatment. On the other hand, the initial displacement was a statistically significant predictor of the success of treatment for cut-off points at least 30 % of the diameter of the tibial shaft. There was no unacceptable intra- and interobserver variation in measurements of true initial displacements. In general, the error varied between 1-10 % in respect of both intra- and interobserver variation.

7.3. Outcome of plaster-cast treatment and intramedullary nailing of tibial shaft fractures (Study III)

Thirty-three fractures were treated with an reamed IMLN and 54 with a plaster cast. In the unmatched material the mean age of the patients in the plaster cast and IMLN groups were 37.4 (SD 14.5) and 44.7 (SD 12.9) years, respectively ($p=0.027$). Follow-up times in the plaster cast and IMLN groups were 47 (SD 17.0) and 32 (SD 10.8) months, respectively ($p<0.001$).

Delayed unions occurred in 15% of the patients in the plaster cast group. There were no delayed unions in IMLN group. The difference between groups was statistically significant ($p=0.022$). In the plaster cast and in the IMLN groups 11% and 0% of the patients had ankle joint stiffness, respectively ($p=0.078$). One (4%) and 26 (79%) of patients in the plaster cast and in the IMLN groups suffered anterior knee pain, respectively ($p<0.001$).

In 23 out of 25 matched pairs both patients had an AO type A fracture and in one pair AO type B1 fracture, and in one pair a nailed patient had AO type A and plaster-cast treated AO type B1 fracture ($p=1.000$). In 22 pairs the fractures were closed and in one pair, the plaster-cast treated patient had an open grade I fracture and the IMLN patient a closed fracture. In two pairs, the IMLN patient had an open grade I fracture and the plaster-cast treated a closed fracture. In respect of the wound there was no statistical difference between the study groups ($p=1.000$). In matched pairs of patients no significant difference was found between the IMLN and plaster cast groups when treatment outcome was assessed according to the Johner and Wruhs (1983) method ($p=0.146$). In 21 pairs both patients were employed; of these, in eight pairs both had heavy work (i.e. work involving much standing or walking) and in seven pairs both had light work (mainly sedentary work or retirement). In two pairs the IMLN treated patient had a heavy work and plaster cast treated patient a light work. In four pairs IMLN-treated patient had light and the plaster cast treated patient heavy work. In respect of work profile no statistical difference was found between the study groups ($p=0.687$). The mean healing time was 19 (SD 6.65) weeks in the plaster cast group and 12 (SD 4.39) weeks in the IMLN group ($p<0.001$). The mean hospitalization time was 8 (SD 4.8) days in the plaster cast group and 7 (SD 2.7) days in IMLN ($p = 0.686$) Mean sick leave in the plaster cast group was 195 (SD 6.65) and 106 (SD 106) days in the IMLN group ($p = 0.001$).

7.4. Anterior knee pain following intramedullary nailing of tibial shaft fracture (Study IV)

The study groups were highly comparable with respect to sex, age, body mass index, nail protrusion and follow-up time (from nailing to the follow-up examination or from nail removal to the follow-up examination. Two patients refused removal of the IMLN because the nail did not bother them at all (one in the transtendinous group and one in the paratendinous group).

Eighteen (51 percent) patients in the transtendinous group and seventeen (49 percent) patients in the paratendinous group had anterior knee pain before nail removal (p=1.000; RR = 1.06, 95%CI 0.81 – 1.39). Twelve of the eighteen (67 percent) patients in the transtendinous group and eleven of the seventeen (65 percent) patients in the paratendinous group experienced complete or marked resolution of pain after nail removal. The remaining six patients in each groups reported no change or worsening of the symptoms after nail removal.

