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SUMMARY OF THE PhD THESIS

RESEARCHES REGARDING THE BIOMECHANICS OF THE AXIAL DEVIATIONS OF THE HUMAN LOWER MEMBER AND THE DEVELOPMENT OF THE CORRESPONDENT SURGICAL DEVICES

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CHAPTER 1
Introduction. The importance and motivation of the study

This PhD dissertation resulted from theoretical and experimental research studies developed during several years of study. This dissertation is grounded in an interdisciplinary field, *medical engineering* also known as *bioengineering*. There were several reasons to choose this field, as follows:

- **Opportunity to perform thorough engineering studies**

Bioengineering allows complex engineering studies; the overlap between the medical field (orthopedics and traumatology) and the technical and technological fields offer research opportunities less often approached by the engineering researchers.

- **Special social impact**

The surgical care of lower extremities impacts both elderly persons whose joint friction is a normal consequence of the aging process and young persons with an unhealthy life style that creates osteoarticular system stress.

- **Increased precision of the surgical act**

Even for very well trained surgeons, high precision surgical devices will increase the performance of the surgery. Also, specialized software that simulates the surgical intervention will be beneficial in the pre-surgical phase by allowing the surgeon to select the best treatment strategy.

- **Interdisciplinary research**

Currently the relationship between the surgeons from the Orthopedic and Traumatology Department and the engineers from the College of Engineering in Sibiu is of a very high professional, scientific and human quality. Future joint research efforts will therefore increase the value of this collaboration.

- **Tradition**

The dissertation advisor and his research team have more than 20 years experience in research of osteoarticular surgery.

CHAPTER 2

Current state of research in osteoarticular surgery

2.1 Elements of knee joint anatomy

This chapter presents the current state of research in the osteoarticular surgery. In the first sub-chapter, *Notions of knee joint anatomy* we discuss the anatomy of knee joint and its main components: femur, tibia, patella, .articular cavity, ligaments, menisci.

The objectives of this study are:

- Thorough understanding of the joint anatomy to identify the areas suited for bio-mechanical research;

- Transposing the medical problem to the engineering field.

The bibliographical research focused on the bone structure of the knee joint. Because these are long bones, structurally they have two epiphyses (the bone ends) and a diaphysis (the long tubular midsection of the bone). The diaphysis can be assimilated with a tube, made up of cortical bone which contains bone marrow, while the epiphyses are made of spongious bone covered with a layer of compact bone.

As for the long bone with a non-homogenous structure, we can **conclude** the following:

- *The bone can be assimilated with a tubular hard structure (the diaphysis) filled with a soft substance (marrow) and having compact ends (epiphysis level);*
- *It is important to establish the dimensional ratio (diaphysis/epiphysis) for each bone studied;*
- *The tubular zone has an homogenous bone structure;*
- *The epiphysis areas are not homogeneous, the density of the bone tissue increasing from interior to exterior;*
- *The width of the hard bone structure is relatively constant along the tubular zone and decreases in the spongious area of the epiphysis.*

These conclusions allow a 3D modeling which simulates well the bone behavior.

Another important issue resulted from the bibliographical study was the **mechanical bone characteristics,** as follows:

- *As a material, depending on the depth of the research, the bone can be considered isotropic, orthotropic, anisotropic or transverse isotropic;*
- *The mechanical characteristics have values that vary from one research study to another. The variation is dependent on the biological aging or the existence of certain diseases. The analytical and experimental study of these variations could be an interesting research topic;*
- *The values of the mechanical bone characteristics can also be determined with specialized software that processes the X-ray images.*

The values of the elastic modulus and other mechanical characteristics can be determined either by averaging the values found in the literature or as actual measured values.

2.2. Elements of knee biomechanics

The human body bones are geometrically complex and therefore their geometry must be reported to a reference system for evaluation. When defining the evaluation reference system, the lower limb axes are especially important. For a clear definition of these axes we started with a larger approach: the plans and axes of the human body. The establishment of a reference system will help with the engineering approach of this problem.

We started with the tri-orthogonal system of the human body used in medicine. The main plans are: sagittal, transverse and frontal. Based on the human part under study, these plans will be translated but will hold the same names.

Next we studied geometrically the axes of the lower limb, particularly the mechanical and anatomic axes of the leg and their relative position for a healthy subject.

The understanding of the knee anatomy and biomechanics is very useful for the study of locomotion in general and, also, for the diagnosis and treatment of the knee injuries. The knee joint has 6 degrees of freedom – 3 rotations and 3 translations. The main movement is flexion-extension, a complex movement in which all the femur, tibia and cruciate ligaments take part.

2.3. Current research in biomechanical modeling

The use of modern techniques of biomechanical modeling as research method of the human body stimulated an important progress in the medical field. Since the objects of the study are human body parts that cannot be taken apart and studied, modeling methods proved even more effective.

There are two modeling strategies:

- Classical modeling – harder to implement because of the complexity of the bones;

- Reconstruction modeling with its two methods:

- Reconstruction through tridimensional scan of real bones (in vitro method) – needs the bone to scan and therefore uses bones from corpses;

- Reconstruction through transformation of X-ray images or CT-scans in spatial models (in vivo method);

CAE numerical simulations proved their utility in the biomechanical field especially because of the nature of the research object. The research object cannot be tested in the prototype phase and cannot be dissembled, tried and assembled back like a typical mechanical device. Therefore, CAD modeling followed by CAE analysis have applicability in the osteoarticular field under analysis. Numerous research studies in the field support the above conclusion.

