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- Master of Philosophy Thesis -

Towards Robust Prosthetic Socket Design through Simulated Pressure Casting

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To Vincenzo Zappia, my grandfather,
my father, my dear friend and more.

Emanuele Zappia

Academic Thesis: Declaration Of Authorship

I, EMANUELE ZAPPIA

declare that this thesis and the work presented in it are my own and has been generated by me as the result of my own original research.

Towards Robust Prosthetic Socket Design through Simulated Pressure Casting

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Abstract

Every year a considerable number of people undergo a lower leg amputation and start using prostheses. After a period of testing and fitting of various prostheses, gradually more suitable for the patient and sized on his/her needs, the definitive prosthesis is created.
However, the use of prostheses, even if definitive, especially if prolonged over time, can lead to problems for the patient. In fact, despite the final fitting, problems may still arise due to the routine use of the prosthesis or, in specific cases such as athletes, to achieve high-level performance. Because of this use, pathological remodelling phenomena or even lesions and tissue damage often occur. As a result, a major line of scientific research focuses improving prosthetic socket design. Techniques are moving gradually from hands-on plaster casting and modification to hands-off plaster methods like p-casting, and digital methods known as CAD/CAM. Bioengineering contributions involve modelling and characterizing the amputated limb, to provide predictive tools to prosthetists. Modelling has been applied to analyse conventional hands-on plaster sockets, and CAD/CAM, but simulations of the p-cast procedure have not been reported in the literature.
The aim of this work was to provide a basic model and a biomechanical FEM simulation routine for the lower leg stump. Specifically, the p-cast procedure useful to form the socket mold has been simulated, consolidated, and tested through biomechanically accurate and usable FEM simulations. The final future aim will be to optimize the socket design. Specifically, for future work, the mechanical behaviour of the leg in contact with the socket could be simulated and optimized to increase its robustness. Also identifying biomechanical factors (input design parameters) to improve the mechanical stump/socket interaction.
Finite element simulations of the p-cast process were performed, on the meshed model of a lower leg stump derived from medical imaging data. Different variations of the biomechanical and general simulation properties have been implemented (patient weight, different material properties of the stump, constitutive models of the liner, etc...). From the FEM simulations several contour plots of the different mechanical quantities of interest (displacements, strains, first and third principal strains and max shear strains) have been produced, showing their distribution for the different built models. Furthermore, key values such as maximum, minimum, and average values of the main mechanical quantities were also extracted from the models and showed accordingly. The obtained results showed the differences and the similarities of the models, in terms of quantitative comparison and different distribution of the strain, displacements, principal strains.
The results showed that even slightly changing the material properties such as Young's modulus and Poisson's ratio to simulate old patients and in particular sportive patients has substantial effects on the distribution and above all on the intensity of displacements and strains. It can be said that these changes are significant but do not affect the robustness of the system, as the intensities do not vary by many orders of magnitude with respect to the reference model.
Furthermore, biomechanical considerations on the cases examined have been illustrated in this work. Different liners produce different states of displacements and strains, also a different shape deformation of the liner and of the stump themselves. Furthermore, it has been shown that heavier patients generate higher pressures in the p-cast process as well as displacements and strains, while the sportive model has all these values very low.
On the one hand, it might be interesting to explore the effects of these changes also considering other factors, but above all the natural continuation of the work would be to include the socket in the FEM simulations, to fully evaluate the performance and robustness of the prosthesis/stump bio-mechanical interactions.

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I Introduction

There has been an increasing interest in the study of biomechanics of the lower leg stump and in the study of prosthetic leg design, and in its biomechanical interaction with the residual limb. This interest is due to the increasing number of amputations [1]. An average around 5000 patients per year undergo a below knee leg amputation surgery in England [2].

The main causes for below knee amputation surgery are vascular disease, diabetes mellitus, tumours, and various kinds of trauma [3]. The procedure itself may vary, depending on the limb or extremity being amputated and the patient's general health. There is also evidence [27] that the lower leg stump undergoes volume changes throughout the wearing period of the prothesis, so, since the socket is not an adaptive mechanical element but rather a static one, it cannot be independently "dynamically" adapted to the different external conditions or to the changes and remodelling of the stump that occur during the wearing period, but it is possible to act on the prosthesis such as some patients who try to remove or add socks to the stump to get a better fit. Therefore, by neglecting manual expedients on the prosthesis for a better fitting during the wearing period, a careful planning of the prosthesis design is necessary upstream, to consider as much as possible all this type of phenomena, especially the most important and those that give major problems for the patient [4]. Normally, once the socket and the prosthesis have been produced, it is not possible to adjust the size of the socket; however, in order to give a small range of control to accommodate tiny, short term volume fluctuations of the amputated leg, clinicians suggest adding or removing orthopaedic socks on the amputated limb.

As the socket is the crucial interface between the stump and the prosthesis the features that the socket should guarantee are: well-fitting, appropriate load transmission (stump / socket), stability and control; but at present a substantial proportion of persons with amputation still have important prosthesis-linked problems during routine activities mostly due to socket related issues. From a study [125] in which prosthesis users filled in a questionnaire to assess different issues linked to prostheses wearing (especially skin issues) has emerged that poor comfort and reduced functionality arise from skin damage experienced by 63-82%, and an abandon rate around 25-57%.

The factors (input design parameters) that are of the utmost importance to improve socket / stump mechanical interactions are sketched in figure 1.1 and among these are socket shape and socket materials that combined together influence directly the obtained displacement field and the mechanical response of the soft tissue residuum so the biomechanics of the limb/prosthesis itself.

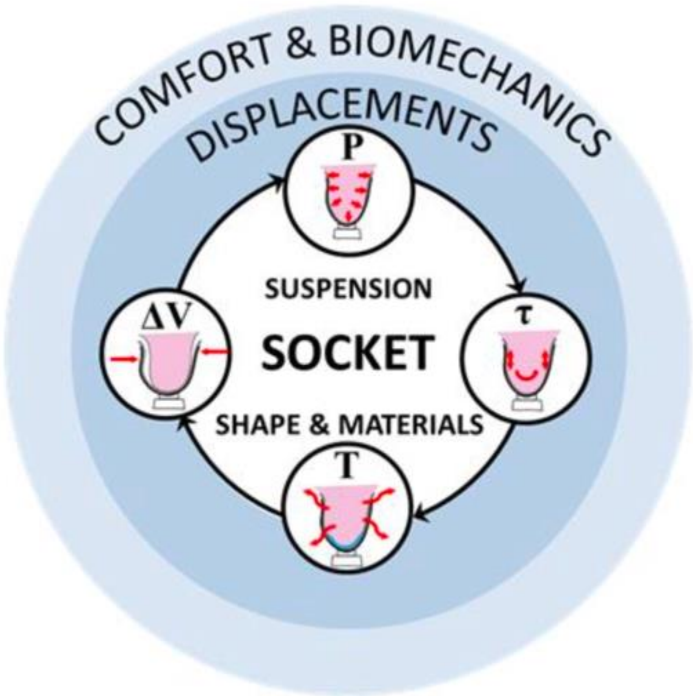

Figure 1.1 Schematic representation of the main factors affecting the stump/socket interface and their interplay (P = pressure; τ = shear stress; T = temperature; ΔV = volume fluctuations; displacements = relative movements between the stump and the socket) [122].

After defining the input design parameters, we need to consider the output parameters as values that represent the general mechanics of the socket in terms of functional stability and the ability to avoid typical issues that affect the user's satisfaction [122], these are control temperature (T), volume variation (ΔV) and shear stress (τ) on soft tissues at the limb/socket interface.
The residual limb is not physiologically adapted to bear the loads applied by the prosthesis (i.e. reaction forces, shear, and transverse compression) then prosthetists are faced with the challenge of designing a suitable socket able to mitigate the load transfer issues. These are compounded by a high difference in stiffness between the socket and soft tissues, and unpredictable environmental factors, both mechanical, thermal, and biochemical. For these reasons, some driving points from which one should start to improve the socket design should be achieve minimal movement between residual limb and prosthesis in order to maximize the efficiency of the socket / limb coupling load transfer under static and dynamic conditions. Indeed, poor socket fit will increase the number of unwanted forces in the residual limb, lead to pain, lead to a general not satisfactory experience for the user [122].

The goal of the project is to develop an anatomically based and accurate model of the lower leg and carry out FEM mechanical simulations to establish a robust computational routine of the biomechanical model, so as to draw biomechanical considerations on the model.
Furthermore, such a model may serve in the future as an efficient basis for producing a computational model to find the optimal socket design to improve the mechanical performance of the prosthesis.

Then this thesis has been structured in the following way:
Chapter 1 will present the biomechanics of lower leg residuum including the common sources of injury and related biomechanical phenomena like stump volume changes, in order to understand the requirements that the socket prosthesis needs to satisfy and the common issues the patients with amputation face in routine activities.

Chapter 2 will present a state of the art in socket shape design methods, followed by an introduction to finite elements modelling (FEM) technique. After these premises and considering the aims of this project, a selected design technique will be highlighted: the p-cast process, discussing its advantages and how it can be exploited as an efficient socket design method.
In Chapter 3 a methodology will be presented, it will be illustrated in detail how to build a computational reference model of the amputated lower leg and other models of the amputated limb indicative of particular situations such as a heavy patient, an athlete, an old patient and the case of a liner in gel material instead of silicone. Furthermore detailed information will be given on how to perform FEM simulations of the p-cast process.
In chapter 4, the generated model(s) and the results of the FEM simulations will be used to present the trends of the various mechanical quantities of interest such as displacements, strains, first and third principal strains and maximum shear strains also discussing the key variables that influence the process; in addition to these analyses, particular attention will be paid to the potential impact of these variables on the patient's routine activities.
Finally, in Chapter 5 the results will be discussed deeply, and comments on limitations, future works and application to different cases will be illustrated.

1.1 Motivation: modelling the p-cast process to design a robust prosthetic socket

Research question:
Can we accurately model the biomechanics of the lower leg residuum in the p-cast process employing cutting edge robust FEM simulations to aim for a robust socket design?

Rudiments of robustness: why aim for socket with a robust design
Starting from the definition of robustness given by Knoll and Vogel [123] the robustness can be defined as the property of systems that allows them to survive unpredictable or unusual circumstances. Aiming at a robust system could mean looking for a system that is not necessarily optimal in absolute terms but extremely more stable, therefore less subject to being influenced by external and internal changes which therefore do not compromise the performance of the system itself.
Going to gradually define the robustness in a more quantitative and statistical manner, one can mean by robustness the relative insensitivity of a statistical procedure to the deviations from the presumed distribution of the Gaussian error.

An example of a robust system could be a robust building structure: let consider a bridge, if this structure has been well designed but not for robustness then, although it was designed to resist a set of physical conditions (i.e. climatic or seismic effects), it still succumbed to some of these because they turned out to be of greater magnitude than foreseen [123]. In contrast, a robust structure would have been designed to face even unpredictable conditions, being stable in more conditions than a "standard" structure even if may be perform worse than the other structure in other aspects. Then, a robust structure is more reliable and safety despite not necessarily reaching the absolute optimal performance in some areas.
Regarding the socket, the variations of design variables are inevitably produced which may lead the unexpected shank deflection and directly influence on gait efficiency of a person with an amputation and other unexpected effects [124]. To avoid or reduce to the minimum instability effects related to

these or other similar unexpected variations, the prosthesis should be designed to be minimally sensitive to the variation of design variables and so as much robust as possible. This concept will be illustrated more in detail in chapter 2.

On the other hand regarding the lower leg model, building a computationally robust model means that setting minimal variations of the simulation input parameters (material mechanical properties, weight and therefore pressure of the p-cast and others described with accuracy in chapter three) the variations of the output quantities (displacements, strains, principal strains, etc...) will be minimal or in any case not such as to have to devise a specific socket design for each variation considered.

Aim: Modelling in an effective way the lower leg residual limb, focusing on analysing the related dependencies from biomechanical variables to support the "design for robustness" approach for lower leg prosthesis socket.

Novelty: The approach to the project involves the use of sophisticated FEM techniques simulating the p-cast process in order to obtain a set of biomechanical results data that can be used to derive the optimal design of the prosthesis socket. The novelty lies in the choice to employ a computational approach that simulates the p-cast process to obtain an optimal robust design of the prosthesis socket.

Scope of the project: The main objective of this research project is to develop a new biomechanical model of the lower leg residuum as a basis for FEM simulations deriving considerations on the biomechanical parameters of the amputated leg. To create a basis for future simulations including the prosthetic socket. We will perform FEM simulations of a p-cast process to state biomechanical considerations on the mechanical behaviour of the amputated leg and from them hopefully, in future works, obtain the optimal prosthetic socket design.

