Medical University – Varna
“Prof. Dr. Paraskev Stoyanov”
Faculty of medicine
Department of Orthopedics and Traumatology

Dr. Biser Alexandrov Makelov

ONE-STAGED LOCKED EXTERNALIZED PLATING FOR THE TREATMENT OF UNSTABLE PROXIMAL METADIAPHYSEAL TIBIAL FRACTURES

ABSTRACT

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Scientific Supervisor:
Prof. Dr. Dimitar Raykov, Dcs.

Scientific Consultant:
Prof. Boyko Gueorguiev-Rüegg, Dcs.

Official reviewers:

1. Prof.Dr. Hristo Georgiev, MD, PhD., Dcs
2. Assoc.Prof.Dr. Nedko Dimitrov, MD, PhD
3. Assoc.Prof.Dr. Venelin Aleksiev, MD, PhD
4. Assoc.Prof.Dr. Kalin Mihov, MD, PhD
5. Assoc.Prof.Dr. Martin Burnev, MD, PhD

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The references include 179 titles, of which 8 in Cyrillic and 171 in Latin.

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Abbreviations used

LEP	- locked externalized plating
CT	- computed tomography
UPTFx	- unstable proximal tibial fractures
ACS	- acute compartment syndrome
RTA	- road traffic accident
AO/OTA	- fracture classification system
AOFAS	- American Orthopaedic Foot and Ankle Society Hindfoot Score
CAD	- computer-assisted design
DCO	- damage control orthopaedics
EAC	- early appropriate care
FEM	- finite element model
HSS	- Hospital for Special Surgery Knee-Rating Scale
IFM	- interfragmentary motion
LCP	- locking compression plate
LHs	- locked head screws
LISS-DF	- less invasive stabilization system for distal femoral fractures
LISS-PT	- less invasive stabilization system for proximal tibia
MIPO	- minimally invasive plate osteosynthesis
MVA	- motor vehicle accident
ROM	- range of motion
PWB	- partial weight-bearing
FWB	- full weight-bearing

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I. Introduction

The anatomical location of the tibia at the level of contact between the car and the pedestrian, cyclist, motorcyclist or passenger in another car determines the high incidence of tibial fractures due to road traffic accidents.

Unstable proximal tibial fractures are a heterogeneous group of injuries which treatment is determined by the type of fracture pattern and the condition of the surrounding soft tissues. Due to their high variability, the standardized treatment algorithms are difficult to apply to them. They are difficult to treat when isolated, and combined with multiple trauma, they become high-risk because, apart from the affected limbs, the patient's severe general condition does not allow to perform extensive and prolonged surgical interventions. In multiple trauma patients, early initial, as well as definitive treatment is crucial for the outcome, which is often accompanied by complications. The main problem in these patients is related to a life-threatening condition that results from the involvement of several anatomical sites, combined with significant local soft tissue damage. During their treatment, the trauma surgeon is faced with the choice of an operative method with the lowest risk of complications, requiring an adequate, scientifically proved and easily applicable in practice, surgical algorithm. Restoration of the anatomical proportions and the biomechanical function of the limb are the basis of modern surgical treatment.

For several decades, open reduction and internal fixation with plates has been the gold standard treatment for this type of injury, but extended dissection through the primary injured soft tissues further impairs the blood supply to the fractured bone fragments. The achieved anatomic reduction of the articular component is often followed by complications, which result from the additional soft tissue injury by the applied surgical techniques, such as skin wound disruption, deep infection, septic arthritis, osteomyelitis, joint contractures, nonunion or malunion of the bone fragments, and even amputations of the limb. The poor results due to the mentioned complications led to development of minimally invasive surgical methods and techniques (MIPO), such as buttress plating techniques, considering the principles of biological fixation. This is a combination of indirect reduction and internal bridge splinting with preservation of bone and soft tissue blood supply by achieving sufficient stability and optimal axial alignment. Precise anatomic reduction is not mandatory in cases with extra-articular multifragmentary fractures.

The unsolved issues are related to the application of surgical techniques~~,~~ avoiding additional injury at the fractured site, technique of staged or one-staged approach, precise timing according to the complexity and duration of operative intervention, as well as the availability of necessary equipment and a qualified team. These still unsolved problems motivated us to investigate and apply a novel operative technique, which we called one-staged locked externalized plating (LEP). In this work, we aim to justify our proposed method based on both a previously generated three-dimensional biomechanical finite element model (FEM), as well as on a prospective clinical study of the surgical outcomes in 25 patients with unstable tibial fractures with metadiaphyseal localization and/or with intra-articular involvement, as a result from a high-energy trauma and treated with a single-stage application of externally placed LISS DF plates or LCPs. The combination of minimal internal osteosynthesis supported by an externally placed metaphyseal LISS plate meets the criteria for biologic fixation. The method is based on indirect anatomic reduction techniques and percutaneous screw fixation in presence of an intra-articular fracture component, combined with a metadiaphyseal tibial locking external fixation. The function of the metaphyseal locking LISS plate as a single-stage, externally placed splinting device is to restore and preserve the three-dimensional anatomic axial orientation of the limb until secondary bone healing occurs within the generally accepted timeframe. This allows early partial weight-bearing (PWB) of the injured leg, immediately after surgery thus stimulating the process of secondary bone healing. The method results in minimization of life-threatening systemic complications such as fat embolism, compartment syndrome, acute pulmonary or multiple organ failure. The final result of the application of LEP is restoration of bone integrity with improved quality of life for patients through an early, one-staged, soft tissue and blood supply preserving, low-risk surgical intervention.

The advantages of the method are its minimal invasiveness, safety, soft tissues friendly simplified surgical technique with minimal blood loss in combination with short operative X-ray time. The comfortable low-profile LEP, which can be easily hidden under clothing and does not interfere with the patients' daily activity, makes the method acceptable to them. The approach allows a rapid return to normal daily life and saves additional surgical interventions. Once the fracture has healed, the plate can be removed within a few minutes without any anesthesia and the patient can go home by himself.

II. Literature review

Unstable proximal tibial metadiaphyseal fractures are defined as multifragmentary, open or closed, extra-articular and/or non-displaced intra-articular fractures involving both tibial condyles, caused by the impact of a high-energy traumatic mechanism and accompanied by significant damage to the adjacent soft tissue covering. The zone of interest for the present clinical study consist of the proximal metadiaphyseal zone of the tibia and may include a simple bicondylar intraarticular fracture component without articular fragmentation or impaction. It can also consider no articular involvement but an accompanying severe soft tissue injury, open fracture type and/or multiple injured patient.

Unstable high-energy metadiaphyseal tibial fractures usually occur among the adulthood population and have a prevalence between 2% and 11%.

A review of the methods for treatment of UPTFx shows that there are many unsolved problems when using the standard surgical approach for open reduction and internal fixation, which does not always result in good final outcomes in patients with high-energy fractures and severely soft tissue damaged envelope. Standard surgical methods for staged approach with precontoured locked plates, intramedullary nails, or one-stage external fixation devices, have both advantages and disadvantages. The combination of multilpe injury and limb fractures significantly worsens the prognosis and increases the risk of complications, and if the injury includes simultaneous unilateral fractured femur and tibia, called "floating knee injury", often the final functional outcomes are not satisfactory.

III. Aim and objectives

The aim of the present study is to investigate the feasibility and to evaluate the results of the application of one-stage externalized fixation with locked plates in the treatment of unstable proximal tibial fractures.

Objectives:

1. To perform a systematic review and critical analysis of the methods established for the treatment of unstable metadiaphyseal proximal tibial fractures.
2. To investigate the biomechanical and biological aspects of locked external stabilization with LCP/LISS-DF plates by creating an experimental computational three-dimensional finite element model.
3. To report, systematize and analyze the final clinical and functional outcomes.
4. To present a comprehensive evaluation of the therapeutic effect of the proposed method for the treatment of unstable proximal tibia injuries when applied in the clinical practice.

IV. Materials and Methods

Study design

Prospective study of clinical case series. The longitudinal clinical study include patients who met the inclusion criteria and were followed up with a visit and functional outcomes measurement at the 4^{th} week postoperatively and at the end of treatment, one month after LEP removal.

Planning and organization of the study

Selection of patients in the period between 2013 and 2021years.

Development of a biomechanical finite element model of the unstable proximal tibia fracture in collaboration with AO Research Institute Davos.

Clinical approval of the surgical method and follow-up of the patients' clinical and functional outcomes. Collection, statistical analysis and processing of patient data organized in a database created for the study.

Patients who met the inclusion criteria were treated with LEP.

Radiographs were read and, if necessary, volumetric reconstruction was performed by a qualified radiologist.

Operative treatment was performed within the 24th hour period after hospitalization, if the patient's overall status allowed it.

All patients are followed in the initial period every 2 weeks, after the 2nd postoperative month, and once monthly after that in absence of complaints. If the personal visitation wasn't possible, we conducted a telephone interview.

Statistical processing of the data and their presentation at international scientific meetings.

Subject of the study were operatively treated patients with unstable tibial fractures in the Department of Orthopedics and Traumatology at the University Hospital "Prof. Dr. Stoyan Kirkovich AD", Stara Zagora. Our specification of unstable fractures included multifragmentary metadiaphyseal fractures of the tibia, as well as those involving the condyles of the tibial plateau, but without severe articular fragmentation or joint impaction, open or closed fracture types, fractures with significant injury of the adjacent soft tissues, such as skin breakage with contused or devitalized edges, skin abrasions or extensive skin degloving injuries, either in isolation or as part of multiple trauma occurring in the patients with short stature usually caused by high-energy trauma after a road traffic accident or falling from height.

Inclusion criteria

Absolute:

- Age above 18 years.
- Radiographically confirmed diagnosis of an unstable metadiaphyseal tibial fracture with additional CT imaging – if necessary to exclude articular comminution and joint impaction. UPTFx with bicondylar involvement and metadiaphyseal separation, according to Schatzker classification of type VI and by AO/OTA of type 41 C2.1, 41 C2.2 and 41 C2.3 (table. 1).
- Proximal extra-articular metadiaphyseal fractures of AO/OTA types 41 A2 and 41 A3 with severe soft tissue injury.

- Proximal metadiaphyseal fractures type AO/OTA 42 C3i and distal metadiaphyseal fractures type AO/OTA 42 C3k, with marked soft tissue injury and threatening ACS.
- Unstable extra-articular distal tibial fractures type AO/OTA 43 A2 and 43 A3, open or in association with soft tissue injury.
- Soft tissue injury combined with high-energy fracture patterns and risk of ACS, multiple trauma with unilateral "floating knee injury” of ipsilateral femur and tibia.
- Gustilo type I, II, IIIA multifragmentary fractures, with suspected severe wound contamination.

Relative:

Patients with short stature due to narrow medullary canal.

Patients with advanced peripheral venous disease with severe trophic dermatological injuries.

Injured, high risk elderly patients, in order to facilitate care as part of the DCO/ EAS approach.

Table 1. Criteria for surgical treatment with LEP of UPTFx with intra-articular involvement.

Criteria for the application of surgical treatment for intra-articular involvement	
Bicondylar fractures with metadiaphyseal separation	
Lateral/medial tilt	>5°
Articular step-off	>2 mm
Condylar widening	>5 mm
Unstable extra-articular proximal metaphyseal tibial Fx	Axial malalignment
Unstable extra-articular distal metaphyseal tibial Fx	Axial malalignment >5°, -rotation, shortening

Exclusion criteria

- Low-energy fractures with intact soft tissue coverage.
- Fractures with a critical bone defect, with an aggregate fracture defect greater than 2 mm.
- Avulsion fractures type AO/OTA 42A.
- Isolated intra-articular tibial plateau fractures type AO/OTA 41 B.
- Complex multifragmentary intra-articular fractures with articular depression of the tibial plateau type AO/OTA 41 C3 and/or of the tibial plateau type AO/OTA 43 B and 43 C.
- Open fractures with Gustilo types III B and III C requiring plastic reconstruction.
- Age less than 18 years.
- Patients with severe intellectual deficits and addictions, without an adequate environment due to the inability to follow up and comply with the therapeutic regimen.

Study design:

Patients in our prospective clinical study were assigned to study groups of interest according to the following four categories.

1. Age - up to 50 and over 50.

2. Fracture zone - proximal or distal metadiaphysis of tibia.

3. Articular surface involvement by the fracture line -

“complex”, with joint involvement, bicondylar fracture types AO/OTA 41 C2 or extra-articular, "simple", multifragmentary metadiaphyseal fracture types AO/OTA 41 A3.

