MECHANICAL ANALYSIS OF THE NEWLY DEVELOPED 3D PRINTED PROSTHETIC SOCKET FROM PA12GB

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This paper is focused on the complex evaluation of the prosthetic socket (of a hand) manufactured by the usage of additive technologies. Main advantage of this method is a significantly shorter production time and lower production cost. The durability of the socket is generally between 12 and 24 months. It is caused by the atrophy of the patient's tissues and also by the mechanical loading during the usage. The laminating of the carbon fibers on the model of the internal socket is used nowadays. This method is technologically and time demanding. The newly developed production process is using the 3D printing method by the HP MultiJet Fusion 4200 printer. The considered material is HP PA12GB. It is the thermoplastic material (polyamide) with 40% of glass beads. Production of the socket is reduced to few hours. This paper consists the mechanical comparison of the laminated (old design) and the 3D printed (new design) socket. The real mechanical testing is simulating the most critical loading by impact to the edge of the table. The evaluation in terms of durability and fatigue is performed also using the software nCode and Siemens NX.

KEYWORDS

Prosthesis, socket, limb, 3D print, fatigue, FEM

1 INTRODUCTION

The upper limb prosthetics are generally produced the similar way like sockets for a lower residual limb. In the first step a negative mold of the limb is created. Consequently a positive model is done based on the negative mold. From that point, the way of the production is a little bit different to a production of lower socket. In case of the upper limb prosthetic, the final prosthetic consists of an inner socket and an outer socket in the one body.

The inner socket made of soft thermoplastic material is formed on the positive model of the residual limb. [O' Connor 2018] In this moment, the creating of the outer socket starts. The shape of the outer socket subjects to three requirements. The largest possible area of a contact with the inner socket is required as well as a proper shape of wings fixing the prosthetic through epicondyles on the residual limb. A length and a curvature of the socket specifics the position of the hand. The third requirement is a volume of outer socket that would be corresponding to the second arm. [Hsu 2013]

This generally used process is time consuming and usage of new progressive methods (like additive manufacturing) can lead to minimizing delivery time and costs. The modification of the socket during the CAD modeling is easier comparing to the laminating method.

1.1 Strength requirements

The strength of the upper limb prosthetic is mostly defined by the user. The limb prosthetics could be used only for “cosmetic reasons”, where the strength is not so an important parameter, through daily activities, to very specific hard load usages as sport activities and hard works. Unfortunately, no standards and specifications for the design of the prosthetics exist. Every limb socket is individually constructed with the knowledge of the patient’s requirement and with the experience of the prosthetics. [Paterno 2018] [Saqib 2018]

1.2 Description of the selected 3D printitng technology

Additive technology called Multi Jet Fusion (MJF) was used for 3D printing. This technology belongs to the category of production processes of the Material Jetting type. Compared to other techniques, this type of additive production technology offers the advantages of high productivity and relatively low cost per unit volume (in terms of energy and material consumption). One of the biggest advantages of this technology is that there is no need to create auxiliary structures in the form of supports for fixing the printed part.

The MJF technology is characterized by the use of a binder in the form of a fixing agent, which is selectively blasted onto the surface of the applied layer. To increase heat absorption (allowing the material to coalesce in the desired area) by radiation, the fixing agents contain co-solvents and surfactants which contribute to the desired wettability and thermal behaviour of the material. [Kroczek 2022]

Polymer powders are used as the basic building material for material production processes, which consist mainly of polycrystalline thermoplastics (e.g. polyamides, polyethylene or polypropylene) and also include amorphous thermoplastics (e.g. polycarbonate or polystyrene) and last but not least thermoplastic elastomers.

The advantages of this modern technology include:

•High geometric freedom and the possibility of producing components with very complex shapes

•Integration of multiple components into one unit (into one CAD model

•Production of components tailored to the customer, e.g. from a 3D scan (prosthetic aids)

•Efficient use of material from economical and ecological point of view

•Use of hybrid / multimaterial structures (in this case PA 12 with glass particles)

•Material recyclability

2 THE PRODUCTION WORKLFLOW WITH THE USAGE OF ADDITIVE MANUFACTURING

The use of AM for a production of a prosthetic brings two main challenges. Digitalization of a shape of a residual limb (3D scanning) and a creating prosthetic with construction convenient for patient’s requirements as well as requirements of AM.

