NATIONAL UNIVERSITY OF SCIENCE AND TECHNOLOGY
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FACULTY OF MECHANICAL ENGINEERING AND MECHATRONICS

SUMMARY

DOCTORAL THESIS

Studii şi cercetări privind optimizarea protezelor modulare de gambă și coapsă

Studies and Research for Optimization of the Calf and Thigh Modular Prostheses

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Keywords: modular prosthesis, lower limb, residual limb, prosthetic socket, daily volume changes, diabetes, discomfort, skin lesions, defective peripheral blood circulation, adjustable mechanical clamping system, manually operated, dimensional adaptation, good fixation of the residual limb, customizing the silicone liner, biocompatible properties, increasing the degree of independence, improving the method of fixation and use of the prosthesis.

Chapter 1. Introduction. Thesis objectives

1.1. Introduction

Lower limb prostheses involve the use of devices to replace parts of limbs lost due to amputation or congenital disease to restore movement and functional independence to people with movement disorders.

Socket connection systems have a significant impact on amputee comfort, mobility, and satisfaction. Today's suspension systems, especially vacuum systems, pose several problems related to changes in stump size. Therefore, the prosthetic socket, liner, and residual limb should have acceptable contact to ensure appropriate pressure distribution. Problems caused by dimensional changes are traditionally solved by changing the fastening system (prosthetic socket) or supplementing the structure with stuffed socks (made of textile material), but in most cases the results are unsatisfactory.

1.2. Incidence of lower limb amputations

The main causes of limb amputation surgery (upper, but mainly lower limb) are vascular and arterial diseases (54%), diabetes, trauma (45%) and, finally, cancer (less than 2%) [1].

Since the major cause of lower limb amputations is diabetes, it is estimated that in Romania, approximately 62 amputations occur daily among people with diabetes [2]. In the coming years, as the global population and life expectancy increase, the number of people in need of prosthetic services will increase. Therefore, research and development activities on new technologies are needed to produce lower limb prostheses using lightweight and biocompatible materials for affected tissues and ultimately to produce high-performance and affordable prostheses.

1.3. Problems of constructive and functional optimization of lower limb prostheses

The dimensional adaptation of the residual limb by the prosthetic socket is considered to be the biggest problem faced by people after lower limb amputation. [3][4][5]. Daily changes in lower limb volume can precedence to changes in the geometry of the contact between the post-amputation residual limb and the prosthetic socket, which can lead to discomfort and pain if the socket is too tight against the amputation base or vice versa. If the socket on the amputated limb structure is too wide, a piston effect may occur, leading to damage to the residual limb's connective tissue over time [6].

Considering existing technical solutions at the national and international level in the field of clamping system for lower limb prostheses, the following aspects can be notable that determine an innovative achievement that will meet the requirements for its optimization:

- the need to adapt the suspension system of the prosthesis to the particularities of the residual limb, especially in the case of its volume variations;
- ensuring the functionality of the prosthesis without affecting the patient's blood circulation;
- checking the patient's stability;
- the use of materials with controlled elastic properties, low weight and meeting the requirements of applicable regulations that capture the effects of skin contact;
- designing the appropriate anatomical shape ensures the patient's mobility and comfort.

1.4. Thesis objectives

The need for prosthetics for a continuously growing number of people, according to the statistics and the deficiencies reported, cause discomfort to the prosthesis wearer, in all aspects, from skin or tissue injuries and defective peripheral blood circulation. To cover the maintenance costs and regular replacement of prostheses, a research direction has been proposed to realize a purely mechanical suspension system for it, in which the prosthetic socket passively compensates for the volume changes of the residual limb and maintains a limited distribution of the residual limb pressure socket during walking.

The general (main) objective of the thesis is the conception and realization of an adjustable mechanical clamping system (prosthetic socket) for lower limb prostheses, manually operated, through which the geometry of the residual limb can be dimensionally adjusted as well as supported. The purpose of the research carried out in this doctoral thesis is to ensure a good fixation of the residual limb in the new prosthetic socket, despite the volume in the case of diabetic subjects, and the customization of the silicone liner, having biocompatible properties with the tissue, thus eliminating the current disadvantages of commercial liners, available in two-by-two sizes. The system is designed to help lower limb amputees feel comfortable, and confident in their prosthesis and have a pain-free residual limb while improving their quality of life. The final goal aims at increasing the degree of independence of the wearer and improving the way of fixing and using the prosthesis, especially for patients who suffer from diabetes and have significant volume fluctuations in the residual limb.

Considering these aspects, the following objectives of the research carried out in the framework of the thesis were outlined:

1. Scientific documentation regarding the functional anatomy of the lower limb, its biomechanics, and the gait cycle, aspects that contribute to the constructive and functional analysis of the prosthetic components used to create a lower limb prosthesis.

2. Preparation of a study on the present state of progress in lower limb prosthetics at both national and international levels. The study will involve the identification of prosthetic principles and methods and analyzing their effectiveness at the interface between the prosthetic and the body. The study will also evaluate the extent to which prosthetic components satisfy medical requirements, including their adaptability to changes in residual limb volume.

3. Documentation of general and special instruments used to analyze and record kinematic variables (position, velocity and acceleration) or dynamic variables (forces and pressures) for conducting experiments.

4. Conception, production techniques and implementation of systems for attaching a prosthetic socket to a residual limb, as well as mechanical systems for adjusting the dimensions of the socket. The system includes:

- the carbon fiber prosthetic socket, which allows manual adjustment of its dimensions by means of a tightening device with cables connected to the walls of the prosthetic socket; this allows the adaptation and fixation of modular prostheses for any type of residual limb, including those with dimensional variations, ensuring gait stability, safety, and independence of the prosthetic subject.
- the silicone liner, made according to the individual measures of the amputated subject and biocompatible with the skin, fulfils the role of protecting the residual limb, for comfort and maintaining the state of integrity of the skin tissue.

5. Measuring the pressure between the residual limb and the prosthetic socket for a modular transtibial prosthesis.

6. Testing, validating and analyzing the performance of the manufacturing materials of widely used silicone liners and comparing them with the performance of the manufacturing materials of custom silicone liners.

7. Developing a hybrid protocol of experimental and theoretical studies by measuring the kinematic variables of the thigh and calf separately as well as the ground reaction forces and using the obtained data to determine the acting moments of the knee joint based on an inverse dynamic model.

8. The theoretical and experimental data obtained are used to evaluate the load strain on the residual limb-silicone liners-prosthetic socket interface and compared with the experimental results obtained.

9. Final conclusions are presented and future research directions in the field of lower limb prosthetics are proposed.

10. Patented solutions and research results in journals and/or international conference volumes, indexed by WoS and/or Scopus.

Achieving the stated objectives, intended to contribute to increasing the quality of life of prosthetic wearers who have volume variations in the residual limb, will remove, at reasonable costs, the medical problems, and complications, as well as the discomfort created by wearing a prosthetic socket and commercial liner, insufficiently adapted to the anthropometric measurements of the residual limb.

Chapter 2. The evolution and state of the art in the development of prosthetic components to meet anatomical and physiological requirements

2.1. Anatomy of the lower limb

The human lower limb is well suited for bipedal support and performs two important functions: supporting the body and locomotion. The bones of the lower limbs are composed of three segments:

- the skeleton of the thigh made up of the femur bone and patella;
- the calf skeleton consisting of two long bones - the tibia and the fibula (fibula);
- the skeleton of the foot consists of 26 bones arranged in three groups: the tarsus (7 bones), the metatarsus (5 bones) and the bones of the fingers (14 phalanges).

2.2. Movements in the lower limb joints

In this chapter, the movements of the lower limb joints (hip, knee and ankle) are studied, in the following planes:

- In the sagittal plane, the movements are performed around a transverse (frontal) axis: the flexion-extension movement;
- In the transverse plane, the movements are performed around a vertical (longitudinal) axis: the abduction-adduction movement;
- In the frontal plane, the movements are performed around the sagittal (anteroposterior) axis: the internal/external rotation movement.

It should be noted that these movements do not occur equally and simultaneously in all lower limb joints.

2.3. The effects of amputation and the assessment of the activity in the pre-prosthetic and post-prosthetic stages

Lower limb amputation has many negative effects on the musculoskeletal system and leads to functional imbalances characterized by nutritional diseases such as muscular dystrophy and hypotonia or osteoporosis, which affect the remaining segments and must be managed through appropriate exercise programs, as Zur Verth explains, "Every amputee becomes an athlete".

In the first few days after an amputation, patients may experience severe pain and phantom limbs, characterized by the mistaken belief that the lower limb has not been amputated. Therefore, the greatest risk of injury occurs during this period, as amputees are unaware of the damage they have suffered and therefore tend to kick with both feet and fall.

2.4. Gait cycle

The gait cycle is the period that begins when the heel first contacts the ground and continues until the same heel contacts the ground again. The basic unit of human gait is the gait cycle, which is divided into two basic phases: the support phase and the swing phase.

For people with below-knee amputation (tibial amputation), the support phase of the leg prosthesis is important because, during this phase, the leg prosthesis is in full contact with the ground and the load is transferred from the other leg (the healthy leg) to the ground. Further transfer of the entire load to the prosthetic limb through the support.

2.5. Prostheses construction

For most people, the weight distribution is 50:50, which allows for ideal symmetrical loading of the lower limb joints. With the right design and component selection, a prosthesis can support at least 40% of the patient's body weight.

The design of modular calf prostheses must consider the function of the affected limb. Support and movement are optimally ensured and achieved with a secure connection to the residual limb. To do this, it is necessary to adhere to several general rules: to be as consistent as possible with the geometry of the residual limb, to achieve optimal blood circulation, and be functional to allow the rehabilitation and reintegration of the disabled person into social life and be light and aesthetic, to avoid the development of inferiority feelings.

2.6. Evaluation of the activity level in terms of prosthetic components selection

When a modular lower limb prosthesis is made, it is necessary to evaluate the activity level of each subject, before and after the amputation surgery. Thus, five functional levels (also known as "K levels") are defined for people with unilateral (and even bilateral) amputation of the lower limbs:

- Level 0 – Does not have the ability to support itself on the healthy leg.
- Level 1 – Can rise in the healthy leg.
- Level 2 – Has the potential to walk and overcome obstacles at a low level.
- Level 3 – Able to perform locomotion at a variable cadence.
- Level 4 – Has the potential for prosthetic use beyond basic abilities.

2.7. The current state regarding the development of prosthetic socket

2.7.1. Prosthetic socket and attachment systems

The prosthetic socket is the primary interface between the residual limb of the amputee and the rest of the prosthesis, ensuring good fixation, but also high comfort during movement.

2.7.2. Types of prosthetic socket for transtibial prostheses

- *PTS socket (acronym of French words „protheses tibial supracondylien”)*

The calf socket with supracondylar support completely covers the knee up to the upper border of the patella and has the advantage of protecting the knee joint, limiting its hyperextension [7]. It is used especially in the case of short residual limbs.

- *PTB socket (acronym of English words „patellar tendon bearing”)*

The calf socket with subpatellar contact is characterized by the fact that the proximal edge of the socket covers half of the patella and half of the femoral condyles.

The PTB socket provides good lateral stability thanks to its lateral wall, which reaches to the middle of the femoral condyles.

- *KBM socket (acronym of the German words „kondylen bettung munster am unterschenkel stumpf”)*

The full-contact prosthetic socket ensures load transfer over the entire surface, and the prosthesis is attached to the stump in the supracondylar area. The patella is completely free, the condyles of the femur are covered, the hamstring muscles are free, and there is counter-support in the popliteal area, thanks to which the knee flexion and extension movement is free.

- *SSS socket (acronym of English words „Silicon Suction Socket”)*

This type of prosthetic socket involves applying a silicone insert directly to the residual limb and inserting it into the socket. Clamping the prosthesis can be done in two ways, depending on the type of silicone liner [8]: mechanical clamping (prezone) and vacuum.

2.7.3. Types of prosthetic socket for transfermural prostheses

- *Quadrilateral socket*

The prosthesis is supported in the ischial tuberosity by means of an ischial support [9]. The prosthetic socket is attached to the residual limb by a pressure difference (vacuum) or by using a quick attachment system with a pin.

- *Socket with integrated ischium*

The support is carried out on the entire surface of the residual limb, without locating a specific point, which will take over most of the load exerted on the prosthetic socket, during locomotion. This type of socket has a higher upper edge so that it incorporates the entire ischium.

2.8. Evolution of prosthetic feet

Currently, numerous models of prosthetic ankle-foot joints are marketed for people with transtibial (calf) and transfemoral (thigh) amputations, each of which aims to increase the 3C level (control, comfort, and cosmetic). In general, prosthetic ankle-foot joints can be classified into three categories: conventional, passive, and finally, active, or bionic [10].

2.9. Optimization of modular prostheses and attachment systems

At the level of the competitive market, the Ottobock company proposes several types of suspension systems.– the Harmony Vacuum Pump from Ottobock. Harmony is a modern suspension system that ensures the efficient connection of the prosthetic socket to the residual limb. The active vacuum system pumps out all the air between the prosthetic liner and the prosthetic socket, regulating the vacuum within a certain optimal range. Also, the Ossur company proposed the suspension of the modular calf prosthesis using the vacuum produced and controlled by the Unity liner vacuum system [11]. This is the first system that produces the vacuum in the socket using the energy created by the natural movement of the prosthetic foot.

2.10. Conclusions

Currently, available suspension systems are accompanied by several problems, which are related to the continuous change of the residual limb volume, especially in the case of mechanical residual limb socket attachment systems. In other words, the residual limb, liner, and prosthetic socket should ideally be in full contact to ensure proper pressure distribution. The continuous change of the residual limb volume (long-term, shrinking) leads to the loss of contact in certain areas and the interruption of the uniformity of the pressure distribution throughout the system. As a result, the concentrated pressure increases in some areas of the socket, which leads to injury to the residual limb, causing dissatisfaction. This is due to injuries and damage associated with socket misalignment, which results from changing the size and shape of the residual limb.

To respond to these expectations, innovative research and development are required as well as cost-effective and easy-to-use solutions that can emerge by addressing the topic in both academic and industrial environments.

Chapter 3. Instrumentation for recording and analyzing human gait and for measuring contact pressures and forces

3.1. Instrumentation for motion recording and analysis

Gait measurement and analysis systems, instruments and software can be used to assess prosthetic gait, thus amputees are assessed to monitor progress achieved by wearing the prosthesis, but also to assess its control and balance during locomotion. Their progress can be considered satisfactory even if it is not carried out at full capacity. For this reason, it is recommended to use several gait analysis systems and equipment for amputee subjects so that, after synchronizing the data, the obtained results provide a clearer picture of the important parameters in the locomotion process. Some examples of systems used for recording and analyzing human motion are: Vicon [12], BTS GaitLab [13], Xsens [14][15], Caren [16][17], Simi Motion [18], Templo Clinical Gait Analysis [19] and Optojump Next [20].