The following are conclusions regarding modeling and simulation of the human osteoarticular system:

- *Modeling research is very important in this field since research on real components, in vivo, is impossible;*
- *Modeling is possible in the 3 variants previously presented;*
- *The scanning method, more accessible, is very precise but has the disadvantage that it needs an actual bone that is typically taken from corpses and therefore the result is not „patient oriented";*
- *The most exact method which also is „alive patient oriented", although not the least expensive, is the use of X-ray images or CT scans;*

- *The models can be used for surgery simulations to optimize the surgical procedure;*
- *Using the finite element method we can simulate the bone system behavior before and after the surgery using various methods.*

2.4 Axial deviation of the lower limb. The biomechanics of axial deviations. Geometrical elements.

To highlight these deviations we'll make first analyze the normal alignment of the axes in a healthy patient. The test of correct alignment is provided by the collinearity of the centers of the femoral head, knee and ankle. **Any deviation from this axis represents an axial deviation.**

There are various geometrical elements, axes and angles who define these deviations.

According to the cause that produces them, deviations can be classified as:

- Axial deviation with no changes in bone shape (caused by deformation or joint wear);
- Axial deviations whith changes in bone shape

Axial deviation with no changes in bone shape (caused by deformation or joint wear)

These deviations could occur in both frontal and sagittal plans. The deviations in the frontal plan of the lower limb, around the knee joint, can be *genu varus* and *genu valgus*. In the sagittal plan, the deviations can be *genu recurvatum* or *genu flexum*.

In all the cases of „axial deviation", the mechanical axis through the femural head and the ankle center do not align with the knee center anymore. This type of misalignment is known in medical field as arthritis. One of the most common type of arthritis is osteoarthritis, and is characterised by the wear of the joint cartilage. Osteoarthritis is common especially for hip or knee joints.

Axial deviations whith changes in bone shape

In this case, there is no wear in the joints; the deviations are due to bone malformation as a result of either improperly healed fractures or malformations. To study these axial deviations following parameters are used: Amplitude, CORA (center of rotation angulation), Deformation Plan and the Deformation Direction.

When this problem is analyzed from a biomechanical perspective, by studying the knee load, the existance of an axial deviation increases the load in the joint, which leads to an increased deviation. *Therefore, the wear in the joint and axial deviations are mutually reinforcing elements.* Therefore, to exit this vicious circle, a correction of deviation is needed. Treatment strategies are influenced by the developmental stage of the disease, in many cases poitning toward a surgical solution.

There are three **types of surgeries**:

The first surgery type addresses arthrosis femur-tibia without misalignment or with very small misalignments. In these situations, osteochondral transplants (mosaicplasty) are recommended.

The second surgery type addresses the misalignment arthrosis in frontal or sagittal plans (genu varum, genu valgum, genu flexum). In these situations **correctional osteotomy** is reccommended. This type of intervention will be presented in more detail in the following chapters.

The third surgery type addresses severe arthrosis (generalized or complex) treated by reconstruction operations or joint replacement arthroplasty.

2.5 Proximal tibial osteotomy

The **Proximal Tibial Osteotomy** is a common surgical procedure used to correct axial deviations of lower limbs. This procedure can be very well used for both knee osteoarthritis and axial deviations due to changes in bone shape. The associated technique will be developed and discussed in extension from a biomechanical perspective in this dissertation.

Tibial osteotomy is a surgical technique that involves creating a bone wedge at the proximal tibia level to realign the bones of the lower limb. The osteotomy technique is fully recommended for younger patients because in their case it the recovery is relatively quick. In addition, this technique does not exclude the possibility of partial or total prosthetic intervention, if needed later on.

The purpose of the proximal tibial osteotomy *is the realignment of the mechanical axis of the lower limb and the redistribution of the forces in the joint to unload the impacted area.*

The dissertation includes a detailed classification of the osteotomy of the lower limbs as well as a presentation of the advantages and disadvantages of each type of osteotomy considered in this study.

The bibliographical research indicated that the most recommended technique is the bi-planar medial osteotomy. This technique creates bone contact surfaces that are significantly higher than those created with all other mono-planar techniques. Therefore, this technique will be studied in detail in this dissertation.

We have synthesized the results of this extensive bibliographical research in a SWOT analysis that helped us define the niche of our research as well as the dissertation’s objectives.

CHAPTER 3

Disertation objectives

The main objective is to contribute to the optimization of the lower limb osteoarticular surgery, especially the mechanical aspects, using engineering procedures and research methods.

