The T2^{TM} Tibia Nail
A Prospective Multicenter Clinical Study

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„Every surgeon carries about him a little cemetery, in which from time to time he goes to pray, a cemetery of bitterness and regret, of which he seeks the reason for certain of his failures.” (Rene Leriche, 1879-1955)

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1 Abbreviation Directory

AO	Arbeitsgemeinschaft für Osteosynthesefragen
ARDS	Adult Respiratory Distress Syndrome
CRF	Clinical Review Form
CRPS	Complex Regional Pain Syndrome
CT	Computer Tomogram
e.g.	exempli gratia (for example)
Fig.	Figure
ICN	Interlocking Compression Nail
kg	kilogram
LCP	Locking Compression Plate
LIF	Locked Internal Fixation
Lig	Ligamentum
LISS	Less Invasive Stabilization System
LP	Locking Plate
min	Minute
MIPO	Minimal Invasive Percutaneos Osteosynthesis
N	Number
ORIF	Open Reduction Internal Fixation
OTA	Orthopaedic Trauma Association
sec	Second
SPSS	Superior Performing Software System
T2 nail	Titanium nail
VAS	Visual Analog Scale

2 Deutsche Zusammenfassung

2.1 Einleitung

Es gibt verschiedene Verfahren, mit denen Tibiafrakturen behandelt werden können. Es stehen sowohl konservative, als auch operative Verfahren zur Verfügung. Die operativen Verfahren können in extramedulläre, z.B. Plattenosteosynthesen und externe Fixateure, und intramedulläre Verfahren, wie z. B. aufgebohrte und unaufgebohrte Marknägel, unterteilt werden.

2.2 Konservative Behandlung / Frakturreposition

Nachdem im Jahr 1852 der Gipsverband vom holländischen Arzt Mathijsen erfunden wurde, konnten hölzerne Schienen zur Immobilisierung von Gliedmaßen zunehmend ersetzt werden. Mit dem Gipsverband soll die verletzte Region mit dem Ziel der Knochenheilung ruhig gestellt werden.

Im Ersten Weltkrieg wurde der Algorithmus „Reposition, Retention und Rehabilitation“ durch Lorenz Böhler geprägt und so ein standardisiertes Behandlungsschema von Frakturen geschaffen (Trojan, 1984). Das sogenannte „Drei-Punkte-Prinzip“ erhöht die Stabilität im Gipsverband dadurch, dass die Ligamentotaxis auf der konkaven Seite der Fraktur die Fragmente in der korrekten Stellung hält (Bayne et al., 2006). Nach Sarmiento et al. (1989) kann über diesen Effekt ein Großteil der geschlossenen Frakturen frühfunktionell beübt werden. Eine Voraussetzung hierfür ist, dass eine Verkürzung der Fraktur von weniger als 10 mm und eine Achsabweichung kleiner als 5° vorliegt.

Durch Verbesserungen in der operativen Versorgung hat die konservative Behandlung von Tibiafrakturen in den Industrienationen stark abgenommen. Gleichwohl gibt es für diese noch immer Indikationen. Auch wenn die oben genannten Verfahren inzwischen eher selten zur Anwendung kommen, kann eine Tibiafraktur grundsätzlich erfolgreich konservativ behandelt werden.

2.3 Operative Behandlung

Zur operativen Behandlung stehen verschiedene Verfahren der plattenosteosynthetischen Versorgung und Marknagelosteosynthesen zur Verfügung. Die Grundprinzipien der operativen Frakturversorgung mit einer konventionellen Plattenosteosynthese sind einerseits die direkte anatomische Reposition, andererseits die stabile Fixierung der Fragmente (ORIF = Open Reduction and Internal Fixation). Hierzu ist nicht selten eine weite chirurgische Exploration der Frakturerforderlich, um gute Sicht auf die zu reponierenden Fragmente zu erlangen.

Folgende Verfahren und Techniken der plattenosteosynthetischen Versorgung werden angewandt:

2.3.1 Konventionelle Plattenosteosynthese (ORIF)

Direkte, offene Reposition und stabile Osteosynthese mit Platten (winkelstabile Verfahren zeigen eine größere absolute Stabilität) konnten sich als ein Verfahren zur erfolgreichen chirurgischen Behandlung von Frakturen etablieren.

2.3.2 Biologische überbrückende Plattenosteosynthese

Indirekte, geschlossene oder offene, aber weniger invasive (“no-touch technique”) Reposition und biologisch überbrückende Plattenosteosynthese zeigten eine größere relative Stabilität (Gautier et al., 1994; Leunig et al., 2001).

2.3.3 MIPO - Minimally Invasive Plate Osteosynthesis

Das Ziel dieses Verfahrens ist, der Fraktur durch eine geschlossene Reposition und Plattenosteosynthese gute relative Stabilität zu geben ohne dabei den Weichteilmantel über der Fraktur zu verletzen (Perren, 1995, 2001, 2002; Sandelmaier et al., 1999; Tepic et al., 1995).

2.4 Marknagelosteosynthese

Bei der Marknagelostesynthese werden die unaufgebohrte und die aufgebohrte Technik unterschieden.

2.4.1 Unaufgebohrte Marknagelosteosynthese

Verschiedene Studien zeigten einen substantiellen Kortikalisschaden mit Beeinträchtigung der endostal Blutversorgung sowohl durch Plattenosteosynthesen als auch durch die Hitzeentwicklung beim Bohrvorgang im Zuge der Vorbereitung des Nagelbettes. Aus diesem Grunde wurde ein unaufgebohrter intramedullärer Marknagel entwickelt (Danckwardt-Lilliestrom et al., 1970; Klein et al., 1990; Huppel et al., 1998).

Der Vorteil in der Versorgung einer Tibiafraktur mittels unaufgebohrtem Marknagel besteht darin, dass der Markraum nicht präpariert werden muss.

2.4.2 Aufgebohrte Marknagelosteosynthese

Bereits 1952 hat Küntscher ein regelhaftes Aufbohren des Markraumes, initial durch Handbohrer, ab 1954 durch elektrisch angetriebene Bohrer mit speziellen Bohrköpfen, empfohlen. Seit 1969 wurde durch Küntscher das Aufbohren über einen Führungsdraht etabliert. Dieser war flexibel und konnte leichter gereinigt werden als seine Vorgänger (Küntscher, 1962). In den darauffolgenden Jahren wurde das Design der Marknägel zahlreiche Male modifiziert. Eine essenzielle Modifikation stellte die Einführung einer starren Kurvation durch Herzog dar (Herzog, 1958).

2.5 Ziel der Arbeit

Das Ziel dieser Multicenter-Studie war die Evaluation klinischer und radiologischer Ergebnisse von Patienten, die sich eine proximale, diaphysär oder distale Tibiaschaftfraktur zugezogen hatten und mit einem neu auf dem Markt etablierten

Marknagelsystem versorgt wurden. Durch einen Vergleich der erhobenen Resultate mit den Ergebnissen von anderen internationalen Studien sollte die Effektivität dieser neuen Marknagelosteosynthese gegenüber bereits etablierten Verfahren bei der Versorgung spezifischer Tibiafrakturen untersucht werden.

2.6 Materialien und Methoden

Von Januar 2003 bis Dezember 2004 wurden 102 Patienten mit einer proximalen, diaphysären oder distalen geschlossen Tibiafraktur behandelt (AO 41,A-C 1-3, AO 42 A-C 1-3, AO 43 A-C 1-3) behandelt. Drei europäische Level 1-Traumazentren waren in die Akquisition der Daten involviert: Vrije Universiteit Medical Center, Amsterdam, The Netherlands, Hospital Universitario Ramon y Cajal, Madrid, Spanien und Klinikum Hannover Nordstadt, Hannover, Deutschland. Es wurden demographische (z.B. Alter und Geschlecht), präoperative (z.B. Traumaursache und Frakturtyp), allgemeine operative (z.B. Operationszeit und Blutverlust) sowie postoperative Daten (z.B. radiologische Knochenheilung, Belastung, Aktivitäten des täglichen Lebens, Wiederaufnahme der Arbeit, anteriorer Knieschmerz) erfasst.

Bei allen Patienten wurde das neue T2®-Tibia Marknagel System der Fa. Stryker angewandt. Dieses System ist Europa CE- gekennzeichnet und von der Amerikanischen Food and Drug Administration (FDA) genehmigt.

Alle Daten wurden prospektiv erhoben und mittels eines standardisierten klinisch-wissenschaftlichen Formulars dokumentiert. Zudem wurden alle Patienten radiologisch nachverfolgt. Studienpatienten wurden präoperativ, perioperativ und zu drei festgelegten postoperativen Zeitpunkten (4-6 Wochen, 4 Monaten und 12 Monaten) klinisch und radiologisch nachuntersucht. Es wurde gewährleistet, dass alle Patienten in den entsprechenden Ambulanzen von den gleichen betreuenden Ärzte gesehen wurden, die bereits initial mit der Dokumentation begonnen hatten. Die visuelle Analogskala (VAS) wurde zur subjektiven Einschätzung der Schmerzen benutzt. 0 Punkte wiesen hierbei auf eine komplette Schmerzfreiheit hin, während 10 Punkte den größten vorstellbaren

Schmerz darstellten (Downie et al., 1978). Die radiologische Auswertung erfolgte gemeinsam durch Chirurgen und Radiologen.

2.7 Ergebnisse

Nach 4-6 Wochen konnten 62 Patienten, nach 4 Monaten 53 Patienten und nach 12 Monaten 71 Patienten nachuntersucht werden. Radiologisch war nach 4-6 Wochen bereits in 85,5 % (n = 53/62) der Fälle eine fortgeschrittene Knochenheilung in Form einer Kallusbildung zu erkennen. Nach 4 Monaten war die Fraktur in 86,8 % (n = 46/53) der Fälle, nach 12 Monaten in 91,5 % (n = 65/71) der Fälle komplett konsolidiert.

Hinsichtlich der Schmerzen fand sich initial ein VAS von durchschnittlich 3,1 nach 4-6 Wochen, der sich nach 4 Monaten auf 2,8 und nach 12 Monaten auf 2,3 verbesserte.

Nach 4-6 Wochen erreichten 22,6 % der Patienten (n = 14/62), nach 4 Monaten 45,3 % der Patienten (n = 24/53) ihre präoperative Funktionalität und konnten ihre Arbeit wieder aufnehmen. Nach 12 Monaten waren es 54/71 Patienten (76,1 %).

Das Anziehen von Schuhen und Socken war bereits nach 4-6 Wochen kein Problem für 51,6 % der Patienten (n = 32/62) bzw. für 83,1 % der Patienten (n = 59/71) nach 12 Monaten. Nach 4-6 Wochen stellte das Aufstehen aus einem Stuhl ohne Hilfe der Arme keine Schwierigkeit für 43,5 % der Patienten (n = 27/62), nach 12 Monaten für 83,1 % der Patienten (n = 59/71) dar.

Treppensteigen ohne Beeinträchtigung war nach 4-6 Wochen für 35,5 % der Patienten (n = 22/62) und nach 12 Monaten für 81,7 % der Patienten (n = 58/71) problemlos möglich. Die Vollbelastung des betroffenen Beines war nach 4-6 Wochen 30,6 % der Patienten (n = 19/62), nach 4 Monaten 77,4 % der Patienten (n = 41/53) und nach 12 Monaten 53,5 % der Patienten (n = 38/71) möglich.

Nach 4-6 Wochen beklagten 11 der Patienten Knieschmerzen an der Insertionsstelle des Marknagels, nach 4 Monaten 14 Patienten und nach 12 Monaten 13 Patienten.

Hinsichtlich postoperativer Komplikationen zeigte nach 4-6 Wochen von 62 Patienten 1 Patient ein Hämatom, dieses war oberflächlich und wurde konservativ behandelt, 3 Patienten beklagten Gefühlsstörungen im Unterschenkel, bei 1 Patienten bestand eine tiefe und bei 3 Patienten eine oberflächliche Infektion, die konservativ mit Antibiose behandelt wurden. Zwei Patienten entwickelten ein CRPS Typ 1.

Nach 4 Monaten hatten von 53 Patienten 6 Patienten Probleme mit den Schrauben (Lockerung oder Perforation durch die Haut). Nach 1 Jahr bestanden bei 9 von 71 Patienten mechanische Probleme mit der Osteosynthese, 4 Patienten hatten Gefühlsstörungen im Unterschenkel, 3 Patienten zeigten oberflächliche Infektionen, 4 Patienten entwickelten ein CRPS Typ 1. Bei 1 Patienten wurden heterotope Ossifikationen im Bereich des Frakturspaltes nachgewiesen. Diese war nicht weiter gradiert.

Eine Dynamisierung des Nagels erfolgte bei 4/62 Patienten nach 4-6 Wochen, bei 5/53 Patienten nach 4 Monaten und bei 5/71 Patienten 12 Monaten. Die Gründe für die Dynamisierung waren eine verzögerte Knochenheilung oder Probleme mit den Schrauben. Revisionen (wegen Malrotation, Malposition oder Migration des Nagels nach proximal) erfolgten bei insgesamt 7 von 102 Patienten.

Daten zur Metallentfernung lagen von 47/102 Patienten (46,1 %) vor: Die Gründe für die Metallentfernung stellten 34 Mal die Konsolidierung der Fraktur, 11 Mal anteriore Knieschmerzen, 2 Mal gebrochene Schrauben und einmal der Wunsch des Patienten dar.

2.8 Diskussion

Das T2®- Tibia Marknagel System der Fa. Stryker sorgt durch sein Design mit proximaler und distaler Verriegelung und Aufbohrung vor Nagelinsertion für eine hohe Stabilität der Fraktur und fördert somit die Konsolidierung der Fraktur. Dieses ist nicht neu. Folgt man der Literatur, werden Konsolidierungsraten von über 90 % nach aufgebohrter Marknagelosteosynthese bei der Versorgung von Tibiafrakturen berichtet (Klemm et al., 1986; Court-Brown et al., 1991; Alho et al., 1990).

Bei allen in dieser Studie eingeschlossenen Patienten wurde der Markraum aufgebohrt. Dieses Verfahren hat zwei Vorteile. Zum einen wirkt das Bohrmehl, welches durch das Aufbohren entsteht, in der Frakturzone wie eine autologe Spongiosaplastik (Reynders et al., 2000). Zum anderen sorgt das Aufbohren für einen besseren kortikalen Kontakt zwischen Knochen und Marknagel, der wiederum durch einen dickeren Durchmesser eine höhere Primärstabilität gewährleistet (Chapman, 1998).

Durch die hier genutzten zusätzlichen Kompressionsschrauben konnte die Stabilität des Marknagels noch weiter erhöht werden. Experimentell ist dies schon gezeigt worden (Hutter et al., 1977; Gonschorek et al., 1998.), diese Daten scheinen sich nun auch im klinischen Alltag zu bestätigen. Welcher der einzelnen Faktoren in welchem Maße zu der guten Konsolidierungsrate in unserem Patientengut beitrug, lässt sich im klinischen Setting kaum bestimmen, dennoch spricht vieles dafür, dass es die Kombination derselben ist, die die Knochenheilung positiv beeinflusst. Da der unaufgebohrte Marknagel vor allem bei offenen Tibiafrakturen Verwendung findet, lassen sich die beiden Nagelsysteme hinsichtlich der Ergebnisse im klinischen Alltag kaum miteinander vergleichen. Auch eine offene Reposition und interne Fixation mittels Platte ist heutzutage in den meisten Kliniken anderen Indikationen als der „einfachen“ Tibiafraktur vorbehalten, sodass der Vergleich zwischen unserem Nagel und einem solchen Verfahren hinsichtlich klinischem Ergebnis (z.B. back-to-work) und radiologischer Konsolidierungsrate von vorneherein hinkt.

Unsere Ergebnisse zeigten, dass 75 % der Patienten ihrer präoperativen Arbeit nachgehen konnten. Die Aktivitäten des täglichen Lebens (Sockenanziehen, Treppensteigen, Vollbelastung und maximal mögliche Gehstrecke) verbesserten sich im Verlauf, auch wenn nicht alle Patienten ihre volle präoperative Funktion erreichten. Diese Ergebnisse sind kongruent mit Daten aus der Literatur, in der ebenfalls nicht alle Patienten ihre volle präoperative Funktion erreichten (Keating et al., 1997; Karladani et al., 2000).

Der postoperative vordere Knieschmerz kristallisierte sich als häufigste und signifikanteste Komplikation unserer Versorgungen heraus. Er stellte in unserem Patientengut die häufigste Indikation zur Entfernung des Implantats dar. Auch hier deckt sich unsere Datenlage mit der Literatur. Court-Brown et al. (1990) präsentierten die Ergebnisse einer prospektiven Studie von 125 geschlossenen bzw. offenen Tibiafrakturen des Typs 1 nach Gustilo und Andersen. (1976), die mittels aufgebohrten Grosse-Kempf-Tibianagel versorgt wurden. Auch hier klagten über 40 % der Patienten postoperativ über einen vorderen Knieschmerz, vor allem bei knieenden Tätigkeiten. Bei den meisten dieser Patienten ließ der anteriore Knieschmerz nach Entfernung des Nagels nach, wenngleich dies mehrere Wochen dauerte. Folgt man der Literatur, scheint es sich also um ein verfahrenimmanentes und nicht um ein implantatspezifisches Problem zu handeln, über das auch andere Autoren berichten, die andere „Nageltypen“ verwenden. Dieses spiegelt auch den klinischen Alltag wieder.

2.9 Zusammenfassung

In dieser prospektiven klinischen Multicenter-Studie wurden in drei europäischen Level 1-Traumazentren zwischen 01/2003 bis 12/2004 Tibiafrakturen von 102 Patienten mit einer aufgebohrten Marknagelung (System $T2^{TM}$, Fa. Stryker) versorgt. Es wurden demographische (z.B. Alter, Geschlecht), päoperative (z.B. Traumaursache, Frakturtyp), allgemeine operative (z.B. Operationszeit, Blutverlust) und postoperative (z.B. radiologische Knochenheilung, Gewichtsbelastung, Aktivitäten des täglichen Lebens, Rückkehr zur Arbeit, anteriore Knieschmerzen) Daten ausgewertet. Nachuntersuchungen fanden nach 4-6 Wochen (n = 62), 4 Monaten (n = 53) und 12 Monaten (n = 71) postoperativ statt.

Es handelte sich um 63,7 % männliche und 36,3 % weibliche Patienten eines mittleren Alters von 42 ± 16 Jahren. Am häufigsten kamen AO 42-B1-B3 Frakturen vor (45,1 %), gefolgt von einfachen (AO 42-A1-3, 24,5 %) and komplexen diaphysealen Frakturen (AO 42-C1-3, 17,6 %). Die restlichen 15 Frakturen waren 10 distale (AO 43-A1-3, AO 43-B2, AO 43-C1-3) and 5 proximale Frakturen (AO 41 A2-3, AO 41-C3). 65 Patienten (63,7 %) hatten ein hochenergisches und 7 Patienten (36,3 %) ein niedrigenergetisches

Trauma erlitten. Die Unfälle hatten sich meistens im Verkehr (31,4 %), auf der Straße als Fußgänger (22,5 %) oder zuhause (22,5 %) ereignet. Nur bei 36 Patienten (35,2%) lag eine singuläre Fraktur vor, bei 51 Patienten (50,0 %) war auch die Fibula frakturiert und 15 Patienten (14,7 %) waren polytraumatisiert.

Nach 12 Monaten wurde die Knochenheilung radiologisch bei 91,5 % (n = 65/71) bestätigt. 76,1 % (n = 54/71) hatte ihre Arbeit wieder aufgenommen und 74,7 % (n = 53/71) konnten mit ihrer früheren Kapazität arbeiten. Der mittlere Schmerzscore nahm von 3,1 ± 1,2 (4-6 Wochen) auf 2,6 ± 2,2 (4 Monate) und 2,3 ± 1,7 (12 Monate) ab. Nach 12 Monaten litten 13 Patienten unter anterioren Knieschmerzen, der bei 12 Patienten so leicht war, dass sie arbeiten und das Bein belasten konnten. Ein polytraumatisierter Patient hatte wegen einer Pseudarthrose einen Schmerzscore von 8 Punkten und benötigte mehrere Reoperationen.