3.2. Human motion analysis software

Using motion analysis software is a much more cost-effective alternative for determining important parameters to assess human locomotion. They are commonly used in various fields such as sports, recovery and rehabilitation medicine, research and even for the diagnosis of locomotor disorders.

The software often uses motion capture systems to track the movement of certain landmarks placed on the body as you move. Most of the time, commercial cameras are used for video recording, without the need for specialized video cameras, which incur an additional cost. Moreover, free programs have appeared over time, which can be downloaded and used as an alternative to those purchased from professional manufacturers, and which have proven to be able to provide acceptable results in certain areas of activity that do not require very high data accuracy. Among the software used are: Kinovea [21], OpenSim [22] [23], Quintic [24] and SkillSpector [25].

3.3. Equipment and systems for recording ground reaction force and plantar pressure

For the assessment of the ground reaction force, the force platform is used most of the time, which highlights the interaction between the foot and its supporting surface. Although some force platforms provide useful information regarding the vertical and horizontal components of the ground reaction force but do not provide much information regarding how the plantar surface is loaded relative to the support surface [26]. Some such systems are: the Optima fixed force platform (Advanced Mechanical Technology, Inc.) [27] and the AccuGait mobile force platform (Advanced Mechanical Technology, Inc.) [28].

Plantar pressure measurement systems have different pressure sensor configurations that can be adapted to the requirements of the respective field of application. These systems are of two types: plantar pressure distribution measurement platforms and in-sole measurement systems. The most important characteristics when selecting a plantar pressure measurement system are spatial resolution, measurement frequency, accuracy, sensitivity and calibration mode [29][30]. The most used plantar pressure measurement systems are: Matscan [31] and F-Scan (Tekscan) [32], Pedar (Novel) [33] or Xsensor (XSENSOR Technology Corporation) [34].

3.4. Prosthetic socket design software

The traditional method of creating prosthetic sockets involves the utilization of a negative cast that generates a positive model of the remaining limb, this is a faithful reproduction of the shape of the remaining limb. To make the prosthesis socket, the model must be modified manually. To reduce the pressure in the "pressure-sensitive" areas, material (plaster) is added, and in the "pressure-tolerant" areas, material is removed. With the traditional method, the alteration of the positive cast is primarily based on the individual abilities and knowledge of the specialist, the result of this process is primarily subject to interpretation.

The development and use of computer-aided design and computer-aided manufacturing systems (CAD / CAM) greatly facilitates the process of making prosthetic sockets. However, as with the traditional method, these systems can only ensure compatibility with the external anatomical features of the amputated lower limb. As the constructive characteristics of the sockets are also determined by the relative position of the leg bones to the socket wall and the mechanical properties of the soft tissue between them, it is extremely difficult to design the shape of the prosthetic socket without visualization of the internal structure of the limb. The optimal design of the prosthetic socket requires knowledge of the internal and external structure of the limb. Currently, there is no software solution to integrate the information regarding the external and internal configuration of the residual limb [35].

Designing the prosthetic socket in MeshMixer and Fusion 360 requires a 3D scan of the residual limb so that the prosthetic socket is individualized for the amputee. In this sense, it was chosen to exemplify the process of making the prosthetic socket based on an STL type file, which contains the scanned image of a subject with calf amputation.

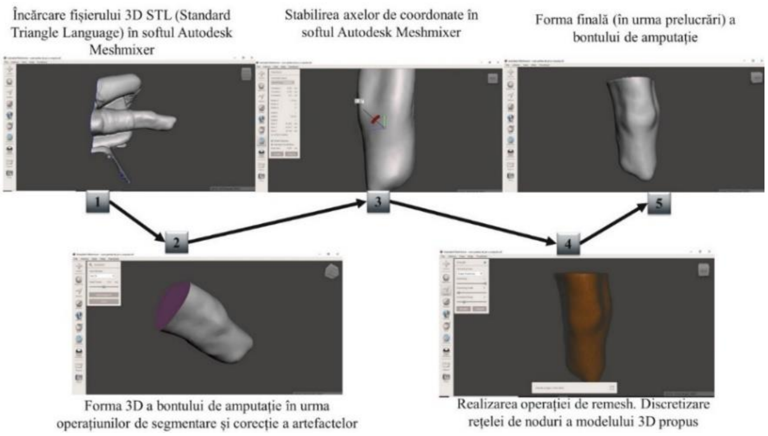


Figure 3.1. Processing of the STL file with the scanned amputation residual limb and the final shape (after processing with Meshmixer) of the amputation residual limb.

Designing the prosthetic socket in Meshmixer software

The residual limb geometric model determined in the first part of this section is the basis for prosthetic socket design. Similar to the traditional method where a positive cast is used to obtain the shape of the amputation residual limb, in this situation the 3D model of the residual limb will be used. Thus, the areas that will be covered by the prosthesis socket have been marked. The selection of these areas was made based on the experience of the author, who works as an employee in a prosthetics company, but also in collaboration with a team of prosthetic technicians.

A few modifications are required to attach the adapter to the prosthetic socket. First of all, it was decided to remove the upper part of the adapter to create a hole, having the role of releasing the distal end of the amputation residual limb. The newly created piece will be connected to the rest of the assembly. The final shape of the prosthetic socket can be seen in the images in figure 3.2.

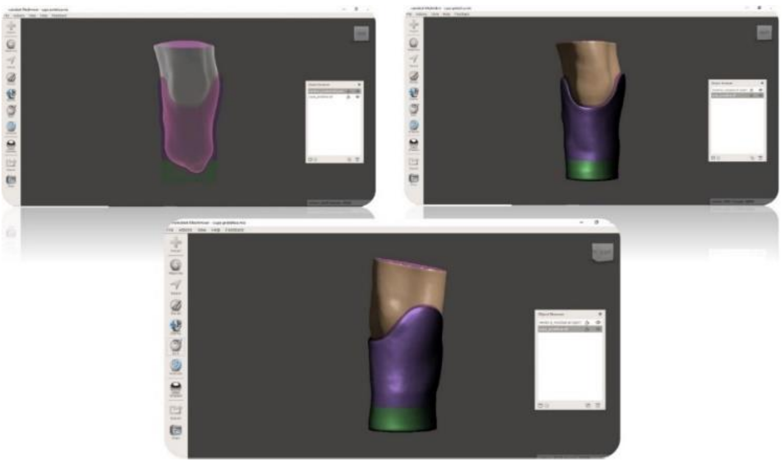


Figure 3.2. Visualization of the prosthetic socket on the residual limb, made in the MeshMixer software according to technical-scientific requirements.

Designing the prosthetic socket in Fusion 360 software

For the design of the prosthetic socket in the Fusion 360 program, the file scanned and processed in the previous subsection is used. Thus, the customized prosthetic socket is designed, depending on the dimensions of the residual lower limb remaining using the scanned image of the calf residual limb, previously processed in the MeshMixer software.

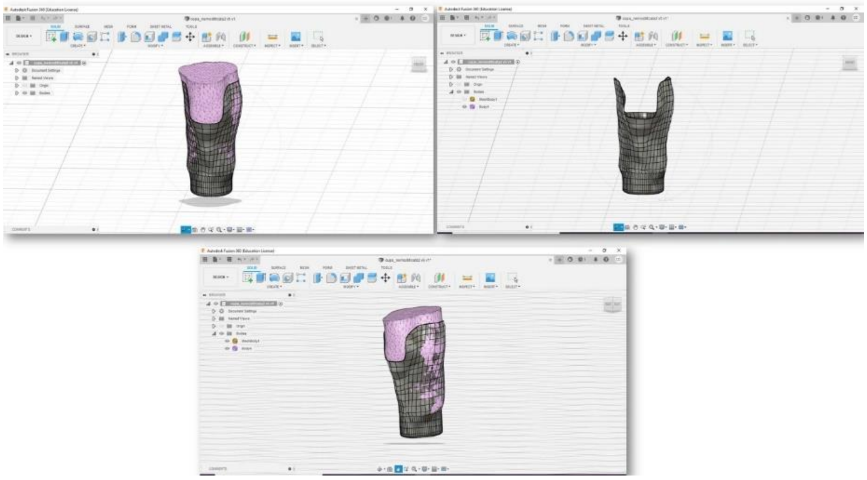


Figure 3.3. Visualization of the prosthetic socket on the residual limb, made in Fusion 360 software according to technical-scientific requirements.

The intended goal of developing a novel prosthetic socket design to relieve all pressure distal to the residual limb has been achieved.

3.5. Conclusions

The innovative part of this prosthesis consists in the design of the prosthetic socket, which fulfils two functions: the first function is given by the clamping system optimized by designing the adapter as an integrated part of the prosthetic socket, and the second function consists in releasing the sensitive area of the residual limb.

Chapter 4. Theoretical and experimental analysis of an optimized prosthetic ankle joint

4.1. Biomechanical knowledge of the ankle-foot complex

Plantar pressure is generated at the interface between the foot (prosthesis) and its contact surface, to evaluate it sensors are used in the form of instrumented insoles that can be inserted into shoes or mat, sensors highlight the interaction between the foot and contact surface. *This issue was the subject covered in two articles written by the authors, which disseminated the results obtained after analyzing plantar pressure for calf and thigh prostheses [36], but also for hip disarticulation prostheses [37].*

4.2. Anthropometric study and dimensions

For a subject with calf amputation of height $H = 1{,}80\ m$ and body mass, $m = 128\ kg$, the length of the leg can be determined (L_{foot}=0,274 m), foot width (l_{foot}=0,099) and the length of the calf from the knee to the ground (L_{calf}= 0,513), but also the mass of the foot (m_{foot}=1,856 kg) and calf mass (m_{calf}=5,952 kg). This data are used to select the prosthetic foot that was the basis of the scientific study in this chapter, but also to determine the total height of the prosthesis, which can be adjusted, by means of the prosthetic tube.

4.3. Experimental studies and measurements

In this subchapter, two types of analysis, static and dynamic, are presented, using the F-scan equipment, from Tekscan, which has the associated F-Scan program. The tests were performed, both during prosthetic and static walking, with five different prosthetic feet, with progressive levels of performance (figure 4.1) [38].

Figure 4.1. Prosthetic feet were tested and evaluated in this study. From left to right: SACH (Ottobock), Balance Foot J (Ossur), Winged Foot (IB-ER Prosthetic), Terion 1C10 (Ottobock) Trias 1C30 (Ottobock).

Result

The tests were carried out for a subject with amputation in the middle third of the calf on the left side, within the company Activ Ortopedic SRL. Following the protocol for measurement and procedure, the individual analyzed had five different types of ankle-foot prosthetic joints, namely: SACH (Ottobock), Balance Foot J (Ossur), Winged Foot (IB-ER Prosthetic), Terion 1C10 (Ottobock), Trias 1C30 (Ottobock).

Table 4.1. The values of forces and contact times were recorded for the healthy and the prosthetic leg, with the five prosthetic legs.

The name of the prosthetic components used (ankle-foot prosthetic complex)	Ground reaction force for the prosthetic foot [N]	Contact time for the prosthetic foot [s]	Ground reaction force for a healthy foot [N]	Contact time for the healthy foot [s]
SACH (Ottobock)	1075,6	0,86	1403	1,09
Balance Foot J (Ossur)	1209,18	1,01	1393,47	1,07
Winged Foot (IB-ER Prosthetic)	1478,93	0,94	1225,81	1,18
Terion 1C10 (Ottobck)	1317,92	0,94	1404,09	1,06
Trias 1C30 (Ottobock)	1351,88	1,09	1320,63	1,12

Major differences were observed in locomotion with the Winged Foot prosthetic joint produced and marketed by the IBER Prosthetic company, for which the highest ground reaction force value of 1478.93 and a contact time of 0.94 s was recorded. This force value has a negative effect on the residual limb's amputation. This effect is transmitted to the prosthesis and poses a threat to the health of the residual limb, additionally, the lack of adaptability during movement is indicated. On the other hand, the lowest value recorded for the ground reaction force was in the case of wearing the SACH prosthetic foot marketed by the Ottobock company, for which a value of 1075.6 N was recorded. However, in this situation, a maximum value for the healthy leg of 1403 N was recorded.

On the other hand, for the Trias 1C30 prosthetic foot, produced by the Ottobock company, the closest ground reaction force values were recorded for the right (healthy) leg of 1320.63 N and the left (prosthetic) leg of 1351.88 N. Thus, it can be stated that force distribution, both for the healthy and for the prosthetic foot, is optimally achieved when wearing the Trias 1C30 prosthetic foot.

4.4. Conclusion

In this chapter, the theoretical and experimental analysis of the prosthetic ankle-foot complex was carried out for the optimization of transfemoral and transtibial modular prostheses.

The experimental study involved the evaluation of the stability and comfort experienced by the subject wearing a modular lower limb prosthesis with five different types of prosthetic feet (SACH-Ottobock, Balance Foot J-Ossur, Winged Foot-IBER Prosthetic, Terion 1C10-Ottobock and Trias 1C30-Ottobock) and by analyzing the plantar pressure distribution, obtained with the F-scan equipment (Tekscan).

From the perspective of the design and realization of the optimized customized prosthesis, a prosthetic foot with performances similar to those determined for Terion 1C10 or Trias 1C30, is an optimal solution for the satisfaction of the subject and the costs with which it is obtained.

Chapter 5. Research and development of an optimized modular prosthetic device

5.1. Analysis of normal and prosthetic human gait

Human motion analysis can provide important information to improve the performance of modular lower limb prostheses, assess recovery after surgery such as amputation, or prevent injuries after prosthetic procedures.

The development and implementation of passive lower limb prostheses should be based on scientific research, analyzing the prosthetic performance, stability, and balance of prosthetic subjects, and comparing the results with healthy subjects. To carry out the research, 15 subjects were analyzed, from a comparative perspective (8 healthy subjects, 3 subjects with calf amputation and 4 subjects with thigh amputation) for which the kinematic and dynamic characteristics were evaluated, with the aim of constructively improving the prosthetic components used in the construction of modular calf and thigh prostheses.

