Design for Disability: Prosthetic BK Socket's Manufacturing with New Digital Methodology

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Abstract

This study presents the definition and validation of a new process methodology for the creation of sockets for transtibial amputations and has the objective of automating and digitizing the prosthesis production process through digital transformation activities of the orthopedic workshop, additive manufacturing and advanced manufacturing solutions, as well as simulation for Gait analysis.

The work is part of an interdisciplinary project which sees, in addition to the experience of the orthopedic technician, the involvement of the mechanical engineer, the biomedical engineer and the designer.

The elements of digital innovation concern: the acquisition of the digital 3D model of the stump through scanning with the scanner and MRI; physically based modeling and FEM simulation of the stump to obtain the "compressed and stylized" model through new quantitative rules developed by the work team; rapid prototyping of the 3D model of the stump; the autoclave lamination process of prepreg fabrics or the socket printed directly in 3D thanks to the use of innovative printers; the acquisition of 3D models of leg, foot and cover foot or leg for the creation of customized parts; static and dynamic alignment; validation of the prosthesis via Gait analysis; monitoring the patient's health status during the life of the device supplied with the Gait analysis system.

The innovations made and the new methodology certainly revolutionize an obsolete sector and speedup the creation of prostheses, with aspects of eco-innovation of the product and process and with significant energy savings.

In this context, "inclusive" design aims to allow all disabled people to have equal opportunities for participation in every aspect of social and cultural life, thanks to innovative prostheses that improve the quality of their life. This holistic and innovative approach constitutes a creative and ethical challenge for all designers because human diversity, social inclusion and equality are aspects to be considered in the design process, enhancing human needs and aspirations. To achieve this, end-user involvement is required at every stage of the design process. Furthermore, technological innovation brings benefits for everyone and competitive and economic advantages, since the possibility of remotely producing the orthopedic prosthesis customized for each patient makes the technology accessible to users, guaranteeing high technology at low costs.

The methodology was tested on seven patients with transtibial amputation: the results obtained and the final considerations can be considered satisfactory.

Future research, in this way, can increase the fields of application using the same digital methodologies.

Keywords: prosthetic socket, new methodology, physically based modeling

1. Introduction

The state of the art in the world of lower limb prosthetics sees artisanal micro-enterprises that make the plaster cast manually and laminate the sockets (the container of the stump) with boat infusion methods and use rigid feet or low-efficiency mechanical knees, creating in a long time, poorly performing prostheses which do not allow the amputee to completely reacquire motor autonomy and social reintegration.

In particular, one of the most interesting and important factors for the success of a prosthesis is the organism-prosthesis interface, for which the socket represents the most critical and perhaps most important element of a prosthesis. The successful design and fitting of a prosthetic socket result in the effective transfer of forces from the socket to the residual limb, such as the amputee can maintain daily activities without damaging tissue or experiencing pain: in fact, the most common reason for residual limb pain is due to an intolerable pressure applied to the stump. So uncomfortable socket may cause many clinical problems, such as dermatitis or skin lesions, due to the friction against the prosthetic components; the altered biomechanics induces a postural disequilibrium with progressive decrease of quality of life [1].

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There is a difficulty in finding biomechanical guidelines due to the highly dynamic environment of the stump-socket system. Furthermore, from the analysis of the existing bibliography, we note that most of the studies have mainly focused on the design intent of the socket respect to objective quantitative rules to follow; since, in current practice, the success of a prosthesis is entrusted to the clinical experience of the orthopedic technician in the design and production of the socket obtained manually thanks to appropriate rectifications to optimize the stresses at the interface of the leg. It must be considered that the general characteristics of the stump, such as geometry, dimensions and load tolerance, vary from person to person.

Starting from the traditional procedure with negative plaster cast which allows to obtain the impression of the deformed stump according to steps defined by Radcliffe in 1961 [2] to create a PTB (patella-tendon-bearing) socket for BK (below knee amputee) amputations, all studies conducted on residual limb prostheses focus on the analysis of finite elements in relation to: mechanics of the stump-prosthesis interface, internal mechanics of the soft tissues of the stump, identification of the characteristics of the stump tissues, proposals for incorporating FEA into the prosthesis fitting process, analysis of the influence of prosthetic component concepts to improve the transfer of the load on the stump and the conformity of the socket, analysis of osseointegrated prostheses [3].

