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Transfemoral Prostheses: Importance of Proper Fitting and Materials for Socket 3D-Printing

Donatas DAUBLYS*, Aurelijus DOMEIKA, Birutė SINKUTĖ*****

**Kaunas University of Technology, Studentų St. 56, 51424 Kaunas, Lithuania, E-mail: donatas.daublys@ktu.lt*

***Kaunas University of Technology, Studentų St. 56, 51424 Kaunas, Lithuania, E-mail: aurelijus.domeika@ktu.lt*

****St. Ignatius of Loyola College, Vilniaus St. 29, 44286 Kaunas, Lithuania, E-mail: birute.sinkute@ilk.lt*

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1. Introduction

Lower limb prostheses can replace missing parts of the body and improve a patient's quality of life. The prosthesis socket must be comfortable, functional, and attractive, so it is very important to properly select the materials from which it will be made, select and adapt its design (that is, the shape of the product, considering mechanical and biomechanical parameters, the appearance of the product, etc.), and considering human health, activity level, weight, and other parameters [1].

The prosthesis socket can be made of various biocompatible materials such as plastics, metals, leather, carbon fiber, and composite materials [2]. Over the last two decades, the process of printing thin layers of materials began. Polyamide 12 (PA12) based powders are very widely used in selective laser sintering (SLS) technology. This additive manufacturing technology is characterized by its flexibility and process stability, making it suitable to produce various functional products. Polyamide (PA) due to its properties can also be used in various industries, including the medical industry [3].

Due to the properties of SLS technology, only 5-15% of the powders in the work zone are currently being used. Therefore, a large portion, sometimes up to 95%, of unsintered powders can be recycled or reused [4, 5]. The percentage of powders in the working zone that are actually used in the SLS process can vary depending on several factors: powder spreading, part geometry, and support structures. Various powder manufacturers recommend renewing powders by mixing used and new powders in different proportions. The recommended mixing ratio for PA2200 powders is 50-50%, but the mechanical properties of such material are not provided. Moreover, there is no information on how the mechanical properties of the materials change when the old powders are used a second time. The most extensive studies reveal the properties of products made from new powders, but the properties of materials printed using double-used powders and their influence on the quality of the printed product have not yet been studied in detail and require additional research, especially if the printed object will be used in the medical field.

According to the World Health Organization, prostheses must be biomechanically compatible. Scientist's study one of the most important parameters of a prosthesis to maintain a comfortable and stable movement function, i.e., the proper adaptation of the prosthesis to the patient's limb, or how the compatibility of the prosthesis and the limb affects various biomechanical parameters. Improper fitting of the prosthesis affects gait biomechanics and can lead to serious injuries such as skin injuries, injuries to the healthy leg, lower back pain, shoulder, and neck injuries [6, 7]. In addition, skin lesions occur in 63 to 82% of amputees of the lower extremities, resulting in a prosthesis rejection rate of the prosthesis of approximately 25 to 57% [8]. To avoid additional injuries while wearing the prosthesis, an individual fitting of the prosthesis is required, as well as a full examination of the gait of the person wearing the prosthesis.

The aim of the research is to investigate the mechanical characteristics of the prosthesis socket printed using SLS technology from double-used PA2200 powders to achieve the efficiency of the production of sockets and the biomechanical gait characteristics of this printed prosthesis socket, as well as other components of the prosthesis, to evaluate the suitability.

2. Methods

2.1. Methodology of mechanical characteristics

The Tinius Olsen H25KT universal testing machine (Tinius Olsen, Ltd, England) is used to test the properties of the materials. Machine load measurement accuracy: ± 0.5% of the indicated load from 2% to 100% capacity. For the tests, the samples were printed using SLS technology from 100% new PA2200 powder and 100% used powder. All samples were printed with the Formiga P110 printer (EOS GmbH, Germany): printing resolution 0.1 mm, laser power – 30 W, scanning speed – 200 mm/s, bed temperature – 170 °C.

Tensile tests were performed according to the ISO 527-1:2019 standard. The shape and dimensions of the samples are selected according to the ISO 527-2:2012 standard (Fig. 1).

