UNIVERSITY OF MEDECINE AN PHARMACY OF CRAIOVA

DOCTORAL SCHOOL

PhD THESIS

THE PLACE OF METAL OSTEOSYNTHESIS IN OPEN LEG FRACTURES

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INTRODUCTION:

Open leg fractures were and will remain the most common open fractures far from other locations, which is why they have become a "classic type" description of these lesions.

The history of open fractures in general, and the open leg fractures in particular, is extremely rich and the progress throughout the clinical, pathological and especially the therapeutic field, marks the fundamental stages of this history. Fractures have always existed with a high frequency and severity in wars and natural disaster (earthquakes, landslides, volcanic eruptions, floods). "To write a thorough history of the treatment of these fractures, is to review the history of surgery" (Sc.Popescu 1934)).

Their treatment is complex, very much discussed, and controversies are still numerous. In the last five decades, trauma and prestigious plastic surgeons have published extensive clinical and experimental studies, bringing classifications and fundamental explanations for the adoption of the most appropriate treatment.

As a result of an extensive experience, the AO School has developed a practical code for approaching the treatment of open fractures. The code includes eight successive steps or stages witch are well known and I will not insist upon them. I will only referto the fifth stage, namely: to stabilize the open fractures by primary osteosynthesis. The Code of Practice for open fractures, developed by the AO School, applies perfectly to open leg fractures, in particular for open tibia fractures.

In type I and type II open fractures and sometimes in type III A, primary osteosynthesis is performed according to the same methods as in closed fractures. In type III open fractures III B and C, primary osteosynthesis with external fixator is the only recommended method, because it provides the mechanical and biological stabilization of **the focus** (nu inseamnacevrei) by aligning the bone and the soft tissues. This alignment favours venous return, reduces edema, stimulates the local neovascularisation and prevents a number of sequelae at the soft tissues'level.

The primary osteosynthesis of open fractures with external fixator, ensures a high percentage of good and very good results, but involves a rigorous technique, quite particular application and presents some risks that must be strictly avoided. The results are even better when the primary osteosynthesis with external fixator is converted, after one or two months, in intramedullary nailing (sequential osteosynthesis).

In a 13-year period (2001-2013), we registered 1617 cases with a diaphyseal fractures of the leg amongst witch, 568 isolated fractures of the tibia (37.5%) and 1049 fractures of both bones (62.5%). The series of 1049 fractures of both bones included 755 cases with closed fractures (75.5%) and 245 cases with open fractures (24.5%).

In this personal statistical and clinical study, two lots of open tibia fractures will be analyzed. The first lot includes "benign", open fractures which can be treated by osteosynthesis with a the same means as closed fractures (brooches, intramedullary nail,screws and plates) and the second lot includes severe and complex open tibia fractures,where external fixators represents the best solution.

In the finite element experimental study, I intended to show the relationship between the direct production mechanism and the severity of open fractures, both in bone lesions and soft tissues injuries.

GENERAL PART or **STAGE OF KNOWLEDGE** is theoretical and contains the following chapters:
- Introduction
- Elements of descriptive anatomy of the leg skeleton , leg bone joints, leg muscles.
- Data of topographical anatomy with the 3 regions anteroexterna, anterointerna, posterior.
- Particularities of consolidation in open tibia fracture.

Wide open tibia fractures pose particular challenges by seriously damaging the local biological conditions necessary for consolidation. Immediately after the accident, the severity of soft tissues injuries, possibly in the context of polytrauma, can even jeopardize lives. The destruction of soft parts is the first element that disturbs the local mechanisms of consolidation. Immediate bone fixation in open tibia fractures stabilizes the bone lever and provides optimal condition for recovery of soft tissue. In turn, the healing of injured soft parts largely ensures callus formation and maturation. Open tibia fractures treatment aims to stimulate consolidation’s natural factors.

The consolidation process of open tibia fractures is influenced by two factors: the specific biological condition of the fracture type and the biomechanics condition performed during the selected osteosynthesis. Optimal biological condition for the healingof open tibia fractures involves: very good blood supply at the outbreak, absence of infection, the intervention of certain factors inducing bone formation, the action of some external noninvasive stimuli and metallic biomechanics fixation with osteoinductive effect. Any method of osteosynthesismustspare as much as possible the local vascularization, already affected by the injury (Muller et al.)

