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THE PARAMETERS THAT INFLUENCE THE EFFECTIVE FIT OF A TRANSTIBIAL PROSTHESIS: STATE-OF-THE-ART REVIEW

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Abstract. *To ensure mobility and stability for patients who have partial lower limb amputation, the load transmission between the patient's residual limb and the prosthetic socket must be optimally adjusted. The lack of a customized fit can lead to numerous health problems for the patient, as well as compromising the rehabilitation and functionality that the prosthetic process offers. In addition, the fitting of the prosthesis is one of the items responsible for the high rejection of its use by users. In this context, the article addresses a review from the identification of design parameters and relevant characteristics in the literature, in order to identify ways to reduce the impact and rejection generated by the transtibial prosthetic socket and promote a better fit of the it. The state of the art has focused on pre-protection procedures, protetization design, manufacturing process and monitoring. Through this study it was possible to identify how each process since the amputation to use the prosthesis is relevant to ensure a good fit and consequently re-establish the amputee's mobility.*

Keywords: *Transtibial Prosthesis, Socket, Prosthesis Fitting.*

1. INTRODUCTION

Amputation may become necessary in cases of congenital diseases, peripheral vascular diseases, trauma, and malignancies (Ribas *et al.*, 2015). It is estimated that in the United States currently, over 1.5 million people are living with limb amputation, and the prediction for the next three decades is that this number will more than double, lower limb amputation accounts for 87% of the total number of procedures performed (Arun and Kanagaraj, 2016, Keszler *et al.*, 2019). The term lower limbs refer to the limbs present in the foot to hip extension, in which lower limb amputation can be performed along these joints (Pires and Sandoval, 2010).

The choice of the ideal level of amputation is fundamental to ensure decreased mortality, avoid reamputation, and reduced mobility of the patient (Czerniecki *et al.*, 2017). According to Domingues (2016), amputation performed while maintaining a considerable distance from the joints is able to ensure greater comfort for the patient in the use and removal of the prosthesis, in addition to reducing effort during gait. Different levels of amputation result in different conditions of the soft tissue of the residual limb, which impacts the mechanical conditions of the prosthesis since the size of the stump directly interferes with the control of the stump/socket interface (Cavaco *et al.*, 2016, Matsumura *et al.*, 2013).

Among lower limb amputations, transtibial amputation is the most recurrent, according to Matsumura *et al.* (2013), is performed at a ratio of 2:1 compared to transfemoral amputation. Because it involves limb removal, amputation is a limiting procedure for the patient, affects locomotion (Arun and Kanagaraj, 2016), and causes pain in the residual limb and phantom limb (Cavaco *et al.*, 2016, Keszler *et al.*, 2019). The process of protetization ensures the restoration of the patient's mobility, but for successful rehabilitation, constant care of the residual limb is required since surgery (Chen *et al.*, 2016, Czerniecki *et al.*, 2017, Pires and Sandoval, 2010, Ribas *et al.*, 2015.).

Prostheses are devices that replace the amputated body part and are designed to provide stability and mobility, and through adjustments support load transmission between the stump and the socket (Chen *et al.*, 2016, Dickinson *et al.*, 2017, Lenz *et al.*, 2018). The contact of the residual limb with the prosthesis socket can cause numerous skin damages, which becomes an aggravating factor in the patient's rehabilitation (Ali *et al.*, 2012, Mak *et al.*, 2001, Rajtukova *et al.*, 2014). The ideal adjustment of the prosthesis fitting is essential to maintain comfort and avoid the complications mentioned above, the pain and sores from the maladjustment of the fitting cause part of the patients to abandon the rehabilitation process in the prosthetic phase (Dickinson *et al.*, 2017, Sewell *et al.*, 2012). This adjustment is performed

from some physical parameters such as pressure, friction, and temperature, considering the characteristics and particularities of each patient (Arun and Kanagaraj, 2016, Chen *et al.*, 2016, Laszczak *et al.*, 2016, Lenz *et al.*, 2018, Li *et al.*, 2015, Mak *et al.*, 2001, McLean *et al.*, 2019). In their study, Sewell *et al.* (2012) cite that about a quarter of amputee patients are unable to make regular use of the prosthesis, compromising rehabilitation, because of discomfort (29%), excessive pain (25%), and the device not fitting (12%). The limiting factors presented can be avoided through periodic monitoring and adjustments of the stump/socket interface; a well-designed socket restores mobility and ensures patient satisfaction (Laszczak *et al.*, 2015).

