ADDITIVE TECHNOLOGIES APPLICATION IN TRANSTIBIAL SOCKET DESIGN

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Mentor rada: doc.dr.sc. Sven Maričić

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PROLOGUE

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LIST OF ABBREVIATIONS

3D - Three Dimensional

2D - Two Dimensional

ABS - Acrylonitrile Butadiene Styrene

AM - Additive Manufacturing

Bpp - Bits per pixel

CAD - Computer Aided Designing

CAE - Computer Aided Engineering

CAM - Computer Aided Manufacturing

CNC - Computer Numerical Control

CT - Computerized Tomography

DCC - Digital Content Creation

DDR3 - Double data rate type three SDRAM

FDM - Fused Deposition Modelling

FFF - Fused Filament Fabrication

Fps - Frames per second

GB - Gigabyte

GHz - Gigahertz

HD - High Definition

HIPS - High Impact Polystyrene

KBM - Kondylen Buttung Münster Socket

Kg - Kilogram

MIT - Massachusetts Institute of Technology

Mm - Millimeters

Mp - Megapixel

MRI - Magnetic Resonance Imaging

NC - Numeric Control

PETG - Polyethylene Terephthalate with a glycol modification

PLA - Poly lactic acid

PVA - Polyvinyl alcohol

PTB - Patellar Tendon Bearing Socket

RP - Rapid Prototyping; name for additive manufacturing

SDRAM - Synchronous dynamic random-access memory

SLA - Stereolithography manufacturing process

STL - Stereolithography file format

TSB - Total Surface Bearing Socket

INTRODUCTION

Medicine of today wouldn't exist on this kind of level without the implementation of tools and machines that are developed by engineers. From the infirmary to the surgical room, machines, tools and computers are all around us and help doctors provide better health service. This research paper will demonstrate how mechanical engineering with its new components, can help doctors in treating patients of the future in the best possible way.

Statistics acquired in the USA (up-to-date and easy available) estimate that number of amputations will double by 2050 to 3,6 million [1]. Diabetes, as one of the most widespread illnesses, has complications with vascular etiology that can result with amputation. Furthermore, vascular diseases are cause of 54% of limb amputation, trauma (45%) and cancer (less than 5%) [1]. Ratio of lower limb to upper limb amputation is 4:1. Another key point is that almost 50% of the individuals who have an amputation due to vascular disease will die in next five years [2]. Below-knee amputation, also known as transtibial amputation, is one of the most common amputation procedures and consequently, need for transtibial prosthesis exists.

Focus of this graduate thesis is put on additive manufacturing (AM) and its usage in creating transtibial socket for prosthesis. AM is term that describes technologies that creates objects by adding layers of material one on another. Common to AM is the use of computer and related 3D modeling software (Computer Aided Design - CAD). Except of CAD, designed model needs to be sliced in layers and prepared in machine specific language. There is a lot of software solutions with which the model is being prepared for 3D printing. The main purpose of this graduate thesis is to design and to manufacture transtibial prosthesis using so far collected knowledge. Moreover, prosthesis will be able to adapt and match wide group of people who have the need for the use of transtibial prosthesis. Using AM the process of creating transtibial prosthesis will be more simple, faster and cheaper what will contribute with the extensive application of this kind of prosthesis. In the end, this will be an illustration of how networking of different fields of science can result with synergy. Synergy with the goal of raising medicine of today onto next level of treating patients.

Additive technologies

As mentioned above, characteristic of AM is that it creates three dimensional model by adding two dimensional layers one on another. That is one of the reasons it is called 3D printing. Actually, 3D printing is phrase created by the media to give the name to describe something as interesting and amusing but yet so advanced and complex. First robotic 3D printer was developed on MIT by Charles W. Hull in 1984 and it was commercialized by 3D Systems in 1989. This technology starts with its revolution in the last ten years. Development in this field is increasing rapidly and today there are 3D printing technologies that can print at the molecular level (two-photon polymerization) [3].

Its actual usage in mass-production industry is limited because of low speed, cost, materials and accuracy if using low-budget machines. Notwithstanding, its flexibility of creating designs with almost no limitations makes a big advantage. The AM enables creating of objects that existing processes cannot manufacture. That possibility of creating complex structures without late processing is its biggest advantage. This technology is experiencing exponential evolution and sometimes is referred as the main impact for “Fourth industrial revolution“ that is about to happen. The procedures of creating models in AM are getting numerous and so are the materials used for manufacturing. This technology has been around us for around forty years and it has changed the way final products are being made. Instead of producing by taking material away, it adds material layer by layer and because of that is highly customizable and flexible what makes it suit most sectors of industrial production.

Additive manufacturing can be divided in three categories: selective binding, selective solidification and selective deposition. Selective binding technology creates the object from powder by heating it or by applying binding agents. Most common used powders are metal and gypsum. Selective solidification technology creates and then selectively focuses energy to solidify the liquid layer by layer. For example, in stereolithography (SLA) method UV light is used to solidify the layer. Selective deposition technology is able to place material in given way in one by one layer and subsequently create 3D model [3]. There are major differences in quality, accuracy, complexity and of course in price of printers using these technologies. Recently the use of AM in making final products increased in medical and aviation field. However, it is estimated that 90% of the products manufactured by AM are mainly prototypes while less than 10% are final products [4]. These numbers will change fast in future and additive manufacturing will soon become cornerstone of manufacturing from fields of engineering, architecture and agriculture to medicine.

Although 3D printing looks like an complexed technology, it is present in nature for eons. “Some of nature’s many 3D printers include mollusks that give us seashells. As they get bigger, mollusks start adding calcium carbonate to their outer shell, which gives the growing animal more room inside. If you look carefully at seashells, you will see lines of growth [3].“

An example of using additive manufacturing also known as rapid prototyping (RP), can be presented in collaboration of Centre for Biomodelling and Innovations in Medicine and Development Agency of Primorsko - Goranska County. Mentioned Centre stems from Faculty of Medicine, University of Rijeka and its purpose is developing new approaches to treat and secure population. This collaboration has developed the idea of designing and producing helmet, which will be able to obtain, process and provide wide range of informations depending on the appliance and the needs of the users. The first prototype will be specially produced for needs of the workers on shipyard or laboratory staff. The helmet will primarily have protective function to prevent users from acquiring head injuries and hearing or sight loss. Special designed inner matrix along with helmet shell will provide proper absorption and deflection of applied force. Additionally, the helmet will be able to provide hearing and sight protection with incorporated noise isolators and interactive visor. Secondarily, helmets will be connected to central server so all workers can communicate when needed. That connection can be used for safety reasons and for improving the communication between workers and/or superiors to ameliorate the production effectivity. Important to mention is that produced helmet will be able to provide instructions and feedback on how tasks should be done in real time because of integrated camera and mentioned connection to central software.

For this graduate paper, the designing and manufacturing process is briefly described. In first case study, director of the Regional Development Agency (*Javna ustanova Regionalna razvojna agencija Primorsko-goranske županije*) was model for 3D scanning process (Figure 1). After the head was scanned using handheld 3D scanner (described later), designing of helmet was done using appropriate software. Soon, the helmet will be produced with the use of 3D printer and initial testing will start. This is illustration of RP and its usage in practice (Figure 2).

