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Digital Human Models of Lower Limb Amputees for Socket Modelling and Simulations: An Overview of Current Technologies, Limitations and Future Possibilities

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Abstract. Discomfort when using lower limb prostheses is still a major problem, leading to limited use of the prostheses and reduced mobility of the patient. The production of the socket is still more or less handcrafted, and modern Computer Aided Engineering (CAE) technologies are rarely used due to the time-consuming and complex process. However, several researchers have already shown that the transfer of Computer-Aided Design and Finite Element Modelling to the practical work of socket and liner design, a better fit socket can be obtained for improved comfort and safety. In Finite Element Modelling, static analysis has been predominant until now, although many previous researchers have suggested that dynamic computer simulations should be used to simulate the socket-limb interaction. This paper aims to present past efforts in Computer Aided Design and simulations of prosthesis socket fit, and to present state-of-the-art technologies. Also presented are the capacity and limits of transient computer simulations. Furthermore, based on the paper review, we want to investigate to what extent this technology is used in everyday prosthetic work. As we can see, the technology for the data-driven design of lower limb prostheses is already available, and provides improved results in comparison to traditional methods. However, CAE and numerical simulations still present too high an effort to benefit ratio.

Keywords. Finite Element Method, Lower Limb Amputees, Prosthetics, Socket Fit

1. Introduction

The loss of limbs is a traumatic event for a person, putting them in a challenging psycho-physical situation. Among all amputations, lower limb amputations due to trauma or disease are the most common. We can divide leg amputation into transfemoral (above the knee) and transtibial (below the knee), the latter being the most common [1]. Prostheses are a replacement for the musculoskeletal system of the leg, which enables the amputee to stand upright and walk. The forces transmitted from the socket to the limb often cause discomfort, skin problems and soft tissue soreness, which can lead to chronic pain. On a monthly average, patients experience three different skin problems such as

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dermatitis, skin oedema, hyperaemia, redness, hygiene problems, etc., which force them to limit the use of the prosthesis [2]. This leads to a poorer quality of life and the inability to integrate normally into social life.

Adequate socket fit and a suitable liner can improve the user experience significantly, and, thus, influence the amputee's mobility and quality of life directly. The evaluation of the prosthesis is still determined by the subjective assessment of the user and Prosthetist, and is not based on an objective scientific method. It is, therefore, difficult for Prosthetists to understand the relationship between the properties of the socket and the comfort of use. In recent years, great effort has been made to describe and understand the mechanical behaviour of the socket and the residual limb – the desire is to describe the behaviour in a quantitative manner [3-6]. The progress is more than obvious, but, due to its subjective nature, the problem is still solved largely in an artisan way, and, therefore, the successful fit depends mainly on Prosthetists` skills and experiences.

Currently, in lower limb prosthetics, in order to distribute pressure more evenly over the amputated limb, mostly, (up to 85%) soft and flexible elastomeric liners are used mainly in combination with a TSB (Total Socket Bearing) socket [7]. In contrast to older foam liners (Pelite) which are attached directly to the socket, usually PTB (Patellar Tendon Bearing) elastomeric liners are donned on the residual limb similar to a sock, creating an intimate interaction due to the sticky properties of the elastomeric material, which is beneficial in terms of limiting relative movement and transferring shear forces between the liner and the limb. According to amputees, the most common problem is a change in volume of the residual limb, which can lead to premature replacement of the liner, or even the socket [8].

In the current socket manufacturing process, the Prosthetist first examines and assesses the condition of the limb. Then a mould (negative) is produced, which is made by the technician by shaping the plaster directly onto the limb. The negative is used to produce a positive mould, which is then reshaped artificially. This step emphasises the practical skills of the Prosthetist, who removes or adds material manually in areas where he or she wants to relieve or burden the limb further. The shape is also adjusted according to the patient's age and lifestyle – younger and more active users generally want a tighter fit than older people and people with sensitive skin [9]. The next step is to shape the thermoplastic material thermally onto a positive mould, in order to obtain a test socket which is later validated by the user. At this stage, certain modifications can still be made to the socket before the final phase begins. Typically, the final socket is made of lightweight composite materials (usually carbon fibre) with a total thickness of approximately 4 mm.