More recent studies have created a guide system for 3D modeling of the socket by applying the correct geometric deformations necessary to create a functional socket (high comfort and high degree of patient mobility) with load and off-load areas corresponding to the critical anatomical zones.

To identify the position of such critical areas, several neural networks have been trained using a dataset generated from real residuum models, but this model has limitations in shaping the upper border of the socket [4]. Other studies have presented methods of numerical optimization of the shape of the socket which could benefit the prosthetist and the amputee to evaluate the possible "candidates" for the various types of socket or the socket's design based on clinical models provided by expert prosthetists, evaluating the tendency in the stump's shape; however, they are preliminary studies and not experimentally validated, but which demonstrate the tendency to make the socket's design become a more engineering process [5, 6]. Furthermore, some studies have used photogrammetry technique for transtibial prosthetic socket design development with image processing in the software for the 3D generation and rectification process and subsequent 3D printing, especially for low-cost prosthetics for amputees in underserved areas, who currently face large barriers in both cost and physical access to proper care; but this method has limitations in accuracy, and socket rectification (i.e. modeling a limb model into a prosthetic socket) is the most critical step in any virtual model workflow for prosthetic design [7, 8].

Our study responds to the need to make optimizations to the prosthetic BK socket's manufacturing process with 3D digital methodologies: reducing the weight of the socket with new materials and applying the right deformations in the anatomical critical points identified, evaluating the pain thresholds (the minimum pressure inducing pain) and pain tolerance (the maximum tolerable pressure) of different regions of the residual limbs of transtibial amputee [9].

The paper presents an innovative methodology based on a correct patient history to define the right type of socket with particular attention to the shaping of the upper border of the socket, digital data and IT tools for the optimization of the design of limb prostheses lower and direct production with Rapid Manufacturing techniques. The methodology was tested experimentally on seven patients with limbs amputated below the knee: the patients were all men, one of whom was a bilateral amputee, aged between 22 and 63 years, with an average of 31 years of amputation and with a length of average stump 139.25 mm infrapatellar, from sub patellar to the distal end of the stump (see Table 1).

2. Method

2.1. Traditional socket manufacturing process

The manufacturing of the socket with the traditional method involves the creation of a negative plaster cast which allows obtaining the impression of the deformed stump according to the following steps [2]: have the amputee sit on a examining table with the thigh supported and the back of the knee approximately 10 cm from the edge, position the stump at approximately 30° of flexion, wrap the cap with a layer of transparent protective film, collect information on the patient's stump (length, sensitive points, circumferences, etc.), mark with an indelible pencil the sensitive areas and protuberances (outline of the patella, mid patellar tendon, tubercle of the tibia, head of the fibula, anterior crest of the tibia, distal end of the fibula, anterior distal end of the tibia, medial flare of the tibia and medial border of the tibia, as well as horizontal lines at which the circumferences of the stump are taken and marked on the technical sheet) (Fig.1), wrap the stump with plaster bandages previously soaked in a basin containing water and wrung out, covering the femoral condyles well, work the cast until it hardens by exerting appropriate pressure with the fingers on the stump to outline the patellar tendon and compress the popliteal tissues, wrap the fingers around the knee and press the pads of the fingers into the popliteal area until the plaster has hardened, finally remove the cast from the stump by pulling down with an anterior-to-posterior-rocking action (Fig.2). After the chalk negative cast, the fluid plaster is poured to form the chalk positive cast.

Fig. 1. Stump measurements with liner and marking of reference points

Fig. 2. Chalk negative cast

When the chalk positive cast is ready, the orthopedic technician compares the measurements of the cast with those taken initially and stylises the cast in the most appropriate way (Fig.3). The socket is created by laminating a series of tubular meshes of Nyglass, Perlon and carbon fiber on the positive cast with acrylic resin and vacuum drafting using PVA bags and suction pipe, after choosing the connection system with the tubular structure of the entire prosthesis. The decades of experience of the orthopedic technician in the creation of the socket is the only determining element in the current orthopedic procedure.