In the transtendinous group and in the paratendinous group, fourteen of the twenty-one (67%) and fifteen of the twenty-one (71%) patients experienced anterior knee pain during one or more of the studied activities, respectively (p=1.000, RR = 1.07, 95% CI 0.71 – 1.61). No statistically significant difference was found when the groups were compared in respect of prevalence and intensity of anterior knee pain during rest, walking, running, squatting, kneeling, stair climbing and after long-term sitting. Of patients experiencing anterior knee pain, thirteen of the fourteen in the transtendinous group (93%) and ten of the fifteen in the paratendinous group (66%) reported that this pain also caused mild-to-severe impairment during daily activities (p=0.536). Of these impaired patients, five of the thirteen in the transtendinous group (38%) and two of the ten in the paratendinous group (20%) had moderate, and one in both groups severe, impairment (p=0.669).

No significant difference was found between the study groups in respect of either subjective or objective parameters (Table 9).

Table 9. Mean scores and (SD) in subjective and objective functional tests

	Transtendinous Group		Paratendinous Group			Between-groups	
	N = 21	SD	N = 21	SD	P-Value	difference (points)	95% CI
Subjective functional tests							
Tegner scores	0.52	1.21	0.19	0.81	0.301	– 0.33	-0.98 to 0.31
Lysholm scores	90.4	13.9	92.1	13.7	0.698	– 1.67	-10.28 to 6.95
Iowa knee scores	95.4	6.5	96.1	8.7	0.765	– 0.71	-5.50 to 4.08
Objective functional test	9.8	3.6	10.0	2.6	0.883	– 0.14	-2.09 to 1.81

Isokinetic thigh muscle strength tests showed no statistically significant differences between the transtendinous and paratendinous groups.

8. GENERAL DISCUSSION

8.1. Evaluation of results

One of the most striking findings in the present study was that the plaster cast-treated patients had longer convalescence periods compared with those treated with IMLN. This phenomenon has previously been reported by other authors (Puno et al. 1986, Alho et al. 1992, Bone et al. 1997, Downing et al. 1997, Karladani 2000). Based on the present findings the favourable results of IMLN treatment can be explained by the shorter healing time. On the other hand IMLN-treated patients can usually start full weight bearing before radiological signs of union can be seen (Court-Brown et al. 1991). The shorter convalescence period, in turn, can be explained by fewer complications such as ankle stiffness and delayed unions, which were clearly associated with plaster cast treatment. Restricted ankle joint movement occurred in 11% of plaster cast-treated patients (Study III), which was clearly lower when compared with observations in previous studies (Nicoll 1964, Jahna 1977, Önnerfelt 1978, Digby et al. 1983, Waddell and Reardon 1983, Sarmiento et al. 1984, Merchant and Dietz 1986, Alho et al. 1992). The good joint function can be explained by the fact that patients evincing low compliance and those with major general illness were excluded from the study and fractures in this study involved only minor soft-tissue injuries. Despite the diversity of criteria used to define healing, the healing times presented in this study (Study III) are highly comparable with those previously reported (Puno et al. 1986, Sarmiento et al. 1989). Delayed unions occurred solely among patients treated with plaster cast. The excellent union rate of IMLN treated fractures of this study can be explained by our treatment policy favoring early dynamization of the nail if the consolidation problems were suspected. The incidence of delayed union in this study (Study I and III) is in line with that given elsewhere (Nicoll 1964, Puno et al. 1986, Alho et al. 1990, Bone et al. 1997, Downing et al. 1997).