5.1.1. Experimental tests

In this subchapter, two types of analysis are presented for the evaluation of prosthetic gait with a modular calf prosthesis. The determination of the ground reaction force, using the mat equipment from Tekscan, associated with the F-Mat Clinical program, and the analysis of gait in view of obtaining the angles made by the joints of the lower limb, in a complete gait cycle, using the Kinovea open-source software.

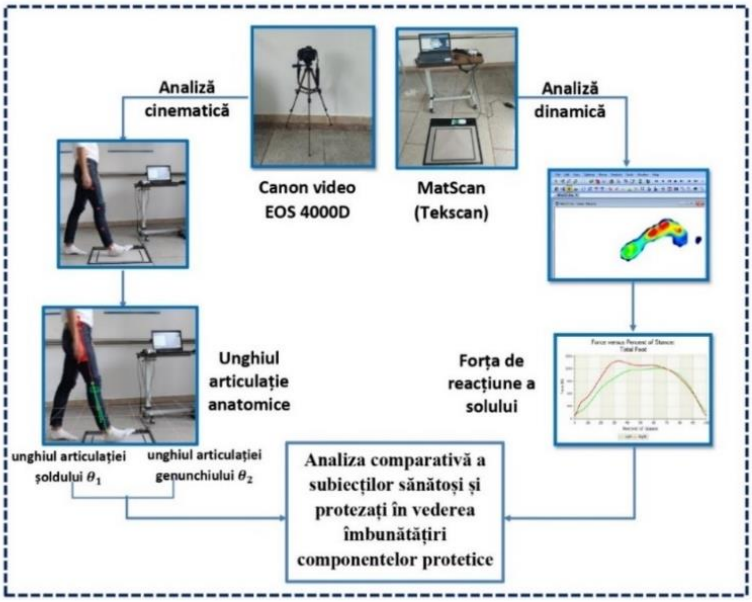


Figure 5.1. Diagram of prosthetic gait analysis with Tekscan equipment and Kinovea software for comparative analysis of normal and prosthetic human gait.

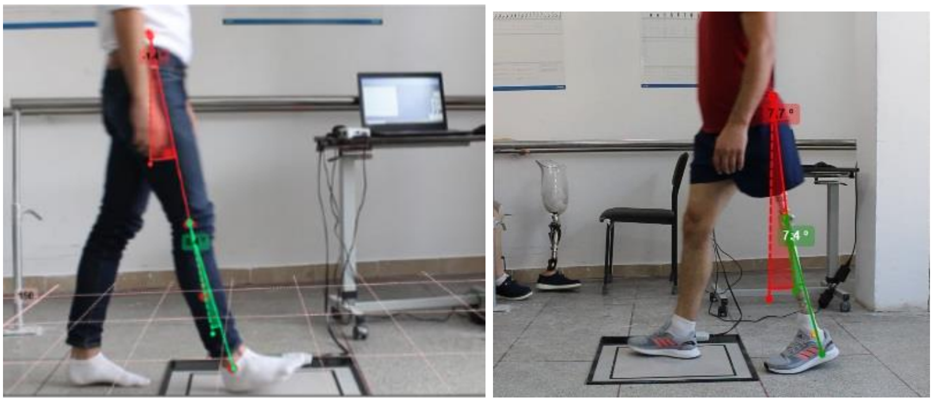
5.1.2. The target group

The study was carried out on a group of healthy subjects, but also on a group of subjects with calf and thigh amputations, wearers of modular calf prostheses and modular thigh prostheses. In order to carry out a comparative study, which would highlight the performance of the prosthetic components used, the subjects wearing modular prostheses with different degrees of mobility (7 prosthetic subjects) were tested and evaluated using the MatScan equipment and the Kinovea software, comparing the results obtained with similar data for healthy subjects (8 healthy subjects).

5.1.3. Used computer equipment

The program "FootMat clinical" was used to analyze the functionality and the normal and pathological behavior of the foot. It also investigates the pressure distribution of the foot and the value of the ground reaction force.

"Kinovea" software is used for video analysis of recordings. For the videos recorded, Kinovea is used to assess the position of the markers, located on the ankle, thigh and hip joints, these joints are tracked during the gait cycle.



a) b)

Figure 5.2. Positioning of landmarks on a healthy subject (a) and on a prosthetic subject (b) to measure the hip and knee angle and record the reaction force.

In the figure above, two suggestive examples are presented for the evaluation of the kinematic characteristics of the walking cycle, in the case of a healthy subject (figure 5.5 a) and a prosthetic subject with a modular thigh prosthesis (figure 5.2 b).

5.1.4. Obtained results

To estimate the moments in the hip and knee joints it is necessary to determine the variation in the joint angles of the lower limbs and the variation of the ground reaction forces during the gait cycle.

The maximum ground reaction force value is obtained using the FootMat Clinical software, for healthy subjects and those with modular calf and thigh prostheses. Also, the correlation coefficient with the force of the person's weight, given by the formula, was determined:

$$r = \frac{F_y}{G} \tag{5.1}$$

where G is the force of gravity of the analyzed subject, and F_y is the maximum vertical ground reaction force for the same recorded subject.

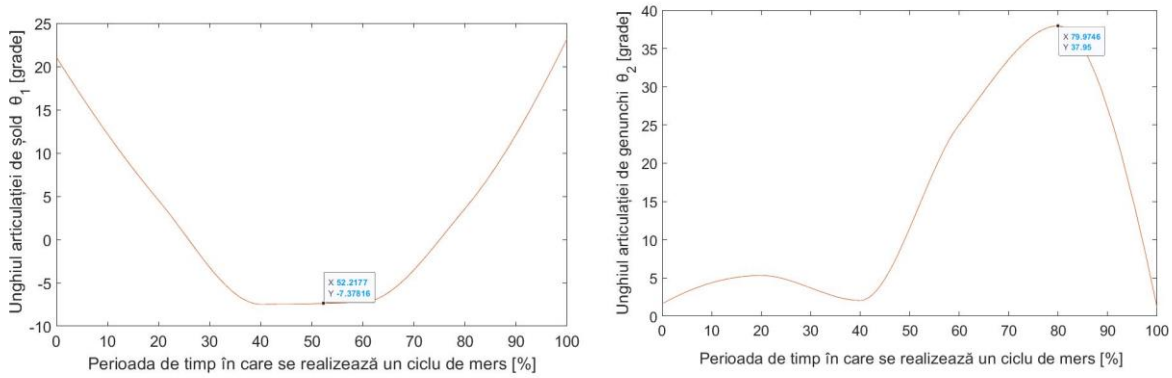
The results obtained for the correlation coefficient of the ground reaction force with weight, in the case of healthy subjects, are in the range of 1.112-1.228, resulting in an average value of 1.17. This value is taken as a reference and considered an accepted value within normal limits, later being compared with the values obtained for the force restitution coefficient in the case of subjects that wear modular prostheses.

It can be seen that in the case of prosthetic subjects (except for subject 9, who has a bilateral amputation), the healthy collateral limb is affected, regardless of the amputation level, the values being included in the range of 1.301-1.523, with a mean value of 1.331 in the case of subjects with calf amputation (subjects 10, 14 and 15 marked in green) and a mean value of 1.413 for subjects with thigh amputation (subjects 11, 12 and 13 marked with green colour). Thus, it can be concluded that the level of amputation influences the loading mode of the healthy limb. The higher the amputation is performed, the higher the value of the ground reaction force for the healthy foot.

On the other hand, in the case of the prosthetic lower limb, the correlation coefficient of the reaction force for the calf prosthesis is in the range of 1.208-1.239 (subjects 10, 14 and 15 marked by the orange colour) with an average value of 1.227, and in the case for the hip prosthesis, the range is between of 1.214-1.321 with an average value of 1.266 (subjects 11,12 and 13 marked by orange colour). Therefore, a small difference is noticeable between the subjects wearing calf prostheses and those with thigh prostheses. In this situation, the reaction force is greater in the case of subjects with thigh amputation, caused by the lack of two important joints (the ankle joint and the knee joint), so that the wearer of the prosthesis makes a greater effort during locomotion to ensure balance in the support phase.

The importance of the contact between the prosthetic socket, the silicone liner and the residual limb, the kinematic variables of the recorded subjects were analyzed during locomotion. Due to the small amplitude, this motion has a limited impact on the position of the calf and thigh, the movement of the leg around the ankle joint is therefore ignored.

To determine the angles made by the knee and hip joints in the sagittal plane, the video recordings were processed using the Kinovea software, and the data obtained were centralized and compared for healthy and prosthetic foot.



a) b)

Figure 5.3. Plots of mean hip (a) and knee (b) angles for the calf amputee during a complete gait cycle.

The small values of the angular displacements of the hip and knee joints for the prosthetic legs indicate instability of the contact between the residual limb and the prosthetic sockets. One cause of this instability can be attributed to internal displacements at the prosthetic residual limb-liner-socket interface, which causes distrust and fear, affecting the quality of prosthetic gait. To solve this problem, an adjustable mechanical clamping system (prosthetic socket) is proposed for lower limb prostheses, manually operated, with which the dimensional adaptation to the geometric configuration of the residual limb and the tightening force for supporting the prosthetic socket by the residual limb is achieved.

5.2. The need for the clamping system adaptable to volume fluctuations

Based on the research performed in the first sub-chapter, a prosthetic socket model capable of compensating for residual limb volume changes is proposed. The proposed component, for attaching the residual limb to the prosthesis, adapts to the variable dimensions of the residual limb, through the special shape, with cutouts, which allows deformation under the action of cables connected to a stretching system. This system facilitates the maintenance of artificial liner-socket contact and distributes pressure at the residual limb-liner-prosthetic socket interface during walking. Unlike previous research, the system proposed does not focus only on short-term dynamic situations (3-6 months), but in particular, on those in which the volume of the lower limb changes over a longer period of time, without knowing predictable data in this regard. Mechanical components and systems were used to adjust the shape of the prosthetic socket according to the oscillating dimensions of the residual limb.

A silicone liner was also made, customized, and adapted to the prosthetic socket with a mechanical adjustment system, which is recommended to all wearers of modular lower limb prostheses with volume fluctuations. The major advantages of this silicone liner start from the technological process of its realization and manufacture, which is individualized according to the anthropometric dimensions of each wearer, thus eliminating the disadvantages of the mismatch of the currently available series silicone liner in two sizes. The custom silicone liner is cut so that the posterior area of the knee is cleared for the popliteus muscle to perform the flexion movement of the knee joint. In the case of standard silicone liners, the activity of the popliteus muscle is limited, because their construction requires covering this area and fixing the liner up to the middle third of the thigh.

The medical devices that are the subject of this research, the prosthetic socket with mechanical dimensional adjustment system and the customized silicone liner, ensure a good fixation of the amputation residual limb in the innovative prosthetic socket, despite the volume variations of the residual limbs, especially in the case of diabetic subjects. The proposed system is expected to help lower limb amputees feel comfortable and confident in the prosthetic device and pain-free in the remaining limb, improving their quality of life. The originality of the proposed solution consists of the creation and testing of a prosthetic socket with a mechanical adjustment system and the customized silicone liner, adapted for modular lower limb prostheses. The final product can be an innovative solution, intended to contribute to increasing the quality of life of prosthesis wearers who have volume variations in the residual limb and will eliminate the medical problems and complications, as well as the discomfort created by wearing a lower limb prosthesis with a socket insufficiently adapted to the anthropometric measures of the residual limb.

5.3. Realization of the prosthesis attachment system, adaptable to the volume variations of the residual limb

In order to highlight the technological process of creating the adjustable mechanical clamping system (prosthetic socket) for lower limb prostheses, manually operated, with which the dimensional adaptation to the geometric configuration of the residual limb is achieved, a case study was carried out for a male subject, with unilateral amputation in the middle third of the calf. The first phase involves assessing the amputee's health (any adjacent medical conditions he has) and then completing an action sheet to obtain anthropometric data and assess the health of the remaining limb. A 37-year-old subject with lower calf amputation was analyzed.

A skin biocompatible silicone was used to make the custom silicone liner. According to the manufacturer, RTV addition silicone is "the most stable polymer discovered to date" [39], also known as liquid silicone (or liquid silicone rubber). It is made by mixing two ingredients, called a base and a catalyst, in equal proportions and then pouring them over the model to be replicated. In the case of the present research, the model is the positive cast that is used to obtain the silicone liner according to the geometric configuration of the residual limb [40].

The biocompatible addition silicone is evenly distributed over the entire surface of the positive mould, being further connected to the vacuum pump, which has the role of removing all the air from the layers of cotton stockings, deposited between the two PVA films. Through successive movements, the silicone is evenly distributed over the entire surface of the model, and finally it is left to harden for 24 hours.

After the silicone liner has hardened and dried, it is removed from the positive mould and finished to the anatomical shape of the amputated lower limb. In this sense, the liner is cut around the popliteal space, so that the flexion-extension movement of the knee is not affected. Ultimately, its edge is smoothed out taking care to eliminate any roughness or sharpness (figure 5.5).

Figure 5.5. The custom silicone liner obtained from the technological process.

The process of making the prosthetic socket with a mechanical system for manually adjusting the dimensions, depending on the geometric configuration of the residual limb, is similar to that for making the silicone liner, the only differences being related to the types of materials used and the finishing phase. *The BOA Fit System* mechanism [41], mainly used in the field of sports shoes, was used to create the fastening system adaptable to volume fluctuations. Being a mechanical system for adjusting the degree of compression, using resistance cables, it was necessary to embed them in the final prosthetic socket, to obtain the mechanical clamping system adaptable to the geometric configuration of the residual limb and manually adjustable according to the user's perception. Thanks to the patents filed within the project *"Modular lower limb prosthesis with pneumotronic, controlled and personalized suspension system", project code: PN-III-P2-2.1-PTE-2019-0484*, in this research another approach was proposed from a technical point of view for the clamping adaptable system to the geometric configuration of the residual limb [42] [43].

The guide tubes as well as the *BOA Fit System* are positioned on the surface of the previously obtained prosthetic socket. To fix the system components in the socket walls, a new carbon fiber lamination is made with the help of the vacuum pump.

After curing and securing the laminate components, the prosthetic socket is cut and trimmed to remove the positive cast covered by the custom silicone liner. The final socket obtained is finished through the polishing process, to eliminate the sharp areas left after the cutting of its walls, and the cables are inserted into the guide tubes, through which the system will achieve the mechanical fixation and attachment of the prosthesis to the residual limb.

a) b) c)

Figure 5.6. Adaptive and customized prosthetic suspension system: a) front view, b) side and c) rear view

5.4. Evaluation of the adjustable mechanical attachment system for lower limb prostheses

In order to evaluate the costs of making a lower limb prosthesis with an adjustable mechanical clamping system, consisting of a prosthetic socket and a customized silicone liner, the economic aspects related to the costs of purchasing components and materials for making the clamping system are analyzed, compared to commercial systems available, in order to validate an important optimization criterion, namely accessibility.