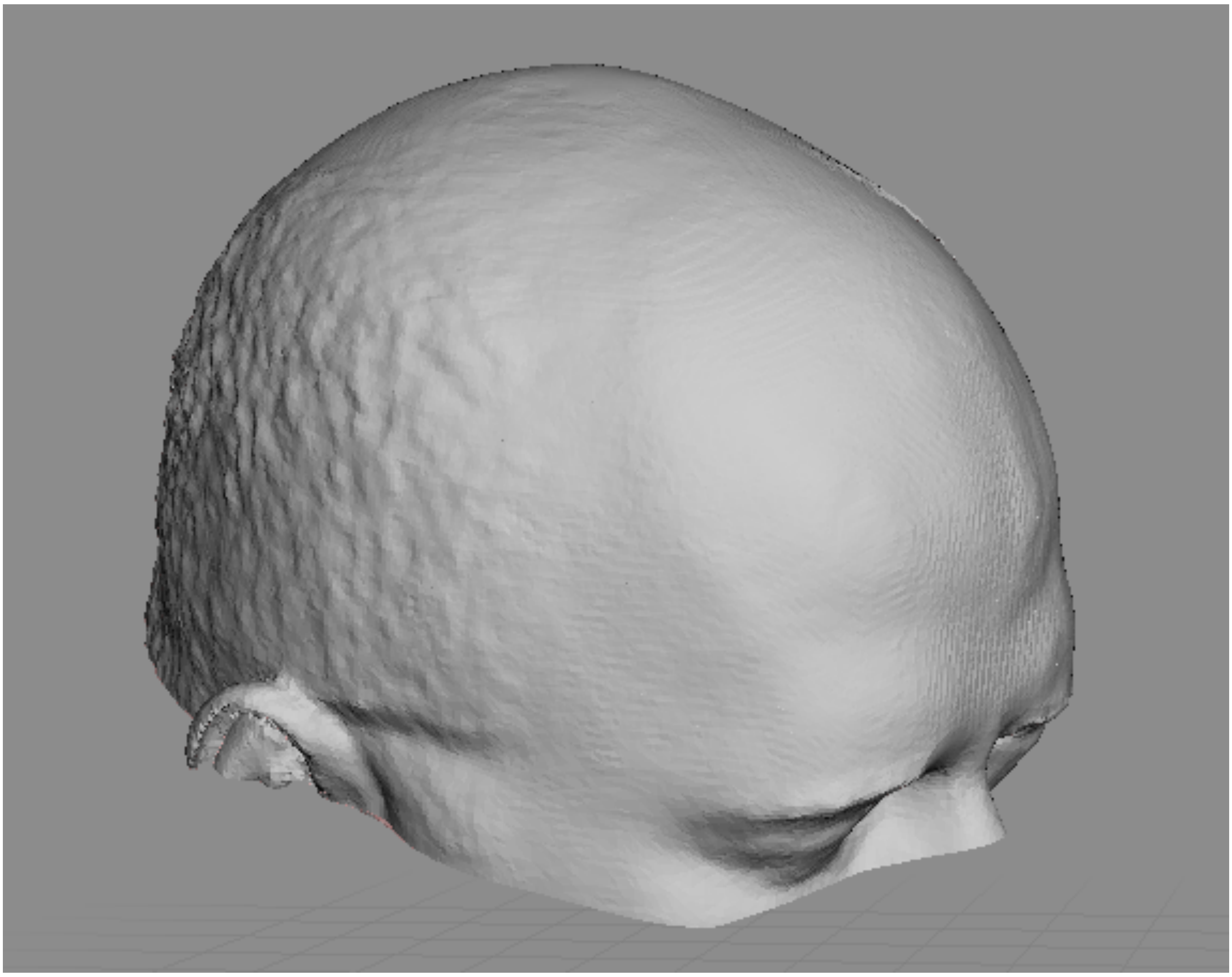

Figure 1: *Head scan in Artec Eva Studio*

To conclude, after fully developing helmet for the needs of shipyard workers, process and appliance of the helmet will be expanded. These helmets will be adapted to all industries and sciences including medicine. Ultimate goal is creating product that will be able to secure and enhance experience of all motorcyclists, cyclists, adventurers and general population.

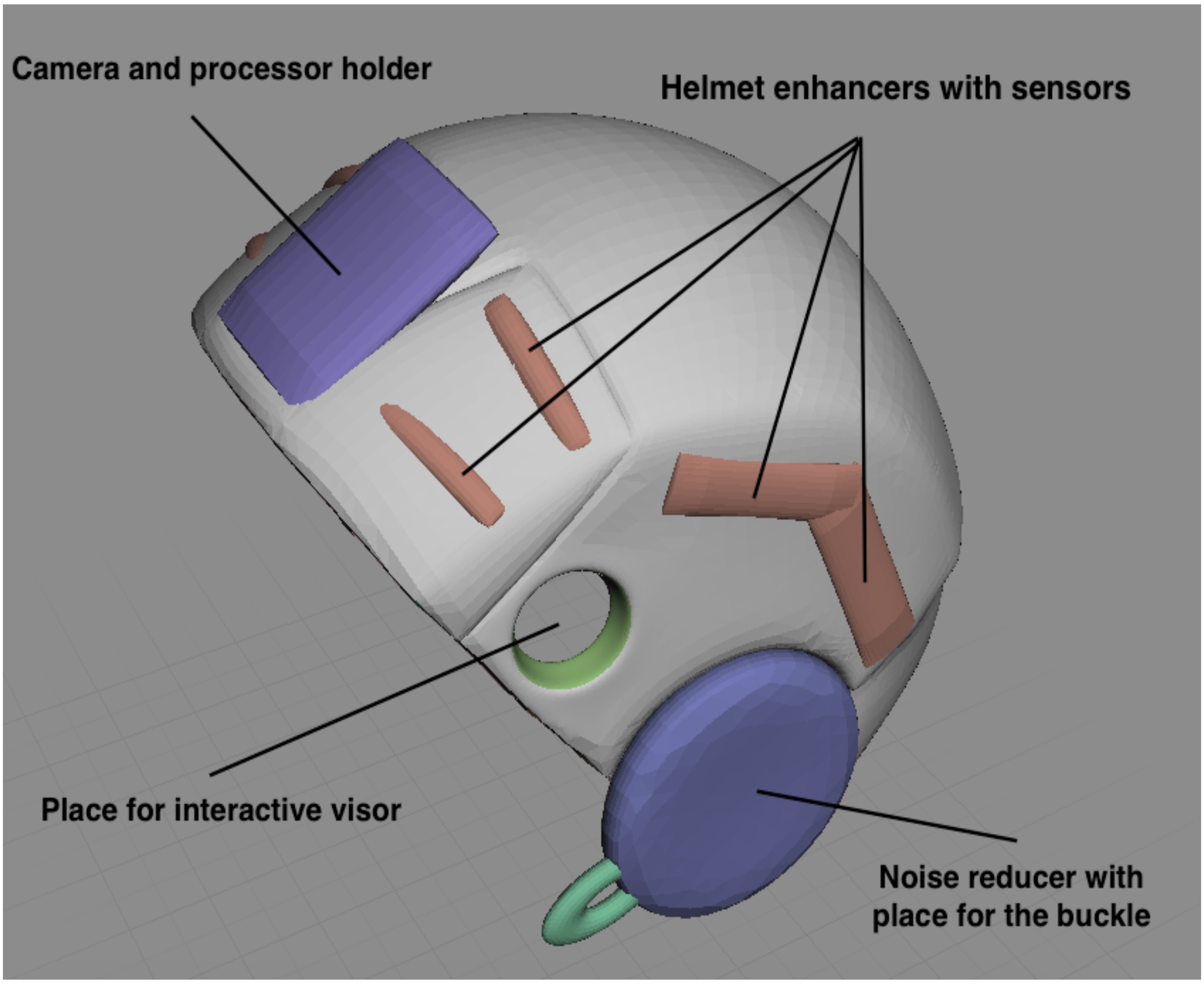

Figure 2: *Ultimate prototype of helmet with descriptions*

In future activities, model of specialized helmet will be will be based on the protected industrial design label D20150145 (Maričić, S. 2015) in order to achieve savings on 3D prints. Figure 3 presents head and face design according to which prototype of protective helmet will be designed and dimensioned. Figure presents wire model that was obtained from intersection of coronal and sagittal plane.

