University of Medicine and Pharmacy CRAIOVA

DOCTORAL THESIS

ABSTRACT

DIAGNOSTIC AND TREATMENT ALGORITHM OF TIBIAL SHAFT FRACTURES, CLINICAL AND EXPERIMENTAL STUDY

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Table of contents

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Introduction

The diaphyseal fractures of the leg are the fractures which matter for one or both bones at a diaphyseal level. The tibia interests the most, the tibia fractures being 20% from all the fractures; the superficial situation of the bones of the leg (the anterior-medial surface and the inner ridge of the tibia being covered only by teguments and fatty tissue) makes them more vulnerable at the direct impact trauma. They can happen isolated or in the polytrauma and they represent another important public health problem with important socio-economical implications because of the disabling character of the disease determined, on the one hand by the severe allergic syndrome and on the other hand by the immobilization or the prolonged recovery time, and also by the characteristic sequelae: joint stiffness, muscular atrophy, persistent oedema, spotted osteoporoses of the metatarsal (the Sudek-Leriche syndrome), the algo-neuro-dystrophic syndrome, which in their turn need a supported treatment, sometimes for a long time.

The treatment of the diaphyseal fractures of the leg is complex, an orthopedic treatment (immobilisation in a cast) and/or a surgical one (osteosynthesis with locked, unlocked or elastic intramedullary rod; plaques with screws, external fixators); when you choose which terapeutical methods you should use you should be careful at the morpho-pathological characters of the fracture (number, premises, the type of the fracture, etc), the age, the general state of the patient, the presence of the shock, especially if the fracture is part of a polytrauma and not the least the logistics of the service and the expertise of the surgical team, who directly influence the results.

A very important element, which influences the consolidation type, the evolution, the prognosis, the functional recuperation and the restoration into work of the patients with diaphyseal fractures of the leg, is the type of the materials and the osteosynthesis technics. The clasical intramedullary rods used at the fractures of the tibia have important advantages, as the orientation, the handling and the complicate positioning into the bone and, in the same time, the difficult positioning of the distal screws using the guide of the classical rod.

Also, all this maneuvers can lead to errors or to additional holes into the tibia, causing the decrease of the bone's resistance and in the same time to the extension of the surgical intervention for the bones reconstruction. The extension of the orthopedic surgery can lead, also, to an additional irradiance of the medical stuff and that of the patient.

Based on the above, we conducted a prospective and retrospective complex statistical and clinical experiment following the objectives:

-the results evaluation of the surgical treatment of fractures of the leg depending on the fracture type, the surgical procedure and the used material for the osteosynthesis;

-the identification of the most used material for the osteosynthesis;

-the identification of the average time of the consolidation depending of the osteosynthesis material used;

-the improvement of the existing rod with lock: easier installation and less radiation to the patient and the physician.

To achieve this ultimate goal, we conducted experimental studies and virtual analyses from the idea to design more innovative models of intramedullary rods to eliminate the disadvantage of using orthopedic screws. All the three innovative models made had one basic principle: the fixing of the rod to be made in the tibial medullary canal by using different mechanisms and metal components.

We wish in this way to thank Mr. Assoc. Prof. Dan Grecu, Head of the Orthopaedic Clinic in the Craiova Emergency County Hospital, which allowed us to use the clinic's clinical trial and generously offered us tips and knowledge useful throughout the research and we also bring warm thanks to Mr.. Popa Laurentiu Dragos, ph.D, Associate professor from the Faculty of Mechanical

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GENERAL PART

It contains the following chapters:
Notion of bone anatomy and physiology:

-elements of compact functional anatomy of the skeleton leg (tibia, fibula, joints, static calf, leg biomechanics);

-structure long bones, bone physiology elements.

Consolidation of fractures;
Diaphyseal fractures of the leg:

-ethiopatogeny, production mechanism;

-classification of the diaphyseal fractures of the leg;

-diagnosis (clinical diagnosis, laboratory diagnosis);

- the treatment (surgery).

Complication.

SPECIAL PART

CLINICAL STUDY

The diaphyseal fractures of the lower leg (fractures that interest one or both bones at the diaphyseal level) remain a major public health problem , with important socio-economic implications because of the crippling character of the disease caused, on the one hand, by the severe pain syndrome and on the other part by the immobilization or prolonged recovery time and the characteristic sequelae : joint stiffness , muscle atrophy, persistent edema, osteoporosis tarnished metatarsals (Leriche syndrome - Sudek) , algo - neuro- dystrophic syndrome , which in turn require a sustained treatment, sometimes longer.