2.1 Scanning

Firstly, the model from the flexible plastic material (the future inner socket) and the part of the model made of foam are prepared by a prosthetist. Then two scans are done. In the first step, the whole scanned model consisted of the flexible part and the part of the foam. In the second step, only the flexible part (the inner socket) is separately scanned. The scanning was performed by the device Zeiss Prismo 7.

Finally, both scans were aligned according to one coordinate system in the software Geomagic Design X.

2.2 Remodelling

Siemens NX was used as a CAD software for the remodeling of the 3D scan. The obtained facet geometries from 3D scanning were repaired and cleaned up from failed facets. Then the geometry has been smoothed and re-meshed. The two separate scans allow the creation of a bigger contact area with an inner socket inside of the outer one. This inner geometry of the outer socket is almost impossible to create by standard lamination. Images of the CAD geometry for each step of the production are obvious in the schematically diagram of workflow shown below (Fig.1). The final design was developed with prosthetic producers, lattice structures and results from topological optimization were not considered in this case (research in this field was performed with producer and patient).

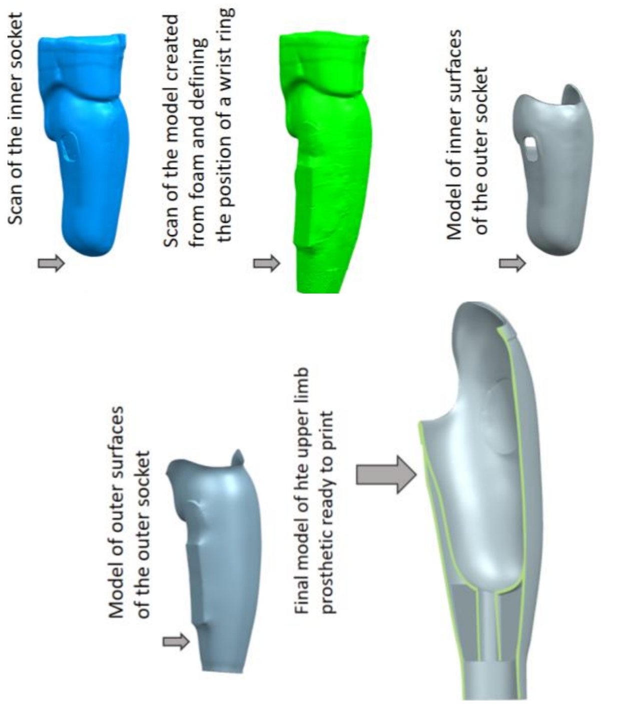

Figure 1. Workflow of the socket design

3 TESTING AND PROPERTIES ANALYSIS OF 3D PRINTED PROSTHETIC SOCKET

The procedure can be divided into some individual design steps. These steps are: scanning of the residual limb, smoothing the STL file from scan, volumetric reductions, design changes (implementation of interfaces, etc.), additive manufacturing and final surface coloring. [Steer 2019], This process is deeply described in previous paragraph. This process can last less than one week (with respect to the complexity and functions of the prosthesis). [McGarry 2008] [Bruns 2019]

3.1 Testing and evaluation

Each new product has to be tested and evaluated for the further usage. This step has to be performed before first usage of the prosthesis. In the further text are described some virtual and real testing methods. [Ranganath 2021]

3.2 Material properties of PA12GB

The used powder material in the HP MultiJet Fusion 4200 printer is a 40 % glass beads filled polyamide 12 with a high reusability (up to 70 %). Exact material properties are shown in the Fig 2.

Powder melting point (DSC)	186 °C
Particle size	58 µm
Bulk density of powder	0.48 g/cm^3
Density of parts	1.30 g/cm^3
Tensile strength, max load, XY	30 MPa
Tensile strength, max load, Z	30 MPa
Tensile modulus, XY	2800 MPa
Tensile modulus, XY	2900 MPa
Elongation at break, XY	6.5 %
Elongation at break, Z	6.5 %
Izod impact notched (@ 3.2 mm, 23°C), XYZ	2.7 KJ/m^2
Poisson's ratio	0.4
Heat deflection temperature (@ 0.45 MPa), Z	173 °C
Heat deflection temperature (@ 1.82 MPa), Z	121 °C
Refresh ratio for stable performance	0,3