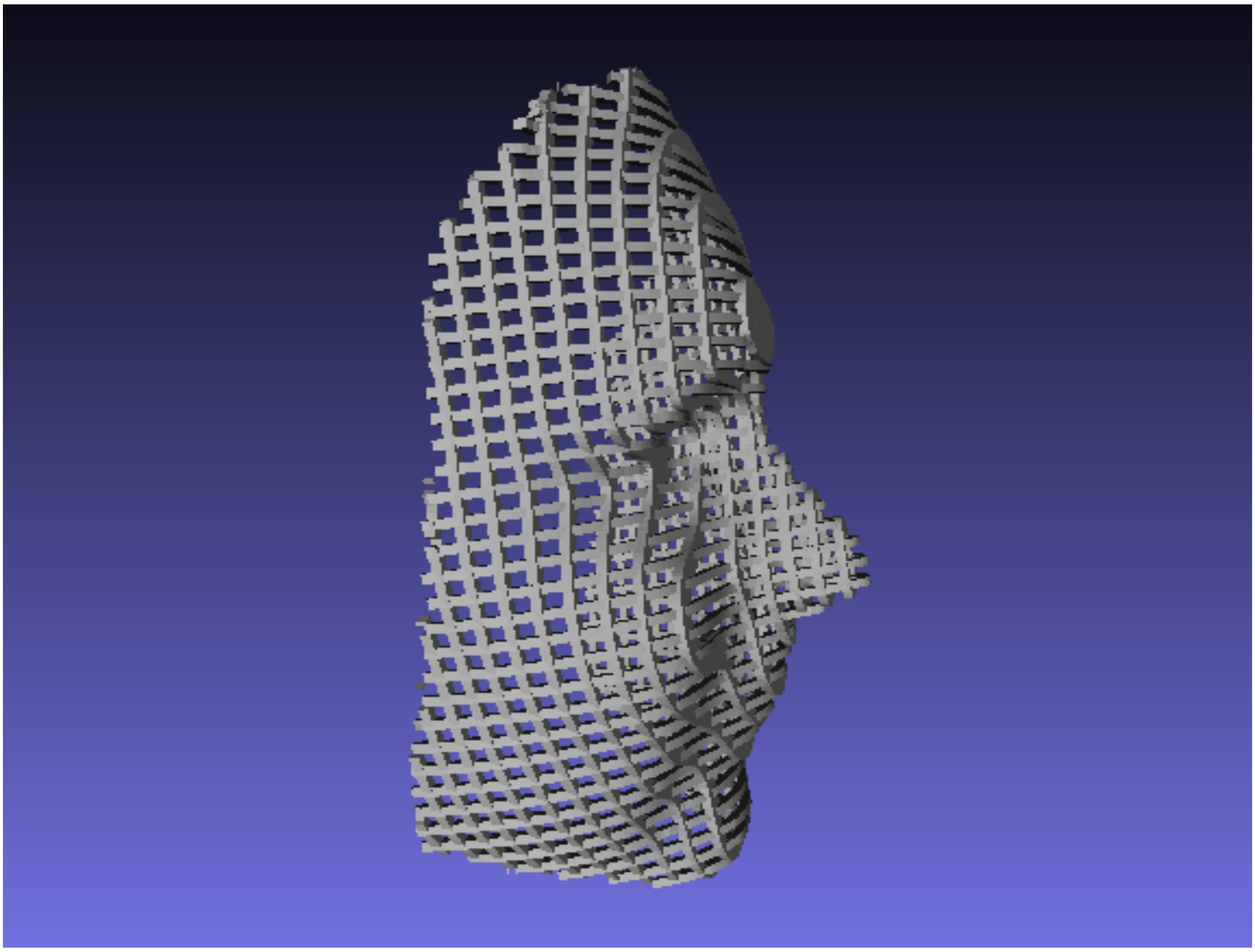

Figure 3: *Render of model D20150145 on which intersection of coronal and sagittal plane is seen (Maričić, S. 2015)*

Additive technologies in medicine

The latest advances in additive technologies have increased possibilities of its application in medicine. AM already found its purpose in medicine within dental medicine, prosthetics, orthotics, production of medical equipment, education, surgery planning, and in manufacturing organs [5]. The application of 3D printing in dental medicine, orthotics and prosthetics is clear, according to needs of the user model is designed and printed. Since there is no real tissue and living structures, obstacles in creating model are minimised. Advantages are that personalized model can be manufactured and then incorporated. Similar methods are used for education, surgery planning and manufacturing of medical instruments. An example of how 3D printing can be used for medical education is AnatoMRI project. AnatoMRI is smart-bone project that stems for Anatomy learning model from Faculty of Medicine in Rijeka and its purpose is to enhance the process of learning human anatomy by recreating human skeletal system (Figure 4). AnatoMRI is fully developed by Faculty of Medicine and presents one of first medical application learning toolkit made with 3D technologies in University of Rijeka. These models are intended for students of medicine, stomatology and sanitary engineering. Mobile application is being developed along with models so bones can be scanned and their description and location are reproduced on mobile, tablet or computer screen. Another example of 3D printer use in medicine comes from University of Rijeka. In collaboration of Faculty of Medicine with Faculty of Civil Engineering 3D model of cerebral aneurysm along with cranium basis was created to help in planning of surgery (Figure 5). Surgery was complexed because bypass of the aneurysm needed to be created prior to elimination of aneurysm. This model helped neurosurgeons to plan and develop personalized approach to the aneurysm and vascular structures around it. This was first time in medicine that technology of 3D printing was used for described procedure. 3D model was designed and developed by asist.prof. Sven Maričić with the help of CT scan. One of the leading neurosurgeons in the world, prof. Laligam N.Sekhar from Harborview Medical Center in Seattle, came to perform surgery with the help of assoc.prof. Dinko Štimac from Clinical Hospital Center Rijeka. Team led by three mentioned experts successfully completed the project, surgery passed very well and the patient was able to leave the hospital in one week.

Figure 4: *Comparison of different 3D models realization*
Source: Faculty of Medicine, University of Rijeka

Figure 5: *Photograph of aneurysm model while surgery was being performed*
Available from: http://www.novilist.hr/Vijesti/Rijeka/Uspjeh-rijeckih-lijecnika-Pomocu-3D-modela-uspjesno-premostili-opasnu-aneurizmu
[cited 2018, Jun 2].

A bit more complex part of additive manufacturing is being developed in medicine: “3D printing have increased feasibility towards the synthesis of living tissues. Knowns as 3D bioprinting, this technology involves the precise layering of cells, biologic scaffolds, and growth factors with the goal of creating bioidentical tissue for a variety of users [6].“ Advantages to conventional bioengineering strategies can be seen from 3D bioprinting early success. According to Elliot S. Bishop and colleagues, there are three central approaches to bioprinting and those are biomimicry, autonomous self-assembly, and a microtissue-based method. These strategies are not exclusive to bioprinting and are applied to many areas within regenerative medicine [6]. Bioprinting strategies are described in Table 1.

Table 1: *Bioprinting strategies and their descriptions, advantages and disadvantages*
Source: Bishop ES et al, 3-D bioprinting technologies in tissue engineering and regenerative medicine: Current and future trends, Genes and Diseases. 2017. p. 185–95.

Strategy	**Biomimetic**	**Self-assembly**	**Microtissues**
Description	Duplicating environment and growth cues for a target tissue	Replicating embryonic environment	Forming smallest possible structural and functional units that can be combined
Advantages	Control at each step High precision in cellular positioning	Fast and efficient Scalable for automation High cellular density	Fast and efficient Scalable for automation Vascular tissue engineering
Disadvantages	Slow and often inefficient Complexity	Difficult to change outcome during self-assembly process	Difficult to create microtissue

“A complex 3D microenvironment can be generated by using a bioprinting system, in which the cells are then integrated in [7].“ Process of bioprinting is arranged in three major steps: Pre-processing in which model is being created with the help of imaging techniques (CT/MRI) and CAD technology; In Processing phase bioprinting technique is chosen according to components of bioink and according to biomodel; Phase of Post-processing involves maturation of tissue in bioreactor and in the end bioprinted tissue is ready for *in vivo* use. Bioprinting methods are divided in four groups: inkjet 3D bioprinting, microextrusion 3D bioprinting, laser-assisted 3D bioprinting and stereolithography. The difference between these methods is in process of bioprinting, speed, cost and accuracy but all of them use bioink as a material. Bioink is composed of cellular material, additives (signaling molecules, growth factors, etc.), and a scaffold with function of support [6].

Possibilities of additive manufacturing are bigger from day to day, organs are being printed and soon mankind will be able print the DNA. If growth of these technologies stays permanent in next 50 years we will be able to print organisms and maybe 3D printed humans will walk among us.

Transtibial prosthesis

Lower-extremity amputation is famous as one of the oldest surgical procedures dating back to prehistoric times. It is known that neolithic humans have survived traumatic, ritualistic, and retributive rather than therapeutic amputations. On top of that hand imprints on cave walls that demonstrate the loss of digits have been found. Also, mummies have been found buried with cosmetic replacements for amputated extremities [8].