4. Degree of soft-tissue injury - with mild to medium or severely damaged soft tissue envelope, according to the AO classification system for soft-tissue injuries (IO).

Variables for comparison:

1. Time required for fracture healing measured in weeks.
2. Operative time.
3. Functional assessment using the HSS scoring systems for the knee joint and the AOFAS for the ankle joint, at the 4th week postoperatively and at the final examination after removal of the LEP.

4. Knee and ankle joint range of motion, for each group separately, at the 4th week after surgery and at the final examination after removal of the LEP.

1. Patient demographics

For an eight-year period of investigation from 2013 to 2021, twenty-six patients with unstable tibia fractures were treated at the Department of Orthopaedics and Traumatology at the University Hospital "Prof. Dr. Stoyan Kirkovitch" - Stara Zagora according to the proposed methodology; one of the patients had open fractures of both lower limbs. In 18 patients, the fracture localization was in the metadiaphyseal zone of the tibia. Three patients, 2 females and one male, were dropped out of the study. Eighteen patients were followed up for up to 60 months from the time of placement of the LEP.

The study subjects were assigned to study groups as follows:

- **By age and sex**

15 men, aged between 22 and 78 years and 3 women, aged between 53 and 85 years. The average age of the subjects was 51 years.

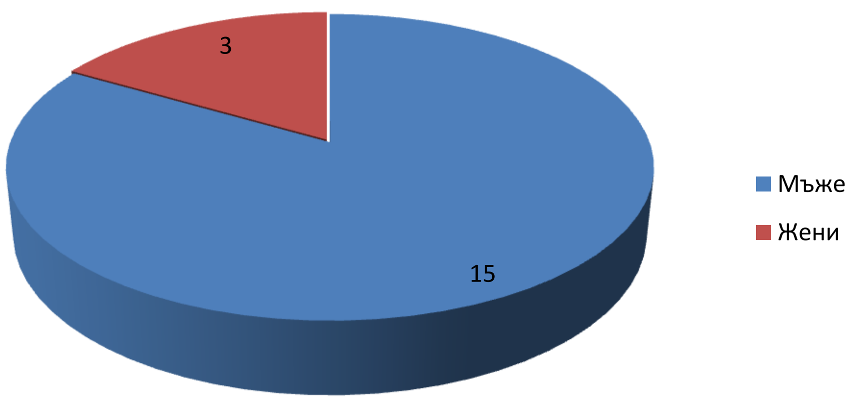


Figure 1. Distribution of fractures by sex.

- **By the mechanism of trauma**

Due to traffic accident – 10, between

A pedestrian and a car	Pedestrians - 4
A motorcyclist or cyclist and a car	MVA - 2

Two vehicles MVA - 4

High altitude trauma – 8

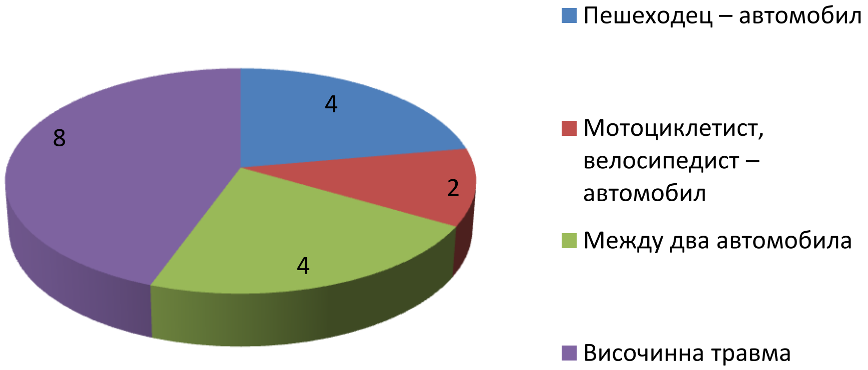


Figure 2. Distribution of fractures by the mechanism of injury

- **By affected side.**

Left - 9, right - 5, bilateral – 4

- **According to the localization of fractures**

➢ ***Proximal metadiaphysis*** - 12 patients

With intra-articular component, called complex - in 7 patients

From AO/OTA type 41 C2.2 - 6, type 41 C2.3 - 1

Without intra-articular component, called simple - in 5 patients

AO/OTA type 42 A3 - 1

From AO/OTA type 42 B3 - 1, type 42B3a - 1

From AO/OTA type 42 C3i - 2,

➢ ***Distal metadiaphysis*** - in 6 patients

Without intra-articular component

From AO/OTA type 42C3j - 2

From AO/OTA type 43A3.1 - 1 and type 43A3.3 – 3

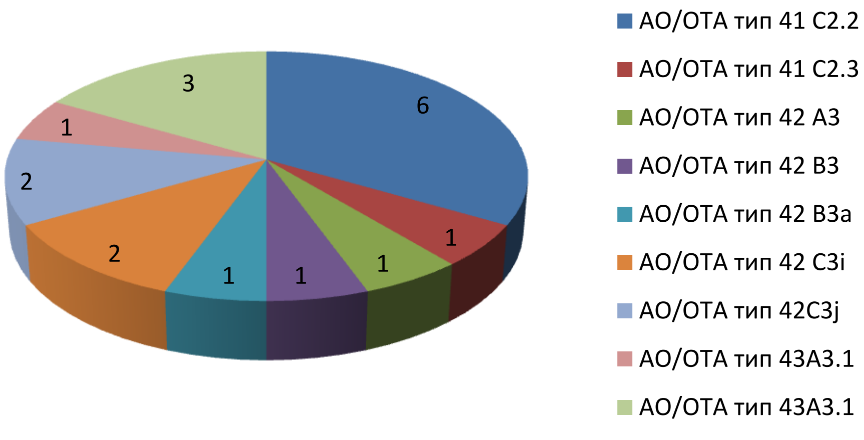


Figure 3. Distribution of fractures according to the AO/OTA classification.

- **According to the severity of soft tissue trauma**

Grade of soft tissue injury, by AO IO:

Grade 2 - 10 patients

Grade 3 - 6 patients

Grade 4 - 2 patients

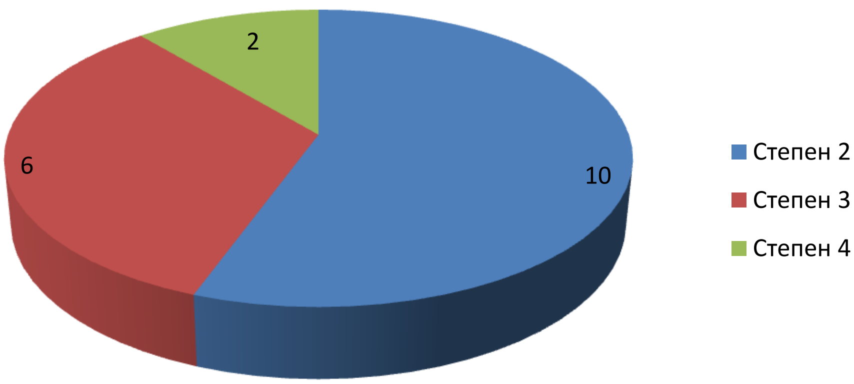


Figure 4. Distribution of fractures according to the AO classification for closed soft tissue injuries - IO.

- **According to the presence of an open fracture**

In our group, the open fractures evaluated by Gustulio were grade II in 7 patients, grade IIIA in 3, and grade IIIB/C in 1 patient, in whom the remained for a period of 6 months, after which he proceeded to alloosteoplasty of the 8 cm bone defect and conversion of the fixation, for which was excluded from the study.

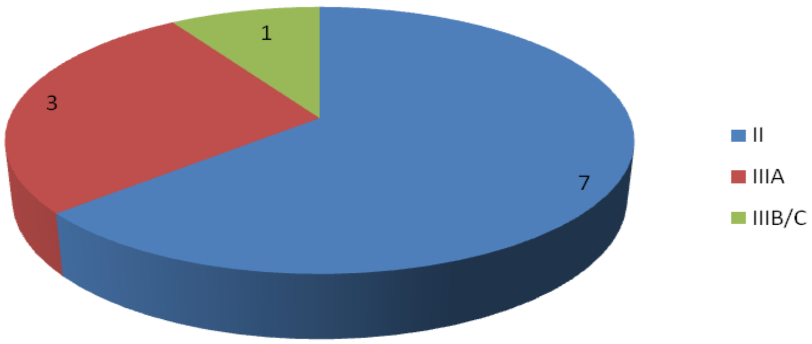


Figure 5. Distribution of fractures according to Gustilo's classification.

- **According to the location of the wound on the tibial surface**

Anterior - 9, anterior-medial - 3, anterior-lateral - 5, total circumference -1

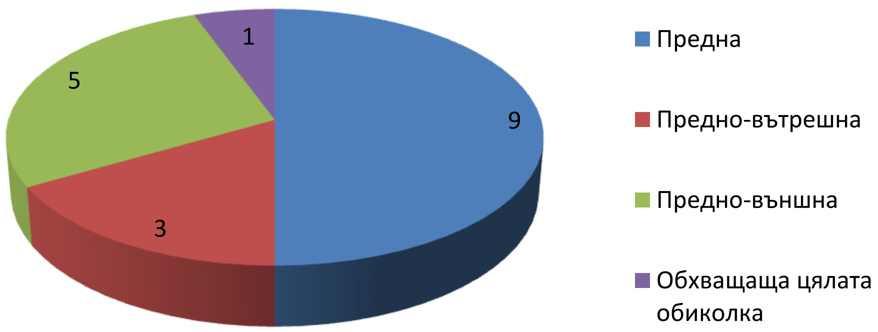


Figure 6a. Distribution of fractures according to wound location.

- **According to the presence and severity of multiple trauma assessed by the ISS scale**

Stable - 10, borderline - 4, unstable - 3, critical – 1

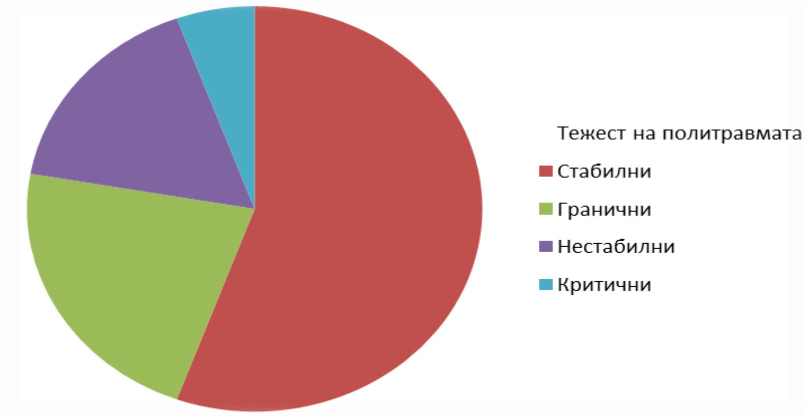


Figure 6b. Distribution of fractures according to the presence and severity of multiple trauma.

- **By type of plate used:**

LISS-DF - 9, LCP - 2, LISS-PTP - 1, contra lateral LISS-DF - 6

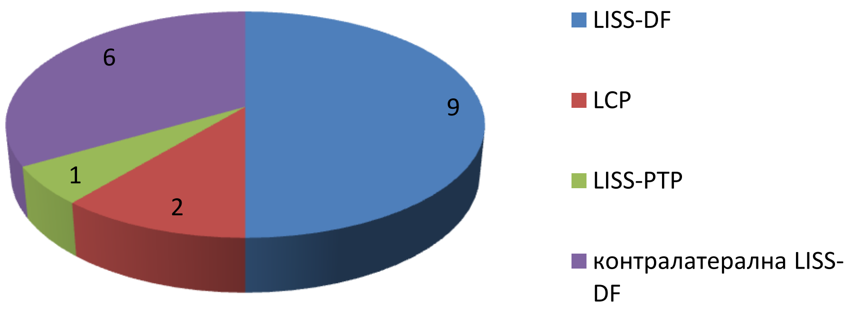


Figure 7. Distribution of fractures according to the type of locked plate used.

2. Preoperative preparation and planning

It includes the following mandatory diagnostic stages: assessment of general and local status, characteristic, type and localization of soft tissue injury, presence of open fracture, presence of joint dislocation, assessment of neurovascular status and symptoms of threatening acute ACS.

