UNIVERSITATEA
LUCIAN BLAGA
DIN SIBIU

Engineering Sciences and Mathematics doctoral school
PhD field: Mechanical Engineering

PhD THESIS – ABSTRACT

STUDIES AND RESEARCHES REGARDING THE BIOMECHANICS OF THE FOOT AND THE AXIAL DEVIATIONS WITHIN IT

PhD Candidate:
Eng. ANDREI HORIA BRĂNESCU

Scientific coordinator:
Eng. NICOLAE FLORIN COFARU, Professor, PhD

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SUMMARY

The PhD thesis entitled ”Studies and researches regarding the biomechanics of the foot and the axial deviations within it” includes:

- 9 Chapters;
- 281 figures;
- 25 tables;
- 111 references.

The studies and researches related to this thesis were carried out over three years and the paper approaches from a biomechanical point of view the axial deviations conditions of the foot, specifically the Hallux Valgus pathology.

KEY WORDS: foot surgery, gait biomechanics, Skeleton systems method, constructive-anatomical entity, real bone structure, parameterized assembly, CAD, CAE, finite element analysis, MT1 open wedge osteotomy, CORA (Center of Rotation of Angulation), geometric planning optimization, CNC program, Haas ST-15Y.

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Introduction

This PhD thesis is the outcome of the theoretical and experimental researches carried out over three years, the main topic is an interdisciplinary one, and the field in which it focuses being the biomedical or medical engineering.

The reasons why we decided to approach such a topic will be presented as follows:

The first reason is that this field of medical engineering or bioengineering requires in-depth engineering approaches. The human body as a whole is of a very high complexity, having to perform varied and elaborate functions and, unfortunately, can also be affected by various pathologies. In order to treat these pathologies, it is necessary to accurately reproduce these natural functions, which is complex task.

The anatomical site covered is that of the human foot, focusing on the axial deviations that can occur in this area. The study of these pathologies of the foot requires in-depth engineering approaches, based on methods in the engineering field. A conclusive example of this is the fact that in current treatment strategies, to achieve the precision required for interventions, it is necessary to use various geometric and dimensional references, especially when optimising a process.

The second reason why we decided to study the biomedical theme is due to the fact that the results of the research carried out could have a favourable social impact.

Today's society often imposes certain wardrobe standards and often, for the sake of inclusion in a certain group or simply because we want to be in step with fashion, we are willing to make certain compromises, such as wearing an uncomfortable or tight type of footwear. Wearing this type of footwear or high heels favours the development of Hallux Valgus type axial deviations or can aggravate existing ones, which is why around 25% of men and 58% of women (30% of whom are under 25) are affected by this pathological condition.

The third reason for approaching this topic is the goal of increasing the precision of the surgical procedure. Thus, the study of the biomechanics of the foot and related pathologies using CAD-CAE methods, the virtual simulation of surgical procedures, the establishment of reference systems, well-defined dimensional and geometric references make the geometric planning of surgery clearer and safer.

The results of the thesis can be a guide to developing sound treatment strategies, planning operations, using the best methods for preserving corrected positions and determining optimal post-operative recovery possibilities.

CAD modelling of the osteoarticular assembly of the foot was carried out taking into account the real bone structure and aiming at a complete parameterisation of it, for a good control of basic and associated movements, gait simulation and intermediate phases, as well as easy generation of related pathological conditions.

The correction method that we decided to investigate further was the proximal opening-wedge osteotomy of the first metatarsal, a relatively recent, viable method that shows satisfying results. The main aspect studied was the optimization of this type of surgery in terms of osteotomy positioning, relative to the bone surfaces, by carrying out both CAD-CAE studies and relevant experimental research.

From our point of view, this scientific approach is an important and interesting one in the field of optimizing surgical interventions performed at the osteoarticular foot level. Also, based on this study, other research directions can be derived, such as the study of the biomechanics of the foot in post-operative form, the design of specialized guiding devices to ensure the optimal position of osteotomes or other variants of devices to preserve the positions resulting from angulation correction.