The precise number of amputations worldwide is difficult to determine, as many countries do not keep exact records of the number of people with limb amputation [9]. According to limb loss statistics of the USA there are around two million people living with limb loss in the USA [1]. Besides that, diabetes is one of the most common medical conditions and at least 9% of Americans are suffering from diabetes [10]. Of non-traumatic amputations in the USA, 60% are performed on patients with diabetes and throughout the world, it is estimated that every 30 seconds one leg is amputated due to diabetes [1, 11]. "Of the approximately 1 million unilateral lower-extremity amputations due to dysvascular conditions, the most common were toe (33,2%), transtibial (28,2%), transfemoral (26,1%), and foot amputations (10,6%) [9]." (Figure 5)

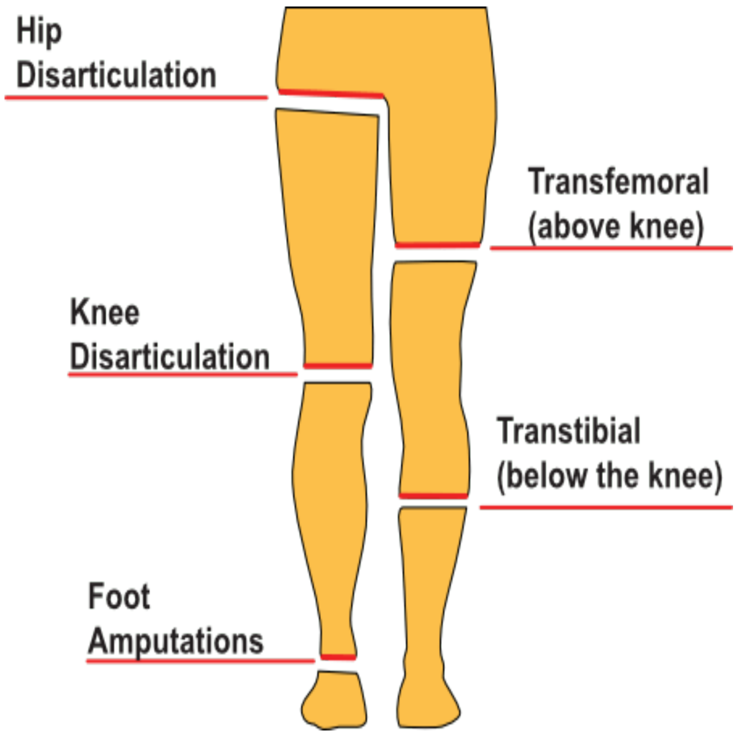

Figure 6: *Levels of leg amputation.*
Available from: https://centralbrace.com/prosthetics/lower-limb-prosthetics/
[cited 2018, Jun 10]

Consequently, conclusion can be made that transtibial amputation is one of the oldest and most common surgical procedures. Thereupon, the need for good and versatile transtibial prosthesis is confirmed.

Prosthetics is probably as old as amputation but first written use of prosthetics dates from ancient Egypt when wooden sticks were used as prosthesis if patient survived the amputation of limb due to high rate of infections and hemorrhage. Modern prosthetics date since World War II when thousands of people lost their limbs and the need for prosthetics was increased. Prior to World War II wood and leather were used as materials and after WWII thermoplastic resin laminations were introduced and prosthetics started to grow. Since focus of this research is transtibial prosthesis, the development, function and appearance of transtibial prosthesis will be summarized in the next few paragraphs.

Transtibial prosthesis main functions are to guide and protect the residual limb. The prosthesis uses forces from limb to make a movement. Parts of transtibial prosthesis are Socket (Figure 6-a), Pylon which is compound out of few elements (Figure 6-b), and Foot (Figure 6-c). Socket consists of silicone suspension sleeve that ensures contact and proper fit with stump. Soft inner socket and composite definitive socket are parts that give firmness and proper adherence to the prosthesis. In this research serial produced Pylon and Foot will be used while sleeve and socket parts will be newly designed and adapted to users of transtibial prosthesis.

Figure 7: *Parts of transtibial socket*
Available from: https://www.physio-pedia.com/Prosthetics
[cited 2018 Jun 11].

Today, most commonly used sockets are Patellar Tendon Bearing Socket (PTB), Total Surface Bearing Socket (TSB), and their alterations. Both of them do not have any major differences in comparison to first ones that have been created decades ago and that is the main reason why this research has been created. In 1957 Patellar Tendon Bearing Socket was created at the Symposium of Below Knee Prosthetics at Berkeley, California. They were formally introduced in 1959 and it radically changed former practices through inclusion of total contact and selective loading theory [12] (Figure 8).

Biomechanics of this socket is that PTB uses internal protrusions to bear the weight. Those protrusions use pressure tolerant areas of residual limb which are: patella tendon, medial flare of tibia, residual pretibial musculature and fibular shaft, popliteal area/gastrocnemius muscle belly (Figure 9).

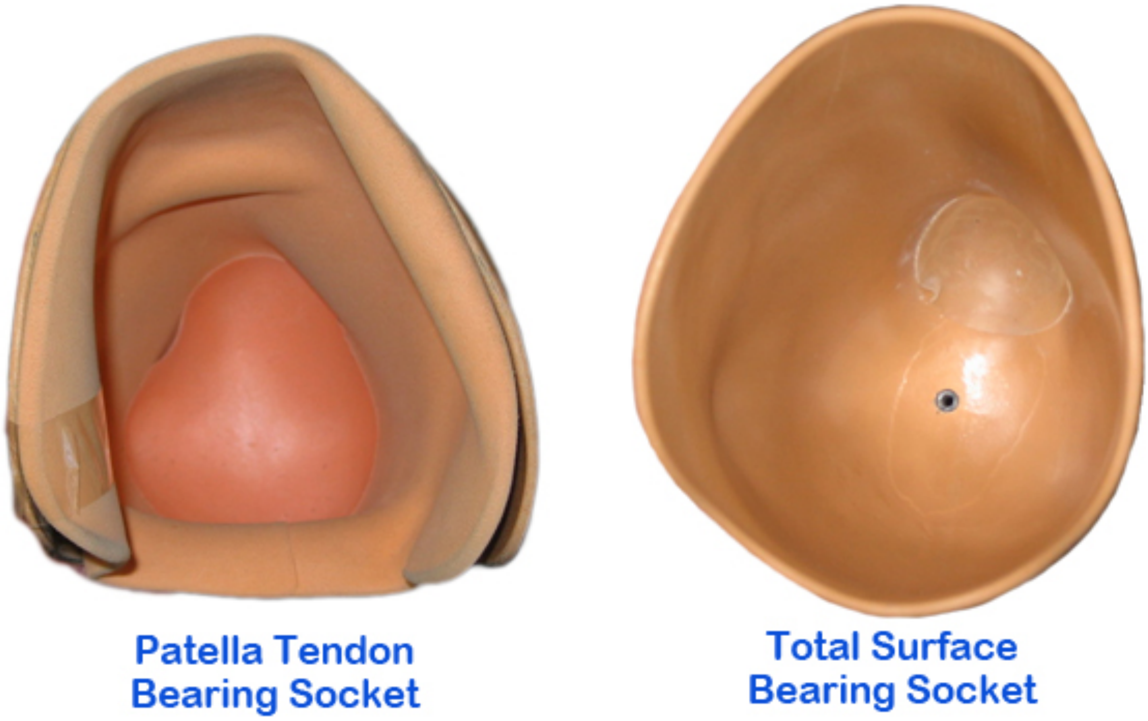

Figure 8: *Difference between Patella Tendon Bearing Socket (PTB) and Total Bearing Surface Socket (TSB)*
Available from: http://www.austpar.com/portals/prosthetics/transtibial_sockets.php [cited 2018 Jun 13].