In accordance with the international research studies, the disertation has the following main objectives:

1. Synthesis and structure of the current state of research regarding the osteoarticluar surgery of the lower limb, and especially the knee joint;
2. Development of a CAD method to generate a three-dimensional model of the human tibia and femur bones, with possible dimensional customization;
3. Modeling the healthy and sick human leg to better simulate and then optimize target surgical aspects;
4. Introducing a novel concept – the medical constructive-anatomical entity of the leg skeletal system (an analogy of the constructive-technological entity) for modeling automation;
5. 3D modeling the leg bones considering the bone structure as a sum of predefined entities;
6. Development of a complex product which integrates the leg model with medical aspects such as diagnosis and treatment;
7. Parametric and generalized modeling of the tybial osteotomy surgery; simulation and optimization of concrete surgical situations using the finite element method;
8. Conception, modeling and design of an original specialized device for tibial osteotomy that will ensure a high surgical precision and create a non-aggressive solution for the patient.
9. Conducting experimental research studies to model the state of stress and strain in the surgical area of the osteotomy (surgical and post-surgical); design and execution of an experimental modular stand that will ensure the optimal conditions for conducting tibial osteotomy (surgery) in multiple versions. Experimental validation of theoretical and numerical investigations carried out.

CHAPTER 4

CAD biomechanical modeling of the osteoarticular system of the lower limb

4.1 CAD modeling of the human tibia and femur

Computer-aided modeling proves to be very useful in the biomedical field since the objects of the study, human body parts, cannot be removed and studied as experimental objects.

A thourough modeling and simulation of the pathology and treatment strategies of the lower limb, particularly the knee joint, requires as a first step a CAD geometric modeling of the main joint bones (femur and tibia). To accomplish this, we recommend 3D modeling using reverse engineering, more exactly reconstruction through a three-dimentional scanning of real bones (in vitro method). The results are CAD models

(CatPRT extension) for tibia and femur which are the starting point of extensive research studies regardin the following:

- Bone assembly for healthy or sick subjects
- Modeling diseased bones
- Performing virtual surgeries and comparing different treatment strategies
- Evaluation of preoperative, intraoperative and postoperative subject behavior
- Analysis of all situations regarding stress and strain of CAE systems.

All these studies are possible using powerful modeling CAD tools which allow superior information processing.

4.2 Triaxial parameterisation of the model

The great disadvantage of the scan reconstruction modeling method is that it is impossible to be applied in vivo because it requires the physical bone. Alternate custom models can be used, such as tomographic scan reconstruction, but the method is expensive, hard to conduct, aggressive and therefore not always justified.

We propose a simpler method to obtain custom models from scanned models by using 2D radiographic images.

We proposed that the size of the model obtained by scanning and captured in the projection planes xOy and yOz (frontal and sagittal) represent the standard dimensions. These two planes allow an easy X-ray of the tibia as well as the evaluation of the bone dimentions of the subject to be investigated. Adjustment coefficients will be determined by the ratio of the actual dimensions to the standard dimensions using parametrical CAD-specific tools such as Catia V5R20.

4.3. CAD modeling of the real bone structure.

Another issue considered to ensure model accuracy is the actual bone structure. From the mecahnical behavior point of view, bones do not have a homogeneous structure and therefore modeling thier structure is quite complex.

Therefore, we propose a new concept to be used in computer-assisted programs, **the medical constructive-anatomical entity.** The medical constructive-anatomical entity can be defined as a geometrical form of an anatomic configuration along with an ensemble of specifications that can connect one or more medical actions like diagnose, pathology, treatment, etc.

As an example, tibia has four entities: articular cartilage, proximal epyphisis, diaphysis and distal epyphysis. Specifications corresponding to each entity are: shape, size, stress and structure. These specifications need to be connected to medical actions, such as wear or functional depreciation, disease, or treatment.

Medical actions and specifications can be stored in databases, and the retrieved and used with specialized software. The relationship between the entity specifications and the medical actions can be made on both the assembled model or on separate entities.

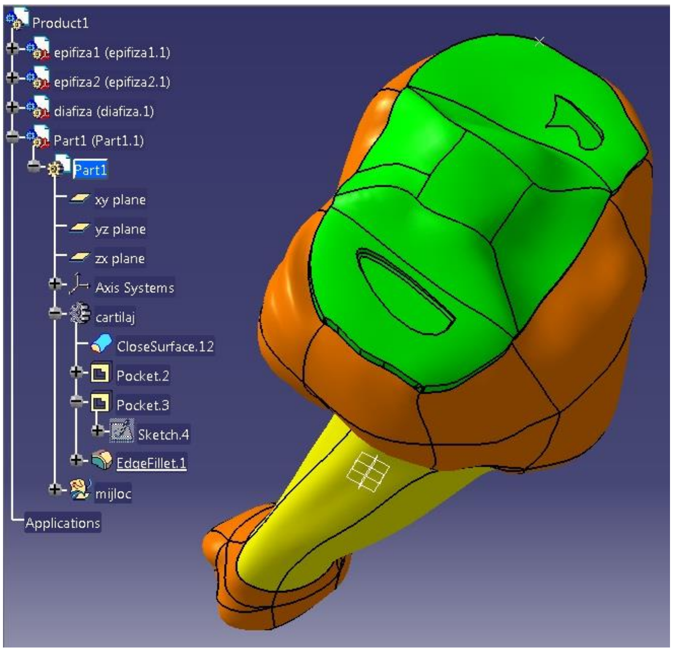

Figure 1 Ghonartrosis CAD modeling

The modeling of the real structure of the tibia will start with a model obtained by 3D reconstruction based on scanning. The scan result is a full homogenous body that doesn't allow a correct CAE approach because it does not consider the mechanical characteristics of the bone component entities.

Therefore, we modeled each entity (articular cartilage, the two epiphyses and the diaphysis) with Generative Shape Design and Part Design Catia V5 R20 modules. After creating each independent model, we assembled them using the Assembly Design module.