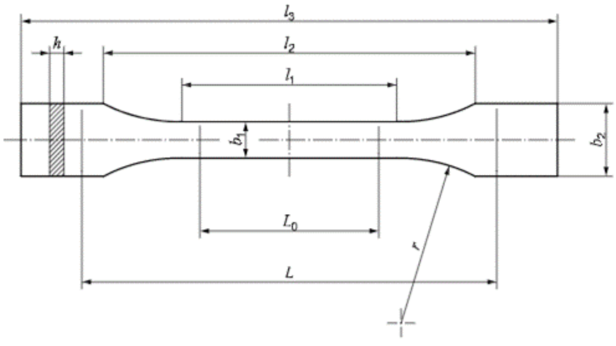


Fig. 1 Tensile test scheme [9]

According to standard requirements, it is established that to study the mechanical properties of a material, at least 5 samples made of the same material must be examined [9]. After evaluating that additive manufacturing technology will be used to produce the samples, it was decided to use 7 samples for each test.

Table 1

Parameters of the tensile test specimens

Marking	Parameter	Size, mm
l_3	Overall length	150
l_1	Length of narrow parallel-sided portion	60 ± 0.5
r	Radius	60 ± 0.5
l_2	Distance between broad parallel-sided portions	108 ± 1.6
b_2	Width at ends	20 ± 0.2
b_1	Width at narrow portion	10 ± 0.2
h	Thickness	4 ± 0.2
L_0	Gauge length	50 ± 0.5
L	Initial distance between grips	115 ± 1

Bending tests were performed according to the requirements and recommendations of the ISO 178: 2019 standard (Plastics, Determination of bending properties) (Fig. 2). The standard is used to determine the mechanical properties of plastic products and to evaluate their behavior during bending [10]. In each material group, as in the tensile test, 7 specimens were tested. The standard describes the determination of the bending properties using the 3-point bending method.

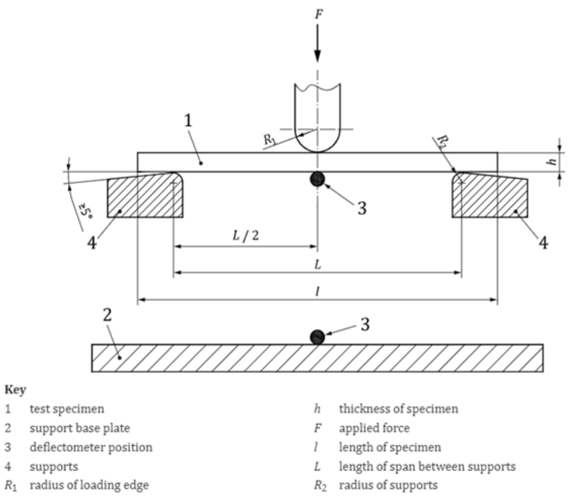


Fig. 2 Bending test scheme [10]

Table 2

Parameters of the bending test specimens

Marking	Parameter	Size, mm
l	Length	80 ± 2
b	Width	10 ± 0.2
h	Thickness	4 ± 0.2

2.2. Methodology of biomechanical gait characteristics

In the study of biomechanical gait characteristics, a subject with a right leg amputated above the knee (male, 32 years old, height 186 cm, weight 94 kg) volunteered to participate. The subject wears a mechanical knee prosthesis.

The subject was asked to put on the printed prosthesis socket and walk straight for six meters at a comfortable chosen speed. The gait is repeated 6 times, taking 1–2-minute breaks between the gaits.

Motion analysis with depth (3D) cameras and a standard video camera is used to measure and evaluate gait parameters. Kinematic data were acquired using a Qualisys motion analysis system (Qualisys AB, Gothenburg, Sweden) and 12 high-speed digital 3D cameras Oqus 7 at 120 Hz. In addition, two force plates (AMTI, USA) are used to measure reaction forces related to human movement. The analysis systems record infrared reflective markers attached to the subject's body (Fig. 3).

Fig. 3 Subject with attached markers

Markers are attached to anatomically important parts of the body according to the recommendations of the Rizzoli Orthopedic Institute, which are generally applied during gait studies [11].

The collected data are processed using special software "Qualisys Track Manager (QTM), with which a simplified model of a moving skeleton is automatically created based on the measurement results (Fig. 4).