In view of the above, this article presents a state of art on the parameters that influence an effective fitting of the socket on the stump of a transtibial prosthesis. For this, it was analyzed how the surgical procedure, the socket design, the manufacturing process, and the monitoring of prosthesis use impact the quality and acceptance of the socket. The physical indicators that affect user acceptance, the type of material used, the type of prosthesis, and the computational methods employed were considered as design issues. It is expected to provide relevant information for the development of socket designs as well as to point out the challenges for better user acceptance.

2. METHODOLOGY

The base of articles used to write this document was selected from the search on the Science Direct and Google Academic platforms, using as keywords: 'Socket Upper Limb'; 'Residual Limb'; 'Prosthetic Socket'; and 'Prosthesis Fitting'. From the results obtained, the selection criteria were articles that presented studies focused on lower limb amputations, especially transtibial amputations, and that analyzed the impacts of prosthesis use on the residual limb. In addition, articles that were referenced in the selected papers and had very specific information on devices or methods related to prosthetic fitting were included.

The state of the art analyzed relevant factors for the best fit of the prosthesis considering the process from the surgical stage to the use of the transtibial prosthesis, as shown in Figure 1. Therefore, information about the influence of the surgical procedure (section 3), the design (section 4), the manufacturing processes (section 5), and the monitoring (section 6) were evaluated.

3. PRE-PROTECTION PROCEDURES

Amputations that avoid the joints promote less effort during gait, ensure greater comfort and reduce the number of prosthesis components, which reduces the final cost of the device (Domingues, 2016). Consequently, one has a higher incidence of transtibial amputations compared to transfemoral amputations, since the preservation of the knee joint is of utmost importance to exert gait (Matsumura *et al.*, 2013, Rajtukova *et al.*, 2014).

Czerniecki *et al.* (2017) developed the AMPREDICT-Mobility tool that is able to determine the best level of amputation considering the physical characteristics of the patient, which makes it possible to have an idea of the type of mobility that the patient will achieve before the procedure. The results obtained showed that besides chronic diseases, advanced age and a history of mental illness are also factoring that contribute to decreasing the patient's chances of rehabilitation. On the other hand, patients in good socioeconomic conditions have higher chances of achieving mobility, which demonstrates the importance of analysis beyond the physical parameters of the amputee to restore locomotion (Czerniecki *et al.*, 2017).

The condition of the stump is crucial to start the process of prothetization, due to the fragility of the soft tissue and complex format of the residual limb, numerous skin complications can occur, the presence of these complications prevent the patient from using the prosthesis, which hinders its manufacture, and thus delays the habilitation (Laszczak *et al.*, 2015).

After the surgical procedure to remove the limb, the bandaging technique is performed soon after the stitches are removed. Compressing the residual limb with an elastic band reduces edema, prevents venous complications, models and prepares the stump for prothetization, and alleviates discomfort and pain in the phantom limb. With a healthy residual limb in good condition, the prothetization process is started through gait training, the evolution of the treatment is carried out through the observation of the stump volume parameters, which determines the start of the prothetization, and in the post-prosthetic period, the change from provisional to the definitive prosthesis (Matsumura *et al.*, 2013).

4. PROTHETIZATION DESIGN

A prosthetic process that ensures optimal socket fit ensures the functionality of the prosthesis, a well-designed socket provides quality of life and lower maintenance cost to the patient (Aydin and Okur, 2018). In this section, the steps for making a functional socket are presented.