They are the most common fractures: quoted in the literature with around 20 % of all fractures (23% in personal study , with an average of 107 new cases / year) , most often interest the decades 4 and 5 (45 % of the studied cases studied) , predominantly in males (64%) , the explanation being that these patients are the most exposed through their direct involvement in professional activities with the highest risk. As regarding the area of origin , the predominance of the patients from the rural areas (60 %) somewhat contrary to the data of 20 years ago , when large existing industries and building sites concentrated the population in the industrial, urban environment, more exposed to accidents of all categories. The tibia is the most frequently concerned, Its superficial posiiton (surface anterior- medial and anterior crest of the tibia are covered only by skin and fat) making it more vulnerable to direct impact trauma .

The circumstances of production were varied , most of the tibial diaphyseal fractures were recorded in the personal study after falling from the same level ((214 cases , 40 %), followed in order by traffic accidents (135 cases , 25%), local trauma direct , falling from a height , physical , animal aggression , indirect trauma , industrial accidents and other causes. They can occur in isolation (86%) in polytrauma (11%) or in polifractured (3%) , of particular importance especially in terms of treatment , because the polytrauma , the therapeutic gestures must be ranked according to the vital risk of the lesions associated to the fracture .

By definition in the polytrauma there are at least two or more serious injuries, of which at least one life-threatening immediate or at distance. In accordance with the standards established by the emergency service of the University of California an injured person with musculoskeletal injuries can be classified as multiple trauma if it meets the following criteria : the victim of a severe trauma , presents at least two major injuries , one immediately life-threatening or at distance two systems minimum, presents unstable fracture of a long bone , of the pelvis , and of the spine.

The clinical diagnosis of the diaphyseal fractures of the tibia do not raise special problems; it was based on the classic signs subjective and objective ones of probability and certainty among which the functional impotence, the region deformation, the high pain in the focus of fracture , crepitus and the clicking of the bone and the bone continuity interruption were present in 90 % of the cases. The rapidity with which the patients arrived in the emergency department depended at a large extent on the timing, how fast the ambulance services arrived at the place of the accident and on the distance to the hospital and less patient .

The simple radiography mandatory in two incidences (front and profile) confirms the diagnosis of the fracture and sets exactly indispensable morphological parameters for the therapeutic decision: the number of the broken bones, the level and the type of the fracture.

Found in almost equal proportions (270/266) in the two lower members the diaphyseal fractures take interest into the two bones of the calf in most cases (89 %) compared with isolated diaphyseal fractures of the tibia (59 cases , 11%), isolated diaphyseal fractures of the fibula did not receive surgical treatment but only orthopedic treatment and were not included in the study group . 1 / 3 lower part of the diaphysis is the location of choice (44%) , decreasing the incidence of fractures to the upper end of the tibial diaphyseal (21% at the reunion of1.3middle with lower1/ 3 , 20 % at the level1/3 middle , 3% at the reunion of 1/3 middle with 1/3 high and 5 % in the upper 1/3) . The tibial diaphyseal fractures associated with fractures of the fibula in 75 % of cases, the fracture was at ½ of the lower leg bones for both, while the combination of tibial distal fracture to peroneal proximal fracture was found only in 25 % of the double fractures cases. Three types of fracture dominated the studied group: the unifocal fractures with fragment displacement (61.00 %), comminuted fractures (36.19 %) and spiroid fractures (29.47 %).

The situation of the tibia just below the skin makes that the percentage of open fractures in the calf to be much higher (21.64 % in the personal study) than in other long bones, well protected by the muscles. The analysis of the open fractures revealed the presence of severe open fractures as theose named Gustilo -Anderson type III - Mendosa, requiring complex medical and surgical treatment in 34 % of cases, the rest being of type I and II fractures with minor skin lesions without large skin flaps or big avulsia of the skin with less contamination and therefore minimal risk of infection.

The treatment of the diaphyseal fractures of the lower leg is complex; orthopedic or, and surgical(osteosynthesis with blocked centromedular stretches, unblocked or elastic ones plaques with screws, external fixing device) while choosing the therapeutic methods, we have to have in mind the morphological characters of the fracture(number, premises, type, area), age, general condition of the patient, even if the fracture is part of a polytraumatism; and not the least, the logistic of the service and the surgical team expertise that can, without any doubt, influence the results.

The surgical indications were established based on the following criteria: instable fractures, which have an absolute indication the surgical treatment, stabile fractures, but where the orthopedic treatment would go at a high rate of local or general complications, fractures which present the risk of secondary displacements in gypsum as a result of the orthopedical treatment.

The osteosynthesis material was chosen based on the type of the fracture: the Kuntscher rod for the fractures with two fragments, the rod with lock for the comminuted fractures or the rod with a blockage, two Ender rods in a secant bow and immobilization in femuropodal gypsum device or jam rod (with blockage) in the fractures 1,3 lower part of the diaphysis where there is the marrow channel

and the Kuntscher rod is not tight anymore in the distal channel and transcalcaneo-astragalo-tibial brooch together with immobilization in femuropodal gypsum device for the diaphysis distal fractures associated with metafisar fractures.