Figure 2. Material properties of the HP PA12GB material [HP 2022]

4 FINITE ELEMENT ANALYSIS- FATIGUE

The finite element analysis (FEA) was performed with a software Siemens NX and NX Nastran. The CAD model of the outer prosthetic (see Fig. 3) was not simplified for the purpose of the structural analysis, because its geometry reminiscent of a textile sleeve texture could act as a stress concentrator. The FEA was focused on an evaluation of stress caused by the deformation while the socket is taking on an upper residual limb. While the residual limb is putted in, the wings of the socket go to the opposite directions. The considered deformation is 5 mm. The structural analysis results are used for a durability computation. [Raz 2021]

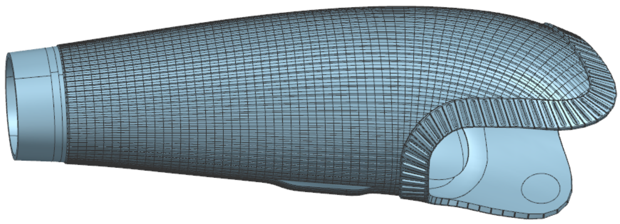

Figure 3. CAD model of the outer upper limb prosthetics

The CAD model was meshed with use of 3D tetrahedral elements. An overview of mesh parameters is shown in the following Fig. 4.

Element Type	CTETRA(10)
Element Size	1.4 mm
Surface Maximum Growth Rate	1.3
Midnode Method	Mixed
Jacobian	10

Figure 4. FEM mesh parameters

Young's modulus 2850 MPa and Poisson's ratio 0.4 were set up in the linear structural analyses. A slight anisotropy (less than 10%- caused by the printing technology and printing process) of the printed PA12GB was neglected.

In the following Fig. 5 are shown boundary conditions, where the load is specified by the forced deformation 0.5 mm of the wings in the opposite directions. The deformation is applied to selected surfaces by usage of the 1D connection with master node (element type RBE 3 – rigid body element).

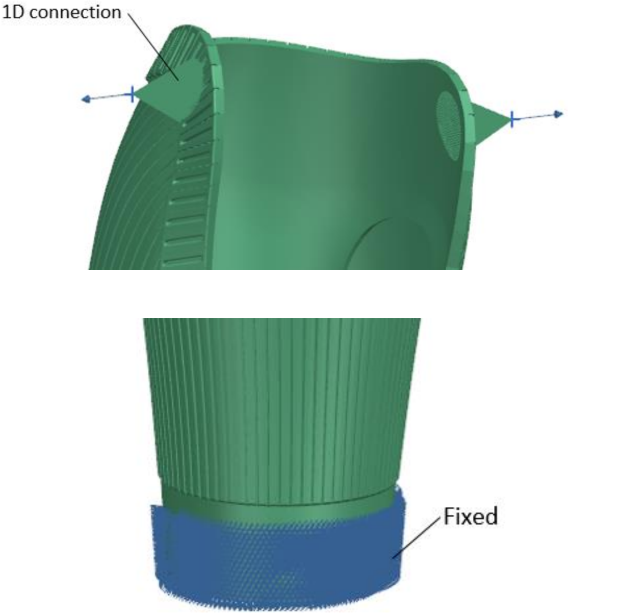

Figure 5. FEM boundary condition (1D connection with enforced displacement (upper) and fixing of the model (lower)

4.1 *Fatigue analysis*

The software nCode was used for the fatigue analysis. The fitting of the prosthetics was used as the critical loading scenario. The maximal loading is caused by opening the prosthetics by 5 mm during putting it on the residual limb. The stress distribution (solved by the Siemens Nastran solver in the previous step) is used as an input for the nCode software (with knowledge of the S-N curve of the used material). Result of this analysis is maximal number of "putting on and putting out" procedure, before rupture of the prosthetics.

This socket has to operate correctly minimally 4 years. When considering 2 cycles per day, is the minimal durability required around 3000 cycles (see Fig 6.).