The modeling process described above presents multiple advantages. First, creating the model as a sum of different components allows the research to assign different characteristics to different entities. Second, different wear situations can be simulated on each component (figure 1), which will be later reassembled in the model. The approach is very important from the CAE modeling perspective.

An example of the use of modeled entities for various pathological situations is the cartilage wear in osteoarthritis (a medical term that describes the degradation of joints, including the articular cartilage and its underlying bone). The obtained cartilage model is an anatomical constructive entity that can be re-modeled in various stages of wear and later reassembled in the tibia model.

4.4. Generalized modeling of the human lower limb

An generalized assembly (figure 2) of the main bones of the human lower limb has as main goal to create the premises of a computer-assistenbiomechanical system that will serve in the study of a wide range of pathologies.

Using three-dimensional CAD models of the main bones of the human lower limb, we created an assembly which can ilustrate both a healthy subject and one affected by axial deviation.

For this modelling, we created reference systems that map the anatomical and mechanical axes of the lower limb. These reference systems were later assembled

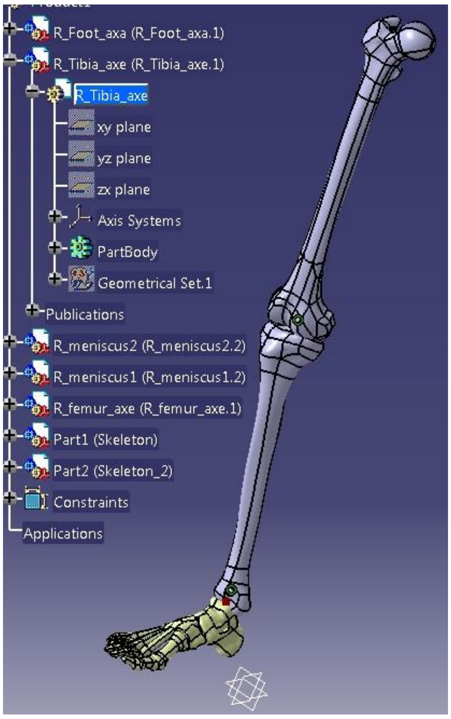

Figure 2 CAD modeling of the ower member

offering various easy customization options. A generalized model was then developed for the healthy and sick leg assembly. Customization using this generalized model is possible for all possible axial deviations.

Since there is a large number of pathological situations that involve a multitude of medical strategies, we recommend a computerized application. We developed an informational flow and a database to colect patient information to be transferred to CATIA software and obtain the 3D patient and disease models. The program was developed in Microsoft Access.

4.5 . Modeling human tibia affected by changes in shape

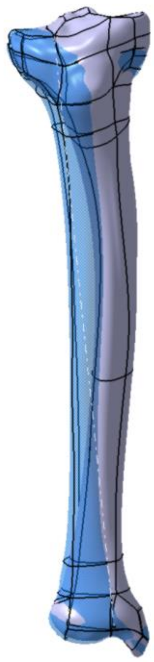

Figure 3 CAD modeling of the deformed tibia

Along with the CAD modelling, we also consider important to model the bone structures affected by modifications of form (e.g. tibia bent), due to either viciously consolidated structures or specific diseases.

In general these changes cause misalignments that change the balance of static and dynamic bone. The modelling of bone structures with modifications of form will start with the non-modified bone structure and then using known deformation parameters we will generate the tibia deformed model. Model parameterization can be done using links between Catia and Excel data tables which can generate virtually any deformation. The affected bone can be assembled on a healthy femur generating this way the model of the affected leg .

The correction of such situations can be achieved through tibial osteotomy surgery performed under tibial tuberosity in CORA on the hard bone corical area specific for the diaphysis.

4.6. CAD modeling of surgical strategies to correct the axial deviation of the lower limb through tibial osteotomy

The advantages of CAD modeling are: a better assessment of the actual situation on the custom model, compatibility analysis with implants and transplants found in 3D databases, and the educational role in suporting the learning these techniques using virtual models.

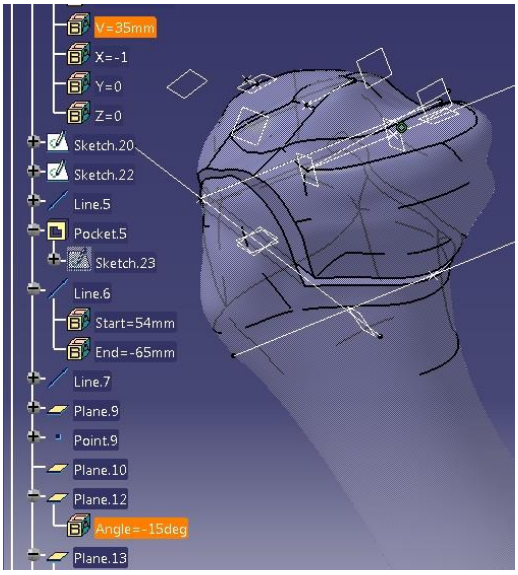

Figure 4. CAD modeling of tibial osteotomy

The correction of the deformations due to gonarthrosis or axial tibial deformities (most common) can be solved most often by tibial osteotomy.

