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SUMMARY

PhD THESIS

RETROGRADE NAIL – MODERN OSTEOSYNTHESIS METHOD FOR FOR DISTAL FEMORAL FRACTURES

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This PhD thesis is dedicated to distal femoral fractures surgical treatment, with a special focus on the retrograde nailing. The choice was driven by several reasons, listed below:

1. Distal femoral fractures are complex lesions, with a variable pattern of bone component and, associated, very often, with important soft tissue injuries.
2. Long term complications are frequent and are difficult to treat.
3. The diagnosis, apparently easy, is seldom incomplete – in respect to the correct mapping of fracture fragments and theirs displacements as well as to the accurate evaluation of soft tissue injury.
4. The variety of available implants is constantly increasing, however if the surgeon is not mastering the surgical principles, the specificities of the implant, the appropriate reduction techniques for each fracture type and implant and the particularities of insertion for a specific implant – the final result might be a failure.
5. Every implant has its advantages and disadvantages and can be more appropriate for a specific type of fracture.

Consequently, the idea of this thesis was an in depth study of this subject, aiming to find solutions to improve the treatment.

The starting point was the review of the anatomical and biomechanical elements interfering with the diagnostic and treatment of distal femoral fracture based the literature concerning mechanical comparisons between different osteosynthesis methods. Further way we have analyzed the clinical results of our practice, highlighting the strong and weak points of the methods available for our use. We also performed a mechanical comparison between the most modern implants used worldwide for distal femoral fracture treatment. Finally we imagined a reduction and provisional fixation system for distal femoral fracture, designed to help the surgeon to obtain and maintain reduction during surgery, until the definitive fixation of fracture with a nail (which, in my opinion, is the weak point of the method). Positioned in a specific way, the device can be also used for extramedullary fixation with plates and screws.

Last but not least, the current work opens the way to further research - on the use of navigation to reduce and achieve the fixation of the distal femoral extremity, as well as to a potential attachment of the innovative reduction device to a surgical robot which might help on the reduction phase of the treatment - therefore increasing the accuracy of the result and, not to forget, decreasing the level of X-Ray exposure of the surgeon.

GENERAL PART

Chapter 1. Fractures of distal femur

The fractures of distal femur are occurring quite seldom, but are usually complex and difficult to treat. This lesion is usually characterized, on the short term, by difficult surgical procedure, long hospitalization, prolonged and hard to achieve rehabilitation. Long term result of this lesion is, often, unsatisfactory - with multiple functional complaints for the patient - due to the wide lesions of the joint cartilage, severe comminution and associated soft tissue lesions.

The fractures of distal femur are **defined** as those fractures involving the last 15 cm of the femur (measured from the knee joint line). It includes the metaphyseal fractures (supra condylar fractures) and the fractures of the joint surface (intra-articular fractures). Due to the similarities in treatment indications and surgical techniques, we also included in the thesis below the fractures of the distal third of the femoral shaft.

The **epidemiology** of the distal femur fractures is accounting for them as 7% of all the femoral fractures, placing them well below the widely spread hip fractures.

If we are looking for the **fracture mechanism** , most of them are the result of an extreme axial load combined with a valgus, varus or rotational stress force. There are two main categories of patients with distal femoral fractures: the young subjects- suffering from this lesion as a result of a high energy trauma such as falling from a certain height or being victims of a traffic accident; and the elderly subjects - to whom the traumatism is usually a low energy- falling from the same level, slipping on the affected limb, usually with on the flexed knee.

The **diagnosis** of the lesion is a clinic and imagistic one.

The clinical diagnosis, despite the wide choice of imagistic techniques available today, remains of outmost importance, should be done systematically, with care and offers important information on the circulatory status, on the nervous, sensitive and motor functionality of the affected limb.

The anteroposterior (AP) and lateral view X-Ray examination is the standard imagining first step when suspecting a distal femoral fracture. Oblique X-Rays are useful for the systematic diagnosis of the undisplaced or minimal displaced intercondylar fractures. The oblique x-rays are useless when the decision to perform a CT scan is taken from the beginning. The CT scan offers a valuable help in completing the diagnosis of osteocondral (intraarticular) fractures as well as in the diagnosis of Hoffa type fractures, frequently not identified with a classic X-Ray examination. Additionally, the CT scan is extremely useful in identifying all the fragments involved and in achieving a detailed and accurate pre-operative planning.

Some particular cases might need an arteriography to ensure a correct evaluation: if the fracture was associated with a knee dislocation, if the distal arterial pulse is diminished, in the presence of a voluminous thigh hematoma, if we are in front of an open wound with a persistent arterial bleeding.

The MRI exam (to identify the associated soft tissue lesions) is not indicated in the emergency. If, after the stabilization of the fracture, there is still a suspicion of a ligament and/ or joint cartilage lesion, an MRI might be prescribed as a 2nd step diagnostic exam.

Chapter 2. Fractures of distal femur – modern methods of osteosynthesis

Over the last 20 years the treatment of the supracondylar femoral fractures evolved significantly.

Many authors, from various trauma centers have proposed, used and promoted different osteosynthesis materials. All these led to one single conclusion: the internal fixation principles should be respected irrespective of the stabilization method chosen.
These principles, not to deviate from, are:

1. Anatomical reduction of the joint surface of the distal femur
2. A stable internal fixation, with the reconstitution of the mechanical axes of the femoral shaft,
3. Minimal stripping of the soft tissues
4. Fast postoperative active mobilization

There are numerous debates on the optimal implant for the distal femoral shafts.