Bei insgesamt 14 Patienten wurde eine Dynamisierung des Nagels wegen verzögerter Heilung und/oder Schraubenproblemen vorgenommen. Eine Revisionsoperation wurde bei 7/102 Patienten vorgenommen. Bei 3 Patienten war die Revision wegen einer Malrotation nach Schraubenbruch nötig, bei 2 Patienten wegen Schmerzen durch die proximalen Schrauben und bei 2 Patienten wegen einer Schraubenlockerung mit der Gefahr der Hautperforation.

Die Ergebnisse unserer Studie über das T2^{TM}-System sind mit anderen Studien über die aufgebohrte Marknagelung vergleichbar und belegen die Hypothese, dass diese Osteosynthesemethode effektiv ist und relativ wenig Komplikationen aufweist.

2.10 Literaturverzeichnis der deutschen Zusammenfassung

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3 Introduction

There are different ways on how a tibia fracture can be treated. It can be treated conservatively, surgically by extramedullar procedures of osteosynthesis e.g. plates and external fixator, or surgically by intramedullar procedures of osteosynthesis, e.g. reamed and unreamed nails.

3.1 Conservative treatment/fracture reduction

From the year 1852, the plaster cast introduced by the Dutch medical officer Mathijsen replaced the use of wooden splints in numerous modifications in order to enable bone healing by immobilisation of the fractured leg. Additionally, the Steinmann pin, presented by Steinmann in 1907 in Bern, facilitated the traction and reposition of the fracture ends and prevented displacement, but pin track infections wer common. In the course of the First World War Lorenz Böhler introduced reposition, traction and plaster fixation as a standardized treatment technique, but satisfying treatment results could not be achieved (Trojan, 1984). At the beginning of the 1950s Charnley in England recognized the importance of the soft tissue for the fracture stability. In his so-called three point principle he pointed out that the intact soft tissue on the concave side of the fracture deformation enhances the relative stability in plaster by taking the fragments to the right position (Bayne and Turner, 2006). Fracture reduction technique can be done by calculated pressure and counter pressure.

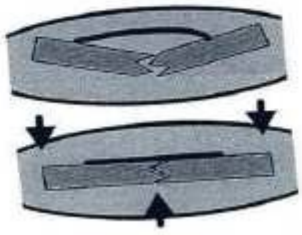


Fig. 1: Fracture reduction technique(Habermayer et al , 1990)

Böhler suggested that axis deviations between 3° and 15° can be corrected by wedging the plaster (Böhler, 1965). This procedure is not possible in case of an intact fibula. Based on the x-ray, it is possible to transfer and to mark the axis position on the plaster. The cut into the plaster takes place at the intersection of the axes on the concave side of the dislocation. The plaster has to be cut and wedged open by more than half of the circumference. It is wedged and opened until the marked axes correspond. The position is fixed by pieces of cork and is plastered again after x-ray control.

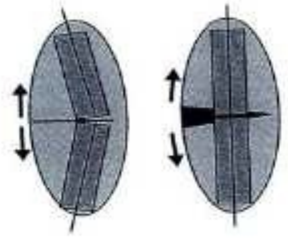


Fig. 2: Technique of wedging open the plaster (Habermeyer et al., 1990)

To reduce transverse fractures the fragment reduction requires traction e.g. supported by a Steinmann pin. The right technique of traction treatment starts with a correct positioning of the calcaneus wire to avoid failure in correction of malalignments. The calcaneus wiremust be placed vertically to the distal tibia proportion. According to Jahna and Wittich (1985) one marks the correct point of incision on the inside ankle 2 cross fingers in the extended tibia axis and 2 cross fingers dorsally in adults. The lateral exit point of the wire is one cross finger beneath and dorsal to the tip of the lateral malleolus. After an exact marking the extension wire can be drilled from medial to lateral (Fig. 3). For traction of the lower leg a weight of 3-4 kg is usually sufficient.

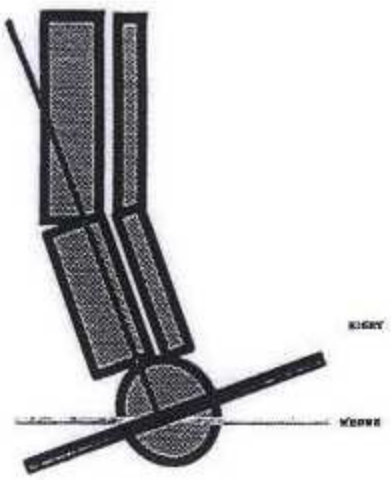


Fig. 3: Traction treatment technique (Habermeyer et al., 1990)

When a dislocation appears during traction treatment, it requires correction. Valgus and varus dislocation can be avoided by an absolute correct setting of the traction pin wire and can be corrected by a modified point of start at the extension clamp. Antecurvation faults can be adjusted if the direction of the traction runs upwards parallel to the proximal tibia proportion. Conversely a recurvation position requires a correction of the traction downwards (Fig. 4).

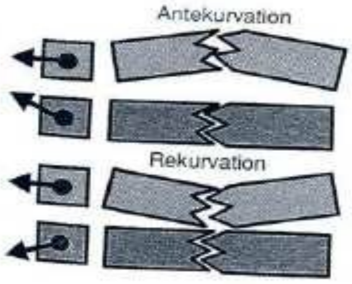


Fig. 4: Correction of axis positions during traction treatment (Habermeyer et al., 1990)

One common mistake is the plastering in the talipes equinus position. In case of weight bearing, the recurvation of the lower leg results as a consequence (Fig. 5).

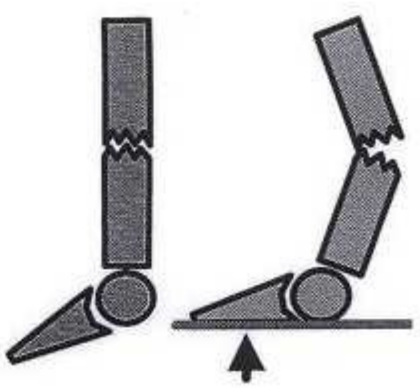


Fig. 5: Avoidance of the talipes equinus position (Habermeyer et al., 1990)

Based on the knowledge of the fracture stabilization by means of soft tissue, particularly of the membrane interossea, Dehne et al. (1961) introduced the early weight bearing in upper extremity plaster. In 1967, the introduction of 'brace treatment" by Sarmiento described the development of this early functional treatment. The external splinting of the fractured extremity by a brace creates a hydraulic system. This hydraulic mechanism of soft tissue in brace prevents a further shortening of the fracture fragments (Sarmiento et al., 1989). A controlled motion in the fracture gap leads to an osteokinetic stimulus by thermoelectric and vascular changes. Studies have shown that this results in a faster callus formation (Hulth, 1989; Cornell and Lane, 1992; Aro and Chao, 1993; Lacroix and Prendergast, 2002; Isaksson et al., 2006; Jagodzinski and Krettek, 2007; Gonzalez-Torres et al., 2010; Gomez-Benito et al., 2011).

In adults with closed, not dislocated and uncomplicated fracture types the healing of conservatively treated tibia fractures usually takes between the 10th and 13th week. Dislocated fractures heal between the 13th and 16th week and open fractures as well as fractures in fragments between the 16th and 26th week (Leach, 1984).

Drawbacks of the conservative therapy

In the following cases, the conservative therapy is contraindicated and a surgical procedure preferable:

A. Fractures that cannot be reduced
    1) with a displacement of more than shaft width
    2) angle larger than 10
    3) primary diastase
    4) primary shortening larger than 10 mm
B. Instable fracture forms
    1) with redislocation
C. accompanying ispsilateral femur fracture

In case of an intact fibula and a dislocated tibia fracture (and thus a ruptured membrana interossea) a blocking mechanism and a delayed fracture healing or rather a formation of a pseudarthrosis is frequently seen, thus surgical management is justified, too. Conversely in the case of an intact fibula without dislocated tibia fracture an above knee plaster with a stretched knee may be indicated because an intact fibula increases the stability of the tibia and reduces the degree of the dislocation of tibial fragments (Nicoll, 1964). Without doubt an intact fibula may lead to varus deformity. For this reason Sarmiento recommended the fibula-osteotomy at the level of the tibia fracture (Sarmiento et al., 1989). Varus and Valgus deformities as well as ante and recurvation deformities are described especially by oblique and transverse fractures (den Outer et al., 1990).

All fractures with an open or closed soft tissue damage of 2nd-3rd grade that are initially stabilized surgically by external fixation are not ideal for further conservative management. Per definition, the threatening and manifest compartment syndrome is among those that require the opening of all four loges and thus urgent surgery is necessary (Rammelt et al., 2004).

In general, a high rate of complications is seen in conservatively treated tibia fractures. Leach (1984), Oni et al. (1988), and Puno et al. (1986) found 61 % of complications with an intact fibula, among them 26 % with delayed union.

In a study on the longterm outcome, 572 subjects who had sustained a tibial shaft fracture and were treated with cast immobilisation more than 27 years ago were compared with matched controls without fractures. It was shown that the functional status was worse in the fracture group than in the control group with regard to knee pain, functional tests such as climbing stairs, and the physical function score on the SF-36 (Greenwood et al., 1997).

Indications

The Böhler school recommended the conservative treatment of all closed lower leg shaft fractures as long as they are stable and reducible (Böhler, 1965). According to Sarmiento et al. (1989) most of the closed fractures can be treated functionally at an early stage if the leg shortening is less than 10 mm and the axis deviation is smaller than 5° after reposition. First-grade open fractures with slight soft tissue damage can also be treated by the Sarmiento-technique. A further indication arises in cases where there is a change of procedure after external fixation immobilization.

In view of the improvements in surgical fracture management, conservative treatment of tibial fractures has become increasingly more seldom in industrialized countries.

Nonetheless, there are indications for conservative treatment, for example in patients with an increased operative risk or in patients who refuse a surgical therapy.

3.2 Plate osteosynthesis

Developments in plate osteosynthesis

Robert Danis is regarded as the founder of modern osteosynthesis. In 1949 he developed plates which provide compression through the implant and narrow the fracture gap. Fractures treated by those plates healed “directly”, i.e. without callus formation. In 1958 Danis’ principles were taken over by the Swiss “Arbeitsgemeinschaft für Osteosynthese” (AO) which propagated precise reduction and absolutely stable fixation mainly using compression to allow a solid reunion of fragments (Li et al., 2012).

Standard plates produce compression between the implant and the bone and only work, if they are pressed to the bone. With conventional plate osteosynthesis, wide exposure of the bone is usually necessary to gain access to and provide good visibility of the fracture zone to allow reduction and fixation of the plate. This procedure requires pre-contouring of the plate to match the anatomy of the bone. The screws are tightened to fix the plate onto the bone. The actual stability results from the friction between the plate and the bone. The so-called Open Reduction and Internal Fixation (ORIF) by means of plates and screws has established itself as a standard and successful technique for treating bone fractures.

However, the biological shortcomings of direct open reduction and conventional compression plating are damage to the blood supply (compression of the periosteum) to the bone, which can lead to biological complications. Compression plating needs good bone quality and precise anatomical reduction is often not possible without the risk of an iatrogenic bone and soft tissue trauma (Perren, 1995; Rüedi and Murphy, 2000; Perren, 2002).

Therefore, new surgical techniques and devices that aim to preserve the blood supply, reduce the contact area between plate and bone and alter the load of the plate to provide pure tension forces on the plate were developed. Examples include the wave plate (Brunner and Weber, 1981) and bridge plate (Heitemeyer and Hierholzer, 1985). ”Biological bridge plating“ means indirect, closed or open but less invasive (no touch technique) reduction with biological bridging and delivers greater relative stability (Gautier and Ganz, 1994; Leunig et al., 2001).

An indirect, closed reduction and bridging of the fracture zone was realized by the Locked Internal Fixators (LIF) where the screw can be locked in the plate. Plate and screws form one stable system and the stability of the fracture depends on the stiffness of the construct. Locking the screw into the plate to ensure angular as well as axial stability eliminates the possibility for the screw to toggle, slide or be dislodged which leads to a secondary loss of reduction (Wagner, 2003).

Since the 1990s a paradigm shift has taken place: Rather than rely on absolute rigid fixation by compression, the “biological osteosynthesis” focuses on the biological characteristics of the bone. “The basic idea of biological osteosynthesis is, during fracture reduction and the process of fixation, maximized protection should be done to preserve the regional blood supply therefore healing of fractures becomes faster and prevent many complications” (Li et al., 2012). This Less Invasive Stabilization System (LISS) minimizes the compressive forces exerted by the plate on the bone, the damage to soft tissue and blood supply is less extensive, and more rapid fracture healing can be achieved (Wagner, 2003).

The LISS plates are precontoured to match the average anatomical form of the relevant site and do not have to be further adapted intraoperatively. The development of the locked internal fixator method has been based on scientific insights into bone biology especially with reference to its blood supply. The basic locked internal fixation technique aims at flexible elastic fixationto initiate spontaneous healing, including induction of callus formation. The method of screw fixation without the plate-bone contact is of particular advantage in Minimal Invasive Percutaneous Osteosynthesis (MIPO) which describes indirect, closed reduction and submuscular/subcutaneous sliding techniques. The aim of MIPO is to bridge the fracture zone using the plate as an internal fixator, and to give greater relative stability (Perren, 1995; Tepic and Perren, 1995; Schandelmaier et al., 1999; Perren, 2001, 2002). This in turn allows the use of an aiming handle which maintains congruency with the implant. It is therefore possible to insert the internal fixator through a small incision remote to the site of the fracture with blind application of the self-drilling screws. Avoids a traumatizing surgical approach and allows the treatment of fractures with contused skin in which the remote skin incision should be an advantage (Perren, 2002).

Wagner (2003) summarizes the prerequisites for successful internal fixation by MIPO as follows:

1) Indirect closed reduction without exposure of the fracture.
2) Small incisions for the insertion of the implants.
3) Elastic bridging of the fracture zone with a locked internal fixator (LISS, LCP).
4) Implants with minimal bone contact. Slightly elevated plate from the bone surface to eliminate any mismatch of the pre-contoured plate to the anatomy of the bone.
5) Self-drilling and self-tapping locking head screws for mono or bicortical insertion.
6) Only for LISS: A geometrical correlation between aiming handle and plate for ”closed” application.
7) Relative stability (elastic fixation) increases callus formation.

Rationale of Locking Plate (LP)

The development of the Locking Compression Plate (LCP) is based on the experience gained with the LISS (Wagner, 2003). The LCP system has the advantage of allowing the pre- or intraoperative decision whether or not to use conventional screws, locked screws or a combination of both. This led to the development of the combination hole for the LCP (Wagner and Frigg, 2000; Frigg, 2001, 2003; Wagner, 2003).

LP refers to the screw heads that are threaded and, when tightened, locked into threads in the plate. A fixed angle construct is created. Such constructs are much less prone to loosening or toggle than traditional non LPs (Cantu and Koval, 2006). The precise anatomic shape of the LP prevents primary dislocation of the fracture caused by inexact contouring of a normal plate and allows a better distribution of the angular and axial loading around the plate (Frigg, 2001, 2003). Minimally invasive surgery using LP uses indirect reduction and maintains alignment by bridging the fracture without compression. Percutaneous plating maintains arterial vascularity by preserving the soft tissue envelope and periosteum. Surgical trauma is minimized. Moreover, screw locking minimizes the compressive forces exerted by the plate on the bone, and thus avoids disturbance of bone blood supply (Frigg, 2001, 2003). LP is best described as ”internally placed external fixators” or “locked internal fixators“. This construct converts axial load into compression force rather than shear force as in dynamic compression plates. The system works as a flexible elastic fixation that stimulates callus formation (Wagner, 2003) based on evidence that bone continuity after a fracture can be restored by primary and secondary healing (Carter et al., 1998). Some flexibility is therefore desirable in the final fixation to stimulate callus formation and secondary bone healing. Low fracture strain results in minimal to no callus formation and at best primary bone healing. As the fracture strain increases, secondary healing or callus formation occurs (Greiwe and Archdeacon, 2007) while moderate strain is advantageous. There is a level where it becomes counter productive. Studies have shown that strain between 10 % and 30 % would result in bone resorption and nonunion (Hente et al., 2004).

The LCP in tibia is indicated as an alternative method to intramedullary nailing in cases of:

1. Extension of the fracture into the joint.
2. Multifragmentary shaft and metaphyseal fractures.
3. Narrow as well as very large medullary canals.
4. Preexisting bone deformity.
5. Shaft fracture in children.
6. Polytrauma with severe brain or thoracic injury.
7. Simple shaft/metaphyseal fractures with soft tissue compromise.

Surgical technique (Ronga et al., 2009)

Depending on the skin condition, surgery has to be planned when the ankle swelling has subsided and the “wrinkle sign“ is present. In the wrinkle sign, the ankle is dorsiflexed while the anterior aspect of the ankle is observed, the absence of a skin crease or wrinkle suggests severe swelling (Tull and Borrelli, 2003). Temporary skeletal stabilization can be achieved by simple splintage or bridging external fixation until surgery is performed. Good quality plain radiographs (antero-posterior, lateral and lateral alignment views), if necessary, CT scans are obtained to determine optimal plate location. Identification of the size and location of possible articular fragments is essential before reconstruction. In the distal tibia the plate is normally applied on the antero medial aspect of the bone. Several precontoured plates specifically designed for these locations are commercially available. Anatomical LP should not be bent because bending alters the biomechanical properties of the plate, possibly leading to fatigue failure (Ahmad et al., 2007). Great care should be taken to ensure that the fracture can be clearly visualized on anteroposterior and lateral views. Both legs are prepared an draped above the knee, thus allowing intraoperative alignment to be checked against the normal limb. Using manual traction, or through a single Steinmann pin inserted into the calcaneus, the fracture is reduced. Depending on the quality of tibial fracture reduction reached, a fibula fracture, if present, can be plated first using a one third tubular plate to provide lateral stability and restoration of the correct length and to prevent over distraction at the fracture site. The main fracture fragments of the distal tibia are aligned and reduced percutaneously or through separate stab incisions and are then fixed with individual lag screws. With the fracture adequately reduced, an adequate transverse incision is made distal to the medial malleolus and a subcutaneous tunnel is created. An LP is then passed along the tunnel, bridging the fracture site. The plate has to be long enough to bridge the metaphyseal zone and to allow at least two bicortical screws insertions proximal to the fracture. It is critical at this stage to make a thorough assessment of the limb alignment and to establish that the correct rotation has been achieved by comparison with the other limb. At either end of the fracture, there must be at least 2 bicortical screws.

3.3 Intramedullar nailing

As early as in the 19th and the beginning 20th century, surgeons from Europe saw the advantages of nailing. Bircher (1886) and König (1913) described the use of metal pegs. Lambotte (1913) from Belgium was the first to use the metal nailing. According to Peltier (1990), intramedullary nailing that is familiar today was introduced about 1930 in England by Heygroves, in America by Rush and Rush and in Germany by Küntscher.

Two different approaches of tibia nailing are discussed controversially until today: the insertion of the nail with and without preceding drilling, respectively. The drilling of the intramedullary canal, described by Küntscher, should fixate the elastic nail into the stiff bone and enlarge the contact area between the implant and the bone. Therefore, the application of a nail could be expanded to more complex, as well as to proximal and distal, fractures (Küntscher, 1959). In 1962, Küntscher reported possible risks of drilling the intramedullary canal in terms of pulmonary complications (Küntscher, 1962), and in the 1990s, the Arbeitsgemeinschaft für Osteosynthesefragen (AO) developed the unreamed nail as an alternative to the external fixateur for the first primary care of open fractures.

Special interest in compression nailing was reported for the first time in the late 1960s (Hutter et al., 1977) as a reaction to the then innovative method of compression plating. The initial compression nail had a tie rod placed within a Küntscher nail, which was anchored to the distal fracture fragment by cross pinning. An external system was used to achieve compression that was maintained by a collar locker with a set screw (Hutter et al., 1977).

