THE PRODUCTION OF HYBRID PROSTHETIC SOCKETS THROUGH THE INTEGRATION OF 3D PRINTING AND CONVENTIONAL LAMINATION

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Abstract

Currently, due to the relatively high number of active users with amputation of the lower limbs, it is important to increase user comfort, innovate and optimize the connection between the residual limb and the prosthesis, i.e. the prosthetic socket. The purpose of this work is to combine the potential and advantages of both conventional and innovative (modern) production processes for the design and fabrication of personalized hybrid sockets to optimize production, comfort, and patient safety. The socket was designed and constructed for a highly active user (Functional Classification Level 4) to ensure comfort and safety during high-stress sports activities (skiing). Unlike traditional plastering, a 3D scanner was used to take measurement data. The 3D model of the stump was edited in a software environment instead of laborious and lengthy processing of the plaster positive. Subsequently, a matrix of the prosthetic socket was made from PETG material using FFF 3D printing, which was laminated to increase strength. 3D printed samples of PETG material were tested for tension and pressure according to the relevant standard (EN ISO 527-2: 1996). The last phase was static and dynamic testing of the hybrid socket. No deviations were recorded in the monitored parameters, both at a slow (1.0 km/h) and at a standard (2.5 km/h) walking speed. Once the socket integrity has been assessed, a greater dynamic load was initiated in the form of activities with higher dynamic levels (lateral leaning on the knee and jumps). According to the test results, there has been no change in the shape or integrity of the socket, and the subjective point of view of the volunteer rated the hybrid prosthetic socket as comfortable.

Keywords

hybrid socket, below knee prosthesis, fused filament fabrication, lamination

Introduction

The traditional production of prosthetic sockets using the lamination method is still the most common and the most popular technique. A standard production of a prosthetic socket places high demands on the skills and experience of the CPO (Certified Prosthetist Orthotist) [1], as well as on material consumption and environmental safety, complexity, and laborious production. One of the negative aspects of conventional production is the duration of the development process. There are two main implications of this fact. The first is the required production time, which is long and unpredictable, and the second is the psychological impact on users. Since it takes several days to create and test a wearable socket, a subsequent visit to the orthopaedic-prosthetic workplace is necessary.

The modern approach includes the possibility of collecting measurements using 3D scanning, modifying the model in CAD (Computer Aided Design) software, and producing the models using additive technology [2, 3]. Even though additive manufacturing has been used for a few decades, the professionally produced sockets have still not been accepted by the public. It is possible that factors such as quality, uncertainty, the strength of the socket [3, 4] and issues with manufacturing and the technology used might be responsible for this [5]. Despite this, extensive testing is still necessary to verify the comfort and suitability of 3D printed prosthetic sockets [3–5]. Evidence regarding the resistance of prosthetic sockets [6] is limited and the mechanical properties of the resulting device [6, 7] are affected by a variety of factors (type of material, manufacturing technology, machine settings, etc.).

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Several 3D printed lower limb sockets have failed to function properly [5, 6]. In a study by Rogers et al. [5] the socket failed due to incorrectly set printing parameters for the selected material. In a study by Campbell et al. [6] 3D printed sockets cracked under cyclic stress in the medial popliteal region (seven of nine sockets) and in the lateral mid socket region. Due to the low number of tested sockets, they were unable to determine the cause of their failure. They stated that the error may be in the infill density of the 3D printed sockets. Kim et al. [8] document that failure mainly occurs at the distal end of the socket, around the pin-lock holes or the pyramid attachment.

The objective of this work is to combine the potential and advantages of both conventional and innovative (modern) production processes for the design and fabrication of personalized hybrid socket to optimize the production, comfort, and patient safety and to improve and verify additively manufactured sockets, as they have an increased risk of failure and destruction.

Materials and Methods

The pilot study involved an amputated 45-year-old male volunteer. His right leg was amputated below the knee. This condition is the result of a secondary amputation planned after a cancer diagnosis. The actual state is that the shape of his stump is conical without significant scarring, the skin is slightly hardened in places of stress, but painless, and the distal end tolerates the stress. The subject reports no pain in the shin area and tolerates the device he´s using. A lower limb prosthesis with a PTK (Patellar Tendon Kegel – a socket principle is application of higher pressure on load-bearing areas, relief of sensitive areas and load transfer via the patellar tendon) socket and a pin lock attachment system is being used by the subject. The user is included in the Functional Classification Level 4 and his weight is 65 kg. He is an active skier who demands a secure mechanical grip to his socket. The subject can walk outside without any assistance and has no other serious illnesses.

The participant received information on risks and benefits and signed a consent form before being admitted to the study. This study was accepted by the Ethical committee of Technical University of Košice and the protocols followed all ethical standards.