- Steps to open tibia fractures

Treatment of open tibia fracture, as in any other open fracture has a twofold purpose:
• bone consolidation and
• healing of soft tissue injuries

In other words, bone and skin lesions should be treated simultaneously as earlier and completely as possible. The AO / ASIF group established a code of practice for the treatment of open tibia fractures. This code contains eight steps, or successive stages:
• emergency treatment;
• complex initial evaluation to detect possible life-threatening injuries;
• establishment of antibiotherapy even in the emergency room and for a period of 2-3 days;
• the immediate and wide debridement of the wound associated with a copious irrigation, and in severe open fractures, debridement resume after 24-72 hours;
• stabilization of the fracture;
• wound remains open for 5-7 days;
• earlier cancellous bone;
• recovery of broken leg.
- Stabilization of the bone:

The stabilization of primary fracture site practiced immediately after debridement, involves a "biological stabilization" of soft tissues neighboring the fracture.

It prevents lesions to soft tissues and to the neurovascular packages, improves regional vascularization, restores the anatomic bone, muscular and neurovascular positions, decreases inflammatory stimuli, pain, edema and muscular contractions, provides easy access for wound care, allows early mobilization and decreases the risk of pulmonary complications.

However, there are controversies regarding the introduction of reaming preceding the intramedullary nail, especially in open fractures of type II and III. It is currently recommended to avoid in these open fractures intramedullary reaming and the authors discuss the benefits of nail locked in type III open fractures compared to external fixator.

Another current attitude is sequential osteosynthesis, which consists of initial osteosynthesis with external fixation followed by intramedulary nail osteosynthesis locked in open fractures type II and type III. The smallest infection around the fixator contraindicates the switching to intramedularyosteosynthesis. Keeping the external fixator over 21 days increases the risk of secondary infection (osteitis)

According to the modern conception, the intramedullary osteosynthesis is the first option in all fractures,if possible.

In type I open fractures, treatment is similar to closed fractures treatment: cast immobilisation, nail locked osteosynthesis without reaming, Ender or Küntsher rods.

In type II open fractures the use ofintramedularynail without reaming, Ender or Küntscher rod, is indicated.

In type II open fractures, surgical treatment consists of: external fixators nontransfixiant (external fixator 30-45 days followed by intramedullary nail osteosynthesis without reaming) .

From a therapeutic standpoint, the classification of open tibia fractures features two absolutely distinct groups:

- simple open fractures: type I, type II and type IIIA
- severe open fractures: type IIIB and IIIC type

Simple open fractures involve similar treatment as closed fractures.

However the wide open fractures of the tibia (severe fractures) have three therapeutic and evolutionary modalities:

- successful rescue attempt may have satisfactory or unsatisfactory functional results, the unsatisfied patients might require late secundary amputation ;
- unsuccessful rescue attempt with evolving sepsis requires early secondary

amputation
● primary amputation

PERSONAL CONTRIBUTION:
I. STUDY CLINICAL AND STATISTICAL:

The personal contribution has, in fact, two main objectives namely, intramedullary nail fixation and plates with screws, on one hand and primary fixation with external fixators, on the other hand.

Table I presents a series we have studied, of 245 cases with open tibia shaft fractures in adults, (isolatedor in cases of open fractures on both bones of the leg).

TableI. Open tibia shaft fractures

Age Group	M	F	Total	
25-34 years	24	5	29	206 cases (84,1%)
35-44 years	35	18	53	
45-54 years	61	17	78	
55-64 years	32	14	46	
65-74 years	13	12	25	
75 years and over	9	5	14	
Total	174 (71%)	71 (29%)	245	

This table shows the distribution of cases by age and sex. The highest frequency stands between 25-64 years with 206 cases (84.1%), the most active period of life, with negative consequences, professionally and socially. The frequency of open leg fracture is about two and a half times higher in males (71%) compared to females (29%). Other authors have found a greater frequency.

Table II, include the distribution of cases in our series, based on the classification by Gustilo and Anderson.

Table II

type of fracture	Number of cases
type I	72
type II	68
type III A	57
type III B	36

type III C	12
Total	245

After investigating this table, it appears that we have registered 140 cases with open fractures type I and type II (57%), 105 cases with fracture type III A (57 cases), type III B (36 cases) and type III C (12 cases). The relatively small number of serious open fractures (type III B and especially type III C) can be explained by the fact that, often, these fractures are part of the clinical picture of poly-trauma and are directed towards hospitals with special services and equipment.