Clinical diagnosis

The diagnostic algorithm for unstable tibial fractures includes:

History. Provides information on the type, mechanism of injury, and extent of soft tissue damage. The initial clinical examination clarifies the severity of the injury, the presence of concomitant vascular-nerve lesions or of an initial compartment syndrome.

Physical examination. It reveals the presence of open wounds, suffusions, hematomas, excoriations, forced position of the limbs, visible axial deformities, and limb length discrepancy. Open wounds shall be inspected to ascertain their size and contamination. The skin is assessed for oedema, excoriations or bullae. The age of the patient, the mechanism of the fracture, and the energy of the trauma are noted. Comorbidities such as diabetes, vascular insufficiency, and addictions are described.

Diagnostic imaging

An AP and lateral x-ray of the affected femur, including the knee and ankle joints, is performed after provisional splinting of the extremity. In all intra-articular fractures, a CT scan is needed.

Choice of timing for surgical intervention

It is determined by the patient's condition, the fracture personality and the degree of soft tissue damage in the area of trauma. Our aim is to do the for operative intervention within the first 24 hours of trauma, though the method allows immediate surgery after stabilization of the patient's general condition**.**

3. Surgical technique

Our novel technique gives optimal results with a total fracture gap, measured as sum of the width of all longitudinal fracture gaps of up to 20 mm.

Our surgical protocol includes preoperative planning based on orthogonal X-ray images, closed indirect reduction combined with percutaneous screw fixation of the articular component, followed by 3D alignment of the limb in coronal, sagittal and transverse planes and concludes with the placement of one-staged LEP.

The applied surgical technique achieves anatomic reduction and stable fixation of the intra-articular component with one or two cannulated 6.5 mm compression screws and/or multiple (three or four) 2.7/3.5 mm subchondrally positioned "raft" screws, followed by external locked stabilization of the metaphyseal segment to the diaphyseal fracture extension. For this purpose, traction along the limb axis and indirect closed reduction based on the principle of ligamentotaxis is applied. The articular capsule of the knee joint should not be opened, thus avoiding the risk of septic arthritis and subsequent joint stiffness or permanent knee contracture.

Patient positioning

The patient is placed on the operating table in a supine position, with a semi-extended knee joint - flexion of 30° to 45°, supported by a rolled sterile roll placed under the knee joint, which neutralizes the muscle pulling forces and thus prevents procurvatum - apex anterior deformity (Fig. 8). This position allows the length of the both limbs to be compared and the injured limb to be easily aligned in the all three dimensions. The biomechanical axis of the lower limb follows a line from the center of the femoral head, passes through the center of the tibial plateau, and then terminates at the center of the ankle joint. This axis can be restored and verified intraoperatively by using the cautery cable to obtain and to estimate the position in frontal plane, the so-called "Bowie technique". The cable is placed from the spina iliaca anterior superior through the centre of the knee and between the first and second toes of the foot. In addition, to restore the biomechanical axis of the limb the absence of malrotation in transversal plane, ante or recurvation in the sagittal plane, must be ensured after the final fracture fixation (Fig. 9).

Figure 8. Patient position - supine, semi-extended to fully extended knee joint.

Figure 9. Bowie technique (three-dimensional alignment with the electrocautery) for rapid intraoperative assessment of the mechanical axis of the limb.

The Clemens technique, modified and popularized by Eckhardt, is applied for assessment of intraoperative rotation alignment.

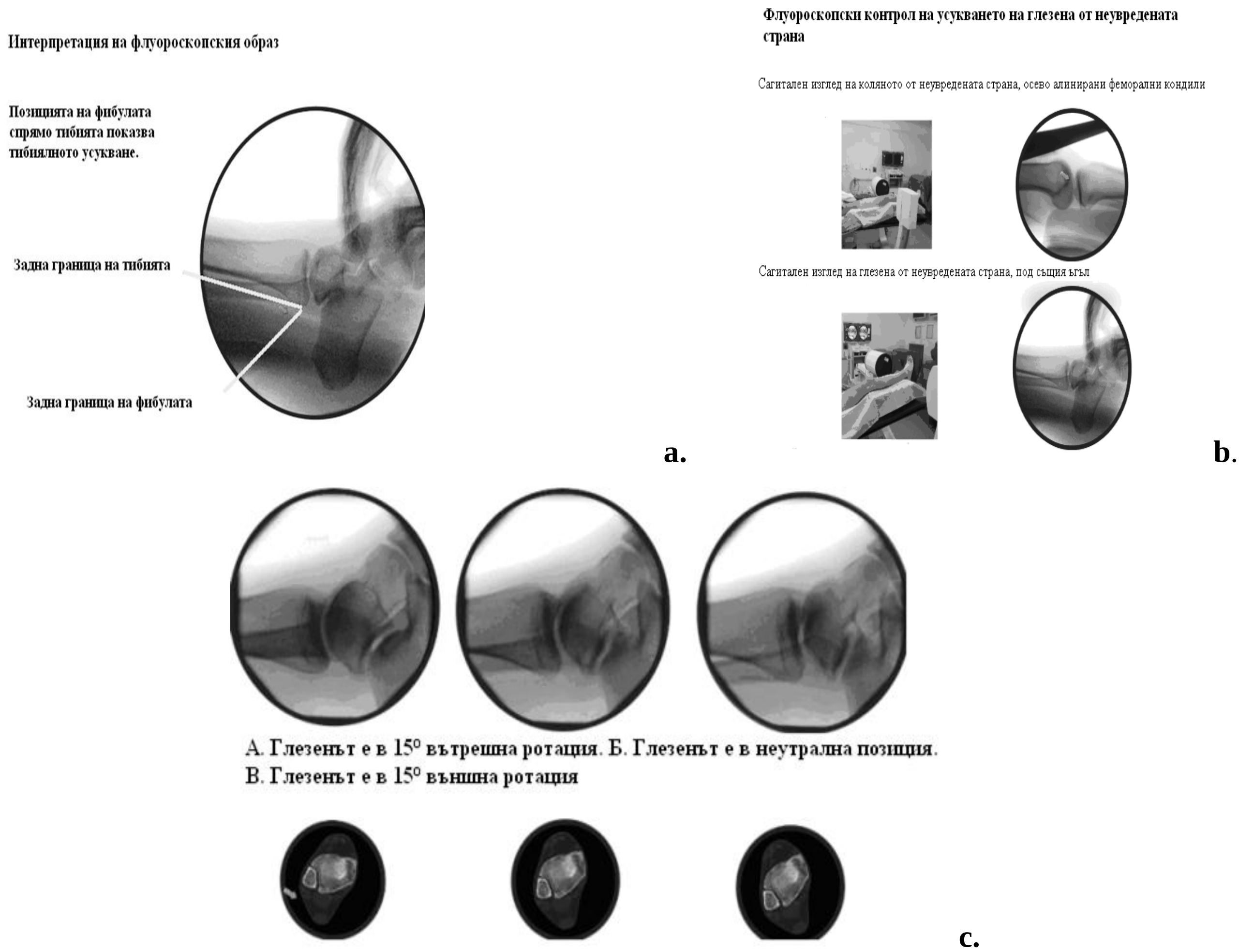


Figure 10 a.b.c. Assessment of intraoperative ankle rotation alignment.

Clinical preoperative assessment on the non-injured side. Cortical width alone is an imprecise measure, useful only in simple fractures. Fluoroscopic control of fibula and tibia position is an accurate measure.

3.2. Fracture reduction

In the presence of an intra-articular fracture component or a bicondylar fracture, the first step is done by a manual traction and indirect reduction, called ligamentotaxis, to reduce the two tibial condyles anatomicaly by using reduction forceps, patellar or Weber's clamp, placed under the tibial articular surface. The goal is to achieve an anatomic reduction, restoring articular congruency, without tilt in the frontal and sagittal planes, and without any residual condylar widening, assessed under C-arm control.

Joint surface reduction is the next step, which is achieved by percutaneous techniques (Fig. 11).

After anatomic articular reduction and temporary fixation with 2.0 mm K-wires has been achieved, we proceed with compressive osteosynthesis”ad minima” by placing one or two 6.5 mm cannulated screws and/or three to four 2.7-3.5 mm cannulated "raft" screws. If anatomic reduction of the articular component is difficult to be achieved by indirect reduction technique (ligamentotaxis), direct manipulation of the dislocated fragment could be performed through minimal fenestrations or stab incisions under fluoroscopic control. For this purpose, a bone elevator is used for direct manipulation of the fragment – the "joy-stick" technique. Using this method, all fractures of type AO/OTA 41 C2 were anatomically reduced and fixed with one or two cannulated screws, thus converting the fracture pattern from type AO/OTA 41 C2 to type 41 A2.

Figure 11. Indirect articular reduction and compression screw fixation with “raft” screws.

Then we proceed to the proper axial alignment of the diaphyseal segment to the already anatomically fixed articular complex of the short proximal segment via an externally placed locked LISS-DF plate (Fig. 12).

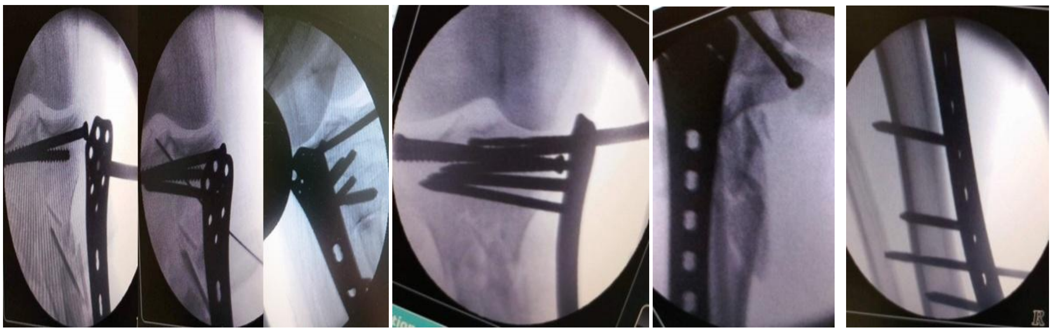


Figure 12. One-staged LEP – initial external plate fixation steps.

Once the normal anatomical reduction of the condyles is achieved, the diaphysis is aligned and fixed by the externalized locked plate. No additional surgical incisions are used in the application of the technique. Small incisions of limited size assisting reduction may be applied only if necessary. Manipulation of the fragments through the primary wound in open fractures is feasible, but only using a gentle technique and after copious irrigation and debridement of the area due to the risk of subsequent infection.

3.3. Plate selection and surgical technique

We have used three different types of osteosynthesis devices to implement the technique:

1. LISS DF for left or right femur with different number of holes and lengths, 9, 11 or 13 holes, in nine patients of our study.
2. LCP- broad/narrow with 12, 14 or 16 holes, in two patients.
3. LCP-PTP - contralateral 11hole plate, in one patient.
4. LCP-DF - contralateral 11hole plate, in six patients

Figure 13. Simplified instrumentation (Mahe Medical, fully matching the instrumentation offered by DePuy Synthes). LISS DF-left and right, K-wires for temporary plate fixation, different length locking head screws, guides, gauge, torque screwdriver (4 Nm).

Plate positioning and locking screw placement sequence are demonstrated using an ipsilateral 11-hole metaphyseal locked plate, the LISS DF. The externally positioned locked plate is positioned on the anteromedial aspect of the tibial bone, using a simple, quick, and atraumatic surgical technique. The proximal ‘cluster” zone of the applied LISS DF plate, offers 7 optional hole positions for the placement of locking head screws (LHs), indicated by letters from A to G, which gives us more variants for a successful screw fixation to the short proximal tibial segment.

Four of these holes, A, B, C, and G, are with prefabricated fixed screw direction and are located in the center of the cluster zone, and the rest of the holes (D,E,F) are positioned at the periphery. Therefore, the cluster zone of the externalized LISS DF plate offers more opportunities for precise screw placement of sufficient in length LHs in the short proximal metaphyseal zone. The seven proximal cluster zone holes, allow optimal screw configuration and sufficient depth of screw fixation in the short proximal metaphyseal bone segment, either mono- or bicortical. The working length of the plate is determined by a single bicortical "drop-screw" placed just below the distal border of the fracture site. The use of an optimal working length ensure adequate stability of the construct and allows early mobilization and partial WB on the affected leg.

Most frequently, four LHs are inserted proximally above and four LHs- distally below the fractured zone. Different screw placement options into the cluster zone holes can be used, to accomplish the mandatory extra articular screw positioning, with minimal distance of 14-15 mm below the articular surface – a safety border zone.