The prosthesis with the new mechanical dimensional adjustment system (prosthetic socket) and the silicone liner, made according to the geometric configuration of the residual limb, generates twice lower production costs (5125 RON) compared to the current technology for making prosthetic sockets adaptable to volume variations of the residual member (10260 RON).

5.5. Conclusions

A firm contact between the residual limb and the prosthetic liner-socket assembly proved to be an objective necessity of prosthetic walking, for the comfort and safety of the subject. As a result, prosthetic residual limb attachment systems have been designed, which have the ability to adapt dimensionally to the volume variations of the residual limb.

Chapter 6. Pressure evaluation at the residual limb - liner - prosthetic socket interface

In the process of constructing a prosthesis tailored to a specific patient, it is worth knowing, at least approximately, the value of forces and pressures that act when the stump comes into contact with it while walking. The theoretical approach is only possible in combination with the measurement of kinematic variables (positions, velocities and accelerations) and ground reaction forces. A simplified geometric model, in which the vertical displacement of the ankle joint is unbound, during the support period, due to the small value compared to the raising and lowering of the S (hip) and G (knee) joints, is presented in figure 6.1.

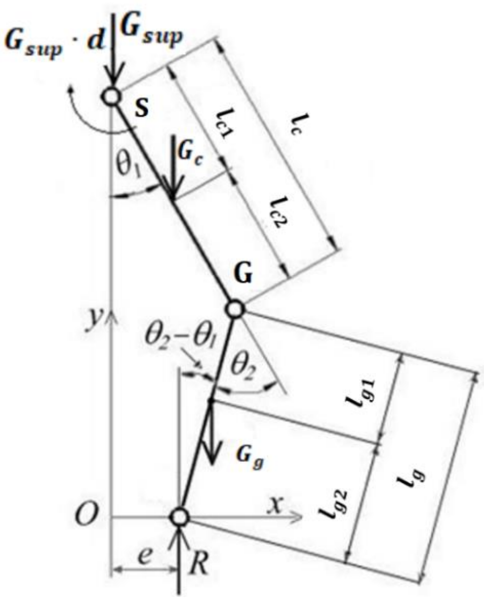


Figure 6.1. The simplified geometric model of the lower limb, consisting of the thigh and calf.

6.1. The inverse dynamic model

For this purpose, the Lagrange equations were used, for which the potential energy of the open kinematic chain was evaluated.

From the inverse dynamic model, made with the help of the Lagrange equations, the motor torques required in the hip and knee joints are obtained, if it is known: the time variation of the positions, velocities and angular accelerations of the thigh and calf, as well as the value of the contact reaction force with the ground, respectively the masses of the thigh, calf and foot and the positions of their centers of mass. As it resulted from the measurement of the kinematic variables (positions, velocities, and angular accelerations), the values of the angular velocities, mainly subunits (>90%) are negligible, because they intervene to the second power or as a product, leading to the further simplification of the Lagrange equations.

$$M_S = G_c l_{c1} sin\theta_1 + G_{gp}\left[l_c sin\theta_1 - l_{gp1} sin(\theta_2 - \theta_1)\right] - R\left[l_c sin\theta_1 - l_{gp} sin(\theta_2 - \theta_1)\right] - \{J_{Sc} + m_{gp}\{\left[l_c cos\theta_1 + l_{g2}\cos(\theta_2 - \theta_1)\right]^2 + l_{g2}^2 sin^2(\theta_2 - \theta_1)\}\ddot{\theta}_1 + m_g\left[l_{g1}^2 cos^2(\theta_2 - \theta_1) + l_c l_{g1} cos(\theta_2 - \theta_1) cos\theta_1 - l_{g2}^2 sin^2(\theta_2 - \theta_1)\right]\ddot{\theta}_2 - G_{sup} d \quad (6.1)$$

$$M_G = \{J_{Gg} + m_g[l_{g2}^2 + (2l_{g1}l_{g2} + l_{g2}^2)sin^2(\theta_2 - \theta_1)]\}\ddot{\theta}_2 - m_g[l_c l_{g2} cos\theta_1 \cos(\theta_2 - \theta_1) + l_{g1}l_{g2}cos^2(\theta_2 - \theta_1) + l_g^2 sin^2(\theta_2 - \theta_1)]\ddot{\theta}_1 - (G_c l_g + G_g l_{g2})sin(\theta_2 - \theta_1) + G_c l_{c2} sin\theta_1 + G_g l_{g1} sin(\theta_2 - \theta_1) - R l_g sin(\theta_2 - \theta_1) \quad (6.2)$$

where: M_S – motor torque, required in the hip joint, M_G – motor torque, required in the knee joint, G_c – thigh weight, G_g – calf weight; R – ground reaction force and G_{sup} – the weight of the trunk, hands, head and unsupported leg; d – the horizontal distance between the center of mass of the upper part of the body and the hip joint.

6.2. Determination of the geometric and inertial parameters involved in the inverse dynamic model

The equations, which are used to calculate the torsion moments in the joints, contain inertial parameters, the values of which are dependent on the masses of the considered body segments and the height of the subject, which conditions the length of these segments, respectively the position of the centers of mass in the axial direction of the segment.

Information on the moments of inertia involved in the model (of the thigh and calf) is divergent in different sources due to the difficulty of measurement, so the method of equating the thigh and calf with the frustum of a cone is a convenient approach.

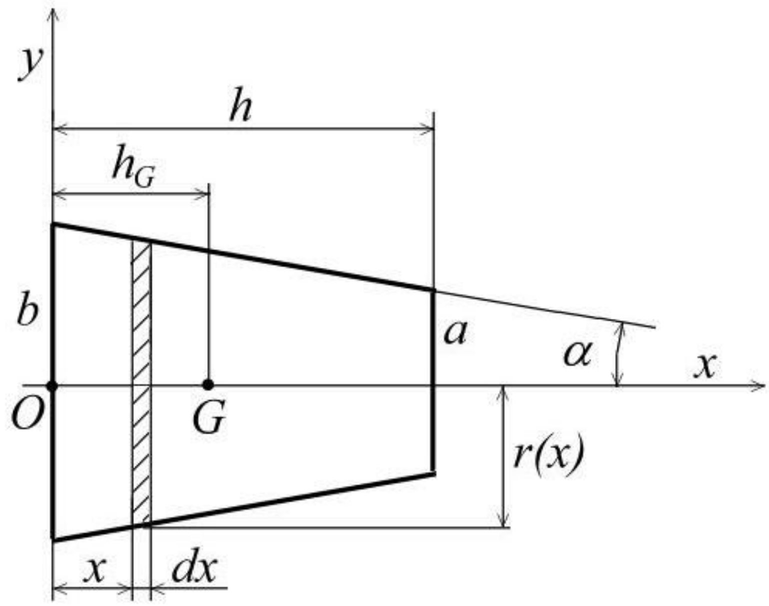


Figure 6.2. The moment of inertia of the thigh in relation to the hip joint and the center of mass [44].

In this case, the moment of inertia of the thigh or calf (considered a cone trunk), in relation to the hip joints, respectively the knee, if they respect the relative position of the center of mass, are: $J_o = 0.271Mh^2$, respectively $J_G = J_o - Mh_G^2 = 0.08Mh^2$, according to Steiner's theorem.

To determine, by calculation, the values of the masses and moments of inertia of the body segments, it is necessary to know the subject's mass and height, respectively the length and center of gravity of each part of the body, determined by anatomical studies. In the specific case of the research carried out in the thesis, for a male subject with a total body mass of 85 kg and a height of 1,68 m, masses of body segments were calculated as a percentage of whole-body mass, while lengths of the same body parts were calculated as a percentage of whole-body length.

Table 6.1 summarizes the values of the geometric parameters and masses of the segments of the subject's body, which were determined by direct measurement or calculation and used in the inverse dynamic model to determine the moments in the joints. New model based on transtibial prosthetic isolation determines the forces in the knee joint that load the residual limb-liner-prosthetic socket interface.

Table 6.1. The physical and geometric parameters of the subject used in the dynamic model.

Determined physical / geometric size	The physical/geometric size determined according to the body segment/prosthetic components	The value obtained
Mass of prosthetic segments and components	Total mass of the prosthetic components $m_{gp}[kg]$	4,027
	Thigh mass m_c $[kg]$	8,926
	Upper body mass $\frac{G}{g}$ $[kg]$	46,835
Length of prosthetic segments and components	Length of prosthetic components l_{gp} $[m]$	0,419
	Total thigh length l_c $[m]$	0,437
The position of the centers of mass in relation to the length of the human body segments and components	The position of the center of mass of the thigh in relation to the hip joint l_{Sc1} $[m]$	0,189
	The position of the center of mass of the thigh in relation to the knee joint l_{Gc2} $[m]$	0,248
	The position of the center of mass of the prosthetic leg in relation to the knee joint l_{Gg1} $[m]$	0,184
	The position of the center of mass of the prosthetic leg in relation to the ankle joint l_{Gg2} $[m]$	0,235
Weight of prosthetic segments and components	Total weight of the prosthetic leg $G_{gp}[N]$	39,505
	Thigh weight $G_c[N]$	87,564
	The weight of the upper part of the body $G_{sup}[N]$	459,451
Moment of inertia of prosthetic segments and components	The total moment of inertia of the prosthetic leg, compared to the knee joint [kgm^2]	0,2414
	The total moment of inertia of the thigh in relation to the hip joint [kgm^2]	0,47

6.3. Determining the values of the kinematic variables used in the inverse dynamic model

Human motion analysis can provide important information to improve the performance of modular lower limb prostheses, to assess rehabilitation after surgery such as amputation, or to prevent injuries following the prosthetic process. Kinematic features include positions, velocities, accelerations, and trajectories of segments of the human body during walking. To determine the kinematic parameters in a complete gait cycle, the Xsens MVN motion capture system (Xsens Technologies BV) was used, courtesy of the National Sports Research Institute.

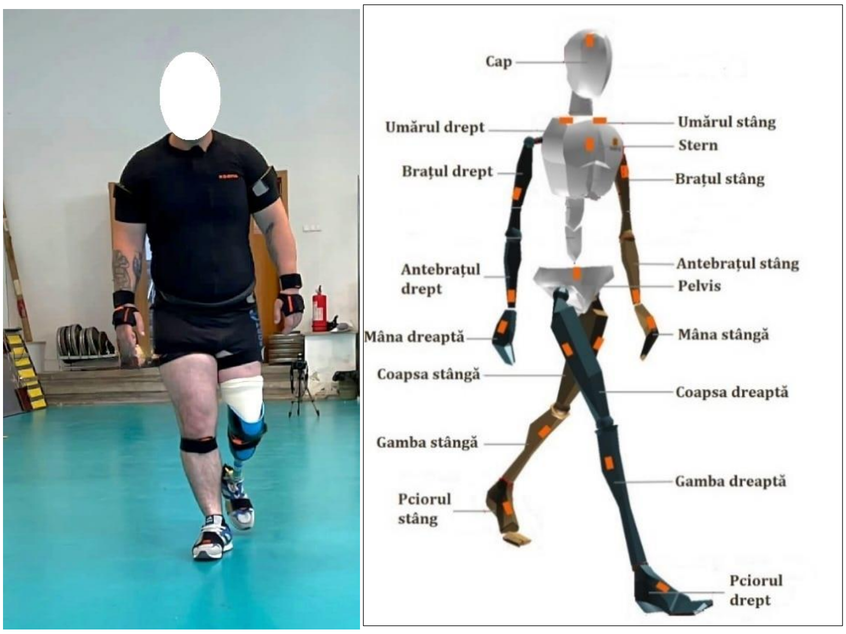
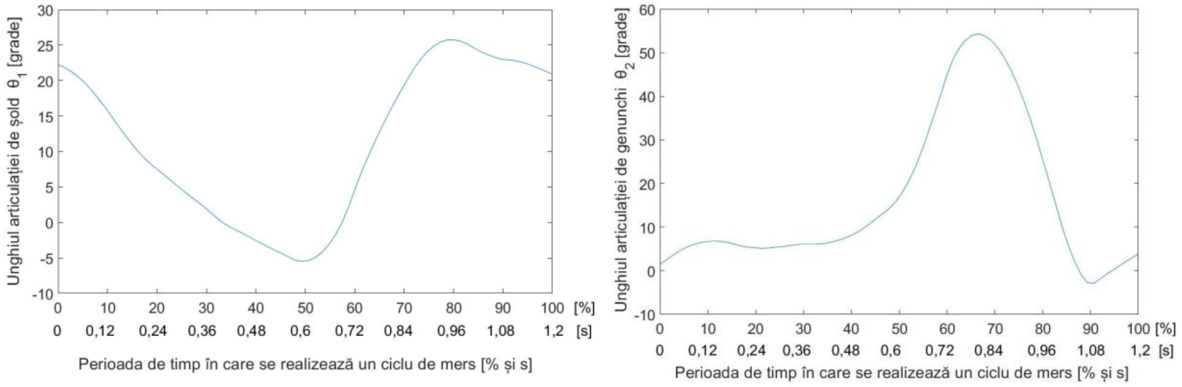


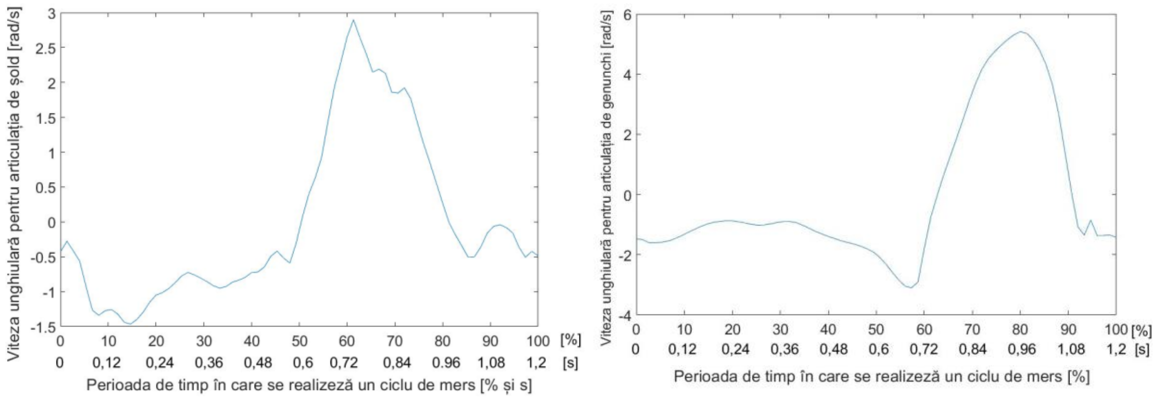
Figure 6.3. Positioning of the 17 MTw sensors on the analyzed subject.

