Nonconventional Technologies Review
Romania, September, 2018

DEVELOPING AN OPEN SOURCE FOOT PROSTHESIS FOR 3D PRINTING

Rares Ghinea[1], Daniela Popescu[2] Mihai Dragomir[3]and Calin Neamtu[4]
[1] Technical University of Cluj-Napoca, Design Engineering and Robotics, Bd. Muncii 103-105, rares.ghinea@muri.utcluj.ro
[2] Technical University of Cluj-Napoca, Design Engineering and Robotics, Bd. Muncii 103-105, daniela.popescu@muri.utcluj.ro
[3] Technical University of Cluj-Napoca, Design Engineering and Robotics, Bd. Muncii 103-105, mihai.dragomir@muri.utcluj.ro
[4] Technical University of Cluj-Napoca, Design Engineering and Robotics, Bd. Muncii 103-105, calin.neamtu@muri.utcluj.ro

With all the advantages of additive manufacturing, it is possible to obtain a prosthesis that can be more efficient and comfortable than a classic one. In this case, it is possible to use more materials in making the leg prosthesis which by using soft material that can be printed can provide a higher degree of comfort. In the development of the prosthesis were used state of the art techniques and instruments: laser scanning, revere engineering, 3D printing TRIZ.
KEY WORDS: additive manufacturing, 3D printing, solid ankle cushioned heel, TRIZ,

1. INTRODUCTION

The Solid Ankle Cushioned Heel or SACH (Figure 1) is the simplest and cheapest prosthesis available on the market.

Figure 1 Solid Ankle Cushioned Heel

The foot of is a very important element of our mobility that ensures both balance and contact with the ground while walking. The leg prosthesis should provide the body support in the phases of the stepping process (Figure 2) A, B, C and D, and operate on the principle of energy-storing-and-return.

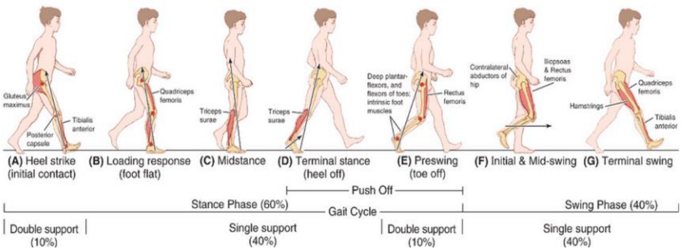

Figure 2 Phase of Gait Cycle [1]

SACH-type prostheses are simple, made of foam and wood or plastic, easy to maintain and without any degree of freedom; they are normally recommended for people with a lower activity level.

The *single axis* type of prosthesis offers a type of rotation named tilt up and down (Figure 1 center). This movement allows the prosthesis to sit fast on the surface as the heel touches the ground, thus increasing stability during travel. This type of prosthesis is recommended for patients who move slowly and have a problem in the knee joint. In this type of prostheses there is a need for maintenance operations that are somewhat more difficult compared to SACH type.

The multi axial prostheses offer more degrees of freedom and are designed to ensure stability and comfort even when used on uneven surfaces or in rapid steering (Figure 3).

Figure 3 Multi-axial feet [2]

In multi axial prostheses, the design is similar to the one shown in the figure above, the two parts of the prosthesis move independently, thus providing a better balance than the SACH or single axis prostheses. These types of prostheses are recommended to active people and require periodic simple maintenance and adjustment work. Dynamic response prostheses (Figure 4) also known as “energy storing feet” use a system similar to a spring that accumulates and releases energy while the patient is moving. The spring effect obtained using various shapes and material types provide extra energy for the user by significantly reducing the patient's effort while walking. Energy is accumulated in stages A, B and C (Figure 2) and released in stages D, E and F. This type of prosthesis is recommended for active people and can be used during sports activities. The active prostheses are the most technologically advanced and incorporate sensors, actuators and microprocessors.

Figure 4 THRIVE - **r**esponse with no extra load (upper), response with extra load (bottom) [3]

Figure 5 Powered prosthesis [4]

The advantages of motor-powered prostheses are: a walking sensation similar to that of the normal foot; speed and ease in changing travel speed, easy displacement on ramps and uneven terrain. The main disadvantages of these systems are the need for battery charging and its capacity, cost and weight higher than for other types of prostheses. The SACH type prostheses are obtained by using the plastic injection process (Figure 6); this process as all those that require the use of molds offer a low degree of customization.

Figure 6 Manufacturing of SACH using injection mold

Multi-axial and dynamic or motor-powered prostheses typically have components made of composite materials, they are made using molds as shown in [5]. Additive manufacturing is a process that begins to be used in the manufacture of prostheses and orthoses as shown in [6].

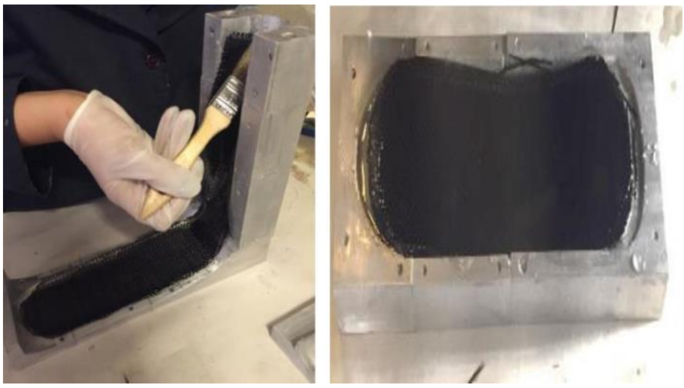

Figure 7 Manufacture of components of composite materials [5]

In [7] the model from Figure 8 is presented and explores the possibilities of prosthesis development for children from developing countries - specifically referring to the variance in sizes as the child grows.