The stable fixation is often difficult, especially on osteoporotic bone, due to the high degree of comminution and of the reduced capacity of the bone to retain the fixation material. The use of the most appropriate implant is not necessarily synonym with the stable fixation. There are some older studies demonstrating the clinical success in the treatment of the distal femoral fractures by using the blade-plate. However, its use is linked to a massive periosteal stripping and a significant harm of the soft tissues, both potentially impairing the physiological bone healing process. The use of intramedullary nailing offers some potential biomechanical advantages compared to the plates and screws, mainly because the intramedullary positioning of the nails is leading to a lower stress of the implant, with a higher potential for “load-sharing” and due to the minimal aggression of the soft tissues.

The use of the retrograde nail for distal femur fractures treatment represented a new treatment option. It offers a biomechanical advantage versus the conventional treatment methods (which are placing the fixation material in a lateral position) because of its intramedullary positioning and it also offers, compared to the anterograde fixation, the practical advantage of handling and direct reduction of the distal fracture fragment.

The main surgical treatment options can be classified as follows:

A. Classical methods- with open reduction, wide surgical approach, massive periosteal stripping, para-cortical stabilization, sometimes needing bone graft for the supracondylar defect which remains after reduction, with moderate to abundant bleeding often needing blood transfusion (blade-plate, DCS, molded plates)

B. Intra medullar methods - with no (or minimal) approach of the fracture site, without massive periosteal stripping, with indirect reduction, intramedullary fixation. It doesn't need bone graft, has minimal bleeding and doesn't need blood transfusion (anterograde femoral nail, retrograde femoral nail).
C. Angular stable plates – placed with minimally invasive techniques or with the partial opening of the intercondylar fractural site (LCP- classical open approach; LISS- minimally invasive approach and monoaxial angular stability; NCB- angular stability and poliaxial screws)

The most widely used classification of the long bones fractures is, currently, the AO classification (and we referred to it in this work). It classifies the distal femoral fractures in extra-articular (type A), partially articular (type B) and complete intra-articular (type C). This thesis presents the treatment options for each of the types seen in the distal femur fractures.

We are describing the retrograde femoral nail used in the Orthopedics Clinic of the "Floreasca" Emergency Hospital- the SCN produced by Stryker). In our experience, we noticed that the main disadvantage of this retrograde nail is the big distance between the tip of the nail and the first distal locking hole. This leads to a lot of cases when the 2nd hole for distal locking is placed in the fracture site (mainly when this one is in a very distal position).

The indications of the fixation with retrograde nail are:

a) Fracture 33-A (AO/ ASIF classification)- extra-articular
b) fracture 33- C1 and C2 (AO classification)- simple intra articular fracture line
c) fracture 33 – C3, with complex intra articular lines have a relative indication (as per certain authors it is formally contraindicated).
d) Fractures of the distal 1/3rd of the femoral shaft
e) Fractures of the distal 1/3rd of the femoral shaft in patients with prior surgery on the injured femur (distal - knee prosthesis, proximal- DHS, gamma nail, partial and total hip prosthesis)
f) Floating knee – ipsilateral fracture of proximal tibia and distal femur
g) Fractures of the median or distal 1/3rd of the femoral shaft in obese patients where it is very difficult to find the trochanteric entry point for the anterograde nail
h) Multiple trauma patients (quick fixation technique, not very invasive, minimal bleeding)

The contraindications of the fixation with retrograde nail are:

a) Patella baja - where a short patellar tendon is not allowing to approach the correct entry point
b) The flexion of the knee below 80 degrees (which prevents the correct positioning on the operation table, the identification of the correct entry point and the proper insertion of the nail)
c) Massive comminution of the articular fracture or the pre-operative estimation of an impossible anatomical reduction of it.

Chapter 3. Anatomical and biomechanical particularities in distal femoral fracture treatment

The management of the distal femoral fractures associated with adjacent soft tissues lesions, as well as their surgical treatment are mandating a deep knowledge of the anatomy of the impacted area and of those surrounding it.

This chapter is not aiming only to review the anatomical elements of the area, but is looking for 3 objectives:

1. Highlighting the link between the various anatomical structures and the distal femur fracture (displacement of fragments, reduction opportunities during the surgery)
2. The relationship between the anatomical elements and the type of the material used for stabilization (the retrograde nailing), in order to promote the most correct technique and to avoid the complications due to the injury of the anatomical elements,
3. The documentation (with bibliographical references) of the various injuries of the anatomical lesions linked to the use of the retrograde nailing.

For these reasons, in this chapter we can find:

“Attention”- anatomical elements at risk during the surgery and the ways the surgeon can harm these

“Recommendations” – practical means to avoid lesions of anatomical elements (extracted either from the bibliographic references, either from the personal experience)

“***Observations***”- practical hints and tips from the personal experience

In this chapter, the following regions are described, as all can be influenced and touched by the treated context: the anterior and posterior thigh, the bone plane, the anterior and posterior knee and the knee joint. The anatomical description is not following the classical systemic style but is focused on the interrelationship between the various structures.

Chapter 4. Mechanical comparative studies between different osteosynthesis methods of distal femoral fractures

The most frequently used implants for the fixation of the distal femoral fracture are the blade-plate (95°), the Dynamic Condylar Screw (DCS), the angular stable plates (LISS) and the retrograde femoral nail.

The clinical results obtained following the use of the retrograde nail are good, however its insertion into the comminuted fractures of the distal extremity of the femur is difficult, as per the experience of several authors. Another issue seems to be the stability of the distal locking screws of the retrograde nail in the osteoporotic bone

In this chapter we are presenting an extensive research of the existing literature, covering the articles published on comparative biomechanical studies in respect to the femoral retrograde nailing. There were several types of research studies:

- Studies comparing the retrograde nailing with the anterograde nailing

- Studies comparing the blade-plate, DCS, retrograde nailing , angular stable plates in various combinations
- Studies comparing the various retrograde nails

The studies comparing the anterograde and retrograde nails are less relevant for this thesis because the indications of the two methods are different (the anterograde nail no longer being used in the treatment of the distal extremity of the femur- mainly because the numerous complications due to the poor reduction quality and the low stability of the fixation). The only indication in which the two methods can be properly compared is the intramedullary fixation of the distal 1/3rd of the femoral shaft, for which the results of the two methods are comparable.