The Xsens software records the accelerations, velocities and angular positions of the specified segments, providing the data in the form of an Excel file. Of interest for the inverse dynamic model are the positions, velocities and angular accelerations of the thigh and calf prosthesis, presented in figures 6.4, 6.5, 6.6, in graphic form, made in Matlab.



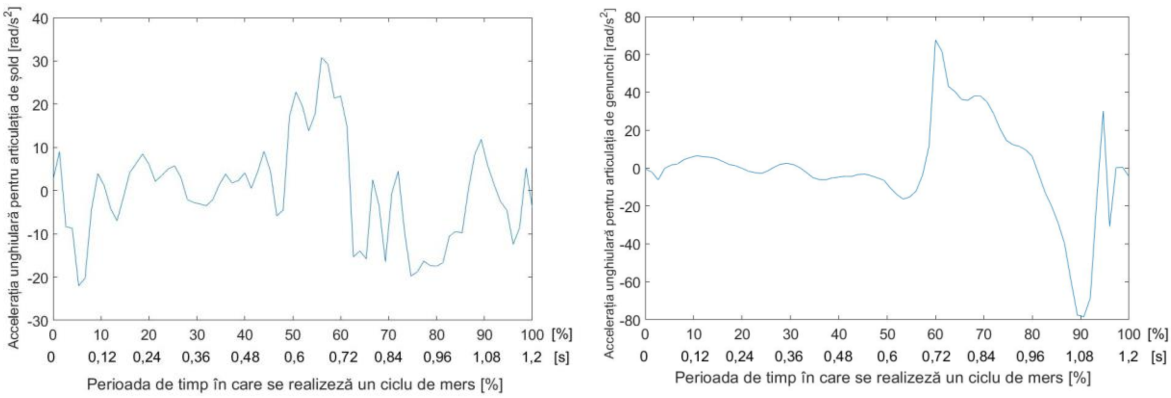
a) b)

Figure 6.4. Graph of the angle made by the hip joint (a) and the knee joint (b) during a complete gait cycle.



a) b)

Figure 6.5. Graph of angular velocity for the hip joint (a) and knee joint (b) during a complete gait cycle.



a) b)

Figure 6.6. Graph of angular acceleration for the hip joint (a) and knee joint (b) during a complete gait cycle.

According to the normal human gait, the following conclusions can be strained regarding the angles formed by the hip and knee joints. During the stance phase, at the moment of heel strike, the knee joint must be stabilized as the foot begins plantar flexion. During this loading period, the prosthesis has two major functions: supporting body weight and reducing the impact of heel strike. As depicted in Figure 6.6, b, the swing phase begins when the knee is at an angle of 30 degrees, reaching a maximum value of 55 to 65 degrees, and the time to achieve this range of motion is relatively short. The calf prosthesis should start with minimal flexion resistance and automatically adapt to a wide range of walking speeds. It can be concluded that, in the support phase, the important aspects are related to the resistance of the prosthetic system and the stiffness of the components, and in the balance phase, the dynamics of the movement prevail.

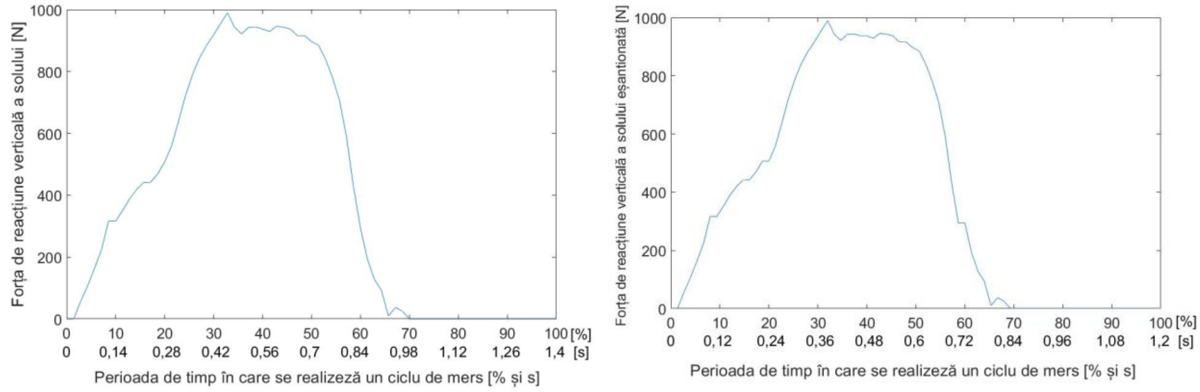
6.4. Determination of the ground reaction force

In the dynamic model adopted for the walking cycle, the ground reaction force of the prosthetic foot intervenes, which, together with the torques developed in the joints and the moments created by the inertial forces, loads the different segments of the body. As solving an inverse dynamic system requires knowledge of the evolution over time of the kinematic quantities (positions, speeds, accelerations) and of the external loads that must be compensated by the actuation torques in the joints, the ground reaction force was measured. Commonly used tools for this purpose are force plates and pressure mapping systems. In the case of this research, the determination of the ground reaction force was carried out using the MatScan equipment, of the "mat" type from Tekscan, which has the associated FootMat data acquisition and processing program.

a) b)

Figure 6.7. The beginning (a) and the end (b) of the gait cycle for the prosthetic foot, recorded with the MatScan equipment (Tekscan).

The ground reaction force (GRF) is a vector defined by mode (length), direction and point of application, which, in a triorthogonal reference system, has 3 components: anteroposterior (*Rx*), vertical (*Ry*) and mediolateral (*Rz*). For the present study, the first two components of the ground reaction force, Rx and Ry, are of interest. The value of the vertical component of the reaction force is obtained from the gait analysis, performed with MatScan equipment from Tekscan and, according to [45], represents 90% of the total reaction force value, while the anteroposterior reaction component represents only 10% of the same total reaction force, being determined by calculation. The mediolateral component, although important, does not intervene in the assumed dynamic model. The results obtained for the vertical reaction force, with the help of the Mat-Scan (Tekscan) equipment, are represented graphically in figure 6.8, a, after processing the data using a Matlab program.



a) b)

Figure 6.8. a) Graph of the vertical ground reaction force for the prosthetic foot and b) graph of the vertical ground reaction force after synchronization with the Xsens positions.

It is observed that the graph has percentages of the walking cycle as the abscissa, because the durations of the walking cycle when determining the kinematic variables, respectively the ground reaction force, differ. The algorithm for synchronizing the force values with the moments of time specific to the kinematic variables, synchronization required when entering their values in the inverse dynamic model is presented in figure 6.8, b).

6.5. Determination of the actuation moment and the forces in the knee

Current values M_G serve to determine the forces in the knee joint, which load the prosthetic foot, respectively the residual limb - liner - prosthetic socket interface. Moment variation M_G is presented in figure 6.9.

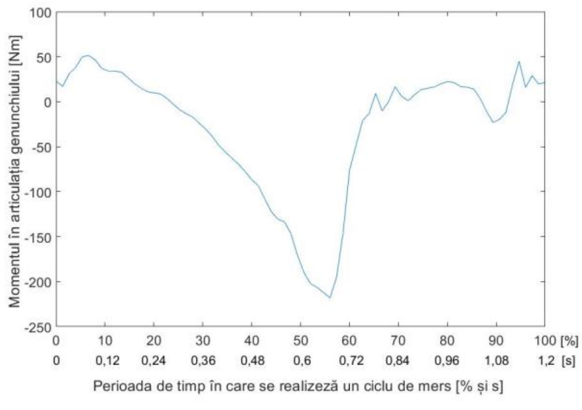


Figure 6.9. The variation of the actuation moment from the knee of the prosthetic leg.

As stated before, the dynamic calculation model used assumes that the displacements in the planes *xOz* and *yOz* they are negligible and do not contribute to the progress of the subject

Also, the lack of relative movement between the residual limb and the silicone liner, respectively the prosthesis socket, during walking, is another assumed condition. In figure 6.10, the prosthetic leg is isolated from the rest of the body, its influence on it being replaced by the forces F_{Gx} și F_{Gy}.

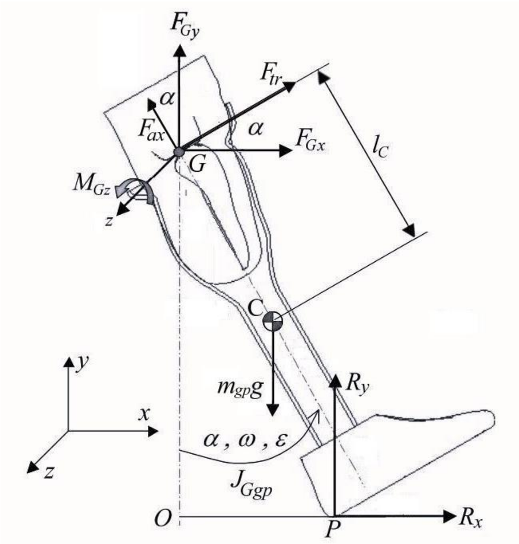


Figure 6.10. Prosthetic Calf Isolation Diagram [processing 46].

Knowing the knee actuation moment values, M_{Gz}, of the ground reaction force (R_x, R_y), respectively of the position, velocity and angular acceleration of the calf, as functions of time, of the gravitational forces and of the total moment of inertia of the prosthetic calf, J_{Ggp}, from the kinetostatic equations, the instantaneous values of the force components acting in the knee joint can be determined, F_{Gx} *and* F_{Gy}.

$$F_{Gy} = -R_y + m_{gp}g - m_{gp}l_C[(\ddot{\theta}_2 - \ddot{\theta}_1)\sin(\theta_2 - \theta_1) + (\dot{\theta}_2 - \dot{\theta}_1)^2 cos(\theta_2 - \theta_1)] \quad (6.3)$$

$$F_{Gx} = -R_x + m_{gp}l_C[(\ddot{\theta}_2 - \ddot{\theta}_1)\cos(\theta_2 - \theta_1) - (\dot{\theta}_2 - \dot{\theta}_1)^2 sin(\theta_2 - \theta_1)] \quad (6.4)$$

According to figure 6.10, the force in G, with the components F_{Gx} și F_{Gy}, it can be broken down in the axial and transversal directions, in relation to the prosthesis:

$$F_{ax} = F_{Gy}\cos(\theta_2 - \theta_1) - F_{Gx}\sin(\theta_2 - \theta_1) \quad (6.5)$$

$$F_{tr} = F_{Gy}\sin(\theta_2 - \theta_1) + F_{Gx}\cos(\theta_2 - \theta_1) \quad (6.6)$$

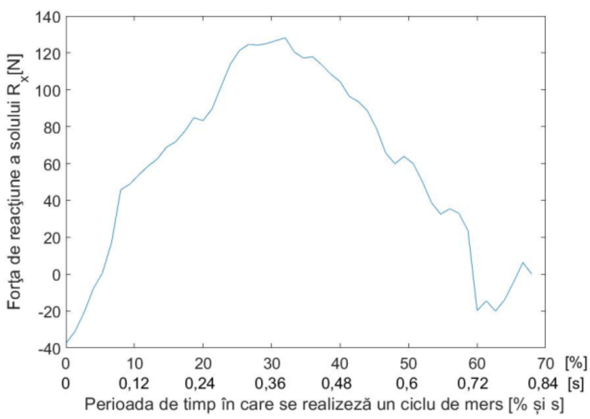
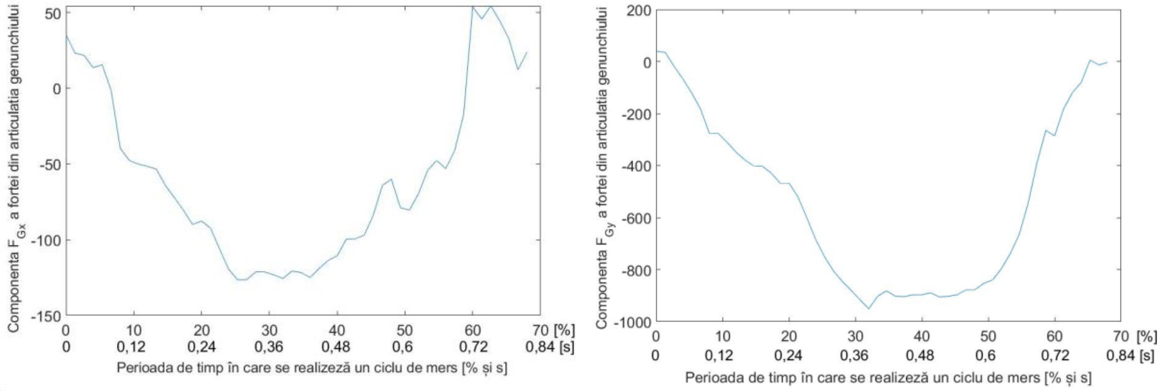
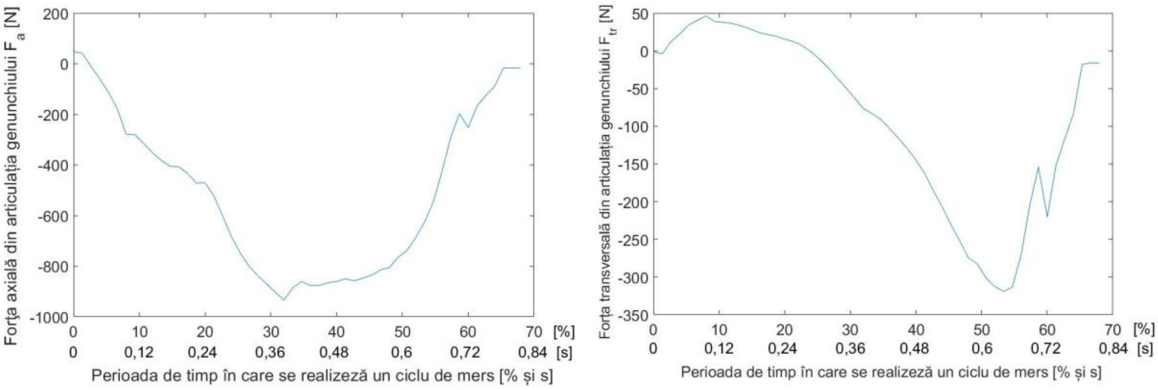


Figura 6.11. Plot of the R_x component of the ground reaction force.



a) b)

Figure 6.12. Graph of a) component F_{Gx} of the force in the knee joint and b) the component F_{Gy} of the force in the knee joint.



a) b)

Figure 6.13. Graph a) of the axial force F_{ax} from the knee joint and transverse force F_{tr} from the knee joint.