The objectives of the PhD thesis

Based on the interdisciplinary approach of the thesis, the process of establishing the topic has been very thorough, due to the fact that there are many subjects on which studies of interest can be developed, such as the study of non-invasive technologies or devices for the correction of axial deviations of the foot - specialized orthoses, the development of customized prostheses executed by additive manufacturing, the optimization of osteotomies layouts according to the behaviours of post-operative configurations, etc.

The main aim of this PhD thesis is to carry out in-depth biomechanical studies of the existing bone structures of the foot in the orthostatic position or in gait and of Hallux Valgus axial deviations, with the surgical possibilities of correcting this pathology, developing in particular the proximal opening-wedge osteotomy of the first metatarsal.

In conclusion, **the main objective** of the thesis is to conduct experimental and generalized CAD-CAE researches aiming to study the foot biomechanics in general and Hallux Valgus deviation with surgical corrective variants in detail.

The goal is to optimise the proximal opening-wedge osteotomy of the first metatarsal, to achieve precise and correct geometric planning, with a focus on the stability of the surgical area, an efficient post-operative recovery and to prevent cracks during the opening process.

Furthermore, in line with the studies and researches approached at theme level, through this PhD thesis we aim to achieve certain aspects of interest, consequently, the main objective is achieved by materializing the following objectives:

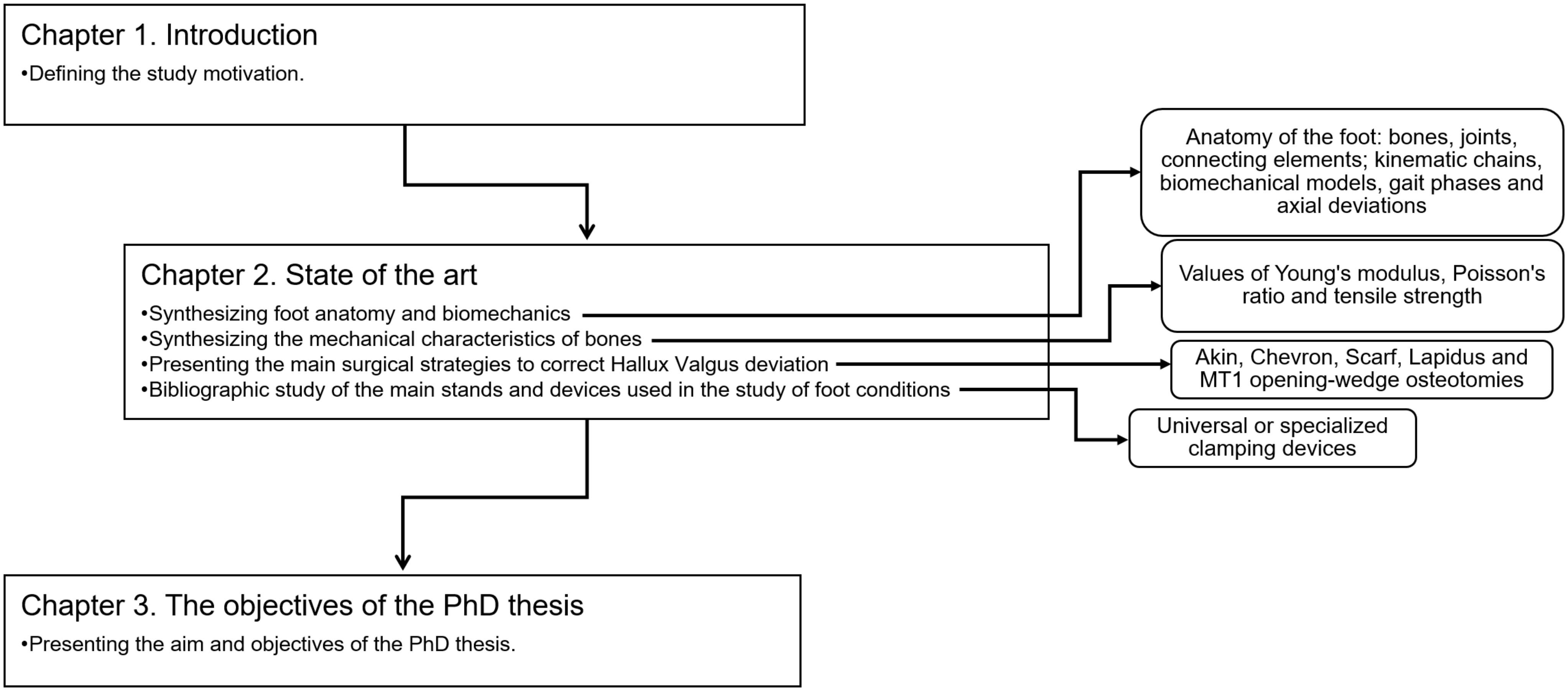
1. Synthetizing of the state-of-the-art of studies on surgical strategies for the correction of Hallux Valgus axial deviations, computer-assisted approaches to the problem and experimental studies in the field;
2. 3D modelling of certain bones of the foot, respectively those affected by Hallux Valgus deviation (first metatarsal and proximal phalanx), taking into account their real structure, using the concept of constructive-anatomical entity;
3. Development of the generalised and parameterised assembly of the human ankle-foot structure, allowing the reproduction of the six basic movements of the foot, using the Skeleton Systems method;
4. Development of the parameterised foot assembly for modelling the three phases of gait using the Skeleton Systems method;
5. Development of a parametrized assembly of the proximal phalanx of the hallux, the distal phalanx of the hallux, the first two metatarsals and the medial cuneiform, allowing CAD generation of the three forms of Hallux Valgus disease: mild, moderate and severe;