The studies comparing the fixations with blade-plate, DHS, retrograde nailing, angular stable plates in various combinations are leading to the following conclusions:

- The decision to use either the retrograde nailing either the DCS shouldn't be based on the severity of the fracture
- if the choice goes to DCS, there is recommended a configuration with dispersed screws, including the most proximal hole of the plate - in order to obtain the highest resistance to torsion and an equal resistance on the shaft loading (compared to the fixation with retrograde nail GSH)
- if the implant of choice is the retrograde nail (GSH), it is recommended a grouped configuration of the screws, which are absorbing more energy during shaft loading (compared with the DCS plate or with the retrograde nail with dispersed screws).
- All the 3 implants (LISS, blade plate and retrograde nail) are offering enough stability to torsion and enough proximal stability to achieve the shaft loading within safe conditions.
- The LISS system offers a better distal fragment fixation, especially in osteoporotic bone, by a higher shaft loading and a higher tolerance to the energy before it breaks as well as a lower incidence of the loss of distal fixation.

Analyzing those studies, we have noticed several interesting discussions. Even the fine balance between the rigidity and the micro-movements in the fracture site is not exactly known, it is acknowledged that excessive movement into the fracture site (instability) is leading to nonunion. To allow the patient a precocious mobilization, the micro movements of the fracture site should be minimal, but not absent. The excessive movements can lead to nonunion, malunion and implant failure.

I haven't found studies on osteoporotic bone models, therefore the results shouldn't be extrapolated to this type of bone.

Studies comparing the various types of retrograde nails. During the last two decades, there were designed several types of retrograde nails, mainly to stabilize the distal femoral fractures. All those have proven their utility and clinical benefit, however there are few biomechanical data documenting the stability of the fixation and the mechanical rigidity of the various types of nails.

The conclusions I have retrieved following the analysis of the literature I found were: the bending resistance of the various retrograde nails available seems to be independent of the design variations and the resistance to torsion is varying from one nail to the other, but not in relation to the number of locking holes existing on each nail.

All the evidences are leading to the conclusion that the retrograde supracondylar nail, if correctly inserted (with the proper technique) will offer enough rigidity to provide femoral support and will also offer enough stability during the bone healing period.

SPECIAL PART

Chapter 5. Clinical particularities of distal femoral fractures osteosynthesis with retrograde nail

The objective of this clinical research is to retrospectively assess the results of the intramedullary osteosynthesis of the distal femur fractures, using the retrograde nailing, on patients operated in two emergency hospitals from Bucharest. These two hospitals have a wide experience in the treatment of limb fractures, commonly treating fractures resulting from both low energy (elderly patients) and high energy (traffic accidents), including and multiple trauma patients.

In the study there were considered two lots of patients:

1. 62 patients with distal femoral fractures, for which retrograde nails were used and who were operated during 2001-2007 in the Orthopedics Clinic of the “Floreasca” Emergency Hospital,
2. 71 patients with the same fracture operated with the same type of implant, during 2001-2007, in the Orthopedics Clinic of the “Pantelimon” Emergency Hospital,

The following section is describing the operative technique used in the “Floreasca” Emergency Hospital, insisting on those aspects and details significantly influencing, as per our experience, the result of the surgical intervention. These aspects are linked to the correct positioning of the patients on the operation table, the correct positioning (pre-operatively) of the image intensifier in order to obtain a good quality of both AP and lateral views, at the knee level but also at the level of proximal locking- harder to access (especially for the long retrograde nail for which there is a proximal targeting system). I am presenting several aspects linked to the surgical approach, both for extra-articular and intra - articular fractures (for those being important to properly see the femoral condyles and to correctly reduce the intra-articular fracture). I am continuing with the presentation of our technique to fix the intra- articular fracture lines, so that the screws used are not embarrassing the subsequent insertion of the retrograde nail, as well as with the most important aspects linked to the proper identification of the entry point, fracture reduction, nail insertion and locking (distal and proximal). The chapter considers also the postoperative care of the patients with retrograde nailing.

The next section presents the clinical cases from our clinical research.

From the moment of the accident to the bone healing moment, the following parameters were evaluated:

a. Time to the surgical intervention
b. Blood loss, need for transfusion
c. Grade of comminution
d. Grade of opening (open fractures) as per Gustillo- Anderson classification
e. Grade of knee mobility
f. Complications

From the 133 patients considered into the study, only 119 were followed up to the fracture healing or to the surgical re-intervention, however, for all 133 we considered those parameters collected from the admission to the hospital up to the postoperative radiological control done before the hospital discharge.

From the 119 patients completely followed up, 15 of them (12.6%) needed a re-intervention: in 6 cases for unsatisfactory reduction, 1 case for bone grafting (bone defect due to the accident), in 5 cases because of nonunion with implant failure and in 3 cases because of malunion. From all patients enrolled, there was only one patient with an infectious complication.

The results of the study can be summarized as follows:

133 subjects (76 women- 57,14% and 57 men- 42,86%) with distal femoral fractures were surgically treated with retrograde nailing. The median age was 54 years (min 24, max 80). The majority of patients, 65,41% suffered low energy trauma (falls from the same level), the others (34,59%) were involved in high energy accidents (traffic accidents, falls from various heights). Despite this distribution, there were frequent that severe comminutive fractures followed a low energy trauma.