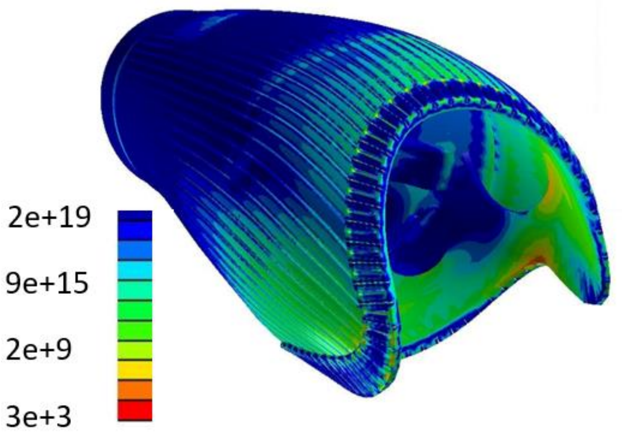

Figure 6. Results from the fatigue analysis [number of cycles]

The linear damage rule was applied in the calculation of durability. The generic bilinear SN curve was used for the fatigue life calculation. There was used the Haibach modification of the sloped part of the S-N curve. [Haibach 1970]

The minimal number of durability was achieved with the safety factor 7. The socket is theoretically able to withstand approximately 28 years of daily usage. This value is not possible to achieve with respect to atrophy of patient´s tissue (limiting factor for change of the socket).

5 TESTING OF MECHANICAL PROPERTIES AND COMPARING WITH REGULAR PROTHESIS WITH LAMINATED STRUCTURE

Main aim of this research was to compare the 3D printed prosthetics with the laminated one in terms of stiffness and maximal loading. The mechanical test is simulating the impact of the prosthetics on the edge of the table. Important parameter, which has to be mentioned is the weight of each design. The laminated structure (original solution) has 143 g, the 3D printed one has 318 g. This weight increasing is not problem and it is caused by different material properties.

5.1 *3D printed prosthetics*

The 3D printed part (Fig. 7) was able to be fully loaded up to 100 kg. After this force occurred the rupture. This test is not considering the inner soft socket and the residual limb, which also able to transfer some loading.

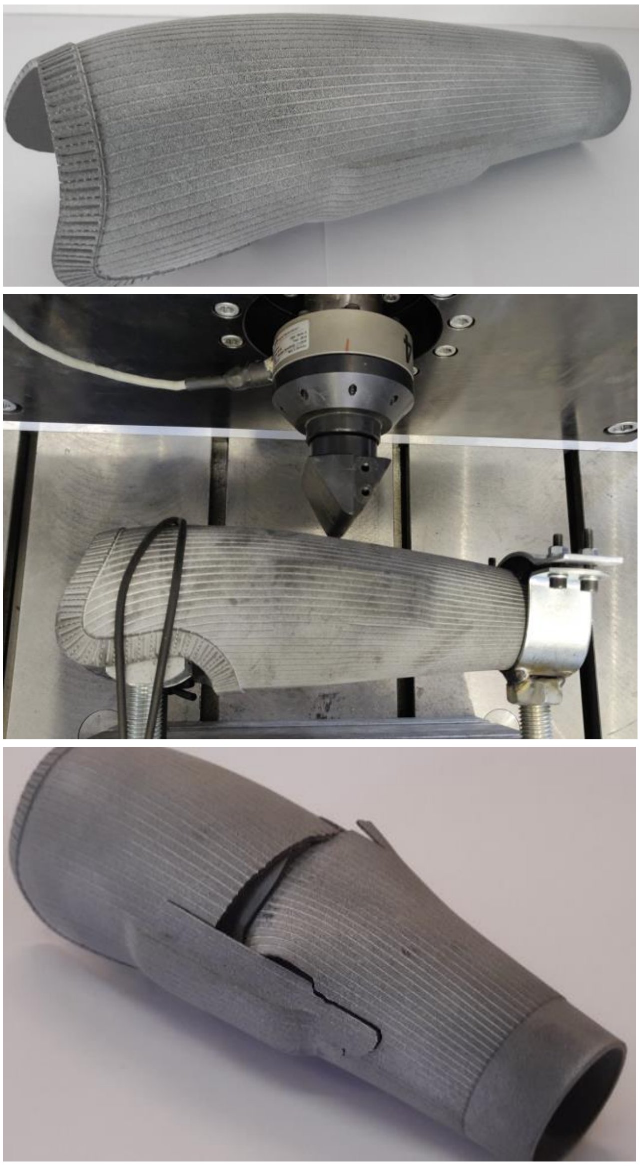

Figure 7. 3D printed prosthetics before testing (upper), during testing (middle) and after testing (lower)

5.2 *Laminated prosthetics*

The laminated part (Fig. 8 and 9) was able to be fully loaded up to 100 kg (same as the 3D printed part). After this force occurred the rupture. This test is not considering the inner soft socket and the residual limb, which also able to transfer some loading.