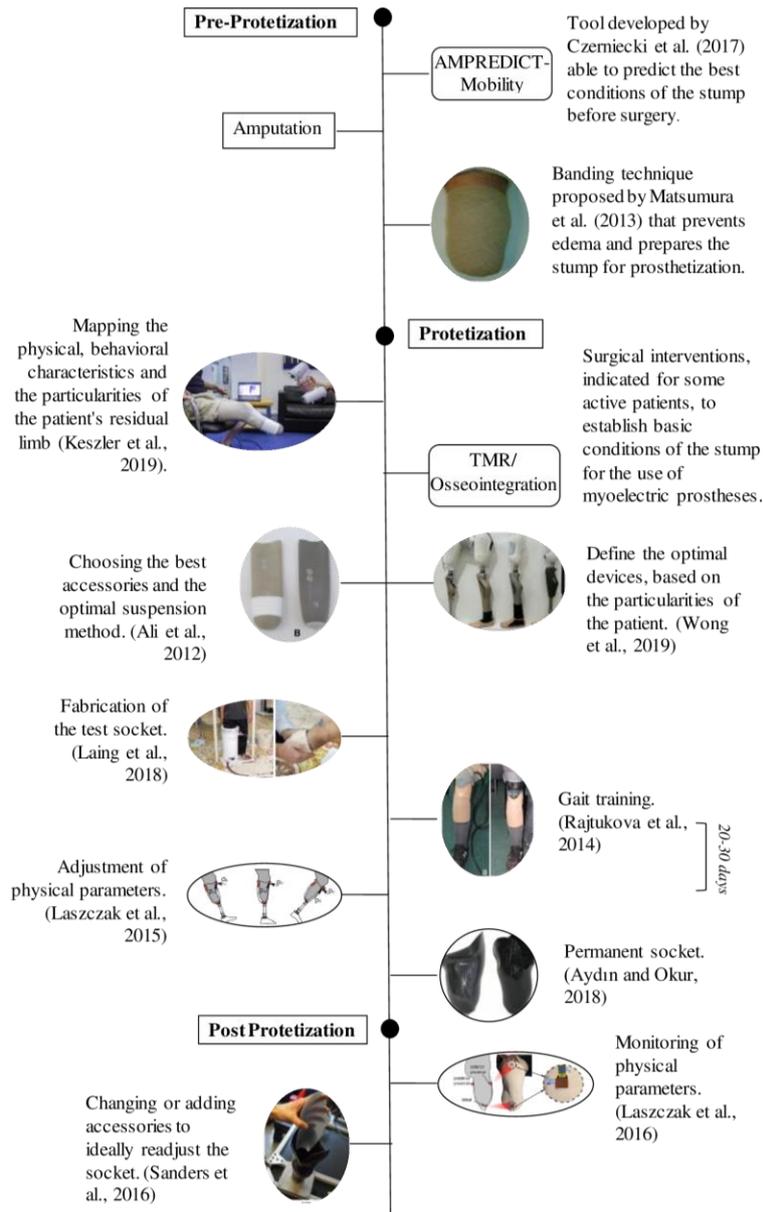


Figure 1. Factors relevant to achieving an optimal socket fit.

4.1 Physical Parameters

The fitting interface is the part of the prosthesis that has direct contact with the residual limb, because of this its quality has a great impact on the patient's gait comfort and rehabilitation (Aydın and Okur, 2018). It is through mapping and controlling physical parameters such as pressure, temperature, friction (Arun and Kanagaraj, 2016), and detachment (Lenz *et al.*, 2008), that the quality and safety of the fitting will be ensured.

When reestablishing their daily activities, the lower limb amputee is faced with the fact that the skin of the stump and the underlying tissues are not used to withstanding the load and pressure of the prosthesis. It is estimated that a pressure applied to the residual limb around 8 kPa is sufficient to cause ischemia in the tissue (Laszczak *et al.*, 2015). This can result in the emergence of some skin complications such as rashes, ulcers, irritations, and allergies on the residual limb (Ali *et al.*, 2012, Ali *et al.*, 2013, Arun and Kanagaraj, 2016, Cavaco *et al.*, 2016, Laszczak *et al.*, 2015).

Follicular hyperkeratosis, allergic contact dermatitis, infections, veridical hyperplasia, and degenerative tissue ulcer are complications attributed to the constant pressure peaks applied to the stump, which are due

to poor pressure distribution in the prosthesis. According to Laszczak *et al.* (2015), with the use of a transtibial prosthesis, the amputee's residual limb is exposed to normal and tangential stresses at the frontal and posterior upper points and at the base of the socket. The factors presented make monitoring the pressure at these points a determining parameter to ensure the quality of the device since pain and discomfort from skin problems are conditions that cause patients to stop using the prosthesis (Ali *et al.*, 2012, Ali *et al.*, 2013).