After we realized the general model of all osteotomy types (figure 4), we modeled in detail the open osteotomy with parametric modeling of the tibial osteotomy, with the possibility of creating custom models for open uniplanar and biplanar osteotomy closed osteotomy .

Modeling all intervention steps in a parameterized way generated new possible research topics such as: a) the need of a relief hole in the tip of the wedge, b) study of the diameter of the hole, c) position of the "hinge" point of the osteotomy, d) dimensional position situated on the cortical area, opposed to the hinge, e) modelling of the ascending transverse plane specific for biplanar osteotomy, or f) angular position of the previously described plane. The different combinations of the above parameters can be easily molded and researched through other methods.

In this stage models were developed to be studied with the finite element method.

CHAPTER 5

Numerical simulations concerning the osteoarticular surgery of the lower member

The analyses using the finite element method proves its full efficiency in the study of the osteoarticular surgery, being a method that we can use in order to simulate a high range of situations, in the following scenarios: pre-surgery, during the surgery and post-surgery.

Numerical simulation of the tibia's behavior in osteotomy surgeries offers a pretty accurate image of the stress state and allows us to take the most appropriate decision regarding the surgery planning, to choose the parameters in the most efficient way, so as to allow us to obtain the best possible result.

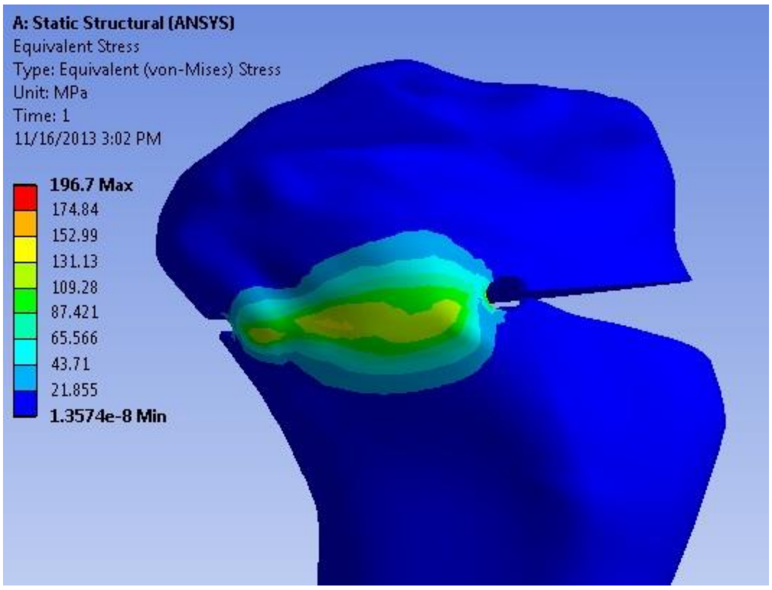

Figure 5 Equivalent von Mises stress in CORA

The software that we used is ANSYS 12. The stages used to realize the simulations are those consecrated in the field of the finite elements method.

The conclusions reached after undergoing these analyses are:

- FEM analyses that were made had as purpose the optimization on geometric and dimension criteria of the surgical intervention of tibia osteotomy;

- Analyses were made in three hypothesizes: uniplane opening osteotomy, closing osteotomy and biplane opening osteotomy. The focus was on the stress values in the hinge area (CORA);

- the optimal pressure values were obtained in the case of the uniplane opening osteotomy for the position of the plane being situated at 40mm(middle value) towards the tibial plateau;

- in the case of the uniplane closing osteotomy the lowest pressures were those afferent to the value of 12 mm distance of the CORA hole towards the lateral surface of the tibia;

- the lowest pressures gained while realizing the biplane opening osteotomy were achieved for the lowest inclination of the second osteotomy plan, 105 ^{o};

-in all of the researches, a higher correction angle led to higher stress on the hinge;

- as a comparison, from all of the three surgical interventions, the lowest stress values were achieved in the case of the biplane opening osteotomies.

CHAPTER 6

Specialized device for realizing tibia osteotomies

From previous researches we have observed, both on local and on national level, an attitude of restraint in the persons of the orthopedic surgeons when it comes to using the tibia osteotomy as a treatment strategy for correcting axial deviations. While trying to find a reason for this attitude, we have reached the conclusion that the lack of precision implied by the realization of this technique might not lead to the best results.

That is the reason for which we have planned to realize a specialized device that we will be used to undergo this surgery technique.

The purpose is to improve the dimensional and geometric precision of this surgery technique, especially for the realization of the depressuring hole(CORA),both as a position