Data acquisition, socket design, and fabrication

With the subject in a sitting position, a 3D scan of the patient's residual limb with a liner was performed, along with orientation marks, using the 3D Sense II scanner (IT3D, Sagunt, Spain). Technical parameters were set as follow: Image depth: 640×480 px (w×h), Maximum image performance: 30 fps, Resolution x/y at 0.5 m: 0.9 mm, Depth resolution at 0.5 m: 1 mm. The Fusion 360 (Autodesk, Inc., San Rafael, CA, USA) software was used for the socket design. The edge of the designed socket passes horizontally through the middle of the patella and continues proximally to the sides. On the medial side, the edge runs above the area of the supracondylar suspension, marked on the scan. On the lateral side, the course of the edge is symmetrical. The medial and lateral edges meet on the dorsal surface of the positive. The horizontal line of the edge on the dorsal surface is located at the level of the middle of the patellar tendon at 5° flexion in the knee joint. The popliteal area forms the back wall of the triangular profile of the socket, which was subsequently modelled into a plane. Soft tissue modification begins below the medial tibial condyle and ends approximately 20 mm from the distal end of the residual limb. Approximately 2 mm of mass was removed on the medial side of the tibia, specifically from the tibial roughness to an area approximately 15 mm from the tibial end. The area below the lateral tibial condyle and the area 15 mm from the distal end of the tibia were also modified. The body of the fibula was modified just below the head, 15 mm from its end. The depth of the modification is greatest in the centre with a longitudinal concave shape. About 4 mm of mass was added to the head of the fibula. The next step was to add 3 mm of mass to the area 15 mm from the end of the residual limb, and the relief areas of the distal end of the residual limb and the distal end of the tibia were connected. Finally, holes were created to relieve the front edge and condyles of the tibia and the distal end of the fibula, which will be additionally filled with silicone during lamination. Consequently, space was created to accommodate part of the pin-lock mechanism, according to the user's requirements.

Final prosthetic socket model was 3D printed on the German RepRap X400 (German RepRap GmbH, Feldkirchen, Germany) FFF (Fused Filament Fabrication) 3D printer. The model was manufactured with a wall thickness of 1.8 mm (Fig. 1) and the printing parameters were set as follows: 0.2 mm layer height, 0.8 mm wall shell thickness, 90% model infill density. The PETG (Polyethylene Terephthalate Glycol) (Devil Design Sp.J. Mikolów, Poland) material has been chosen for the hybrid socket production.

Dog-bone type 5A samples were printed from PETG for mechanical testing. Modeling and testing were carried out according to the relevant standard EN ISO 527-2: 1996. The samples were produced on the same printer as the final socket with the same print parameters. The tensile and compressive test was carried out on the Inspekt table blue 5 machine (Hegewald & Peschke, Nossen, Germany). The tested samples were placed vertically during the printing process, because when using FDM printing technology the standard orientation of the socket is vertical. After printing, the socket was filled with plaster and prepared for one-layer lamination. To minimize the possibility of the socket failure, a matrix made by FFF technology is laminated

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by saturating special fabrics with resin to form a surface layer. This layer increases the socket's strength, shortens production time, and decreases the amount of material used. Two-component silicone was injected into the holes created for the remission zones (Fig. 1) and two layers of carbon fabric were applied locally and afterwards, the socket was delaminated with one layer of UPR (Unsaturated Polyester Resin) material. The final thickness of the socket after lamination was about 2.3 mm. Finally, the plaster was removed and finished, and a pin-lock was attached at the distal end (Fig. 1).

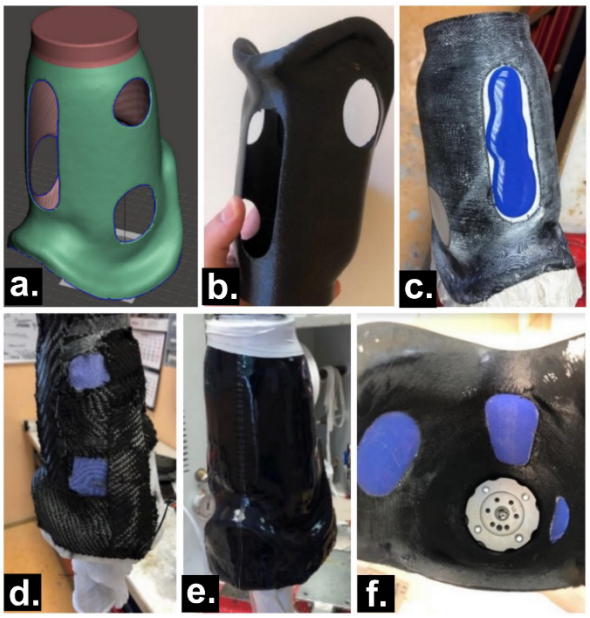

Fig. 1: Hybrid socket: a. digital model of prosthetic socket, b. socket made by FFF technology (PETG 1.8 mm), c. filling holes on the positive with silicone, d. preparation of PETG socket for lamination—application of the carbon fibre, e. laminated socket and f. inside of the final hybrid socket with the silicone remission zones and a pin lock adapter.