The first Interlocking Compression Nail (ICN) was described by Gonschorek et al. (1998). It had a low complication rate and could also be used for the treatment of pseudarthrosis, malalignment and arthrodesis.

3.3.1 Unreamed nailing

Due to reports on the substantial damage of the corticalis by interference with the endostal blood flow and heat development during the drilling procedure, a solid unreamed nail was developed (Danckwardt-Lilliestrom et al., 1970; Klein et al., 1990; Hupel et al., 1998). By additional damage to the bone on the one hand and a remaining “dead area” in a cannulized nail on the other hand a heightened risk of infection in case of open fractures was postulated (Klemm and Borner, 1986; Gustilo et al., 1990). By repeated drilling of the femoral canal, an increased washing in of fat and particles from the marrow area into the lungs was also shown (Pape et al., 1992; Pape et al., 1995; Wenda et al., 1995). Especially for polytraumatized patients with a restricted lung function and lowered immune resistance, this fact was connected with fat embolism syndrome and ARDS (Adult Respiratory Distress Syndrome) potentially with lethal ending. These considerations lead to the development of solid tibia nails that are inserted undrilled and are protected from rotation by screw fixation in the proximal and distal part of the nail (Attal and Blauth, 2010). The following advantages were described, too: Lower intraoperative blood loss and shorter operation time, diminished risk of bone necroses by excessive reaming, reduced risk of osteomyelitis development caused by bone sequesters as well as decreased damage of endostal blood flow (Attal and Blauth, 2010).

In contrast, the mechanical principle of the unreamed nail is the intramedullar splinting without tight fixation in the bone. Therefore, it provides less stability of the implant-bone-construct with an increased risk of material failure, and an increased rate of delayed healing and pseudarthroses (Attal and Blauth, 2010).

Consecutive studies showed that the unreamed nailing technique was not only suitable for open fractures but also achieved good results in the care of closed fractures (Gregory and Sanders, 1995; Krettek et al., 1995; Riemer et al., 1995; Schandelmaier et al., 1995; Runkel et al., 1996; Tornetta and Tiburzi, 1997). Yet one of the first prospective randomized studies concerning the tibia showed no advantages for the unreamed nailing technique, except the shorter operation time, but complications in terms of delayed bone healing and implant failures with the unreamed nailing were seen (Blachut et al., 1997). In a randomized prospective study, Clatworthy et al. (1998) compared the use of new titanium nails in the femur in reamed and unreamed technique and found a significantly longer healing period and a higher rate of implant failure in the unreamed group. This forced the groups to abolish the studies early.

To compensate for the disadvantages of the lower stability of the unreamed nails compared to the reamed procedure, the Angular Stable Locking System (ASLS) was developed. The locking screws are supplied with tubes made of bioresorbable polylactide which extend and tighten the nails corresponding to the new osteosynthesis principle of “intramedullary fixators”. A significantly increased stability compared to the conventional locking could be proven in a biomechanical study (Horn et al., 2009). Whether or not the increased stability results in fewer pseudarthroses and a lower rate of delayed healing needs to be shown by means of future randomized prospective studies.

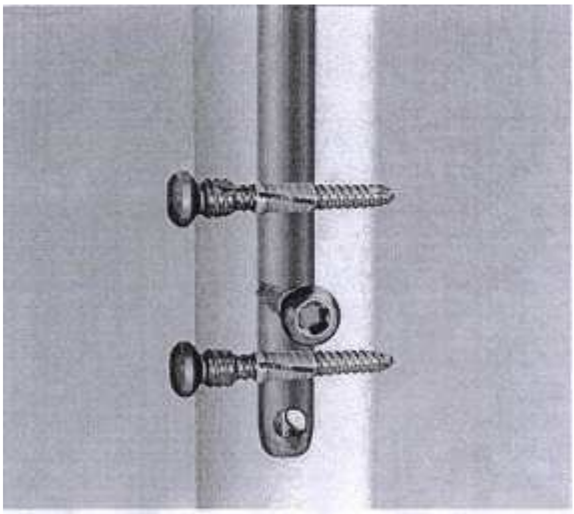


Fig. 6: Angular Stable Locking System (ASLS) (Attal et al., 2010)

3.3.2 Reamed nailing

In 1950, Küntscher recommended routine reaming, at first by already existing hand reamers, then from 1954 by means of electrically driven reamers with shafts and heads. In 1969 Küntscher suggested reaming over a wire that was flexible and could be cleaned more easily than its predecessors (Küntscher, 1962). In the following years the nail design received several modifications. Essential developments were the introduction of a fixed curvature of the tibia nail by Herzog (1958) and the invention of nails with a proximal screw thread to facilitate the insertion and removal (Schneider, 1961). The so-called “locking nails” by Klemm and Schellmann (1972) and Kempf et al. (1978) should prevent a rotation of the fragments against each other and - in case of compound and oblique fractures - the shortening in the fracture area by means of bolts which were inserted perpendicularly to the axis. A compression at the fracture was made possible by special compression aids or by putting weight on the extremity in case of a “dynamic” arrangement (Pfister, 2010).

3.3.2.1 Mechanical effects of reaming

Theoretically, reaming a long bone produces a canal of the same width and length as the nail. Practically however, this is not possible because of the different mechanical qualities of spongious bone near the joint and in diaphyseal area. The diameter of the applied drilling head is therefore especially important: A nail with a diameter of the drilling head or smaller cannot result in an elastic locking in the horizontal direction. In case of a nail with a slit and a larger diameter this seems to be possible, but is limited by the existing risk of fracture dislocation due to too much pressure. Using straight femur nails when nailing the tibia, however, an elastic 3-point locking in longitudinal direction can be achieved. This depends significantly on the fracture type and localisation. Anatomically formed nails result in a pure splinting function (Rehm and Übing, 1963; Kempf et al., 1978; Pfister and Frigg, 1980). Understandably a crosswise locking of the nail by screws offers more protection from rotation, a tilting of fragments near a joint in case of an unfavourable fracture course and from a compression of fragments (long oblique fracture defects and comminuted fractures).

Fracture stabilization achieved by nailing is understood in the sense of splinting and is therefore called “relative stability”, in contrast to the classical plates or compression screws osteosynthesis that should lead to “absolute stability” (Pfister, 2010).

3.3.2.2 Effects of reaming on blood flow and fracture healing

The corticalis of long bones is fed in the inner part by the intramedullary, in the outer part by the periosteal and paraosseal vascular system (Schneider, 1961; Rhinelander, 1968). Numerous animal experimental studies showed that the reaming procedure causes a considerable damage of cortical circulation (Danckwardt-Lilliestrom et al., 1970; Rhinelander, 1974; Stürmer and Schuchardt, 1980; Klein et al., 1990; Hupel et al., 1998), although this effect reverses within 8 weeks, and no negative influence on the callus formation could be proven (Schemitsch et al., 1998).

Reaming the intramedullary canal results in the risk of loss of vascularity of the inner cortex. The extraosseal and the periosteal blood flow increase and the centrifugally directed blood flow into the corticalis reverses to a centripetal direction. Blood vessels from the outer cortex grow into the inner cortical stratum, and non-vascularised cortex is the basis for new formed osteons. The newly formed intramedullar vascular system grows into the necrotic bone and hereby revascularization and remodeling occurs (Danckwardt-Lilliestrom, 1969; Pfister et al., 1979; Rahn, 1995; Pfister, 2010). The persisting damage of the inner stratum is clearly visible if an infection arises after intramedullary nailing. The whole inner stratum remains unsupplied by blood and acts as a sequester. In extreme situations a ring sequesters around the nail (Trueta and Cavadias, 1955; Rhinelander, 1968; Danckwardt-Lilliestrom, 1969; Pfister et al., 1979; Rahn, 1995).

Apart from this direct destruction of the intramedullary vascular system, reaming leads to an indirect damaging by causing pressure to the medullary canal (Wehner et al., 1966; Stürmer and Schuchardt, 1980). The contents of the marrow is pressed into the Volkmann ducts and the Havers systems of the corticalis and thereby blocks the vessels (Danckwardt-Lilliestrom, 1969; Olerud and Danckwardt-Lilliestrom, 1971). A further reason of vascular obstruction seems to be an activation of clotting because a majority of the vessels are filled with microemboli (Müller et al., 2009).

During reaming the arising debris settles in the groove of the drilling head which blocks the medullary canal proximally, and pushing the reamer forward further increases the pressure in the distal medullary canal. This can be particularly dangerous in case of a well reduced fracture and during the reaming of the distal fragment as the pressure cannot be relieved over the fracture. Therefore new reaming systems have been developed. To avoid a stamp pressure effect, the removal of the debris was facilitated by redesigning the lamellae of the reamer head, reducing the diameter of the drilling shaft, and by sucking and irrigation during the reaming procedure by means of the RIA (Reaming Irrigation Aspiration) principle (Müller et al., 1993; Wieling et al., 1999; Müller, 2003; Joist et al., 2004; Husebye et al., 2006; Müller et al., 2009). Experimental studies showed that intramedullary pressures are significantly lower or even negative as compared to the pressure when inserting an unreamed nail (Stürmer and Tammen, 1986; Müller et al., 1996; Müller, 2003).

By reaming, a thermal damage of the corticalis is created. A rise in temperature occurs by friction of the drilling head against the corticalis that exceeds the heat tolerance of the bone. A durable damage is assumed if a temperature of > 47^0 C lasts longer than 1 min., but normally such values are not reached (Krause et al., 1982; Eriksson und Albrektsson, 1983; Henry et al., 1987; Herzig et al., 2001). Dangerous rises in temperature occur in case of a hard corticalis. Reaming procedure is prolonged, too, in a narrow canal if blunt reaming heads are used and if the procedure is not performed in stages but all at once with a reaming head which is too large in relation to the diameter of the medullary canal (Povacz, 1979; Ochsner et al., 1998). In case of narrow canal passage and pseudarthroses, the medullary canal should be opened by hand before applying the smallest machine driven reaming head size. To avoid thermal damage sharp reaming heads should be used and only little forward pressure utilized (Herzig et al., 2001; Müller, 2003). An increase of the periosteal and paraosseal blood flow after reaming stimulates periosteal callus formation which is important for the primary stabilization (Chapman, 1998; Larsen et al., 2004; Forster et al., 2005; Bong et al., 2007). Apart from the described local effects on the long bone, a washing in of marrow material into the big veins and into the pulmonary circulation is known. In the transoesophageal echocardiogram, emboli of significant size have been shown (Wenda et al., 1990; Wenda et al., 1995; Coles und Gross, 2000). These are mixed thrombi that develop by the aggregation of blood components around an element of the intramedullary canal (Wenda et al., 1990; Wenda et al., 1995; Coles und Gross, 2000). In case of unreamed nailing an increased pressure in the intramedullary canal during the placement of the nail leads to the washing in of contents into veins and the lung circulation. In reamed nailing, a repeated increase of pressure occurs and quantity and size of an embolization are raised (Wenda et al., 1990; Pape et al., 1992; Strecker et al., 1993; Pape et al., 1995)

The vascular damage together with actual trauma leads to further weakening of bone vitality and is assumed to increase the risk of infection during the care of open fractures. Therefore, open fractures were generally considered to be contraindications to the reamed nailing technique (Klemm and Borner, 1986; Gustilo et al., 1990). Wiss and Stetson (1995) reported an infection rate of 21 % with reamed nailing technique of open tibial fractures..

First grade open fractures do not show any increased infection rates after reaming. The risk of infection after reaming of second and third grade open fractures is estimated differently. The intramedullary nailing carried out after reaming in case of open fractures of second and third grade is seldom applied in European countries, and if, then after primary stabilization by external fixation and control of the soft tissue damage as a secondary procedure. In North America it is used as a primary procedure in case of higher grade open fractures (Gustilo 111A) (Bhandari et al., 2000; Bhandari et al., 2008).

3.3.2.3 Operation technique in intramedullar reamed tibia nailing

The positioning of the patient is a decisive step during the preparation of the operation. Incorrect positioning can complicate the fracture reduction and nail insertion, and lead to considerable perioperative complications. The positioning on the extension table is recommended for reamed nailing. It has the advantage that the reduced fracture does not dislocate during reaming or needs to be reduced repeatedly. In case of unreamed nailing, an exact reduction is only necessary once while the nail is inserted and so the extension table is not necessary. The positioning on the extension table is time-consuming and also leads to complications, such as pressure damages of the soft tissue, nerve damages due to traction and pressure, and an increase of the compartment pressure (Pfister, 2010). It is difficult to change the traction after sterile draping, an intraoperative rotation control before locking and the distal locking itself are only possible after the removal of the draping and the traction.

It has to be taken into account that the knee of the patient, positioned on his back on the extension table, is bent > 90°, so that the later manipulations are possible without damaging the soft tissue around the nail insertion site (Pfister, 2010). The comparison of the axes of the knee joint and of the foot fixed in the extension shoe or in the heel wire extension allows a good rotation control.

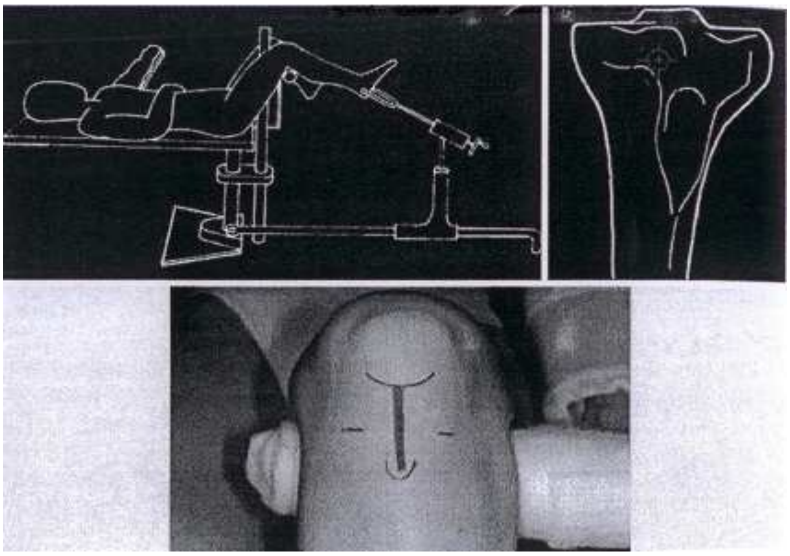


Fig. 7: Intramedullary nailing of the tibia (Pfister, 2010)

In Europe the Ligg. patellae are mostly split by incision to open the intramedullary canal. In contrast, the whole ligament is predominantly held lateral in North America. The transligamental access allows a more exact presentation of the access point. In the lateral approach the reamer is often pushed away by the ligament. Follow-up studies show no differences in relation to the function and the pain sensitiveness of both accesses (Orfaly et al., 1995; Pfister, 2010). The opening of the entry point is performed in the direct axis of the intramedullary canal, the access point is about 1 cm medial of the palpable front edge of the tibia and proximal of the tuberositas tibiae. The access point has to be met precisely, especially in case of proximal lying fractures, as otherwise a dislocation of the proximal fragment during the nailing can result. The first reaming is carried out with a drilling head that cuts towards the front and side. After this, the canal is reamed in 0.5 mm steps. A very strong reaming should be avoided. Because of the curvation of the medullary canal, the drilling pin is always situated at the dorsal corticalis and so there is the danger of perforating the dorsal cortex. The nail is inserted about one cm above the knee joint. It should be hammered in so far that its end is just palpable and can be found easily in case of a later removal of the metal.

3.3.2.4 Indications of intramedullar reamed nailing

The standard indications for intramedullar reamed nailing are given as follows:

- Horizontal and short oblique fractures in the middle third of the shaft (AO 32-A1-A3, 42-A1-A3),
- fractures with a small wedge in the middle third of the shaft (AO 32-B1-B3, 42-B1-B3),
- pseudarthrosis in the middle third of the shaft.

An extended indication may be considered in the following cases:

- Horizontal, short oblique fractures and pseudarthrosis at the junction to the metaphyseal third,
- fractures in the middle third with a larger wedge (AO 32-B1-B3, 42-B1-B3),
- segmental fractures (AO 32 C1-C3, 42 C1-C3),
- pathological fractures,
- comminuted fractures in the middle shaft area (Weller and Knapp, 1975; Krettek, 2001).

3.4 General treatment considerations

The optimal management of distal tibial fractures remains controversial. External fixation may result in inaccurate reduction, malunion or nonunion and pin tract infection (Rammelt et al., 2004). Classic open reduction and internal plate fixation require extensive soft tissue dissection and periosteal stripping with high rates of complication, including infection, delayed union and nonunion (Olerud et al., 1972; Fisher et al., 1978). Several minimally invasive plate osteosynthesis techniques have been developed, with good results at medium-term follow-up (Helfet et al., 1997; Francois et al., 2004; Maffulli et al., 2004). These techniques aim to reduce surgical trauma and to maintain a biologically favorable environment for the fracture healing.

Intramedullary nailing is considered the standard method for surgically managing diaphyseal fractures of the tibia, but the distal tibia poses concerns regarding the stability of fixation, the risk for secondary displacement of the fracture on insertion of the nail, breakage of the nails and locking screws, and final alignment of the tibia (Boenisch et al., 1996; Vallier et al., 2008).

Initial clinical series using these methods for distal tibia fractures demonstrated favorable results with low rates of infection and nonunion (Helfet et al., 1997; Collinge et al., 2000; Maffulli et al., 2004; Redfern et al., 2004). Several complications, such as angular deformities greater than 7°, implant failure, and nonunion have been reported (Helfet et al., 1997; Francois et al., 2004; Maffulli et al., 2004).

Coles and Gross (2000) published a meta-analysis on the care of closed tibial shaft fracture. Plaster treatment, plate osteosynthesis and nailing were compared; 13 studies with 895 fractures were examined for bone healing, dislocation and infection. The authors found a rate of delayed healing and pseudarthrosis of 8.0 % related to the reaming technique and 16.7 % with the unreamed technique. Superficial infections were more frequent (2.9%) in the reamed group compared with the unreamed technique (0.5 %). The rate of infections in the plate osteosynthesis group was significantly higher with 9.0 % superficial infections. There was no difference with regard to deep infections.

In a further meta-analysis, Bhandari et al. (2000) found a significant advantage for the reamed nailing technique concerning bone healing and implant failure over the non reamed technique. Larsen et al. (2004) provided a prospective randomized study concerning the comparison of both procedures in open and closed tibia fractures. A significantly longer healing period was found for the unreamed technique. Furthermore, a tendency towards more dislocation and follow-up operations was noted.

A large multicenter randomized study at 29 clinics in Canada, the USA and the Netherlands compared reamed and unreamed nailing of the tibia shaft in 1314 patients (Bhandari et al., 2008). In closed fractures there predominated the advantages of reamed nailing, whereas there was no difference regarding bone healing and infection rate of open tibia fractures.

3.5 Aim of the study

The objective of this multicenter study was to evaluate the clinical and radiographic outcome of patients treated with a new nailing system after simple and complex proximal, diaphyseal and distal tibial fractures (AO 41, 42, 43).

In particular this study should answer the following questions:

- Is the new nailing system appropriate for the intramedullar reamed nailing of tibia fractures of all types?
- Do perioperative data reveal some distinct prognostic factors?
- Is bone healing comparable to other treatment methods?
- Do postoperative parameters such as activities of daily living and pain show advantages as compared to other treatment methods?
- Which complications arise after reamed nailing with the new system?

Problem

In industrialized countries, more than 90 % of diaphyseal fractures are treated by internal implants. These fractures are prone to complications such as nonunion. These nonunions require secondary operations and additional rehabilitation and time off work. These additional operations cost a lot of money and there are also indirect costs due to decreased productivity. Certain management strategies might best minimize these frequent complications. One of the strategies is the use of the T2 TM intramedullary tibial nailing system.

The advantages of this nailing system are:

1. Three different nail designs dedicated to proximal, distal or shaft fractures,
2. the possibility to control the bone fragment apposition/compression,
3. not limiting the approach to a certain nailing technique,
4. providing locking options for all types of fractures, plus the advanced Locking Mode for increased rotational stability.