In the first year following the amputation, an average of nine corrections of the socket are required [10]. The development of computer technology and numerical methods has the potential to reduce the number of iterations required to fabricate the final socket and determine the appropriate liner drastically. For several decades, attempts have been made to simulate the interactions between the residual limb, the liner and the socket. The beginnings of the use of the Finite Element Method (FEM) in Prosthetics for the productions of leg prostheses date back to the late eighties of the last century [11]. During this period, a number of numerical models of the residual limb, the liner and the socket were developed, to describe the interaction between them as accurately as possible. The method is suitable, because it provides us with results that are very difficult, in some cases even impossible, to obtain with experimental tests. A good feature of the computer procedure is also the provision of repeatability. Despite all these advantages, the mass use of numerical methods in Prosthetics is still not noticeable.

2. Data-driven process

The proposed data-driven procedures to produce sockets for lower amputees are based on similar basic steps. Instead of using a plaster mould to capture the geometry of the limb, it is proposed to capture the external shape with a 3D scanner and the internal structure with Magnetic Resonance Imaging (MRI) or Computed Tomography (CT) [9, 12, 13]. The acquired data are imported into a computer program that prepares the geometry of the limb automatically, including the corresponding internal structure. At this point, the Prosthetist can use various commands on the virtual model to change the size by adding or removing material in certain areas and, thus, adjusting the shape. Once we have a desired virtual limb with the corresponding socket, an FEM analysis is carried out automatically [9]. The purpose of the analysis is to inform about inner stresses and contact pressure. With the results we can modify the socket further. When we are satisfied with the design, the final socket is produced using additive technologies (3D printer). Newer printers with multiple nozzles enable multi-material printing, which allows us to change the material properties in different areas of the socket gradually [9, 13].

The idea of the described procedure is to reduce the number of iterations by omitting the test socket and producing the final version directly. New additive technologies allow us to print complex shapes from variable materials, creating a flexible socket with perfect fit to the limb. There is currently no standardised procedure which is necessary to introduce a computer-controlled process for manufacturing a socket, although the idea is more than a decade old [12]. The described data-driven process with basic steps is shown in Figure 1.

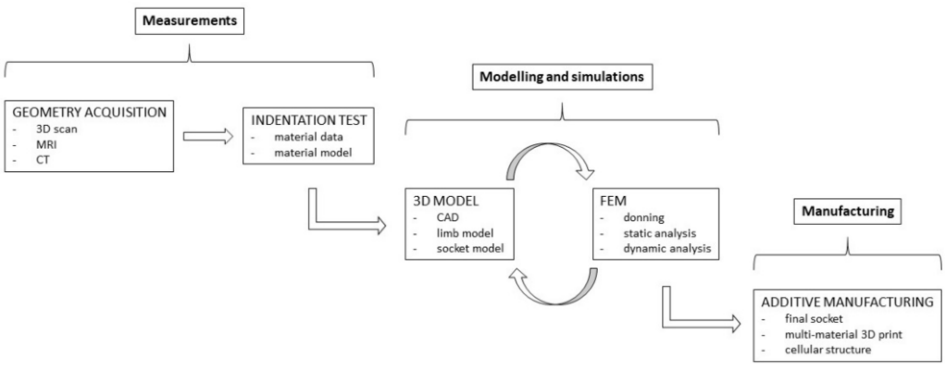

Figure 1. Data-driven process.

2.1. Data acquisition

The first step in a standardised, data-driven prosthesis manufacturing process for a given amputee is to capture the geometry of the limb using either a 3D scanner, MRI or CT. The data obtained from the measurements are converted by software into a single representative 3D model of the limb. For an accurate numerical description we also need material data, which can vary greatly from person to person. One of the proposed methods is to perform an indentation test in vivo on the amputee's limb [6]. An inverse FEM simulation was performed using force, displacement and time from the test, to acquire a material model that describes the mechanical properties of the limb (Ogden 2nd order). Two material models have been developed, one for the description of skin-adipose and one for the description of muscle-soft tissue, including their hyperelastic and viscoelastic properties. Previous research on the material properties of biological tissues has concerned mainly animal tissue [14-16]. Due to the specific nature of biological material, the results of these studies have been difficult to use directly to describe the properties of human tissue.