The important result of the present study was the observation that the cost-benefit ratio of IMLN treatment was superior to that of plaster cast treatment. Higher overall costs in the plaster cast group were clearly attributable to longer sick leave. The study by Alho and colleagues (1992) accords with our result in reporting that sick leave times were, on average, five weeks shorter in the IMLN group than in the functional brace group. On the other hand, Downing and colleagues. (1997) suggest that there was no significant difference in the costs between plaster cast and IMLN groups. This obvious discrepancy can be explained by methodological differences and differences between the British and Finnish communities. Cost associated to the treatment of some particular injury are always inherent to the society were analyses have been undertaken. It would seem that hospitalization times in Great Britain are more prolonged than those presented in this study, which may partly explain the discrepancy between results (Downing et al. 1997). Here the proportions of the indirect costs were 81% and 67% in plaster-cast and in intramedullary nail treatment, respectively. Sarmiento and colleagues (1985) claimed that indirect costs constituted only 20% of the overall costs caused by tibial shaft fractures. This discrepancy can also be explained by differences in social structure between the USA and Finland. However, a closer examination of the study by Sarmiento and group reveals that when they refer to indirect costs attributed to tibial shaft fracture they also included minor injuries like sprains and strains in their calculations (Praemer et al. 1992). On the other hand, in a study by Downing and colleagues (1997) indirect costs also formed the largest part of the costs. The mean hospitalization period and out-patient appointments among plaster cast-treated and IMLN-treated patients reported in the present study are highly comparable to those given elsewhere (van der Linden and Larson 1979, Kay et al. 1986, Court-Brown et al. 1990, Hooper et al. 1991, Downing et al. 1997). In the studies I and III no major complications, such as deep infections were encountered. The risk of deep infection, in turn, is in fact so small that considering this risk would not essentially change the outcome of this study. Based on the incidence of deep infections in association with IMLN treatment it is possible to calculate that one patient with osteitis could have been out of work more than 12 years and treatment costs could have been 5 times higher than those without osteitis, and still the costs would have been comparable to corresponding costs inherent in plaster cast treatment.

The most frequently occurring drawback in plaster cast treatment is reported to be the loss of acceptable reduction and development of malunion (Slätis and Rokkanen 1967, Böstman and Hänninen 1982, Böstman 1986, Waddell and Reardon 1983, Sarmiento et al. 1984, den Outer et al. 1990). Initial displacement of more than 50% of the width of the tibial shaft has traditionally been considered the critical cut-off point after which a fracture should be treated surgically (Slätis and Rokkanen 1967, Böstman 1986). However, this cut-off point has been selected arbitrarily and until now we only know that spiral fractures displaced more than 50% of the width of the diaphysis of the tibia do not respond well to plaster cast treatment. In the present study, the critical cut-off point was set at 30% of the diameter of the tibial shaft. The increased risk itself was less than twofold with a 95%CI whose lower limit was close to one and maximal measurement error varied between 10 to 20%. Such an increased risk alone is thus of minor clinical significance. However, even 46% of the treatments failed when the fracture was initially displaced more than 30% of the diameter of the tibial shaft. In addition, it was of note that the true initial displacement of all fractures whose treatment was converted to IMLN because of failure to retain the fracture in an acceptable position was between 30 and 50 %. In view of this finding the plaster cast management of spiral tibial shaft fractures with a true initial displacement exceeding 30% of the diameter of the diaphysis must be questioned. In daily routine the lowering of the threshold for IMLN treatment would involve a rise in direct costs, which in turn, entails economic pressures on the hospital. On the other hand, the present results clearly show that use of the IMLN in the treatment of tibial shaft fractures means cost savings for society as a whole. It must be emphasized, however, that there is no panacea in the treatment of tibial shaft fractures and the results of this study give only guidelines which may help physicians during the decision-making process. If appropriate treatment for a particular patient has been selected, similar clinical and radiological outcomes can be achieved either with plaster cast treatment or with IMLN in cases of low-energy tibial shaft fractures. It must, however, be borne in mind that average costs associated with plaster cast treatment remain higher compared to IMLN treatment.