II–Literature Review

Prosthetic types

A first classification of prosthetic types could be based on their design (1) (monolimb, modular), their fabrication (2) (type of material, technological process), and finally their different performance objectives (3) (everyday use or for high performance in sport activities). These different types have distinct structure and functional properties, and their classification can be based on these different features [20].
A few dominant approaches have emerged to address the challenges previously described. The primary design goal is to restore gait symmetry and effort to able-bodied levels. In addition, there is the need to reduce abnormally high loads in the joints or the residual limb, improving the ability to perform specific tasks and increasing balance and stability. To cope with these objectives the design approaches can be generally categorized according to what the prosthesis is being designed to functionally provide: a) support, b) propulsion (or the force needed to detach the foot from the ground and continue the gait motion), c) flexibility and/or d) wearability (avoiding the onset of typical prosthesis fitting problems). Regarding the support, the main feature is to replace the missing skeletal structure with a mechanical surrogate able to provide static structural support. Components like prosthetic knees can provide active support for balance and/or stability. Regarding the different types of prostheses, the analysis of the scientific literature produced could be greatly extended by considering also components relating to the knee or foot on which there is also a vast literature but, in this thesis, we are not taking into consideration the components and we have limited the scope to below the knee/transtibial. In conclusion, the state of the art regarding the types of prostheses is vast and it is clear that different designs and distinct approaches are improved and considered for different biomechanical and functional objectives. We therefore focused on shaping this literature review by focusing on the objectives of our project, giving emphasis to articles regarding the choice of prosthetic materials and other fabrication parameters. Moreover, the scope of the project is precisely focused on the socket design, the main part in contact with the residual limb as showed in the next section.
So the part on which we have focused and which we believe to be of utmost importance is the socket, as it is the main part in contact with the residual limb and is therefore the most important part to consider for the purposes of comfort (and robustness). Therefore, although the design of the prosthesis can be optimized to ensure a more comfortable and functional experience for the patient, without an optimal (robust) socket design it will be much more difficult to ensure that the prosthesis is functional and adapts to different

external stimuli and, at the same time, to all the activities for which it has been designed.

Socket design methods

To obtain a satisfactory socket design the final version of the socket should be able to achieve:

- Optimal load transmission, stability, efficient control for mobility
- Avoid common “Socket related” issues: skin injuries, pathological remodelling
- Satisfactory biomechanical robustness to ensure adequate experience for the patient

To obtain such features in designing the socket the central topic is the biomechanical understanding of socket-limb interactions. Looking at the evolution of different socket designs it is evident how the improvement of this prosthesis part is strongly linked with the understanding of the limb anatomy and biomechanical phenomena involved. For example, one of such early designs is the “plug fit” a cone shaped socket with no rationale behind its design that led to an ineffective load distribution [75]. To provide a more effective and comfortable experience, successive designs were produced: for example, regarding transtibial sockets the patellar tendon bearing transtibial socket (PTB) has been developed, another alternative design to the PTB, but which still insists on the patellar tendon, is the PTK (Patellar Tendon Kegel) featured by higher proximal medial-lateral walls. Instead, there are obviously other design approaches, such as the main one as an alternative to the PTB which is the TBS (total surface bearing) where the surface on which the socket insists is not on specific regions but on the entire stump area [122]. Designs such as the PTB intend to provide a more effective load distribution around the residual limb as more load is charged on load tolerant areas and less on the more sensitive ones. One measure of how and if a prosthesis would be successful or not is the user opinion on the prosthesis’s satisfaction.

Standard Clinical approaches for prosthesis manufacturing

PLASTER

This is one of the most common clinical approaches in use. The design and production procedure for plaster prosthesis are described below [44]:

Plaster Procedure: The cast

Before the prosthetist can begin to design the prosthetic limb, he or she must take precise measurements. If possible, the prosthetist may begin to take measurements of the patient’s body before the limb is amputated and meet with the surgeon before the operation to get more details about the amputation [21]. Then, the first step in the fitting process is the making of a cast of the residual limb. This is done by wrapping the residual limb in plaster bandage. When the plaster is set, it is removed. Plaster of Paris is poured into the cast to make a replica of the residual limb.

Plaster Procedure (p-cast): The Positive Mould

The basic idea of the plaster procedure is to create a negative in the shape of the stump as much as identical to the original limb. Subsequently the cast is filled with the plaster to create a positive mould which is then modified to optimize the fitting of the socket, this process is called "rectification" and is extremely important for the final fitting of the prosthesis and therefore to guarantee an adequate experience for the patient; in fact, these modifications are implemented trying to uniformly distribute the stresses and minimize stress and strains in the most sensitive areas of the stump, tuning the thickness in the most critical areas.

Some complementary factors must be taken into consideration when designing the artificial limb such as the patient overall health and the location of muscles, tendons and bones in the residual limb. In the case of a lower limb, the prosthetist must also align the limb to fit the prosthesis user’s unique gait pattern by making mechanical adjustments while the patient uses the limb in simulated situations as the functional goals activity described before.

Plaster Procedure (p-cast): The Diagnostic Socket

Next, the patient places his healthy leg on a scale and places the residuum in a diaphragm wrapped in a plastic bag and places it in a cylindrical tank. This tank is pressurized with a water system whereby once the patient can stand normally, i.e. with half of the weight distributed on each leg, the water pressure is stabilized and recorded. This was accomplished by first having the participant stand on a weight scale with his or her leg intact, then slowly transferring weight to the residual limb onto the diaphragm in the reservoir. Pressure in the reservoir was adjusted by flowing water in and out of the reservoir to match the weight applied by the residual limb until the participant achieved a normal, level standing position. The upright position was ensured by checking the height of the participant's right and left iliac spines. In the standing position, the scale would register approximately half of the participant's body weight. Subsequently, the shell of the plaster injected into the tank is given time to harden, after which the tank can be depressurized, and the plaster form is removed. Then from the negative casting a positive plaster shape is made which is modelled and rounded and from this shape the socket is made by building a distal pelite cap to allow for inner socket length adjustability during fitting. This was dependent on the tolerance level of the participant. A polypropylene hard socket was then moulded from the cast; the prosthetist engages in the meticulous process of modifying the positive mold to reflect the envisioned design principles and to create a wearable interface (molding process).

The plaster replica of the limb is used to make a transparent socket using a thermoplastic material. The diagnostic socket enables the prosthetist to see “inside” the prosthesis to check it is a good fit and that pressure, weight-bearing, and alignment are optimised.

Once the appropriate fit is achieved, the plastic socket will be transformed into a more durable carbon fibre or acrylic laminated or vacuum formed (e.g. polypropylene) definitive socket and assembled to form the definitive artificial limb.

Interfaces

To make the interface of the socket and residual limb a close and comfortable fit, an interface is typically worn; these are made out of silicone or gel [137] [130] [59] and are rolled on a bit like a sock or stocking (liners) [21]. In a study [126] it was highlighted, using different liners, that the contact area increased with the reduction of the liner stiffness, not always inducing a reduction of the interface stress peak. The peak stress that was found was moderately sensitive to liner stiffness. It can be summarized that there is a significant effect in the contact mechanics depending on the different liner used, in any case a better analysis considering the strains as an indicator also of stump tissue damage could be carried on, but also as better signals of comfort and above all of fitting compared to stress, which was also noted to be the sum of the contribution of different mechanical sources.

Componentry

Componentry (or Hardware) is the term used for the functional part of the prosthesis and depending on level of limb loss, different components are incorporated to restore function and support. There are many different types of prosthetic joints available. The prosthetist or rehabilitation consultant will advise the patient about the most suitable hardware for him/her.

The Cosmesis

The hardware is skeletal and mechanical in appearance. Many persons with amputation are proud to wear their prosthesis without any cover but some will opt to have a life-like cover. The cover is usually made of foam, shaped to match the remaining limb to create the appearance of a normal limb. Some patients opt for a high-definition silicone skin, which is custom made with lifelike tone and texture, including details such as freckles and hair.

Design Techniques

Looking at some design techniques described in this section (such as CAD/CAM (Computer Aided Design/Computer Aided Manufacturing)

and FEM/Auto ((FED) Finite Element Design methods) 2.1.1.2 techniques) it appears clearly that the trend regarding the design in biomechanics [41] is oriented more and more towards the employment of automated methods and the aid of "smart" algorithms and AI-based techniques (not employed in this area only [45][46]). This approach is giving more room to non-human controlled routines in design, letting the modellers and in general the researchers, to focus on more fundamental and specialized tasks as developing better mathematical and physical biomechanical models in order to improve the design itself based on these models and then the final performances of such planned biomechanical structures and/or systems. Considering stump-lower limb prosthesis interface, there are several aspects to be considered to finalize a satisfactory design. Although stresses at the residual limb socket interface can be measured, a full-field experimental evaluation of the load transfer remains difficult.
Those difficulties associated with experimental measurements can be overcome by computational modelling, provided an appropriate model can be developed.

CAD/CAM as currently used is limited because it is employed in the same, judgement-based approach as conventional plaster methods. However, CAD/CAM has the potential for enhancement by coupling with predictive methods using simulation or machine learning. The socket mechanical assessment is directly linked to the design features of this part and the robustness itself as design needs and features can be translated in mechanical attributes (as stress concentration and distribution, strain threshold), that are also quantitatively measurable and/or expressible as scores, as numerical ratings and comparisons are easier to be carried out.
Computational models for socket analysis are mainly based on finite element methods [37]. There are two major advantages in using FE analysis. First, full field information on the stress, strain, and all mechanical quantities of interest as well as motion anywhere within the modelled objects can be predicted. Second, it is relatively convenient to do parametric analysis for an optimal design. It has been also confirmed how there is a direct correlation how these mechanical adjustments and considerations directly affect the quality of life of patients with prosthesis [47].
Aspects of the utmost importance include the fit of the socket with residual limb, the prosthesis mechanical functions and its qualities and the ability to adapt to new prosthesis with the support of professionals [47]. Moreover, it has been suggested from several studies [48][49][50[51] that employing computational optimization techniques such as evolutionary ones and in particular genetic algorithms (often coupled with Finite Element methods [50]) that the use of these advanced computational techniques could theoretically give a tremendous advantage in the design process of prosthetic devices, even if this approach is not yet in clinical use, especially aiming to reach a robust design [52].
In this context, the emergence of next-generation computational methods such as artificial intelligence (AI) could greatly support the prosthesis design process. In fact, AI drastically cuts down

the time for operations like designing or modifying the design for a new or existing model otherwise performed by a human operator.

Currently AI has reached a point where it can easily outperform human engineers in many fields of expertise including the design and manufacturing processes. Artificial intelligence in CAD/CAM is already present, above all being already integrated into design and manufacturing software providing tools for recognizing similar or duplicate parts (*Solidworks*) [128]. Or even exploited to automatically generate the toolpath for computer assisted manufacturing machines, automating the manufacturing phase; or also by automatically eliminating the noise from some images (AI Denoiser) up to automatically generating designs (AUTODESK) by exploiting the evolutionary approach of nature (as in genetic algorithms) [127]. Neural networks on the other hand are very different from knowledge-based systems. Artificial neural networks (ANN) or connectionist systems are computing systems that are inspired by, but not identical to, biological neural networks that constitute animal brains. Such systems "learn" to perform tasks by considering examples, generally without being programmed with task-specific rules. This is a very important tool for future CAD/CAM systems as it can serve as a design suggestion tool where the designer is uncertain. Such system could recommend new and innovative design solutions to the designer.

Computer Aided Techniques for prosthesis Design and Manufacturing

More recently socket designs in lower leg prosthesis are made employing advanced computational techniques allowing the creation of highly customized products. This approach is employed especially in the socket design process (CAD Computer Aided Design) as well as in the socket manufacturing one (CAM Computer Aided Manufacturing), since this prosthetic part requires a high level of customization in order to satisfy functional and robustness requirements [33]; however, due to the clear advantages of these computational procedures (customization, portability, speed up of the design process, etc...), these techniques are used to develop other prosthetic parts as well [53]. Specifically, the CAD/CAM procedure consists of:

- Acquire the stump data through imaging techniques (such as Laser, IR and white light scanning and others)
- Import the stump data in a design computational environment
- Modify the prosthetic design due to mechanical needs to avoid structural failure
- Finalize the .stl geometry file and send it to a fabrication centre where they programme a craver, carve a mould, and then do a vacuum form draping mould

CAD/CAM are promising methods but currently used in the same, largely qualitative, judgement-based manner as plaster methods, even though they offer great potential for a more quantitative approach supported by biomechanical modelling and analysis.

Biomechanical Modelling Strategies for the stump-prosthesis System

One of the best tools for the analysis of physical problems, including the ones associated with biological structures and with biomechanics, is modelling, both analytical/computational and numerical-driven [54]. Considering computational models as an evolution of mathematical models, it has been said that: "*Systems of interacting forces and stimuli don't have to be very complicated before the unaided human intuition can no longer predict accurately what the net result should be. At this point computer simulations, or other mathematical models, become necessary. Without the aid of mechanicians, and others skilled in simulation and modelling, developmental biology will remain a prisoner of our inadequate and conflicting physical intuitions and metaphors.*". From this quote (1994) from a research biologist Albert Harris [55] it appears clearly how there is the need to develop more and more sophisticated and enriched models to study and characterize complicated systems as the biological ones and the biomechanical systems of our body. In the next section, some candidate techniques to model the prosthesis-residuum biomechanical system will be illustrated. Also, Table 2.1 shows the main phenomena of interest for the prostheses to be modelled and the associated techniques for these models and the problems related to the patient's health that can give, with an impact score ranging from 1 to 10, to have a quick idea on the importance of the phenomenon and with which technique this mechanism can be modelled.