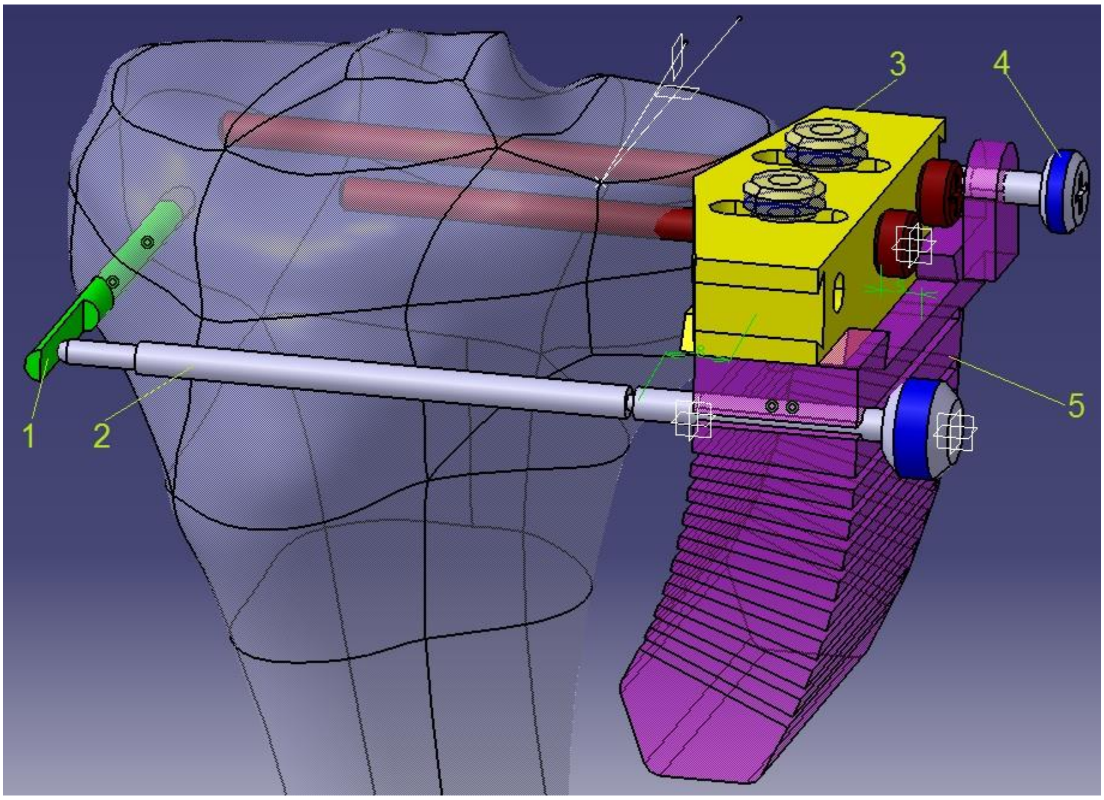

Figure 6 Specialized device for realizing tibia osteotomies

and as a diameter, and for positioning of the cutting plane or planes at the exact angle

The design of the device (figure 6) has as starting point the requirements and needs that the device must satisfy.

A first request would be that the device addresses both opening and closing osteotomies, both medial and lateral ones, both uniplane and biplane osteotomies. Also the processes of generalizing, parameterizing and modulation are basic principles that were used for the design of this device.

The main functions that the device must fulfill are:

I. *Positioning, orientation and fixation of the orientation element of a short prism type on the tibia in accordance with the planes that are important for the realization of the osteotomy;*
II. *The existence of a positioning system of the CORA in relation to the orientation prism;*
III. *The possibility to make a hole in CORA with the facility to modify the hole's diameter;*
IV. *The possibility to move CORA in a controlled manner on two perpendicular axes;*

V. *Realizing the necessary cut or cuts for the realization of the osteotomy wedge;*
VI. *The possibility to control the wedge's angles;*
VII. *Finalizing the cuts mandatorily in the hole from CORA*

Having as a starting point these functions, technical-constructive solutions were searched for fulfilling them.

The designed device satisfies the necessities to realize all types of osteotomies with a high degree of precision and accuracy in the realization of the section planes and of the de pressuring holes.

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CHAPTER 7

Specialized stand designed for experimental researches regarding tibia osteotomies

The accuracy of the engineering research implies, as a necessity, to experimentally validate all the theoretical or numerical studies that were realized. Therefore, starting from the osteoarticular affections that were presented and taking into consideration the recommended surgical interventions, we propose the design and modeling of an experimental stand destined for the study of the biomechanics of the knee's articulation biomechanics after applying these interventions.

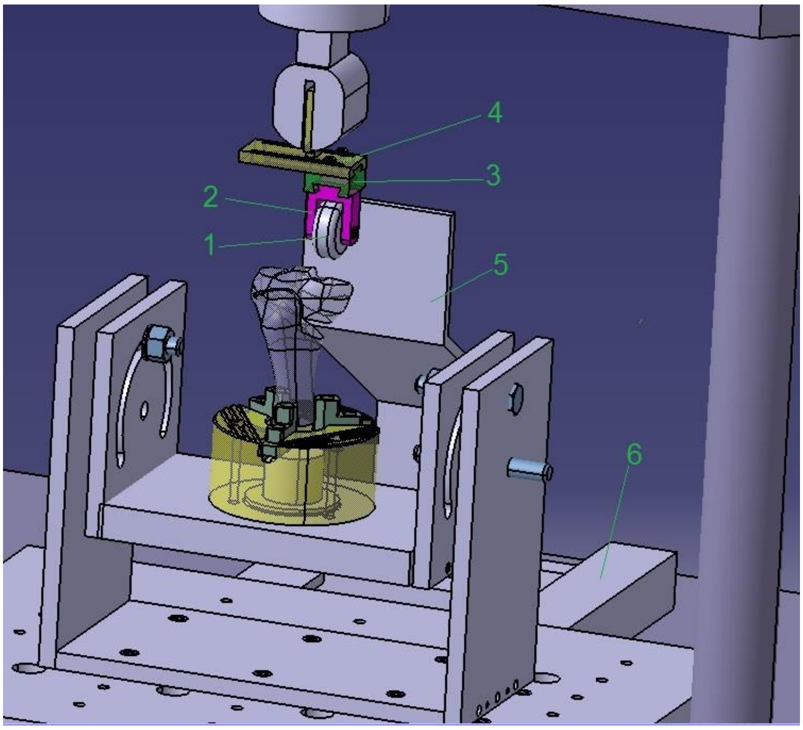

Figura 7 Device for testing closing osteotomy

The stand's structure was determined after establishing the functions and the constructive solutions and taking into consideration the equipment and the machines on which the projected stand will be installed.