MRI is used not only to obtain the geometry of the limb and the internal structure, but also to assess the quality of the fit between the plaster and the limb at the time of mould making. Different materials used in the mould can influence the accuracy. An initial study was conducted on this subject [17]. Safari and colleagues in the study tested 7 different materials commonly used to make a mould, and their influence on the accuracy of the results obtained by MRI [18]. The obtained analysis of the 3D geometry showed small deviations, which confirmed the accuracy. The development of an indentation device for non-invasive measurement of soft tissue material properties compatible with an MRI device was described by Moerman et al. [19, 20]. An automatic 3D reconstruction of the limb using MRI images was proposed by Colombo et al. [21]. The procedure consisted of three steps: Image preprocessing, voxel segmentation, 3D model generation. In addition to the MRI, the author also proposed the use of a 3D scanner for the precise acquisition of an external topology [9]. CT would be the best measurement method solely for the automatic generation of a 3D model. However, since CT is an invasive method that is harmful to the patient, MRI is the better choice, which can be used several times without major consequences for the patient. MRI data may also be useful for designing a variable-impedance prosthetic socket for transtibial amputees [22].

In addition to capturing the geometry, experimental measurements of the contact pressure at the stump-socket or liner-stump interface are common, which are carried out with a pressure sensor inserted into the prosthesis [23, 24]. The results of a dynamic or static experiment can be used to validate computer simulations. Dynamic measurements are particularly important because only in this way can a dynamic process such as walking be fully described. Until now, not many researchers have used a motion capture system to simulate the amputees' gait kinematics. However, it is a crucial step to completely record and simulate the entire gait cycle. The motion analysis system was used to compare the piston movement of the transtibial prosthesis socket using two different types of suspension liners [25]. Besides gait simulation, dynamic analysis can also be used to simulate other amputee activities such as cycling [26].

2.2. Modelling and simulations

So far, much has been done in the field of virtual representation and simulation. Computer technology can reduce drastically the time required to produce a prosthesis and ensure a better fit. With the help of FEM, we can predict the stress concentrations and high-pressure areas in the limb that have a negative impact on comfort. This is also the reason for the great interest in computer technology in the prosthetic field since the early days of 3D modelling and computer simulation. Figure 2 shows the results obtained on a generic 3D model of a transtibial limb and the prosthesis by FEM (a) Displacement in the sagittal plane (b) Contact pressure at the socket-liner interface.

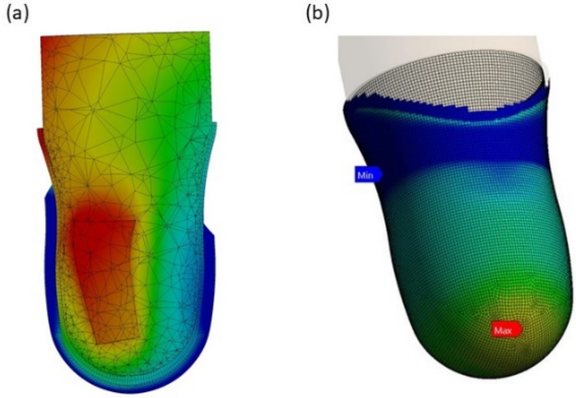

Figure 2. FEM results (a) Displacement (b) Contact pressure.

At first, 2D geometry and simple linear elastic material models were used, which tried to describe the behaviour of the limb. Over time, it became apparent that we need nonlinear material models for an accurate description. In 1999, Fisher and his colleagues took an important step towards reducing stresses and redistributing loads in a prosthesis with polyurethane liner using the nonlinear Finite Element Method [27]. The well-known Mooney-Rivlin material model and the 2D limb geometry were used to simulate the liner. A similar analysis was carried out by Zhang and co-workers, who simulated the donning of a socket [28]. The 3D model predicted pressure, shear stress and slippage between the residual limb and the socket under various loading conditions. In the same year, Zhang compared the numerical model with clinical measurements of interface pressure in a transtibial socket [29]. He proposed the use of nonlinear mechanical properties for soft tissue and dynamic gait simulation. A research team with Fisher updated their 2D model and extended it with a 3D design [30]. Their main purpose, like many others, was to minimise discomfort and pain when using prostheses. In his dissertation, Faustini described the modelling and fabrication of prostheses using the selective laser sintering process [31]. He proposed the use of the above-mentioned process to make the fabrication of complex prosthesis shapes more precise and easier. The same author conducted a study of the quasi-static reaction of a transtibial socket [32]. The problem of hyperthermia in the residual limb when wearing a prosthesis was raised by Peery, who created a 3D numerical model to simulate the temperature in the socket [33]. The analysis was validated by measurements on five amputees. A comparison of different liners for TSB prostheses using FEM was conducted by Wu et al. [34]. As expected, the simulation shows that the contact pressure increases with increasing stiffness of the liner. One of the few who have used explicit dynamic analysis is Lacrox, with which they have simulated the donning of a prosthesis [35]. Rotariu and colleagues developed a numerical model to understand better the interaction between limb, socket and liner [36] – the results show the pressure distribution in the socket. In his dissertation, Cagle provided a detailed analysis of the various liners and a tool to help facilitate the choice between different suppliers [37]. He also proposed a method for measuring the mechanical properties for an objective comparison of the different liners, and made a 3D numerical simulation of three amputees to compare them with limb injuries caused by wearing prostheses. The model had proven to be good, because it predicted the areas where the damage occurred fairly accurately. For future work, he proposed a more robust numerical model that would allow the simulation of the entire gait. Fatone carried out extensive research on transfemoral amputees, with the aim of producing a flexible prosthesis for active users [38]. Moerman and his colleagues took an important step towards automation and standardisation of the prosthesis manufacturing process when they attempted to implement a non-invasive method of geometry acquisition, indentation tests to obtain material data, automatic generation of a given 3D design, the Finite Element Method of a 3D model, and final production with additive technologies [13]. In 2018, an article was published on the use of additive technologies for ankle-foot orthoses using the Finite Element Method [39]. Constitutive material models of biological tissue can also be taken from modelling studies of other body parts, such as a healthy leg [40], where much has already been developed.