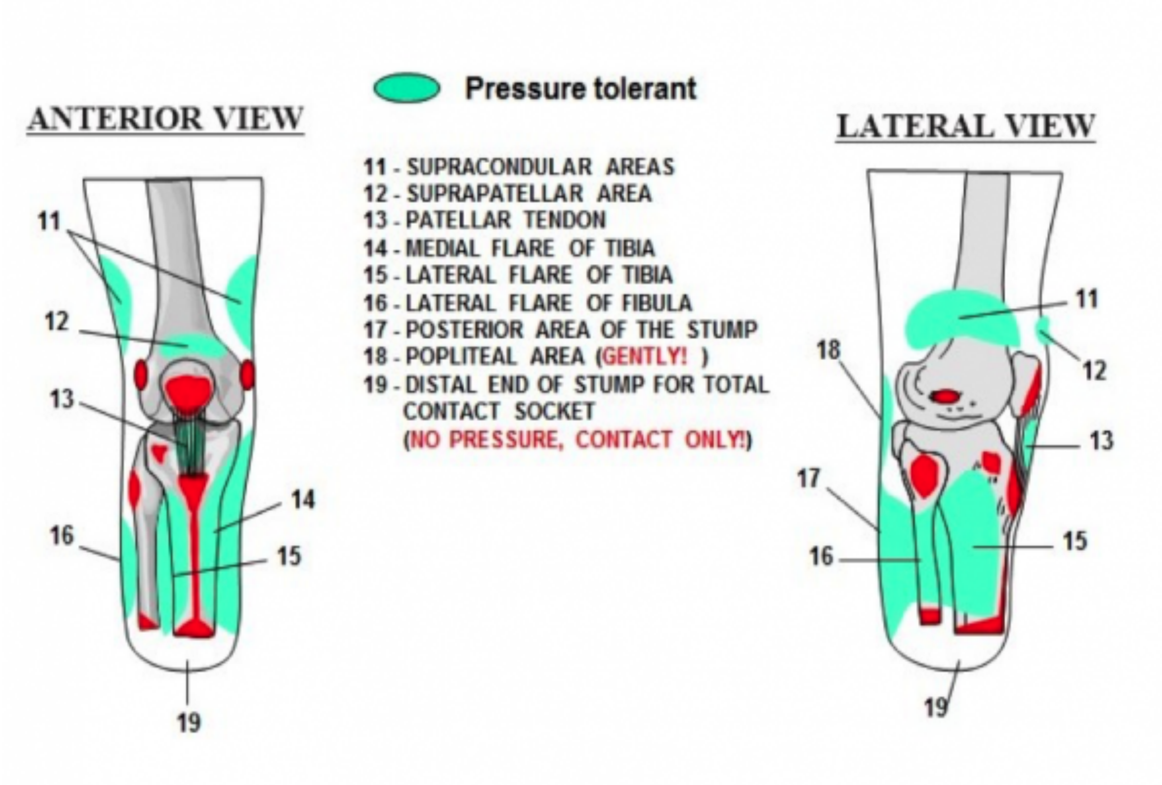

Figure 9: *Pressure tolerant spots of transtibial stump*
Available from: https://www.physio-pedia.com/Prosthetics]
[cited 2018 Jun 11].

PTB socket also usually have an inner liner of softer material to assist in moulding an accurate shape and providing more comfort. Wool or cotton socks of various thickness are being used to protect the stump against shear forces and to assist in coping with perspiration and stump volume fluctuations. Newer materials can also be used for additional protection and comfort. Few variations have been proposed over time such as Patella Tendon Supracondylar (PTS) socket in France that has higher medial and lateral walls to add more stability [13]. Furthermore, in 1960. KBM socket (Kondylen Buttung Münster) was designed with a removable medial supracondylar wedge to improve suspension. PTB has various designs depending on suspension method. Traditionally, PTB socket is suspensioned using suprapatellar cuff which sits above the patella.

Each of mentioned variations has its advantages and disadvantages. PTB advantages are that it can be fit to accommodate various stump shapes; it is designed to accommodate the dynamic changes in pressure through the gait cycle; gait can look normal except for the movement of plantar flexion. PTS advantages over PTB are that it eliminates suprapatellar strap and subsequently reduces the risk of constriction; increased mediolateral stability; reduced pistoning (losing of suspension) [14].

In 1970s Total Surface Bearing Socket began its evolution. It strives for perfect skin contact so the pressure is distributed equally through stump (Figure 8). The development of TSB socket happened thanks to new materials. These sockets are manufactured using a pressure casting system because accurate impressions of the stump are necessary. It is assumed that in TSB sockets pressure is distributed more evenly across the stump, and therefore peak pressure should be lower than in a PTB socket. However, Dumbleton et al. (2009) found higher interface pressures with a pressure cast TSB compared to a manually cast PTB [15]. Use of TSB sockets may also cause a loss in stump volume of up to 6,5% with use which causes deterioration in the fit of the socket and increases the risk of skin irritation [16]. Main advantages of TSB are greater range of knee flexion; less traumatisation of the skin [17]; lighter and less pistoning than PTB [18]; better proprioception and stability [18]. In opposite, disadvantages can not be neglected, not recommended for patients with fluctuating stump volumes (e.g. patients with nephropathy) [14]; Increased perspiration, itching & odour [18]; possible discomfort during swing phase [18]; more costly materials than for PTB [19].

Liners are important part of transtibial socket because they present interface between socket walls and the leg stump. In addition, liners created from different materials are being used; foam, silicone, polyurethane, copolymer, and mineral oil gel liners. Their characteristics are cushioning the load between stump and socket; reducing friction; contributing towards suspension; must be able to cope with fluctuations in the stump size [14]. Liners are important because they should simultaneously provide several features, reducing perspiration and skin irritation. Additionally, adequate fit and maintaining secure suspension need to be retained.

Currently sockets are manufactured from conventional molds by technician with his art and skill and the quality depends on technician. Socket technology for lower limb went through revolution during 1980s when new materials and new technologies started to be used in this branch of medicine. As new materials were developed, prosthetics evolved and products become much more efficient and functional. Some of new materials include: vacuum formed polycarbonate, lightweight metals and liners shifted from cotton and wool to silicone and urethanes.

Application of additive technologies in creating transtibial prosthesis

The future of designing and creating of prosthesis and orthosis is in AM and 3D printed prosthetic limbs are considered as one of the next revolutions in medicine.

The use of 3D printer with the help of Computer Aided Designing and Manufacturing (CAD/CAM) technology in developing transtibial prosthesis was introduced in 2013 in USA. Researchers created perfect fitting 3D printed transtibial leg socket in 2015. “We decided to use a laser scanner and CT to capture the stump of the patient...Subsequently, we imported the files in .stl extension to CAD software to begin the process of design, based on the real anatomical data of the specific patient.” described the author of the research [20].

Running-specific transtibial prosthesis prototype was designed and tested by Institute of Industrial Science from University of Tokyo in 2016. AM enables to partly integrate the socket, the connective parts and joints into one part. While being fit for the amputee’s individual set up, designing these integrated sockets that are both functionally and aesthetically pleasant is technically possible. Moreover, by using the freeform characteristics of AM, there is a possibility of realizing a superior performance in strength and lightweight properties [21].

These two studies present us how AM in creating transtibial prosthesis can provide a lot of enhancements in compare with existing manufacturing process. Lack of studies with this subject is present and that shows us the need for similar research papers. Hopefully, this research paper will result with new methodology, and new ideas that will be born and then incorporated in existing process.

Introduction in research paper methodology

The main functions of socket are to guide and protect the residual limb. The socket transfers forces from limb to prosthesis throughout the time the limb is in motion. The socket needs to be comfortable what we can ensure by making it lightweight and designing it according to anatomy, physiology and function of leg and leg stump. The main reason of discomfort is improper socket fit that is result of manual measurement and rigidness of the socket. In this research both of these factors will be affected and perfect fit will be achieved for patients using created transtibial socket. Manual measurement will be changed with scanning technique which is far more accurate and rigidness will be offset with the design and materials used for manufacturing.

The first step in this process is scanning of the leg stump with 3D scanner that allows us to recreate leg stump in software. Another key point of the process is creating and designing perfect fitting socket which will be adjustable so the user can make it tighter or looser depending on their need. The socket base will be manufactured with 3D printer while the serial-produced fasteners will be fused on the base and provide possibility of adjustments. To explain, if prosthesis user has to be faster, socket must be tight so better transmission of force can be ensured. That possibility is acquired with fasteners located on socket. Furthermore, when standing or walking for few hours legs swell, and so does the leg stump. The proposed socket can be loosened as easy as it can be tightened. As a result, when leg stump bulge, user can loosen the fasteners what makes this prosthesis fully comfortable and functional.

Non-medical terminology

A vast number of non-medical terms will be used and most of them will be described when mentioned. For introduction, most important terms that will be used throughout the whole research paper will be described here.

Computer aided design (CAD) is the use of computer to help in the process of creating, analyzing, developing and optimizing the design (model). To improve the designers productivity, the CAD software is being used. CAD software can be used to create two-dimensional (2D) or three-dimensional (3D) designs with almost no limitations. It is widely used in production of special effects for movies or technical and advertising manuals what is called digital content creation (DCC). Moreover, CAD is important part of modern industry. Automotive, shipbuilding and aerospace industry of today can not function without CAD. Digital product development is the activity in which one of the parts is CAD. Besides CAD, other tools are used and these tools can be present as stand alone software or incorporated as a module within CAD software. To analyze engineering tasks Computer aided engineering (CAE) is being used and it includes analysis of thermal and fluid flow, dynamics and kinematics, stress analysis and optimization process of product. Additionally, subsequent process is computer aided manufacturing (CAM) that is used as a software for machine tools control. 2D and 3D structures created in CAD are translated in numbers so CAM is considered as numeric control (NC) programming tool.