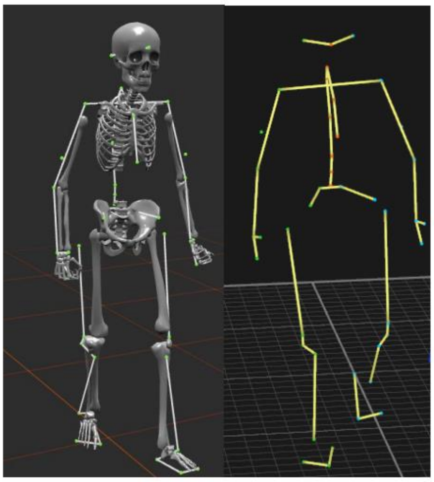


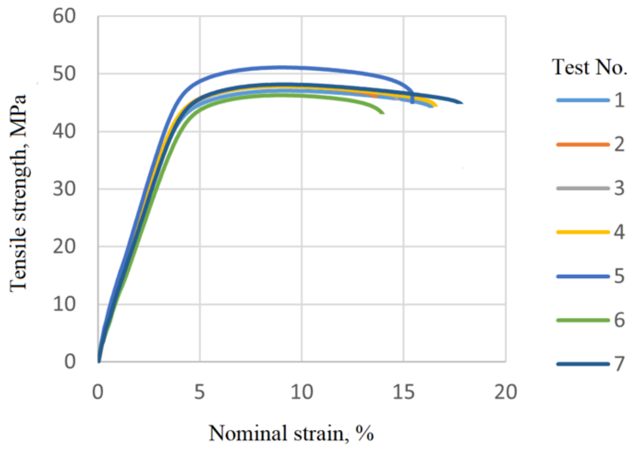
Fig. 4 Models of the subject's skeleton

Additional gait analysis was performed with the Rehawalk HP Cosmos (h/p/cosmos sporsts & medical gmbh, Germany) treadmill and the Zebris FDM-T (zebris Medical GmbH, Germany) system. The system has an integrated matrix of pressure sensors, capture frequency 120 Hz. Zebris analysis is performed to assess the center of mass of the body, balance, and the amount of load on the feet.

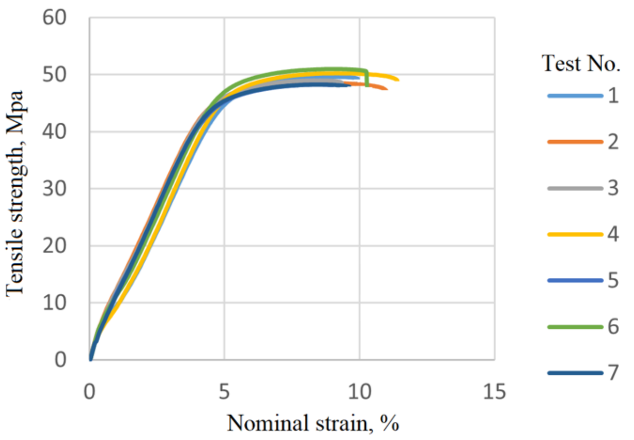
3. Results

3.1. Mechanical characteristics of the materials from which the socket of the prosthesis is made

Because products using additive manufacturing technologies have anisotropic properties, it was decided to examine the samples that were positioned in relation to each axis. However, when positioning the samples along the x and y axes, the results were very similar. Also, during the tensile test, a greater spread of results is observed when evaluating the results when the samples were printed by positioning them along the z-axis, this is because of the principle of manufacturing which results in delamination. Therefore, it was decided to leave only y-axis results. The y-axis tensile stress curves with PA2200 material made from 100% new powder and 100% double-used powder are shown in Fig. 5.



a



b

Fig. 5 Tensile test of specimens made from 100% new powder (a) and 100% double-used powder (b)

The results show that the confidence intervals overlap, so it can be assumed that there are no statistically significant differences between the groups, but to reduce the probability of error, the *p*-value is also calculated and the α level is chosen as 0.05. Tensile strength, $p > \alpha$, $p = 0.09$. Max force, $p > \alpha$, $p = 0.83$. Looking at the results, it can be concluded that, for tensile, the difference in means between the material made from new and double-used powders is not large enough to be statistically significant.