Fig. 3. Chalk positive cast

2.2. New digital methodology

The work of definition and validation of a new process methodology for the creation of sockets for transtibial amputations is part of an interdisciplinary project which sees, in addition to the experience of the orthopedic technician, the involvement of the mechanical engineer, the biomedical engineer and the designer.

Compared to the artisanal procedure of taking the cast on the stump by shaping plaster bandages, the process involves in a first phase the acquisition of the external digital 3D model of the stump through scanning with the 3D scanner and the complete model of bones, muscular parts, soft parts and skin, through MRI (magnetic resonance imaging); from the overlap of the two 3D models in Rhinoceros

(commonly called Rhino or Rhino3D, a software for 3D modeling of surfaces created by Robert McNeel & Associates, in the USA) the complete digital model of the stump is born (Fig.4, Fig.5, Fig .6).
During this phase, all the legal problems related to 3D geometric reconstruction were considered: the patient and stump positioning for the different acquisitions, alignment strategies for the different digital models in order to define a protocol procedure for creating sockets with instruments CAD and Rapid Manufacturing techniques [1].
The integration between the external surface and the bone models allows obtaining a complete digital model of the residual limb. This model is essential to permit simulations that repeat both the technician's manipulations and the stresses between the stump and socket during patient's movement [10].

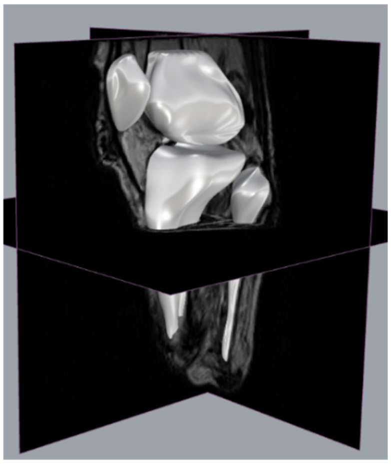
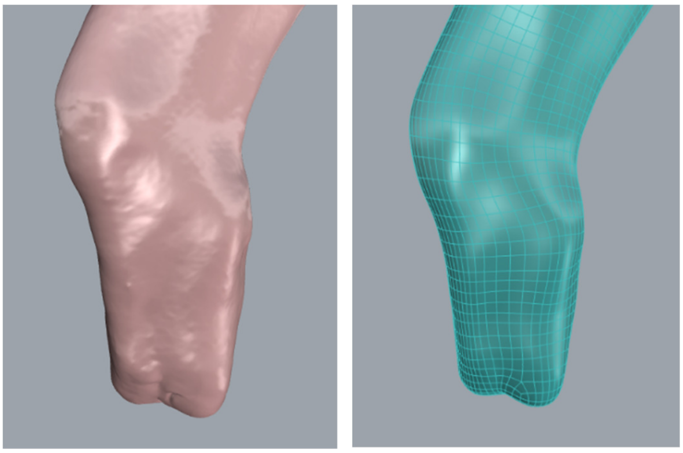


Fig. 4. 3D stump model from MRI



(a) *(b)*

Fig. 5. 3D stump model from scan (a), conversion to SubD (b)