The plate is positioned under C-arm control, parallel to the anteromedial face of the tibia, with the end of the cluster zone including the holes indicated by letters “A-B-C-D-E-F-G at the level of the articular gap, only if the hole “E” is prelocated at the level of the subchondral plate.

The fixed distance between the centre of the “A” and “E” holes is 15 mm, and therefore we can be sure that the “A” hole remains outside the area covered by the joint capsule, which ensures extra articular position of the proximal screws.

Usually, we use screws with lengths of 75-85 mm for the proximal and between 45-65 mm for the distal zone. A bone depth gauge is used once before the insertion of the first proximal and first distal bicortical locking screws. Their already fixed positions determine the size of the bridging span of the LEP.

The medial and/or anteromedial positioning of the plate, parallel to the anteromedial face of the tibia, allows the LH screws to be positioned in a way that stabilize the anteromedial and postero-lateral segments of the tibial plateau without the risk of penetrating the postero-medial tibial surface, thus avoiding the risk of injury of popliteal vessels.

Under fluoroscopic control with an orthogonal C-arm, a K-wire with a diameter of 2.0 mm and a length of 280 mm was inserted through the proximal accessory opening of the LISS

DF plate, thereby temporarily fixing it, in the desired “safe distance” between the proximal end of the external plate and the knee joint line. By using the second K-wire with same diameter and length, we can measure the length of the first LH screw, adding it to the desired length of the plate - bone offset, which can be up to 30 mm, taking into account thinner or thicker soft tissue coverage, and the presence or absence of soft tissue edema.

Screw No. 1 is placed, according to the preoperative planning, in the “A” hole parallel to the articular (knee joint) surface. This is the first LH screw with longest length (usually 85 mm), but without penetrating through the postero-lateral cortex. This position is preset at the “A” and “B” holes in the cluster area of the LISS DF plate. At this stage LH screw No.1 is not yet locked.

Manual traction of the limb along its axis is applied, with the knee joint in a semi-extended position, assisted by a sterile roll positioned under the popliteal fossa, with the patient in supine position on the operating table.

After a stab incision with a No. 11 scalpel, under the protection of a fabricated drill guide, the distal diaphyseal tibial segment is drilled, bicortically, with the corresponding screw-size burr in position, **three empty plate holes** below the preoperatively planned working length of the locked external splint, thus configure the **maximal length of the initial bridging span.** An offset spacer is prepared in advance using a periosteal raspatory or rolled gauze roll of 20-25 mm. Most often, we use for rough measurement, the end phalanx of the index finger with a size of 15 mm, of the third finger- with a size of 20 mm, and the thumb- with a size of 25 mm, respectively, for thinner or thicker soft-tissue envelope, as an intraoperative guide for plate-bone offset. For a plate with a total length of 11 holes (with corresponding numbers from 1 to 11), and a planned working length of four holes the first proximal screw has been inserted and locked into the “A” hole of the plate. Following manual traction technique an optimal axial alignment is achieved in the frontal and transversal planes. Then, a temporarily placed drill is inserted into the plate hole No. 7, to "fine-tune” the plate-bone offset. Distally, **we insert the screw No.2,** with a length corresponding to the precalculated plate-bone offset added to transverse bone diameter, **in hole No.8, tightened**, but not locked. In this way, we determine the initial length of the bridging zone of the plate. Just below the fracture zone, we put the screw No.3, a limiting screw - "drop screw ", which minimizes the shearing forces in the fracture zone and determines the size of the effective "working length", corresponding to the fracture boundaries. At this stage, a mandatory fluoroscopic control is performed to verify the axial alignment in coronal and transverse planes. The supine position of the patient allows easy comparison and detection of limb length discrepancies, and the application of the Bowie technique aids rapid verification of the alignment in the frontal plane. If optimal axial alignment is achieved, with the help of temporary left "in situ" drillbit, in plate hole No. 7 we lock with a torque screwdriver (4 Nm) screw No.2 (5 mm diameter) in hole No.8. This completes the axial and rotational alignment of the limb. The uncorrected sagittal deformities, i.e. ante- or recurvatum, are corrected by applying a manual pressure in sagittal plane, and fixed the aligned bone fragments, by initial reverse dynamization with additional positonal screw, outside the splinting locked plate.

The sequence of insertion and locking of the remaining screws begins with screw No. 3 in the first distal hole below the fracture, after that No. 4 in the first proximal hole above the fracture, labeled as the "B" hole in Fig. 14. The next screw is No. 5 in the "G" hole, No.6 in the "C" hole, No.7 in the seventh plate hole, bicortically, screw No.8 in the sixth plate hole, and screw No.9 is put monocortically in the ninth hole of the plate. That fixed sequence of placing screws prevents the axial deformities. The screws in "G" and "C" located in the cluster area have a factory preset slightly convergent stroke for increased axial retention resistance. All screws in the proximal tibial metaphysic should be of maximal length, which avoid perforating through the opposite cortex, in order to successfully counteract the critical torsion and dominating shearing forces at the short metaphyseal zone, above the fracture site.
The procedure concludes with final C-arm control, manual testing of passive range of motion in joints, adjacent to the fracture zone, and postoperative control orthogonal radiographs.

A contralateral plate is applied using the described technique for the treatment of unstable distal metadiaphyseal tibial fractures of AO/OTA types 43 A2 and 43 A3. The shape of the plate matches to the distal metadiaphyseal tibial surface, and the placement of the screw holes in the cluster zone allows uneventful insertion of three to five LHs. An intact distal metaphyseal zone with a minimum size of 4 cm is needed for adequate screw insertion with enough construct stiffness for natural bone healing.

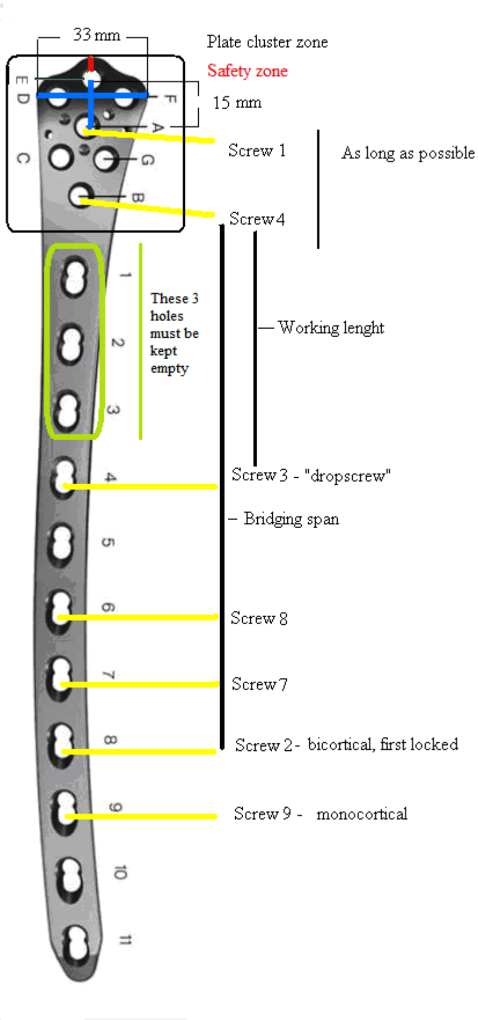


Figure 14. One-staged LEP screw sequence insertion algorithm.

Figure 15. A. Plates types used, screw configuration and insertion direction.

Figure 15.B. Removal of the plate in the ambulatory setting without anesthesia.

4. Postoperative protocol.

According to the FDA definition, bone union is defined as healing of the fracture within 6 months, delayed union is defined as healing in a period between 6 and 8 months, and the healing period with duration of over 9 months with no change in radiological pattern in the last 3 months is defined as nonunion.

Clinical signs of bone union, according to Sarmiento's criteria, are lack of motion in the fractured zone, walking without crutches and full WB of the limb without pain, and X-ray detectable callus formation in two orthogonal planes.

The RUST radiological system proposed by Whelan for the evaluation of bone healing for tibial fractures was used only as a guidance tool. In our study, a sum of 8 points was taken as a threshold value indicating the presence of sufficient bone union that allow FWB of the limb for a month with the plate left "in situ". In the absence of patient's complaints, 4 weeks after FWB – without support of crutches and after a new set of orthogonal x-ray taken, the LEP was removed in an outpatient clinic, without anesthesia, within a few minutes. Blood loss during screws removal is minimal, and after irrigation of the screw holes with a solution of iodine - povidon (braunnol) and after application of a sterile wound dressing, patient leaves the clinic walking freely and with a smile on his face.

Follow-up orthogonal x-rays are taken up to 24 hours postoperatively, at the third, sixth, and twelfth weeks, and at every two-months interval thereafter. Controlled PWB started after the 2nd postoperative day, and FWB is started by the 12th postoperative week. FWB is allowed, when the RUST score was at least 8 points.

Postoperative protocol for active rehabilitation.

From the data published by Rowey et al. it is concluded that a range of motion from 0° to 120° is a reasonable goal to achieve for the knee ROM (tabl. 2).

Table 2. Average ROM necessary in common daily activities.

Walking	0° to 60°–67°
Climbing stairs	0° to 83°–94°
Descending stairs	0° to 90°–93°
Tying shoelaces	0° to 106°
Sitting	0° to 93°–110°
Squatting	0° to 117°–130°

From day 1 to day 7 after surgery, passive or active walking is started and depending on the patient's condition, followed by proprioceptive training with an electronic weight scale for PWB up to 25 kg. Patients are trained to use assistive devices, and in the initial period they walk without WB, "tip toes" on the affected leg.

During the period of early fibrous callus formation, cyclic IFM is required in the fracture defect zone with longitudinal strain (LS) values of up to 30% According to our biomechanical study, FWB at 22 mm plate-bone offset provides a longitudinal strain of 17.5% and 27.8% at 32 mm plate-bone offset. The cyclic loading schedule was administered twice daily with 400-600 cycles followed by 10 min period of relaxation on the operated limb for a 1 sec, averaging between 40-60 cycles per minute (total 400-600 cycles in 10 min). The duration is up to the 6th postoperative week, when a follow-up radiograph is taken and, if there is evidence of callus formation, continued with a gradual progressive increase of PWB. The rest of the time the patient walks on crutches with PWB up to 25 kg.

In fractures with an articular component of type AO/OTA 41 C2, the cyclic loading protocol is delayed, until the 2nd postoperative week and walking with PWB started after the 21st postoperative day. In the final phase of callus maturation with clinical evidence of fracture stabilization, walking with PWB of the limb is continued until positive x-ray verification of bone union (Table. 3).

Table 3. LEP - Early active rehabilitation protocol for patients with external plate fixation.

Postoperative protocol: cyclicity and active dynamization in the fracture zone			
Post-injury period	Bone healing stage	Rehabilitation	Active locked external system (OLES)
From day One to day 7	Inflammatory phase - passive or mobilization without loading – depending on the patient's condition.	Stability - verticalization and patient training with electronic scale for up to 25 kg.	IntraArticular -Walking with 2 Crutches - No WB. After day 7 - cycling exercises – 2x10 min (Full WB for a second-400-600 cycles for extra-articular fractures)
Starts between day 1 to 7 and continues until week 3 Callus formation.	Callus formation 1.Articular (Simple) PWB up to-25 kg, after day 21. 2.Extra-articular unstable – from day 7 PWB up to 25 kg.	Cyclic IFN 2x 10min (relaxation with FWB: 300- 400 cycles), after day 14 to week 6 2x 10 min (relaxation with FWB: 400- 600 cycles) after day 7 to week 6.	Intra-Articular – PWB to 25 kg On day 21 post op. Extra-articular unstable-early PWB Up to 25kg on day 7-14 ,after the opp.
From 6-8 up to 12-24 weeks post op.	Callus maturation -Clinical signs stabilization and X-ray control.	Active dynamization by gradually increasing load from PWB to FWB crutches	Gradual transition from PWB to FWB and walking without crutches

Protocol for skin and external splint care.

Immediately after surgery, small sterile gauzes soaked in a solution of Braunol are placed around the screws. The affected limb and plate are covered with a sterile bandage.

The frequency of cleaning of the screws is initially at every 3 days, and after stabilization of the skin-screw interface, by the 12th to 14th postoperative day, patients are advised to clean the area under the plate twice a week with a 70% alcohol solution, with a protective 24-hour limb bandage for the entire treatment period. Patients are advised to use antibacterial soap to thoroughly disinfect the area during showering.