Table 3

Tensile results of materials made from 100% new powder

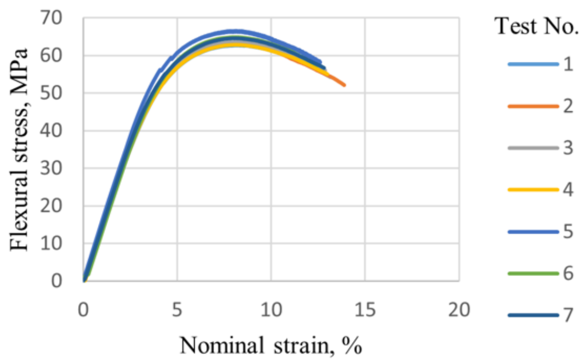
Test No.	Tensile strength, MPa	Max force, N
1	47.0	2102
2	48.0	2093
3	47.8	2084
4	47.9	2068
5	51.1	2088
6	46.3	2101
7	48.2	2103
Avg. ± Sd	**48.04 ± 1.45**	**2091.28 ± 12.62**
CI 95%	**[47, 49.1]**	**[2080, 2100]**

Table 4

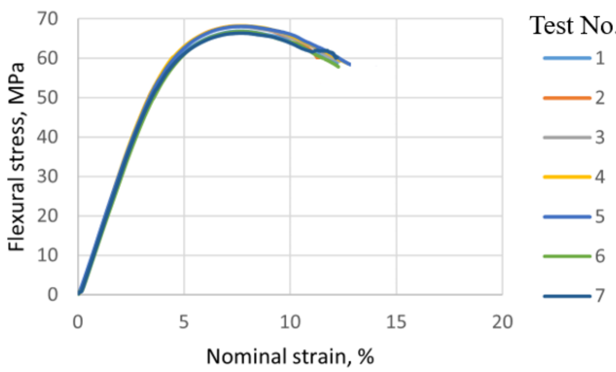
Tensile results of materials made from 100% double-used powder

Test No.	Tensile strength, MPa	Max force, N
1	49.6	2153
2	48.6	2128
3	49.0	2058
4	50.3	2139
5	48.2	2053
6	51.0	2263
7	48.3	2133
Avg. ± Sd	**49.28 ± 1.06**	**2097.14 ± 69.98**
CI 95%	**[48.6, 50]**	**[2050, 2150]**

In the case of bending test, when evaluating specimens with different orientations, the orientation does not have a significant effect on the mechanical properties of the specimens. So, it was decided to left only x-axis results. Seven x-axis bending tests results with PA2200 material made from 100% new powder and 100% double-used powder shown in Fig. 6.



a



b

Fig. 6 Bending test of specimens made from 100% new powder (a) and 100% double-used powder (b)

Table 5

Bending results of materials made from 100% new powder

Test No.	Flexural strength, MPa	Max force, N	Flexural modulus, MPa
1	62.7	125.5	1473.3
2	63.4	122.0	1447.4
3	63.6	127.6	1527.5
4	62.8	126.5	1501.6
5	66.5	122.5	1578.2
6	64.9	119.6	1410.3
7	64.5	127.0	1535.3
Avg. ± Sd	**64.06 ± 1.35**	**124.39 ± 3.03**	**1496.23 ± 57.08**
CI 95%	**[63.1, 65.1]**	**[122, 126]**	**[1460, 1540]**

Table 6

Bending results of materials made from 100% double-used powder

Test No.	Flexural Strength, MPa	Max force, N	Flexural modulus, MPa
1	64.9	117.1	1381.6
2	66.2	118.2	1512.9
3	66.1	121.4	1626.7
4	64.2	126.7	1629.1
5	65.1	133.1	1593.0
6	66.7	123.6	1549.6
7	66.4	117.5	1603.1
Avg. ± Sd	**65.6 ± 0.93**	**122.51 ± 5.85**	**1556.57 ± 87.79**
CI 95%	**[64.9, 66.3]**	**[119, 127]**	**[1500, 1630]**

Flexural strength $p > \alpha$, $p = 0.069$. Max force, $p > \alpha$, $p = 0.89$. Flexural modulus $p > \alpha$, $p = 0.12$. Looking at the results, it can be concluded that for bending, the difference in means between material made from new and double-used powders is not large enough to be statistically significant.

3.2. Biomechanical gait characteristics

Gait tests were performed to investigate the individual walking parameters of a person wearing a prosthesis with printed socket. This article presents subject gait results that are most divergent from the normative values of the control group. The control group consists of 18 healthy adults (10 men, 8 women). In the figures presented, the gray line represents ± 1 standard deviation from the mean normative value. The vertical line represents the event where the left or right leg was moved. The red curve represents the left leg, and the blue curve represents the right leg (with prosthesis). In the presented graphs, the time interval (x-axis) is defined by one full step (left + right footstep), normalized by time from 0 to 100%.