The axial force, with negative values, leads to a pushing effect of the residual limb and the liner in the prosthetic socket, while the transverse force creates a moment of overturning of the residual limb and the liner in the prosthetic socket, having the effect of increasing the pressure in the anterior and posterior areas of the contact residual limb-liner-prosthetic socket, which is also found in the usual practice of prosthetics, thus the transverse component changes its meaning at about 20% of the walking cycle and is 3 to 8 times smaller than the axial one. Constructively, the influence of the transverse force can be reduced, by cutting the prosthetic socket in the mentioned areas, as in figure 6.14, a, b, c.

a) b) c) d)

Figure 6.14. Adaptive and customized prosthetic suspension system: a) front view, b) side view, c) rear view, and d) pressure tolerant areas [47].

The front and rear cuts of the rigid prosthetic socket make it possible to compensate for the transverse force through the elastic reaction of the prosthetic liner, whose deformation is not prevented by the wall of the socket, in the cut-out areas. At the same time, rigid contact is avoided in the sensitive area on the front side of the residual limb (figure 6.14, d), directing the additional pressure given by the transverse force to the tolerant areas. Anyway the theoretical approach of the contact from the residual limb - liner - prosthetic socket interface is simplified, considering a model with only axial loading.

6.6. Theoretical and experimental research of the residual limb-liner-prosthetic socket contact

This subchapter presents theoretical and experimental investigations of the contact pressure distribution at the interface of the residual limb and a custom-made prosthetic socket with an adjustment mechanism for optimal dimensional fit. The experiments were performed using medical sensors type 3000E [48], connected to the Tekscan F-Scan system, to record the time variation of the contact pressure and loading force of the prosthetic socket-liner interface.

The theoretical investigation of the phenomena occurring at the contact between the subject's skin and the prosthetic socket liner requires some experimental data on the friction coefficient and Young's modulus for the tissues and materials used to make the prosthetic liner and socket. Another difficulty, related to the theoretical approach, is the high non-linearity of the behavior of these materials, which leads to approximate results. For example, experiments have shown the dependence of frictional forces on skin surface conditions, being lower when the skin is dry, oily, or very moist, and higher if the skin is slightly moist.

6.6.1. The contact model of residual limb - liner - prosthetic socket

External forces acting at the interface between the residual limb and the prosthetic socket liner cause normal and shearing stresses on the tissues, which can lead to skin damage and blood circulation disorders. The simplified theoretical model, presented in figure 6.15, is based on the assumption of a linear elastic behavior of the materials, with the aim of approximating the normal and shear stresses in the contact area, between the skin and the liner of the prosthetic socket, for three different materials.

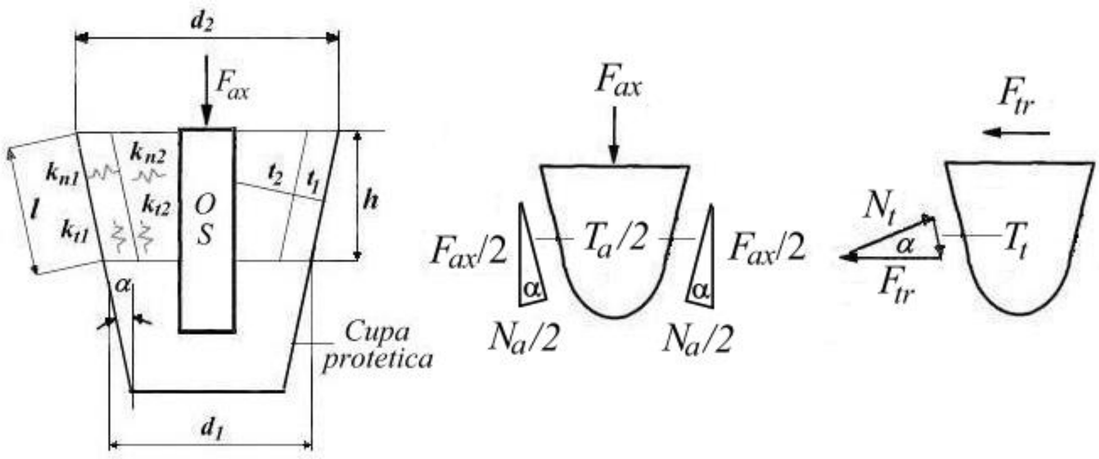


Figure 6.15. Simplified model of prosthetic residual limb-socket loading [49].

In order to model the complex phenomena at the interface between the residual limb, the liner and the prosthetic socket, the diagram in figure 6.15 was created, choosing a frustoconical shape for the surfaces of the prosthetic socket, the liner and the residual limb, which is bounded by the circles of diameters d_1 și d_2, respectively the lateral area of the truncated cone, with the length of the generator, l.

The forces which act on the contact surface are those determined with relations (6.5) and (6.6). F_{ax}, oriented along the bone of the residual limb is the axial force from the knee, and F_{tr} is the transverse force, oriented perpendicular to the bone. Both are broken down into normal components, $N_{a,t}$ at the level of the interface, respectively tangential, $T_{a,t}$.

The media subject to this state of stress and strain are the tissue and liner layers, which, although non-linear, are usually approached as obeying Hooke's law along the specified directions, but of interest is the normal direction for which a linear dependence with stiffness is assumed:

$$k_{n1,2} = \frac{E_{1,2}A_{1.2}}{t_{1,2}} = \frac{N_{a,t}}{\delta_{1,2}} \tag{6.7}$$

where $E_{1,2}$ is the longitudinal modulus of elasticity of the layer (*1* - tissue; 2 liner) and $t_{1,2}$ - average thickness of each layer. Obviously, the non-linearity and hysteresis of the tissue and liner material have been ignored.

Considering the fixation of the liner in contact with the prosthetic socket, the tangential component of the axial force, F_{ax}, is balanced by the frictional force:

$$T_a = \mu_2 N_a \tag{6.8}$$

According to figure 6.15, the vector balance of forces leads to:

$$F_{ax} = N_a sin\alpha + T_a cos\alpha = N_a(sin\alpha + \mu_2 cos\alpha) \tag{6.9}$$

Or,

$$N_a = \frac{F_{ax}}{sin\alpha + \mu_2 cos\alpha} \tag{6.10}$$

The normal compressive stresses in the residual limb and liner tissue are:

$$\sigma_{n1} = \frac{N_a}{A_1} \tag{6.11}$$

$$\sigma_{n2} = \frac{N_a}{A_2} \tag{6.12}$$

where: N is the normal component of F_{ax}, which acts to deform both layers in contact; $A_{1,2}$ – contact areas. Assuming that Hooke's law is applicable, the deformations of the two layers are calculated with the relations:

$$\delta_{n1.2} = \frac{\sigma_{1,2}}{E_{1,2}} t_{1,2} \tag{6.13}$$

The stiffnesses of both layers (liner and tissue) are arranged in series in the normal direction, while in the tangential direction they are driven by different forces. By combining the equations for both layers, it results:

$$\frac{\delta_{n1}}{\delta_{n2}} = \frac{E_2 A_2 t_1}{E_1 A_1 t_2} \tag{6.14}$$

Equation (6.14) indicates that at a greater thickness of the liner, the deformation of the tissue compression is smaller, and its operation under normal conditions is less disturbed.

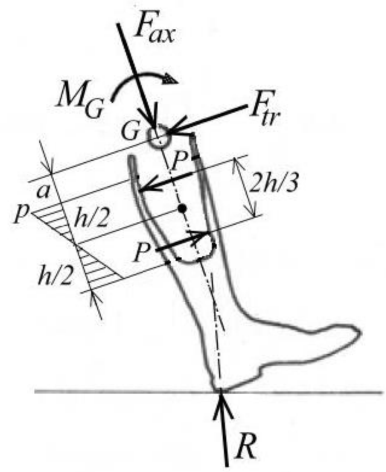


Figure 6.16. The effect of the transverse force on the residual limb pressure.

Basically, the action of the transverse force is presented in figure 6.16. This creates an overturning moment of the residual limb in the socket, defined by the transverse force, which produces a variable pressure along the residual limb, which manifests itself at its interface with the prosthetic socket, both in the anterior area of the interface and in the posterior. The maximum pressures appear at the ends of the residual limb-socket contact area, and the longitudinal variation is assumed to be linear. Each triangular pressure distribution has a resultant, which is placed in the center of gravity of the diagram. Thus, the resultant force is:

$$P = p_{med} \cdot d_{med} \cdot \frac{h}{2} = \frac{p(d_1+d_2)h}{8} \tag{6.15}$$

where: $p_{med} = p/2 -$ average pressure; p – maximum pressure; $d_{med} = 0{,}5\ (d_1 + d_2)$ – the average diameter of the truncated cone; h – the height of the residual limb-socket contact. The force P is determined from the equality of the moments given by the torque P and the moment of the transverse force compared to the middle of the contact height of the residual limb-socket:

$$F_{tr}\left(a + \frac{h}{2}\right) = P \cdot \frac{2h}{3} \tag{6.16}$$

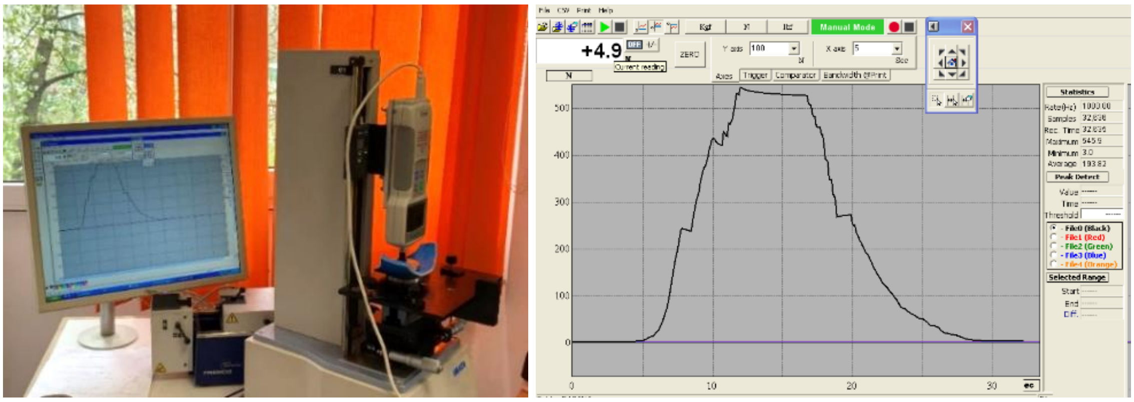
where: $a -$ the distance between the knee joint and the upper edge of the butt-socket contact.

The result is the maximum value of the additional pressure created by the transverse force, in the area of the contact extremities between the residual limb - liner - prosthetic socket:

$$p = \frac{12F_{tr}}{(d_1+d_2)h} \cdot \left(\frac{a}{h} + \frac{1}{2}\right) \tag{6.17}$$

6.6.2. Determination of the material properties of prosthetic liners

Determination of the material properties of the prosthetic liners for the materials from which the liners are made, a loading and unloading experiment of samples of the three different types of materials was carried out using the HV-500N IIS vertical manual test stand, from Schmidt Control Instruments (figure 6.17, a). The three samples with different thicknesses and materials were subjected to compression, by means of a steel disc with a diameter of 50 mm and a thickness of 6 mm. The compression force was applied in steps of 20N, in the range 0 - 480 N, both in the direction of loading and unloading, reading the values of the corresponding deformations. These data served to raise the specific stress-strain curves, from which the elasticity modulus of the material was determined. The rate of force variation over time was displayed by the measuring stand (figure 6.17, b).



a) b)

Figure 6.17. a) Experimental stand with samples of the three different types of prosthetic liner materials; b) force variation over time.

The materials analyzed were: RTV silicone (cast at room temperature), which can be modeled to follow exactly the contour of the residual limb and is the one used for the actual liner of the developed prosthesis, having a thickness of 6 mm; 3 mm thick silicon (MC97228) from Ossur and 6 mm thick silicon (SPDTHD) from ALPS South Italy. The specific strain - normal stress diagrams, for the 3 materials, are presented in the figures below:

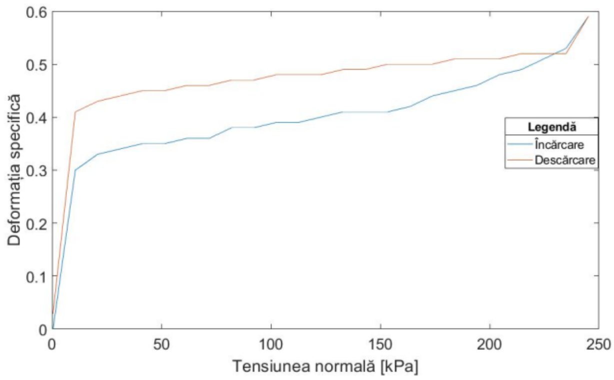


Figure 6.18. The deformation characteristics of RTV silicone (which can be molded to exactly follow the contour of the residual limb).

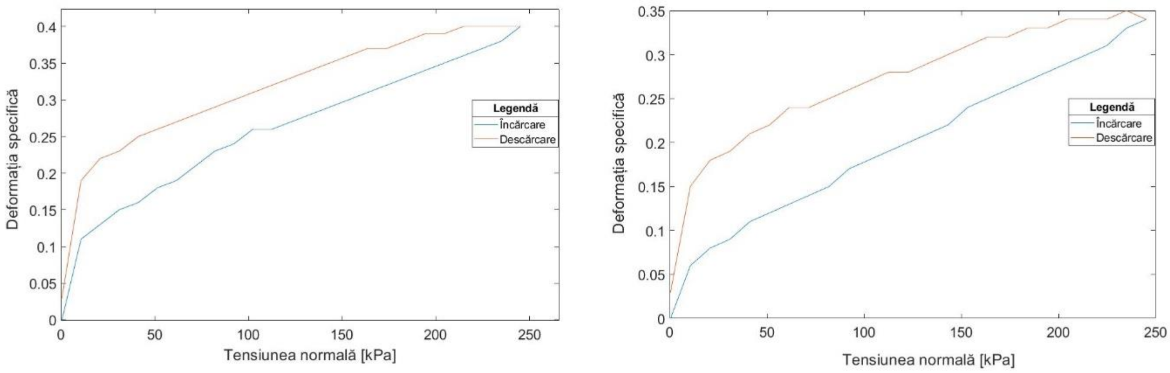


Figure 6.19. Deformation characteristics of commercial silicone liners a) MC97228 (Ossur) and b) SPDTHD (ALPS South Italy)

For RTV silicone, the approximate longitudinal modulus of elasticity has the value *E≅940 kPa*, while for silicone Ossur *E≅780 kPa* and for silicone ALPS, *E≅830 kPa*.