Regarding AO classification, from the whole number of fractures, 50 (37,59%) were type A1, 37 (27,81%) type A2, 18 (13,53%) type A3, 14 (10,52%) were type C1, 9 (6,76%) were type C2 and 3,75% were type C3.

24 fractures (18, 02%) were open fractures, spread as follows as per Gustillo-Anderson classification: Type 1 – 15 fractures (11,27%), type II - 5 fractures (3,75%), type IIIA – 4 fractures (3%), the rest of 109 fractures being closed fractures.

We also have analyzed the special indications of the retrograde nailing:

1. Fractures of the distal 1/3rd of the femoral shaft in patients with previous surgery on the same femur: 1 case with knee prosthesis, 10 cases with proximal lesions operated previously- DHS, gamma nail, partial or total hip prosthesis.
2. Obese patients- where the trochanteric entry point (for anterograde nail) is hard to find or, for which, even if this point is properly positioned it is difficult to penetrate the axis of the femoral shaft- 15 cases
3. Multiple trauma patients- 12 cases
4. “Floating knee”- ipsilateral proximal tibial and distal femoral fractures, where both fractures are approached via the same trans patellar tendon incision- 5 cases
5. A special case- the treatment of a septic non-union of the distal 1/3rd of the femoral shaft, with multiple previous surgical interventions leading to an important bone loss. The bone defect was replaced with a customized cage (manufactured to fit the length and width of the missing bone) and filled with bone graft (from the patient’s own iliac crest)

In respect to the intraoperative incidents, these were of two types:

- intraoperative femoral fracture - occurred in only one case and was approached by changing the standard retrograde nail with a long retrograde nail, in order to also stabilize the iatrogenic fracture, placed just at the tip of the standard nail
- failure to achieve proximal locking- this occurring in 6 cases (even for standard nails where the targeting device for proximal locking was used). In all 6 cases, the error was discovered at the final intraoperative X-ray examination and the correction was done during the same intervention.

The immediate complications occurred during our study were:

- one single postoperative infection - septic knee arthritis. None of the open fractures treated in our study presented postoperative septic complications,
- the shortening of the limb occurred in 5 patients, varying from 1-2 cm (3 cases)
- there were quite a few patients where the postoperative reduction of the fracture was unsatisfactory (imperfect reduction), beside the shortening of the injured limb. The criteria for assessing the reduction quality were: varus/valgus deviation > 5 degrees or flexum/ recurvatum > 10 degrees. Only 18 patients were reoperated, in all the cases the surgical approach being a paracortical implant by an open approach. In all those cases the closed reduction of the fracture was impossible, therefore as the opening of the fracture site was mandatory, there was more logical to use a paracortical implant.

Subsequently, we are presenting and discussing some cases (from the studied group) where an important malalignment was present post-operative. We considered this discussion as the malalignment is the main reason for criticizing this method (the retrograde nailing). I consider that a careful pre-operative reduction and, eventually, the use of the reduction and stabilization device presented in chapter 7 can reduce significantly the occurrence of this complication.

From the analysis of our cases presenting postoperative an insufficient reduction of the fracture, we can summarize the causes leading to this complication: wrong surgical indication, insufficient preoperative planning, incorrect/ incomplete reduction of the fracture before inserting the retrograde nail, deficient surgical technique, with loss of the alignment during the intervention, insufficient fixation (not enough intercondyllar screws for type C fractures, distal or proximal locking screws).

The late complications occurred as follows, on the cases followed up to the bone healing :

- in 12 cases (10,08%) persisted the anterior knee pain. The main cause was the intra-articular protrusion, below the level of the joint cartilage, of the distal end of the retrograde nail. The 2nd cause was the irritation at the level of the distal locking screws.
- The 2nd late complication was the malunion. Despite the incorrect position (valgus/ varus/ external rotation), the fractures of the distal femur where the osteosynthesis was done using retrograde nail have a natural tendency to consolidate- because they are located in the metaphyseal- epiphyseal area and because the fixation is achieved without opening the fracture site. From the studied cases, 3 of them were re-operated 6 months after the initial intervention, with corrective osteotomy and paracortical fixation.
- The 3rd late complication is the knee arthritis (1 case), due to the fixation, occurred because of the distal migration of the implant, with the migration of the distal tip of the nail in the joint. The tip of the nail dug into the joint tibial cartilage, then in the subcondral bone leading to a severe deterioration of the joint. The therapeutic approach was the removal of the locked nail and the osteosynthesis with angular stability plate and screws.

The conclusions of our clinical research were:

- The majority of the fractures stabilized with retrograde nail (78,93%) were extraarticular fractures (type A as per AO classification). The intra-articular fractures (AO type C) are an exceptional indication of this osteosynthesis method.

- The percentage of the retrograde nails placed using the “optimal technique” (minimum 2 distal and 2 proximal locking screws) was only 72%.
- In 12,6% of the cases (15 patients) a re-intervention was needed: in 6 cases for insufficient alignment, in one case to add the bone graft, in 5 cases because of the evolution to non union with failed implant and in 3 cases for mal union.
- In 18,05% of cases the retrograde nail was used for open fractures, this high proportion being a proof of the preference of the surgeon for an intramedullary, less invasive method.
- The clinical results are very good for the wide majority of subjects, only 4 of them (3%) presenting secondary stiffness of the knee.
- The postoperative risk for infection is low (only 1% of the whole lot, which included several open fractures, even Gustilo type III)
- There is a relatively high proportion of imperfect reduction- 4% of the patients had a shortening of the limb, 18,9% had a varum/valgum/ flexum/ recurvatum deviation. This was, probably, due to the lack of experience at the time of the research (and of the period of “learning curve” of the surgeons).
- There is a relatively high proportion (10%) of patients presenting anterior knee pain as a late postoperative complication.