The route of approach varies depending on the osteosynthesis material used: internal paratuberositar for the Kuntscher rod, retrotuberositar for jam rod and paratuberozitar internal and external for Ender rod. In the studied group, the Kustcher rod was used in most of the cases (73%, followed in order by Ender rod in secant bow), the rod with lock, the external fixator, screws, brooches and others (wire serclaj, etc.).

In the developed countries the rod with lock is mostly used for the intramedullary osteosynthesis, because it provides a very good stability of the fragments and it doesn't require additional plaster immobilization which gives to the patient a higher comfort and prevents complications as knee joints and ankle stiffness, prevents secondary osteoporosis after restraint and the appearance of the algoneurodistropphic syndrome.

In Romania, due to the limited financial possibilities, the rod with lock is used only in special cases, like comminutive fractures were other cheaper material for ostheosintesys can't be used.

We mention that in our personal study the rod with blockage was used only in the comminutive fractures were other cheaper material for ostheosintesys could not be used due to the economical reasons.

In economically developed countries they are no longer used the Kuntscher rod, the Ender rod and the tibial shaft fixation brooches because they require additional femuropodal immobilization in plasture device and the patient can perform auxiliary support walking with partial charge on the late osteosythesized member, which creates less comfort for the patient.

That is the reason why only rods with blockage are used even they are more expensive.

The results (favorable evolution 96.71%, postoperative morbidity 4.29%), based on the following parameters: postoperative morbidity rate, consolidation time, and the number of days of hospitalization, were comparable to those in the literature.[104,105,106,107,108,109,110]

The consolidation time, defined as the time between the osteosynthesis and the radiologic appearance of primary callus, which allows mobility resumption and the starting of the recovery was the main parameter used in the evaluation of the postoperative evolution and especially of the postoperative results registered according to the used osteosyntesis material. Overall, the average consolidation time was about 40-50 days, but the analysis of the consolidation time versus the main synthesis materials used showed that the shortest average time was registered after the osteosynthesis with Ender rod, followed by Kuntscher rod, lock rod and external fixators. Although the lock rod is thought to be the most effective and safer, the consolidation time is longer than when Ender and Kuntscher rods are used. The explanation comes from the fact that in our study the lock rods were used only on some tipes of fractures (comminutive, bifocal or with over floors with a prolonged consolidation time).

Regarding the external fixator, it was used only in open fractures (when the primary hematoma was lost, essential for a quick consolidation) with sepsis risk (which delays the consolidation). that explains the long average consolidation time of 116 days.

Regarding the hospitalization days, considering the favorable evolution of the surgered sick persons, 70% of them were released from the hospitals in the first 10 days with the surged wound healed and the recovery already begun. The patients with open fractures and postoperativ complications needed a longer hospitalization time, especially the ones with fractured tibia was due to a plolytrauma.

EXPERIMENTAL STUDY

Starting from the premise that the osteosynthesis materials are perfectible, the main objective was to obtain a most fully virtual model of the human biomechanical walking system , allowing the study of some real situations, incidental, clinical, pathological or surgical ones and finaly to develop experimental models, leading to the improvement of the existing rod with lock which is used for the osteosynthesis of the tibia diaphyseal fractures - easier mounting under a minimal radiation of the patient and of the physician . In the conventional models with the lock rods for internal fixation of diaphyseal fractures of the tibia, the blockage is carried out by screws at both ends, proximal and distal, of the rods. Percutaneous screws are mounted using special guides that are attached to the rods when mounting. Because while inserting the rods , most often they sag (buckle) driving under the influence of the fractured bone fragments and muscle traction , the position of the distal screw holes upon the guiding does not correspond to the position of the distal holes of the rod, the orthopedic surgeon being required in this situation to apply distal screws without guiding by numerous successive attempts to target the distal holes in TV radiologic - screen, which leads to a significant additional radiation for the medical staff and for the patient (sometimes a bigger irradiation than that required for the mounting rod) . Therefore , the removal of this extra irradiation has become imperative and appeared to us feasible through the development of new models of rods that do not require external targeting of the distal rod hole .

In this paper we proposed three prototypes of rods, the fixation is performed by expanding in the medullary channel of the tibia of some mechanisms auctioned from the inside of the rod with a screwdriver or special keys, without the need of external distal targeting of the screw holes as with the conventional rods .