Complications related to the appearance of blisters, calluses, abrasions, and pain in the gait movement of lower limb amputees are attributed to friction and the transfer of soft tissue load due to the direct contact of the prosthesis interface with the stump (Arun and Kanagaraj, 2016, Cavaco *et al.*, 2016). With amputation, muscles and soft tissues, and depending on the level of the procedure even some bones, undergo changes due to the shear and transverse compression that these regions are not used to experiencing. The emergence of these skin complications in the amputee's fitting phase can delay the rehabilitation process since it would be necessary to suspend the use of the prosthesis until the tissue recovers (Li *et al.*, 2015). Which makes the correct fit essential to avoid dermatological complications and ensure the patient's mobility and quality of life (Dickinson *et al.*, 2017, Li *et al.*, 2015). Thus, analyzing the linear friction coefficient is an important step to obtain improvements in the materials that make up the prostheses (Arun and Kanagaraj, 2016, Cavaco *et al.*, 2016).

With limb amputation, the individual faces several body changes, including the way his/her body temperature starts to be distributed since the body surface area becomes smaller. Thus, the heat starts to dissipate in a different way, which may cause excessive sweating in the amputated limb (Klute *et al.*, 2007). When performing the necessary movements to establish the gait with the use of the prosthesis, the patient who suffers the amputation of the lower limb, due to perspiration and prolonged contact with the socket material, may face an increase in temperature and discomfort in the residual limb. This increase in temperature, and consequently moisture, is responsible for causing complications due to maceration and bacteria proliferation on the skin (Arun and Kanagaraj, 2016, Cavaco *et al.*, 2016, Dickinson *et al.*, 2017, Huff *et al.*, 2008, Klute *et al.*, 2007). Moisture present at the socket interface from perspiration is also a factor responsible for producing low coefficients of friction, however, in optimal amounts, it can protect the stump from tissue damage by reducing sustainable threshold stresses (Dickinson *et al.*, 2017). Motivated by the lack of sockets that optimize thermal properties, Webber and Davis (2015) created a prototype socket with a cooling channel between its layers, the socket showed a temperature difference in its internal wall compared to the control socket made of the same materials and methods, but without the cooling channel, which indicates potential for development and clinical application and improvements for future work.

Finally, there is the parameter related to volume. In Larsen *et al.* (2019), through an adjustable socket, the changes of fluid volume in the residual member are analyzed. After tests done in the laboratory and in the field, it was noted that the volume of the fluid had a behavior directly proportional to the adjustments of the socket, in the increase of the size of the socket the fluids increased, and with the decrease of the size, the fluids decreased. Assuming that during walking there are greater variations in fluid volume, and those socket size adjustments are able to recover the stump volume without impairing gait, Sanders *et al.* (2019) implemented an automated adjustment system. McLean *et al.* (2019) based on the socket implemented by Sanders *et al.* (2019) investigates what range of adjustment volume is acceptable by users, and statements about the behavior of fluid volumes in the residual limb and whether the parameter is amenable to control. The participants of the study were active people, and with a good time of prosthesis use, this is an important point to analyze the results with caution for generalization, since during the studies presented, we realize that the trends for amputee patients are very personal.

Therefore, due to the large number of complications attributed to pressure, friction, temperature, and displacement, monitoring and adjusting these parameters are extremely important to achieve a well-designed die/socket interface. Identifying the pressure points allows for a more assertive choice of socket shape and suspension method, as well as defining the best friction coefficient and temperature facilitates the choice of material types, and identifying displacement determines the best accessories for the interface.

4.2 Type of prosthesis

Lower limb prostheses generally consist of a socket that may have a liner or interface, a suspension method, and an ankle-foot assembly. The foot-ankle assembly is the base that sustains the impacts during ambulation. Wolf *et al.* (2009) tested how the use of a Proprio-Foot™ foot prosthesis by Össur (Reykjavik, Iceland), which adapts the ankle angle using a microprocessor-controlled stepper motor, influences the control of socket pressures when ascending/ descending stairs and ramps. Components with such functionality are indicated for young and very active patients because they demand greater biomechanics from the patients. The results of the research showed that the adaptability in the ankle was able to distribute

the pressures on the stump more evenly. The stem is the component that connects the foot-ankle assembly to the socket portion and is responsible for transmitting the user's weight to the base of the structure (foot). The socket is the component of the prosthesis that has direct contact with the stump, also known as a residual limb, it is through it that the forces and moments that make it possible to exercise the gait are transmitted, its suspension can be made by a pin, belt, straps or knee pad and it is this that prevents the prosthesis from disengaging from the residual limb during ambulation (Wong *et al.*, 2019).