6. Generalised modelling of the five main types of surgical procedures related to the correction of Hallux Valgus disease: Akin, Chevron, Scarf, Lapidus and proximal opening-wedge osteotomy of the first metatarsal;
7. Numerical simulation of the corrective angulation process specific for the proximal opening-wedge osteotomy of the first metatarsal, using different CORA positions to perform this procedure;
8. Design and manufacture of a specialized clamping device for performing experimental research, writing a CNC program for simulating osteotomies and validating the working methodology using bone replicas developed by additive manufacturing methods;
9. Conducting experimental research on the displacements and maximum openings of several variants of osteotomy arrangement for opening the first metatarsal and experimental validation of the numerical research.

In terms of methods and tools used, the following can be listed:

- The use of CATIA V5 software for the development of models of real structures and assemblies corresponding to the Skeleton systems method;
- Parameterisation of the assemblies by linking the 3D structures with the corresponding Microsoft spreadsheets, more precisely Excel;
- Use of the Dassault Systemes suite for the development of numerical simulations, via ABAQUS 2020;
- Design algorithms and experimental modelling;
- Interpreting the experimental data using STATISTICA 12.5 and Minitab 18 software.

The graphical algorithm of the PhD thesis



Chapter 1. Introduction

- Defining the study motivation.

Chapter 2. State of the art

- Synthesizing foot anatomy and biomechanics
- Synthesizing the mechanical characteristics of bones
- Presenting the main surgical strategies to correct Hallux Valgus deviation
- Bibliographic study of the main stands and devices used in the study of foot conditions

Anatomy of the foot: bones, joints, connecting elements; kinematic chains, biomechanical models, gait phases and axial deviations

Values of Young's modulus, Poisson's ratio and tensile strength

Akin, Chevron, Scarf, Lapidus and MT1 opening-wedge osteotomies

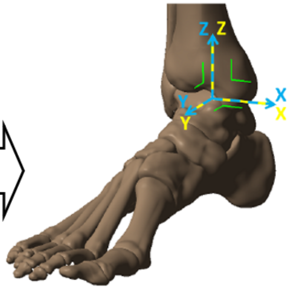
Universal or specialized clamping devices

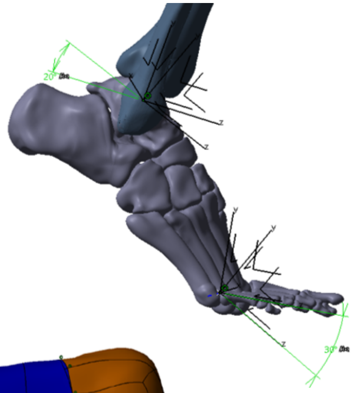
Chapter 3. The objectives of the PhD thesis

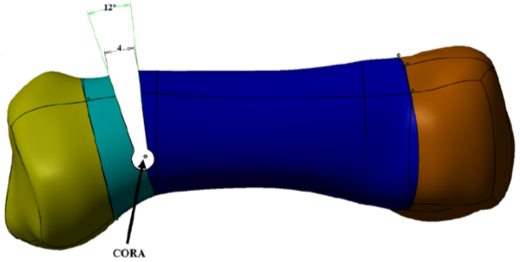
- Presenting the aim and objectives of the PhD thesis.