To date, not much has been done in the field of transient simulations for leg amputees. The reason for this is the high computing intensity (non-linear behaviour, contacts, complex geometry ...), which requires computing time and advanced computer equipment. A major problem in the calculation of complex nonlinear dynamic load cases is also the achievement of convergence. In order to prepare the dynamic load case accurately, the motion capture experiment should be performed to preserve the amputee's gait kinematics. Jia et. al. used quasi-dynamic and dynamic nonlinear FEM analysis to investigate the mechanics of load transfer between the lower leg prosthesis socket and residual limb [41-43]. They suggested that it is preferable to consider the material inertia effect in a dynamic FE model.

2.3. Additive manufacturing

In contrast to the traditional manufacturing process, where the Prosthetist forms a thermoplastic test socket on the mould, and only later forms the final composite socket, the proposed computer-controlled method uses additive manufacturing to produce the final socket directly. This reduces the number of iterations, and ensures repeatability. With the development of 3D printing, the possibilities for the production of complex shapes have expanded greatly. The range of materials that can be printed has also increased. Additive technologies, combined with a data-driven process, provide an advanced tool that reduces socket manufacturing time.

The advanced idea of multi-material printing enables the production of a socket with graded stiffness. Where the thickness of the soft tissue is the smallest, the material with the lowest stiffness should be used, and vice versa. Doubrovski and colleagues proposed an innovative process for simultaneous 3D printing of multiple materials, based on a voxel-based fabrication rather than the traditional volume-based workflow of 3D printing [44]. They achieved a graded stiffness of the material along the desired areas of the transtibial socket, which is determined by inverse FEM analysis. MRI data of the stump, a 3D scan of the inner surface of the existing well fitted socket and the contact pressure at the limb-socket interface are used, measured with custom made sensors in the unloaded state. In addition to the fabrication of the graded socket, they also propose the production of built-in sensors using multi-material printing. 3D-printed capacitive elastomer sensors for measuring pressure and shear loads at the limb-socket interface have been proposed by Laszczak et al. [45]. The results showed that the sensors were capable of measuring both compressive and shear stresses up to 380 kPa and 80 kPa respectively. The separation of loads into compressive and shear stresses is particularly promising for understanding the behaviour within the stump. A similar use of additive technology is also used for amputees of the upper extremity [46]. As part of this research, they used a 3D printer to produce a socket for an amputated arm and a silicone cast for the rest of the arm. The geometry of the arm was obtained with a CT device. The study is a successful presentation of advanced computer-controlled procedures (CT imaging, CAD, 3D printing and silicone casting). The additive technologies are also used in Orthotics for the production of leg splints. The paper describes the performance of a 3D printed splint using FEM [39].

3. Discussion and conclusions

3.1. Discussion

The presented computer-controlled processes show great potential for a faster, more cost-effective, more accurate and repeatable socket manufacturing process. The results provide the predicted stresses within the stump and the contact pressure at the limb-socket interface. Hereby, we can determine objectively the sensitive areas that will help us design the socket. Mainly static analyses are used, which are simpler, but only describe one loading situation. Since walking is a highly dynamic process, more attention must be paid to transient numerical simulations that describe the entire gait. To validate the transient simulation, it is necessary to capture and describe the movement with motion capture systems. The transition from time-independent to dynamic analysis is crucial for a more accurate description of the entire gait and the conditions within the residual limb. In addition to the gait cycle, dynamic analysis can also be used to analyse the donning of a socket where a pre-stress condition occurs in the stump.