V. Follow-up, documentation and statistics

The study of the medical records includes the patient's history of the disease, the ward journal, operative protocols, outpatient documents of the patients with the corresponding fractures for the study period. Patient history data, including the mechanism of injury, time to emergency and hospital care, length of hospital stay, antibiotic administration – type, number and duration of administration, patient complaints, comorbidities, family history, physical examination , laboratory tests , x-rays and computed axial tomography imaging.

Statistical methods

The following statistical methods were used to process and analyze the information related to this dissertation.

1. Descriptive analysis

Descriptive variance analysis was performed on all quantitative variables in the whole cohort, as well as to the individual groups of patients, and the corresponding means, standard deviations and ranges were determined.

2. Graphical representations

Graphical representations of the variables studied are presented in the form of histograms, pie charts and bar charts.

3. Normality tests of quantitative variables

The type of distribution of a quantitative variable - normal (Gaussian) or skewed - determines the type of methods used to explore the statistical significance of the influence of individual factors on that variable. Accordingly, in case of a normal distribution, parametric methods are applied, and in absence of such a normal distribution, i.e. when the distribution is characterized as deviating from normal, non-parametric methods are applied. It should be noted that the latter could also be applied in case of a normal distribution, as they are more robust than parametric methods, but have lower power than the parametric methods. The test for normality of distribution of quantitative variables in this dissertation was performed using the Shapiro-Wilk test, and it was shown that not everywhere in the individual groups there is a normal distribution of variables. Therefore, the investigation of the statistical significance of the influence of individual factors was carried out using non-parametric statistical methods.

4. Non-parametric statistical methods of analysis

As noted above, nonparametric methods are applied to examine the statistical significance of differences between two or more groups when the distribution of patient characteristics and parameters deviates from the normal distribution in some of them. During the nonparametric statistical analysis, quantitative variables are treated as rank variables. The following nonparametric methods were applied in this dissertation: Mann-Whitney Test to compare the ranks of a variable in two independent groups, Kruskal-Wallis Test to compare the ranks of a variable in more than two independent groups, Wilcoxon Signed-Rank Test to compare the ranks of a variable in two dependent groups, and Friedman Test to compare the ranks of a variable in more than two dependent groups.

The cutoff value for the level of statistical significance was set to the standard value of 0.05. If the statistical significance (P) value calculated from the corresponding test is less than 0.05, the effect tested is considered statistically significant, and if the value calculated is greater than 0.05, the effect tested is considered statistically insignificant.

VI. Results and complications

Functional assessment was performed using the HSS scoring systems for the knee joint and the AOFAS for the ankle joint, by follow-up groups, at the 4th week after surgery and at the final examination, one month after plaque removal, respectively.

Knee joint functional outcomes using the HSS scoring system

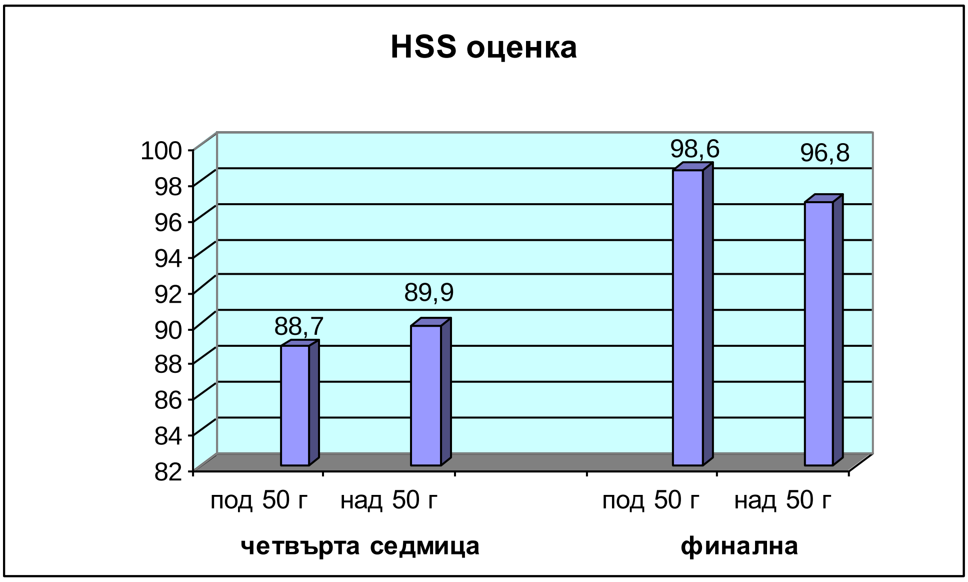


Figure 16: HSS knee joint assessment performed at 4 weeks after surgery and at final follow-up in patients younger or older than 50 years, with no statistically significant difference between the two groups of patients at each follow-up ($P \geq 0.54$), and with a statistically significant increase between the two follow-ups in each group ($P \leq 0.01$).

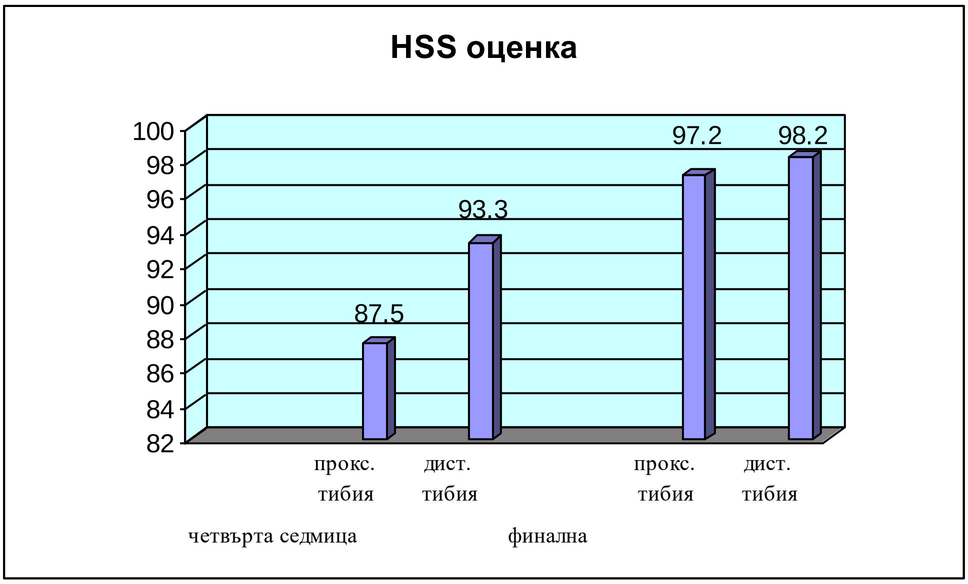


Figure 17. Knee joint HSS score performed at 4 weeks after surgery and at final follow-up in patients with proximal or distal localization of the fracture, with no statistically

significant difference between the two groups of patients at each follow-up (P ≥ 0.18), and with a statistically significant increase between the two follow-ups in each group (P ≤ 0.04).

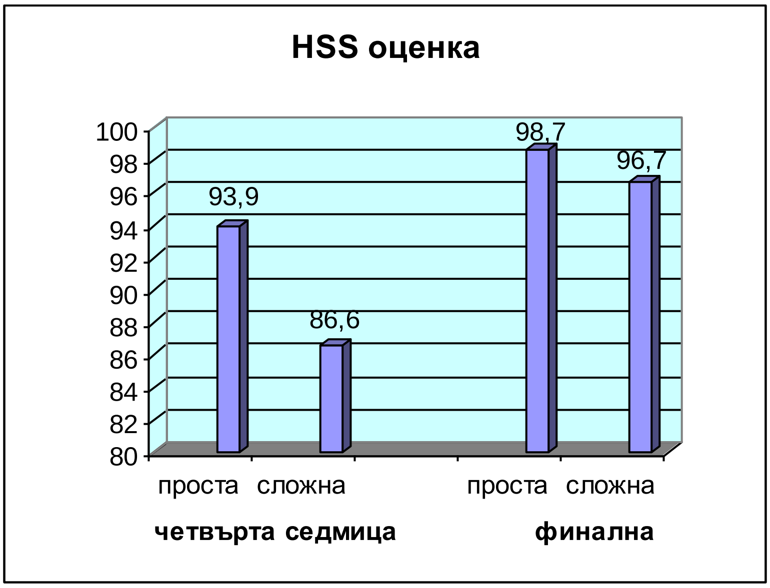


Figure 18. HSS assessment of the knee joint performed at 4 weeks after surgery and at the final examination in patients with simple or complex (compound) fracture. While the assessment at 4 weeks was statistically significantly higher in patients with a simple fracture compared with a complex fracture (P = 0.04), the final assessment was not statistically significantly different between the two groups of patients (P = 0.21), and there was a statistically significant increase in HSS between the two follow-ups in each group (P ≤ 0.04).

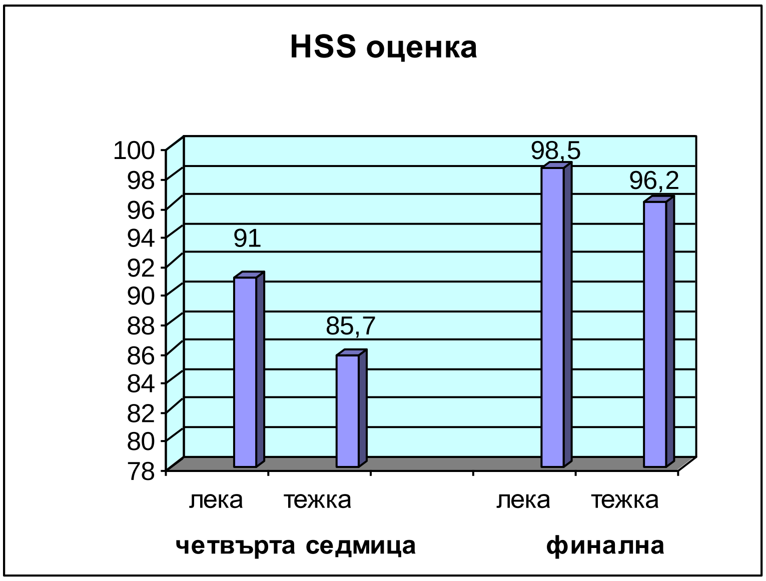


Figure 19. Knee joint HSS score performed at 4 weeks after surgery and at final follow-up in patients with mild or severe soft tissue injury, with no statistically significant difference

between the two groups of patients at each follow-up ($P \geq 0.27$), and with a statistically significant increase between the two follow-ups in each group ($P \leq 0.01$).

1. Clinical results

- **Healing time**

The clinical criterion for bone union is assumed to be pain-free FWB of the injured limb.

- **Age under 50 or over 50 years**

Patients under 50 years of age had time to union with a mean of 20.7 weeks, a standard deviation of 6.1 weeks, and a range of 12-28 weeks, which was not statistically significantly different from that of patients over 50 years of age, which had a mean of 20.9 weeks, a standard deviation of 3.6 weeks, and a range of 16-29 weeks (P = 0.93).

- **Proximal or distal fracture localization**

Patients with proximal fractures had time to union with a mean of 21.8 weeks, a standard deviation of 3.6 weeks, and a range of 16-28 weeks, which was not statistically significantly different from patients with distal fractures, which had a mean of 19.0 weeks, a standard deviation of 6.1 weeks, and a range of 12-29 weeks (P = 0.25).

- **Simple or complex fractures**

Patients with simple (A, B) fractures had time to union with a mean of 18.4 weeks, a standard deviation of 2.9 weeks, and a range of 14-22 weeks, which was statistically significantly shorter than that of patients with complex (C) fractures, which had a mean of 22.4 weeks, a standard deviation of 4.9 weeks, and a range of 12-29 weeks (P = 0.04).

- **Operative time**
- **Age under 50 or over 50 years**

The operative time in patients under 50 years of age had a mean of 31.4 min, a standard deviation of 7.1 min, and a range of 25-45 min, which was not statistically significantly different from that in patients over 50 years of age, which had a mean of 34.4 min, a standard deviation of 6.6 min, and a range of 20-45 min (P = 0.25).

- **Proximal or distal fracture localization**

The operative time in patients with proximal fractures had a mean of 32.4 min, a standard deviation of 6.8 min, and a range of 20-45 min, which was not statistically significantly different from that in patients with distal fractures, which had a mean of 34.8 min, a standard deviation of 6.8 min, and a range of 25-45 min (P = 0.38).