The analysis of the three innovative models of the intramedullary nailing of the tibial fractures allowed us the following findings and observations:

- The three models with intramedullary fixation mechanisms have a low degree of wearing after fatigue simulations proposed for analysis;
- The safety factor calculated for the three structures of intramedullary nailing has much higher values than the 1 value that indicates the failure of the used the materials ;
- For the three models, biaxiality indicator has values close to zero, indicating a relatively well distributed disposition of the efforts among the analyzed components;
- Although fatigue analysis simulations show good values of key indicators, there are additional components required, but without causing special problems;
- All the three models eliminate the use of the locking screws (may optionally be used in the proximal side of the rods to stabilize the proximal metaphyseal fractures), and hence their implantation operations involving a risk of increased radiation of the medical stuff and of the l patient especially when mounting distal screws ;
- The innovative variants are based on relatively simple actionning mechanisms known in engineering ;
- Using CAD programs and software tools , the latest generation of FEM analysis or fatique (fatigue) allowed the development of complex studies that have validated the three models proposed in this thesis ;
- The studies presented above have analyzed and concluded that these virtual models of intramedullary nail have a sufficient stiffness but include relatively complicated subsystems with small metal components , relatively difficult to obtain technologicaly;
- The real obtantion of these models would require the use of special technology, complex equipment, precision mechanics or specific technologies like now growing fast prototyping (Rapid Prototyping) the adapted process of controlled metals melting;
- The innovative models proposed eliminate important disadvantages of the conventional rods, such as orientation, handling and

- Difficult positioning in bone in the same time, the difficult positioning of the distal screws using the conventional rod guide (the rod can undergo a process of bending and the rod holes in the bone no longer correspond to those of the guiding, in that case the distal holes must be targeted through exploration Rx - TV screening, in which the medical staff and the patient are subjected to a very high exposure to radiation). This also eliminates the operations that may lead to errors or additional holes in the tibia, which leads to decreased bone strength.
- All the three proposed models lead to reducing the duration of the orthopedic surgery and thus to reduced the exposure to additional X-ray irradiation for the medical staff and patients.
- All the three innovative models have one simple basic principle: the rod fixing is performed in the tibial medullary channel by using different mechanisms and metal parts that expand and secure the medullary channel.

Conclusion

1.The diaphyseal fractures of the lower leg - the most common fractures (20%in the literature vs 23 % in our personal study)
2.Prevalent in males (64%), with peak incidence in the age decades 4 and 5, the category of the most exposed patients through direct involvement in professional activities with the highest risk.
3.There are various circumstances of production, mostly recorded after falls from the same level , followed in order by traffic accidents, direct local trauma, falls from height, physical and, or animal assault, accidents at work.
4.Most of the fractures are isolated fractures (86%) , but can be found in polytraumatized patients (11 %), where therapeutic gestures must be prioritized according to the vital risk of the injury associated with the fracture.
5.The rapidity with which traumatized patients reach the hospital depends primarily on the promptness of the ambulance services and on the distance from the hospital and depends lesson the patient.
6.The clinical diagnosis is an easy one, based on classical subjective and objective clinical signs of probability and certainty (functional impotence, sore at the palace of the fracture, crepitation / crackles interrupting the continuity of the bone) , present in 90% of cases.
7.The plain radiography (front and profile) confirms the diagnosis of the fracture and sets the main morphological parameters underlying the therapeutic decision: the fracture, fractured bones number, the fracture type.
8.Encountered in equal proportion to the two legs, they interest the both bones of the leg in 89 of the cases, 1/3of the tibial shaft bottom is the location of choice (44%).
9.The unifocal fractures with displacement of fragments, the comminuted fractures and the spiroide fractures are the main morphological types of diaphyseal fractures of the tibia.
10.The open fracture incidence is much higher in the calf (21.6 %) than in other long bones well protected by muscle.
11.The treatment of the diaphyseal fractures of the calf is a complex treatment, an orthopedic one (reduction + cast immobilization) and / or a surgical one (osteosynthesis) the treatment option is based on the morphology of the fracture, on the age and general condition of the patient, on the presence of shock if the fracture occurs in the presence of a multiple trauma, on the logistics service and the expertise of the surgical team.
12.The operating tips are based on the following criteria: unstable fractures, stable fractures with a high risk of local and general complications, fractures treated conservatively with displacement risk under plaster.
13.The selection criteria for the osteosynthesis materials are: the Kuntscher rod for the fractures with two fragments, the rod jam for the comminuted fractures, secant bow in Ender rods or rods with

blockage for the diaphyseal fractures of the lower 1/3 part, transcalcaneo - astragalo - tibial brooches for the distal diaphyseal fractures associated with metaphyseal fractures

14.The results are: 96.71 % with favorable evolution, postoperative morbidity 4.29 % overlapping the literature data.

15.The shortest consolidation average time recorded after fixation was that with Ender rods, followed in order by the Kuntscher rod, the rod with jam and external fixator, with the mention that the blockage rod, rated as the most effective and safe, was used only in comminuted fractures bifocal or with multiple floors.

16.All the three proposed models lead to the decrease of the orthopedic surgery duration and thus to a diminished additional exposure to X-rays for the medical stuff and for the patient.