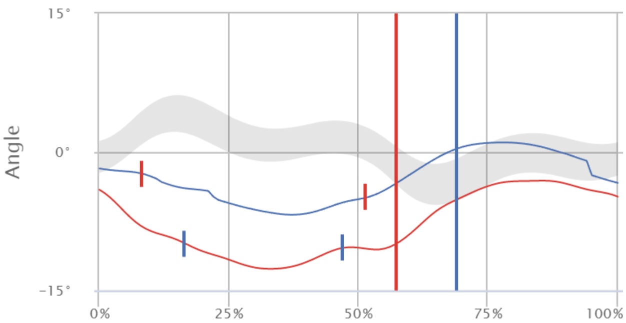


Fig. 7 Pelvic up obliquity

From the graph, the length of the right leg (blue curve) is longer than the healthy left leg, so prosthesis components need to be adjusted. The pelvis is tilted to the left side (during support of the left leg) by 12°. This leads to back pain, asymmetric gait, and difficulty walking.

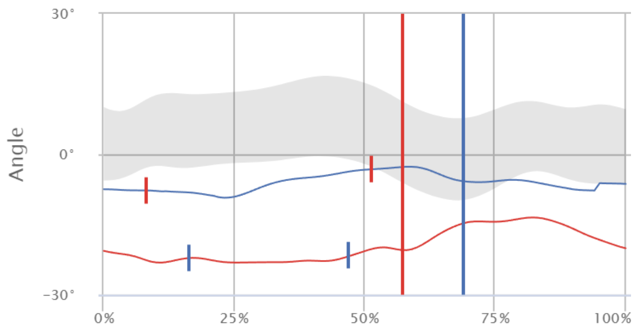


Fig. 8 Hip internal rotation

From the hip rotation graph, during the right leg support, the left hip rotation is 26° outward from the normal value. During the support of the left leg, it is slightly lower - 12°. Hip joint rotation is a complex body mechanism that involves multiple muscles and bone joints. It could indicate that there is weakness or imbalance in the leg muscles.

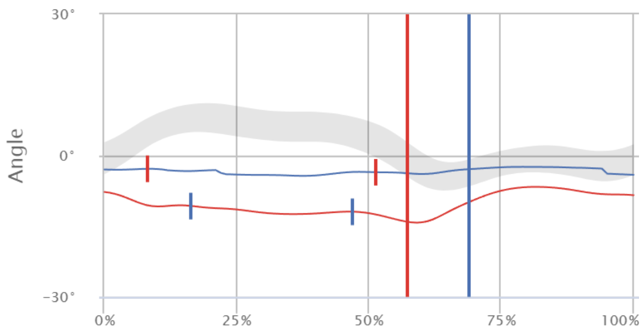


Fig. 9 Hip adduction

The left and right hips are not fully adducted to the midline of the body. Increased abduction of the hip joint can cause instability and discomfort in the hip region, and it may lead to compensatory movements that can cause further problems in other parts of the body. Some of the possible causes of increased hip joint abduction include hip dysplasia, leg length discrepancy, or muscle imbalances.

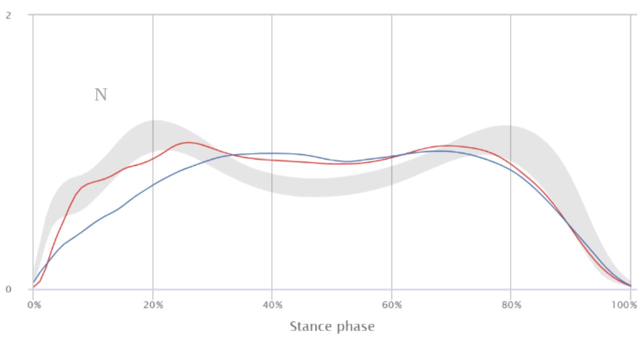


Fig. 10 Vertical ground reaction force

The vertical force of the right leg is lower than that of the left leg during foot placement and push off. This may indicate that the subject is possibly shifting their weight centers too much onto the left leg, it may indicate that the subject is trying to compensate for the tension and pain caused by the prosthesis in the leg muscles and joints and is therefore putting less stress on the right leg during the gat.

Table 7

Gait parameters

Description	Unit	Side	Avg ± SD
Stride length	m		1.29 ± 0.34
Stride width	m		0.17 ± 0.02
Step length	m	Left	0.55 ± 0.02
		Right	0.65 ± 0.03
Step time	s	Left	0.62 ± 0.02
		Right	0.71 ± 0.05
Stance time	% gait cycle	Left	70.04 ± 1.94
		Right	56.60 ± 7.69
Initial double limb support	s	Left	0.23 ± 0.14
		Right	0.23 ± 0.03

From the table the step of the left leg is 10 cm shorter than the right, the step time of the left leg is shorter, and the leg spends a longer time in the support phase, this may be because the patient feels that the support of the right leg is weaker (force asymmetry).