Chapter 6. Comparative mechanical study of fixation methods with plates and screws versus intramedullary nails for the distal femoral fracture.

In the last years in the specialized literature we can find the idea that angular plate osteosynthesis is more stable than intramedullary nailing for distal femoral fractures. After an extensive research in orthopedic literature I couldn't find a comparative mechanical study comparing new types of retrograde femoral nails (with multiplanar interlocking possibilities) with locking plates. Together with research group from Romanian National Institute of Mecatronics (Bucharest), we imagined a mechanical study, simulating, on synthetic femurs, three types of fractures – supracondylar simple, supracondylar simple with a simple intraarticular component and supracondylar with a butterfly fragment and intraarticular simple component. For these fractures we performed an osteosynthesis with 4 types of implants (for each type of implant): DCS (Dynamic Condilar Screw), LISS (Less Invasive Stabilisation System) for distal femur, simple SCN (Supracondylar nail) and modern retronail (T2) with multiplanar interlocking possibilities. Static and dynamic tests were done for 12 models for mechanical stress similar to that in-vivo and we measured the total displacement, the variation of fracture gap. A statistical analysis of the four implants models was done.

The purpose of the study was to elucidate the aspects regarding stiffness and fatigue strength of four models of fracture fixation implants for distal femoral fractures, to facilitate the choice of implant with better stability and durability.

For the tests, a number of 13 synthetic femurs, produced by SYNBONE AG Company, were used.

The following orthopedic implants were used:

1. LISS plate (Less Invasive Stabilisation System) – Synthes
2. DCS plate (Dynamic Condylar Screw) – Synthes
3. Intramedullary retrograde nail T2 – Stryker (titan)
4. Supracondylar intramedullary nail SCN – Stryker – stainless steel

The fracture model selection was done so that the fixation systems should be subjected mainly to axial load forces. To obtain a maximal effect of load, the supracondylar osteotomy had a 10mm distance between the proximal and distal fragments. This distance doesn't allow the direct bone contact during load, maximizing the effect of axial load.

The fracture model selection was done so that the fixation systems should be subjected mainly to axial loading force. By cutting the synthetic femoral models, three supra and intercondylar fracture patterns were simulated as follows:

1. Simple extra-articular fracture – type 33-A1 (horizontal metaphyseal);
2. Complete simple articular fracture, simple metaphyseal fracture, type 33-C1 (T – shape, reduced displacement);
3. Complete simple articular fracture, multifragmetary metaphyseal fracture-type 33-C2 (fith a "butterfly" fragment). For this experimental model, the presence of a "butterfly" fragment oblige, in the situation of a plate and screws osteosynthesis, to a larger distance between the screws situated close to the fracture site (proximal and distal). As a direct consequence, it will be higher construct instability and a smaller resistance to axial, bending and

torsion load. The same situation doesn't change anything for intramedullary nailing.

For static tests, a universal testing equipment H10KT HOUNSFIELD type was used, operating assisted by an external computer. Two types of software components are available for static tests: QMAT XT and QMAT Professional, both operating with Windows Microsoft. The testing equipment can be used to determine the materials and devices behaviors to traction, compression, bending and shearing forces. The characteristic loading curve to a applied force can be visualized in real time on the computer monitor connected with testing equipment. QMAT program include 1157 testing subprograms, having as a base International and European regulations for physical and mechanical properties determinations for materials.

Endurance testing of the constructs was performed using universal testing equipment INSTRON 8872, by which static and dynamic tests can be performed with very high travel speeds:0.005 to 60000mm/min; work temperature from -70°C to 250°C, maximal work frequency 1 KHz , pressure without load 24bar, work pressure 207bar. Working curve form can be sinusoidal, triangular, quadrangular etc.

Samples were placed on the platform so that the centre of the femoral head should be along the axis of testing equipment. For the loading force transmission, a low friction mechanism was mounted on the working head, which was designed to minimize forces whose direction is not coincident with the loading force. The support at the bottom of the sample was achieved by positioning the femoral condyles on a bearing element of a total knee prosthesis made from high molecular polyethylene (UHMWPE).

With respect of these positioning conditions, each sample was tested statically and dynamically for100000 cycles.

In a first stage of static tests, the constructions were tested non-destructively, at two loading levels: 500N and 700N respectively, determining the total displacement of the specimens and plotting the characteristic curves of the tests.

The second phase of the static tests consisted in loading assemblies with increasing force from 100N, with a 100N increment. Maximum loading force was 800N, corresponding to a total of 8 loading levels. For each level, vertical movement of the lateral and medial extreme points were measured and recorded and changes in the osteotomy gap in 4 points of the anterior region and 4 points of the posterior region. Differences between implants regarding total displacements and variation of osteotomy gap were analyzed. Characteristic curves of testing were compared and we obtained diagrams for rigidity and displacements.

Fatigue testing was performed by controlling the amount of force supported by femoral constructs. The applied force varied as a sinusoid between a maximal force (F0) and a minimal one (Fu), with the relation Fu=0.1xF0 – (1). The maximal force was 500 N, because the bones elasticity didn't allow superior values. Corresponding to this value we have a minimal force Fu=0.1x500=50N.

The frequency of testing was also limited by the elasticity of models. The best machine calibration was obtained for a frequency f=1Hz (1 load/second). This frequency led to prolonged testing, but the loading pattern is reproducing the physiological load during stance phase of walking. The constructs were loaded at 100000 cycles, after this number the test was stopped even the models didn't break.