Finite Element Methods:

The FE method is a full-field analysis for determining the state of stress and strain and other mechanical quantities of interest in the field. This approach is well suited for parametric analyses in the process of design [37].

The FEA method for residual limbs and prosthetics

FE analysis is implemented by dividing a complex problem domain, to which there is yet no analytical solution or the analytical solution is very difficult to obtain, into a finite number of smaller domains or elements, each admitting simpler approximated solutions. The solution obtained in this way is approximate, as the model can only allow a finite number of degrees of freedom. The accuracy of the solution is largely dependent upon the number of elements of the model, a higher number of elements potentially enabling a more accurate solution to be found. However, a penalty must be paid in terms of the amount of computing time required. In practice, a balance is to be achieved between the accuracy of the solution and the computing resources available. Furthermore, other factors affecting the accuracy of the analysis involve model assumptions and parametric inputs of the geometry, material properties, boundary conditions and external loads. There are many advantages in using FE analysis. First, it can be used to determine a particular stress, strain or other relevant mechanical quantity and motion anywhere within an object that would theoretically be impossible to obtain by other analytical or experimental method. Secondly, it can be used as an effective tool for parametric analysis. This means that structural parameters can be changed, even slightly, and their effects studied very conveniently. In addition, is it possible to implement different constitutive models and accounting for different mechanical behaviours in the FEM analysis, therefore it results that this tool is versatile and flexible, especially for design purposes. Recalling the limitations due to the accuracy of the FEM method presented above, these difficulties mean that the method has a difficult possibility of repeatability if the system is created without using routine calculation procedures (code) but preparing the system through user interface methods.

Finally, it can be said that the FEM is one of the best candidates as leading method to verify and test different constitutive models, mechanical boundary conditions and in general to identify the best path and parameters selected to improve our model, prosthesis socket fitting and its robustness. An example of a finite element model of a transtibial prosthetic socket and the stump is shown in figure 2.1; here the model has been built to carry out analysis of pressure distribution to improve the prosthesis design starting from the manufacturing phase.

COMFORT ISSUE/ INJURY TYPES	**IMPACT SCORE***	**METRIC/ *BIO*MARKER**	**CAUSE**	**HOW TO MODEL IT**	**TIMESCALE**	**CHANGE/ COMFORT**
Skin lesions	**7.5**	**Scar formation**	**Superficial shear stress**	Continuum Damage Mechanics (FEA) / Superficial Shear stress threshold	from **seconds** to 50 – 100 **hours**	Skin tissue morphology
Pathological remodelling	**6**	**Biomolecules associated with growth/depletion**	**Tissue Growth/Depletion - stress localization**	Growth Continuum Modelling (FEA)	2 – 10 **months**	Soft tissue mass change and loss of adequate socket fit
Mass Grow			Tissue growth			
Mass Depletion			Tissue Depletion			
Internal tissue damage	**7.5**	**Strain threshold**	**Internal strains**	Continuum Damage Mechanics (FEA) / Internal Shear stress threshold	30 – 50 **hours**	Internal damage of soft tissue
Calluses and tissue stiffness changes	**6**	**Increased stiffness, fibers reorientation**	**Localized stress**	HGO fibers continuum model (FEA)	4 – 10 **months**	Soft tissue stiffness and morphology
Infection/inflammation	**5**	**Macrophages and others immune cells**	**Overstress stimulus**	Agent based modelling	1 – 15 **hours**	Inflamed tissue

***IMPACT SCORE** explanation: Importance score (approximately between 1 and 10) for the comfort and overall impact on the patient's health and on prosthesis functions.

Table 2.1: An original table created by the author of this thesis but inspired by tables and information found in the literature concerning common injuries and comfort issues in lower leg amputee. [5 – 6,14, 24, 36 – 37, 39]
IMPACT SCORE explanation: Importance score (approximately between 1 and 10) for the comfort and overall impact on the patient's health and on prosthesis functions.

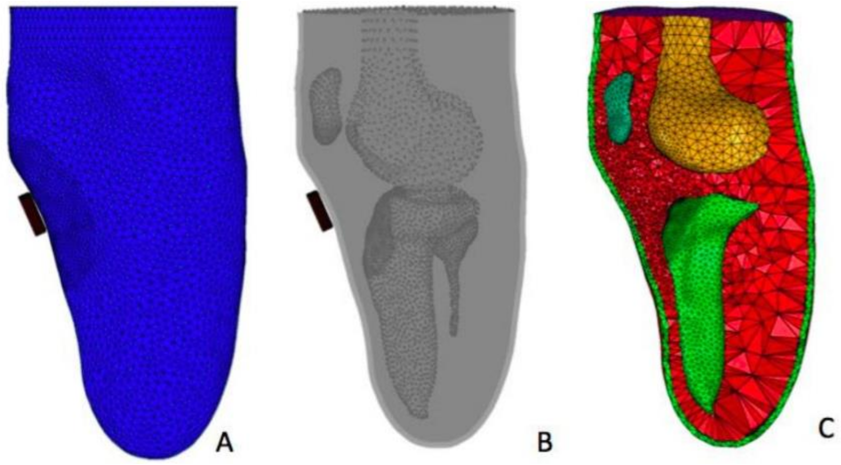

Figure 2.1: Different FEM model renderings: (A) Typical surface model geometry showing local refinement near the indenter (example is for the patella tendon region), (B) transparent surface data showing supported internal surface nodes,
(C) a typical solid tetrahedral mesh showing internal refinement as a function of proximity to the indenter. In addition, the two material regions, i.e. the skin-fat layer (green) and the internal soft tissue (red), and the bone voids are visible. [67]

In the following sections a selection of the literature on biomechanical modelling of the residual limb and prostheses will be presented and analysed in detail with particular emphasis on the use of finite element methods. The most used techniques in biomechanical analysis and in the design of the prosthesis/limb will be initially illustrated, then automatic computational methodologies in the design of prostheses will be presented. Looking at table 2.1, it is possible to have a quick and exhaustive picture of the type of phenomena and what type of modelling to use. Then, the following section 2.1.2 will focus exactly on finite element methods in the context of computer simulations as a tool for the mechanical design of prostheses and how these techniques represent a valid alternative to experimental techniques. Finally, alternative techniques to FEM and related potentialities with respect to the current project will be briefly exposed.

Current uses of FEA in prosthesis-limb biomechanical analysis

Since is not feasible to invasively measure internal strains and stresses in the muscle flap of patients with transtibial amputation, there is almost no information on mechanical conditions in the residual limb during load-bearing phase. To overcome this issue, several solutions have been implemented. For example, in a study [56] it has been tried to characterize the mechanical conditions in a muscle flap of patient with transtibial amputation during static load-bearing. The study illustrates how a patient specific FE can

identify the risk for deep tissue injury. The finite element model has been built integrating MRI data and interface pressure measurements. For this study [56], emerged that there is the possibility to acquire quantitative data from pressure measurements at the interface and, employing biomechanical models and data regarding biological structural tissues involved, is also possible to derive stress and strain in the internal tissue without the need to directly measure them [56]. The pressure measurements were carried out using two thin and flexible pressure-sensing mats based on piezoresistive sensors specifically designed for the project. The pressure-sensing mats were placed between the prosthetic socket and the residual limb to obtain static interface pressure diagrams. In addition, the pressure data were acquired right before the MRI data as was not possible to acquire them simultaneously due to electronic interference issues [56].
The patient-specific finite element modelling process could be summarized in: (a) Creating a plaster cast of the residual limb of TTA patient; then (b) MR coronal and transverse images are acquired in an open MRI at a static posture, with and without load-bearing. Finally (c) a three-dimensional solid model of the residual limb is created from MR images, for export to the FE solver.

Interface limb-socket pressures, calculated from FE model, peaked at 65KPa [56], and were in excellent agreement with the experimental pressure measurements that fluctuated $\pm 10KPa$ around this value with postural sways. Shear stresses on the skin peaked at 51.9KPa under the tibia. The highest muscle flap strains, SED and stresses were found directly under the distal tibial end. To summarize, the study introduced an experimental-computational based technique for quantifying internal mechanical conditions in residual limbs of prosthesis transtibial users; the model predicts with good accordance with experimental data the main mechanical quantities of interest, shedding new light to the complex interplay between load, pressure and prosthesis design at socket interface [28]. However, the proposed model presents an analysis only for the static case, an implementation of the dynamic case could have completed the analysis or could be a suggestion for a future work.

Finite Element and Automated methodologies in prosthesis Design

Mechanical stress at the interface between the socket and the residual limb is one of the most important design considerations for the manufacture and finalization of the lower limb prosthesis. Numerical estimation of interface stresses through finite element analysis (FEA) can potentially provide researchers and prosthetists with a tool design the prosthetic shape, especially considering interface variations and secondly accounting also thickness modifications and reliefs with respect to different prosthetic regions and so different stress levels required for the leg stabilization [58] as well as internal tissue strain magnitudes. Hence the importance of analysing and comparing different FEA methodologies for prostheses and tissues of the residual limb. In fact, it has emerged that computational mechanical analyses with finite elements are among the most widely used and well-established techniques for the design of prostheses [68] [37] and in general for biomechanical analyses; so why is FEA so effective and widely used for prosthetic design in scientific context? I will try to answer this research question central to the project in the following sections as well. To better expose the central theme of this section, the computational tools that allow the development of complex numerical models for new ad-hoc designs of the sockets following the needs of patients will be described first. Then, the main clinical and experimental features will be described that allow the evaluation of the validity of the FE analyses and which outputs of the models can be used for interpretation of the risk of injury and to comfort problems. Linked to this, the optimization techniques and principles used in biomechanics will be introduced and specifically for what purposes in this project. Then the main criticisms and the common problems of which these computational routines are affected by will be highlighted, with particular attention to the concept of robustness in the biomechanical field. Finally, two main research questions of the area regarding FEA and design optimization will be presented, in particular by explicitly identifying those for this project and comparing the main research lines of the area, highlighting the necessary research themes to be developed.

To employ computational design methodologies in the prosthesis design, FE models of the residuum should accurately describe: patient geometry, non-linear behaviour and viscoelastic mechanical properties of the soft tissue [63] [64]. To design and evaluate advanced prosthetic fitting systems there is the requirement for comprehensive anthropometric data, analysis and visualization methods; especially if automated design techniques are employed like Finite Element Design (FED) methods, even though these techniques are not commonly used at the moment in clinical practice.

Plasters, and in general contact casting methods, cannot provide information, especially in a digital format, regarding the shape, mass properties and tissue characteristics of the residual limb to allow the use of modern CAD software to design efficient prosthesis parts (as the socket). This is where computational aided design methods should be used, focusing on three major areas to improve the fit of prosthetic devices: imaging, modelling, and fabrication.

Regarding the imaging, the common and more useful techniques used to acquire a digital image of the stump are the Optical Surface Scanning and the Computed Tomography as well as 2D ultrasound techniques [41]. In this image acquisition phase, geometrical data of the residuum are acquired as digital data. After the image acquisition, a solid modeler should be employed to continue the modelling process and import in a computer a mathematical and graphical description of the stump, that can be successively manipulated and used to design the prosthesis. Another useful imaging technique is the Magnetic resonance (MRI), as with this technique is possible to distinguish different hard and especially soft tissue structures. Moreover, this technique doesn't employ radiations of any type. Finally, to complete the modelling phase, a FEM analysis on the three-dimensional mathematical model of the stump can be done and a FED analysis can be achieved. In this way, different design geometries of the prosthesis could be tested in a computational framework where is possible to analyse and catch the mechanical issues of different designs; without relying on slower and usually not automated experimental methods [41]. However, as already said, the FED is not in use in clinical practice; maybe this because the implementation of such method needs the presence of a figure in between a clinician and an expert technical FEM user (as for CAD/CAM methods). It could be possible to automate the FED process as much as possible to let even users with little knowledge about FEM modelling to employ this technique and produce the desired designs. In particular, the first step of the process involves characterizing the surface topology of the residual limb and making the data compatible with input requirements for later computer processing. The second step involves non-invasively measuring the mechanical properties of the soft tissues that make up the residual limb. To accomplish these techniques to achieve non-invasive measurements must be employed, such as Doppler based measuring systems [57]. From these data a weighted elastic modulus of the soft tissue can be calculated, considering that different values of the elastic modulus could be measured with respect to different regions of the same tissue due to the structural changes that can occur in the same tissue. It should be highlighted that most FEA studies rely on literature material properties data. The third input that is required is the loading function, which can be used to cause the computer program to generate an updated "rectified" cast model, that considers all the morphological variations and mechanical properties of the biological part/tissue considered. The interface pressure can be measured using a pneumatic pressure transducer. Usually, most basic FE models will apply a force to the prosthetic limb's pylon-socket interface connector (where it can be measured) and then use this to predict the limb-socket interface loading [129].