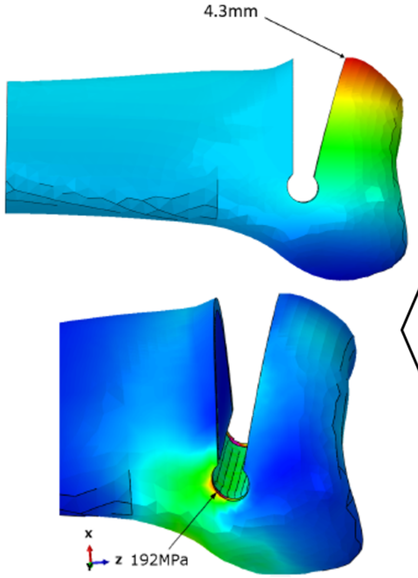
Chapter 4. CAD modelling of the osteoarticular complex of the human foot

- 3D modeling of MT1 and proximal phalanx based on geometric entities;
- 3D modelling of MT1 and proximal phalanx considering their real structure;
- Development of a fully parameterized generalized CAD assembly of the foot, allowing the generation of main and intermediate phases of gait, basic and associated foot movements and pathological situations;
- Simulation of the five main types of surgery to correct Hallux Valgus deviation: Akin, Scarf, Chevron, Lapidus and proximal opening-wedge osteotomy of the first metatarsal.



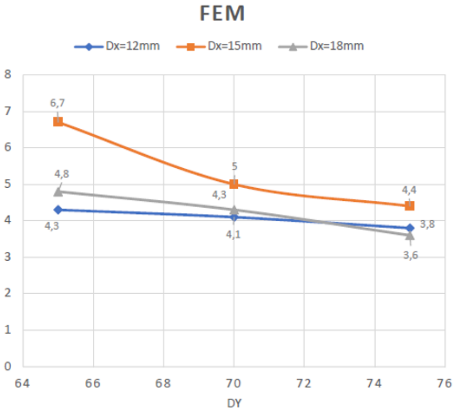






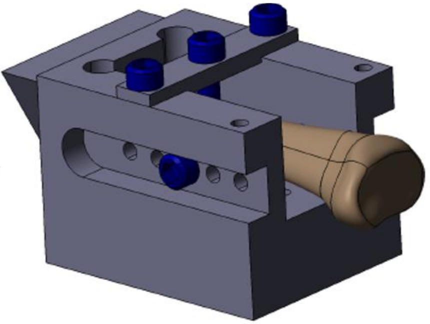
Chapter 5. Numerical simulations of osteotomies for the correction of the Hallux Valgus axial deviations

- Studying the behaviour of the first metatarsal during correction angulation, a specific step of the proximal opening-wedge osteotomy of the first metatarsal. In this study, the aim was to optimise the CORA position to avoid microcracks during angulation for 9 positioning variants;
- The specific steps of a static FEM analysis were carried out, the response functions considered being: maximum opening, the values of the equivalent Von Mises stresses at 2, 4, 5 and 6 mm opening and the shear stresses at maximum opening;
- 2D and 3D graphical representations were made for the maximum opening, which is the most important response function in the FEM study, being a concrete and palpable indicator for surgeons to avoid microcracks in the CORA. It can be concluded in this regard that the best openings are obtained for Dx=15mm regardless of the value of Dy. For Dx=12mm and Dx=18mm the values are fairly close to each other being grouped around 4mm.