First application of CAD/CAM technologies was for car body design and tooling in the 1960s at the Renault.

Most commonly file format used in CAD/CAM is stereolithography (STL) file format. An STL file describes a raw, unstructured triangulated surface using a 3D Cartesian coordinate system. STL file can contain meshes, and a mesh is a representation of a given shape or form, consisting of an arrangement of a finite set of triangles. The next one is “g-code“. G-code is the name for programming language and is used mainly in CAM to control automated machine tools such as 3D printer or CNC (computer numerical control) machine. To make it simple, g-code is language in which people tell machines how to do something. The “how“ is defined by g-code instructions that tell the motor where to move, how fast to move and in what path to move.

PURPOSE OF RESEARCH

Because of the increased number of amputations in the future, a prosthesis that will be easy and fast to manufacture with high quality is needed. Furthermore, it should be able to meet all the needs of the users. As a result of the synergy between the two scientific disciplines, medicine and mechanical engineering, a new methodology was developed. My research is important because it presents that new methodology of planning, designing, manufacturing and new way of using of personalized, functionally satisfying transtibial prosthesis. Moreover, existing process of manufacturing prosthesis and orthosis is slow and artisan dependant. In the future process of manufacturing prosthesis should be more simple, precise and faster. The proposed methodology includes all mentioned features of future manufacturing. Together with that, this methodology provides designing process of adaptable transtibial prosthesis. Using of CAD/CAM technologies is important part of proposed methodology. Computer Aided

Designing and Computer Aided Manufacturing (CAD/CAM) found their path in the field of medicine and the use of these technologies in medicine is expanding every day. In this research paper whole process will be described step by step and it will be demonstrated how these technologies can be incorporated in medical practice and used as tools to help our patients. The great advantage of this methodology lies in its practicality. Namely, the entire fabrication process as well as the final model is easily scalable (tailored-made) and adaptable to other patients who undergo to the below-knee amputation procedure. Most notably, this research is also a kind of demonstration of a new way of using transtibial prosthesis. It refers to the use of special fasteners similar to those used in ski boots. They are thus capable of releasing and tighten at multiple levels in order to better adapt to the current needs of the user. Usually, it is known that these patients are often affected by edema. Thanks to given versatility the users will be able to easily adjust the width of the socket and consequently will function in a better way. His quality of life is expected to improve since main reasons of pain and discomfort have been rectified.

To conclude, the main purpose of this work is integration of mechanical engineering into field of medicine to accomplish better results in treating patients on example of creating transtibial prosthesis for leg amputees.

MATERIALS AND PROCEDURES

Materials

Materials that was used in this research paper are divided in software and hardware. Since CAD/CAM technologies are used, computer is unavoidable part of the hardware. *Apple Mackbook Pro 13*'' from the year of 2012 with *2.9 GHz Intel Core i7* processor, *8 GB 1600MHz DDR3* memory and *Intel HD Graphics 4000 1536MB* graphics was used as the computer for designing and preparing the g-code.

Leg stump was scanned with the structured light 3D scanner *Artec Eva* (Figure 10). It scans quickly, capturing precise measurements in high resolution. Scanners most important specifications are presented in Table 2. *Artec Eva* is ideal choice for making quick, accurate and textured 3D model of medium sized object such as human bust or leg stump.

Figure 10: *Structured light 3D scanner Artec Eva*
Available from: http://docs.artec-group.com/as/11/en/hardware.html]
[cited 2018 Jun 15].

As already mentioned scanner employs the structured-light method for reconstruction of 3D models. Since it captures model using optical technology not all surfaces can be scanned with the same quality. However, using certain techniques such as dusting with talcum powder or covering objects with light spray, can successfully enable scanning of dark, reflective or transparent objects. 3D scanner is used for quality control or for rapid prototyping in wide range of industries, from automotive and aerospace industry to forensics, medicine and prosthetics.

Table 2: *Artec Eva most important specifications*
Available from: https://www.artec3d.com/portable-3d-scanners/artec-eva#specifications]
[cited 2018 Jun 15].

3D resolution	0,5 mm
3D point accuracy	0,1 mm
3D accuracy over distance	0,03% over 100 cm
Warm up period for achieving max. result	0 sec
Colors	24 bpp (bits per pixel)
Texture resolution	1,3 mp (megapixel)
Scanning technology	Structured light
Structured light source	Flash bulb (no laser)
Angular field of view, HxW	30 x 21°
Video frame rate	16 fps (frames per second)
Exposure time	0,0002
Data acquisition speed	2 million points / sec
Multi core processing	Yes
3D formats	OBJ, PLY, WRL, STL, AOP, ASCII, Disney PTEX, E57, XYZRG
Weight	0,85 kg
Dimensions	262 x 158 x 63 mm
Processing capacity	40 million triangles / 1 GB RAM

Interesting to mention is that *Artec Eva* has been used to scan Barack Obama and like that contributed to process of creating first ever 3D portrait of an American president. For purpose of this research Prusa i3 MK2S with Multi-material upgrade was used as 3D printer that manufactured the socket. Prusa i3 MK2S was chosen because of its great specifications compared to the price. This is stable high precision printer that can be used for many purposes since a lot of materials can be used. Main specifications of this printer are shown in Table 3. Manufacturing of socket is easier since 3D printer has *Multi-material upgrade*. It provides the use of different materials during the same printing process so socket can be manufactured with better precision. That function is provided with the use of four extruders. Each of the extruder is connected with nozzle and filaments are changing during the process of printing. Polycarbonate filament was used in first extruder, and PVA (polyvinyl alcohol) filament was used in second extruder as a support material. Filament used for manufacturing the socket was polycarbonate and PVA as support material (Table 4). Polycarbonate is strong and very resistant to impact. It is the strongest material available in consumer 3D printing which is supported by the fact that this material is used when making bullet proof glass. However, you must be able to print at temperatures of 300℃ in order to print with this material. This material was used because of great ratio of rigidness and elasticity what makes it ideal for socket. PVA is water soluble material that was used as support material. Support materials provide better print quality of overhanging parts (>75 degrees) of the printed model.

Table 3: *Prusa i3 MK2S with Multi-material upgrade most important specifications*
Available from: https://shop.prusa3d.com/en/3d-printers/53-original-prusa-i3-mk2s-3d-printer.html
[cited 2018, Jun 15].

Technology	FDM (Fused Deposition Modelling) FFF (Fused Filament Fabrication)
Mechanical arrangement	Cartesian-XZ-head
Printable materials	ABS, HIPS, Nylon, PETG, PLA, Flex, Carbon, Wood, PVA
Filament diameter	1,75 mm
Print size millimeters (xyz)	250 x 210 x 200 mm
Layer resolution	0,05 mm - 3,5 mm
Extruder type	Geared motor
Extruder number	4 extruders - 4 filaments
Nozzle number	1 nozzle - 4 extruders
Nozzle size	0,4 mm (0,6 mm optional)
Max. nozzle temperature	280℃
Max. heated bed temperature	120℃
Max. printing speed	100 mm/s
Best printing speed	45 mm/s
Closed print chamber	No
Display	LCD with steering wheel button
Slicing	Slic3r, Cura, KISSlicer, Simplify3D

Table 4: *Filament for 3D printer (Polycarbonate and PVA) specifications*

Material	**Poly-carbonate**	**PVA**
Diameter	1,75 mm	1,75 mm
Printing temperature	270 - 310 ℃	190 - 210 ℃
Build plate temperature	>100℃	50 - 60 ℃
Ideal printing speed	10 - 40 mm/s	5 - 30 mm/s
Emitting fumes	No	No

Artificial leg stump was used as pattern for model. Artificial stump was created with the use of gypsum by the experienced prosthetist according to real patients transtibial stump. Using 3D scanner, contours of the leg stump were successfully replicated. Dimension of the leg stump were 123 x 148 x 349 mm and according to the leg stump socket model was designed.

Serial produced steel cylinder is used as the pylon for the prosthesis. Diameter of the pylon is 40 mm, height is 300 mm and it weights 1kg. Artificial foot is attached to pylon as the serial part of the prosthesis.