Clinical Experimental Measurements for the Validation and Interpretation of FEA

Pressure sensors have been developed dedicated to stress distribution measurements within sockets can be piezoresistive, strain gauges, capacitive or optical ones. They can be positioned by using dedicated holes or pistons through the socket wall, in direct contact with the skin or the liner. Alternatively, they can be inserted or embedded into the socket [82]. Very few FEA studies have done this, and most rely on literature material property data.

Then, using finite element codes, it is possible to build a patient specific model for the residual limb employing all the data previously collected (the shape data, weighted modulus for composite biological material and pressure data). Then, coupling this finite element model with design optimisation techniques and CAD software it will be possible to compute the shape of the socket that provides the desired surface-loading characteristics [57].

From various studies, and in particular from a review [58] it emerged how important it is to design a prosthesis that allows an optimal distribution of interface stress and then will be comfortable if worn for long times and will not cause injury if used for the activities for which it was designed. However, a design that results in improper stress distribution can induce pain or discomfort leading to blisters, cysts or ulcers in the residual limb, which in the worst case may require re-amputation at a higher anatomical level [59] [60]. Integrated standardized computational routines and mechanical simulations represent one of the best alternatives to experimental tests [61], not only for the preliminary evaluation of prosthesis design but also to pursue the design objectives listed above and to improve prosthesis robustness as well. The analysis of ad-hoc mechanical performance by combining advanced computer-aided manufacturing and mechanical predictive techniques has been employed in order to solve several biomechanical problems as some of the ones mentioned above [57] (or for estimating interface stress [62]), with widespread research using finite element methods (FEM) techniques [61].

Finite element methods are one of the main and most extremely efficient methods to simulate the mechanics of prostheses, in particular among the various advantages in using this method there are: 1) the possibility of accurately mimicking a wide range of physical and mechanical conditions at the prosthetic system is subjected to; 2) there is a lot of literature and protocols at academic and industrial level tested (especially considering design for robustness as synonym for durability and sturdiness) [26] [30] [58] [65] [66] that support its effectiveness and how it is a well-established method over the years as well as an extremely tested method. It is important to underline how the concept of ”design for robustness” in the literature considered is intended as a design to improve the mechanical performance of the prosthesis in general and not with the particular focus and emphasis given to ”design for robustness” in the context of this project. In fact, the precise definition given in section 1.3 and the development of prostheses starting from this specific concept of robustness is one of the novelties of the project itself; 3) there is the possibility to set stress limits, strains, and other quantities of primary interest for biomechanical analyses and to view their magnitudes in a simple and accurate way on reconstructed geometric mesh structures of the residual limb and of the prosthesis. Those listed above are just some of the advantages and reasons why the FEM methods have consolidated over time in the scientific field for the design of prostheses and in general in biomechanics. For clinically-useful mechanical analysis, although currently implemented only in the research field, there is the need to use integrated finite element techniques, including sufficiently sophisticated biomechanical models of the soft tissues [37] [67] [68] [69] [70] [71]. Specifically, computational approaches with the use of numerical modelling tools allows development of complex anatomical models for analysing customized prostheses with relative advantages for both patients and prosthesis manufacturers. These numerical tools are often used by researchers [29] [72] [73] in the form of software packages created ad-hoc for the different needs required and allow to characterize the stresses, deformations and pressure thresholds, as well as other types of interactions that take place between the different parts of the prosthesis and the residual limb. This has been used to understand the effects of the phenomena involved, such as friction [74], and stress distribution [71] [75] [76] [77] as well as in the study of the gait dynamics of patients with prostheses [76] [77]. Others have used FEM to develop protocols for estimating the risk of tissue injury, by applying regression analysis to relate the pressure on the socket-residuum interface and the compressive strain in the limb in order to estimate risk of soft tissue damage, using injury thresholds like the time-deformation cell death curve developed by *Gefen et al.* [78]. Also, it can be said that linear models are often used instead of non-linear models for reasons of simplicity and above all to make these models lighter from the computational point of view at the expense of a more correct modelling of the biological tissue taken into consideration [54]. It is worth noting that the use of sophisticated non-linear biomechanical models does not automatically imply that the result would be so different and closer to reality than when using linear models. Therefore, the compromise to be reached is to use complicated (non-linear) / biofidelic models sufficient to correctly model the main biomechanical phenomena of interest for the intended purposes; so essential to underline that the main guide on which type of biomechanical models to use is goal-related [130]. Therefore the evaluation process on the complexity that the model used must have, starts from an accurate identification of the objectives to be achieved in the mechanical analysis and which model, as simple as possible, can satisfy these requirements. Using these computational tools and following these analyses it is possible to identify which adjustments and accessories need to be made on the custom design of the artificial body part. One of the advantages in using the previously mentioned computational tools is that it is possible to realize customized designs suitable for the different needs of the patient, both physiological related to routine activities [76] [77] or linked to particular pathological states present [63] [71] [72] [78] without the need to physically produce and wear these prosthesis prototypes to the patient, thus avoiding a whole complicated experimental phase which can still be taken into consideration later for a validation of the computational results in the finalization phase of the product. Furthermore, if the quality of the computational model built is high and has a realistic and high-fidelity response, then the model could be used for future simulations as a benchmark to compare the results obtained in different ways.

In figure 2.2 an example of how should be structured the computational routine to get to a satisfactory prosthesis design in a form of a flowchart.

The studies analysed [37] [63] [68], [67] [78] suggest that the development of computational routines that combine optimization techniques together with mechanical analyses of biological tissues is a leading trend in the biomechanical area [37] [39] [48] [58] [59] [60] [61] [62] [79], especially in the prosthetic field as a computational predictive tool is provided that allows to avoid some preliminary experimental mechanical tests on prosthesis prototypes or even on volunteers, which are difficult to find for this type of test [54] [62] [63] [70] [80] [81]. In this way there are clear advantages in terms of costs and test times.

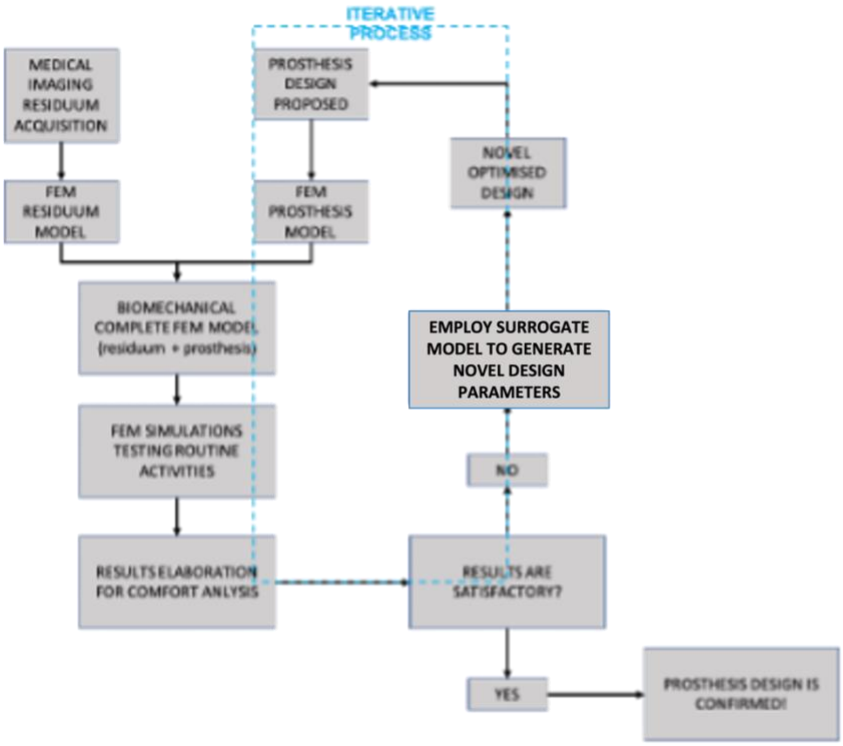

Figure 2.2: FEA computational routine flowchart.

In the previous paragraphs the main trends related to the robustness of the prostheses and their connection with respect to the biomechanical modifications due to the use of the prosthesis have been highlighted [72] [77] [82] :

- Clinical scars and wounds
- Effects on limb functions, like gait difficulty
- Skin issues
- Stress distribution (pressure sensors) and consequent pathological remodelling

General critique on FEA methods in prosthetics

Although significant progress has been made in this area [33] [37] [57] [62] [83] and the topics and studies cited [17] [29] [72] [82] [84] are responding to the knowledge of the gaps indicated in this area of research, critical review of prior studies identified some notable areas where further research would be valuable. The fundamental criticisms can be listed in the following points listed below:

Choice of Biomechanical models to capture longer-term clinical phenomena

1. Reproducibility of results material
2. Lack of theoretical continuum mechanics derivation of constitutive models
3. Need to set Robustness as a main design target/optimization objective

Addressing these items one by one: 1) the careful choice of biomechanical models, which must be at the same time sufficiently biofidelic and computationally efficient to model the phenomena of interest correctly and in acceptable times so to be able to reproduce results conveniently. Many previously reported studies employed simple biomechanical models [16] [54] [56] [71] [76] to study the mechanical response of soft tissues in walking and sitting position as well as the internal mechanical response of these tissues in contact with the prosthesis; however these would not be capable of representing clinically important phenomena occurring at different scales or that involve non-trivial processes such as remodelling or scarring [22] [56] [81] [85], so 2) we need more specific constitutive models able to catch all these phenomena. Finally 3), to make the prosthesis as reliable as possible and usable in complex and even unpredictable scenarios there is a need to set robustness as a main design target/optimization objective and incorporate this criterion into common prosthesis design practice, using then appropriate biomechanical parameters of evaluation for that index.

In conclusion, if the above points are followed and considered among the guidelines for carrying out scientific research, especially in the prosthetic field, it is clear how (also considering the literature cited previously as evidence) the work and the results produced will be of better quality. Specifically, the work would become more usable for the scientific community and would increase its overall impact in the scientific area of the sector. Looking at the different qualities and disadvantages of each modelling techniques listed and described above, it has been chosen the Finite Element Method as the best candidate to model different constitutive relationships of soft biological tissues and carry-on simulations to test the lower leg system in different appropriate computational environments. Indeed, the FEM is a well-established technique and can be connected through several computational routines to include CAD software as well and specifically look at how changes in the prosthesis's design can influence the mechanical performance of the overall prosthetic system.

Carrying out finite elements mechanical simulations permits to estimate the distributions of the interface stresses and volumetric strains as well as to design socket's shapes that obtain specific distributions of the interface stresses [58], even before a prosthesis is worn for the first time by a patient. There is therefore also a predictive potential in the use of these biomechanical simulations, making it possible to predict new designs and the use of materials in the prosthetic field not yet experimentally tested [61].

Moreover, some main questions were asked in this research area [83]: 1) Do the estimates of current FEA models match the experimental data on interface stress? FEA models are "fed" by experimental data and it should be a correspondence between the interface stress experimental values and the ones predicted by such models. Changing the design having these data will produce a more realistic outcome? If so, it would be possible to couple optimization strategies and FEA predictions in order to achieve the objectives outlined in the previous sections? 2) To which parameters are the model estimates more sensitive and to what extent sensitivity analysis of these parameters can improve the design optimization of the prostheses based on these models? Hence, it could be promising to afford these two main problems (comparison between models with experimental data and parametric analyses), to establish indications for improving FEA models and to establish appropriate research directions and trends for future works.

Looking at the relevant literature in the field [40][66][74] as mentioned in the previous sections and especially in section 2.1.1.1; there is a need in this area to model walking dynamics more effectively, especially in the presence of a lower limb prosthesis. Specifically, parametric analyses should be carried out to identify the influence of the different design parameters of the prosthesis on the walking dynamics. Even more interesting, it would be to understand in depth how these parameters can influence the walking experience from the point of view of comfort; specifically analysing those parameters such as stress distribution or strain thresholds during the different walking phases and / or other routine activities. A first step in this direction would also be to carry out simpler simulations in static, evaluating the stress thresholds present at the interface between the residual limb and prosthesis, specifically evaluating how to optimize the socket geometry to reduce as much as possible discomfort.

The concepts illustrated above represent the lines traced in the "recent" past, when the finite element method began to emerge as a fundamental technique for the study and biomechanical modelling of the residual system of the prosthetic limbs. It has been highlighted how these issues are of central importance nowadays and how they can also potentially be carried forward for future developments. From some of the latest results of these studies in this section [17] [57] [77] [79] [83] [84], it is clear that the attention in this scientific sector is concentrated on the search for optimal solutions that combine functionality, mechanical performance and robustness in the use of the prosthesis in daily routine or specific activities;

and therefore how these topics are extremely important in scientific research and in the biomechanics of prostheses. It would therefore be ideal to carry out studies that combine the deepening of the optimization techniques applied to the study of the biomechanics of the prosthesis towards an improvement of prosthesis robustness, especially considering the implementation of non-linear constitutive biomechanical models to predict in a more accurate way the mechanics of the biological system (prosthesis-stump) involved.