4 **Material and Methods**

4.1 Patients

From January 2003 to December 2004 the simple or complex proximal, diaphyseal and distal tibial fractures (AO 41-A2-3 AO 41-C3, AO 42-A1-3, AO 42-B1-3, AO 42-C1-3, AO 43-A1-3, AO 43-B2, AO 43-C1-3) of 102 patients were treated with reamed nailing by means of a T2^{TM} tibial nailing system (Fa. Stryker, Schönkirchen/Germany). Three European Level 1 Traumacenters were involved in this study: Vrije Universiteit medical center, Amsterdam/The Netherlands; Klinikum Hannover Nordstadt, Hannover/Germany; Hospital Universitario Ramon y Cajal, Madrid/Spain.

4.1.1 Inclusion criteria

1) The patient is 18 years or older.
2) The patient has at least one cortical contact at the site of the fracture.
3) The patient agrees to comply with postoperative scheduled clinical and radiographic evaluation and rehabilitation.
4) The patient does not have an ipsilateral condylar fracture.
5) The patient does not have an ipsilateral foot fracture.
6) The patient does not have an unstable spine fracture.
7) The patient has a fixed address and does not plan to move out of the region in the next year.

4.1.2 Exclusion criteria

1) The patient has neuromuscular or neurosensory deficiency that could limit the ability to assess the performance of the device.
2) The patient has pulmonary dysfunction.
3) The patient is physically or mentally compromised in anyway that would affect the results.
4) The patient is convicted of any crime.
5) The patient is taking long term therapy drugs that could alter bone metabolism.

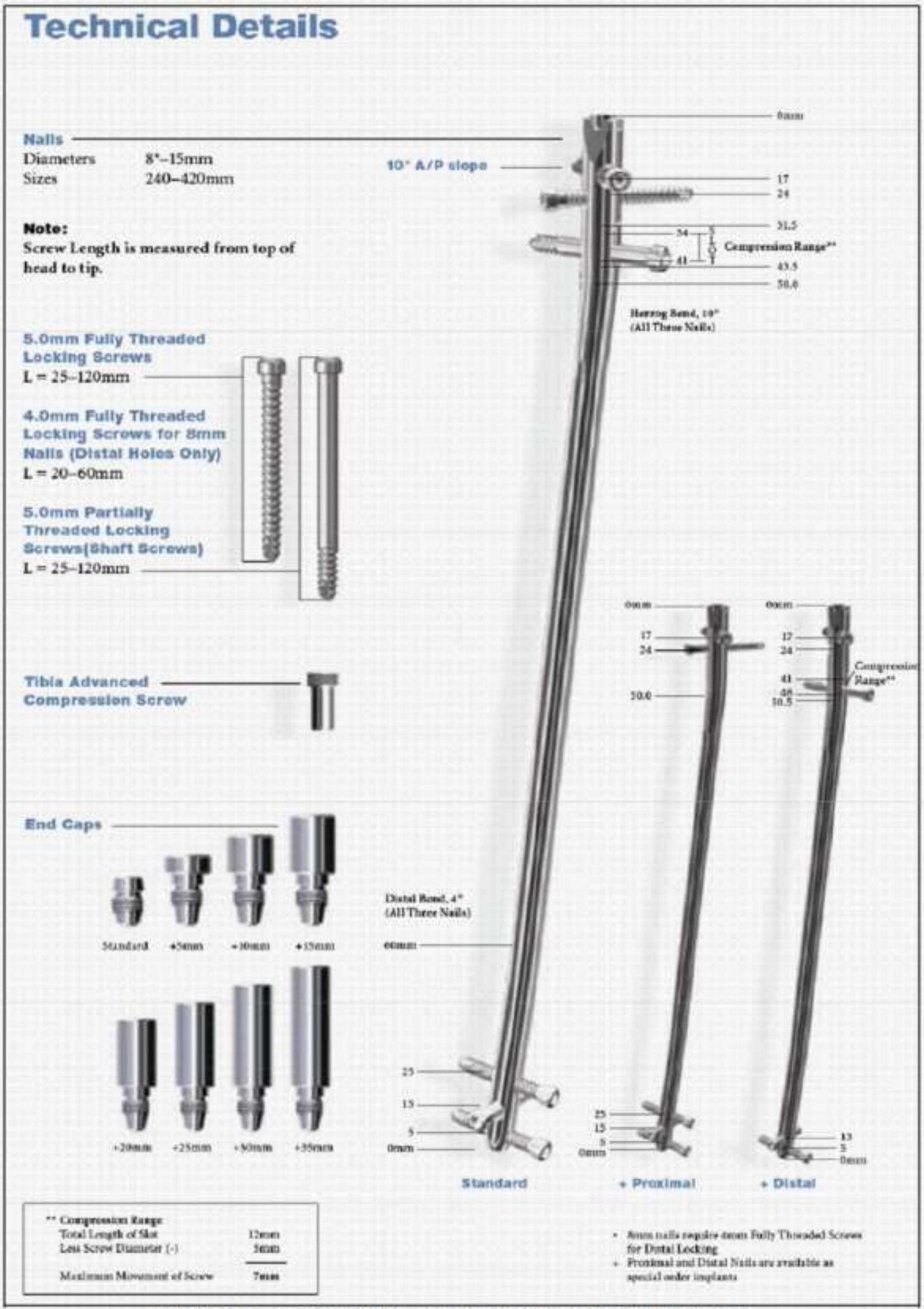
4.2 Surgery

4.2.1 Operative procedure

The operations were performed on a standard or orthopaedic table with or without traction. When traction was applied, the patient`s hip and knee were flexed and the foot was placed in a boot, or calcaneus traction was applied. In case of manual traction the patient was supine on a radiolucent table with the ability to flex the knee> 90° over an aluminium triangle or pile of blankets. This method avoids the use of traction pins, which reduces the operative time and removes the risk of iatrogenic nerve injury or nerve compression from the bolster. It also avoids elevated compartment pressures seen with prolonged traction. After appropriate fracture reduction a good AP (anteroposterior) and lateral view was obtained with the fluoroscopy. The operation was performed under sterile conditions. The proximal incision was through the midline of the patellar tendon, 1/3 from the midline of the patellar tendon or parapatellar. The location of the starting point was distal on the anterior tibial cortex. In the AP view the entry point was in line with the axis of the intramedullary canal and with the lateral tubercle on the intercondylar eminence. In lateral view the entry point is at the ventral edge of the tibia plateau. An awl was inserted perpendicular to the cortex and the position was gradually adjusted more parallel to the cortex as it was advanced. A ball-tipped guide wire was placed through the entry portal into the medullary canal. The guide wire was advanced across the fracture site with C-arm assistance and impacted into the distal subchondral bone. Sequential reaming took place with the knee in flexion to avoid damage to the intra-articular structure or the anterior cortex. After reaming, the nail length was measured appropriately. The nail was attached to the introducer and the aiming guide for the proximal locking screws and inserted over the guide wire. The nail should be countersunk 0.5 to 1 cm to allow nail backslap and fracture compression and avoid soft tissue irritation. The proximal locking screws were placed with the assistance of a jig and soft tissue protector. Distal locking screws were inserted using a freehand technique.

4.2.2 Description of the device: T2^{TM} Tibial Nailing System

The T2^{TM} tibial system (Stryker Howmedica Osteonics (Stryker Orthopaedics) - Mahway, NY) is the realisation of good biomechanical intramedullary stabilisation using small caliber, high tensile strength, and strong cannulated implants for internal fixation of long bones. According to the fracture type the system offers the option of different locking modes. Next to static locking is a controlled apposition/compression of bone fragments that can be applied by introducing a compression screw from the top of the nail. To further increase rotational stability the nail can be locked statically after using the controlled dynamization and apposition/compression option. The beneficial effect of apposition/compression in treating long bones in cases involving transverse and short oblique fractures that are axially stable is well documented (Gonschorek et al., 1998). The compression screw is pushed against the proximal locking screw that has been placed in the oblong hole, drawing the distal segment towards the fracture site. In stable fractures, this has the biomechanical advances of creating active circumferential compression at the fracture site, transferring axial load to the bone, and reducing the function of the nail as a load bearing device (Richardson et al., 1995). This ability to transfer load back to the bone reduces the incidence of implant failure secondary to fatigue. Typical statically locked nails function as load bearing devices and failure rates in excess of 20 % have been reported (Hutson et al., 1995). For very distal tibia fracture, there is a T2 distal tibia nail and is available in only 10 mm diameter with 2 distal locking holes at 5 and 13 mm from the distal tip. The T2^{TM} tibia proximal nail is used for very proximal tibia fractures. This nail does not have an oblong hole for optional controlled dynamisation and compression. All implants in the T2^{TM} tibial nailing system were gun drilled and made of Type II anodized titanium alloy (Ti6AL4V) for enhanced biomechanical and biomedical performance.



Technical Details

Nails

Diameters 8*–15mm

Sizes 240–420mm

Note:
Screw Length is measured from top of head to tip.

5.0mm Fully Threaded Locking Screws
L = 25–120mm

4.0mm Fully Threaded Locking Screws for 8mm Nails (Distal Holes Only)
L = 20–60mm

5.0mm Partially Threaded Locking Screws(Shaft Screws)
L = 25–120mm

Tibia Advanced Compression Screw

End Caps

** Compression Range

Total Length of Slot	12mm
Less Screw Diameter (-)	5mm
Maximum Movement of Screw	7mm

- * 8mm nails require 4mm Fully Threaded Screws for Distal Locking
- + Proximal and Distal Nails are available as special order implants

Picture 1 – Technical Details (taken from Op Technique)

Fig. 8: Description of the device: T2 TM Tibial Nailing System

Only the Standard Nail was used in this study. The length of the nails varies between 240 and 420 mm, with a diameter between 8 and 15 mm. The locking screws are fully or partially threaded with a diameter of 5 mm and the length is between 25 and 120 mm. The end caps (standard/5-35 mm) make the nail longer.

4.3 Follow-up

4.3.1 Clinical assessment

We assessed demographic (e.g. age, gender), preoperative (e.g. trauma cause, fracture type), general operative (e.g. surgery time, blood loss), and postoperative data (e.g. radiologic bone healing, weight bearing, activities of daily living, return to work, anterior knee pain). A complete overview about all data collected is given by means of the Clinical Review Form (CRF, see Appendix, page 92) that was filled out for each patient. Study patients were assessed before surgery, at the time of surgery and at 3 post-operative periods (4-6 weeks, 4 months and 12 months). All patients were seen in the out-patient clinic by the coordinating surgeon who entered the data in the CRF. Overall pain was rated using a Visual Analogue Scale ranging from 0-10 points (Downie et al., 1978).

Visual Analogue Scale

4.3.2 Radiographic assessment

The fracture union criteria´s were bone trabecullae crossing through at least 3 cortices on an x-ray in two directions. The fractures were classified according to AO/OTA Orthopaedic Trauma Association (Ruedi et al, 2000).

4.4 Statistics

Analyses were performed using the software SPSS version 11.5.

5 Results

5.1 Preoperative

A total of 102 patients were prospectively included in this study. The re-examinations were frequented by 62 patients after 4-6 weeks, by 53 patients after 4 months and by 71 patients after 12 months.

There were 44.1 % (n = 45) who were operated on the left and 55.9 % (n = 57) on the right lower leg. The mean age was 42 years (± 16 years). Most patients were involved

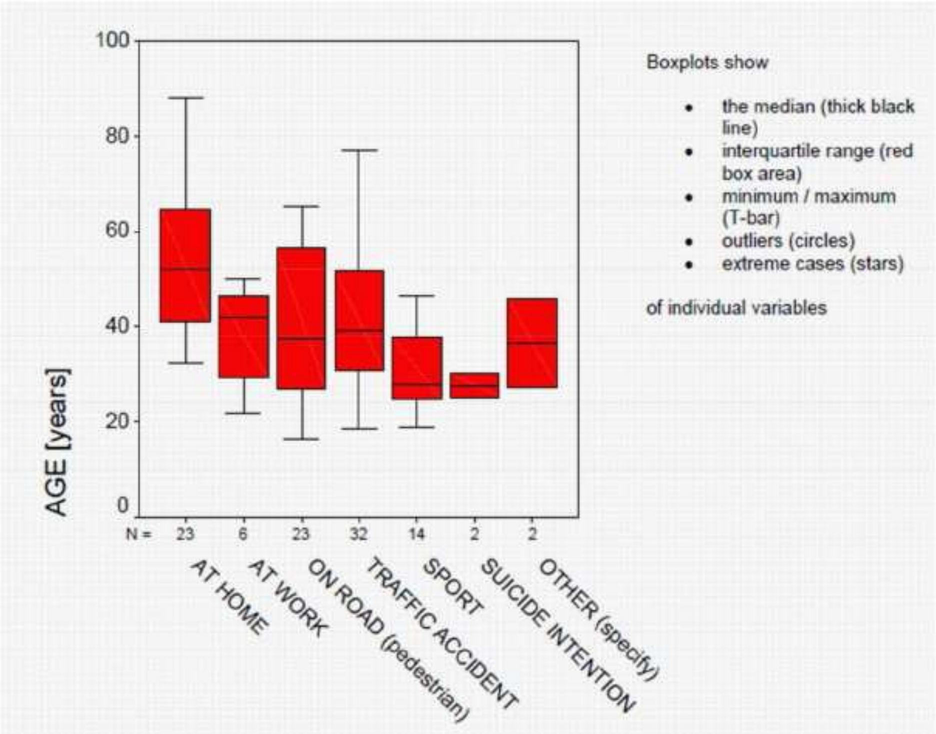
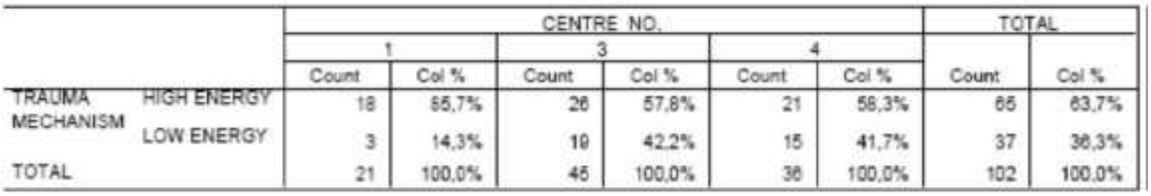


Fig. 9: Age distribution by trauma circumstances (Stryker Trauma R & D)

Older patients were involved in accidents at home (Fig. 9). According to the trauma mechanism, 65 patients were involved in high energy trauma and 37 patients in low energy trauma.

Table 1: Trauma mechanism (high-low energy)



		CENTRE NO.						TOTAL	
		1		3		4			
		Count	Col %	Count	Col %	Count	Col %	Count	Col %
TRAUMA MECHANISM	HIGH ENERGY	18	85,7%	26	57,8%	21	58,3%	65	63,7%
	LOW ENERGY	3	14,3%	19	42,2%	15	41,7%	37	36,3%
TOTAL		21	100,0%	45	100,0%	36	100,0%	102	100,0%

Taking a closer look at the trauma mechanism and the age distribution, it is evident that there is a significant difference between the low and high energy cases in age by performing the non-parametric Mann-Withney-U-test (significance level = 95 %). The cases with low energy fracture mechanism are significantly older than the high energy cases (p = 0.017).

There were 63.7 % (n = 65) male patients and 36.3 % (n = 37) female.

By performing the Chi-Square Test (significance level = 95 %), there is no significant difference (p = 0.186) (Fig. 10).

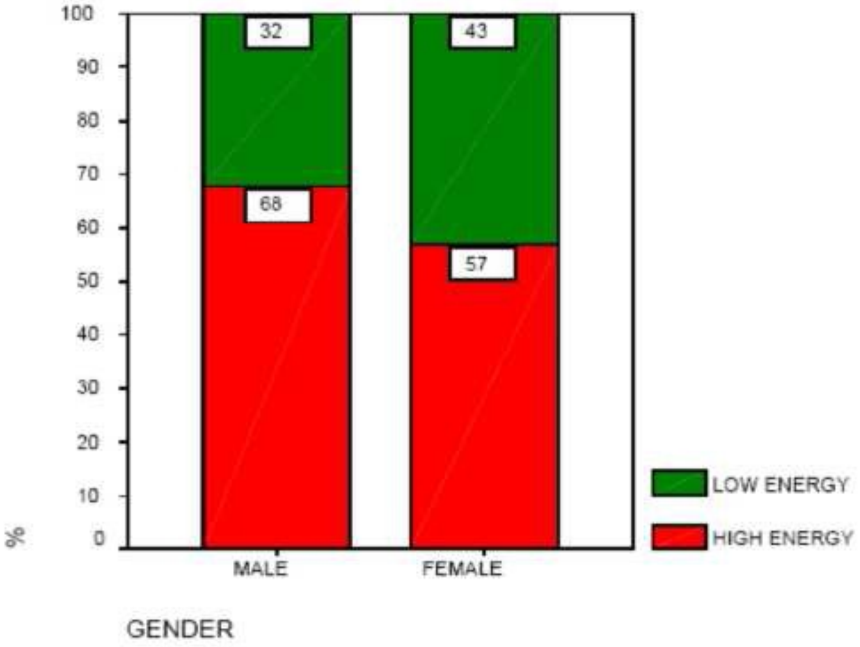


Fig. 10: Gender by trauma mechanism

In addition, coexistent diseases were documented in 20 patients (19.6 %), especially in the elderly. A great variety of comorbities had been described with slight accumulations for cardivascular problems (6/20; 30.0 %), osteoporosis (5/20; 25.0 %), psychological problems (5/20; 25.0 %) or hepatic disorders (4/20; 20.0 %). Analysing the relation between the presence of one or more coexistent diseases and the age distribution, it can be shown that there is a significant difference between the cases in age performing the non-parametric Mann-Whitney-U-test (significance level = 95 %). The cases with the presence of coexistent diseases are significantly (p = 0.025) older as compared to the group without diseases (Fig. 11).

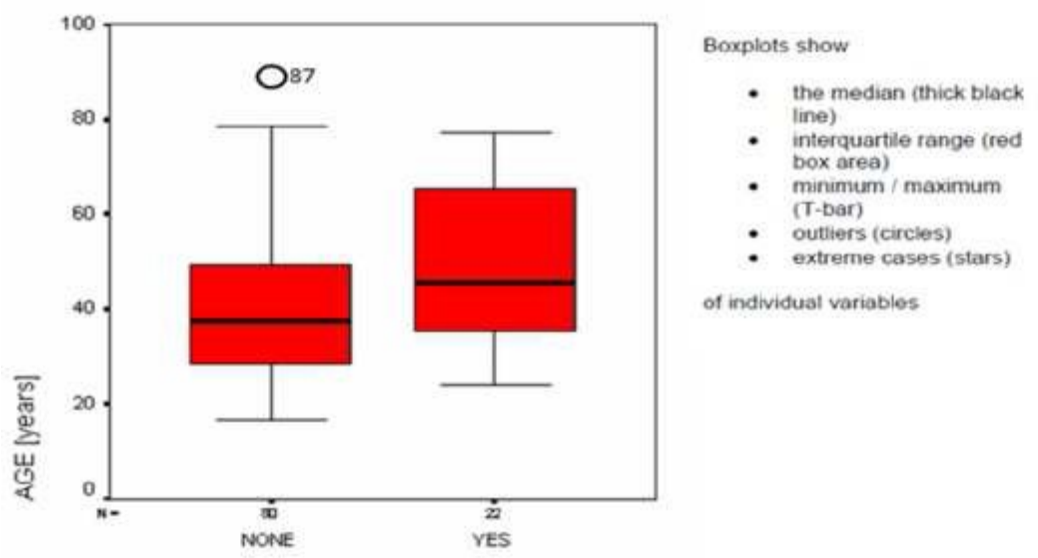
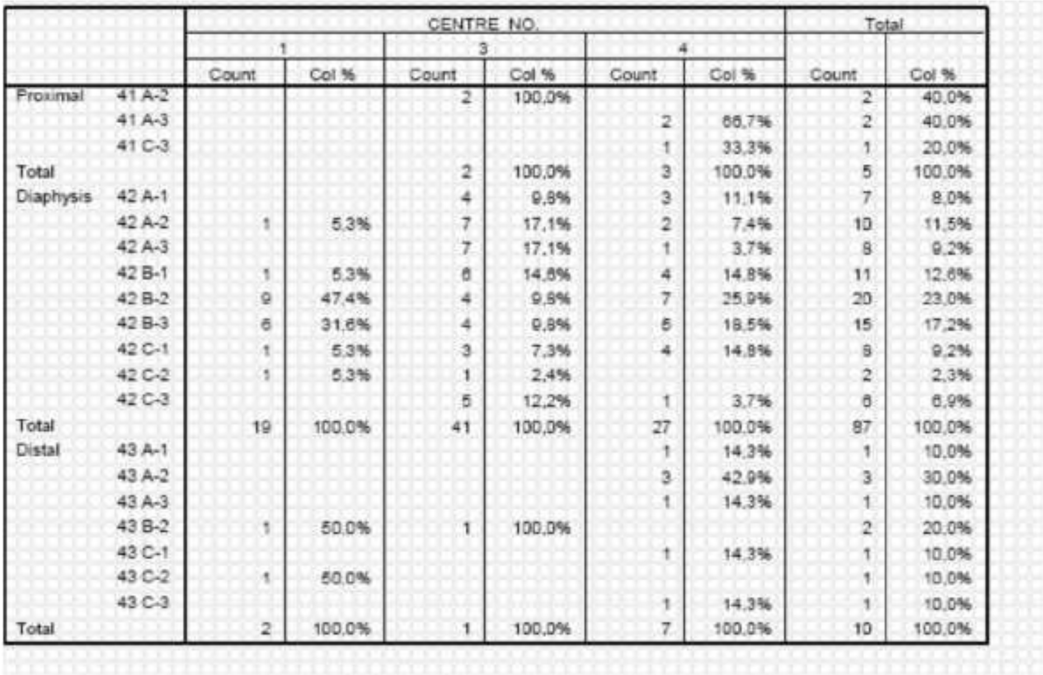


Fig. 11: Coexistent disease

The fractures were classified as proximal AO 41 A-C (4.9 % n = 5), diaphyseal AO 42 A-C (85.3 % n = 87) and distal AO 43 A-C (4.9 % n = 10) (Table 2 and Fig. 12).