Myoelectric prostheses were introduced in the market in the '60s, and work through an external power supply and motor control. For many users, controlling this type of prosthesis is still a challenge, because it is not intuitive and the response time between the user's command and the device's action is slow. Since its creation there have been no significant changes in its system until recently, the Coapt control system (Chicago, IL), cited by Keszler *et al.* (2019), works through a matrix containing 8 electrodes and is able to recognize the muscle patterns of the users and with that instead of the user adapting to the system, the system adapts to the muscle patterns of the patient to perform the control of the prosthesis.

To make use of this type of prosthesis some patients undergo procedures such as Targeted muscle reinnervation (TMR), which consists of transferring nerves to muscles that have lost their functions and are performed to ensure more intuitive control of myoelectric prostheses and reduce pain in the residual limb and phantom limb (Pet *et al.*, 2016). And the Osseointegration procedure, which consists of an implant attached within the bone axis of the stump through an adjacent percutaneous junction, and is able to establish greater comfort and lower energy expenditure in the use of the prosthetic fitting (Tsikandylakis *et al.*, 2014). Both procedures are indicated in specific cases, although they are surgical interventions with the aim of establishing a good condition of the stump and subsequently basic mobility, there are risks and conditions to be considered (Keszler *et al.*, 2019).

4.3 Materials

Due to the chemical compounds in prostheses, the stump injuries can arise in previously healthy tissue, so finding the optimal materials for each patient becomes an important step in the amputee's rehabilitation process (Dickinson *et al.*, 2017). Given the above and due to the sensitive skin of the stump, socket liners play an important role in preventing the aforementioned skin complications. Polyethylene foam with prosthetic patellar tendon support has been used since 1950. In the mid-1990s materials with superior performance to polyethylene, silicone, and other elastomers were introduced to the market (Ali *et al.*, 2012). Plastics and rubbers, composed of polyester resins, epoxies, thermoplastics, elastomers, and foams, have been commonly used in the manufacture of prostheses, replacing materials such as leather, wood, and metals that were used in the early days of production. The properties present in plastics and rubber are able to provide greater comfort to patients, by allowing a better distribution of forces and being lighter, offering better suspension and cushioning (Ali *et al.*, 2012, Arun and Kanagaraj, 2016, Domingues, 2016, Keszler *et al.*, 2019).

In transistibial amputations, it is common to use softer sockets or use liners and prosthetic socks in order to improve prosthesis comfort and cushioning (Keszler *et al.*, 2019, Wong *et al.*, 2019). Liners are gel interfaces that have soft and flexible properties. Cavaco *et al.* (2016) analyzed the friction of three commercial interface types: block copolymer, silicone gel, and silicone elastomer; in the different test cases, silicone elastomer obtained the highest coefficient of friction, while silicone gel obtained the lowest and block copolymer had an intermediate coefficient of friction. Each material is recommended according to the mobility of each patient, for active patients the block copolymer and silicone gel are recommended; and the interfaces produced by silicone elastomer are recommended for patients with more limited mobility, where comfort is the priority, geriatric, diabetic, and sensitive patients. From the results presented it is possible to understand that the ideal friction coefficient is relative and particular for each patient, the choice of the best material needs to consider the physical and mobility characteristics of each amputee.

The adherence of the liner to the skin creates isolation that can become harmful due to the accumulation of heat, which consequently increases the temperature and humidity and causes the adherence to be damaged, compromising the suspension of the prosthesis. In order to solve this problem, the Courtesy of Endolite (Miamisburg, OH) developed a liner with small perforations in its extension, which works for the escape of moisture from the liner, but ends up requiring a greater and more careful cleaning, since the perforations make it more prone to accumulation of dirt and bacteria proliferation (Keszler *et al.*, 2019).

In their study, Arun and Kanagaraj (2016) proposed the reinforcement of MWCNTs (Multi-walled carbon nanotubes) to the epoxy matrix aiming to improve its mechanical properties, found that in addition to the expected improvement the MWCNT was able to slow down the thermal degradation of the epoxy. This ended up bringing stability in temperature, and consequently, the reduction of heat accumulation in the residual member and improvement in the thermal conductivity of the epoxy. The reinforcement, besides decreasing the amputee's metabolic cost, increases the prosthesis comfort and quality.