Goal of the project

Considering the information and knowledge discussed in the literature review, it is possible to reformulate the goal of the project in more detail as follows:

Then the project goal is to simulate the p-cast process able to produce prosthesis socket with desired characteristics, considering different variations of the biomechanical variables and properties to analyse different cases effects of the p-cast process on the stump to support the "design for robustness" approach for lower leg prosthesis socket.

III Material and Methods

Methodology

Project research was conducted by generating a basic model of a transtibial amputated residual limb. This reference model represents the amputated leg of a patient weighing 75 kg and 1.75 m tall (24.5 BMI) and of sedentary activity, with a prosthesis with silicone liner.

This thesis employed an existing model from previously published work. Briefly, that involved the acquisition of DICOM MRI data of the residual limb and the subsequent segmentation process using ScanIP [130]. Subsequently, the imaging data was converted into a baseline FE model by Yozkan Gyuler [131] which was exploited in the present study. The above cited work, included numerical verification of the finite element mesh for comparative analysis of different prosthetic socket and liner variables, which was the same purpose as the present study.

Starting from this basic model, during the approval phase of the study for the analysis of secondary data by the Ethics and Research Governance Office (ERGO, ref. 49306) of the University of Southampton, FE simulations were planned and performed varying the material properties of the model and the simulation loads, generating different models representing specific cases to test the response of the FE model and draw biomechanical conclusions.

Materials

Different types of patients were simulated. This included:

- a simulation that considers an elderly patient, in which there is a different stiffness of the soft tissues of the residual limb. This was intended to represent the loss of water in the soft tissues and therefore a reduced elasticity, or increased Young's modulus [132]. Then
- a patient with different weight has been considered (87.5 kg), thereby influencing p-cast pressure (70 kPa) as a function of weight (in fact, weight scales are used in the cast acquisition phase to evaluate the pressure developed for the given weight in the p-cast chamber [133]). Moreover,
- a limb of a trained sports patient has been modelled, considering a higher percentage of muscle tissue in the soft tissues and then changing the material properties of the tissue accordingly (elastic modulus E=0.5035) (see table 3.1) [134]. Finally,
- simulations with two different kinds of liner's materials have been carried out. Gel liner material [135] and silicone liner material [130] employing for both the Mooney-Rivlin constitutive material model but with different coefficient values.

These different simulations and related changes in the material model are summarized in table 3.1 ("Simulations Variables Plan" table). Specifically, the material properties that have been changed and which highlight the characteristics of the model considered are the Young's modulus E for the isotropic elastic models, and in the same manner for the Neo-

Hookean model. For the Mooney-Rivlin models instead the different constants c_i vary according to the material model considered.

Table 3.1 - Simulations dependent variables and their employed numerical values for the given model simulation and relative target aiming to simulate (Material properties for each part and Pressure casting applied). The values in red are the ones changed with respect to the reference model.

Simulation variables Plan Table					
Parts and Pressure	**Reference Model**	**Heavy Model**	**Sportive Model**	**Old Model**	**Gel Liner Model**
Bones (Femur, Tibia, Patella, Meniscus, Fibula)	*Isotropic Elastic* **E**=12000 MPa; **ν**=0.3; **ρ**=1 g/cm^3	-	-	-	-
Tendons & Ligaments (Patellar tendon, Tibia ligament, Quadriceps tendon)	*Isotropic Elastic* **E**=0.4 MPa; **ν**=0.49; **ρ**=1 g/cm^3	-	-	-	-
Soft Tissue	*Neo-Hookean Elastic* **E**=0.06242 MPa; **ν**=0.495; **ρ**=1 g/cm^3	-	**E**=0.5035 MPa	**E**=0.5824 MPa	-
Liner	*Silicone Liner Mooney-Rivlin* c_1=37.6 MPa c_2=0.54 MPa **K**=2.4 MPa ρ =1 g/cm^3	-	-	-	*Gel Liner Mooney-Rivlin* c_1=0.43x10^{-3} MPa c_2=0.21 x10^{-3} MPa **K**=1.2 x10^{-5} MPa ρ =1 g/cm^3
P_{cast} Pressure	60 kPa	70 kPa	-	-	-

The choice of these different cases is due to the greater interest in the types of cases chosen, among the most common and which can most encounter problems in wearing prostheses [136], as well as for the interest of the biomechanical characteristics and the simulation factors chosen, as of scientific interest regarding the influence on the outcome of the prosthesis and especially in the p-cast process.

To realistically simulate the p-cast process, the boundary conditions and loads must be suitably set in the simulation pre-processing step.

Boundary Conditions

The boundary conditions must represent the continuation of the proximal part of the femur beyond the edge of the FE mesh. This consideration therefore translates into a boundary condition which fixes all the displacements of the upper surface bone (displacements x, y, z = 0 for all steps). While as regards the soft tissues on the top surface of the model, their displacements have been confined in the radial direction $\sqrt{x+y}=0$, also by the contact constraint with the liner also pushed in the radial direction) while the displacements along z have been left free as there is continuity of material considering the continuation of the upper leg.

Loads

As regards the applied loads, a uniform hydrostatic pressure was set on the entire surface of the liner which covers the residual limb (representing the pressure exerted at the junction with the wet plaster inserted in the chamber of the p-cast), thus leaving the upper part of the model free. The applied load was numerically set considering a subject of a given weight and a symmetrical weight distribution on both legs. As a result, for a 75 kg subject the calculated p-cast pressure is about 60 kPa, while for a 87.5 kg subject the p-cast pressure is about 70 kPa as reported in table 3.1.

Model Outcome Measures

The model was analysed in terms of its contact pressure, soft tissue deformation, and the 1st and 3rd Principal Lagrange strains generated in the soft tissue. These were selected because they are likely to represent the maximum tensile and compressive magnitude measures of strain, which together with the maximum shear strain provide an array of markers indicative of soft tissue injury. From basic continuum kinematics theory:

$$E = \frac{1}{2}[(\nabla\otimes u)^T + (\nabla\otimes u)] = \mathrm{sym}(\nabla\otimes u)$$

where E is the infinitesimal strain second rank tensor or Lagrange strain tensor and u is the displacement vector in a continuum deformable material model, the previous relation can be also expressed in the R^3 space as:

$$E = \begin{bmatrix} \varepsilon_{11} & \varepsilon_{12} & \varepsilon_{13} \\ \varepsilon_{21} & \varepsilon_{22} & \varepsilon_{23} \\ \varepsilon_{31} & \varepsilon_{32} & \varepsilon_{33} \end{bmatrix} \qquad \text{with} \qquad \varepsilon_{ij} = \frac{1}{2}\left[\frac{\partial u_j}{\partial x_i} + \frac{\partial u_i}{\partial x_j}\right]$$

So, every component of the Lagrange strain tensor E can be expressed as ε_{ij} as written in the formula above. This measure is mathematically simple, and it quantifies the relative displacement and deformation of material particles in a deforming body. By measuring the change in distances between material particles, it captures the tension, compression, rotation, and shear occurring in the material. Moreover, it accounts for small strains in linear elasticity and can be extended to handle large strains in nonlinear materials. The Lagrange strain measure aligns with the formulation of linear elasticity, where the stress-strain relationship is linear, and fits within the larger context of continuum mechanics, allowing for the integration of strain measures into the formulation of governing equations and constitutive models. Finally, the Lagrange strain measure can be linked to experimental observations and measurements. For example, it can be related to strain measurements obtained from strain gauges, optical techniques, or digital image correlation etc. This compatibility with experimental data enhances its practical applicability and facilitates the validation of numerical simulations against experimental results. This versatility makes it suitable for a wide range of applications, from analysing elastic structures to studying highly deformable materials and so it is a suitable candidate to measure deformation in biological tissues.

FEBio Computational Procedure

The computational procedure through the FEBio software used to carry out the simulations of the p-cast process is described schematically below:

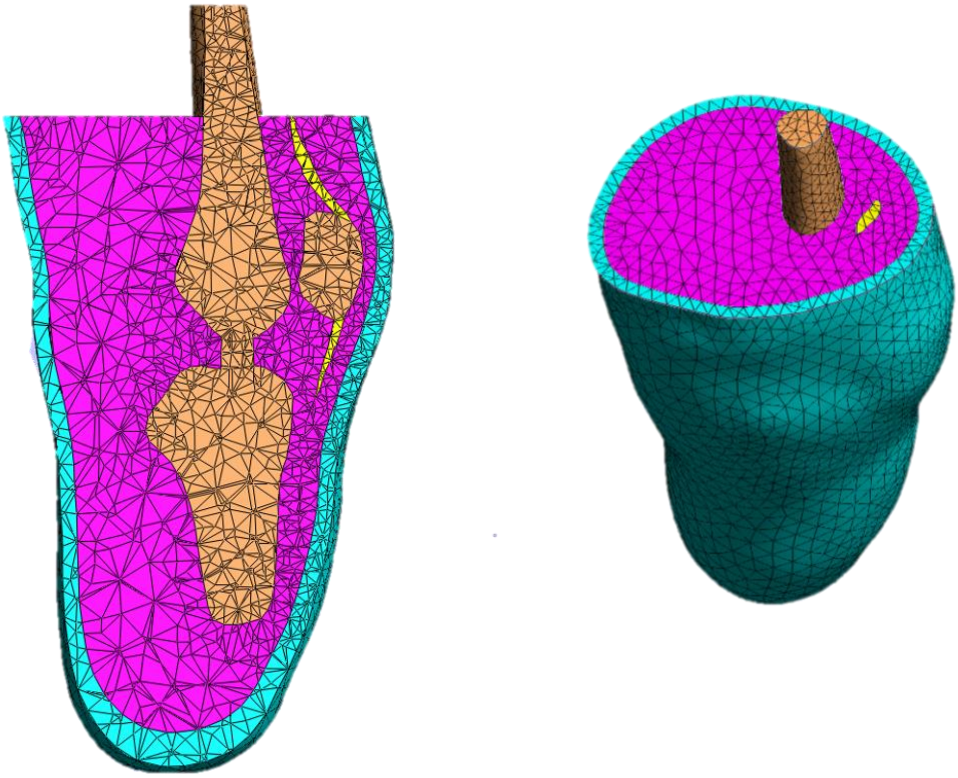

Figure 3.1 -The mesh model of the stump employed for the simulation (sagittal plane on the left and whole model on the right). Different colours are assigned to different parts of the model: fuchsia for the soft tissue, orange for the bone, yellow for the tendons/ligaments and azure for the liner.

I. BEGINNING of PRE-PROCESSOR PHASE –

1. The residual limb finite element mesh was imported (fig. 3.1). Then, a (Structural Mechanics, static) load case was created, with maximum solution timestep 0.1, minimum timestep 0.00001 and initial timestep employed 0.0001. A linear, non-symmetric solver was chosen (the default one employing the Broyden – Fletcher – Goldfarb – Shanno algorithm).

2. Set and assign material properties to each part, as shown in table 3.1.

3. Set the boundary conditions for each interested part (specifically, for the simulations performed, all the degrees of freedom for the surface of the proximal part of the femur were fixed) (fig. 3.2).
   Then, set the loads on the external surface of the part of the leg in contact with the p-cast chamber (fig. 3.3).)