- **Simple or complex fractures**

The operative time in patients with simple (A, B) fractures had a mean of 34.3 min, a standard deviation of 5.5 min, and a range of 25-42 min, which was not statistically significantly different from that in patients with complex (C) fractures, which had a mean of 32.6 min, a standard deviation of 7.6 min, and a range of 20-45 min (P = 0.42).

- **Soft tissue damage assessed by the Gustilo scale**

Operative time in patients with mild soft tissue injury had a mean of 34.0 min, standard deviation of 7.0 min, and range of 20-45 min, which was not statistically significantly different from that in patients with severe soft tissue injury, which had a mean of 32.2 min, standard deviation of 6.6 min, and range of 20-45 min (P = 0.46).

- **Complications observed in the group of patients studied**

On external fixation frame

Loosening of the screws

No screw loosening in 14 patients, up to 3 screws in 2 patients and more than 3 screws in 2 patients.

Skin changes around the screws

No skin changes in 10 patients, granulation up to 4 mm in 4 patients, hypergranulation 4-10 mm in 3 patients and bleeding hypergranulation with secretion in 1 patient.

Infection around the screw channels

In our study, we observed three patients with mild infection of grade 1-2 according to the Checketts-Otterburn classification

Results from a computer-simulated biomechanical model using the finite element method. FEA-model.

Simulation model

A virtual three-dimensional model of the tibia was developed based on two-dimensional CT images using three-dimensional reconstruction software developed by Simpleware. The data set required for the three-dimensional reconstruction was obtained by scanning the right tibia of a patient. A virtual transverse osteotomy was performed simulating an unstable fracture with a defect size of 2 cm, corresponding to a multifragmentary metadiaphyseal fracture with a simple, nondisplaced intra-articular component, defined as a complex proximal tibial fracture type AO/OTA 41 C2.2. The osteotomy defect was located 5 cm below the proximal tibial articular surface. A model of the ipsilateral metaphyseal locked plate, the 11-hole LISS DF, was constructed of stainless steel (316L), 276 mm in length, and corresponding instruments from DePuy Synthes and Mahe Medical were used to stabilize the simulated fracture pattern. **(Figure 20A.B.)** The model was built using a CAD modeling system for automated design. The screw configuration was selected according to the most common placement, orientation, and number of locking 5.0 mm steel screws used in clinical practice.

Figure 20A. Clinical case of fracture type AO/OTA 42 C2.2 and the FEA- model.

Figure 20B. FEA - biomechanical model. The fracture shown was used as a prototype for the finite element method biomechanical model.

Three different groups were modeled for comparison with different distance (offset) of the plate from the bone (Fig. 21). The three experimental groups are designated as the INT-P group with 2 mm offset plate-bone to reproduce standard internal fixation, the EXT-P1 group with 22 mm offset plate-bone simulating external fixation in patients with thin soft tissue envelope, and the EXT-P2 group with 32 mm plate-bone offset simulating external fixation in patients with thick soft tissue envelope.

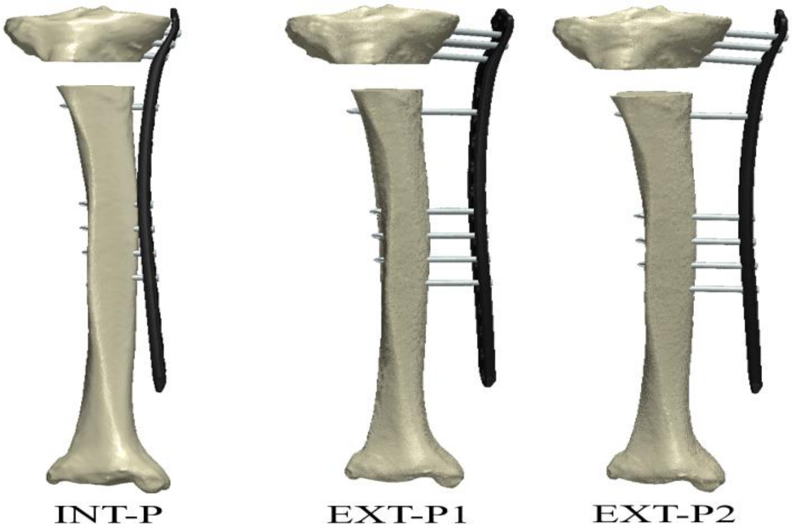
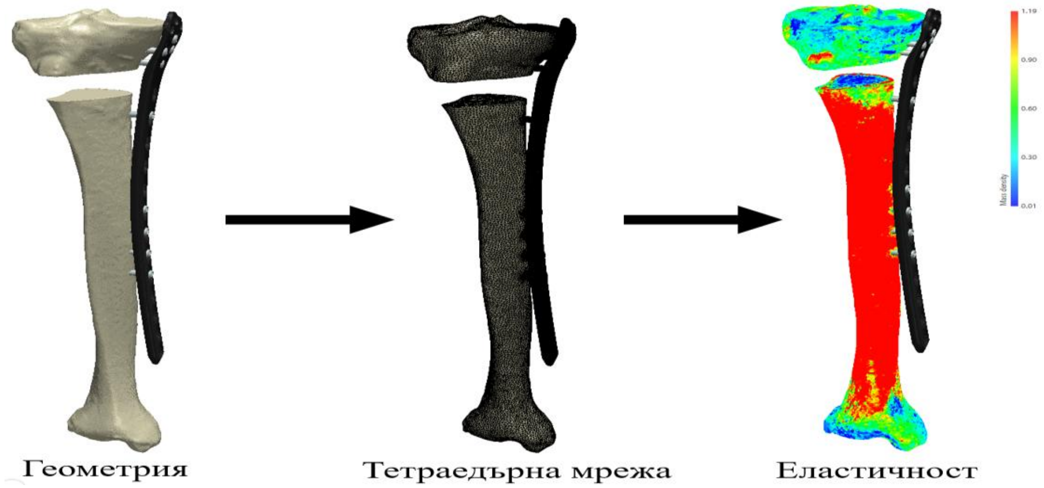


Figure 21. Three different plate configurations with different plate- bone offset.

The proximal and distal screw configurations was modeled by application of four proximal locking head screws with a shorter anterior screw for increased plate elevation. Distally, four bicortical LH screws and one last monocortical locking screw were inserted, but not at the last plate hole (Fig. 22).

Figure 22. Proximal and distal screw FE configurations.

The plate and screws are modelled with parameters characteristic of the material stainless steel (316L). The diameter of the screws is set to 5.0 mm. The width and thickness of the plate are 18.0 mm and 6.0 mm respectively. For the LISS DF-plate, the Young's modulus is set to 110 GPa and the Poisson's ratio to 0.3. All materials are assumed to be linearly elastic and isotropic. The plate and screws are modeled as a homogeneous structure. The mechanical properties of the bone material (elasticity, inhomogeneity, etc.) were modeled based on the bone mineral density values obtained from the performed CAT scan (Fig. 23). The material properties of tibial bone were calculated based on bone mineral density and graded according to the methods used in published studies .



Geometry Tetraedric mesh model Elasticity

Figure 23. Modeling the plate-bone system by connecting and configuring the virtual 3D FE model.

In the short proximal bone fragment, the screw and plate are "bonded" to simulate locking. Contact at the threaded connection between bone and screw was simulated by friction, with a set static coefficient of friction of 0.95 (Fig. 24).

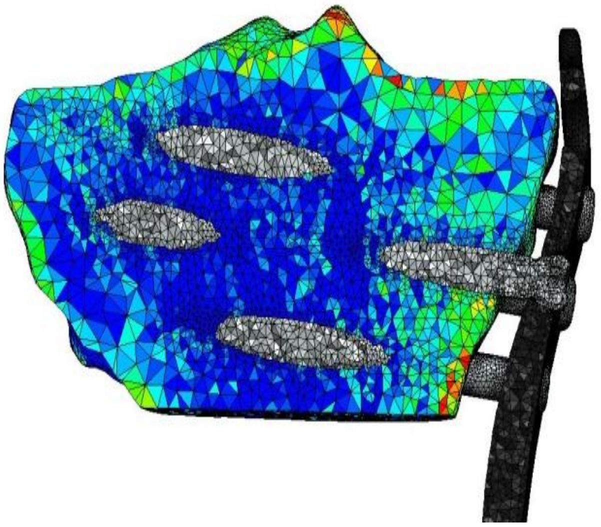
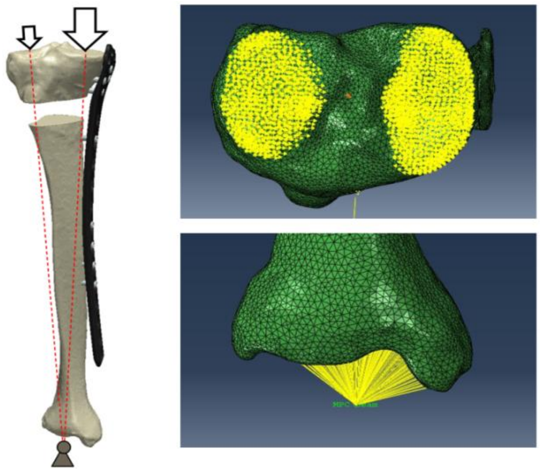


Figure 24. Three-dimensional model of the proximal screw-plate and screw-bone interface

Load parameters and boundary conditions

The distal end of the tibia is fixed in all degrees of freedom. The distal articular surface is constrained by a control point in such a way that only its rotation about the frontal axis is allowed, i.e. it is modelled as part of an articulated joint. The computed force vector of the applied axial load forces is directed centrally at a single point on the tibial plateau in coronal plan (Fig. 25). No forces inducing external or internal rotation of the tibia were applied, i.e., no torsional moment was simulated on the patient's knee during motor activity.

A static axial load of 25 kg (250 N), corresponding to a partial active loading of the limb, and of 80 kg (800 N), corresponding to a full loading of the limb, was simulated and applied to the proximal end of the tibial model and distributed in a ratio of 80% and 20%, respectively, on the medial and on the lateral condyle.



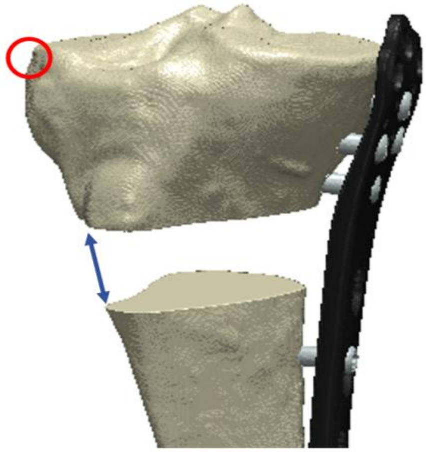


Figure 25. Load distribution and boundary conditions. **Figure 26.** Evaluated parameters: stiffness, interfragmentary motion and longitudinal strain.

The parameters of interest in the simulation were: construct stiffness, equal to the applied force divided by the resultant displacement measured at the most lateral point of the articular surface (indicated by a circle in Fig. 26); interfragmentary motion, equal to the change in osteotomy width at the most lateral aspect of the fracture (indicated by a blue arrow in Fig. 26); longitudinal deformation (strain) in the fracture zone, which represents the deformation of the bone-implant construct and is calculated, according to Perrin's concept of deformation, by dividing the interfragmentary motion by the width of the fracture defect and expressed as a percentage. The analysis was performed using finite element modeling software Abaqus 6.9 from Simulia Corp.

In the virtual model of unstable proximal metaphyseal tibial fractures externally fixed with a LISS DF plate, the stiffness of the simulated construct decreases with increasing plate-bone offset. Under isolated axial loading, the stiffness of the construct was 654.80 N/mm in the INT-P group, 197.08 N/mm in EXT-P1, and 127.56 N/mm in EXT-P2 (Fig. 28). The interfragmentary motion (IFM) at partial load of 25 kg/250 N is 0.31 mm for INT-P, 1.09 mm for EXT-P1 and 1.74 mm for EXT-P2, while at full load of 80 kg/800 N it is 0.97 mm for INT-P, 3.50 mm for EXT-P1 and 5.56 mm for EXT-P2. The IFM was lowest for the simulated 2 mm offset design in the INT-P group, and was highest for the 32 mm offset design in the group designated EXT-P2.