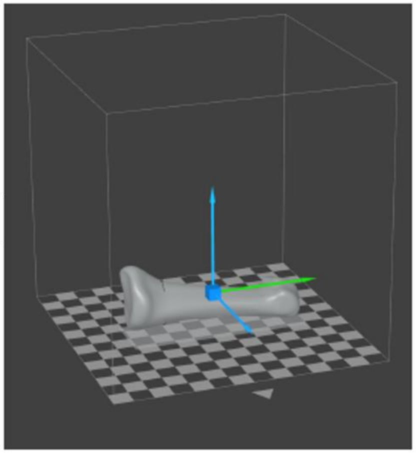
Chapter 6. Design and manufacture of a specialised clamping device for carrying out the experimental research

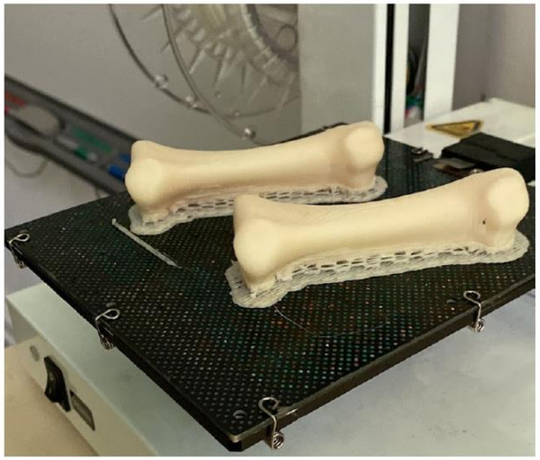
- The requirements to be met by the device and the experimental objectives that can be achieved with such a stand have been highlighted, resulting in the main functions that it should provide;
- Constructive solutions for each function have been considered and designed, resulting in a modular device with good flexibility and wide possibilities of use.

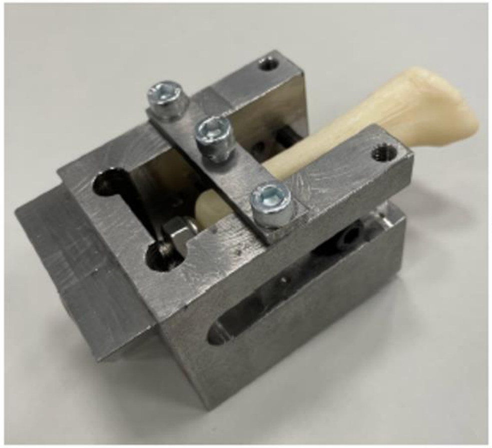


Chapter 7. The use of additive technologies for the study of Hallux Valgus axial deviations

- Bone replicas of human and porcine metatarsals have been developed by Additive Manufacturing in two variants: from ABS by the FDM method and from resin by the SLA method.



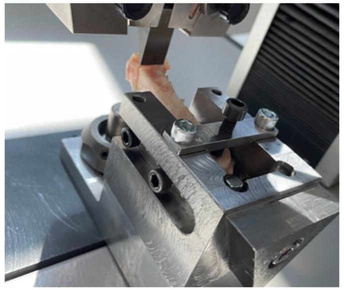


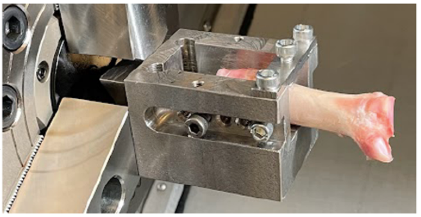


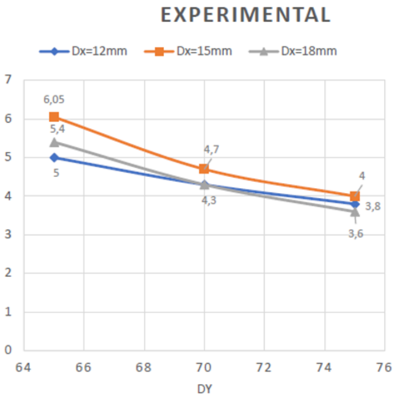
Chapter 8. Experimental research on the proximal opening-wedge osteotomy of the first metatarsal