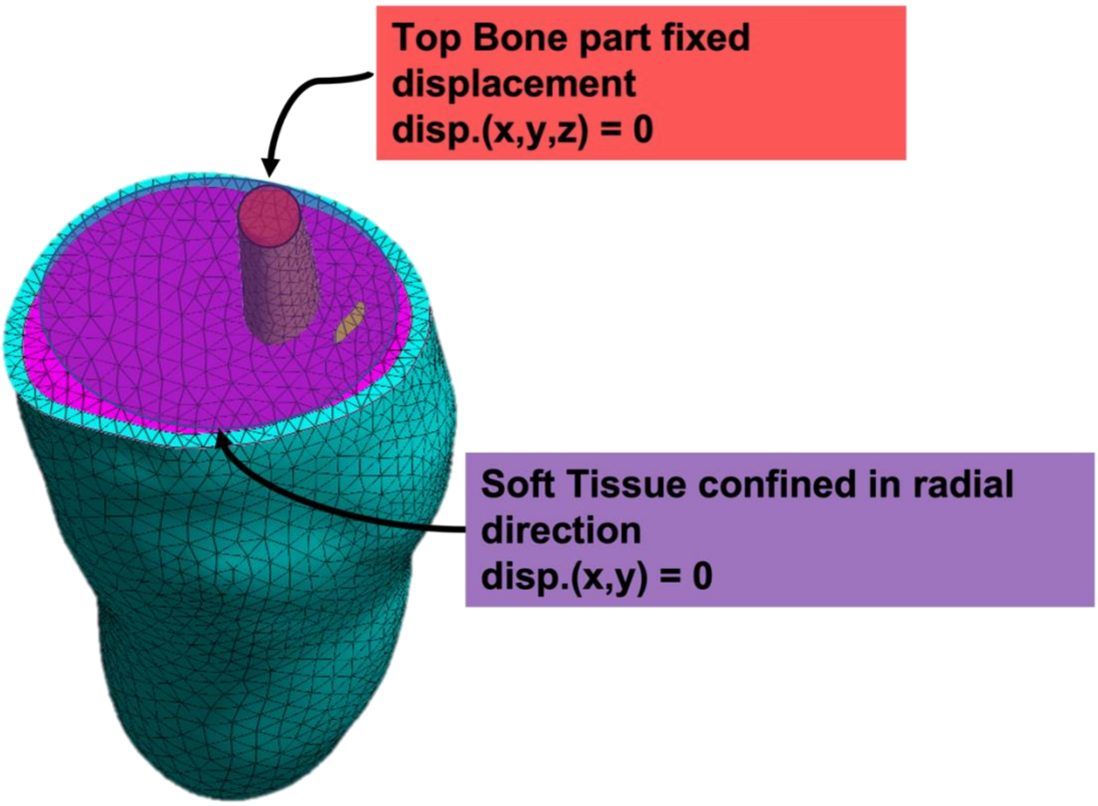

Figure 3.2 -Boundary conditions applied to the model. The top part of the bone is fixed while the soft tissue part is confined in the radial direction.

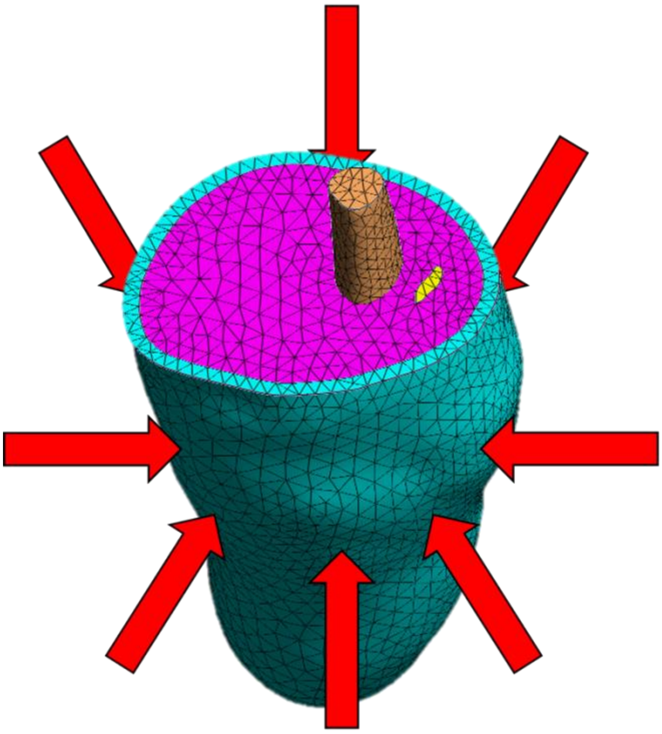

Figure 3.3-The mesh model with a schematic representation of the loading condition: a hydrostatic pressure of 60 kPa (70 kPa for the heavy case) applied to the socket.

4. Check and adequately select the outputs to be obtained from the simulation (for the simulation of p-cast the relevant outputs were strain, pressure, displacements, and surface traction)

END of PRE-PROCESSOR PHASE -
–

II. SOLVER PHASE
In this phase the model prepared in the pre-processor phase is solved through the solver of the FEM package.
Settings to be changed:

Maximum time step:	0.1
Minimum time step:	0,00001
Employed time step:	0,0001
Auto time stepper:	On
Use must points:	Off
Max retries:	10
Optimal iterations:	10
Cutback:	default

Linear solver	
Matrix:	Non-symmetric
Equation scheme:	Default
Non-linear solver	
Displacement tolerance:	0.001
Energy tolerance:	0.01
Residual tolerance:	0
Line search tolerance:	0.9
Minimum residual:	$1*10^{-20}$
Quasi-Newton method:	BFSG(Broyden – Fletcher – Goldfarb – Shanno algorithm)
Spectral radius:	0
Max reformations:	15
Max updates:	10
Reform on diverge	On
Reform each timestep	On
Plot level:	Major Iterations
Plot stride:	1

III. POSTPROCESSOR PHASE

In this phase the results obtained by the solver phase can be explored and maps, plots and values can be visualized.

IV Results & Discussion

In this chapter the results obtained through the FEM simulations will be illustrated and discussed. The results obtained with the simulations concern a single case study for which different scenarios were analysed by changing parameters to represent different patient characteristics as showed in the Methodology part (chapter III).

Specifically, scenarios have been chosen in which the patient wore a silicone liner and another case in which he wore a gel liner. In addition, different physiological conditions of the patient were then considered, adjusting the residual limb material properties to represent elderly and then sportive active subjects. Finally, the p-cast condition was adjusted to consider heavy subjects.

These choices were made to consider on the one hand a wide range of cases and on the other hand to have a set of biomechanical parameters to be varied controllable in the simulations and at the same time verifiable in the literature.

MODELS RESULTS COMPARISON

Displacements

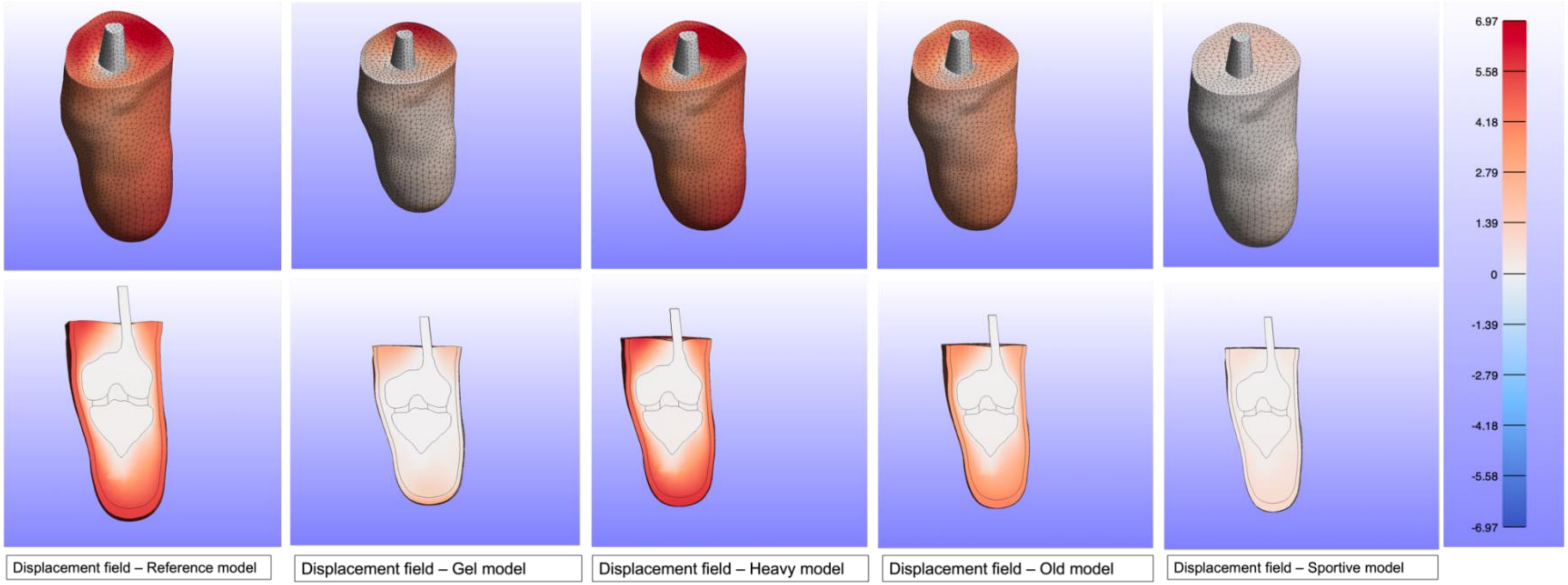

Figure 4.1 - Displacements contour plots of the different models employed in the simulations. Models from left to right: reference, gel liner, heavy, old and sportive cases. Units: mm.

By comparing all the displacements, from figure 4.1 the distributions and values fall approximately in the same range for all models except for the old and sportive cases. The sportive model is the one in which there are displacements close to zero.
In fact, the old model is stiffer due to the lower quantity of water in the tissues and therefore a lower elasticity (lower Young modulus), a similar effect occurs in the sportive model, however, because in this case there is a percentage of muscle tissue which is stiffer than the soft tissue. For all models the area with the highest intensity remains the one in which there is only soft tissues away from bones and tendons. In general, there are almost zero values on the external surface of the models except on the upper part of the model.
Finally, the heavy model has more intense displacements due to the greater pressure exerted by the greater weight in the p-cast process and displacements are localized in the area where there is a pervasive presence of only soft tissues.

Lagrange Strain

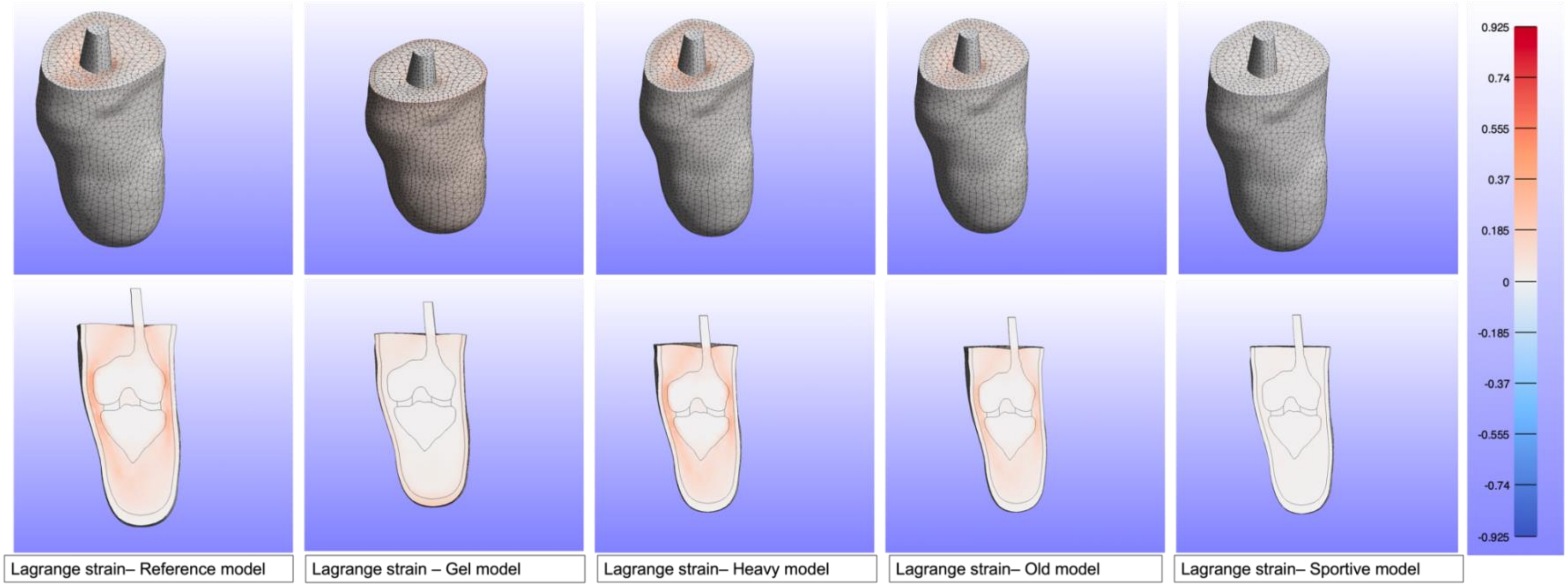

Figure 4.2 - Lagrange strains magnitude contour plots of the different models employed in the simulations. Models from left to right: reference, gel liner, heavy, old and sportive cases. Units: dimensionless.

Comparing all the Lagrange strains, it can be seen how the strains are more concentrated in the area adjacent to the liner and in the areas with a prevalence of soft tissues, far from other tissues. The sportive model is the least deformed and therefore with the lowest strain intensity.