4.4 Computational Analysis

CAD/CAM technology has been used in the manufacture of prosthetic sockets for some decades. Its use, through the digitization of the die, allows the design of the socket with the aid of specific programs for the improvement of the design. Consequently, it is possible to make the socket through the direct manufacturing technique. The main advantages of 3D manufacturing process with CAD/CAM technology are the speed with which the equipment is manufactured, the possibility of changing it quickly and efficiently, and the maintenance of records (Sanders *et al.*, 2016).

The review by Dickinson *et al.* (2017) of the use of Finite Element Analysis to monitor the amputee's residual limb shows us the potential of the method to decrease costs during prosthetics, enabling a more assertive choice of materials and devices. This is possible once the analysis allows visualizing the effects of modifications and properties of the fitting materials, liners, alignment, residual limb geometry, mechanical and friction properties on the distribution of stresses over the stump; predicting deformations, tissue stress, and movement of the stump/socket interface. The accuracy of the method may be compromised, as cited in Zhang and Roberts (2000) and Lee *et al.* (2004), by the fact that the prosthesis socket does not have anatomy identical to that of the residual limb, which makes a detailed knowledge of the soft tissue necessary for better pressure distribution, and although the results are very promising, and there is a considerable time interval between publications, this is still a factor that hinders the modeling and simulation of the interface contact with the presence of friction/slip.

Through computational analysis, it is possible to obtain precise notions of the residual member's characteristics, which ensures that sockets can be made with quality, speed, and efficiency. Advances in this field have a high potential to improve the way sockets are made, providing high quality and low cost.

5. MANUFACTURING PROCESSES

The manufacturing process determines the pressure points and the way the load will be distributed in the socket, the success of this step directly influences the satisfaction and continuity of the prosthesis use. In this section, the conventional processes of lamination and PCAST will be addressed, and the most current process of additive manufacturing through 3D printing.

The lamination is a process used to manufacture the patellar tendon bearing sockets (PTB), which are sockets designed so that the loads are supported by areas that tolerate the applied pressures. It is also used in the manufacture of the carbon fiber socket, carbon fibers are widely used because of their elasticity, resistance to stress, and compatibility with the plastics present in the prosthesis composition. The process is used to make permanent prostheses since the manufacturing method does not allow changes and adjustments (Aydin and Okur, 2018, Domingues, 2016).

Liners can present a significant cost for low-income users. In this case, the pressure molding process (PCAST) becomes an alternative. This process is based on the principles of Pascal's law of fluid dynamics, in which the socket is made from a plaster mold pressurized with water. In PCAST, assuming that the pressure at one point will be transferred to other accommodated flexible tissues, the biomechanics of the socket is not defined for the dynamic forces exerted in each phase of the gait. Because it has a cavity very close to the residual limb, PCAST fitting depends directly on the contact condition of the stump with the socket to ensure mechanical rigidity and elastic coupling. With this, the dynamic forces applied by the gait phases and the stump volume changes for the day are responsible for hydrostatic instability and the need for prosthesis readjustment (Laing *et al.*, 2018). As portrayed by Goh *et al.* (2003), due to its production process, the shape of the hydrostatic socket differs from conventional sockets such as the PTB, for example. In other words, the PCAST has a flush cavity in the patellar tendon area and at the back of the cavity, which does not occur in PTB sockets that have the cavity indented at these points.

In the most recent paper published by Laing *et al.* (2018), patients who participated in the study had some different gait time parameters than with the use of PTB sockets. In the swing phase, both the intact and prosthetic limbs showed an increase in stay time. In the support phase, the dwell time decreased for the intact limb, and in the support phase, the time increased for the prosthetic limb. Using the PCAST socket the biggest cause of discomfort reported by the research participants, was on the premise that because it was a harder material than what they were used to, and with slower gait take-up, the socket would hurt them. The researchers believe that this mistrust is due to the fact that the patients are used to sockets that provide rotational stability since other than the times of some gait phases, there were no major differences to be scored.