Table 2: Fracture classification (proximal, diaphyseal, distal)



		CENTRE NO.						Total	
		1		3		4			
		Count	Col %	Count	Col %	Count	Col %	Count	Col %
Proximal	41 A-2			2	100,0%			2	40,0%
	41 A-3					2	66,7%	2	40,0%
	41 C-3					1	33,3%	1	20,0%
Total				2	100,0%	3	100.0%	5	100.0%
Diaphysis	42 A-1			4	9,8%	3	11,1%	7	8,0%
	42 A-2	1	5,3%	7	17,1%	2	7,4%	10	11,5%
	42 A-3			7	17,1%	1	3,7%	8	9,2%
	42 B-1	1	5,3%	6	14,6%	4	14,8%	11	12,6%
	42 B-2	9	47,4%	4	9,8%	7	25,9%	20	23,0%
	42 B-3	6	31,6%	4	9,8%	5	18,5%	15	17,2%
	42 C-1	1	5,3%	3	7,3%	4	14,8%	8	9,2%
	42 C-2	1	5,3%	1	2,4%			2	2,3%
	42 C-3			5	12,2%	1	3,7%	6	6,9%
Total		19	100,0%	41	100,0%	27	100.0%	87	100,0%
Distal	43 A-1					1	14,3%	1	10,0%
	43 A-2					3	42,9%	3	30,0%
	43 A-3					1	14,3%	1	10,0%
	43 B-2	1	50,0%	1	100,0%			2	20,0%
	43 C-1					1	14,3%	1	10,0%
	43 C-2	1	50,0%					1	10,0%
	43 C-3					1	14,3%	1	10,0%
Total		2	100,0%	1	100,0%	7	100,0%	10	100,0%

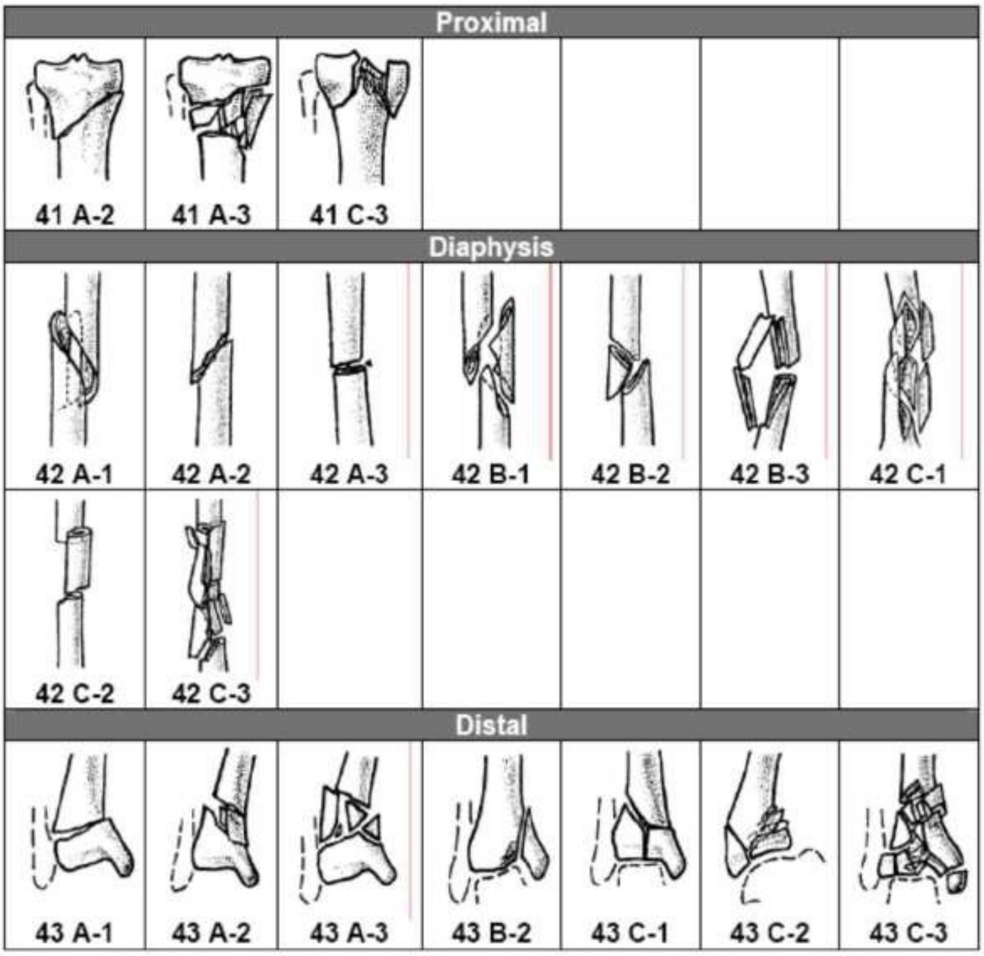
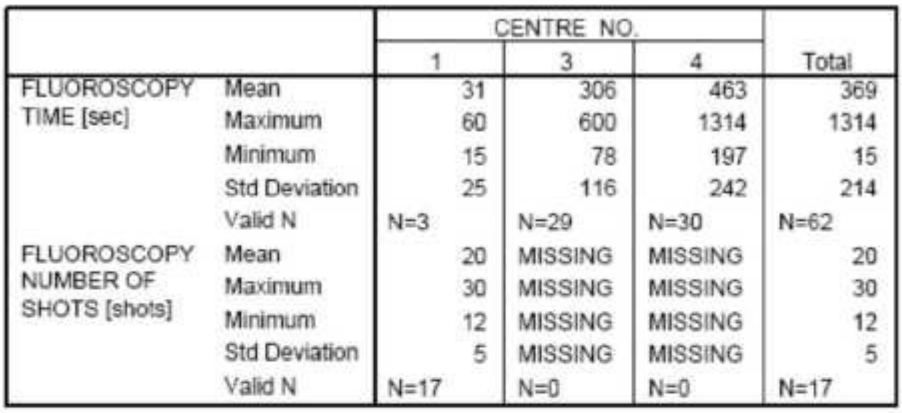


Fig. 12: Classification of Tibia fractures

5.2 Perioperative

The mean intraoperative fluoroscopy time was 369 seconds with a range of 15 to 1314 seconds.

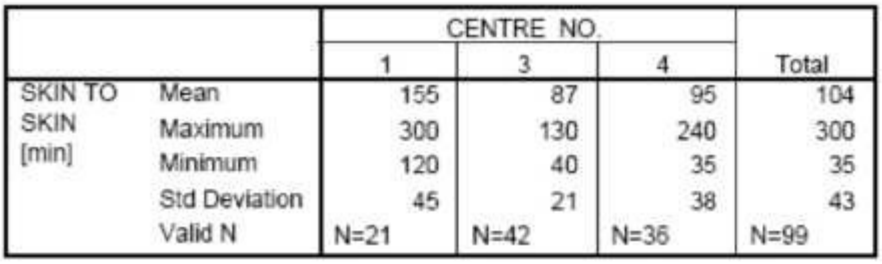
Table 3: Fluoroscopy time



		CENTRE NO.			Total
		1	3	4	
FLUOROSCOPY TIME [sec]	Mean	31	306	463	369
	Maximum	60	600	1314	1314
	Minimum	15	78	197	15
	Std Deviation	25	116	242	214
	Valid N	N=3	N=29	N=30	N=62
FLUOROSCOPY NUMBER OF SHOTS [shots]	Mean	20	MISSING	MISSING	20
	Maximum	30	MISSING	MISSING	30
	Minimum	12	MISSING	MISSING	12
	Std Deviation	5	MISSING	MISSING	5
	Valid N	N=17	N=0	N=0	N=17

Mean operative time (skin to skin) was 104 minutes and a range from 35 up to 300 minutes (Table 4).

Table 4: **Operative time**



		CENTRE NO.			Total
		1	3	4	
SKIN TO SKIN [min]	Mean	155	87	95	104
	Maximum	300	130	240	300
	Minimum	120	40	35	35
	Std Deviation	45	21	38	43
	Valid N	N=21	N=42	N=36	N=99

Analysing the relation between the operation time and the trauma mechanism, it can be shown that there is a significant difference between the low and high energy cases in operation time by performing the non-parametric Mann-Whitney-U-test. The cases with high energy trauma had a significantly longer surgery as compared to the group with low energy trauma ($p = 0.007$).

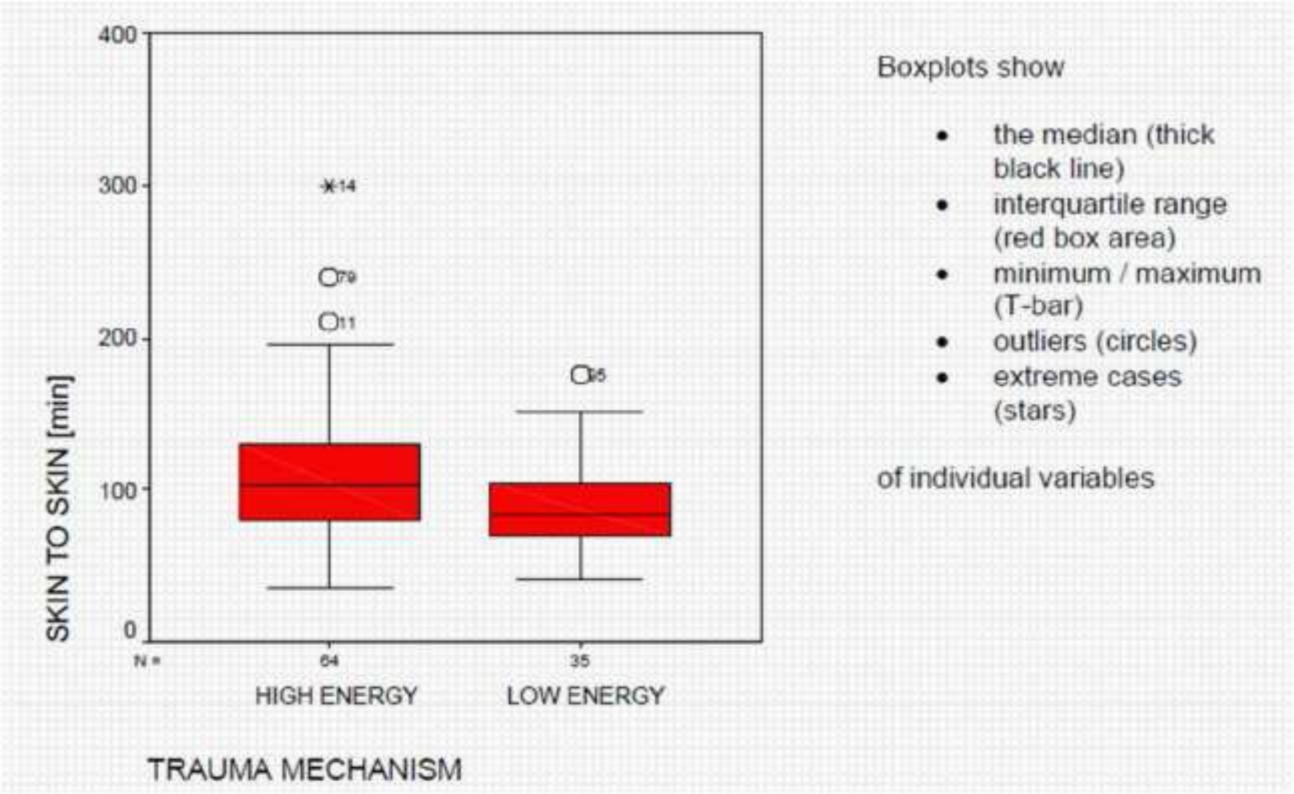


Fig. 13: Relation between trauma mechanism and operative time

The fracture was reduced in 48 % of cases without traction and 18 % of the cases with traction. In 34 % of the cases this information was unknown. Open reduction was performed in 12 % as compared to closed reduction in 88 % of the cases. There were 69 % of the patients who were operated on a standard operation table as compared to 31 % who were operated on an orthopaedic table. Mean blood loss was 184 cc with a range from 10 cc up to 600 cc. Performing the non-parametric Mann-Whitney-U-test (significance level = 95 %), there is no clear significant difference in blood loss between the groups with high and low energy trauma (p = 0.069) (Fig. 14).

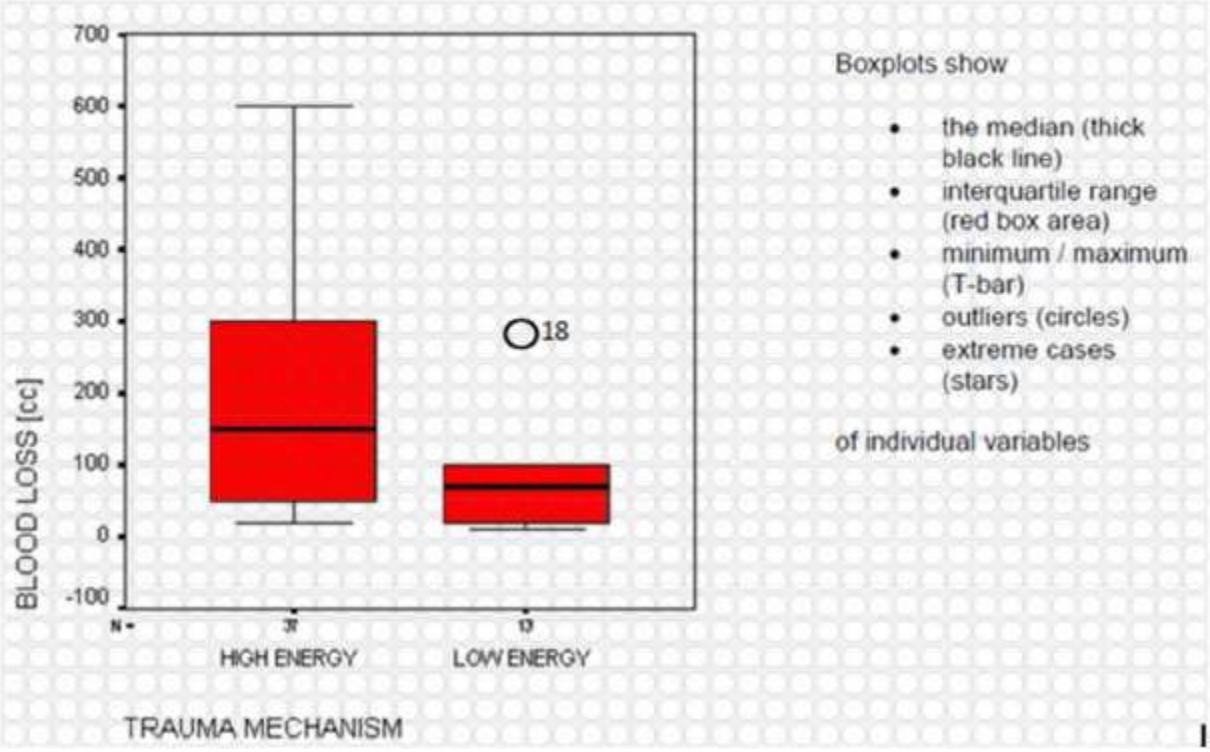
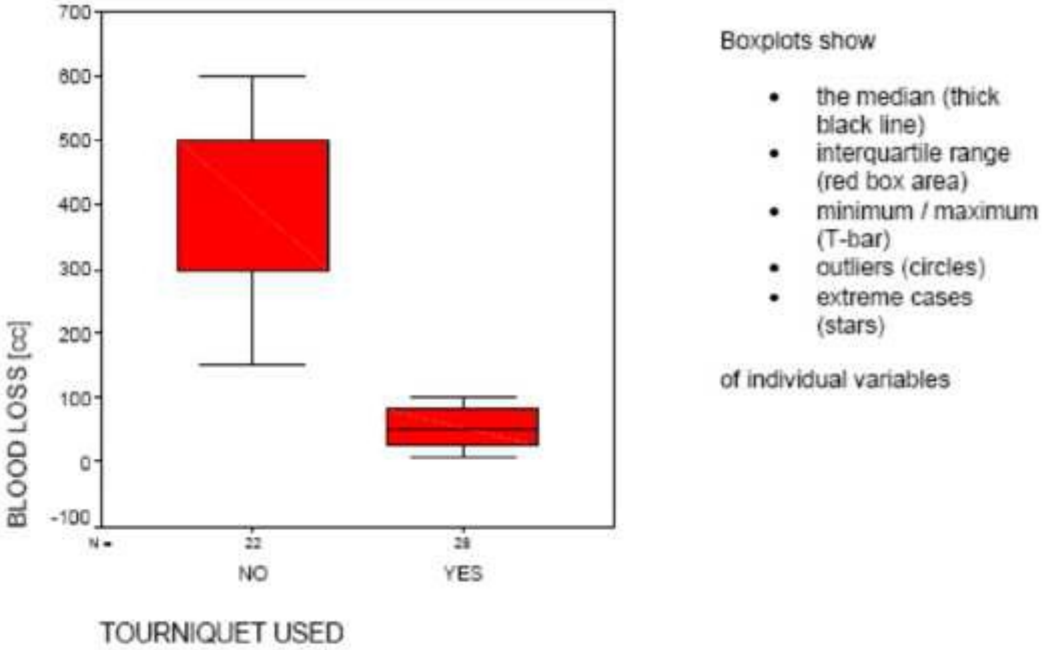


Fig. 14: Blood loss between high-low energy trauma

A tourniquet was used during surgery in 45 % compared to being not used in 55 % of the cases. Analysing the relation between the blood loss and the use or not use of a tourniquet, it can be shown that there is a significant difference between the groups in blood loss by performing the non parametric Mann-Whitney-U-test. The cases where a tourniquet was used had significantly less blood loss compared to the group where the tourniquet was not used (p< 0.001) (Fig.15).