- Experimental research was carried out to validate the results obtained from finite element analysis;
- Technological equipment used: Haas ST-15Y CNC lathe, for machining the osteotomy plane and the CORA hole and Galdabini Quasar 25 tensile-compression machine for the angular correction;
- A preliminary experiment was carried out, on printed bones, in which the osteotomy plane and the hole in the CORA were machined on the mentioned machine, according to the position recommended in the literature;
- After the validation of the preliminary experiment, the input (independent) variables Dx and Dy were established, which characterize the experimental object under investigation, in accordance with the geometric planning of the proximal opening wedge metatarsal osteotomy;
- Three levels of variation were established for each variable (Dx - 12, 15 and 18 mm; Dy - 65, 70 and 75%). A full factorial experimental program was designed, resulting in nine experimental trials, which achieved the combination of all levels of variation of the variables;
- Real porcine specimens were prepared corresponding to two replicates of each experimental point, 18 specimens being required for as many experiments;
- The 18 experiments were performed sequentially, obtaining for each of them the force-displacement diagrams, the maximum force and the maximum opening of the osteotomy wedge;
- Data was collected for both maximum force and maximum aperture on a spreadsheet basis for the 18 planned experiments. The following values of mean, standard deviation, coefficient of variation and empirical dispersion were obtained for the nine experimental trials for each of the two response functions;
- The variation of the maximum force in relation to the input variables Dx and Dy was also performed by two suggestive graphical representations (2D and 3D) made with the STATISTICA12 software. With the same program a second-degree regression equation of the maximum force as a function of the input variables was also determined;
- Graphical representations (2D and 3D) were made showing the variation of the response function in relation to the input variables Dx and Dy, showing that the best openings are obtained when the osteotomy plane is positioned at Dx=15mm, and that the largest of these, 6.05 mm, is achieved in the combination Dx=15mm, Dy=65%;
- A parallel analysis of the variations of the maximum openings obtained by FEM with the experimental ones under the same test conditions was also carried out, from which it resulted that the proposed experiment validates very well the numerical analysis performed and thus, one of the experimental objectives was achieved;
- Due to the importance of the response function, an experimental modelling of the investigated phenomenon was also performed. The homogeneity check of the dispersion of the objective function dmax was evaluated in the model, confirming the homogeneity of the response function for the 9 trials, the reproducibility dispersion and the linear regression model were calculated;
- The significance of the coefficients of the regression equation was checked, resulting that all the coefficients of the regression equation are significant with the specification that Dy has a much more important weight in the regression equation than the coefficient of Dx. Regarding the model adequacy, following specific calculations, it resulted that the experimental model is adequate and represents the coverage of the experimental phenomenon studied;
- The ANOVA analysis performed for the whole experimental model and the residuals analysis was carried out using Minitab18 software and confirmed that the objective function can be controlled using the experimental model carried out, which gives a very good degree of generality and applicability for the experimental field investigated.

Chapter 9. General conclusions. Personal contributions. Future research directions.







General conclusions. Personal contributions. Future research directions.

The scientific approach carried out is driven by the need for in-depth engineering studies that have a direct effect on the optimization of Hallux Valgus surgical interventions, by the social impact that the results might have, given the high frequency of occurrence of the condition, but also by the idea of interdisciplinarity, which has proven that the results obtained interdisciplinarily are much better than those obtained by the separate approaches of the two fields, medical and engineering.

The development of a geometric surgery planning guide for orthopaedic surgeons, with which, for example, an appropriate choice of CORA layout can be made, has important effects on the stability of the surgery site and post-operative recovery.

Also, the development of the generalised CAD-CAE models can be of great benefit to future research in the field.

Based on an ample bibliographical documentation, we can state that the thesis is in line with the studies and research in the field, worldwide.