Important part of this transtibial prosthesis are fasteners. Three fasteners (with aluminium and plastic parts) were used to provide proper firmness while being relatively lightweight so the prosthesis is not overweighty. Fasteners are long 150 mm and weight is 100 g. They have ten tipping levels that can be changed so the bearer of the prosthesis can loosen or tighten the prosthesis depending on the needs at the given moment. Inner silicone socket is used to provide full contact of socket with the skin of the leg stump.

Software used for this research paper was software used for scanner *Artec Studio* that provides a lot of possible functions. Besides managing the process of scanning, Artec Studio accomplish full data post processing, optimize mesh tessellations and do much more to create a quality 3D model. Almost all of operations that can be done in CAD software can be done in *Artec Studio* as well. Most of these softwares are similar and provide equal functions. However, in this research *Fusion 360* was used for CAD. *Fusion 360* is one of the first integrated CAD/CAM/CAE software for product development. What is more, it connects entire product design and development process in one toll and was chosen because of its step-by-step tracking feature that enables easier implementation of taken steps in research paper. For creating g-code *Slic3r Prusa Edition* was used. *Slic3r Prusa Edition* is an open-source 3D printer slicing application. It is easy to use and it is optimized for Prusa developed 3D printers. *Slic3r* provides great environment as a slicing tool with easy to use slicing, filament and printer settings.

Procedures

The first step in creating socket is taking measures of the leg stump. In this methodology, instead of measuring it, the leg stump was scanned with 3D scanner *Artec Eva*. Thanks to the fast development of software the technique of using 3D scanner is much simpler than it used be. Even though, to create quality 3D model, scanning object needs to be appropriately prepared and technique has to be followed. Even light without direct sunlight has to be insured. Best results will be given if object planned for scanning is placed on rotating table. However, scanner can be held in hand while encircling the object. As scanner is being gradually moved, adjacent frame areas overlap and create three dimensional picture. *Artec Studio* automatically in real time aligns captured frames what provides immediate access to the frames in single coordinate system. Scanner shouldn't be moved to fast and objects should be kept as close to the centre of the field view as possible. *Artec Eva* and *Artec Studio* has auto alignment and re-capture option so if object is lost of sight during the scan, user can return to the point where track was lost and start with the further scanning. That feature makes it very versatile and easy to use.

After scanning leg stump, model was revised and patched in Artec Studio and then exported as STL file. According to the STL file complementary socket was designed with the use of *Fusion 360*.

When designing in CAD software everything can be accomplished with the proper use of software and the right vision of end product. Socket was designed in few steps.

After the design of final product was finished (socket for leg stump), g-code was created with the use of *Slic3r*. After uploading final STL file of socket to *Slic3r*, printing settings were arranged. Used settings are defined according to ideal conditions for filament since proper use of material is of crucial importance for high-quality model.

Next step for finalizing process was compositing of the prosthesis. Inner silicone socket is placed and fasteners were attached to the foreseen places. Pylon and foot were combined earlier and then attached onto the socket.

RESULTS

As mentioned earlier, the main purpose of this work is to present new methodology in planning, designing, manufacturing and usage of transtibial prosthesis.

Beforehand, the process was planned and patients leg stump was sculpted by experienced prosthetist using gypsum. Patients leg stump was not scanned directly because of lack of experience using 3D scanner for scanning human body. In future, that step will be eliminated and leg stump will be scanned directly.

At the beginning, model was scanned using structured light 3D scanner. Analyzing and perfecting obtained information led us to perfect leg stump 3D model as presented in Figure 11. Then designing of socket according to prepared leg stump started. Using *Fusion 360* perfectly fitting socket was designed (Figure 12). Type of socket that was designed was something in between Patella tendon bearing and Total surface bearing socket.

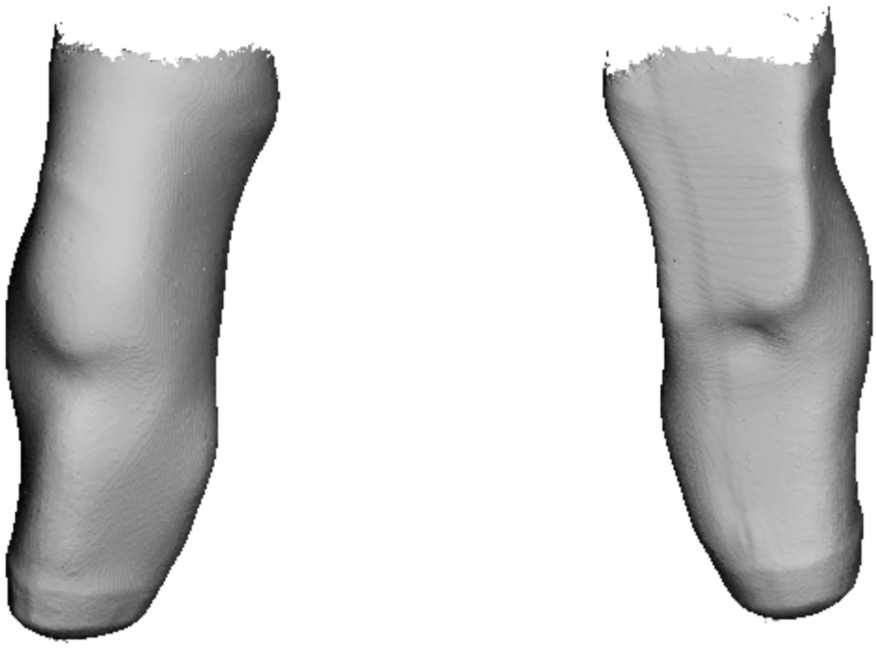

Figure 11: *3D model of scanned leg stump*

The design strived for full contact but internal protrusions were created. Internal protrusions were located on pressure tolerant areas of transtibial stump. Patellar tendon, supracondylar areas, medial flare of tibia, and lateral flare of tibia and fibula were used as pressure tolerant spots. As soon as design was over, model was sliced and prepared for 3D printer using parameters summarized in Table 5. Parameters were adjusted according to analyzed data of material specifications and 3D printer performance with the given material.