Based on retrospective investigations, some authors have claimed that anterior knee pain can be reduced by using paratendinous approach instead of approach through the patellar tendon ligament (Orfaly et al. 1995, Keating et al. 1997). In the present prospective and randomized study the beneficial effect of a paratendinous compared with a transtendinous incision could not be confirmed. On the other hand, our finding parallels the observations of Court-Brown and colleagues (1997). Another difference between previous retrospective studies and this present was that nail removal relieved symptomatic patients (Orfaly et al. 1995, Keating et al. 1997). It is obvious that nail removal will alleviate the symptoms of patients who have had a very prominent nail head (Orfaly et al. 1995, Keating et al. 1997). In the present study nail removal relieved the pain in most cases. Nonetheless, the results of our study showed that about 70 % of patients had anterior knee pain even after removal of the nail. The high prevalence of anterior knee pain in this present study may be associated with damage to the intraarticular structures of the knee during reamed tibial nailing (Tornetta et al. 1999). Based on previous observations of many authors it is reasonable to see the cause of anterior knee pain as multifactorial (Devitt et al. 1998, Tornetta et al. 1999, Herninghou and Cohen 2000). Although anterior knee pain is the most frequently noted complication following IM nailing of fractures of the tibial shaft, the impairment caused by this pain proved to be mild (Court-Brown et al. 1997). Nevertheless, anterior knee pain could be troublesome for manual laborers, especially for those whose work involves a kneeling position.

Two patients with deep infection in were excluded from study IV. Otherwise there were no cases of deep infection in this study. This might be explained by selection bias but the most evident explanation is that even after IM nailing osteitis is found to be rare among patients with low-energy fractures (Nicoll 1964, Waddell and Reardon 1983, Puno et al. 1986, Court-Brown et al. 1990).

There were no compartment syndromes in this study. This phenomenon might be linked to the small number of patients and low causative energy of the fractures in the present analysis. The incidences of compartment syndrome reported in previous studies are in line with the findings here (McQueen et al. 1990, Alho et al. 1990, Court-Brown et al. 1990, Williams et al. 1995, Bone et al 1997, Karladani et al. 2000, Templeton et al. 2000).

Approximately 3% of IMLN treated patients suffered from transient peroneal nerve palsy. This incidence was somewhat less than that described elsewhere (Bintcliffe et al. 1984, Collins DN et al. 1990, Willams et al. 1995). This phenomenon might be inherent to our nailing technique, in which we sought to avoid excessive traction. In respect of incidences of deep venous thrombosis the present study tallies with previous studies (Jensen et al. 1977, Böstman and Hänninen 1982, Johner and Wruhs 1983).

The superior results obtained using IMLN might be explained by biased patient selection, inappropriate plaster cast treatment, relatively short follow-up or the superior ability of IMLN to achieve good reduction and retain a fracture in a functionally favorable position.

8.2. Methodological considerations

Because soft-tissue injuries accompanying closed tibial shaft fractures were insufficiently described in patient records, Tscherne's classification was not used in this present study. Gustilo-Anderson's grade II and III open fractures were excluded from studies I, II, III as not being eligible for plaster cast treatment. The closed and open grade I fractures were combined because these fractures are amenable equally to plaster cast and IMLN treatment. Since studies I, II, and III involved only AO-type fractures A1, A2, A3, and B1, it is manifest that the material was homogeneous in respect of soft-tissue injury (Court-Brown et al. 1995).

Some authors have claimed that the amount of displacement seen on the first X-rays is not the same as that immediately after injury (Johnson and Pope 1977, Johner and Wruhs 1983). It is indeed reasonable to assume that paramedics must reduce severely displaced fracture before transportation to hospital. However, the fractures in the present study (study II) were displaced only 50% or less of the diameter of the tibial shaft. The displacement seen in X-rays taken in the emergency room can thus be considered to correspond to the displacement which appeared upon injury.

Owing to the retrospective study design there might be some incidental costs which have not been considered. Methodologically the design was simplified in that patients with mixed treatments were excluded from the study. It appeared that assessment of the cost of the cases of mixed treatments was ambiguous. In addition, the convalescence time in tibial shaft fractures tends to be long and the use of a trial and error approach in the treatment lacks justification in modern societies.