The use of toxic material, the need for skilled labor, and the need for vast physical space to manufacture the components are some disadvantages present in conventional manufacturing processes. In this context, additive manufacturing (AM) has been gaining prominence in recent years. Keszler *et al.* (2019) state that

three-dimensional (3D) printing and scanning comes as one of the main technologies with the potential to develop quality prostheses covering the disadvantages of current processes, by providing greater safety, automation, and practicality in the production process. The use of this technique for the manufacture of customized prostheses on a large scale considerably reduces the manufacturing time of prostheses and consequently the unit cost of the same. In research conducted by Chen *et al.* (2016) it was possible to state that with the use of MA, sockets with greater comfort than conventional ones were obtained. In addition, it was possible to make a socket in 3.5h, and although the material has a lower tensile strength than those used in common manufactures, it was able to withstand the static loads applied in the cyclic test of 250,000 cycles. As a result, it was possible to decrease the contact pressure by making a prosthesis made from reconstructed MRI stiffness mapping of the residual limb, due to the socket being designed so that the contact points with more compliant tissues rest against a harder material. However, the lack of a specific clinical interface means that despite the advantages the system is not adapted for the manufacture of prostheses. Moreover, according to Keszler *et al.* (2019), points such as durability, and the quality of the mapping of the residual limb, taking into account the characteristics present in the adjacent tissues, are points that need to be improved to consolidate the use of 3D technology in the market.

6. MONITORING

In order to predict the need for socket change without discomfort and complications in the user's residual limb, Sanders *et al.* (2017) sought to identify and quantify acceptable socket measurements for transtibial amputees. In this way, the replacement of the equipment could be performed based on quantitative evidence rather than subjective evidence as is currently done. The anterior canal and anterior-distal regions are good parameters to measure the need for socket change because their fluid volume suffers visible effects when using oversized and well-fitting sockets. It is expected that because of the loosened mechanical coupling between the limb and socket, the use of oversized sockets puts greater stress on the distal anterior canal than a well-fitting socket.

The movement in which the prosthesis is presented in a vertical manner in relation to the stump is called a piston. Aiming to ease the discomfort of the movement, liners are used between the skin and the prosthetic device; however, their use can lead to tissue degradation of the residual limb due to high friction during gait. Because of this factor, understanding the displacement of the liner in relation to the prosthesis and the skin becomes relevant for the patient's health. In this study, Lenz *et al.* (2018) develop a quantitative method to assess this displacement in patients with transtibial amputation. The tests with a replica of the residual limb in plaster, presented the effectiveness of the capture system, which has great potential for clinical use, despite some limitations of the markers in motion and with the use of the liner. The system is able to indicate the region's most prone to skin complication formations through the captured displacement data.

The monitoring of physical parameters during the Protetization process ensures that the fit is the most appropriate in the permanent socket, and the monitoring of the permanent socket assists the replacement or addition of accessories capable of improving wear conditions before serious complications arise. Sensors for temperature, displacement, pressure, and those capable of identifying the stresses applied to the die are employed at this stage.

Klute *et al.* (2007) proposed a device to measure the thermal conductivity of prosthesis liners and fitting materials, and through their study concluded that the higher the thermal conductivity of the material, the greater the chances of decreasing the temperature in the residual limb while wearing the prosthesis. In the liner materials analyzed, the variation in thermal conductivity was more significant for decreasing or increasing the temperature in the residual limb when compared to the fitting materials. Huff *et al.* (2008) describe a temperature meter that makes use of 16 low-frequency thermistors, positioning the thermistors on the anterior and posterior extremities of the residual limb, found that in the initial resting phase of gait the temperatures vary according to the area, on the skin surfaces close to the bone regions the temperatures were lower than in the regions of large muscle masses. Domingues (2016) cites some pressure sensors and some of their characteristics. And identifying that the sensors present in the market so far made a measurement only at the socket interface, were composed of rigid materials that hindered the direct use at the interface and had complex manufacturing methods. Laszczak *et al.* (2015) proposed a sensor that was practical and capable of measuring pressure and shear clinically and simultaneously.

The pressure was the most recurrent analyzed physical parameter. Rajtukova *et al.* (2014) used the TACTILUS pressure sensor, with a measurement range of 0 to 97.19kPa, to map the pressures present in the residual limb of transtibial amputees. The sensor allows each pressure area to be evaluated simultaneously and separately, and from the measurement results, it was possible to identify that the pressures at the liner/socket interface obtained lower values and without great extremes, compared to the pressures at the stump/liner interface. This trend is able to prove the efficacy of the liner use through the reduction of impaction and better pressure distribution observed. Being exposed to an excessive and poorly

distributed pressure compromises the entire prosthesis setting since the temperature and friction parameters depend directly on the pressure being set to be adjusted.

The displacement parameter recently cited by Henrikson *et al.* (2018) who used low-profile sensors attached to adjustable sockets via cable panels to identify the relative displacements between the stump and the socket, is one that is proving increasingly relevant since fluctuating stump volume during the day makes it difficult to remove or place the prosthesis.