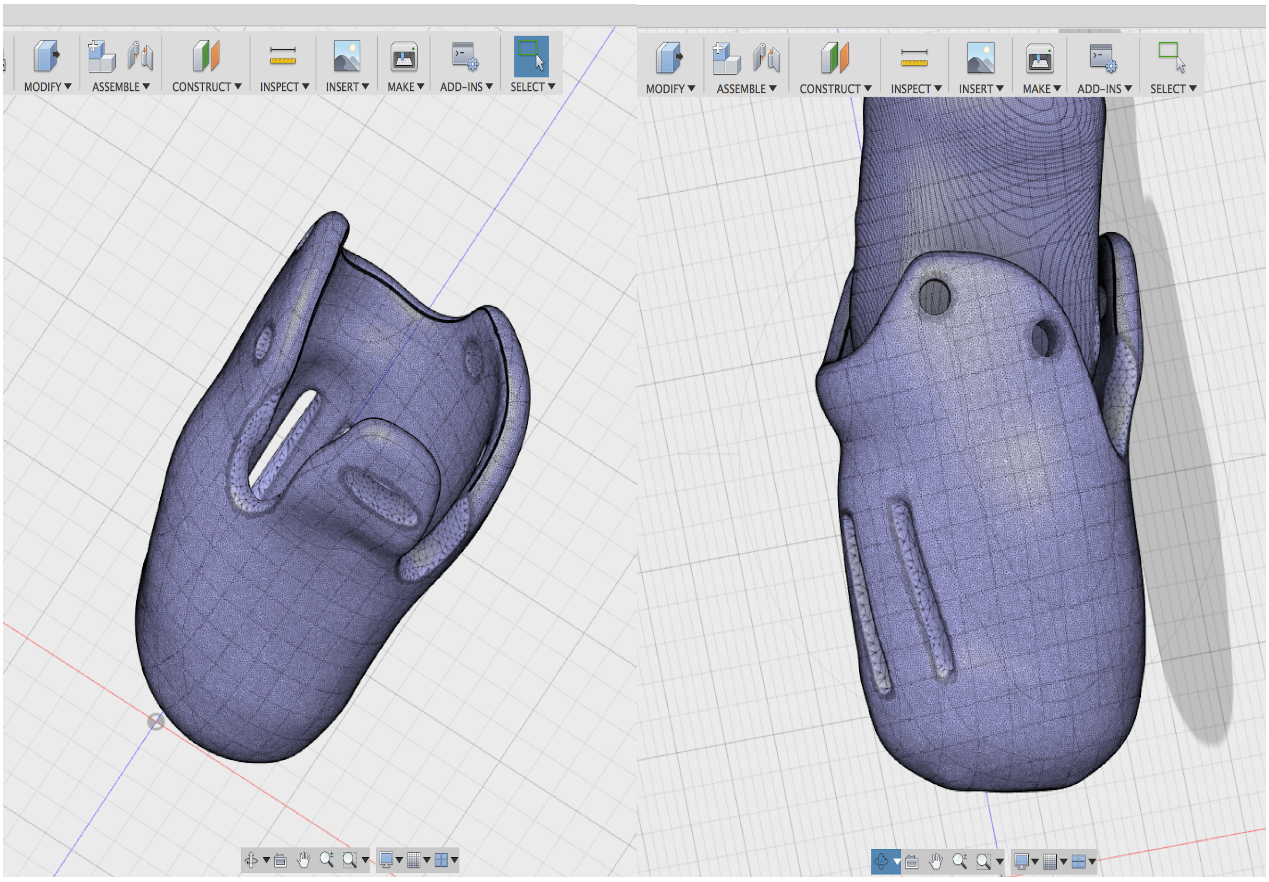

Figure 12: *Designing of socket according to leg stump in Fusion 360*

Table 5: *Slicing settings for socket design*

Layer height	0,1 mm	**Printing speed**	30 mm/s
Wall thickness	2,4 mm	**Infill**	50%
Solid layers top/bottom	4	**Extrusion**	0,98
Support	Custom support	**Retraction**	Enabled

Finally, socket was manufactured, fasteners were fused, inner socket linen was placed and pylon with foot was attached. One fastener was placed on median plane of socket and other two were placed on posterolateral wall of socket. fasteners have eight different levels of tightening. In addition, with fasteners width of the socket can be changed by the user what provides versatility of the socket. To sum up, the idea of presented methodology is to be easily scalable in the world and fully compatible with the user. Given results demonstrate how proposed methodology can be recreated and provide improvements in wide range of patients.

DISCUSSION

Prior researches about application of additive manufacturing in creation of transtibial prosthesis displayed that perfect fitting socket can be designed and manufactured. For example, in Japan on University of Tokyo, running prosthesis was designed, manufactured and successfully tested. There is a possibility of realizing a superior performance in strength and lightweight properties when using AM [21]. Furthermore, in USA perfect fitting socket was designed and manufactured. Whereas, mentioned studies provided no additional benefits except for production methodology. Additionally, this studies are innovative only by methodology of designing and production but they miss methodology of using the transtibial socket. In this study, except of testing new way of designing and creating transtibial socket, completely new approach of using transtibial socket was tested. These findings extend earlier results, the socket manufactured in this study provides perfect fit throughout the day whatever the needs are. Thanks to CAD/CAM technologies, the improvements noted in our study were unrelated to age, gender or stump shape. Therefore, this study indicates that the benefits offered by suggested method of manufacturing may fulfil needs across a broad range of patients. Most notably, this is the first study to our knowledge to propose the new way of how transtibial socket is being used. As mentioned earlier, manufactured socket is able to change its width using fasteners. Like that, main factor of discomfort while using a socket for a long time was eliminated. Our results provide compelling evidence for application of this methodology in prosthesis manufacturing process. Subsequently, users will be able to function in more appropriate way and quality of life is expected to improve. However, some limitations are worth noting. Although our hypothesis is supported theoretically, it still needs to go through series of testing on more patients. Also, lack of experience when using 3D scanner, 3D printer or appurtenant software can be from crucial importance in quality of final product. Future work should include few novelties compared to this. Scanning process should be done using rotating table on which patient can stand to provide best and fastest leg stump recreation. To make scanning process more effective and subsequently easier to implement, research about different 3D scanners cost-effectiveness analysis should be conducted. Furthermore, it should be investigated how different arrangement of fasteners can improve the proposed modus of tightening or loosening the socket. Moreover, slicing process, printing options and the 3D printer itself could be changed to ensure better quality of final product. In addition, new materials for socket manufacturing could be tested to explore new possibilities of developing and using transtibial prosthesis. Besides that, instead of using serial produced pylon and foot, additive manufacturing of whole prosthesis should be tested in future. It could provide new features since better incorporation of inner socket, pylon, foot and fasteners is expected when using AM.

CONCLUSION

In summary, we have presented a new technique of how transtibial socket is being designed, manufactured and used. Socket designing and manufacturing was done with the help of CAD/CAM and 3D printer. That provided simpler designing and easier way of producing. The whole procedure is less time consuming and it provides better results when fitting of the socket is questioned. With possibility of width changing, completely new way of how socket is being used was suggested. This method of tightening or loosening prosthesis can be applicable on the other prostheses as well. What's more, the whole presented methodology can be re-performed in production of all prostheses. That makes this research even more valuable since this results can impact on lives of almost all amputees and not only of transtibial amputee patients. We expect this methodology to become cornerstone of manufacturing in prosthetics and orthotics. Besides that, we hope it will open up entirely new ideas and possibilities for application of mechanical engineering, as well as others scientific disciplines, into the field of medicine.

SUMMARY

Focus of this research paper is to present new methodology of planning, designing, manufacturing and way of using transtibial prosthesis. Across the globe, almost every 30 seconds one leg is amputated due to diabetes and by 2050, number of leg amputees will double its number in the USA [1, 11]. Idea of proposed methodology is to simplify and enhance existing process of manufacturing transtibial prosthesis. In addition, existing process of manufacturing is time-consuming, and artisan dependant. Enhancements suggested in this research are acquired using technologies of 3D scanning and additive manufacturing (AM).

Transtibial prosthesis main functions are to guide and protect the residual limb. It uses forces from limb to make a movement. Prosthesis main parts are socket, pylon and foot. In this research serial produced pylon and foot were used while socket was designed and manufactured with the help of Computer aided designing and manufacturing (CAD/CAM) according to model obtained using 3D scanner. New way of using transtibial prosthesis is suggested in this research. Throughout the day, leg stump

volume is changing and so is the need for socket pressure. Presented socket has feature to change its width and pressure on the leg stump using three fasteners located on median and posterolateral walls of the socket. Accordingly, socket can easily be adapted to users needs and quality of life is expected to improve.

SAŽETAK

Ideja ovog diplomskog rada je prezentiranje nove metodologije planiranja, izvedbe, proizvodnje i načina korištenja transtibijalne proteze. Skoro svakih 30 sekundi jedna je noga amputirana zbog posljedica komplikacija dijabetesa, a prema predviđanjima do 2050. će se udvostručit broj osoba s amputiranom nogom u SAD-u [1, 11]. Cilj predložene metodologije je pojednostaviti i unaprijediti postojeći proces proizvodnje transtibijalne proteze. Osim toga, postojeći proces proizvodnje je dugotrajan i ovisi o iskustvu protetičara. Unaprijeđenja predložena u ovom istraživanju dobivena su korištenjem tehnologija 3D skeniranja, modeliranja i tiska.

Glavne funkcije protisibijalne proteze su voditi i zaštititi preostali dio noge. Proteza koristi sile uda kako bi prenio silu i omogućio kretanje. Glavni dijelovi proteze su ležište, stup i stopalo. U ovom istraživanju korišteni su serijski proizvedeni stup i stopalo, dok je ležište dizajnirano i proizvedeno uz pomoć CAD/CAM tehnologija prema modelu koji je dobiven 3D skenerom. U ovom je istraživanju predložen novi način korištenja transtibijalne proteze. Kroz cijeli dan mijenja se volumen nogu, tako i potreba za pritiskom ležišta. Predstavljeno ležište ima karakteristiku da promijeni svoju širinu i pritisak na nogu pomoću tri kopče. Kopče se nalaze na medijanoj liniji i na posterolateralnim zidovima ležipta. Sukladno tome, ležište se lako može prilagoditi potrebama korisnika i posljedično se očekuje poboljšanje kvalitete života.

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CURRICULUM VITAE

Toma Babić was born on June 1st, 1993 in Zagreb, Republic of Croatia. From 2008 to 2012 he attended the Natural Mathematical Grammar School in Zagreb. He has been studying medicine at the University of Rijeka from 2012 to 2018.

From February to April 2016 he successfully completed education about 3D printing and 3D modeling in Porin d.o.o, Rijeka.

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In November 2016 and 2017, as a member of the team "*Solution*", he won a case study competition "*Realizator*" organized by the Foundation of the University of Rijeka.

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