The criteria introduced by Johner and Wruhs was used to compare the ultimate outcome after plaster cast and IMLN treatment (Study III) and take into account functional, radiological and end result as well as the patient's subjective assessment (Johner and Wruhs 1983). The most prominent drawback of this classification is that assessment of gait was the only objective functional criterion in evaluating the final result.

In this study a fracture was considered to be healed when unprotected and painless weight-bearing was possible. In the case of a fracture treated with IMLN this definition is somewhat misleading, because normally the patient can start full weight-bearing before the fracture is ultimately consolidated. However, it adequately describes patients' recovery according to treatment modality.

8.3. Patient selection

Patients with intact fibula were excluded from this study because intact fibula is generally regarded as a causative factor behind the development of varus malalignment (Hooper et al. 1981, Teitz et al. 1980, den Outer 1990, Sarmiento 2000).

Patients sustaining a fracture of the proximal third of the tibia were excluded because (studies I, II, and III) these fractures are more difficult to treat with plaster cast when compared with middle and distal third fractures (Lang et al. 1995, Sarmiento et al. 1995).

Alcoholics and mentally retarded patients were excluded (study III) in view of the risk of low compliance with postoperative routines. Rheumatoid patients were excluded (study III) since a number of joints are frequently involved and comparison of knee and ankle joint function of the affected to the unaffected side might be unreliable. Also the use of drugs depressing the immunological system tend to lower the healing capacity of wounds. Diabetics were excluded because diabetes exposes the patient to infection (McCormack and Leith 1998). The purpose in identifying matched pairs was to improve the comparability of the study groups. Parameters which have been shown to be of greater prognostic significance were used. Ferrandez and colleagues (1991) found that the age of the patient has significant predictive value. We considered $\pm$ 15 years a reasonable matching criterion, implying that patient is over 20 years of age. Sex was considered an important matching criterion in that men's and women's work profiles obviously differ from each other; men's work tends to involve more strenuous activities than women's. Regardless of matched pairs there might be some differences such as social class which affect the end results. This concerns particularly the duration of sick leave. Although we did not include work profile in matching criteria, the pairs were reasonably matched. However, the retrospective nature of the present study made it impossible to define precisely the physical demands of the patient's work and motivation to resume work.

9. CONCLUSIONS

On the basis of the present study the following conclusions can be drawn:

1. Overall costs attributable to plaster cast treatment of low-energy tibial shaft fractures were significantly higher compared with IMLN treatment.

2. When a spiral tibial shaft fracture was initially displaced 30 % or more the possibility of failed plaster cast treatment was unacceptably increased.

3. If a low-energy tibial shaft fracture could be maintained in an acceptable position by means of plaster cast the final result is equal to that obtained by IMLN in co-operative patients without compromising illness. However, IMLN treatment provides faster healing with a fewer malalignments and with low incidence of severe complications.

4. The only considerable drawback involved in IMLN treatment seems to be anterior knee pain, which cannot be reduced using paratendinous instead of transtendinous incision.

10. SUMMARY

The first purpose of this study was to compare outcomes of plaster cast treatment with those of IMLN treatment of low-energy tibial shaft fractures and to assertain the critical extent of true initial displacement of tibial shaft fractures after which the risk of redisplacement was unacceptably increased in plaster cast treatment. In addition, the possibility of reducing the anterior knee pain associated with IM nailing by using the paratendinous approach instead of transtendinous approach was assessed.

The material of studies I-III consisted of 217 at least 15 year-old patients with 217 low-energy fractures which fell in AO-classes A and B1 and were closed or open grade I. In study IV there were 50 patients who were randomized into trans- and paratendinous groups.

Seventy-eight employed patients whose low-energy tibial shaft fracture required closed reduction under anesthesia before either immobilization in plaster cast or application of IMLN was selected. Patients were classified into plaster cast group (52 patients) and IMLN group (26 patients). Both direct costs (treatment, hospitalization and outpatient clinic costs) and indirect costs taken into account. In the plaster cast group, mean direct costs were FIM 22 920 and overall costs FIM 120 486. In the IMLN group the corresponding figures were FIM 26 952 and FIM 82 224 (218 days in plaster cast group and 124 days in IMLN group).