A pre-knee prosthesis attached by a pin-lock suspension system was used to evaluate whether the manufactured hybrid socket could be applicable. To prevent the user from being injured, the socket alignment and testing were performed on safety bars. All tests were performed under the supervision of a CPO, and the process has been visually evaluated. The user tested the socket by simulating movement on a mediolateral load, which is critical for example during skiing especially in the supracondylar areas, where failure usually occurs (Fig. 2).

In the static alignment examination, equal load was applied on both the prosthetic limb and the residual limb. When asked to symmetrically load both limbs, the subject distributed his weight in the proportion of 49% on the prosthesis and 51% on the healthy limb. After the 50:50% correction, he did not experience any change in stability or discomfort. Afterward, the prosthesis was tested for static loads by standing on the prosthetic limb with the entire body weight. After this, a dynamic alignment test was conducted that evaluates knee stability in a mediolateral direction, knee flexion/extension when impacted on the heel, stride length symmetry, stride width, and any gait deviations.

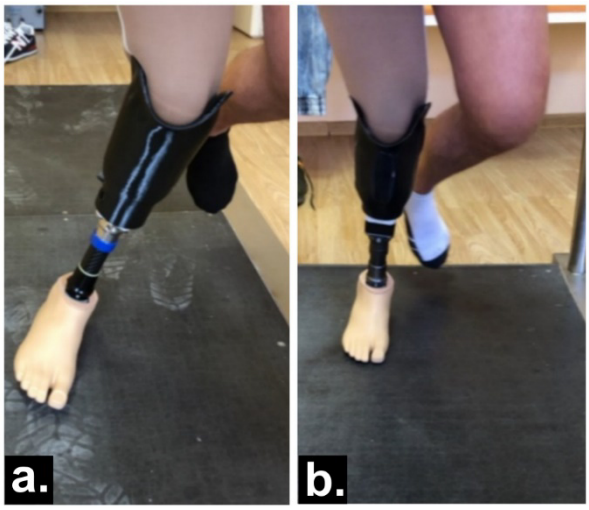

Fig. 2: Testing of the hybrid socket: a. Force applied in the supracondylar area—lateral leaning on the knee, b. vertical dynamic load—jump.

Results

The results of the mechanical tests of the 3D printed PETG samples are: the average tension stress is 49.84 MPa and compressive stress is 44.68 MPa. Based on these results it was evaluated that the material is suitable for prosthetic socket development.

No deviations were recorded in the monitored parameters of the static alignment examination, both at a slow (1.0 km/h) and at a standard (2.5 km/h) walking speed. Once the socket integrity has been assessed, a greater dynamic load was initiated in the form of activities with higher dynamic levels (lateral leaning on the knee and jumps).

Unlike the socket made by the FFF technology, which was not sufficient for an active patient and failed in the supracondylar area, the hybrid socket remained intact (failing or its integrity being affected) even under full vertical and horizontal loads.

The patient rated the socket as more comfortable than the socket he uses normally (traditional manufacturing). Particularly the flexible prominent zones received positive ratings from him. Quality inspection was performed after the user test. The hybrid socket was thoroughly inspected visually and physically, and no changes were noted in its shape or integrity. As a result, the layers of the 3D printed socket were not separated.

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Discussion and Conclusion

In this article, we introduce a newly developed transtibial prosthetic socket, which is made of the additively manufactured PETG matrix with an outer layer of UPR. The combination of the FFF technology and the lamination ensures the adhesion between the individual layers, which can be critical. The main benefit of this method is that it saves time and physical work in positive processing phase. The PETG material used in the production of the hybrid socket is compatible with the human body and has good chemical resistance and transparency. According to Moreno Nieto et al. [9] the water absorption rate of PETG is around 0.15%. The material with a density of 1.27 g/cm^3 shows a low water absorption index of 0.16% along with good mechanical properties. Based on data from the material sheet, the absorption rate is 0.12–0.20%. Based on the given data, the rate of hygroscopicity is low and does not affect the stability of the socket.

Due to the introduction of new technologies in production, it is necessary to design new testing methodologies, which can then be included in the currently valid standards.

In the following steps of the study, it is also appropriate to conduct a FEM analysis of the load of the socket, as well as a simulation of the distribution of the load during selected movements regarding the subject's sport activity. Since this study is focused only on pilot testing of the socket, monitoring of the socket will continue during normal daily activities and long-term impact of this prosthesis on the patient. Subsequently, if it meets all requirements, the hybrid socket will be tested during sport activities. The next step will be to equip more subjects with a hybrid socket, followed by their comments on the selected parameters of the socket, such as comfort, accuracy of the socket's design, secure attachment to the socket, etc.

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