Personal contributions

Through this PhD thesis, numerous original contributions have been made in terms of modelling the foot biomechanics and optimising surgical interventions of correction of the Hallux Valgus condition, the most notable of which are highlighted as per:

- Elaborating a foot anatomy study and transposing the problem into the engineering area;
- Synthesizing the mechanical characteristics of human (cortical-trabecular) and animal (bovine and porcine) bone structures;
- Identifying biomechanical research areas within the foot area and its axial deviations;
- Setting up the Gcs and Tcs reference systems for parametric CAD modelling using Skeleton systems;
- Transposing the main foot joints into classical mechanical friction joints (plane, ellipsoidal, cylindrical etc.);
- Identifying the optimal positioning of the ankle reference system origin (talocrural joint) and the main geometric elements (axes, angles), with respect to which the foot movements and gait phases will be modelled;
- Identifying the geometric and dimensional elements useful in the 3D gait modelling, including the angular elements needed for CAD modelling of axial deviations;

- Identifying the geometric, dimensional and reference system elements that will allow the 3D modelling of the five types of Hallux Valgus correction surgeries;
- Making distinct 3D models for the body, head and base of the proximal phalanx and the first metatarsal and assembling them, as well as distinct CAD models for the cortical and cancellous zones of these bones, in accordance with the constructive-anatomical entities method;
- Elaborating the parameterized foot assembly for generating the pathologies that may occur in the orthostatic position and the basic and associated movements. Necessary reference systems, origins and axes definition and fitting them within the Skeleton systems;
- Taking into account the three levels of severity of Hallux Valgus condition, three variants of the Hallux Valgus axial deviation models were developed, considering the congruency status of the first metatarsophalangeal joint (congruent, deviated or subluxated joint);
- 3D modelling and virtual simulation of the five main types of Hallux Valgus surgeries: Akin, Scarf, Chevron, Lapidus and proximal opening wedge metatarsal osteotomy, using the parameterized CAD models of axial deviations previously developed;
- CAE studies on proximal opening wedge metatarsal osteotomy and CORA positioning optimization;
- Developing a script to automatically generate the results of the 9 numerical simulations, combining the 3 levels of variation of the 2 variables used in the analysis;
- For the resulting parameter (d), regarding the maximum opening wedge opening, 2D and 3D variation graphs were plotted;
- Design and manufacture of a specialized device for experimental research of the proximal opening wedge metatarsal osteotomy;
- Manufacturing of bone replicas by additive manufacturing methods, for the development of the preliminary experiment to validate the experimental methodology;
- Design and implementation of an experimental research program to study the behaviour during angular correction of the first metatarsal in different variations of its opening osteotomy arrangement;
- Development of a CNC program for NC machining for proximal opening wedge metatarsal osteotomy;
- A full factorial experimental program was designed in which the response functions were the maximum force F_{max} and the maximum osteotomy wedge opening d_{max}, where the influence factors were Dx and Dy;
- The variation of force in relation to the displacement (therefore the maximum osteotomy wedge opening) was determined in relation to the influencing factors Dx and Dy;
- The collected results were presented in the three common forms: tables, graphs (2D and 3D) and mathematical relations;

- A processing of the obtained data was carried out with the establishment of the regression model, verification of the dispersion homogeneity of the response function, calculation of the coefficient's significance of the regression equation and confirmation of the adequacy of the model;
- An ANOVA analysis was performed for the whole experimental model, an analysis of residuals and correlation coefficients showing that the objective function can be controlled with the elaborated experimental model.

Future research directions

Starting from the results obtained within this PhD thesis, studies can be extended in the following research directions:

- Based on the generalized model of the foot, studies can be made regarding the compressive stresses of the metatarsal bones or phalanges during walking even a study of the behaviour of post-operative structures in various phases of walking;
- Similar approaches to those in this thesis can be made using the Hallux Valgus deviations CAD models of the other four types of operations presented;
- Using the CAD models for the development of customized orthoses or prostheses for the conservative treatment of the Hallux Valgus condition;
- The microscope study of the angular correction of the first metatarsal, for the accurate establishment of the critical moment of the microcracks appearance;
- Completing the present study regarding the optimization of the geometric planning of the first metatarsal opening osteotomies by choosing another set of parameters: Dx values from 0.5 to 0.5mm and Dy from percentage to percentage, applied around the critical values obtained in this thesis;
- Development of customized Hallux Valgus non-invasive correction devices, executed by additive manufacturing;
- Design and development of innovative position preservation devices for the post-angulation configuration within the proximal opening wedge metatarsal osteotomy;
- Approaching the topic for different mechanical characteristics of bones affected by natural aging or other causes.

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