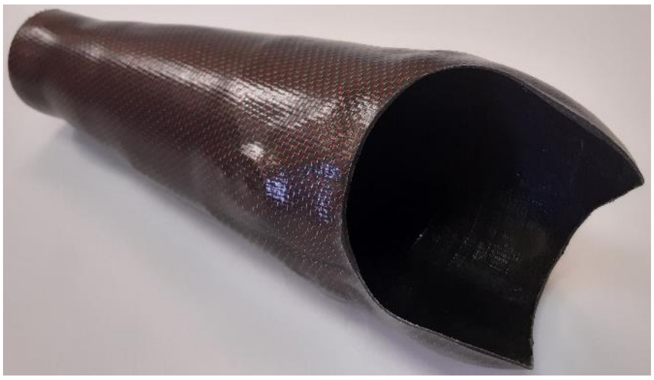

Figure 8. Laminated prosthetics

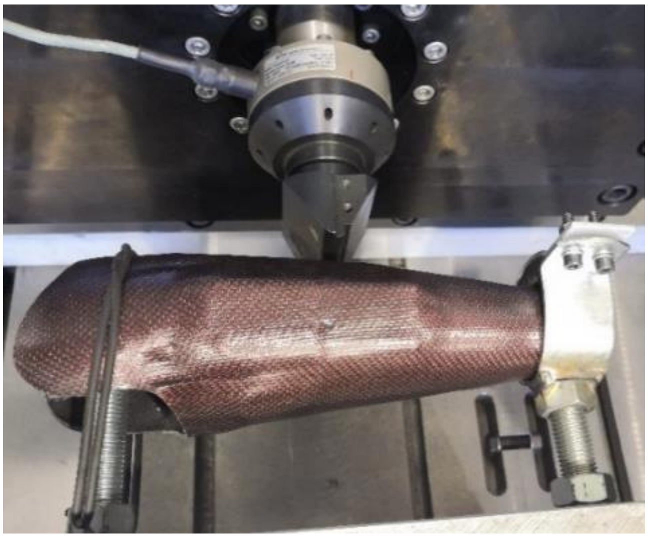

Figure 9. Laminated prosthetics during testing

5.3 *Comparing of results*

It is obvious that both designs have the comparable stiffness and strength limit (as shown in the following Fig. 10). It is obvious, that deformation 25 mm will be hardly achieved during operation from the anatomical point of view. The safety factor of these sockets is sufficient.

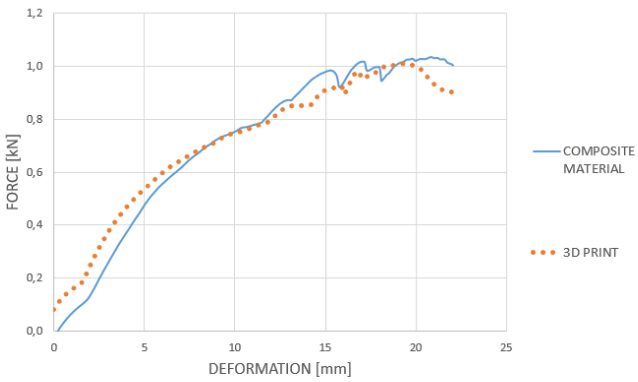

Figure 10. Comparing of results

6 CONCLUSION

This paper is summarizing the approach of usage the non-conventional additive technology for production of the prosthesis of upper arm. The comparison between the laminated design (used nowadays) and the 3D printed design shows the same mechanical properties (strength limit and stiffness). The 3D printed design is approximately twice heavier comparing to the laminated one. This is not problem with respect to the patient (the difference is about 175g). The 3D printed prothesis is cheaper from economical point of view.

The future work will be focused on the usage of various materials, such as PA11 and PA12 without glass. There will be performed the testing with patient and other mechanical tests.

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