The shear stress present in the sockets in tangential directions is a factor that can be as damaging to the residual limb tissue as the applied pressure. Therefore, identifying the shear stresses that the die is exposed to should be considered in order to decrease the risk of tissue breakdown. The monitoring systems present in the market do not take the parameter into account, the proposal of the sensor suggested and developed by Laszczak *et al.* (2015) is to obtain the pressures and shear stress simultaneously. And based on the sensor was developed the monitoring system treated in Laszczak *et al.* (2016). Operated by battery and the communication made through the Bluetooth™ system, the sensor presents optimal applicability without compromising the mobility of patients. Through the results presented in the study, it could be stated that the sensor presents good linearity, which results in good resolutions for the post-signal processing, and consequently a more simplified reading and ease in calibrating the equipment.

The inserts are an alternative used to adjust sockets with clearance, through custom inserts it is possible to improve the coupling and stability between the residual member and the socket without the need to replace it, Sanders *et al.* (2016) proposed the use of CAD/CAM technology for manufacturing inserts, the technology proved promising, with very positive short-term results. The material used for 3D printing does not have great bending strength, but because the mechanical load is transferred and supported by the socket structure, it ended up not being an issue for the insert's performance. Based on the technique of making inserts using 3D printing technology by Sanders *et al.* (2016), Swanson *et al.* (2018) developed an instrumented insert with sensors on the inner surface and below the surface, in addition to the already known benefits, the instrumented insert becomes an excellent solution for coupling sensors at the socket interface, with the wires and sensors inside the insert to a decrease in distortion and skin irritation.

6.1 Artificial Intelligence

Until 2012, the only commercial system on the market capable of measuring the pressure distribution in the residual limb was the Tekscan®, which presented significant deviation errors when the patient used liners. That was when Sewell *et al.* (2012) proposed the use of artificial intelligence to identify the pressures present at the stump/socket interface, through an inverse analysis of the problem. The results proved the accuracy of the technique for measurement in both static and gait phase patients. Besides being possible to analyze the pressures in each step of ambulation. Despite the good results, the method has its disadvantages, such as cost and increased time due to the need for several training and testing patterns and reconfiguration after modifications in the socket, for example.

Mathur *et al.* (2016) on the other hand, used neural network modeling to predict the temperature of the residual limb with the use of the prosthesis. The method consists of a supervised learning algorithm capable of predicting future values based on historical trends. The database is random so that the output of the controller is not random, the use of ANFIS or the Gauss model guarantees more accuracy and reliability, making the data output more adaptive and pertinent to reality.

7. CHALLENGES

This article presented a state of art on the parameters that influence an effective fitting of the socket on the stump of a transtibial prosthesis. It was possible to identify and characterize the main parameters of the stump/socket interface that directly impact the quality of life of lower limb amputees. It is noticeable from the literature that the improvement of prostheses follows the development of technologies related to materials, manufacturing processes, communication, software, and tools.

Technologies aimed at monitoring the parameters mentioned above are essential for the advancement of manufacturing prostheses of the lower limb that are increasingly more comfortable and adaptable to its user. The ideal adjustment of the parameters is extremely important in the role of reintegrating the mobility of amputee patients. Therefore, the knowledge of the interference and of the areas of greatest impact on the residual limb helps to reduce complications and to maintain comfort and health. The study of lower limb prostheses is a field that still allows a lot of research and improvement, and to be able to identify and characterize the particularities of each patient in a fast, safe and efficient way is still a challenge.

8. CONCLUSION

Through the review of articles, it was possible to identify and characterize the main parameters of the stump/socket interface that directly impact the quality of life of lower limb amputees. It is noticeable from the literature that the improvement of prostheses follows the development of technologies related to materials, manufacturing processes, communication, software, and tools.

Technologies aimed at monitoring the parameters mentioned above are essential for the advancement of manufacturing prostheses of the lower limb that are increasingly more comfortable and adaptable to its user. The ideal adjustment of the parameters is extremely important in the role of reintegrating the mobility of amputee patients. Therefore, the knowledge of the interference and of the areas of greatest impact on the residual limb helps to reduce complications and to maintain comfort and health.

The study of lower limb prostheses is a field that still allows a lot of research and improvement, and to be able to identify and characterize the particularities of each patient in a fast, safe and efficient way is still a challenge.

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