Boxplots show

- the median (thick black line)
- interquartile range (red box area)
- minimum / maximum (T-bar)
- outliers (circles)
- extreme cases (stars)

of individual variables

Fig. 15: Blood loss and whether tourniquet was used or not

The following POSITIVE comments were collected about subjective appreciation/ handling and instrument reliability of the T2 Tibial Nailing system (n = 58 patients):

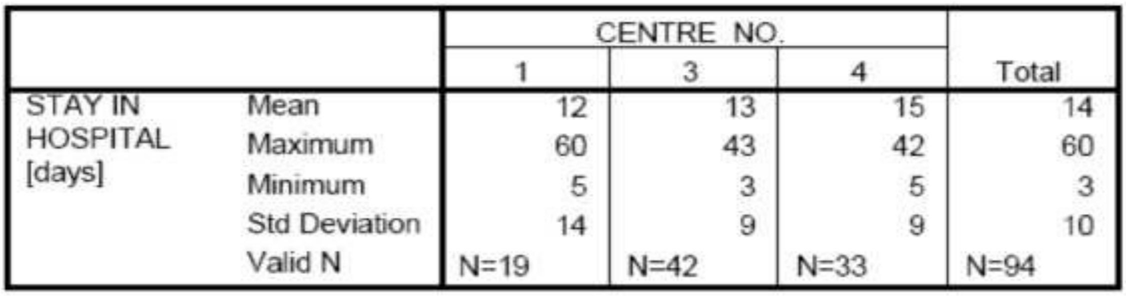
• Good handling/reliable instruments/no problems	n = 54

The following NEGATIVE comments were collected about subjective appreciation/ handling and instrument reliability of the T2 tibial nailing system (n = 58 patients):

• Nail length measurement problems	n = 2
• Difficulties with screw length measurements	n = 3
• Difficulties with locking screw placement	n = 2

Among the 100 cases (2 patients were lost of follow-up) only 5 % (n = 5) reported a deviation of the operated leg. No deviation was measured in 64 %. This information was unknown for 31 % of the cases. In two out of the five cases an axial deviation was detected. For the remaining three cases the deviation was a rotational failure. The axial and rotational failures were re-operated. There were 66 % (n = 100) patients who showed no difference in leg length after surgery. In 2 % (n = 100) the operated leg was shorter compared to the contralateral side and in 32 % (n = 100) this information was unknown. Full weight bearing was possible in 48 % (n = 100) of the patients during the first days after surgery, 18 % (n = 100) were able to do partial weight bearing and 30 % (n = 100) could not do weight bearing within the first days for several reasons (polytrauma, general status). In four percent (n = 100) of the patients this information was unknown. The overall mean stay of the patients in hospital was 14 days (± 10 days) and a range from 3 days up to 60 days (Table 5).

Table 5: Stay in hospital



		CENTRE NO.			Total
		1	3	4	
STAY IN HOSPITAL [days]	Mean	12	13	15	14
	Maximum	60	43	42	60
	Minimum	5	3	5	3
	Std Deviation	14	9	9	10
	Valid N	N=19	N=42	N=33	N=94

In performing the non-parametric Mann-Whitney-U-test (significance level = 95 %), there is no clear significant difference in hospital stay between the group's high and low energy trauma. For details, see Fig.16.

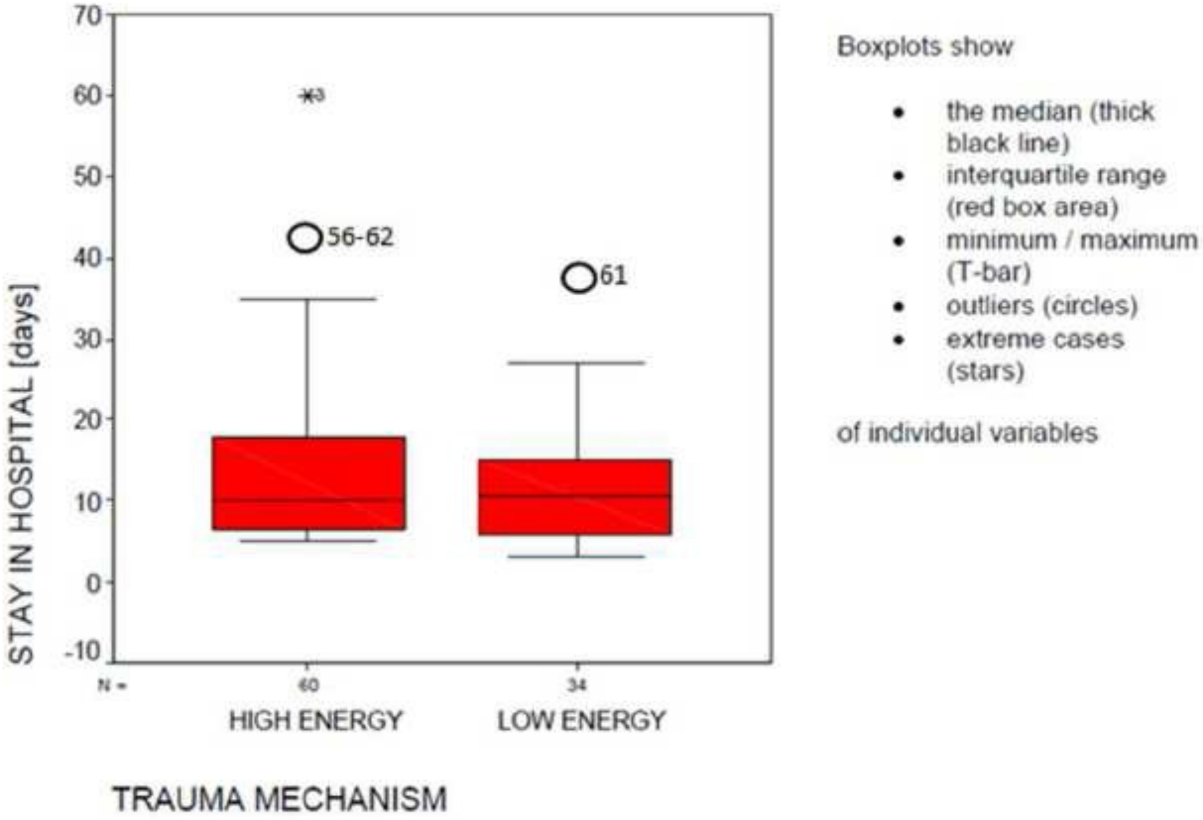


Fig. 16: Stay in hospital (days) by trauma mechanism

(44 %) (n = 94) of the patients' discharge location was back to their homes, 21 % (n = 94) were discharged to another hospital, 9% (n = 94) went to a rehabilitation unit, and 7 % (n = 94) to a health institution. In 19 % (n = 94) of the patients this information was unknown. Taking a closer look at the six cases that developed an early compartment syndrome postoperatively, it can be shown that all six cases were not treated with a tourniquet intraoperatively (p = 0.024).

5.3 Postoperative assessments: 4-6 weeks, 4 months, 12 months

Details about patient participation in follow-up are shown in Table 6. For interpretation of percentage rates, please keep in mind that there are not the same total numbers in the different assessments.

Table 6: Patients population at each follow up period

Center	4-6 WEEKS	4 MONTHS	12 MONTHS
01	21	21	21
03	38	23	19
04	3	9	31
TOTAL	62	53	71

The mean time between day of surgery and the 4-6 weeks post-operative assessment was 53 days (± 25 days). The mean time between day of surgery and the 4 months postoperative assessment was 122 days (± 32days). The mean time between day of surgery and the 12 months postoperative assessment was 427 days (± 141 days).

At 4-6 weeks assessment, signs of bone healing were present in 85.5 % (n = 53/62) of the cases and not present in 14.5 % (n = 9/62). At 4 months, bone healing was present in 86.8 % (n = 46/53) of the cases and not present in 9.4 % (n = 5/53). This information was unknown for 3.8 % (n = 2) of the patients. After 12 months, bone healing was present in 91.5 % (n = 65/71). This information was unknown for 8.5 % (n = 6/71) of the patients. For details, see Fig. 17.

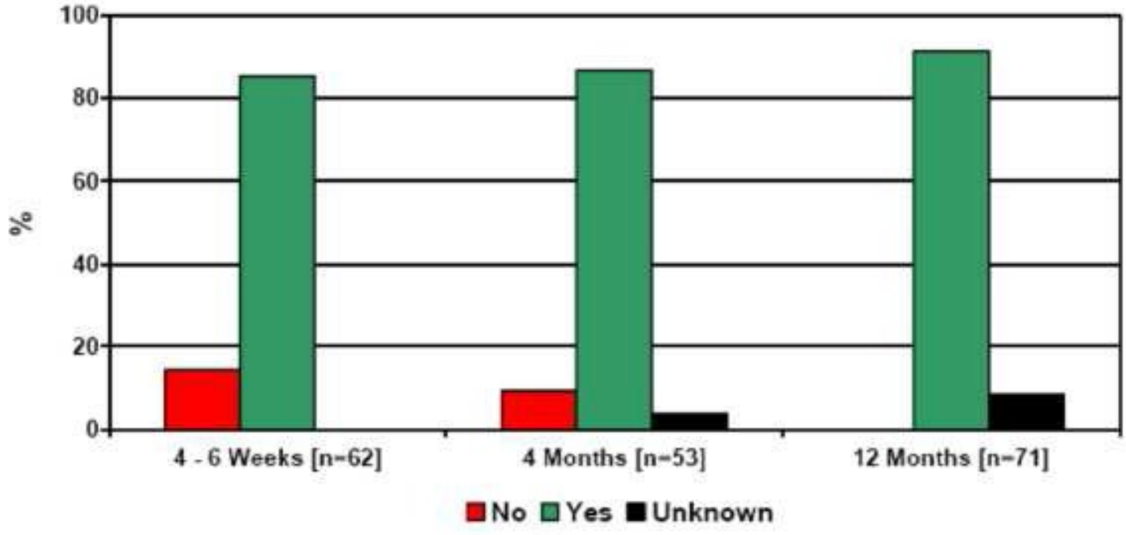


Fig. 17: Bone healing

After 4 months 45.3 % of the patients (n = 24/53) were able to return to work or previous activities. At 12 months this value increases to 76.1 % (n = 54/71). Fig. 18 shows the number of patients who were able to return to work or do their previous activities postoperatively.

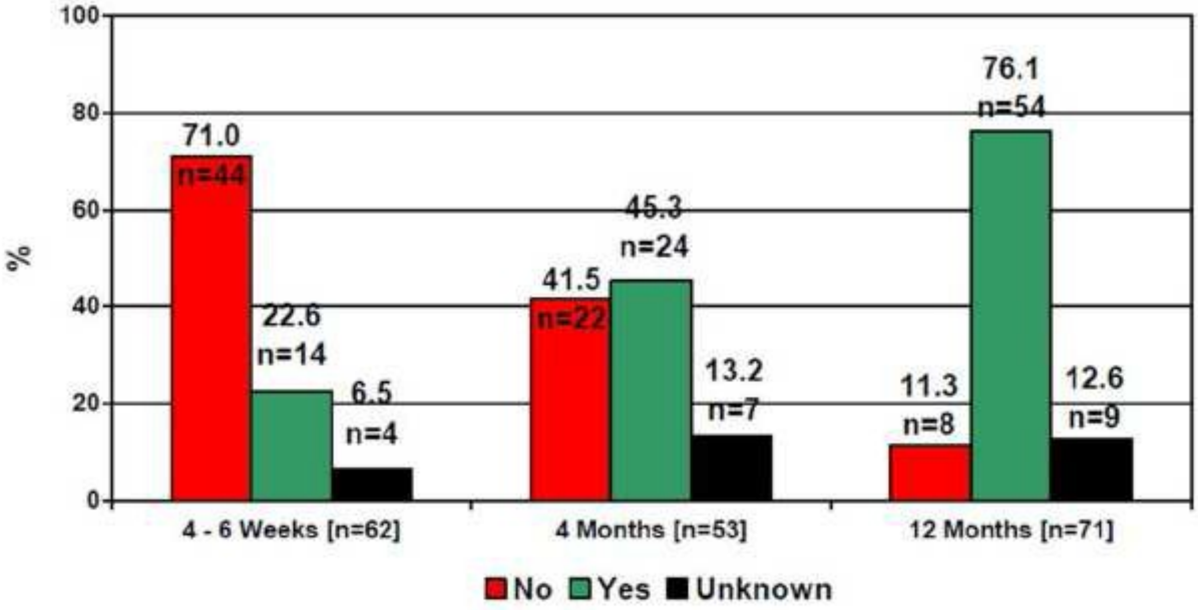


Fig. 18: Returning to work – previous activities

At 4-6 weeks, 22.6 % (n = 14/62) of the patient population were able to work with full previous capacity. 9.7 % (n = 6/62) were able to work up to 75 % of their previous capacity.

There were 17.7 % (n = 11/62) who were able to work up to 50 % of their previous capacity and 41.9 % (n = 26/62) of the patients were not able to reach more than 25 % of their previous working capacity (unknown: 8.1 %, n = 5/62).

At 4 months, 20.8 % (n = 11/53) of the patient population were able to work with full previous capacity postoperatively. There were 47.2 % (n = 25/53) who were able to work up to 75 % of their previous capacity, 11.3 % (n = 6)/53 were able to work up to 50 % of their previous capacity and 11.3 % (n = 6/53) of the patients were not able to reach more than 25 % of their previous working capacity (unknown: 15.1 %, n = 8/53) (Fig.19).

At 12 months, 74.7 % (n = 53/71) of the patient population were able to work with full previous capacity postoperatively. There were 4.2 % (n = 3/71) who were able to work up to 75 % of their previous capacity, 4.2 % (n = 3/71) were able to work up to 50 % of their previous capacity and 4.2 % (n = 3/71) were not able to reach more than 25 % of their previous working capacity (unknown 12.7 %, n = 9/71). Fig. 19 below illustrates the working capacity of the patients.

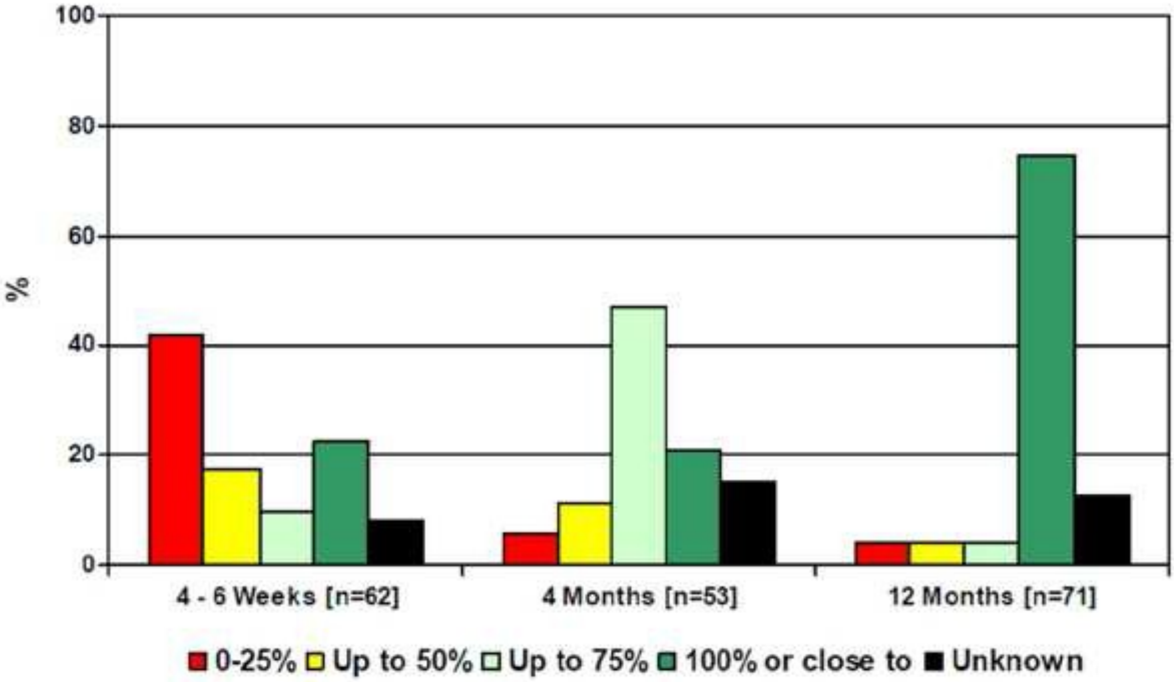


Fig. 19: Working capacity

For 51.6 % (n = 32/62) of the cases, it was not difficult to put on socks and shoes 4-6 weeks postoperatively. At 4 months assessment, this value increases to 67.9 % (n = 36/53). Finally at 12 months assessment, 83.1 % (n = 59/71) were able to put on socks and shoes without any difficulty (Fig. 20).

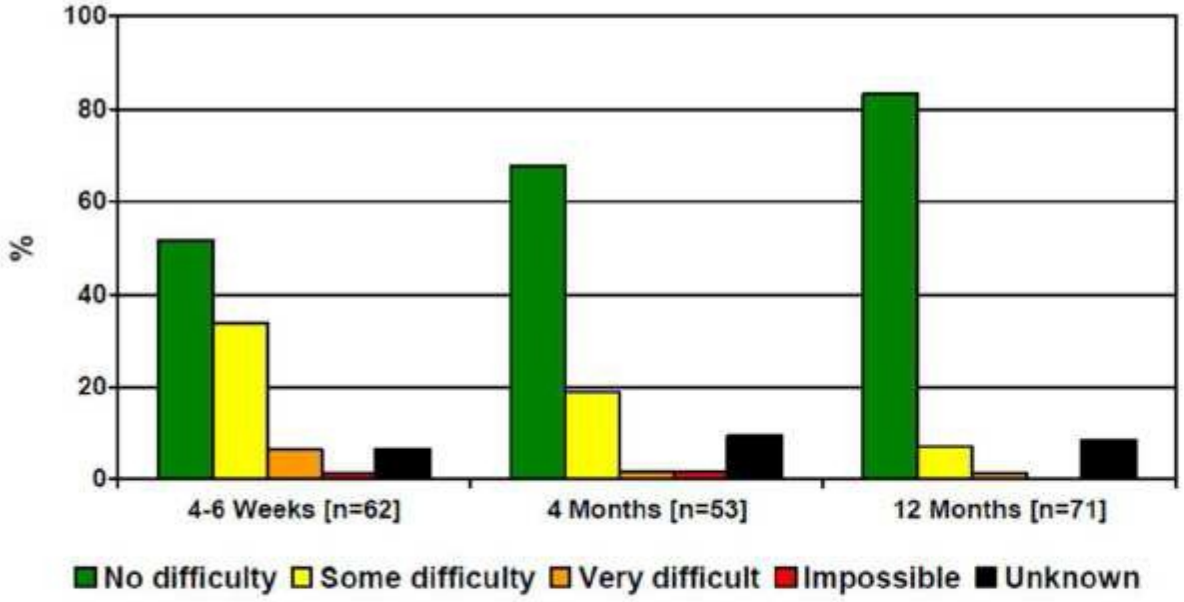


Fig. 20: Putting on socks and shoes

There were 43.5 % (n = 27/62) of the cases who could rise from a chair without upper extremity support 4-6 weeks postoperatively. At 4 months assessment, this value increased to 64.2 % (n = 34/53) and at 12 months assessment 83.1 % (n = 59/71) of the patient were able to rise from a chair without upper extremity support (Fig. 21).