First Principal Lagrange Strain

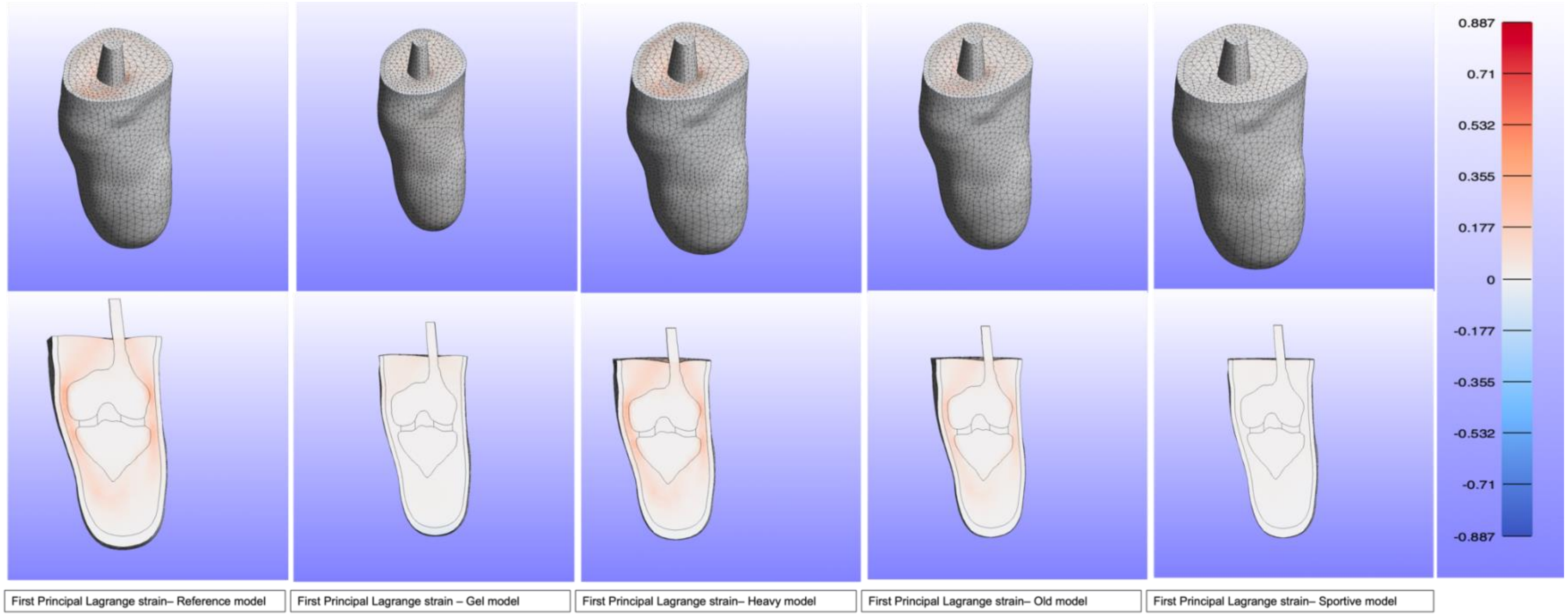

Figure 4.3 - First Principal Lagrange strains magnitude contour plots of the different models employed in the simulations. Models from left to right: reference, gel liner, heavy, old and sportive cases. Units: Dimensionless.

Comparing all the first principal Lagrange strains, apart from the reference, and heavy models they are all low intensity and with almost zero values in the lower part of the model. Even for this quantity, in all models the part with the greatest intensity is the part away from the bones on top. Finally, the sportive model is still the one with the lowest values, almost zero on all parts of the model.

Third Principal Lagrange Strain

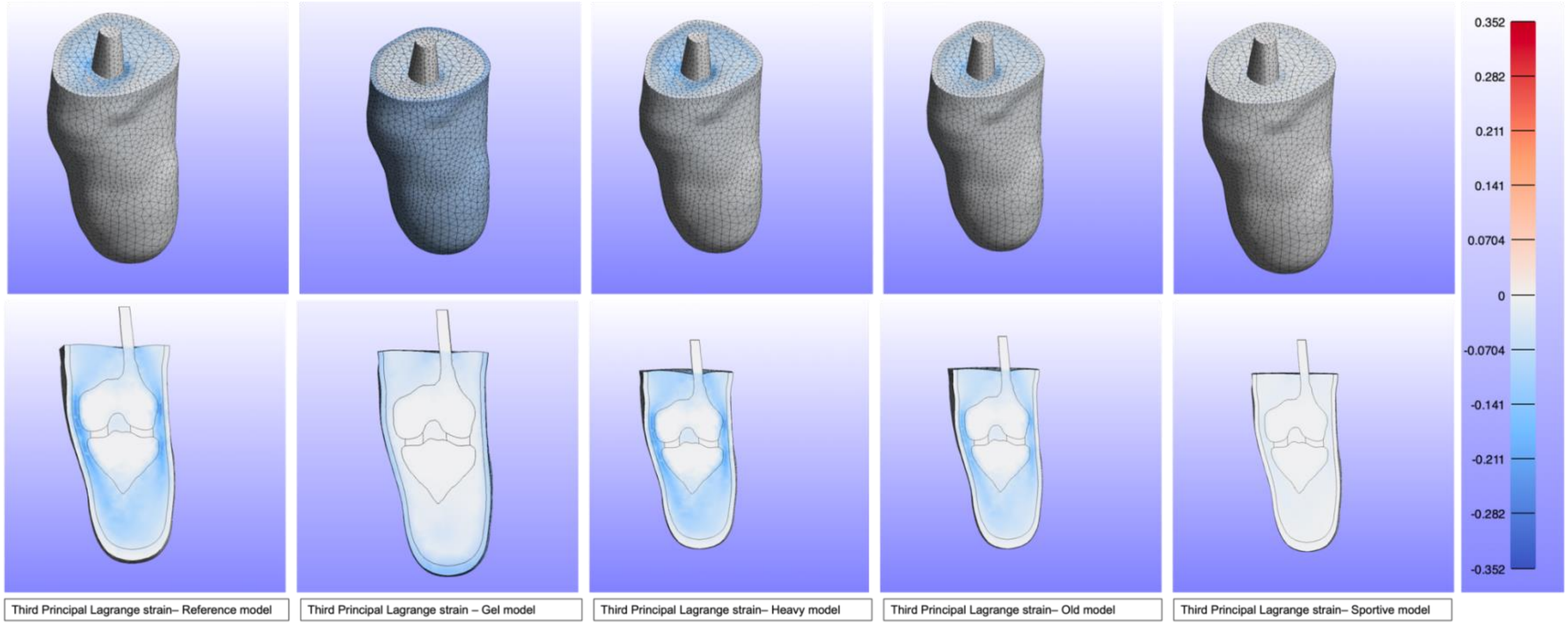

Figure 4.4 - Third principal Lagrange strains magnitude contour plots of the different models employed in the simulations. Models from left to right: reference, gel liner, heavy, old and sportive cases. Units: Dimensionless.

Comparing all the third principal Lagrange strains, the values are generally quite uniform and distributed over the whole model even if there is a greater concentration of the third principal strains in the top part of the models and near the bones. In the sports case, even for this quantity there is a low intensity of the values.

Recalling that the difference between the first and third principal Lagrange strains can give us an idea of whether there are tensile strains (if the difference is positive, therefore the first principal strains predominate) or compressive strains (if the difference is negative, therefore the predominant third principal strains), it can be said, looking at figure 4.4 and 4.3, that for the gel case there is a predominantly compressive deformation, as for the old case, even if less evident. For the sport case, the model would seem to respond to compression, especially near the liner. Similarly, also for the heavy case even if there is a slight tensional component in the soft tissues area away from the other tissues, but which should be evaluated numerically to correctly estimate the type of strains. However, to have a complete picture, it should be evaluated numerically in the area with a prevalence of soft tissues away from the bones, where there is a greater intensity of strains.

Maximum Shear Strain

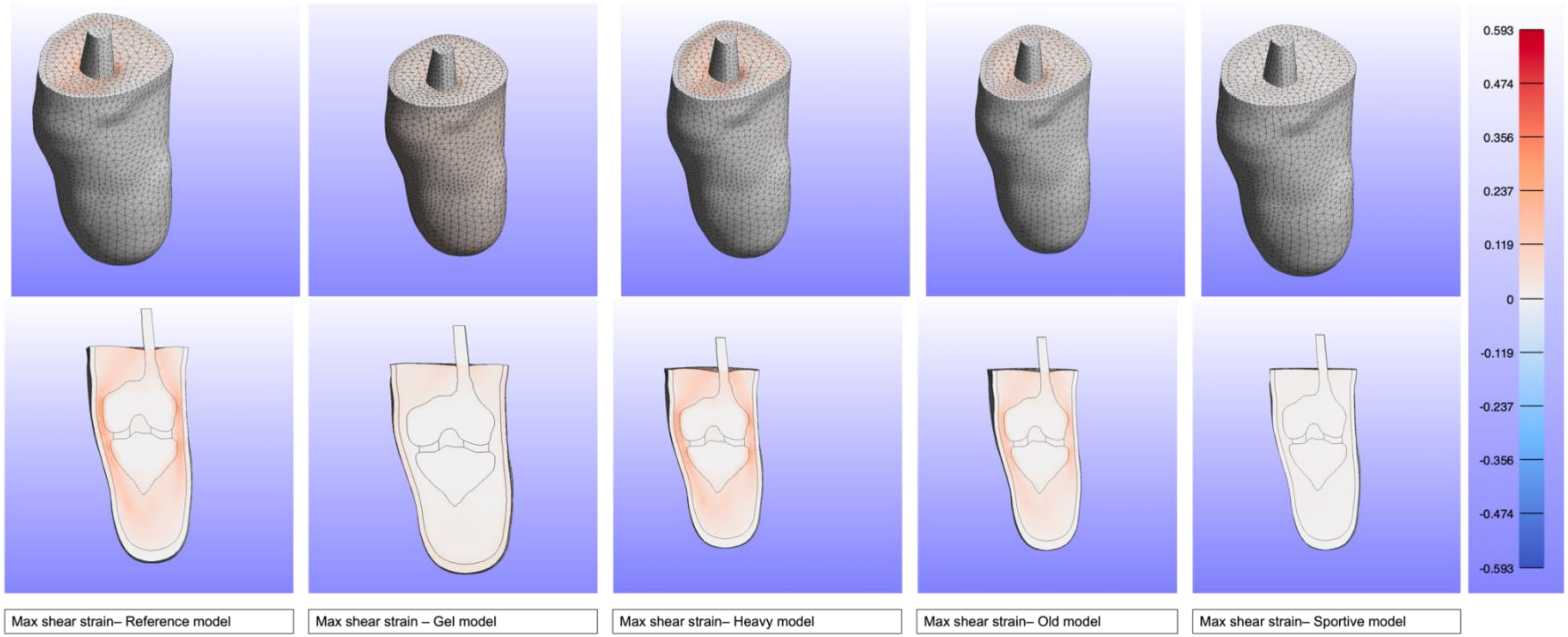

Figure 4.5 - Maximum shear strain magnitude contour plots of the different models employed in the simulations. Models from left to right: reference, gel liner, heavy, old and sportive cases. Units: Dimensionless.

Comparing all the maximum shear strains, in all the models there is a high concentration of the strains at the interface between the liner and the internal soft tissues, with all positive values except almost zero values for the sportive case. Furthermore, even for the maximum shear strains there is a very high intensity in the upper part of the gel model, where a significant shape deformation is noted.