To apply the described model, the data of the same male subject with a body mass of 85 kg and a height of 1.70 m were used. The circumference of the residual limb was measured to approximate the diameters of the bases of the truncated cone, resulting $d_2 = 135{,}6\ mm$ and $d_1 = 92{,}9\ mm$. The other geometric data are: the height of the residual limb, $h = 200\ mm$; the angle of the generator, $\alpha = 6{,}13°$; its length $l = 201{,}15\ mm$.

The axial force, determined by calculation, has values in the range *10,5...930 N*, and the calculated normal component is $N_a = 83 \ldots 1540\ N$, if the values were adopted for the friction coefficients: $\mu_1 = 0{,}61$ și $\mu_2 = 0{,}5$. For the calculation of tissue deformation, the average thickness of 45 mm was used in relation (6.13), and the average distance between skin and bone. The values of pressures and compression deformations of the layers are presented in table 6.1.

Table 6.1. The results of the axial load calculation.

Normal tissue pressure, σ_1 [kPa]	Normal cuff pressure, σ_2 [kPa]	Normal tissue deformation, δ_1 [mm]	The normal deformation of Silicon RTV [mm]	The normal deformation of Ossur silicon [mm]	The maximum normal deformation of Silicon ALPS [mm]
1,6...29	1,45...27	0,017...1,38	0,002...0,16	0,001...0,096	0,002...0,18

The calculation results in table 6.1 show excellent values for the average normal stresses in the tissue, caused by the axial force and comparable deformations of the tested liners. At maximum transverse deformations of the liner, compressed 0.16...0.18 mm, the residual limb can move axially by about 1.38 mm, for an angle of 6,13°, if a regular, frustoconical shape of it is considered. This finding calls for, when adjusting the height of the prosthesis, to take into account the axial displacement of the residual limb in the socket, as a result of the deformations in the normal direction, which appear in the residual limb-liner-prosthetic socket interface.

The maximum values, estimated by calculation, are presented in table 6.2, together with the local deformations of the liners, at the same points, evaluated with the relationship (6.13).

Table 6.2. Maximum pressure and deformations at points at the ends of the contact zone.

Maximum tissue pressure, σ_1+p [kPa]	Maximum liner pressure, σ_2+p [kPa]	Maximum local deformation of Silicone RTV [mm]	The maximum normal deformation of Silicon Ossur [mm]	The maximum normal deformation of Silicon ALPS [mm]
121,6	119,6	0,51	0,31	0,57

The difference between the tested materials is related to how they conform to the specific shape of the subject's residual limb. While the RTV silicone liner is molded to the shape of the residual limb, the other two introduce additional unknown stresses because they are only elastic liners, purchased by size.

The model developed for the evaluation of the pressure at the residual limb - liner - prosthetic socket interface, which led, by calculation, to verifiable results, must be validated by own experimental determinations, applied to the subject with whose data the calculations were made.

6.6.3. Experimental determination of pressure on the prosthetic residual limb-liner-socket interface

To confirm the results obtained from the theoretical model, an experimental check was made, in order to determine the maximum load applied to the residual limb-liner-prosthetic socket interface and the real pressure distribution from it. For this purpose, two Tekscan 3000 E pressure sensors were placed between the liner and the prosthetic socket according to figure 6.20, to record the pressure and forces developed by the subject with the customized prosthesis, during a walking cycle.

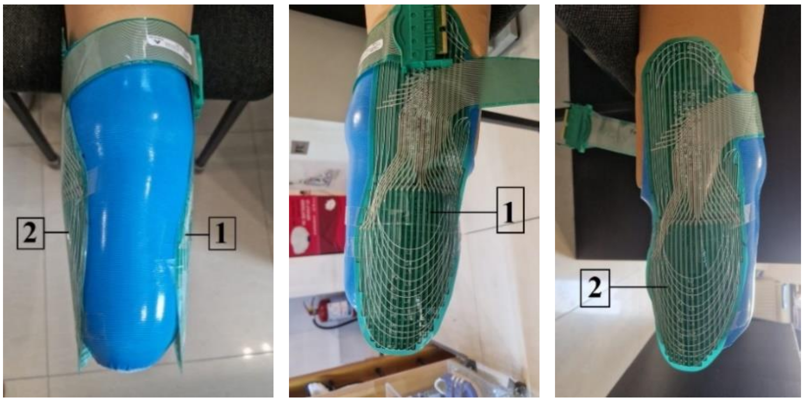


Figure 6.20. Placement of sensors on the residual limb: sensor 1 is fixed on the external side of the residual limb and sensor 2 on the internal side of the residual limb.

Regarding the acquisition and analysis of the signals with the F-scan software, attached to the Mat-scan equipment (Teksan), there is the facility of dividing the sensor into 3 regions, corresponding to the location on the residual limb with the liner: proximal - the area near the knee; median - the middle area of the sensor and distal - the extremity far from the knee (figure 6.21). This facility allowed the highlighting of local pressure peaks, the evaluation of the reaction force of the corresponding area and the average zonal pressure.

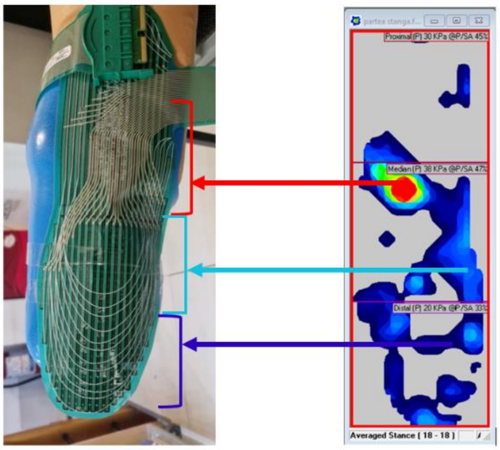


Figure 6.21. Sensor areas corresponding to the color map.

The experiment was carried out with the subject for whom the customized prosthesis was made and for whose data the evaluation was carried out based on the model presented in the previous subsections: a male subject with a body mass of 85 kg.

The forces corresponding to the three zones of the two sensors, recorded during an entire walking cycle, are presented in figures 6.22 and 6.23.

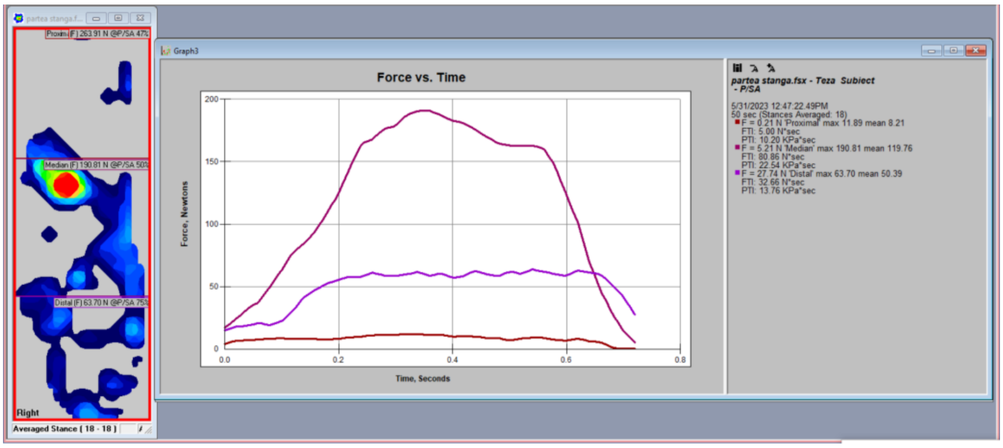


Figure 6.22. Plot of force over time for the three regions of sensor 1.

The forces and pressures, determined with each sensor, have values corresponding to their contact areas, which do not cover the entire prosthetic residual limb-liner-socket contact surface. Considering that there is an important fraction of the surfaces of the prosthetic liner and socket, in direct contact, without a force/pressure sensor, a check of the closeness of the theoretical evaluation to the experimental one could be the closeness of the average pressures at the residual limb-liner-socket interface. For this purpose, the direct contact surfaces between the liner and the socket, respectively the sensor-socket contact surfaces, must be evaluated.

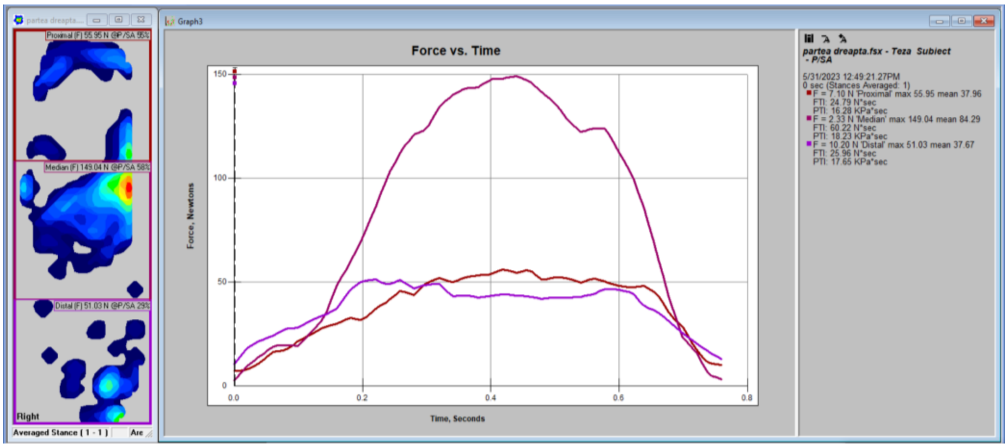


Figure 6.23. Plot of force over time for the three regions of sensor 2.

During the movement of the subject during a walking cycle, for which the contact force curves were raised, the way of loading the cells of each sensor was also investigated, by evaluating the area in the sensor. The results obtained from F-scan are presented in figures 6.24 and 6.25.

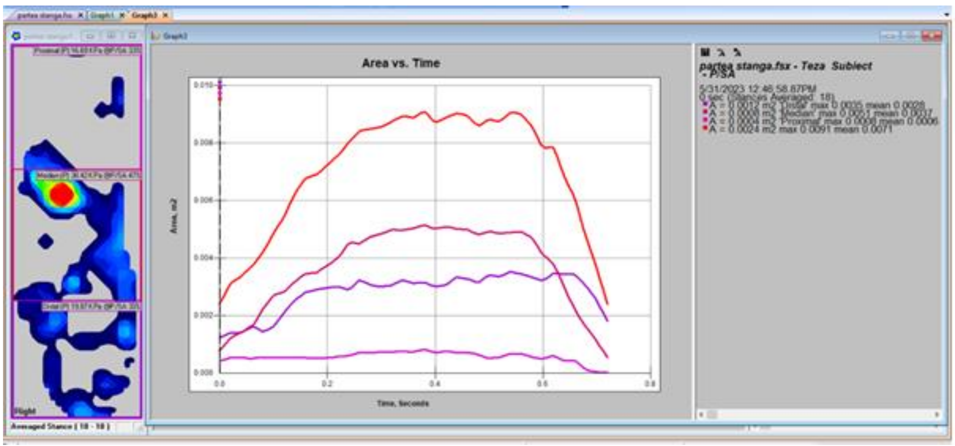


Figure 6.24. The variation of the zonal and total contact areas of sensor 1, for the entire gait cycle.

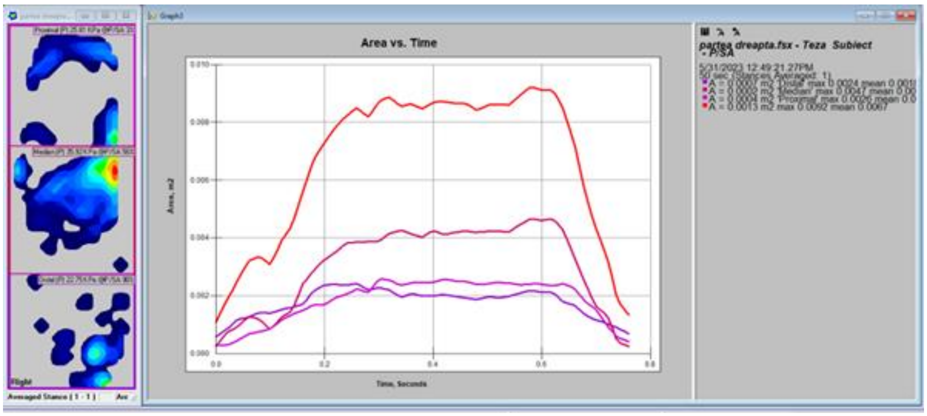


Figure 6.25. The variation of the zonal and total contact areas of sensor 2, for the entire walking cycle.

It can be observed that the loading of the sensors is not distributed in the way, in the case of the outer sensor (1), the proximal third is practically unloaded, and for the inner sensor (2) the proximal contact area does not exceed 3% of the total area of the prosthetic socket. In both cases, the total contact area, through the contribution of the median zone, has a value of over *0,007* m^2 in the interval 0,2 – 0,7s, out of the total of 0,8s of the support phase of the gait cycle. The most loaded area, both at the outer and inner sensors, falls into the pressure-tolerant regions, according to figure 6.14, lateral-anterior and left-right.

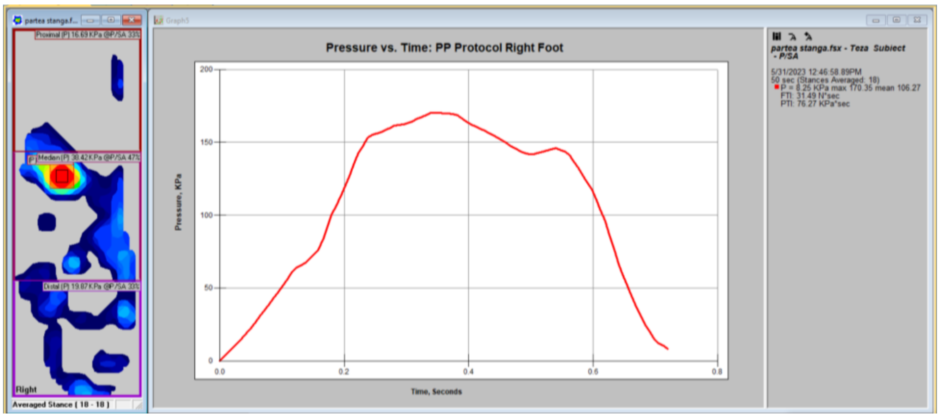


Figure 6.26. Time variation of the maximum pressure measured with the external sensor (1).