A total number of 13 specimens were tested, one for each type of implant and each type of fracture (4 implants x 3 types of fracture) and a synthetic femur without implant for comparison. The first results of static tests are the characteristic curves (force/displacement) of the tests by loading until 500N and 700N respectively. For these tests, the characteristic curves were drawn separately for each model an implant and on these diagrams the curve corresponding to the synthetic femur without implant was introduced and used as a basis for comparison.

The second phase of the static tests consisted in measuring changes in the osteotomy gap in 4 points from the anterior region and 4 points from the posterior region and also the vertical displacement of the lateral and medial extreme points for the 8 loading levels. The evaluation of implants was based on implant stiffness calculation, in each of 4x2 points.

Analyzing the stiffness formula we can see that at the same loading force, the body that deforms less is more rigid. Based on loading force value and on the variation of osteotomy gap we have obtained the curves for 200N, 400N, 600N and 800N. Due to relatively small amounts of displacements, we preferred expressing stiffness in N/µm. For ease of comparison, diagrams have been scaled on the ordinate of the same value (60N/µm). Because of lack of space, only the diagrams corresponding to loading forces of 800N have been presented. The variation of gap osteotomy shows that the absolute displacements in the posterior region of the constructs are higher than those in the anterior one, which means that the osteotomy tends to close in this area, with the increase of loading force. A similar trend was found for the two condylar plates. For these ones the increase of the displacements traveling in the opposite direction of the implant could be observed, but this behavior could be predicted even before the beginning of tests. At the same amount of displacement, we have a greater rigidity in those regions closer to implant.

. Based on measurements of the vertical displacements of the extreme lateral and medial points, the diagrams of variation for the position of condylar bone fragment/fragments were plotted.

After performing static tests, all samples were tested dynamically. For the first test, the loading force value varied in a sinusoid way between 90N and 900N according to relation (1), with a frequency of 1 Hz, but the construct brake after 8 cycles. The cause was a to big total displacement and excessive deformation of middle fiber of synthetic bone. Because of this, the maximal loading force was decreased at 500N, and the frequency was kept at 1 Hz. Before starting fatigue testing for each construction, the total displacement corresponding to maximum loading force was determined. The determined values were used in the machine's control program, for setting the maximum/minimum force and displacement. Using these values, the constructs were subjected to a number a 100.000 cycles. After finishing the dynamic tests, the total displacement recorded for the first cycle (D_1) was compared to that resulted for cycle number 100.000 (D_{100000}) and the differences between them were calculated. For ease of comparison, the differences between displacements were plotted, the greatest differences being obtained for the LISS plate.

The study of total displacements in mechanic test lead to the following ***observations:***

- Displacements in all models of implants increases passing from fracture type 33-A1 to 33-C 2 type;
- Compared with synthetic femur without implant, both condylar plates had higher total displacements, regardless of the simulated fracture type;
- Measured displacements for the LISS plate were greater than those measured on DCS mode;
- Intramedullary nails T2 and SCN showed smaller total displacements in comparison with the synthetic femur without implant for the first two models of fractures, which means that these kind of implants lead to increased total stiffness;
- Because of the low settled speeds (1 mm/min), on some characteristic curves distortion occurred due to the stick-slip phenomenon, but this fact did not affected the final results

From the stiffness study based on interfragmentary movements we concluded primarily that at low loading levels the tests results are not conclusive, so these were excluded from the study. Only appropriate charts for loading force 800N have been presented because of lack of space. Studying these diagrams, we can make the following remarks:

- Regardless of the fracture type, the higher stiffness values correspond to intramedullary nails – namely T2 and SCN;
- SCN intramedullary nail is more rigid than T2, due to greater length (30mm) which makes proximal screws to be closer to the small trochanter. We think that this fact leads to an increased stability compared with T2 nail. We think that increasing the stem length and the distance between the proximal screws, or adding a third fixing screw may contribute to increase implant stability;
- Condylar plates are less rigid compared with intramedullary nails. Comparing the two models (LISS – DCS) based on interfragmentary displacements, we can conclude that DCS plate model leads to smaller movements. This finding is contrary to the conclusions drawn from static measurements, where the LISS model presented lower total displacements. These differences can be attributed to inhomogeneous structure of the used synthetic femurs;
- Regardless of implant type, displacements in the posterior part of the constructions are higher than those in the anterior zone. This means that while increasing the loading forces, fractures tends to “close” in the posterior direction. The phenomenon can be explained by the medium fiber curvature also in the sagittal plane.
- Regardless of the implant model, the displacements are reduced nearby implant and grow while increasing the distance. This make the stiffness of femoral nails greater, not only because of their central position, but also due to lower bending moment applied by reducing force’s arm, leading to reduced movements in both sagittal and coronal plane;
- No significant differences were found between the stiffness of fractures 33-C1 and 33C-2 type, and the values obtained for the four implants type do not allow clear conclusions regarding stability differences.

Based on the measurements of vertical displacements extreme lateral and medial points, the diagrams of position variation for the fragment/fragments of condylar bone were plotted, which reveals rotation of the condylar fragments in the coronal plane. It is a little surprising the finding that displacements for fractures 33-C1 and 33-C3 are slightly lower than those for the 33-A1 type. The explanation for this phenomenon can be found in the rotation tendency of the condylar fragments in the coronal plane, which contributes to increase total displacement.

Cyclic tests of constructions came to support static tests conclusions; in the sense that they showed that the stiffness of femoral stems is greater than that of the condylar plates. Permanent deformations were smaller in T2 and SCN nails, compared with condylar plates. As in the static tests, the stiffness differences between fracture types 33-C1 and 33C-2 were not significant, but the values obtained for cyclic tests have clearly indicated a greater instability in the case of third fracture type.