Because the purpose was to obtain a modular ensemble that will fulfill more than one function, but not all simultaneously, we have opted for the design of a stand with two sub ensembles that can be used in a combined manner depending on the necessities of the realized attempt.

Therefore, the resulted devices have an inferior sub ensemble and a superior one in a cinematic chain through an external machine. Specifically, in the studied case this machine will be a universal machine used for charging at traction, compression and buckling (Instron 5587, maximum force 300 kN), which is at our disposal in our institution.

The lower sub ensemble will be found in all the constructions of devices, even if it is used with the universal axis in vertical position, horizontal position or any other inclination angle of the tibia.

The superior sub ensemble will be different in relation to the experimental attempt that was realized. Mainly, three types of devices can be realized modularly:

-for the study of the closing osteotomies (figure 7)

-for the study of the opening osteotomies

-for the study of the whole knee's articulation that was subjected to different tests.

The experimental stands that were designed and presented were actually realized and used in experimental researches.

CHAPTER 8

Experimental researches regarding the high tibia osteotomy

During this study we will design and realize two experimental programs that have as objective high tibia osteotomies

The main objectives of the experimental research are:

- To determine the variation of the pushing force in relation to the movement of the mobile traverse during the realization of the opening osteotomy wedge;

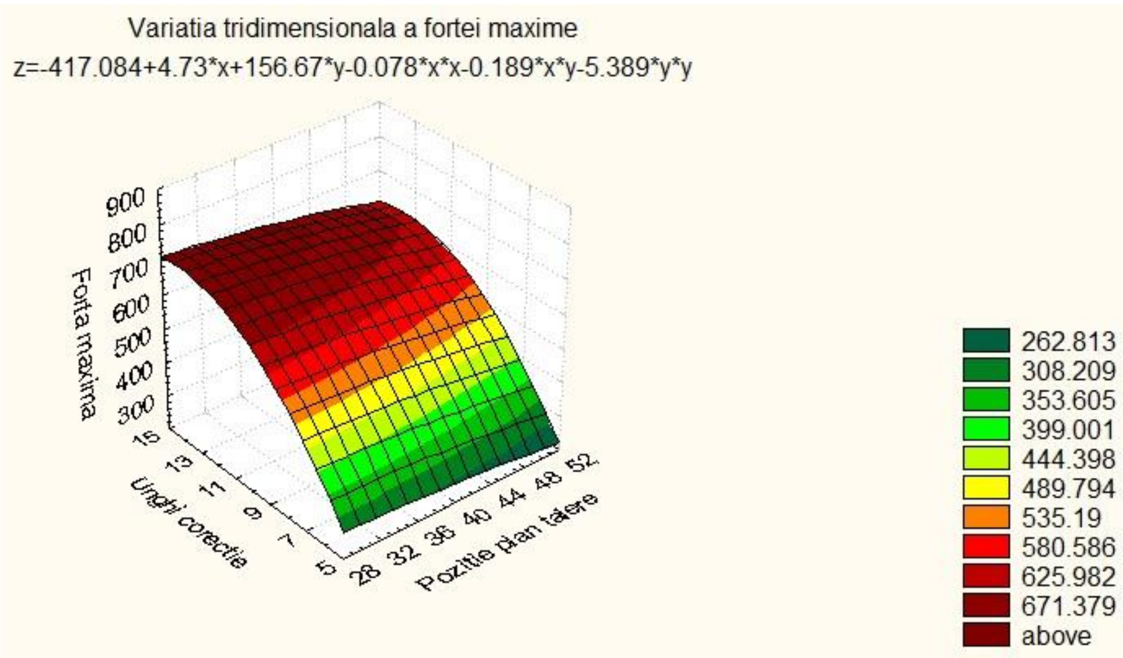

Figura 8 3D variation of the maximal charging force

- To determine the maximal charging force;(figure 8)
- The appearance of the fissures and micro fissures;
- To experimentally determine the deformations in the CORA area;
- The experimental study of a tibia that has undergone a surgery in the conditions of the modification of the application area of the vertical burden on the knee’s width.

For the experimental researches we have chosen entry variables that characterize in a significant manner this phenomenon.

The experiments were undergone on bovine bones which were prepared accordingly for the operation.

Regarding the experimental equipment, we used: the designed stands, a universal machine used for charging at traction, compression and buckling(Instron 5587,and data capturing system ARAMIS 2M.

Experimental researches that were undergone in the first experiment have confirmed the analyses that were realized using the finite element method.

We can observe that the forces have reached maximum values while positioning the osteotomy plan 40mm from the tibia plateau. Therefore, we recommend that the cut shall be realized for osteotomy at this distance when and in the hypothesis in which the finite element obtained the lowest stress values.