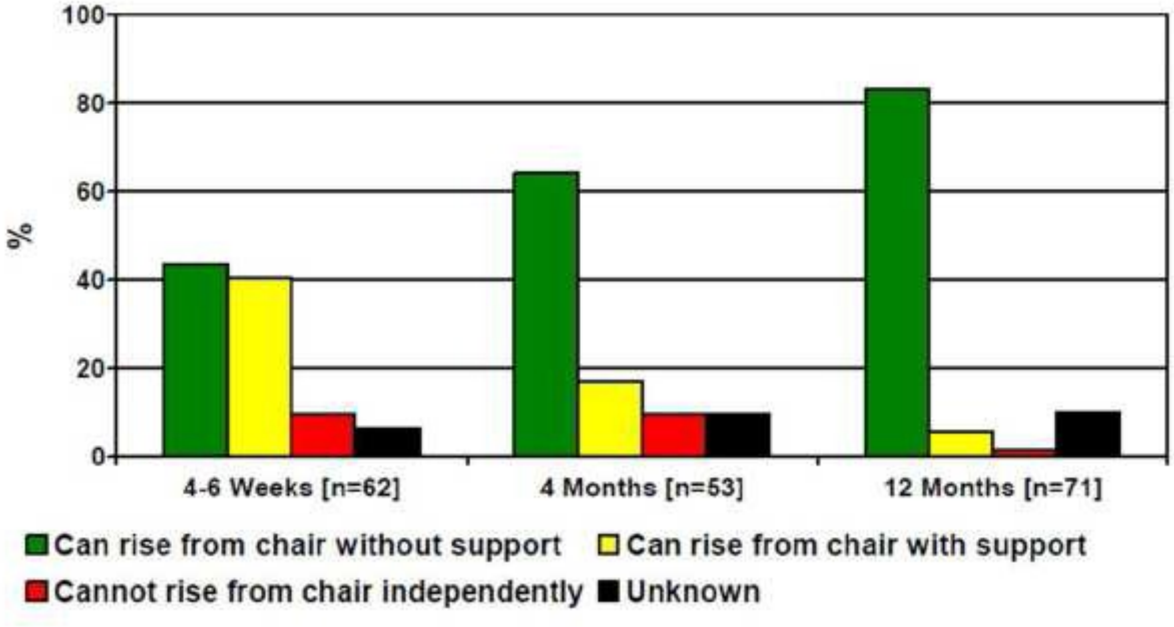


Fig. 21: Sitting and standing

After 4-6 weeks 35.5 % (n = 22/62) of the patients were able to walk stairs up and down normally without help. After 4 months the value increased up to 67.9 % (n = 36/53) and up to 81.7 % (n = 58/71) at 12 months (Fig. 22).

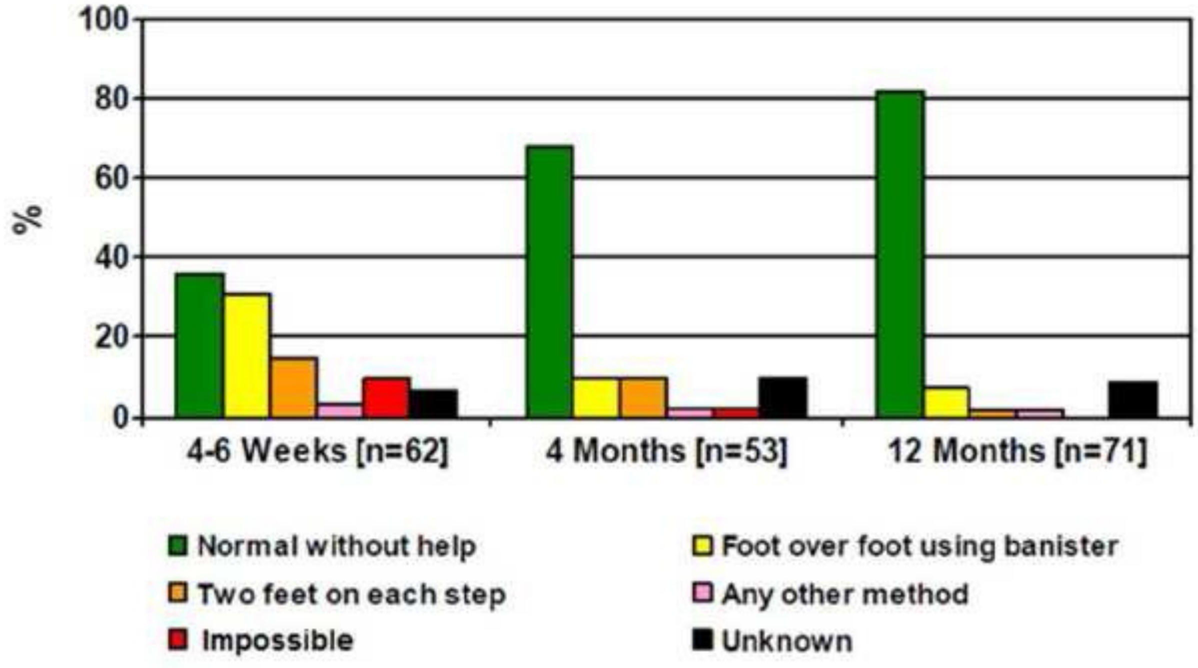


Fig. 22: Walking up and down stairs

After 4-6 weeks postoperatively, 37.1 % (23/62) of the patients did not need any external support after 4 months 69.8 % (37/53) did not need any external support and after 12 months this result was given for 52. 1 % (37/71). Unfortunately this information was unknown for 47.9 % (34/71) of the cases at the 12 months assessment (Fig. 23).

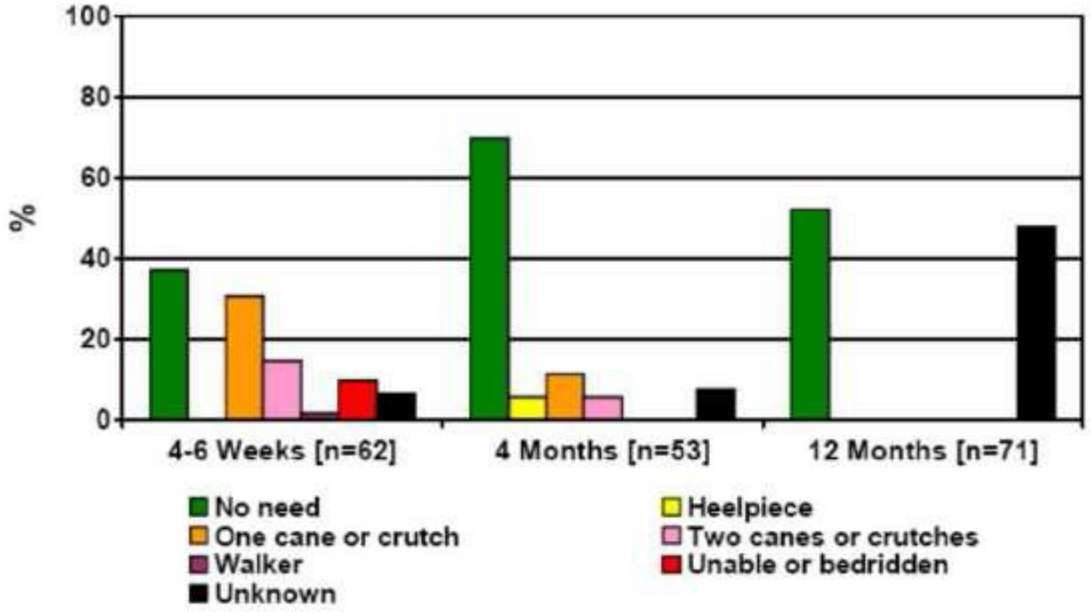


Fig. 23: Walking capacity and external support

Total weight bearing was possible for 30.6 % (n = 19/62) of the cases at the 4-6 weeks post operation assessment. After 4 months the value increased to 77.4 % (n = 41/53). After 12 months 53.5 % (n = 38/71) could perform total weight bearing (unknown 46.5 %, n = 33/71) (Fig. 24).

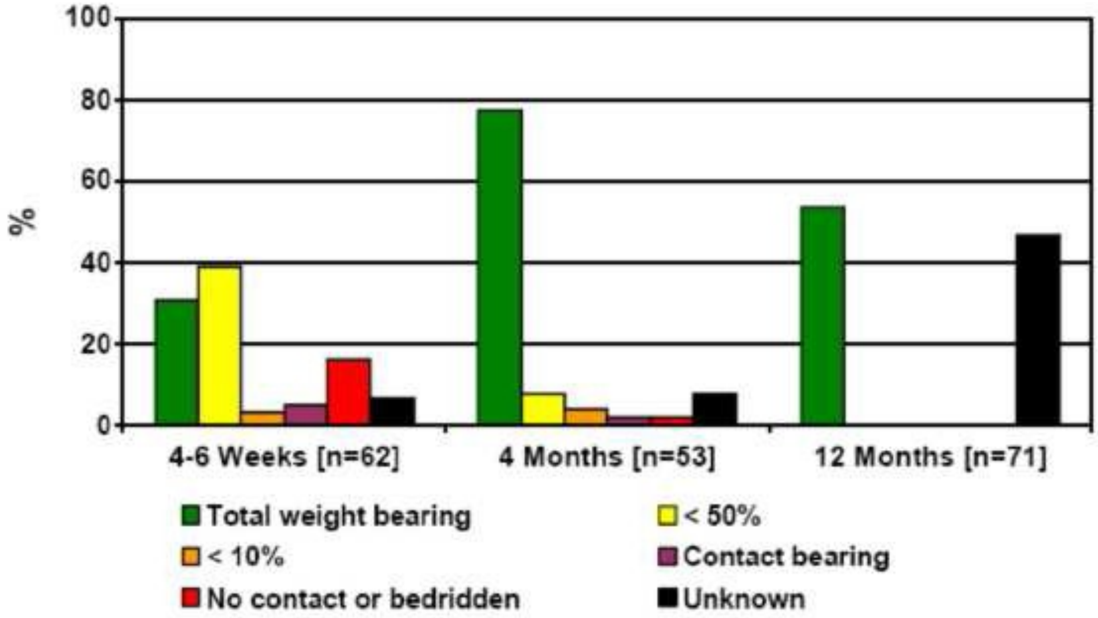


Fig. 24: Weight bearing

Overall pain was rated using a Visual Analogue Scale (0-10 points in which 0 points suggest no pain, and 10 points the worst possible pain a patient can imagine).

Fig. 25: Visual Analogue Scale

Post-operatively at 4-6 weeks the main score (valid n = 24) was 3.1 points (+/ 1.2 points) with a range from 0.4 to 5.5 points. After 4 months, the mean pain score (valid n = 24) was 2.8 points (+/ 2.2 points) with a range from 0.5 to 9.0 points. Moreover, after 12 months the mean pain score (valid n = 28) was 2.3 points (+/ 1.7 points) with a range from 0.5 to 8.0 points.

The following details were given for cases with more than 6.0 points of pain level:

After 4 months pain level above 9 was in 2 cases. One patient had swelling in the knee joint and deep infection. The other had delayed healing and distal migration of the nail.

After 12 months, one patient had a pain level of 8. This specific case had a pseudoarthrosis and needed several re-operations.

Anterior knee pain

At the 4-6 weeks follow-up anterior knee pain was found in 11 patients, at 4 months in 14 patients, and at 12 months in 13 patients. None of the patients included in this study had any chronic knee pain. There was a gradual increase in total weight bearing capacity of the patients. The daily activity (walking up and down stairs, putting on shoes and socks, sitting in a chair or standing from it, walking distance, using one or two crutches) showed improvement. There was no difference in age between the two groups (anterior knee pain mean age 43 years, no knee pain mean age 41 years).

At 4-6 weeks, 62 patients were available for assessment. Eleven patients (18 %) had anterior knee pain (4 paratendinous/7 transtendinous). Patients with a transtendinous incision had more pain compared to those with paratendinous incision. At the follow-up after 4 months, 53 patients were assessed and 14 (26 %) of them had anterior knee pain. The cases were the nail was introduced through the mid-patellar incision (n = 10) had more pain than those with the para-patellar incision (n = 4). At the 12 months follow-up 13 patients (n = 71) had anterior knee pain. It was interesting to notice that patients with a para patellar- incision (n = 7) had more pain compared to those with the mid patellar incision (n = 6). However, the number of patients was too small to make a statistical calculation.

The VAS decreased from a mean of 3.1 at 4-6 weeks to a mean of 2.3 at 12 months follow-up. Despite the fact that there was anterior knee pain, all the patients (n = 13) were able to perform weight bearing and bony healing was inconspicuous in all the patients (n = 13) after 12 months. At 4-6 weeks, 2 patients with anterior knee pain were able to work with full previous capacity and this was increased to 9 patients after 12 months. Two patients (n = 13) were working for 25 % after 12 months. The reason for this was that they were poly-traumatised patients. After 4-6 weeks postoperatively, only one patient could walk up and down the stairs without any help. This was increased to 7 patients after 4 months and to 8 patients after 12 months. Total weight bearing was improved and was possible in 9 patients after 4 months and in 6 patients after 12 months.

Unfortunately at the two months follow-up 7 patients went lost to the study. Putting on shoes and socks without any difficulty was possible in 9 patients (n = 13) after 12 months. There were no missing patients after 12 months. Further daily activities like sitting and standing from a chair without arm support gradually improved and was possible in 8 patients (n = 13) after 12 months. There was only 1 patient missing after 12 months. The time taken until patients could walk without any support was also examined. It showed improvement, but this information was missing for 8 patients after 12 months (n = 13). The use of external support while walking was decreased after 12 months. Again there was information missing in 8 cases.

5.4 Postoperative complications

After 4-6 weeks out of 62 patients 1 patient had a hematoma, 3 had nerve problems, 1 a deep and 3 a superficial infection. Out of 53 patients 2 cases had neurodystrophy (CRPS Type 1) at 4 months assessment, 6 patients had mechanical or implant associated complications (broken screws, risk of proximal screw perforating the skin). After 1 year out of 71 patients 9 patients had mechanical problems, 4 patients a nerve lesion, 3 were reported with superficial infections, 4 with neurodystrophy and 1 with heterotopic bone at the fracture site.

5.5 Dynamisation of the nail

Dynamisation of the nail was performed in 4/62 patients after 4-6 weeks, in 5/53 patients after 4 months and in 5/71 patients after 1 year.

Reasons for dynamisation were delayed healing or screw problems(broken/migration of screws).

5.6 Revision surgery

Revision surgery (malrotation, malpositioning proximal nail migration) was performed in 7/102 patients. Postoperative time between primary surgery and revision had a mean of 134 days (2-362 days).

5.7 Material removal

In 47/102 patients the nail was removed. The mean time between surgery and removal was 422 days (93-1126 days). Reasons for nail removal were a healed fracture, anterior knee pain or broken screws.

6 Discussion

The present study had been planned as a prospective international multicenter trial with a 1-year follow-up. We included 102 patients with all types of tibia fractures who underwent a reamed intermedullary nailing. The re-examinations were frequented by 62 patients after 4-6 weeks, by 53 patients after 4 months and by 71 patients after 12 months. The reason for this variable attendance may be that probably some polytraumatised patients were referred to their local hospital after the first treatment in the trauma centers and did not return for follow-up for medical, practical, or personal reasons. The patients who had no complaints did possibly not feel the need to visit the outpatient clinic, which may have resulted in an overestimation of less-than-ideal results in the present study.

Another limitiation of this study were the differing medical conditions. On the one hand, the operations were performed by surgeons with different experience, working ethics and institutional financial frameworks that could possibly have led to deviating treatment modalities irrespective of the same intramedullary nailing method. On the other hand, the study population was heterogeneous with proximal, shaft and distal fractures of different severity in polytraumatised or monotraumatised patients. Because of the broad range of fracture types, the number of cases in each fracture subtype became too small for a comparative statistical analysis which could have thrown light on some pros and cons for the suitability of the T2 nail for different fracture types.

We suggest that the ideal study ought to be a randomised prospective clinical study. The patients should have only one type of tibial fracture. The T2 nail should be compared with another nail and both should be reamed. Despite these shortcomings, our study population allows an overview over the suitablity of the tested nail system in the daily tasks of a trauma center.The population consisted of 63.7 % male and 36.3 % female patients with a mean age of 42 ± 16 years. Other studies confirm that tibia fractures occur more often in male than in female patients (Weiss et al., 2008; Larsen et al., 2015).

The present study shows that most fractures occurred in traffic accidents (31.4 %) and in accidents on the road as pedestrian (22.5 %) or in the domestic setting (22.5 %). More rarely the accident occurred during sports (13.7 %) or at work (5.9%). High energy traumata predominated low energy traumata (63.7 % vs. 36.3 %). We found some correlations between trauma, age and gender: In younger patients, especially in men, tibia fractures often take place in the context of a high energy trauma caused by traffic accidents while in older patients low energy traumata at home are more frequent. These findings are supported by other studies (Court-Brown and Caesar, 2006; Weiss et al., 2008; Madadi et al., 2010; Larsen et al., 2015). In contrast to our study, Court-Brown and Caesar (2006) moreover reported a high incidence of sport accidents that may be due to regional differences or deviations of age distribution.

In our study, diaphyseal wedge fractures of all severities (AO 42-B, n = 46, 45.1 %) were most common, followed by simple (AO 42-A, n = 25, 24.5 %) and complex diaphyseal fractures (AO 42-C, n = 18, 17.6 %). Only very few studies have reported the AO distribution of tibia fractures, and these are in contrast to our results. Court-Brown and Caesar (2006) reported a predominance of type A42-A3, while in the study of Larsen et al. (2015) fractures of type A42-A1 were most common. These differences are assumedly caused by patient selection: The population of the present study was recruited in large trauma centers while both cited studies were population-based and therefore more reliable represent the real life distribution of fracture types.

The treatment in trauma centers may also be the cause for the observed low frequency of patients with a single tibia fracture (35.2 %) while in the rest of patients the fibula was fractured, too, (50.0 %) or the patients had been polytraumatized (14.7 %), because multiple fractures often occur in a population with a high frequency of high energy traumata (Larsen et al., 2015).

Unsurprisingly, the surgical efforts were correlated with the fracture severity. High energy trauma causing complex fractures resulted in a significantly longer operation time as compared to low energy fractures (p = 0.007). Indirect hints on this relation are also given by high variances of blood loss (184 ± 174 cc) and duration of hospital stay (14 ± 10 days) which ranged from 3 to 60 days. The high variances are due to the wide spectrum of fracture types in our study. Therefore, a comparison with published data is aggravated, and even more so with regard to the complexity of fractures, the classification of fracture types, the number and age of patients, the observation period, the treatment modalities, the endpoints, and other parameters.

Full weight bearing was allowed and possible in 48/100 of our patients during the first days after surgery, while in 18/100 patients a partial and in 30/100 patients no weight bearing was allowed or possible within the first days for several reasons (polytrauma, general status). Especially in static nailing a delay in full weight bearing is recommended until the first signs of bone union are visible (Drosos et al., 2006).

In our patients, bone healing was radiologically confirmed in 85.5 % (53/62) of patients after 4-6 weeks, in 86.8 % (46/53) after 4 months and in 91.5 % (65/71) after 12 months.

Rates of union of more than 90 % after intramedullary nailing of tibial fractures have been reported in other studies, too (Klemm and Borner, 1986; Alho et al., 1990; Court-Brown et al., 1991). In our study the intramedullary canal was reamed in all cases. This has two advantages: Firstly, the debris formed by reaming is deposited at the fractures site and acts as an autologous bone graft (Reynders and Broos, 2000). Secondly, a better cortical contact between nail and bone results, allowing for a larger nail to be inserted and hence improving stability (Chapman, 1998). Thirdly, adding a compression screw further enhanced the stability of the nail. All of these factors helped to achieve the good bone healing in our patients.

In addition to radiological bone healing, the regaining of our patients' daily activities was documented as a reference for fracture healing. Unfortunately, for some parameters the 12-month-data were missing. E.g. we analysed that total (i.e. monopodial) weight bearing was possible in 77.5 % and walking stairs without external support (e.g. cane, crutch, walker, heelpiece) in 69.8 % after 4 months.

As expected, there was a gradual increase over time in the number of patients who went back to work. The percentage of patients who returned to work or to their previous activities increased continuously from 22.6 % (14/62, 4-6 weeks) to 45.3 % (24/53; 4 months) and to 76.1 % (54/71; 12 months), respectively. There were 3 patients whose final working capacity did not exceed 25 %: the first patient with polytrauma (upper extremities, open fractures, nerve problems), the second patient preoperatively underwent extensive sport training in judo and the third patient had been invalid at baseline and needed several reoperations. A total of 11 % of patients were not able to work after one year. It is well known that tibial fractures are severe injuries and may result in permanent disability with significant socio-economic implications (Bode et al., 2012). Taking the complexity of fractures in many of our patients into account, the achieved results are yet very satisfying. In the population of Court-Brown et al. (1990) the mean time to resumption of full activities except sports in those patients who did not have multiple injuries was 14.3 (5-30) weeks and 78% returned to full activities.