Figure 6.26 shows the variation over time of the maximum pressure measured with the external sensor, which indicates a maximum value $PP_{max} = 170{,}35\ kPa$ and an average value $PP_{med} = 106{,}27\ kPa$.

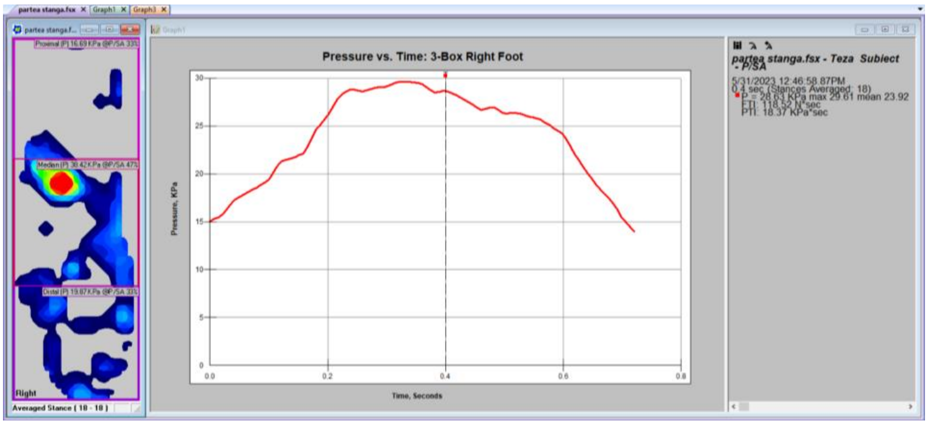


Figure 6.27. Variation over time of the average pressure measured with the external sensor (1).

Figure 6.27 shows the variation over time of the average pressure measured with the external sensor, which indicates a maximum value $P_{max} = 29{,}615\ kPa$ and an average value $P_{med} =$

$23{,}92\ kPa$. Parameter $PTI = 18{,}37\ kPa * sec$, which is equivalent to a static pressure, $P_{med\_static} = 15{,}31\ kPa$, applied throughout the walking cycle, by *1,2 s*.

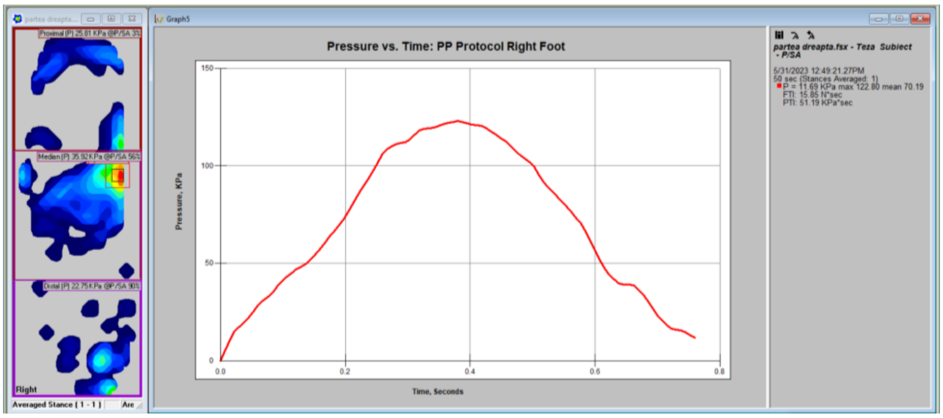


Figure 6.28. Time variation of the maximum pressure measured with the internal sensor (2).

Figure 6.28 shows the variation over time of the maximum pressure measured with the internal sensor, which indicates a maximum value $PP_{max} = 122{,}8\ kPa$ and an average value $PP_{med} = 70{,}19\ kPa$. Parameter $PTI = 51{,}9\ kPa * sec$, which is equivalent to a static pressure, $P_{med\_static} = 43{,}25\ kPa$, applied throughout the walking cycle, by *1,2 s*.

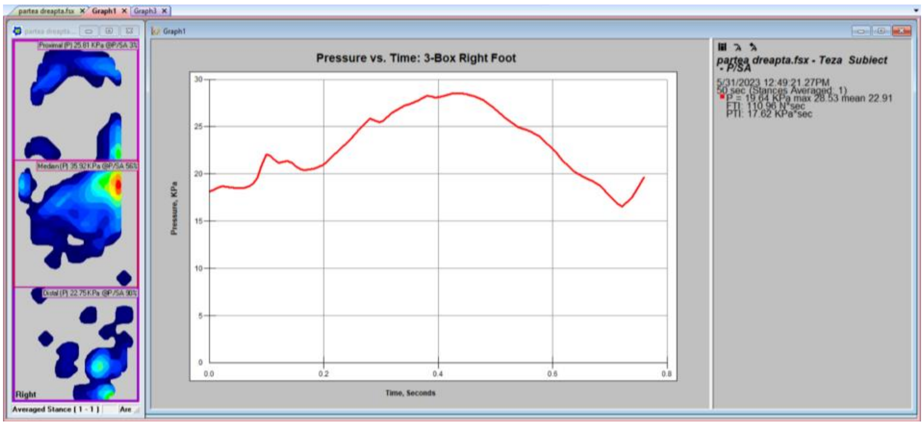


Figure 6.29. Time variation of the average pressure measured with the internal sensor (2).

Figure 6.29 shows the variation over time of the average pressure measured with the internal sensor, which indicates a maximum value $P_{max} = 28{,}53\ kPa$ and an average value $P_{med} = 22{,}91\ kPa$. Parameter $PTI = 17{,}62\ kPa * sec$, which is equivalent to a static pressure, $P_{med\_static} = 14{,}68\ kPa$, applied throughout the walking cycle, by *1,2 s*.

The results of the experimental determinations are concentrated in table 6.3.

Table 6.3. The results of the determinations made with the Tekscan system.

Sensor number	Maximum force F_{max} [N]	Minimum force F_{min} [N]	Maximum peak pressure p_{v_max} [kPa]	Average peak pressure p_{v_med} [kPa]	Maximum mean pressure p_{med_max} [kPa]	Average mean pressure p_{med_med} [kPa]	Average static pressure p_{max_static} [kPa]
1	264	35	170,35	106,27	29,615	23,92	15,31
2	249	22	122,8	70,19	28,53	22,91	14,68

If we compare the theoretical results from tables 6.1 and 6.2 with the experimental ones from table 6.3, we can observe a remarkable closeness between the maximum values of the maximum pressures produced by the theoretical axial loading (29 kPa in table 6.1) and the maximum average pressure (29, 615 kPa for the outer sensor, respectively 28.53 kPa for the inner sensor, in table 6.3), i.e. +2.12% for the first sensor and -1.62% for the second sensor.

The experiments showed that the maximum (peak) pressure can reach, locally, values 5-6 times higher than the average ones, and the theoretical approach highlighted the overturning effect of the force acting transversely to the axis of the prosthesis. In this hypothesis, a major increase in pressure was determined in the extremities of the residual limb-liner-prosthetic socket contact area, which was confirmed only by a single point, at both sensors. From a quantitative point of view, the theoretical maximum pressure, from table 6.2 (121.6 kPa), differs by -1% compared to the pressure measured with sensor 2 and by -28.6% compared to the pressure measured with sensor 1 (table 6.3).

6.7. Conclusions

The model developed for evaluating the pressure at the residual limb-liner-prosthetic socket interface uses, in the equations, several measured values of the physical and kinematic quantities, specific to the subject, which brings the calculation results very close to physical reality, even if for the non-linear behavior of the tissues and silicone materials, a linear law was adopted, which can explain some deviations from the experimental results.

Although applied in the case of a calf prosthesis, the research presented is a simple approach, aimed at quickly verifying whether the dimensions of the prosthetic liners and socket are suitable to develop an admissible pressure under the subject's load, during the gait cycle, both for calf prostheses, as well as the thigh, considering that the latter have a lower load, on a larger surface of the prosthetic socket. In addition, given the importance of the values of the parameters of the materials used, their experimental study highlighted the non-linear character of the constitutive relations and provided concrete, measured data, avoiding their choice from a range available in the literature.

Chapter 7. Conclusions. Reaching objectives. Future research directions

7.2. Reaching objectives and personal contributions

Lower limb prostheses are devices that have the role of replacing a part of the limb that is missing, due to amputation or a congenital condition, and contribute to regaining locomotor independence and orthostatic stability.

The most common problems with these types of devices are related to the inadaptability of the subjects. Most of the time, they experience pain and discomfort due to the volume changes of the amputation residual limb, which causes misfit in the prosthesis socket. In order to solve these shortcomings of the currently made prosthetic systems and to reduce unwanted pressures on the residual limb, research and development of prosthetic components that come into direct contact with the residual limb (prosthetic socket and silicone liner) was proposed, in order to achieve a firm and safe contact between the amputated lower limb and the prosthesis.

Thus, the main objective of the thesis is fulfilled by the design and realization of a mechanical attachment system for lower limb prostheses, where the prosthetic socket passively compensates for the change in the volume of the residual limb and maintains a limited distribution of residual limb-socket pressure during walking. Thus, starting from an existing model of the prosthetic socket with cutouts in the areas sensitive and susceptible to dimensional changes of the residual limb, and which includes a manual adjustment system, integrated in the walls of the prosthetic socket, to adjust its dimensions based on the reverse reaction from the wearer modular prosthesis of the lower limb. A silicone liner adapted to the geometric configuration of the residual limb was also created, having biocompatible properties with the tissue of the amputation residual limb.

The achievement of the objectives and the personal contributions made in the development of the implemented prosthetic system, both on a theoretical and a practical level, can be considered the following:

1. Carrying out a thorough research of the specialized literature regarding the evaluation of the equipment by directly participating in the performance of experimental measurements and selecting the optimal method for determining the dynamic and kinematic parameters, depending on the expected results.
2. Development of a prosthetic socket design protocol in two different 3D design software. This method can be improved and adapted for prosthetic liners as well, being ticked as a future research direction.
3. Theoretical and experimental analysis for five different types of ankle-foot joints, in order to determine the ground reaction force for the healthy and prosthetic leg and to evaluate the pressure distribution in the healthy leg, to determine the degree of adaptability and comfort of the analyzed subject is a method of verification and validation, to evaluate the level of performance of the prosthetic component, in relation to the activity level of the subject, being another personal contribution.
4. Evaluation of dynamic and kinematic parameters for 15 subjects (8 healthy subjects, 3 subjects with unilateral transtibial amputation, 3 subjects with unilateral transfemoral amputation, and one subject with bilateral amputation), indicating contact instability between the residual limb and lower limb prostheses (prostheses of calf and thigh). An adjustable mechanical clamping system (prosthetic socket) manually adjusted and a silicone liner were proposed and made, with which the dimensional adaptation to the geometric configuration of the residual limb is carried out, for total contact.
5. Development and realization of the clamping component that uses a passive mechanical device to tighten the dimensions of the prosthetic socket, by means of cables connected to its cut-out walls. These cables are actuated by the mechanical device, located on the prosthetic socket, to maintain even and constant pressure distribution during walking.
6. Also, a silicone liner adapted to the shape of the amputation residual limb and the prosthetic socket with a mechanical size adjustment system was made, being recommended for all wearers of modular lower limb prostheses with volume fluctuations, but especially for those in whom amputation surgery came from diabetes because it has biocompatible properties with the skin. The major advantages of this silicone liner derive from the technological process of making and making it which is individualized, according to the anthropometric dimensions of the subject, thus eliminating the disadvantages of the mismatch of the series silicone liner, which is currently available in two sizes. At the same time, in the case of serial silicone liners, the activity of the popliteus muscle is limited,

because their construction requires covering this area and fixing the liner up to the middle third of the thigh. In the case of the customized liner, which respects the anatomical landmarks, the flexion-extension movement of the knee joint can be achieved without impediments.

7. Pressure measurement between the residual limb covered by the silicone liner and the prosthetic socket was made, in the case of a modular transtibial prosthesis. Due to the position of the amputation, the load applied to the residual limb-liner-prosthetic socket interface is greater than in the case of transfemoral amputation, so that the experiment with the transtibial prosthesis covers the pressure limitation requirements in the tissue layers, for the thigh prosthesis, respectively the optimization from this point of view. The results obtained are comparable to the research carried out in the specialized literature, although the sensors available to determine the pressure are, in fact, dedicated to the measurement of plantar pressure, but they were placed on the surface of the residual limb.
8. The method of verification and interpretation of the data obtained after testing the material properties and the theoretical evaluation of the load exerted at the residual limb interface – silicone liner – prosthetic socket.
9. Development of a hybrid, experimental and theoretical research protocol for determining, based on an inverse dynamic model, the actuation moment in the knee joint.
10. Determining the value of the maximum load applied to the residual limb-liner-prosthetic socket interface and the actual pressure distribution, by placing two pressure sensors between the liner and the prosthetic socket, to record the pressure and forces developed by the subject with a customized prosthesis, during a cycle of walking.
11. Evaluation of experimental determinations of the pressure at the residual limb-liner-prosthetic socket interface, these being compared with the theoretically obtained results, for which a notable closeness of the obtained values was observed.

In conclusion, progress has been made in terms of optimizing the residual limb-liner-prosthetic socket interface, by researching some materials used in the manufacture of prosthetic liners, which ensure a sanitary protection of the skin and adjacent tissues, but also of a mechanical clamping system (prosthetic socket), with which the dimensional adaptation to the geometric configuration of the residual limb is carried out, to ensure an adequate distribution of pressure in the residual limb.

7.2. Future research directions

Future research perspectives regarding the mechanical attachment system for lower limb prostheses, in which the prosthetic socket passively compensates for residual limb volume change and maintains a limited residual limb–socket pressure distribution during walking, could be related by extending the research to the study of the temperature recorded at the silicone cap-liner interface, as a means of indirectly evaluating the comfort of the users.

Also, a possible optimization is envisioned in terms of the use of materials to make the silicone liner, with superior elastic properties and mechanical resistance, for applications in the field of lower limb prosthetics, which are, at the same time, sustainable and friendly to the environment.

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