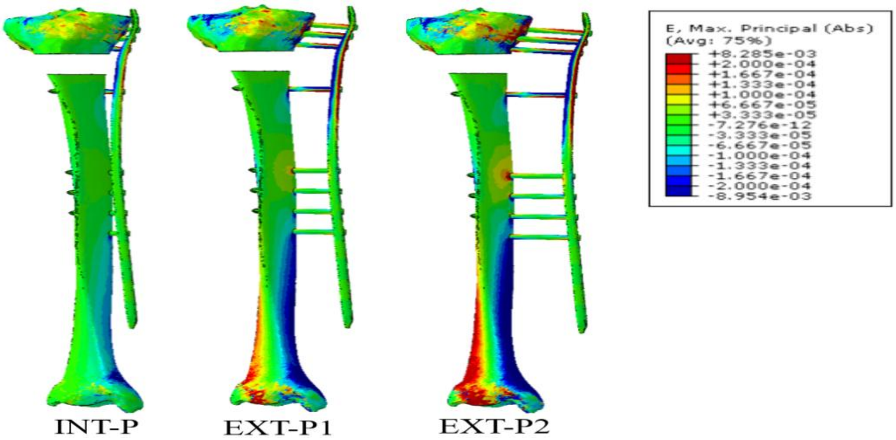


Figure 27. Von Mises equivalent stress distribution under a partial load of 250 N corresponding to a PWB of 25kg.

Maximum stress (Fig. 27) is created in the two locking screws closest to, above, and below the simulated fracture defect, and is highest in the EXT-P2 model with 32 mm offset. The values of the corresponding longitudinal strain at the simulated fracture site under partial loading were 1.55% in the INT-P group, 5.45% in the EXT-P1 group, and 8.70% in the EXT-P2 group. At full load, the values were 4.85% in INT-P, 17.5% in EXT-P1 and 27.8% in EXT-P2 (Fig. 28).

Under axial loading of 250 N, simulating a partially controlled walking load, the structural stiffness in the experimental groups EXT-P1 and EXT-P2 showed values several times lower than those in the control group INT-P. The stiffness decreases with increasing distance of the plate from the bone and this finding confirms the results of the studies of Ahmad et al. From a clinical point of view, immediate rehabilitation by early controlled loading (PWB) would be feasible and safe. The amplitude of IFM under partial loading was up to 1.03 mm and the values of calculated longitudinal deformity at the fracture site were 1.55% for INT-P, 5.45% for EXT-P1, 8.70% for EXT-P2, respectively, thus allowing callus formation by secondary bone healing. The IFM and longitudinal fracture strain values are valid for the simulated 20 mm fracture gap. For small gaps, up to 5 mm in size, full loading would result in 70% deformity in the far cortex at 22 mm offset, whereas at 32 mm offset would result in cortical contact in the far cortex. In the proposed model, lowest stiffness was demonstrated at 32 mm offset in the EXT-P2 group. The analysis of the results leads to the assumption that a construct with plate-bone offsets in the range of 22-32 mm can provide conditions for secondary bone healing with callus formation. The reduced stiffness of the construct in the EXT-P1 and EXT-P2 groups, with values between 70% and 75% compared to the INT-P group, indicates a potentially high stress concentration in the screws placed next to the fracture zone, which could lead to their loosening and even fracture if early uncontrolled loading (FWB) is applied to the limb.

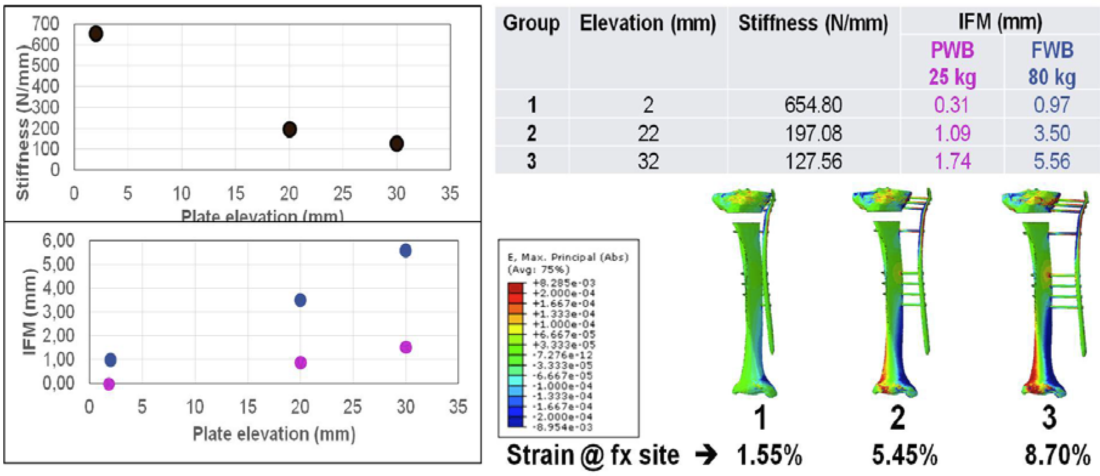


Figure 28. Final FEA results for stiffness, interfragmentary motion (IFM), and longitudinal strain at the fracture site under partial (PWB) and full (FWB) loads of 25 kg and 80 kg, respectively.

With a simulated load of 800 N, corresponding to uncontrolled FWB on the limb, the IFM was between 3.50 mm and 5.56 mm at a plate-bone offset of 22 mm to 32 mm and did not provide the required optimal relative stability, with a serious risk of nonunion. The screws located next to the fracture gap were subjected to the greatest loading, with the deforming forces being most pronounced in the 32-mm offset group and lowest in the 2-mm offset group. Therefore, attention should be paid to optimal screw placement in the short proximal fracture segment. Bone quality and fracture type should also be considered when assessing the risk of fixation failure. The patient should be warned not to FWB on the injured limb in the initial period, and that early PWB is considered to be at low risk and safe. The limitations of our simulation study, including the lack of analysis of the impact caused by different screw configurations and variations in the working length of the plate, may be avoided in future studies. In conclusion, we can summarize that in terms of virtual three-dimensional biomechanical modeling, the one-staged locked external stabilization in unstable proximal tibial fractures with simulated thin and thick soft tissue cover, creates favorable biomechanical conditions for callus formation with values of longitudinal strain in the fracture zone that do not exceed 10% and provides optimal relative stability necessary for the onset of secondary bone healing under controlled PWB in the early postoperative phase of healing (Fig. 29).

Interfragmentary longitudinal strain

100% 10 % 2%

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Hematoma Granulation tissue Fibrous tissue Cartilage Bone tissue

Figure.29. Perren's strain theory.

VII. Discussion.

The application of the external locked plate fixation technique was first reported by Ramotowski et al. in Poland several decades ago, using the external stabilization system called Zespol. Initially, the use of LCP as an external fixation device in the treatment of open fractures and nonunions was described by Kerkhoffs et al. (2003) for the treatment of septic arthritis, and as an adjunctive external stabilization in bone lengthening by distraction osteogenesis, reported by Apivatthakakul (2007). This technique was later termed "supracutaneous plate stabilization" and its application in the treatment of patients with Gustilo type II and IIIA open fractures, nonunions and deep bone infections has been described by Apivatthakakul (2007). In the recent few years, a method of monolateral external fixation using anatomically precontoured metaphyseal locked compression plates, LISS-LCP, as external fixators has been reported. The locked plates are placed above the tibial surface after closed fracture reduction. The plates function as external unilateral locked splinting device, and the LH screws provide enough stability to the construct. These fractures, due to their short proximal metaphyseal segment and combined with significant soft tissue trauma, are indicated for LEP. The region of the anteromedial surface of the tibia is characterized with insufficient soft tissue coverage and no vital vessels, nerves, or muscles to be injured after indirect fracture reduction techniques. Therefore that zone is quite appropriate for biological external fixation by means of externalized locked plating. When closed reduction is not possible, minimal fenestration incisions are used. The proposed method allow early joint mobilization, ease of care and maintenance of hygiene around the skin-penetrating screws, and creates an aesthetically more acceptable design for the patient, compared with wide range of traditional external fixation systems – monolateral, hybrid, ring or hexapod devices. One-staged surgical treatment is performed using the LISS DF plate – an anatomically precontoured locked metaphyseal plate applied as an external fixator. It is originally designed for the surgical treatment of supracondylar femoral fractures. The advantages of the locked plate include preservation of blood supply and better resistance to bending and torsional moments compared to conventional non-locked plate systems, as reported by Wagner (2003). LEP with angle-stable plates is a method that results in effective and safe external biological fracture fixation, termed "biological plating" by Perren and Ganz in the treatment of complicated fractures with soft tissue injury – UPTFs. Through the application of LEP, natural (secondary) bone healing is achieved with the formation of a solid callus within the accepted timeframe combined with easy patient care and uneventful recovery of daily lifestyle. The use of LEP is appropriate in the treatment of elderly patients with advanced osteoporosis.

The advantages of this approach are related to the achieved angular stability of the plate-screw interface, the elasticity of the construct, the quick and easy operative technique, and the lower rate of inflammatory complications compared with traditional external fixation.

The low profile, comfortable design and simplicity of the system make it a promising surgical option. Recently, many authors have presented clinical results demonstrating successful bone healing within generally accepted time frames in the treatment of unstable tibial fractures (Table 4).

Table 4. Comparing results from similar studies with externalized plating and our results.

Parameter / Author	Year of publication	Number of Patients	Indications for External fixation	Bones Involved	Implant Type	Temporary or Definitive	Average Duration On LCP external fixation	Infection %	Nonunion %
Gupta and Parimala (2013)	2013	5	Open fractures	Distal tibia	4.5 LCP	Definitive	15 months	0	0
Sven et al. (2012)	2012	7	Infected nonunion	Distal tibia	4.5 LCP	4 definitive 3 temporary	17.5 Weeks (6-60)	0	0
Woon et al. (2010)]	2010	2	1 Compartment Syndrome, 1 Gustillo grade II open fracture	1 tibial Plateau, 1 open tibia shaft fracture	4.5 LCP	Definitive	6 months (4-8)	0	0
Kloen (2009)	2009	4	Infected Nonunion	1 clavicle 3 tibia	3.5 or 4.5 mm LCP	3 temporary 1 definitive	4 months (2-6)	0	0
Apivatthakakul and Savanpanich, (2007)	2007	1	Bone transport	Tibia	4.5 mm Broad LCP	Definitive	5 months	0	0
Kerkhoffs et al. (2003)	2003	31	9 Open fractures 18 infected nonunion 3 septic arthritis 1 infected pathological n fracture	12 forearm 2 clavicle 4 humerus 6 tibia 4 elbow 1 olecrenon 1 femur 1 shoulder	DCP with nuts and washers	Definitive	12 Weeks (2.23)	2/23 (9) §	4/31 (1)
Ramotowsk+I and Zespol (1991)	1991	1212	850 fractures	191 femur 493tibia 45 humerus 64 radius 52 ulna 5 others ||	Zespol System	Definitive	18 Weeks	NM	44/850 (5)
			445 Nonunions	106 femur 245 tibia 40 humerus 22 radius 31 ulna 1 other		Definitive	21 Weeks	1 (4)	27/445 (6)
Marti and Werken van der (1991)	1991	12	4 open fractures 7 infected nonunion 1 septic arthritis	7 forearm 1 clavicle 1 humerus 2 tibia 1 shoulder	DCP With Nuts And washers	Definitive	NM	2/12 (17)	2/12 (17)
Makelov	2021	18	18 closed fractures w tissue injury of AO IO g	18 tibia	LISS-DF, LISS-PTP	Definitive	21 weeks	0	0

Disadvantages and advantages of the LEP technique

Finally, it is important to mention some disadvantages associated with our proposed treatment approach. The use of LISS plates as an external fixator can lead to complications if optimal axial alignment of the limb is not achieved beforehand. The screws, once locked into the plate, do not allow any further adjustments to the axial alignment of the limb. This finding is confirmed by the experience gained from treated patient included in the study. However, this method can be applied as an adjunctive option for bone transport or bone lengthening in treatment of critical bone defects, bone deformities or limb length discrepancies.

Advantages of the method are :

1. Minimal soft tissue damage, a lower complications rate compared to open reduction and internal fixation of tibial fractures with significantly compromised soft tissue envelope.
2. Due to the low profile of the external fixation plate, it can be easily concealed under the patient's clothing and this makes it more comfortable for them, thus overcoming the disadvantages of standard external fixators.
3. The application of the LEP as a definitive surgical treatment, which avoids immobilization of the adjacent joints and subsequent surgical interventions and hospitalizations.
4. The use of external plate fixation for provisional stabilization is possible, with the option of conversion to definitive internal fixation.
5. The LEP can be easily removed within a few minutes, without anaesthesia, pain or blood loss. Patient is allowed immediately FWB the affected limb.
6. LEP allows additional dynamization of the plate-bone system by removing the screws closest to the fracture, or secondary stabilization by reverse dynamization by inserting additional screws into the plate holes near the fracture zone.
7. LEP is suitable for in-situ osteoplasty and bone transport in combination with a monolateral external fixator.
8. The cost of steel plates and screws is lower than titanium ones.
9. LEP achieves comparable and non-inferior long-term results compared with other surgical methods.