In study II, 131 AO-type A1 tibial shaft fractures which were initially displaced 50 % or less of the diameter of the shaft were analyzed. Treatment was considered successful if plaster cast treatment was continued until the fracture was consolidated and no malunion developed. Fractures were divided into groups according to true initial displacement (cut-off points 10% or less, 20% or less, 30% or less, 40% or less and 41-50% of the diameter of the tibial shaft). Plaster cast treatments failed in 28% when the true initial displacement was 30% or less and in 46 % when the true initial displacement was more than 30 %. In all cases where plaster cast treatment was interrupted the true initial displacement was more than 30%.

Of the 181 patients those with low compliance, those having rheumatoid arthritis or diabetes, and whose treatment was converted to another within 20 weeks were excluded from this study. Thus, 54 patients treated with plaster cast and 33 with IMLN were analyzed. Delayed unions occurred in 15 % and 0 % of cases after plaster cast treatment and intramedullary locking nailing, respectively ($p = 0.022$). Seventy-nine per cent of the patients in the IMLN group and 4 % in the plaster cast group suffered from anterior knee pain. Final treatment outcome, healing time, hospitalization time and duration of sick leave were assessed on the basis of 25 matched pairs of patients. Mean healing time, hospitalization time and sick leave in the plaster cast and IMLN groups were 19 (SD 6.7) and 12 (SD 4.4) weeks ($p<0.001$), 8 (SD 4.8) and 7 (SD 2.7) days ($p=0.686$), and 195 (SD 81) and 106 (SD 31) days ($p=0.001$), respectively. No difference was found between plaster cast and IMLN groups when the outcome was evaluated using the criteria presented by Johner and Wruhs.

Fifty patients with a tibial shaft fracture requiring IMLN treatment were randomized into trans- or paratendinous groups (25 patients in both groups). Twenty-one patients from both study groups attended the final examination, which took place 3.2 ± 0.4 years after nail insertion. In the transtendinous group 14 of the 21 (67%) patients reported anterior knee pain at the follow-up. Of these 14 patients, 13 (93%) were mildly-to-severely impaired because of the anterior knee pain. In the paratendinous group, 15 of the 21 (71%) had similar anterior knee pain, and ten of these (66%) were impaired because of the pain. The Lysholm, Tegner, and Iowa knee scoring systems, muscle strength measurements and functional tests elicited no significant differences between the study groups.

The plaster cast treatment of low-energy tibial shaft fractures is more expensive for society than IMLN treatment. The higher mean overall costs in the plaster cast group were attributable to the longer convalescence involved in this treatment modality. The risk of failed reduction was increased unacceptably if initial displacement of the tibial shaft fracture exceeded 30%. However, equal clinical outcome is possible if patients have been properly selected. Compared with the transtendinous approach, the paratendinous nail-insertion technique does not reduce the occurrence of postoperative anterior knee pain after IMLN treatment of a tibial shaft fracture.