In our series, of 245 open tibia fractures, according to the time the fracture has been open and the importance of soft tissues leisons (the principal element)

PERSONNEL STATISTICAL STUDY:

In a 13-year period (2001-2013), we recorded 35 cases of open tibia fractures, which were resolved by different methods of osteosynthesis, excluding external fixators.

The predominant osteosynthesis, was intramedullary osteosynthesis (20 cases), amongst which osteosynthesis without reaming with lock static (10 cases), with lock dynamic (2 cases), nail fixation reamed without blocking (2 cases), Ender flexible rods (6 cases). As a result, the intramedullary osteosynthesis with static or dynamic nail and rods blocked or without blocking, as well as elastic rods Ender was used in most cases (57.14% of cases).

In second place, are the screwed plate fixations with or without isolated screws (11 cases - 31.4% of cases). In a type II open fracture with long trajectory spiroid we practiced osteosynthesis, at the opened outbreak, with two screws crossed and, in 3 cases, minimal osteosynthesis with cross brooches K.

Osteosynthesis with external fixators in open tibia fractures

Primary osteosynthesis with external fixators is a good solution in case of severe open tibia shaft fractures, sometimes even the exclusive solution, especially on open fractures type III B and III C.

The use of external fixators is based on a rigorous inventory of soft tissue injuries and fracture site, on the prognostic and the evolutionary perspectives.

Primary osteosynthesis with external fixator holds the first place in our statistics as well as in many others.

Along with many other authors, I insist on the need of converting external fixator to intramedulary osteosynthesis (sequential osteosynthesis) after a period of 30-60 days

II. EXPERIMENTAL STUDY ON DIRECT MECHANISMS ON OPEN LEG FRACTURES

This experimental study was performed using the Finite Element Method (numerical method of calculation) and it is focused on diaphyseal fractures of the leg, due to the direct mechanisms, considering a body impactor in frontal plane, striking the leg, from outside to inside and vice versa, causing fractures of the fibula and tibia.

For this experimental study, we used general computing program FEM ANSYS / LS-DYNA. The mathematical model used describes the configuration of the two bones of the lower leg in orthostatic position and the soft tissue of the lower leg namely :skin, subcutaneous tissue and muscle groups of the lower leg along with interosseous membrane.

CONCLUSIONS:

1. Open leg fracture is the most frequent amongst open fractures.
2. The gravity of open leg fractures is related to the solicitation of this segment, to the fact that the tibia, which is the most often affected, is superficial and exposed on a good part of its length and it also, of course, closely linked to the biomechanics of this particularanatomical segment.
3. On the other hand, the alarming increase in the frequency and severity of modern accidents, mainly traffic and work accidents, involve, most often, high-energy trauma, producing extremely serious injuries to the lower leg bone and soft tissues that wrap them.

4. It must be underlined that the gravity of open lower leg fractures (tibia) is determined firstly by the extent and the depth of soft tissue lesions, which

require the participation of the plastic surgeon.
5. When soft tissue injuries, are benign (type. I, type II,sometimes even type III A), their treatment is simple with very good results.
6. When soft tissue injuries are more severe (type IIIB and IIIC), the treatment is more complex the and the results often disappointing.

7. For a more accurate evaluation of bone lesions and soft tissues injuries, numerous classifications have been developed, amongst which Gustilo-Anderson, adopted in this study.
8. Fair and rigorous classification of our cases according to this classification allowed us to opt for the most appropriate treatment and evaluate the quality of the obtained results, in comparison with the most complete scores reported by the literature.
9. In terms of clinical and statistical research, we analyzed two surgical techniques we have used according to the severity of injuries namely:osteosynthesiswith means used in case of closed fractures and osteosynthesis with external fixators.

10. Considering the direct mechanisms producing open tibia fractures, we have developed afinite element experimental study for the opening mechanism, from the inside out and outside in, because the type of the opening and the severity of soft tissues injuries is closely linked to these mechanisms of production.
11. In tibia fractures with simple open wounds and relatively moderate soft tissue damage neighboring the fracture site, osteosynthesis is indicated using the same means as in closed fractures: endomedular rigid rods with or without reaming, with or without blockage, elastic rods.