One-Staged Locked Externalized Plating is an attempt to combine the best of locked internal plate fixation and monolateral external stabilization. The technique is fast, minimally invasive, soft tissue sparing, bloodless, simple with low learning curve, inexpensive therapeutic alternative, first applied in our country in 2013 and then introduced by our team into our daily clinical practice.

Our results attempt to demonstrate that LEP has the characteristics of active locked elastic fixation and one-staged biological fracture stabilization, and is an operative approach with functional and clinical outcomes comparable to the standard surgical methods. This makes the method safe and being at a low-risk when strict inclusion criteria and operative technique are followed.

For emergency trauma and multiple trauma patients, the method offers a successful option for life-saving single-staged fracture stabilization or early individualized care. The method can also be successfully applied to adult unstable patients to facilitate their care and early rehabilitation, as well as to patients with low IQ and those refusing surgical interventions due to religious and/or personal beliefs.

The method is applicable in countries with a low standard of living as well as in natural disasters, military conflicts and terrorist attacks.

The disadvantages can be summarized as follows:

1. Inability to adjust the plate position after locking of the screws, which requires sufficient axial alignment before the final locking of the plate.
2. Preset and fixed direction of the screws - monoaxial, angle-stable stainless steel screws.
3. The use of steel locking screws could increase the risk of subsequent loosening and superfitial or deep infection.

VIII. Conclusions

1. UPTFx present an extremely heterogeneous group of fracture configurations associated to varying degrees with soft tissue injury and/or open skin wounds and open fractures. This diversity is reflected in the number of classification systems proposed, particularly for fractures with an intra-articular involvement. They are caused by high-energy trauma resulting in severe closed or open fractures with soft tissue injuries, multiple musculoskeletal trauma, requiring emergency DCO action for a life-saving fracture stabilization

2. Classification heterogeneity carries over to treatment methods. The existence of several possible operative techniques and methods of fixation demonstrates that there is no single universally accepted approach guaranteeing success and accompanied by negligible complications. The large number of possible combinations of fracture configurations and local soft tissue injuries, together with the accompanying systemic injuries, determines the "personality" of the fracture and requires an individualized approach for each patient.

3.The evolution of treatment methods started from conservative immobilization treatment and evolved to the method of open reduction and internal fixation introduced by AO in the 1960s. Next step was the transition to minimally invasive plate osteosynthesis methods (MIPO) and intramedullary osteosynthesis with nails (IMN) and or their analogues using external fixators. These modern approaches allow earlier mobilization and loading of the operated limb. The goal of these treatment modalities is to minimize the surgical damage to bone and adjacent soft tissues and to reduce the additional injury to the periosteum from the contact with an internal fixator. The current trend is toward relative fracture fixation and secondary bone healing. Thus, the preservation of soft tissue and bone perfusion (biologic stabilization) dominates over the aim to achieve "ideal" fracture reduction and alignment, for the cost of compromised perfusion. The third evolutionary direction is towards the choice of a treatment method that minimizes hospital stays and therefore costs, as well as continued treatment and rehabilitation in an outpatient clinics, called “day-one” surgery and outpatient trauma care.

4. Combining the AO principles of anatomic reduction and stable fixation in the treatment simple articular component with the principle of relative stability applied to the metadiaphyseal fracture zone allows natural bone healing with optimal interfragmentary motion. Application of both principles allow early active rehabilitation with subsequent controlled FWB.

5. There are still unsolved issues in the choice between staged and one-staged approach in patients with severe soft tissue injuries in the fractured zone, with or without ipsilateral femoral fractures and multiple trauma. Although the staged approach has been accepted as a gold standard, its main disadvantage is delayed mobility of the affected joints, due to the temporary spanning external fixation, prolonged patient's bedridden position, and the increased risk of joint stiffening, until the time for definitive fracture fixation. A series of surgical interventions with prolonged hospital stay are required. The surgical interventions are time-consuming, require specialized instrumentation, long learning curve and a highly skilled team. Another major problem with the staging method is the timing for surgery. The choice is made after an assessment of the patient's general condition and the severity of soft tissue injury.

In conclusion, the unstable metadiaphyseal tibial fractures represent a morphologically heterogeneous fracture types, in the context of multiple trauma, mostly caused by a high-energy mechanism. Combined with significant comminution, instability and metadiaphyseal separation in the proximal aspect of the tibia, they can be associated with fractured articular component, with or without impaction and joint cartilage step-off.

The severity of the intra-articular injuries and the skin condition of the covering envelope are the most important factors for determining the treatment outcome. These specific features require careful pre-operative planning, appropriate timing and instrumentation. Often the consequence of the standard treatment is residual pain, various functional problems and early onset of arthritis in the affected joint.

Unstable fractures of the proximal tibia continue to be a unsolved problem in modern trauma care, due to high risk of complications and lack of a unified surgical concept for their treatment.

Multifragmentary fractures with marked soft tissue injury, with multiple trauma, are indicated one-staged locked externalized plating. Intra-articular fractures of the proximal tibia with severe comminution and impaction are contraindicated for the proposed technique. The analysis of prognostic factors shows that in unstable proximal tibia fractures the main influence on the outcome is the age of the patient and the type of fracture while the severity of soft tissue damage does not negatively influence the healing time in proximal tibia fractures

When the indications are strictly followed, LEP provides excellent results. LEP is a method with high biological efficiency and safety, confirmed by the biomechanical analysis and by the low rate of clinically confirmed complications.

IX. Contributions of the dissertation

1. Original:

Methodological: Practical guidelines and an operative algorithm for the application of novel surgical technique for operative minimal invasive treatment of unstable tibial fractures in emergency settings are outlined.

Applied: The advantages of LEP in the surgical treatment of unstable tibial fractures compared to traditionally accepted surgical approaches in terms of bone healing, clinical and functional outcomes and associated complications, as well as patient quality of life have been established.

Theoretical: Based on prospectively followed clinical case series, a three-dimensional virtual biomechanical finite element model was created, providing a scientifically valid conclusion regarding the favorable biomechanical conditions for secondary bone union by locked one-staged external stabilization in unstable metadiaphyseal tibial fractures.

2. Confirmatory:

The optimal limits and values of the parameters determining the required relative stability for a sum fracture gap size of 20 mm, definitively fixed with an active locking one-stage external stabilization, have been experimentally established and clinically confirmed by the finite element analysis (FEA) method.

3. With clinical value:

A technically simplified, low-risk, single-staged operative technique capable of preventing long-term complications and reducing long-term disability in these severe complex injuries has been developed and introduced as a treatment modality in the clinical practice.

X. LIST OF SCIENTIFIC PUBLICATIONS

This paper is based on the following articles printed in the specialized literature and presentations on scientific meetings:

Publications and articles in refereed journals and proceedings:

1. Makelov B, Apivatthakakul T, Gueorguiev B., Definitive external plate stabilization with metaphyseal locked plate LISS-DF in multiple trauma patient with "Floating knee" injury. Bul J Orthop Trauma. 2019,56(1):12-20

2. Makelov B, Silva JD, Apivatthakakul T, Peeva K, Kavrykov T, Externalized metaphyseal locked plating of complex proximal tibial fractures - clinical and biomechanical outcomes. J Science & Research. 2019,3(1):55-66.

3. Makelov B, Silva JD, Apivatthakakul T, Gueorguiev B, Varga P, Externalized locked plating of unstable high energy proximal tibia fractures - a FEA Study,. Bul J Orthop Trauma. 2019,56(3):124-138.

Participation in Bulgarian and international scientific forums (congresses, conferences, symposia) with papers printed in full-text proceedings.

1. Paper-presentation:

27.09-29.09.2018 - BOTA (Bulgarian Orthopaedic and Traumatological Association) - Annual Conference with international participation Tryavna - 2018 -.

Single-stage external stabilization with locked metaphyseal plate in multifragmentary fracture of proximal tibia.

Authors. **Makelov,B**, Prof. Dr.Stoyan Kirkovich, Stara Zagora Bulgaria**, Gyeorguiev,B** - Project Leader - ARI/AOResearch Institute Davos, Gen. Secretary of EORS, Switzerland**, Apivattakakul Theerachai, prof.** - Chiang Mai University Hospital, Thailand.

2. Poster presentation:

10.10-13.10.2018, Montreal OWC 2018: at the 39th SICOT World Congress,(World Congress of Orthopaedics and Traumatology)

Abstract No.49457:

SUPERCUTANEOUS LISS PALTING OF THE PROXIMAL TIBIA IN MULTIPLE TRAUMA PATIENT WITH 'FLOATING KNEE' INJURY.

Authors. **Makelov** Biser, (University Hospital 'Prof St Kirkovitch'), Apivattakakul Theerachai (Chiang Mai University Hospital), Presenter: GUEORGUIEV Boyko (AO Research Institute Davos) Topic: Trauma - Polytrauma Management

3. Report-presentation:

05.06.2019 EFORT 2019 - LISBON, PORTUGAL.

Externalized locked plating of unstable proximal tibia provides sufficient stability under early partial weightbearing.a finite element study.

[1]Makelov B., [2]Silva D.S., [3]Apivatthakakul Th., [2]Gueorguiev B., [2]Varga P.

1. University Multiprofile Hospital for Active Treatment 'Prof.Stoyan Kirkovitch', Stara Zagora, Bulgaria, 2. AO Research Institute Davos, Davos, Switzerland, 3. Chiang Mai University Hospital, Chiang Mai, Thailand

4. Paper-presentation:

EORS 2019/Eugrean Orthopaedic Research Society/-MAASTRICHT, - 04.10.2019

One-staged external locked paltering of unstable proximal tibial fractures gurrantee stability for natural bone healing under partial weightbearing. A FEA-model.

[1]B Makelov, [2]B Gueorguiev, [2]P Varga

1University Multiprofile Hospital for Active Treatment 'Prof Stoyan Kirkovitch', Stara Zagora, Bulgaria, 2AO Research Institute Davos, Davos, Switzerland

5. Report-presentation:

27th International Scientific Conference of the Union of Scientists- Stara Zagora- 07.06.2019: Results in the use of locking external fixation in multifragmentary metaphyseal tibial fractures can provide the necessary stability for callus formation under partial loading.3D finite element model.

[3]Makelov B., [2]Silva D.S., [3]Apivatthakakul Th., [2]Gueorguiev B., [2]Varga P.

1. University Multiprofile Hospital for Active Treatment 'Prof.Stoyan Kirkovitch', Stara Zagora, Bulgaria, 2. AO Research Institute Davos, Davos, Switzerland, , 3. Chiang Mai University Hospital, Chiang Mai, Thailand

6. Poster presentation:

14th Congress of BOTA-Bulgarian Orthopaedic and Traumatological Association: 05.10.19;

One-stage locking external fixation for unstable proximal tibial fractures can provide the necessary stability for early partial loading. 3d-model by the finite element method.

[3]Makelov B., [2]Silva D.S., [3]Apivatthakakul Th., [2]Gueorguiev B., [2]Varga P.
1. University Multiprofile Hospital for Active Treatment 'Prof.Stoyan Kirkovitch', Stara Zagora, Bulgaria, 2. AO Research Institute Davos, Davos, Switzerland

7**. Paper-presentation:**

EORS 2020/28th Annual Meeting of The Etzgorean Orthopaedic Research Society/Izmir-Turkey/First Virtual Congress, - 17-18 September,2020

"Can unstable proximal tibial fractures with soft tissue injury be successfully treated with external locked plating ?"

[1]Makelov B., [2]Gueorguiev B., [3]Apivatthakakul Th.,
1. University Multiprofile Hospital for Active Treatment 'Prof.Stoyan Kirkovitch', Stara Zagora, Bulgaria, 2. AO Research Institute Davos, Davos, Switzerland, 3. Chiang Mai University Hospital, Chiang Mai, Thailand.

Participation in national projects

Thracian University, MF: Project №5/2019.

Topic: FEA computer simulation model for the application of a locking LISS DF plate for one-stage external stabilization in unstable proximal tibial fractures.