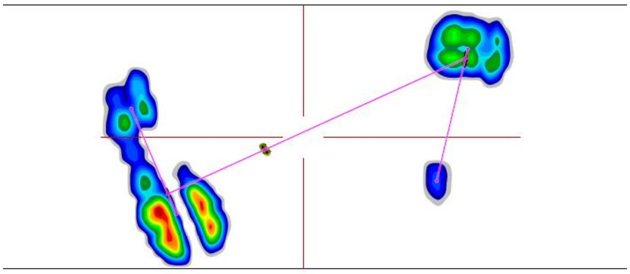


Fig. 10 Measurement of the static position average with pressure platform, the left side shows the left foot, the right side shows the right (right foot with prosthesis)

From the figure, the rear part of the foot of the subject's right leg has a small part of the load. The right leg is pushed forward due to fear of falling and a more stable posture. The center of mass of the body is tilted to the left side, and an asymmetric distribution of the load is visible.

4. Discussion

During the study of the mechanical characteristics of the polyamide material, it was found that the difference between the averages of the samples made from 100% new powders and 100% double-used powders is not large enough to be statistically significant, both in bending x-axis and tensile y-axis tests. However, because of selective laser sintering technology and due to the features of additive technologies, anisotropic properties of printed structures are often encountered; therefore, to ensure the necessary combination of mechanical properties and reproducibility of the products, it is necessary to additionally study how the properties of printed structures change depending on the printing parameters and positioning. Finally, the assumption that imperfect positioning of the specimens during the experiment, errors may occur in the results. After printing the prosthesis socket from double-used powder, an efficient printing process is achieved, and then gait analysis is performed because based on biomechanical indicators, the suitability of the socket to the residual limb is verified, as well as evaluating the remaining prosthetic components. Scientists are researching one of the most important parameters of a prosthesis to maintain a stable and comfortable movement function, which is the proper adaptation of the prosthesis to the patient's limb [12]. Schmalz et al. [13] proves that if components are arranged improperly, the correct gait is lost, and a greater energy expenditure is required from the human.

The results of the gait analysis show that the pelvis and hip angles in most cases do not fall within the 95% confidence interval of the control group. Also, the vertical force of the right leg is lower than that of the left leg during foot placement and push off. This is precisely what happens due to improper fitting of the prosthesis to the prosthetic limb. Gait parameters allow us to make assumptions about how the components of the prosthesis could be improved and which muscle groups should be strengthened in order to improve the quality of the gait, ensure balance and comfort. When assessing a person's gait with a prosthesis, it is important to know about normal gait and how the amputee's normal gait is affected. In addition, there may be deviations that the patient himself will acquire to compensate for weakness or tension in the muscles of the prosthetic leg, lack of balance, and fear. Such insights may provide an opportunity to develop better gait training programs, as well as adjust prosthesis components.

5. Conclusions

In this work, a study of the materials of the prosthesis socket and a biomechanical study of the person who is wearing the prosthesis were carried out. The results of the materials study show that inconsistencies between the new and used powders were found, although no clear and statistically significant trends were observed. The biomechanical study proves that to avoid injuries, it is very important that the innovative prosthesis is selected individually, has a suitable design, and corresponds to the human biomechanical parameters of standing and walking.

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D. Daublys, A. Domeika, B. Sinkutė

TRANSFEMORAL PROSTHESES: IMPORTANCE OF PROPER FITTING AND MATERIALS FOR SOCKET 3D-PRINTING

S u m m a r y

Lower limb prostheses can replace missing parts of the body and improve a patient's quality of life. The 3D printing technique can be used to make prosthesis sockets from recycled PA2200 powder, but the mechanical properties of these printed materials have not been studied in detail. Tensile and bending tests were performed, and the results obtained did not show statistically significant differences. An improperly fitted prosthesis affects the biomechanics of gait. The posture and gait analysis of a person wearing a prosthesis was performed using the “Qualisys”, “AMTI” force plates and “Zebris” systems, and the results showed differences between the prosthetic and the healthy leg.

Keywords: mechanical characteristics of materials, 3D printing, biomechanics of the prosthesis, gait analysis.

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