Placing the initiation point of the cut to the middle of the recommended interval (40 mm in the present situation) is the only option that allows higher correction angles (16-18 degrees) unlike the values of 30 mm and of 50 mm where the maximum obtained values are lower than 11-12 degrees for the correction angles.

As it concerns the second experiment, the final conclusion is that after the medial pressuring of the tibia, bigger deformations and movements intervene, that could lead to the appearance of fissures or even fracture, recommending in this sense that the passing of the foot’s mechanical axes shall be realized through the Fujisawa point situated at 62% from the knee’s extremity

CHAPTER 9

Original contributions. Future research directions

The first task that we approached in the present study is to bring some important contributions in the field of bioengineering with direct reference to the osteoarticular affections of the lower member in general and to the knee’s articulation especially, where the application of the modern research methods can lead to improved solutions.

The most important original contributions, that underline the high degree of innovation brought by this study, are the following.

- A structured synthesis of the actual study of researches regarding the osteoarticular surgery of the lower member in general and the knee’s articulation through an exhaustive bibliographic study from the recent and valuable literature that exists worldwide;

- The transfer of the medical problems that exists in the osteoarticular area of the lower member in the area of focuses, methods, principles that are generally used in engineering.
- A structured synthesis of the previously used surgical techniques in the surgical interventions on the tibia osteotomy
- A personal classification of the axial deviations and of the possibilities to correct them through the proximal tibia osteotomy
- The realization of a SWOT analysis with the identification of the research area and on this basis to further propose the objectives that shall be accomplished.
- CAD modeling of the lower member bones using the reconstruction through scanning method and tying the reference elements used in the modeling of reference systems that are used in order to define anatomical structures.
- Realizing personalized models of the tibia and the femur through a tridimensional scaling, the scaling coefficients being easily obtained from radiographies
- Realizing the 3D model of the tibia taking into accounts the heterogeneous real structure of the bone;
- Introducing the concept of constructive-anatomical-medical entity in analogy with the constructive technological entities;
- Realizing a system that allows the interaction between these entities and implant-transplant data bases, with the diagnostic part, with the treatment strategies and so on, creating the premises for the development of a dedicated software;
- Modeling entities both singularly and in an ensemble system, both for healthy subjects and for those suffering of affections;
- Modeling in a generalized manner the bones of the lower member. Pointing out and inserting on models reference elements, such as: triedre¸ euler angles, axis, important points, and connecting them in geometric systems Skeleton type;
- The development of a system that allows the assembly of bone models that are properly aligned, but also the modeling of all possible axial deviations, both rotation and translation deviations, reaching a high number of pathological situations.
- Realizing a complex software that would manage the aforementioned situations and that would connect them with the diagnosis types, treatment, virtual surgery, optimization;
- 3D parameterized modeling of the tibias affected by form modifications with the possibility to obtain particularized models using defined parameters. The system also allows the introductions of parameters from Excel tables or other databases;
- The modeling of the intervention of high tibia osteotomy with the capacity to realize all the intervention possibilities, only by modifying some parameters in the tree structure structure of the models;
- Realizing CAE models for both the uniplane and biplane opening osteotomy and the closing osteotomy for the optimization of parameters that concern: choosing the best position of the cutting planes, the hinge position(CORA) and the correction angles;

- The design of a modular device that allows the realization of all the types of osteotomies with a high degree of precision;
- The design and the development of experimental modular stands for the study of all the types of osteotomies;
- The design and the development of an experimental research program for the study of the tibia's behavior while realizing the osteotomy wedge**.** The study of the maximum charging force and the variation of the force in connection to the movement of the mobile traverse underlines which is the best position of the osteotomy plane, confirming the numerical studies that were realized through the finite element method;
- The design and the development of an experiment research program that would allow the study of the tibia's behavior after the opening osteotomy surgery and that fixation with a osteosynthesis plate TOMOFIX. The optimal position from the knee's articulation recommended for undergoing the axial correction was underlined.

The presented studies can be the subject of further researches, and in this sense the following research directions are proposed:

- Completing the present study with an approach of this issue from a dynamic point of view;
- Modeling the cinematic of the leg's bones and of the generalized ensemble by approaching the 3D models we have presented, in different situations, such as: walking, running, jumping etc.;
- The further research and the addition of the particularized procedure of the bone models by scaling through researches concerning the validity and the adequacy of the used scaling coefficients
- Further studies on the area concerning the mechanical characteristics of the bones by considering the bones as variables that depend on different parameters. The analytic and experimental study of some variation functions of the mechanical characteristics in relation to the person's gender, biological aging or the appearance of different diseases.
- Creating a software that allows the modeling of the real bony structure connected to options and medical strategies such as diagnosis, treatment;
- Optimizing the necessary tools used for the proximal tibia osteotomy surgery by taking into consideration also the control of the speed in which the osteotomy wedge is realized;
- The study of the speed in which the bone fragments are removed trough the finite element method after experimental researches;
- The experimental study of the appearance of fissures or micro fissures in the hinge area(CORA) through resistive tensometric methods and microscopically analysis;
- Researches and optimizations concerning the placement possibilities of the bone fragments after realizing osteotomy interventions, taking into consideration the possibility to optimize the plate's form or to create personalized plates.