Whisker plots and master results table

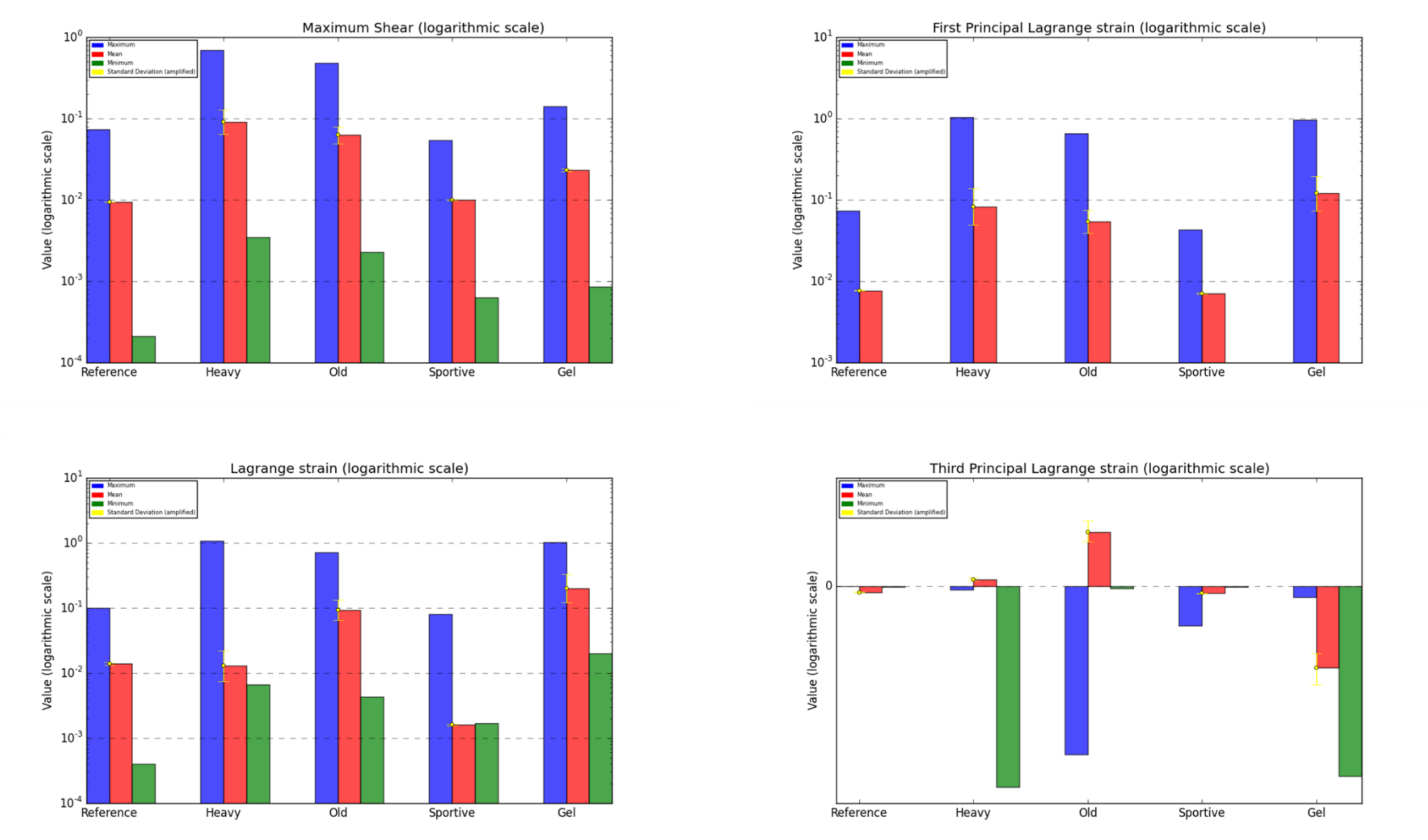

Figure 4.6 – Bar charts plots of different mechanical quantities for the different models simulated. Top left max shear strains, top right first principal Lagrange strains, bottom left Lagrange strains magnitude, bottom right third principal Lagrange strains.

MASTER RESULTS TABLE

SIMULATION MODELS

	Lagrange Strain	1st Principal Lagrange Strain	3rd Principal Lagrange Strain	Maximum Shear Strain
Reference Model	**Max:** 0.1 **Min:** 0.0004 **Mean±Sd:** 0.014±0.05	**Max:** 0.074 **Min:** -0.00071 **Mean±Sd:** 0.0077±0.038	**Max:** -0.00004 **Min:** -0.00071 **Mean±Sd:** -0.011±0.048	**Max:** 0.074 **Min:** 0.00021 **Mean±Sd:** 0.0094±0.0032
Gel Model	**Max:** 1.02 **Min:** 0.02 **Mean±Sd:** 0.2±0.51	**Max:** 0.96 **Min:** -0.015 **Mean±Sd:** 0.12±0.49	**Max:** -0.02 **Min:** -0.35 **Mean±Sd:** -0.15±0.19	**Max:** 0.65 **Min:** 0.011 **Mean±Sd:** 0.13±0.32
Heavy Model	**Max:** 1.086 **Min:** 0.0067 **Mean±Sd:** 0.013±0.54	**Max:** 1.03 **Min:** -0.0082 **Mean±Sd:** 0.082±0.52	**Max:** -0.0067 **Min:** -0.37 **Mean±Sd:** 0.10±0.22	**Max:** 0.69 **Min:** 0.0035 **Mean±Sd:** 0.091±0.35
Old Model	**Max:** 0.72 **Min:** 0.0043 **Mean±Sd:** 0.092±0.36	**Max:** 0.66 **Min:** -0.0057 **Mean±Sd:** 0.054±0.33	**Max:** -0.0043 **Min:** -0.31 **Mean±Sd:** -0.071±0.19	**Max:** 0.48 **Min:** 0.0023 **Mean±Sd:** 0.063±0.24
Sportive Model	**Max:** 0.081 **Min:** 0.0017 **Mean±Sd:** 0.016±0.04	**Max:** 0.043 **Min:** -0.0031 **Mean±Sd:** 0.0071±0.024	**Max:** -0.0017 **Min:** -0.072 **Mean±Sd:** -0.013±0.046	**Max:** 0.054 **Min:** 0.00063 **Mean±Sd:** 0.01±0.027

SIMULATION RESULTS VALUES

Table 4.1 - Maximum, minimum and mean plus standard deviation values of the different models for each mechanical quantities resulted from simulations.

By comparing the various models and their results from the FEM simulations, the evidence wrote below can be highlighted.

Considering the Lagrange strains results, the strains of the different models are all lower than the heavy case. In the sportive case the level of strains is very low, due to the presence of a percentage, albeit low, of muscle tissue with different mechanical properties as it is stiffer than soft connective tissue. For the case of the heavy patient, it can be seen that the strains (Lagrange strains and maximum shear strains) are the greatest among the various cases precisely due to the greater pressure applied to the system due to the greater weight, with a consequent increase in the deformations (for the same mechanical properties of the leg). Finally if a gel liner is used rather than a silicone liner, it will be necessary to consider that the deformations and displacements will be greater and that there will be a significant deformation of the shape of the model, as shown in figures 4.1-4.5.

Considering instead the results of the various models for the first principal strain, in the first place it is evident that the reference and sportive cases are the ones with the lowest value and, as the reference case, an extremely narrow distribution, remembering that this strain value is an indicator of the maximum strain value during the deformation it can be deduced that the sportive case turns out to be the one that deforms less and in general that the heavy model turns out to be the one with the highest strain maximum; as the other models also have values of orders of magnitude similar but lower to the heavy case as well as a high standard deviation.
For the sportive case, the cause lies in the different mechanical properties due to the percentage of extra muscle tissue, which is stiffer.

Greater stiffness also for the case of the elderly patient, due to the loss of water from the soft tissues. For the heavy case it may mentioned that due to the high weight and therefore the higher pressure in the p-cast process this implies a higher deformation of the model.
For the results of the third principal Lagrange strain, we note that they are all negative values. Furthermore, the sportive case seems to have the maximum value of this quantity, with a very small standard deviation range. While the reference model has the largest value (in absolute value), as well as the largest standard deviation.
In general, from the principal strains values it is possible to derive the maximum possible deformations along the principal axes and then evaluate the dimensioning of a possible socket by taking these values as maximum (first principal strain) and minimum (third principal strain) extremes of variation, thus dimensioning this part using these limits.
Finally, considering the max shear strains, all the cases with respect to the heavy case have lower minimum, maximum and average values and therefore a reduced standard deviation, the situation is similar to the Lagrange strains value. In particular, the sportive case has the lowest value.
These considerations can be interpreted in the light of the fact that shear deformations represent a geometric deformation with respect to a shear load, therefore minor deformations represent the ability to oppose geometric distortion deformations with respect to the applied p-cast load, which is connected to the load share of the subject's body weight distributed on the residual limb.

Analysing all the models together and considering the master table it could be said that minor displacements and strains (both shear and in magnitude) were observed for older patients, perhaps due to the lower presence of water in the tissues which make them less elastic; to have a more complete picture for this case perhaps even a stress analysis or implementing a damage model could be useful. While in the case of sportive patients, particular attention should be paid to the level of displacements and strains which is much lower than the other models, evidence that should perhaps be attributed to the different mechanical properties due to the presence of greater muscle mass. Furthermore, for heavy patients it should be considered that the results show higher strain values than the other models. Results in line with the expectations that greater weight translated into greater pressure exerted in the p-cast process, with the same material properties, generates greater deformations.

Finally, if a gel liner is used rather than a silicone liner, it will be necessary to consider that the strains and displacements will be mainly localized in the area close to the liner, in particular, the liner will deform much more together with the internal soft tissues which will have an extremely accentuated deformation, especially in shape, compared to all the other models.

Finally, if we look at the substantial differences between the various models, considering that they were built by introducing small differences in the mechanical properties of the reference model, we can see that the order of magnitude of the various quantities is the same and that we notice mainly a different spatial distribution of quantities, but not so pronounced. Thus, it can be argued that small changes in the model's inputs have produced small changes in the model's outputs and that therefore the model is robust, always considering that, among the material properties under examination, particular attention must be given to the elastic modulus of the model.

V Conclusions & Future Works

In this chapter the conclusions and future works related to the thesis project will be illustrated in detail.

Conclusions

From the results obtained and the versatility of the biomechanical model created, it can be stated that this model is a stable foundation for different and possible future biomechanical simulations and that it can be used and adapted to different conditions and needs. From this study it emerged that changes in the mechanical properties of the stump, described in detail in the Methodology chapter (chapter III), albeit not substantial or not of several orders of magnitude, have led to appreciably different results (not too far from reference case, so stable from the robustness point of view), especially in terms of distribution and sign of the different quantities analysed, this study also highlighted biomechanical considerations with respect to the different models proposed as well as potential future insights on the design of the socket of the lower leg prosthesis.

Placing in context the results obtained, it can be said that from the quantities analysed, the results of the heavy case seem to reflect the effects of the greater weight of the model and therefore higher intensities of displacements and strains values. For the old and sports cases, here too the expectations of lesser deformations were confirmed, on the one hand for the old case as stiffer due to lack of water and less elasticity of the soft tissues, while for the sportive case due to greater muscle mass and therefore increased elastic modulus. Finally, for the case of the gel liner, the results are in agreement with literature [21][59][126] which confirms that it is more deformable than the silicone liner.

In addition analysing the results as a whole, it was evident that from a socket design perspective the differences between the various models presented are not so great as to have to think of different socket designs for each case, as the orders of magnitude of the strains and displacements are often very close. Perhaps the only case that deviates slightly more consistently from the reference model is the sportive model, especially as regards the principal strains and the max shear strains; this evidence can be interpreted considering that perhaps the sportive model is the one that was built more accurately and considering substantially different mechanical properties of the tissues as well as considering that the needs and therefore the conditions to which a sports person is subjected are more "extreme" than those of the other cases, therefore for this case it could be better to deepen the mechanical behaviour with other simulations and possibly develop ad-hoc sockets and in general develop a prosthesis specifically designed for sportive performance, as also illustrated in literature [137].
So, it can be concluded that, even in a discussion relating to robustness, if particular cases are not considered on which an ad-hoc socket (prosthesis) should be designed (such for athletes), they are older patients or with a different weight or still with a gel liner, there is the possibility of developing a robust-oriented socket design, as the mechanical requirements to be met fall within an acceptable range of variation.

Finally, considering the objectives and premises stated in the introduction to this work it was possible to obtain several maps and graphs of the different mechanical quantities of interest, such as displacements, Lagrange strains, first and third principal strains and maximum shear strains according to different conditions and biomechanical parameters. These results lay the foundation for the design of a socket optimized employing the p-cast process and can be exploited to create a socket design in which the robustness of the same is optimized for this type of needs and as much as independently of the biomechanical variations of the model.

Furthermore, different scenarios and physiological conditions of the stump in the p-cast process were simulated to verify how different variations of the biomechanical parameters influenced the outcome of the process and therefore to support the creation of a robustness-oriented design. In particular, variations in the weight of the subject, in the percentage of muscle mass, in age and in the type of liner used were simulated. These results therefore represent an important foundation for the development of a robustness-oriented lower leg prosthesis socket design and per se a biomechanical study on the effects of the p-cast process on the stump.

Obviously the proposed model can be improved. First, different more sophisticated constitutive models can be used and possibly compared with the simpler ones. For example, giving a greater focus to the microscopic remodelling and damage mechanisms and thus realizing a multi-scale model.
Furthermore, we could concentrate on the analysis of the stresses and strains in relevant and more sensitive areas in contact with the socket, considering what could be the limit thresholds that the amputated leg could bear.
Finally, various contact simulations with the socket model could complete the biomechanical analyses considered, verifying which design could be the best and which optimization paths can be undertaken to create a better version of the socket and therefore of the prosthesis.

Future Works

The future works of this project could branch out in two main directions: on the one hand the refinement of the results obtained by enriching the simulations and models used, and on the other the natural continuation of the project by exploiting the results obtained to optimize the socket of the lower leg prosthesis.

As far as the enrichment of the simulations and of the models used is concerned, in the first place more advanced constitutive models could be used, possibly also incorporating more sophisticated phenomena such as tissue remodelling and subsequently also implementing a tissue damage model. Furthermore, for the generation of the stump model itself, statistical models of the patient imaging data could be used [9] more extensively by trying to merge patients with similar pathologies or common characteristics to create a set of different stump models that turn out to be models statistical means of different groups of patients with similar characteristics (e.g. similar age range, gender, type of daily activity and time since amputation).

As far as the optimization of the socket design of the lower leg prosthesis is concerned, FEM simulations of contact mechanics between the stump and the surface of the socket could be carried out, focusing on the contact mechanics and the results at the interface with the socket, considering different shapes of the socket as well as different materials and therefore carrying out an optimization work on these characteristics (also considering innovative optimization techniques such as for example genetic algorithms).

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