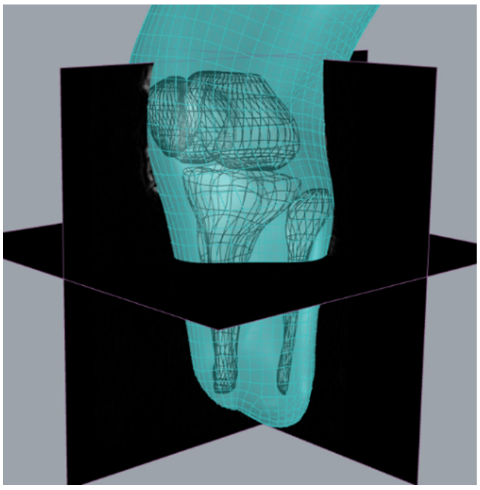


Fig. 6. Overlaying 3D models of the stump

In the second phase, physically based modeling and FEM (Finite Elements Method) simulation of the stump allow the "compressed and stylized" model to be obtained through new quantitative rules developed by the work team and focused on the patient history and his " physical form" (Fig.7, 8).
The possibility of having a complete model of bones, muscular parts, soft parts and skin where to apply the deformations allows us to avoid excessive pressure in critical areas which would cause patient pain. In the current process, the orthopedic technician removes and adds material in the appropriate areas with a rasp, stylizing the plaster cast of the stump which is produced using the so-called "negative" plaster cast as a mold [11]; the success or otherwise of the operation depends entirely on the manual skill and experience of the orthopedic technician.

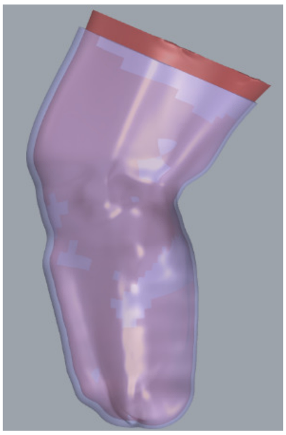


Fig. 7. Compressed and stylized model stump+ liner

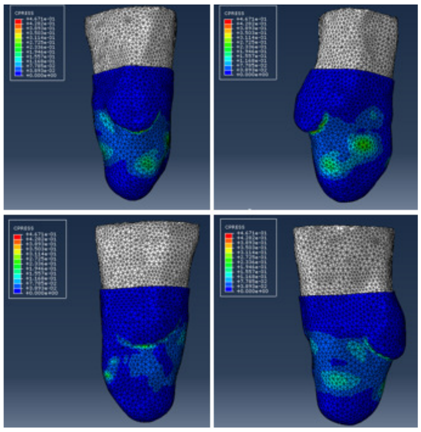


Fig. 8. FEM simulation

In the third phase, the 3D model of the stump is created in rapid prototyping, on which the socket is created through an autoclave lamination process with prepreg fabrics (Fig.9) or the socket is produced directly in 3D using an innovative printer, used in the aeronautical and aerospace sector, which allows the rapid prototyping of carbon fiber structural parts (Fig.10).
Additive manufacturing can potentially allow for cheaper, faster, and customised manufacturing of high-performance composite structures [12].

Fig. 9. 3D model on the left on which to make socket through the lamination process on the right

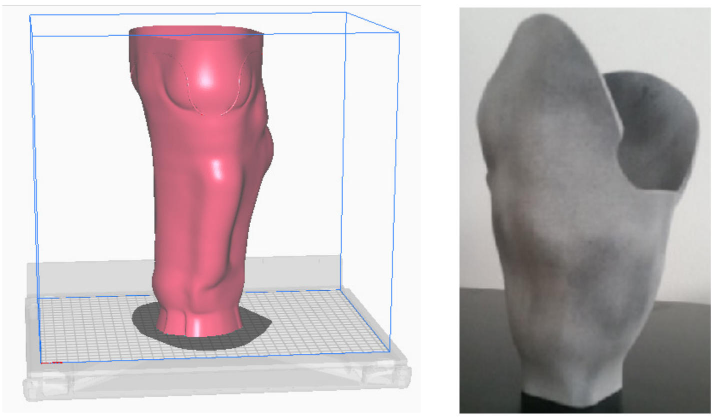


Fig. 10. Socket production with 3D printer

The last phase of the process sees the static and dynamic alignment following the "mirroring" of the healthy scanned limb, as a guide and the validation of the prosthesis through Gait analysis, that allows the measurement the ROM (range of motion) of the joints, and to date this is not used by orthopedic centers [13]. Finally, the monitoring of the patient's health status during the life of the device supplied with the Gait analysis system and in the comfort evaluation of the socket perceived by the amputee.