12. Our series includes 35 cases with open tibia fractures, 33 cases with type I and II, one type IIIA case and one type IIIB Gustilo case.
13. Intramedullary rods fixation was used in 56.7% of cases, with static and dynamic blocked nail, without reaming, rarely with an unlocked but reamed rods with flexible Ender rods.
14. Plate fixation screwed takes the second place, at some distance. Note that in some cases, we accomplished compacting with interfragmentaryMüller device.

15. Thick transplantar K brooches are rarlely useful.
16. With the increase in severity of soft tissue damage, these methods of osteosynthesis gradually lose their interest and external fixators become the optimal solution.

17. Adequate equipment and extensive surgical team experience are necessary factors in achieving fixation of open fractures with limited soft tissue damage.
18. Our results were very good for 90% of the cases. In one case, one month after surgery, one nail brokeandosteosynthesis with a screwed plate was required. Consolidation was achieved after almost five months. In two other casesa local sepsisoccurred which required repeated write-downs. No osteitis occurred.
19. Typically in type III A (rarely), type III B and type III C open fracturesa properly applied external fixator spares, to a considerable extent,endosteal and periosteal circulation which is absolutely necessary for consolidation.
20. Through numerous possibilities for positioning, compacting and stretching, the external fixators allow to a certain extent, appropriate gestures of plastic surgery in case ofsoft tissues injuries.
21. In open tibiashaft fractures the external fixator provides indisputable advantages: simplicity and speed of installation, the possibility of multiple adjustments and total load stability.
22. The disadvantage of external fixators have little significance: easy physical discomfort, less stability of some types of fixators which requires loading cautions, especially on open comminuted fractures with severe soft tissue injuries.
23. Circumferential osteolysis, aseptic or sepsis, followed by the mobilization of sheets and mounting instability leads to the replay of osteosynthesis, delays of consolidation or pseudarthrosis.

24. When soft tissue lesions are definitively resolved, primary osteosynthesis with external fixators should be a previous step in endomedulareosteosynthesis

25 In the 100 open tibia shaft fractures in which we performed primary osteosynthesis with external fixators, we achieved good or very good results for 87% of the cases. We obtained unsatisfactory results for 13% of the cases for which secondary difficult interventions were necessary and the results were questionable.

26. The elements generated for this study can be improved by modeling the foot bones (ankle) and placing ligaments for connection between them that could represent a complete model for studying the lower limb in car accidents.
27. Material characteristics and laws of the material used in finite element

study simulates the actual behavior of bone and soft tissue. It does not work as well formaterial muscle failure criterion which has a complex behavior. This topic can be developed in future research works.

28. The values obtained in this study, for maximum deformation energy (breaking) of the tibia and fibula as well as maximum displacement (arrow bending) correspond to values determined,measured in other papers.

29. Maximum internal deformation energy, taken by tibia and fibula is higher by about 10% when we have strong muscles, preloaded (event. 1.2) compared to relaxed muscules (caz.1.1);

30. In case 1.2 (musculature preloaded), the internal energy for deformation of the skin layer is very high compared to those from the 1.1 (musculature relaxed), where the skin layer does not participate in cushion (close to zero to fracturing two bones);

31. In case 1.1 the line of fractures the tibia and fibula appears at the same level as the contact between the impactor and tibia. For case 1.2, fracturing line is moving (to the area of contact among tibia and impact) approximately 40 mm towards the distal tibia;

32. At the inside to outside impact (case 1), soft tissue (skin, muscles) are heavily destroyed. Instead, if the impact is from the outside to the inside due to tibia fracture, the soft tissue are perforated and penetrated by the tibia (open fracture).

33. If the impact is from the outside to the inside (case 2), tibia and fibula fracture is due to the transfer of mechanical energy from the impact to the bones, not through direct contact but through the muscles.

34. If the impact is from inside to outside (case 1), muscular tonus influence the mechanism of fracture ofthe tibia and fibula, as follows:

- If the muscle is relaxed (if 1.1), much kinetic energy of the impactor is taken of by passive components as muscle and transferred within the footprint of to the fibula, by the interosseous membrane and to the extremities of tibia, the remaining mechanical energy is transferred by direct contact to tibia which succumb first;
- If muscle tone has firmly tensioned (caz1.2), the ability to dissipate the energy decreases, fibula and tibia so that are more claimed, and after fracture (break first and then tibia fibula), muscles take over the remaining mechanical energy.

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