The results of Alho et al. (1990) were better: They reported their experience with locked intramedullary reamed nailing for 93 displaced tibial shaft fractures. After 12 months 90 % of their patients returned to work, 100 % had full weight-bearing, and all fractures showed a radiographic consolidation. The reason for the discrepancy to our results may be the greater number of comminuted fractures and our additional inclusion of proximal and distal tibia fractures.

Interestingly, in the long term the functional results seem to be independent of the decision for a reamed or unreamed nail, respectively. Alho et al. (1990) found no significant difference in time of return to work with an average of 10.9 weeks for the reamed group and 9.3 weeks for the unreamed group, and in another study by Keating et al. (1997), the functional outcome, in terms of knee pains, return to work and recreational activity, did not differ significantly between reamed and unreamed nailing.

Naturally, the functional outcome is influenced by postoperative pain. Anterior knee pain has been identified as the most common and most significant complication of intramedullary tibia nailing. The incidence of knee pain is identical in patients with a reamed or unreamed intramedullary nailing (Court-Brown et al., 1996).

It is the most common reason for nail removal. However the outcome of nail removal is unpredictable. Court-Brown et al. (1990) presented the results of their prospective study about the use of the Grosse-Kempf tibial nail in the treatment of 125 closed and type 1 open (Gustilo and Andersen 1976) tibial fractures. Knee pain was present in 51 (40.8%) patients, and in 33 of them the nail had to be removed. The knee pain usually occured after a few weeks and was associated with kneeling. It was usually abolished by removing the nail although in some cases the relief took several months to occur.

Postoperatively at 4-6 weeks, the main score was 3.1 ± 1.2 points (n = 24) with a range from 0.4 to 5.5 points. After 4 months, the mean pain score decreased to 2.8 ± 2.2 points (n = 24) with a range from 0.5 to 9.0 points. At that time a pain level above 9 was seen in 2 cases due to complications: One patient had a swollen knee and deep infection. The other patient showed delayed healing and distal migration of the nail.

Moreover, after 12 months the mean pain score was 2.3 ± 1.7 points (n = 28) with a range from 0.5 to 8.0 points. There was one patient with a pain level of 8 points as a symptom of complications: He suffered from pseudarthrosis and needed several re-operations.

In patients who underwent an intramedullary nailing postoperative pain, especially anterior knee pain, is associated with the surgical approach. Karladani et al. (2000) performed a prospective randomised study at 53 patients with unilateral, displaced and closed or grade 1 open (Gustilo and Anderson 1976) tibial shaft fractures which were randomised to treatment with an intramedullary nail or a plaster cast. In this study, 12 of 27 patients with an intramedullary nail, but no patient with a plaster cast, suffered from anterior knee pain ($p< 0.001$). Because the nails had been inserted paratendinously, the authors suspected that the dissection in the patellar region, a trauma of the patellar tendon during nail insertion, and iatrogenic damage of the infrapatellar nerve might have caused anterior knee pain. Hernigou and Cohen (2000) studied the relationship between the intra-articular structures of the knee and the entry point used for nailing in 54 tibiae from cadaver specimens. The results showed that in some bones the safe zone is smaller than the size of standard reamers and the proximal part of some nails. The structures at risk are the anterior horns of the medial and lateral menisci, the anterior part of the medial and lateral plateau and the ligamentum transversum. They concluded that unrecognized intraarticular injury of the knee may be one of the reasons for anterior knee pain.

In the present study, 11/61 patients (18.0 %) had anterior knee pain at 4-6 weeks. Four patients had been operated with a paratendinous and 7 with a transtendinous approach, and the patients with a transtendinous incision reported more pain compared to those with paratendinous incision. After 4 months 14/53 patients (26.4 %) suffered from anterior knee pain (paratendinous n = 10; transtendinous n = 4), and after 12 months 13/71 patients (18.3 %) (paratendinous n = 6; transtendinous n = 7). Our database is too small to generalize the results but the transtendinous approach seems to cause more frequent pain than the paratendinous approach. Despite the fact that there was anterior knee pain, all patients concerned were able to perform weight bearing, and bony healing was inconspicuous in all of them after 12 months.

Orfaly et al. (1995) reviewed their experience with intramedullary nailing to determine whether the nail entry point has an influence on the development of knee pain. They operated on 110 fractures in 107 patients with reamed Gross-Kempf nails, and the site of nail insertion had been recorded for 101 fractures. The nail insertion had been conducted by paratendinous incision in 65 fractures, and 33 of these cases (51 %) were associated with subsequent knee pain. When nail insertion was conducted by tendon-splitting 28 of 36 fractures (78%) developed subsequent knee pain ($p < 0.01$). Therefore the authors recommended the paratendinous approach to reduce anterior knee pain.

Toivanen et al. (2002) performed a prospective randomised study comparing two different nail insertion techniques. Fifty patients with tibial shaft fracture requiring intramedullary nailing were randomised equally to treatment with paratendinous or transtendinous nailing.

Compared with a transpatellar tendon approach, a paratendinous approach for nail insertion did not reduce the prevalence of chronic anterior knee pain. There was no significant difference between the two groups. The authors' conclusion was that it is not possible to reduce anterior knee pain by using a paratendinous approach.

Devitt et al. (1998) measured the patellofemoral joint forces and pressures during intramedullary nailing of the tibia in 8 cadaveric knees. They noticed that the contact pressure in the patello-femoral articulation increased after nailing regardless of the approach that had been used. This may result in chondral injury, which in turn may cause anterior knee pain.

Karladani and Styf (2001) described an approach in which the skin incision is located on either side of the patella and the insertion of the nail is performed percutaneously and used it in 13 patients with tibia fractures. After a follow-up of 22 months, all patients could kneel and there was no sign of dysfunction of the infrapatellar branch of the saphenous nerve.

It is obvious that the source of chronic anterior knee pain after intramedullary nailing of tibial fracture is multifactorial. A prospective randomised controlled trial is required to confirm the benefit of the percutaneous technique, but this new approach may have advantages including no dissection around the patellar tendon, a skin incision in an area that is not involved in kneeling and less risk of damage to the infrapatellar nerve.

However, reaming also damages the blood supply to the inner two thirds of the cortex (Klein et al., 1990) which may result in impaired fracture healing and increased infection rates despite the fact that published literature does not reflect these clinical worries (Anglen and Blue, 1995; Mayr et al., 1995; Ruchholtz et al., 1995; Court-Brown et al., 1996; Blachut et al., 1997; Keating et al., 1997; Finkemeier et al., 2000). Further dreaded complications of the reaming procedure are compartment syndrome and the production of emboli by reaming and subsequent fat embolism or pulmonary embolism (Pell et al., 1993). Interestingly, while reaming damages the blood flow to the cortex, it simultaneously induces a six-fold increase of the periosteal blood flow (Reichert et al., 1995). Perhaps this factor accounts for the good clinical results of reamed nailing, but this currently remains speculation.

In our population there were no cases of postoperative embolism or compartment syndrome, but one patient (1/62 (1.6 %) with an open fracture suffered from a deep infection after 4-6 weeks which could be treated by conservative management. In reamed intramedullary nailing deep infection may be regarded as a relatively rare complication which is reported only in individual cases (Finkemeier et al., 2000) while many authors pointed out that there was no deep infection in their population after nailing tibia fractures of different types (Court-Brown et al., 1996; Blachut et al., 1997;

Larsen et al., 2004; Sadighi et al., 2011). Other infections occured during the first 4-6 weeks post operationem in three patients (n = 3/62; 4.8%); they were superficial and healed by antibiotic therapy. The percentage of superficial infections is consistent with published data that reach from 2.0 to 16.0 % for reamed nailed tibia fractures (Gregory and Sanders, 1995; Wiss and Stetson, 1995; Chiu et al., 1996a, b).

In the present study complications associated with the nails or screws were seen later in the course of time: After 4 months there were 4/53 (7.5 %) cases with mechanical or implant associated complications such as broken screws (n = 3/53; 5.7 %) or risk of proximal screw perforating the skin (n = 1/53; 1.9%). After 1 year, 9/71 (12.7 %) patients had mechanical problems: three cases (3/73; 4.1 %) each of screw breakage and screw loosening/migration or pain from screws, respectively. One patient with a migration of the proximal screw to the skin showed a pseudarthrosis. A dynamisation was conducted after 4 months, but in the course of time other (not documented) reoperations were necessary after transfer to another hospital due to his multitrauma and bad general condition.

The design of interlocking nails inevitably necessitates screw holes, and this bears the biomechanical potential for a high local concentration of stress (Bucholz et al., 1987). Thus, the screws bear the stress and act as a weak link in the interlocking nail-to-bone-complex when its strength is lower than the strength of the nail alone. There are reports of interlocking screw breakages occurring in up to 50 % of cases which where nailed without reaming and of nail failures in up to 10 % (Hutson et al., 1995; Whittle et al., 1995; Court-Brown et al., 1996). Especially unreamed nailing is prone to failures of the nails and distal locking screws because the nails do not fit tightly and more cyclical loading occurs.

The risk is growing with decreasing nail diameter as the smaller the nail the smaller (and weaker) must be the screws. In reamed nailing the risk is lower. For example Blachut et al. (1997), Court-Brown et al. (1996), and (Gonschorek et al., 1998) reported of 3/73 (4.1 %), 1/25 (4.0 %), and 13/402 (3.2 %) respectively, of their patients with broken screws, and Blachut et al. (1997) as well as Court-Brown et al. (1996) reported 4/73 (5.5 %) or 1/25 (4.0 %), respectively, with screw migration. These data are comparable to our results, where a total of 3 patients (3 %) had a distal broken screw that needed revision. All affected patients had received a nail with a small diameter, and they were fairly heavy, young and active as well as fully weight bearing within the first week, therefore the osteosynthesis had to bear an outstanding stress.

In other patients, no revision was necessary: In a total of 14/102 (13.7 %) patients a dynamisation of the nail had to be performed due to delayed healing and/or screw problems. The dynamisation was conducted in 4/62 patients (6.5 %) after 4-6 weeks, in 5/53 patients (9.4 %) after 4 months and in 5/71 patients (7.0 %) after 1 year. On the one hand, the rigidity of the osteosyntheses is important to keep the bone fragments in good collaboration, therefore creating the conditions for rapid recovery of medullary circulation, which in turn is an essential condition for the formation of endosteal callus.

Static intramedullary nailing unables movements between fragments which directly stimulates bone formation and formation of angiogenic minimal callus. On the other hand, the fracture phenomenon "dynamization” allows micro-movements at the point of fracture, assuming that axially moved fragments simultaneously reduce fracture gaps, and accelerate callus maturation and bone remodeling. This dynamization should take place early, when the fibrous callus provides stability (Omerovic et al., 2015). The transformation of static into dynamic intramedullary osteosynthesis by dynamization is recommended if the fractures heal inadequately (Wiss and Stetson, 1995; Brumback, 1996), but it is not a mandatory requirement for healing (Brumback et al., 1988). The possibility that dynamization may cause malunion in spiral, short oblique, or high-comminuted fractures has even led to a complete refusal of this method in favour of the static intermedullary nailing (Templeman et al., 1997). In the present study, all cases with dynamisation, except one, had no signs of pseudarthrosis or nonunion.

Revision surgery had been performed in 7/102 patients (6.9%). In 3 patients the revision was indicated because of a malrotation due to screw breakage, in 2 patients because of pain by the proximal screws, and in 2 patients because of screw loosening with the risk of skin perforation. This low rate of revisions underlines the finding that reamed intramedullary nailing leads to low nonunion rates and implant failure rates (Kessler et al., 1986; Bhandari et al., 2000; Forster et al., 2005; Bhandari et al., 2008).

In only 47/102 patients (46.1 %) the nail was known to be removed. The mean time between surgery and removal in these cases was 422 days (93-1126 days). Reasons for nail removal were a healed fracture (n = 34/47; 72.3 %), anterior knee pain despite healed fracture (n = 11/47; 23.4 %), broken/migrating screws (n = 2/47; 4.3 %) or patient request (n = 1/47; 2.1 %).

Unfortunately, no comparisons can be drawn to published data comparable to our results, where a total of 3 patients (3 %) had a distal broken screw that needed revision. All affected patients had received a nail with a small diameter, and they were fairly heavy, young and active as well as fully weight bearing within the first week, therefore the osteosynthesis had to bear an outstanding stress.

Altogether the results of our study show that the intramedullary nailing of tibia fractures by means of the T2 nail led to very satisfying results with excellent healing and low complication rates underlining the efficacy of reamed nailing in comparison to other methods of osteosynthesis, especially to non-reamed nailing. In a review of prospective studies about the management and treatment complications in a total of 895 tibial fractures, Coles and Gross (2000) found out that the reoperation rates of reamed nailing are comparable to plate fixation (5.7 % vs. 4.7 %) and much lower than in unreamed nailing (16.7 %). The incidence of malunion is highest in closed treatment with a plaster cast (31.7 %) but low in operative treatment with best results for plate osteosyntheses (0 %), followed by reamed nailing (3.2 %) and unreamed nailing (11.8%). These good results of plates are limited by a high infection rate (9.0 %) as compared to reamed (2.9%) and unreamed nailing (0.5 %) and plaster cast treatment (0 %). That means that all treatment methods are associated with complications, but that the results of reamed nailing are favorable. Up to now great randomized controlled studies are lacking to get deeper insight in the benefits of reamed nailing and the best method of treatment, respectively.

7 Comments (criticism) on this study

Prospective follow-up of the (poly) traumatised patient is not an easy task. In our study population, there were patients missing at every follow-up period. The reasons for this is that probably polytrauma patients are referred to their local hospital after the first treatment in the trauma centers and these patients do not come back for the follow-up. Another reason for this is that patients without any complaints do not see the necessity for visiting the outpatient clinic. Operations were performed by surgeons with different experience and working ethics. In this study population we had different types (proximal, shaft and distal) of tibial fracture. We had also poly traumatised patients that were compared with patients who had a monotrauma. An international multicenter study is very difficult to coordinate. The patients have different social backgrounds and social systems.

We suggest that the ideal study ought to be a randomised prospective clinical study. The patient should have only one type of tibial fracture. The T2 nail should be compared with another nail and both should be reamed.

8 Summary

In this prospective multicenter clinical study 102 patients with a tibial fracture were operated with the reamed T2^{TM} Stryker tibia nail system in 3 European Level 1 Traumacenters during 01-2003 to 12-2004. We documented demographic (e.g. age, gender), preoperative (e.g. trauma cause, fracture type), general operative (e.g. surgery time, blood loss), and postoperative data (e.g. radiologic bone healing, weight bearing, activities of daily living, return to work, anterior knee pain). The follow-up assessments took place at 4-6 weeks (n = 62), 4 months (n = 53) and 12 months (n = 71) after suegery.

There were 63.7 % male and 36.3 % female patients with a mean age of 42 ± 16 years. Most common were AO 42-B1-B3 fractures (45.1 %), followed by simple (AO 42-A1-3, 24.5 %) and complex diaphyseal fractures (AO 42-C1-3, 17.6 %). The rest of 15 fractures consisted of 10 distal (AO 43-A1-3, AO 43-B2, AO 43-C1-3) and 5 proximal fractures (AO 41 A2-3, AO 41-C3). 65 patients (63.7 %) had been involved in high-, and 37 patients (36.3 %) in low-energy trauma. Mostly, the accidents had occurred in traffic (31.4 %), on road as pedestrian (22.5 %), or at home (22.5 %). Only 36 patients (35.2 %) had a single tibia fracture, in 51 patients (50.0 %) the fibula was fractured, too, and 15 patients (14.7 %) had been polytraumatized.

After 12 months bone healing was radiologically confirmed in 91.5 % (n = 65/71). 76.1 % (n = 54/71) had returned to work and 74.7 % (n = 53/71) were able to work with full previous capacity. The mean pain score decreased from 3.1 ± 1.2 (4-6 weeks) to 2.8 ± 2.2 (4 months) to 2.3 ± 1.7 points (12 months). After 12 months, 13 patients suffered from anterior knee pain, which was mild in 12 patients so that they could work and bear weight. One polytraumatized patient showed a pain score of 8 points due to pseudarthrosis and needed several reoperations.

In a total of 14 patients a dynamisation of the nail had to be performed due to delayed healing and/or screw problems. Revision surgery had been performed in 7/102 patients (6.9%). In 3 patients the revision was indicated because of a malrotation due to screw

breakage, in 2 patients because of pain by the proximal screws, and in 2 patients because of screw loosening with the risk of skin perforation.

Our study about the T2 TM nail system showed results comparable with other studies regarding intramedullary reamed nailing and underlines the hypothesis that this osteosynthesis method is effective and exhibits relatively few complications,

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10 List of figures

11 List of tables

12 Appendix - Clinical Review Form (CRF)

Demographic data
Age Gender
Side: left/right
Height in cm
Weight in kg
Body mass index (BMI)
Trauma circumstances: At home At work On road (pedestrian) Traffic accident Sport Suicide intention Other (specify)
Trauma mechanism: High energy/Low energy
Preoperative data
Surgical tactics: Initial treatment (0-36 h) Initial treatment (< 7 days) Delayed treatment (> 7 days) Revision /reoperation Fixateur externe Pseudoarthrosis
Mono or multi fractures: Only one fracture Multi fractures (specify)
Patient situation: Poly-trauma patient Coma > 7 days Transferred patient Other (please specify)
Activity level prior to accident: Very active/sport Home activity Invalid
Coexistent disease: None Yes (please specify)
General diseases: Respiratory Cardiovascular Renal Hepatic Neurological Gastrointestinal Malignancy Other (please specify)
Skeletal diseases: Osteoporosis
Skin lesion: No Yes Missing
Gustilo-Anderson classification: Grade 1 Grade 11 Grade 111 A Grade 111 B Grade 111 C Missing
Tscherne classification: Grade 0 Grade 1 Grade 11 Grade 111 Missing
Classification of tibial fractures: Proximal (41 A-C) Diaphysis (42 A-C) Distal (43 A-C)
Preoperative complications: No/Yes
General operative data
Time between injury and surgery(days)
Compression done (advanced compression screw): Yes No Missing
Fluoroscopy time (seconds)

Fluoroscopy number of shots (shots)
Operative time skin to skin (minutes)
Blood loss (cc)
Tourniquet used: Yes No Missing
Nail parameters: Length Diameter Missing
Skin incision proximal: Middle of patella tendon Tendon borderline Missing
Stay in hospital (days)
Postoperative assessments: 4-6-weeks, 4 months, 12 months.
Bone healing: 4-6 weeks, 4 months, 12 months Yes No Missing
Leg length (mm): Shortened No difference Longer Missing
Leg Deviation: Axial Rotational No difference Missing
Returning to work/ previous activities: 4-6 weeks, 4 months, 12 months No Yes Missing
Working capacity: 4-6 weeks, 4 months, 12 months 0-25 % Up to 50 % Up to 75 % 100 % or close to Missing
Putting on socks and shoes: 4-6 weeks, 4 months, 12 months No difficulty Some difficulty Very difficult Impossible Missing
Sitting and standing: 4-6 weeks, 4 months, 12 months Can raise from chair without support Can raise from chair with support Cannot raise from chair independently Missing
Walking up and down stairs: 4-6 weeks, 4 months, 12 months Normal without help Two feet on each step Impossible Foot over foot using banister Any other method Missing
Walking capacity and external support: 4-6-weeks, 4 months, 12 months No need One cane or crutch Walker Heelpieces Two canes or crutches Unable or bedridden Missing
Weight bearing: 4-6 weeks, 4 months, 12 months Total weight bearing < 50 % <10 % Contact bearing No contact or bedridden Missing
VAS: 4-6 weeks, 4 months, 12 months
Anterior knee pain: 4-6 weeks, 4 months, 12 months
Postoperative complications: 4-6 weeks, 4 months, 12 months
Dynamisation of the nail: 4-6 weeks, 4 months, 12 months.

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