3. Test/Data

3.1. Patient history

The first step of our research was to define the important information in the patient's medical history for a correct creation of the socket in relation to the BMI (body mass index) which is a parameter related to the state of health; in particular, for people with limb loss, the standard BMI formula must be adapted to take into account the estimated weight of the missing limb [14], as shown in equation 1:

$$\text{BMI} = \frac{\mathbf{We}}{\mathbf{ht}\,(\mathbf{m^2})} \qquad (1)$$

Where ht = height and We = estimated body weight, which is calculated according to equation 2:

$$\text{We} = \frac{W_0}{1-P} \qquad (2)$$

Where $\mathbf{W_0}$ = weight without prosthetic device (total body weight - weight of the prosthesis) and P = percentage of total body weight of the missing limb (Fig.11).

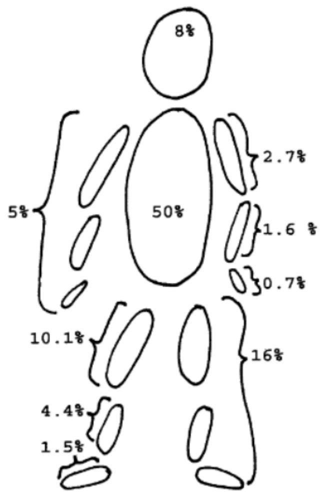


Fig. 11. Percentage of total body weight contributed by individual body parts

Subsequently it is important to know the reason for the amputation since this corresponds to a different reconstruction of the soft tissues (osteosarcoma, trauma, vascular diseases or other); finally, it was decided to prefer a type of PTB socket or rather PTK (Tibial Kegel prosthesis) with grip on the femoral condyles with particular attention to the shaping of the upper border of the socket.

3.2. Laser scanning

Once the initial hypotheses have been defined, we move on to scanning the stumps with a portable 3D scanner (Shining 3D Einscan H) with the patient in a sitting position, positioning the stump at a minimum 15° of flexion without wearing the liner. An excellent scan takes approximately 10-15 minutes and the software used was EXScan H_v1.1.0.1 for SHINING 3D scanner [15], which enables high-speed, high-quality 3D scanning and offers an innovative digital platform for reverse engineering with the possibility of saving files in .stl, .obj, .ply format in post-pocessing (Fig.12). To guarantee the repeatability of the acquisition set-up, settings have been defined such as a resolution of 0.25 mm and medium level mesh optimization, useful for our purpose.

(a) (b) (c)

Fig. 12. Shining 3D Einscan H (a), stump to be scanned (b), stump scan with EXScan H_v1.1.0.1 software

3.3. Medical Imaging with MRI

Magnetic resonance imaging, or MRI, is a noninvasive medical imaging test that produces detailed images of almost every internal structure in the human body, including the organs, bones, muscles and blood vessels. MRI scanners create three-dimensional images of the body using a large magnet and radio waves. No ionizing radiation is produced during an MRI exam, unlike X-rays [16]. These images are used to diagnose a wide variety of pathological conditions. This means that MRI is used in numerous fields of study, such as orthopaedics in our case.
The MRI image acquisition protocol was defined by positioning the patients in a supine position and the stump raised at the Galeazzi Orthopaedic Institute in Milan (DICOM file output).
The complete stack of MRI images is loaded and registered in the image processing environment (Fig.13).

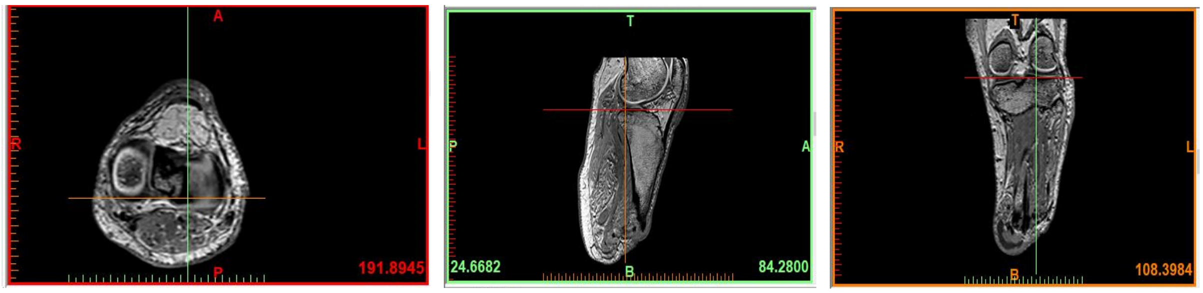


Fig. 13. MRI images of the stump

Using Mimics Medical Image software specifically dedicated to image processing (segmentation), it was possible to extract digital models of bones, ligaments, muscles and tendons, cartilage, connective tissue and skin from the 3D images, useful for FEM analysis (Fig.14).