The final step of the computer-controlled process is the production of the socket. Due to the above listed advantages, 3D printing is currently the most efficient technology for the final production of the socket. Additive manufacturing opens up new possibilities for designing complex shapes, such as cellular structures. Such structures enable us to control the properties by changing the porosity, gradation and shape, so that, with the right design, we can improve the comfort of the prosthesis significantly. One of these structures is the well-known gyroid structure. Figure 3 shows (a) The schematic σ-ε diagram of this structure, and (b) A visual representation of the gyroid model with Gaussian curvature. The advantage of such a structure is a plateau that follows the linear elasticity. This plateau provides deformation at the point where the critical load is exceeded. With the correct design of the cell structure we can adjust the plateau according to the position in the socket. This helps to distribute the pressure over a larger area while maintaining stability.

Research on porous structures fabricated with additive technologies yields promising results, which are also of interest for use in Biomechanics and Prosthetics [47-49]. The main advantages are the lightweight structure, good vibration damping and the possibility of a continuously graded design. The aim of the graded structure is to adjust the stiffness over the socket as required. In practice, we find the use of such structures for the liners of bicycle helmets [50]. In the paper they test the applicability of a 3D printed structure made of TPU material.

The idea of the data-driven process is more than 10 years old and the required technologies are already at a high level, but we still have to overcome difficult obstacles. The question is, why do we not see such a process in practice yet? There are several reasons for that. The first is the expensive equipment we need, which represents a major initial investment. We need an MRI or a CT machine to capture the geometry, suitable

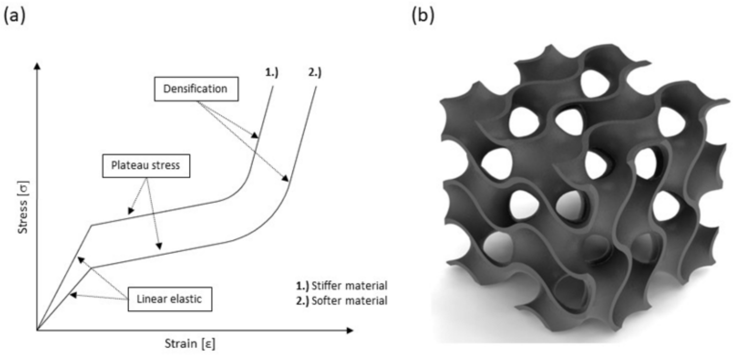

Figure 3. Gyroid structure (a) Schematic σ-ε diagram (b) Virtual model.

software and hardware to perform FEM, and a high-quality 3D printer for production. In addition to the expensive hardware, the limitation is also the current software, which does not yet provide a sufficiently fast and automated procedure that would be easy enough for the Prosthetist to use.

Despite the large initial investment, the cost of fabricating a prosthesis using the data-driven process is reduced significantly over a longer period of time, due to the reduction of iterations. Although the computer procedure requires more time in the initial phase, this time is compensated for by the reduction, or even elimination, of corrections. However, the data-driven process should be more cost and time efficient, and it is only a matter of time before the traditional process will become obsolete. Before this happens, it is necessary to introduce a standard procedure that guarantees the quality of the work. In addition to the procedure, the development of new materials and structures, such as cell structures, will also contribute to the comfort of using a leg prosthesis.

3.2. Conclusions

Currently, the use of advanced procedures in prosthesis design is mainly useful for research purposes to design new materials and structures. FEM is very useful for simulating internal stresses, which is difficult, if not impossible, with experimental testing. The development of additive technologies allows multi-material printing and, thus, graded stiffness. This step can improve the comfort of the prosthesis significantly during the time of use, as, so far, only the shape of the socket has been adjusted to fit the stump. The flexible socket is also more favourable in terms of changing the stump volume, which varies both daily and over a longer period. Furthermore, various mechanical properties of the socket can also be ensured by the cellular structure. For a data-driven socket manufacturing process, it is also necessary to develop and adapt software that enables easy use for Prosthetists. Before the advantage of these ideas can be confirmed, several experiments have to be performed, including the users who can best evaluate the effectiveness of the new socket.

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