In conclusion, the study demonstrates that the use of condylar plates lead to higher displacements in osteotomy gap than intramedullary nails, in the same loading conditions. Cyclic test performed on femoral constructions showed once again increased stiffness of T2 and SCN nails, because for these constructions permanent deformations were lower than those of condylar plates.

Chapter 7. Reduction and temporary intraoperative fracture fixation device for distal femoral fracture fixation

Following the biomechanical research study we have reached the conclusion that the retrograde nail is, in vitro, a fixation method more stable than the paracortical plate and screws (blocked or not). From this perspective, the use of the retrograde nail seems to be more advantageous in the osteosynthesis of the distal femoral fractures.

Following the clinical research we reached the conclusion that, also from this perspective, the retrograde nail has numerous advantages: short duration of the intervention, reduced bleeding (intra and post-operative) and high rate of bone healing.

One of the main difficulties in the use of retrograde nailing as a fixation method is to properly align the fracture (from the beginning) as well as to maintain the reduction for the whole duration of the surgical intervention, up to the final locking of the nail (proximal and distal locking). The essays to align the fracture by using the nail are meant to fail as a general rule and only a high surgical experience (in general and also in using this specific implant type) might allow the surgeon to secondary reduce the fracture, simultaneous with the insertion of the nail.

For this reason it is logical to see the need, during the intervention, of a device allowing the intraoperative alignment and stabilization of the distal femoral fracture. Ideally, this device should address the following practical needs:

1. The possibility of the free and independent maneuverability of the two femoral condyles, as these are getting displaced with various degrees- getting separated, with posterior rotation, antero-posterior translation or varum- valgus displacement
2. The possibility to achieve interfragmentary compression of the two condyles, when there is a single intercondylar fracture line and the fracture surfaces are stable with a good quality of the bone.
3. The opportunity to get the two condyles closer, face to face, in a proper position, when the intercondylar fracture line is comminuted and the interfragmentary

compression would lead to the alteration of the normal anatomy of the femoral condylar area.

4. Sufficient stability of the montage after correct reduction- in order to prevent the displacement of the reduction during the insertion of the retrograde nail.

In collaboration with the research group from Romanian National Institute of Mecatronics (Bucharest) we have imagined and designed a device meeting these requirements. It has the following components:

- Two regular ex-fix pins which are introduced from lateral and superior (percutaneous) in the two femoral condyles.
- Two lateral bars with orientation devices, which are introduced into the two pins. These "clamps" have 3 degrees of freedom and represented the most challenging part of the design process. Each freedom "degree" can be adjusted and blocked with a fixation rosette.
- The central bar on which the lateral bars can glide independently and can be blocked separately. It allows either the inter- fragmental compression, both the approaching and maintaining of the femoral condyles in a correct position up to the insertion of the retrograde nail.

The design and execution of this reduction device for the distal femoral fracture was a challenging task. The biggest difficulty came from the desire to have a device with 3 freedom degrees, so that the femoral condyle can be rotated in 3 plans to achieve a perfect reduction of the intercondylar fracture.

Subsequently we are describing/ picturing the steps to be followed to reduce, with the help of our reducing device, a type 33C1 fracture (AO classification).

As a conclusion, the device designed and executed together with the research group from Romanian National Institute of Mecatronics is an useful tool to reduce and to stabilize distal femoral fracture. For its use the steps presented in this chapter should carefully followed.

Chapter 8. Final conclusions. Personal contributions

This work represents an extensive presentation of the distal femoral fracture and its issues. These fractures are complex lesions, with a various pattern of the bone component, with associated lesions of the adjacent soft tissues (ligaments, menisci, capsule and, sometimes, skin – when we face an open fracture)

The long term complications are frequent and difficult to treat- the best "treatment" remaining, for sure, their prevention- by an appropriate first therapeutic approach.

The diagnosis, apparently easy to pronounce, is often an incomplete one- in respect to the accurate inventory of the fragments and their displacement, on the correct evaluation of the soft tissue damage, this lack impairing the subsequent success of the treatment.

The variety of the available implants in continuous growth and offers a good comfort to the surgeon seeking a treatment option. Not knowing in the deepest detail all the implants available and their features, the treatment principles to be followed, the insertion techniques may all lead to failure of the surgery. Each implant has its own advantages and disadvantages and may be indicated in a certain type of fracture.

As a consequence, the in depth research of this subject, backed up by a continuous search for treatment improvements lead to the idea of this research exercise.

The conclusions of this thesis are the following:

- There are numerous anatomical elements which knowledge helps to achieve a better alignment of the fracture and a more accurate surgical technique of the retrograde femoral nailing
- Knowing or, in reverse way, not knowing some details of the local anatomy (noticed over the years of practicing this technique) may significantly influence the complete success, or may lead, if not known, to multiple complications
- When the chosen implant is the DCS plate, there is recommended to use a montage with dispersed screws (including the most proximal hole of the plate), in order to obtain a superior resistance to torsion and a similar resistance to axial loading, in comparison to the retrograde nailing.
- The DCS plate with dispersed screws has the higher rotational rigidity (compared to the DCS plate with grouped screws, the retrograde nail with grouped screws or the retrograde nail with dispersed screws)
- The LISS system, the blade plate and the retrograde nail are offering enough stability to torsion and sufficient proximal stability in order to bear the axial loading without failure.
- The LISS system is proving to offer a better distal fixation, especially in osteoporotic bone, by a higher axial loading, with higher energy needed to induce failure and with a lower incidence of fixation loss in the distal fragment.
- Considering the micro movements and the rigidity of the montage, the intramedullary retrograde nailing has a significantly higher rigidity, as well as significantly less micro-movements in the distal fragment.
- The retrograde nailing is the most stable for the 33A type fracture, but the least resistance to fatigue in fractures type 33C.
- The resistance to bending of the various retrograde nails we had, seems to be independent of the design variations
- The supra condylar retrograde femoral nail, if well inserted will offer enough rigidity to the femur during the bone healing period.