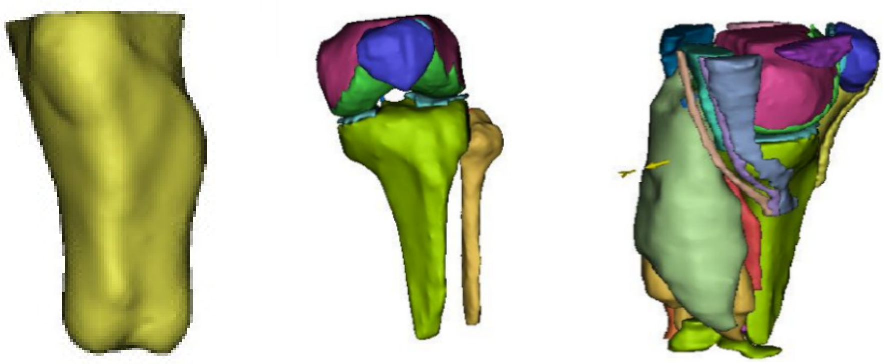


Fig. 14. Extraction of the skin (left), of the bone components (central) and of the musculotendinous components from MRI (right)

3.4. 3D digital model

To obtain the 3D integrated digital stump together with the external surface and the internal structure, the different models were aligned in the same global reference system, using the Rhino 7 software [17], which allows you to insert the MRI of the reference patient via the “Rhino3dMedical” plugin, in addition to the laser scan files (.obj files). By superimposing the 3D models of the stump, using the patella as the main reference (Fig.6), a good positioning of the models is obtained, useful for the subsequent modeling phases of the stump for the creation of the socket.

3.5. Modelling of the stump and creation of the socket

For the modelling of the stump and the creation of the socket with the Rhinoceros software, the following phases were implemented by the work team:

- reduction of the circumferences of the original stump based on the stump length (long stump if >=15 cm, short stump if <15 cm);
- scaling of the circumference gradually according to the patient's characteristics; calculating BFP (Body fat percentage) which also depends on age and sex, as well as height and weight, and relating it to the tone and K-levels (activity levels) of the amputee [18];
- application of the correct punctual deformations (rectifications) on the critical anatomical areas [19,20] (Fig.15);
- 3D socket creation starting from the "compressed" stump, creating constant offset (relative to the liner) as shown in Fig.7, with distal rounding based on the characteristics of the stump (conical/bulbous/cylindrical) and shaping of the upper border of the socket (Fig.16).