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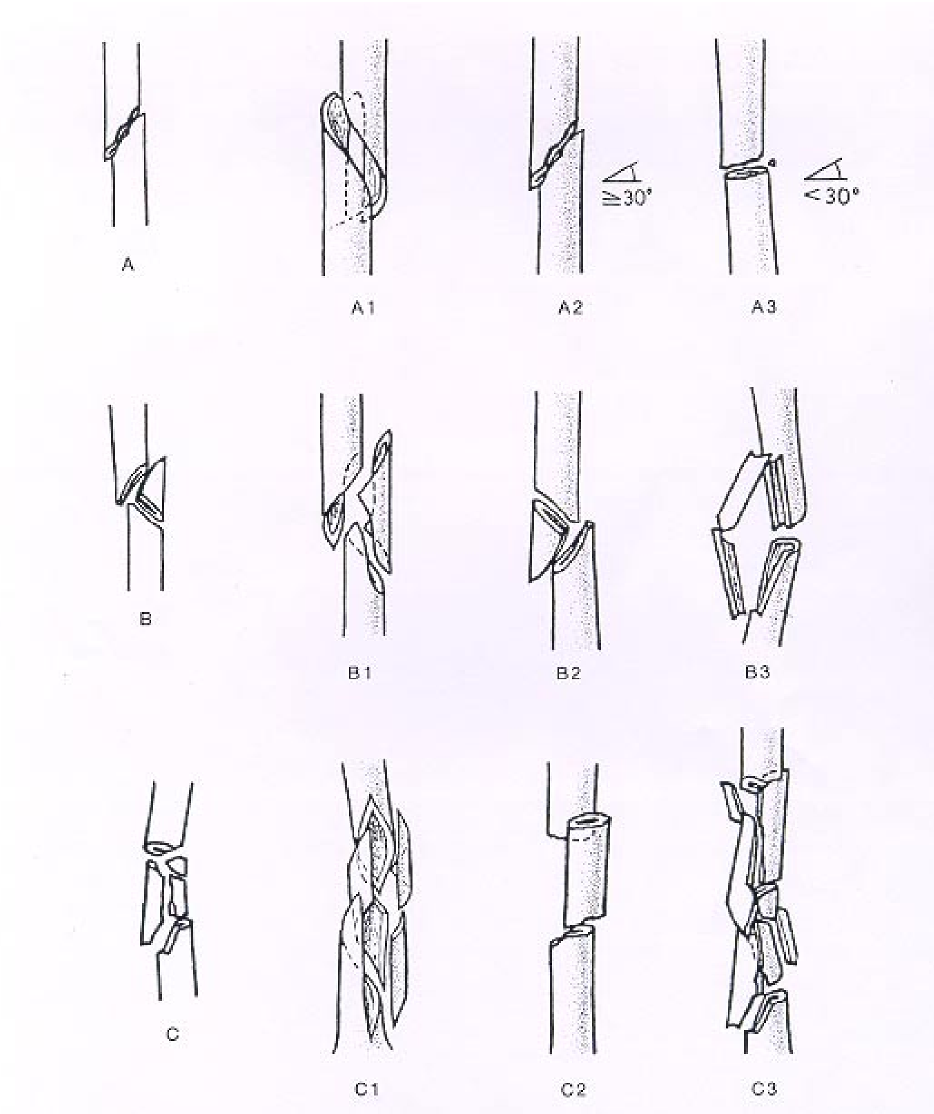
13. APPENDICES

Appendix 1.



From Müller ME, Algöwer M, Shneider R, and Willenegger H: Manual of internal fixation: techniques recommended by the AO-ASIF group, ed 3, Berlin, 1990, Springer-Verlag.

Appendix 2.

	Excellent	Good	Fair	Poor
Nonunion, osteitis, amputation	None	None	None	Yes
Neurovascular disturbances	None	Minimal	Moderate	Severe
Deformity				
Varus/valgus	None	2°–5°	6°–10°	>10°
Anteversion/recurvatio	0°–5°	6°–10°	11°–20°	>20°
Rotation	0°–5°	6°–10°	11°–20°	>20°
Shortening	0–5 mm	6–10 mm	11–20 mm	>20 mm
Mobility				
Knee	Normal	>80%	>75%	<75%
Ankle	Normal	>75%	>50%	<50%
Subtalar joint	>75%	>50%	<50%	
Pain	None	Occasional	Moderate	Severe
Gait	Normal	Normal	Insignificant limp	Significant limp
Strenuous activities	Possible	Limited	Severely limited	Impossible

Source: Johner, R.; Wruhs, O. Clin Orthop 178:12, 1983.

Johner and Wruhs' criteria for evaluation of final results after tibial shaft fracture