The conclusions of the clinical research were:

- The majority of the fractures stabilized with retrograde nailing were extraarticular fractures. The intraarticular fractures remains an exception for this treatment method, due to the risk of displacement or subsequent inter condylar fracture at the moment of the nail insertion.
- There were only almost three quarters of the fractures where the nailing technique was the optimal one.
- 12,6% of the subjects needed re-intervention, some for non-satisfactory reduction of the fracture, others for non-union or mal-union and one for bone grafting.
- There were several cases (18,05%) when the retrograde nail was used to treat open fractures. This high percentage is a clear indication that the surgeons preferred this technique (intra medullary, not so invasive) when treating a lesion with a high septic risk.
- The clinical results were very good for the majority of the patients, only 3% of them presenting postoperative knee stiffness

- The postoperative infection rate was minimal (1%) in our study
- There were a significant proportion of subjects with imperfect reduction-shortening of the limb, varus/ valgum/ flexum/ recurvatum, this being probably linked to the initial period of our learning curve
- 10% of the patients presented anterior knee pain as a late complication.

The conclusions of the mechanical study were:

- The displacement increased in all types of implants tested when moving from type 33A-1 fracture to 33C-2 fracture
- Compared to the intact synthetic bone, both condylar plates presented a lower total displacement, irrespective from the type of the fracture simulated.
- The displacements measured for LISS were lower than those for DCS.
- The intramedullary nails T2 and SCN had lower total displacements than the intact femur for the two first types of fractures, this meaning that the fixation leads to a higher total rigidity.
- In all models, the variation of the characteristic diagram for the 700N load is visible on the 2nd non-linear portion, suggesting the beginning of the plastic deformations of the femoral models.
- Due to the low pressure speed (1mm/min), on some of the characteristic diagrams there were distortions due to the stick-slip phenomenon, not influencing the final results
- Irrespective to the type of fracture, the highest rigidity values corresponds to the intramedullary nails (SCN and T2)
- The condylar plates are less rigid compared to the intramedullary nails. Between the two models tested (LISS and DCS) we observed that DCS was linked to a smaller displacement, this result being in contradiction with the static loading measurements, where LISS presented a smaller total displacement.
- Irrespective to the type of implant, the displacements in the posterior area are smaller. This can be linked to the non – homogeneity of the artificial femurs used in our trial, the rigidity of the anterior side being higher than the one in the posterior area.

Original contribution

In this PhD thesis I wanted (and managed) to bring a number of original contributions in respect to the choice of the retrograde nailing as an osteosynthesis technique for the distal femoral fractures. Secondly, the design and the execution of the original device for the reduction and intraoperative fixation of the intercondylar fracture will represent a step forward for the improvement of the fixation technique for retrograde nailing, in those cases with partial or complete articular fractures of the distal femur.

I have introduced, for the first time in the specialized literature, in the comparative mechanical trial looking for various implants, the retrograde T2 nail, which proved to offer a superior stability to the montage nail-fractured femur.

The high rate of the intraoperative incidents and of the reduction and stabilization imperfections observed in our study can be improved by using the reduction and temporary (intraoperative) stabilization device. I have observed that the nail itself cannot be efficiently used as a reduction device (as it can happen for subtrochanteric fractures), therefore I felt the need to design a helpful device.

The attitude of the orthopedic surgeon, while using the fixation with retrograde nail for a distal femoral fracture should be similar with the tactic used in the fixation with angular stable plates: the implant is inserted only once the fracture is reduced.

The reduction of the femoral distal fractures, as well as maintaining the reduction up to the insertion of the nail and its locking is, often, extremely challenging. In some cases the fracture was properly reduced but this alignment was lost during the insertion of the nail. As the lateral view x-ray is difficult to be obtained during surgery, the lack of image control was leading sometimes to an unsatisfactory result. From these findings, I have identified two main needs:

1. A standardized positioning of the patient on the operation table as well as of the image intensifier, in a manner allowing an easy and fast repeated image in both antero-posterior and lateral views. This was described in detail in this research work.
2. A device which might help obtaining an easier alignment of the fracture and which might help maintaining it for the whole duration of the surgical intervention (up to the final positioning of the nail). Secondarily, the use of the device will lead to fewer errors of the fracture alignment, to a shorter operative time, a lower exposure to x-rays for both patient and surgeons.

The design of the reduction device was a lengthy research process, the most challenging part being the achievement of the 3 freedom degrees for the femoral condyles. The inventiveness of the research team from the Romanian National Institute of Mecatronics led us to the desired result.

Future research directions

This research work will have a logical follow-up: achieving the connection with robotic surgery. A proper reduction of the femoral condyles can be done, in theory, by a surgical robot. Therefore, the procedure is accurate, reproducible and the surgical team is away from the x-ray machine (knowing that the bigger exposure to x-rays is occurring during the alignment and not during the insertion of retrograde nail).

In the same direction, creating a specific software dedicated to the distal femoral fracture and its use for the navigation devices is another research opportunity. A similar software already exists for the fixation of the femoral shaft fracture with plate and screws using the minimal invasive technique. Implementing this approach for the osteosynthesis with retrograde nail is only one step ahead, having a shared objective: less x-ray exposure for both patient and operative team and a higher reproducibility of the surgical procedure.

KEY WORDS

- distal femoral fractures
- femur osteosynthesis
- retrograde nailing

CONTENT