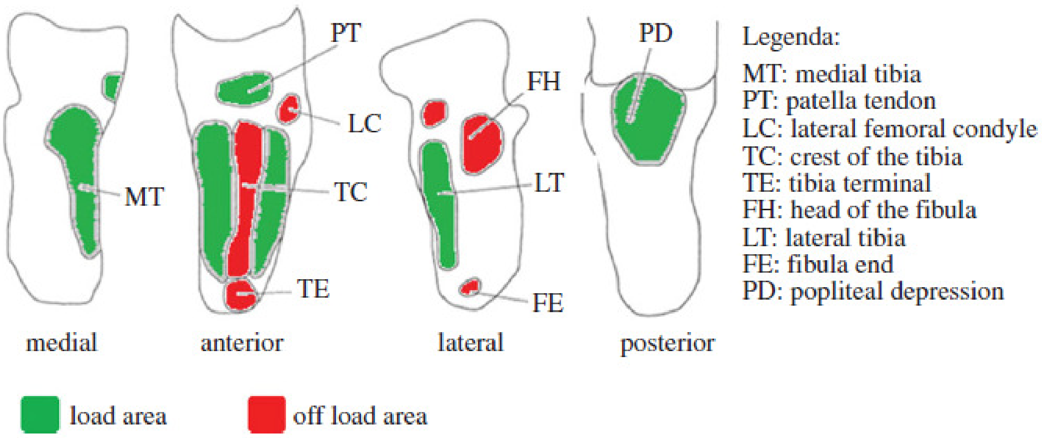


Fig. 15. Critical anatomical areas of the stump

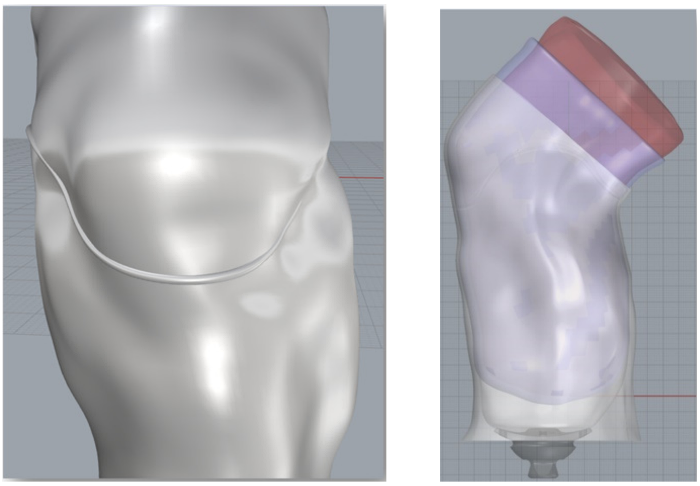


Fig. 16. 3D socket creation

Once the socket has been created digitally, we move on to rapid prototyping of the socket model thanks to which the stylized physical model of the stump is created on which to laminate the test socket with thermoformable sheets. Subsequently, the socket is created directly in 3D thanks to the use of the latest generation printer in long carbon fiber and nylon or through an autoclave lamination process with prepreg fabrics (Fig.9, Fig.10).
Finally, we move on to the validation of the new process with testing of the socket on patients.

4. Results

The new methodology was tested on seven patients with transtibial amputation: the results obtained, and the final considerations can be considered satisfactory. Patients have declared that the socket is more comfortable, and the loads are distributed more uniformly without creating critical areas that generate pain in the stump. Furthermore, the waiting times for the creation of a prosthesis were significantly reduced, maximizing the satisfaction of the patients involved in the study.
Subject characteristics are shown in Table 1. All patients had a medium-high level of mobility, for activities involving strenuous and repetitive actions, with high impact on the prosthesis and for a prosthetic gait that exceeds basic walking capabilities, exhibiting high levels of impact, stress or energy, typical of high-performance and long-use prosthetic requests; therefore, the feedbacks that was received comes from patients with experience in the prostheses world (they have an average of 31 years of using prostheses) and with high expectations for their new socket.

Table 1. Subject Characteristics

Subject No.	Age (years)	Years of amputation	Side of amputation	Weight (Kg)	Height (m)	K-level	Stump length: from sub patellar to the distal end of the stump (mm)
1	52	30	Right	79,5	1.80	4	120
2	52	37	Left	132	1.87	4	140
3	61	54	Right	83	1.83	4	138
3	61	54	Left	83	1.83	4	175
4	58	25	Left	82	1.77	4	180
5	22	5	Left	60	1.78	4	120
6	63	36	Left	70	1.70	3	97
7	63	36	Left	108	1.87	3	144

FEM simulations were used to see the socket-stump interaction in the orthostatic phase and during the gait cycle phases. The pressure imposed in critical anatomical areas for transtibial amputees must be lower than the pain pressure threshold and tolerance values listed in Table 2 to avoid patient problems [20].

Table 2. Pain pressure threshold and tolerance in the critical areas

	Fibula head	Medial condyle	Popliteal depression	Distal area	Patellar tendon
Pain threshold (kPa)	599.6 ± 82.6	555.2 ± 132.2	503.2 ± 134.2	396.3 ± 154.5	919.6 ± 161.7
Pain tolerance (kPa)	789.8 ± 143.0	651.0 ± 111.1	866.6 ± 77.3	547.6 ± 109.1	1158.3 ± 203.2

The introduction of the Gait Analysis report with the acquisition of kinematic and dynamic gait data, as a validation tool for the prosthesis, to be delivered to the physiatrist for testing instead of a declaration from the orthopedic technician, gives objectivity and scientificity to the work performed and allows for optimization in the release of the prosthesis to the patient.
Furthermore, in the new process methodology for the creation of sockets for transtibial amputations are highlighted aspects of product eco-innovation: the process of creating the stump model through

Reverse engineering avoids using plaster bandages to make the cast and plaster to create the positive model, which is then thrown away, reducing the amount of waste generated by an orthopedic workshop. The socket model that was created with rapid prototyping using recycled PLA thread has minimal environmental impact.
The production of the socket in an autoclave allows you to optimize the quantity of materials by going from 10-12 tubular mesh of Nyglass, Perlon and carbon fiber and 400-500 gr of acrylic resin in the traditional infusion process to 3-4 pre-impregnated meshes, used in the autoclave process (30-40%). In this way, the socket turns out to be lighter and more resistant.
The use of machinery with minimal energy consumption (latest generation scanner and MRI) allows significant energy savings and greater production efficiency in the prosthesis manufacturing process, thanks to the reduction in the use of raw materials and energy saving through new and portable machinery.
Furthermore, thanks to the use of prepregs and the autoclave socket production process, the orthopedic technician doesn't create the socket via infusion and is no longer exposed to the risk of inhaling the resins. In this way, the danger of production processes has been reduced to a minimum with the innovative digital design and manufacturing of the socket.
It is found that the new digital methodology for manufacturing prostheses offers a comfortable experience for patients, a friendly and welcoming environment for everyone, creating a workspace full of professionalism, where everyone feels accepted, integrated, valued and safe because they are well looked after and with waiting times shorter than expected.
At last, the acquisition of 3D models of the leg, foot and stump allows the creation of customized parts such as leg cosmetic covers, foot covers and liners for the stump and allows the creation of customized products with new materials and new processes.

5. Conclusions

The new innovative digital methodology can allow significant progress in the prosthetic sector thanks to the use of technologies that have been heavily used for decades in other production sectors and can guarantee the production of better performing sockets for patient's stumps and optimized alignments of the prostheses in order to improve the quality life of amputee patients.
In our study, the main role was played by 3D scanning and processing technologies of the human body by the geometric digital model of the leg stump, which replaces the plaster cast, and forms the basis for a detailed design of the socket with CAD tools and the production of a physical model of the socket with rapid manufacturing techniques.
The aim is to have prostheses which, in addition to aesthetically replacing the missing limb, allow an increase in the mobility of the prosthesis itself. This is possible with the choice of new materials, with a kinematic and dynamic study of the prosthetic components to define their performance and functionality, pursuing the mission of making the technology accessible to users.
Future research, in this way, can increase the fields of application using the same digital methodologies, particularly the use of MRI not only for diagnostic purposes in the medical field, but also for practical purposes in the creation of aids and prostheses for the disabled, since it is considered not harmful to the patient.
From the point of view of existing products, Gait analysis will allow a continuous improvement of product performance and the creation of new products that increasingly reduce the gap with the healthy limb, allowing the monitoring of the patient's health status during the life of the patient device provided, non-existent in traditional orthopedic centers, through gait simulation.
The next objective will be to extend the same innovative digital methodology also to the creation of sockets for transfemoral amputations and for the supply of braces, wheelchairs, orthosis and corsets to disabled/traumatized subjects with particular attention to the possibility of defining new products thanks to the study of new materials, the inclusion of new technologies such as sensors, accessible via APP on a simple smartphone, which in addition to checking the status of the device and the battery charge level, offers access to a functional training program specifically designed for the patient.
We must always remember that technology can be the best ally for people with disabilities so as not to leave anyone behind and knowledge of the latest generation modeling and design software is an indispensable skill in order to guarantee production efficiency, increase the quality of product based on clinical/rehabilitative performance and guarantee a high degree of customization, pursuing growth and continuous learning with the use of technologically advanced equipment.

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