Figure 8 3D printed SACH [7]

The most common manufacturing methods used are: Selective Laser Sintering (SLS) [8], Fused Deposition Modelling (FDM) [9, 10], laser sintering as shaping technology [11].

In Table 1 are presented the equipment and materials of the additive manufacturing category used for prostheses and orthotics.
From the study of bibliographic resources, it has been found that one single prosthetic material is usually used and another one for the support.
Equipment and materials used for foot prosthesis manufacturing

Table 1

Equipment	Materials	Reference
SLA-250/40, 3D Systems	Ciba-Geigy 5170, DuPont Somos 6110	[12]
SinterStataion 2000 / 2500 / 3500	Duraform Duraform PA	[13-15]
Vanaguard SinterStation, 3D Systems	Duraform Polyamide (Nylon 12)	[16]
Z Corporation Z402-3	Plaster infiltrated with PU	[17]
DTS SinterStation2500 plusTM	Duraform Nylon 11 and Nylon 12	[18]
Vanaguard SinterStation, 3D Systems	Rilsan D80 Nylon 11 and Nylon 12	[19, 20]
Objet500 Connex	VeroWhitePlus and TangoBlackPlus TangoBlackPlus and VeroClearTM	[21, 22]

2. FOOT PROSTESIS DESIGN

2.1 Innovation support

The leg prosthesis development process had as its central element the algorithm presented in Figure 9. The TRIZ (Teoriya Resheniya Izobretatelskikh Zadach) method, developed by the inventor and writer Genrich Altshuller between 1946 and 1985 was successfully used in innovation design of medical equipment [23], new product development [24] or in development of plastic parts [25].

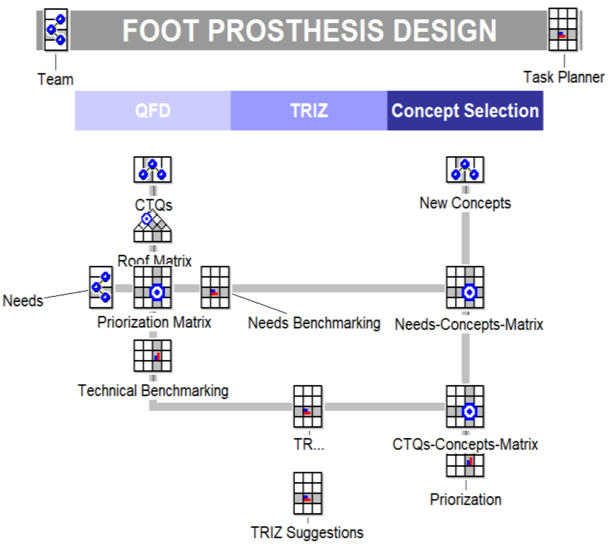

Figure 9 Design algorithm

The TRIZ method was used to generate innovative technical solutions, so CTQs were equated with the parameters from TRIZ (Figure 10), the inventive conflicts and inventive principles have been determined and then generic solutions have been sought on the basis of known prior solutions. Generic solutions based on the principles of the TRIZ method have been interpreted and specific solutions have been established in the form of new concepts.

TRIZ CTQs / TRIZ Classification	TRIZ Parameter	Conflicts	Optimization
1 Dimenison between 22-52	Convenience of use	5	↑
2 Weight between 100 - 300 grams	Weight of moving object	3	↓
3 Global Elasticity	Tension, pressure	3	O
4 Types of materials and quantity	Complexity of device	2	↓
5 Production cost max 40 Euros	Manufacturability	3	↓
6 Number of components	Level of automation	2	↓
7 Mean Time between failures (MTBF)	Reliability	0	↑

Figure 10 Attributing TRIZ parameters

The principles considered useful in developing the prosthesis extracted from the TRIZ method are:

Extraction - Extract (remove or separate) a disturbing part or property from an object, or extract only the necessary part or property

This recommendation has been transposed into practice by designing a prosthesis containing a single component (extract, remove or separate part or property) but allowing the foot to flex during walking.

Dynamicity - Make an object or its environment automatically adjust for optimal performance at each stage of operation. Divide an object into elements which can change position relative to each other. If an object is immovable, make it movable or interchangeable

This recommendation has been transposed into practice by adding parts of elastic material so that certain parts of the prosthesis are not rigid (change position relative to each other)

Self-service - Make the object service itself and carry out supplementary and repair operations. Make use of wasted material and energy.

The implementation of this recommendation has been translated by reducing the number of moving parts of the prosthesis in order to eliminate as far as possible the maintenance of the prosthesis.

Copying - Use a simple and inexpensive copy instead of an object that is complex, expensive, fragile or inconvenient to operate. Replace an object by its optical copy or image. A scale can be used to reduce or enlarge the image. If visible optical copies are used, replace them with infrared or ultraviolet copies

Using a simple and inexpensive copy - has led to a reduction in the total number of components, the resultant prosthesis is made up of a single piece made of two materials: one rigid and the other one elastic.

2.2 Prosthesis design

The external shape of the prosthesis was obtained by scanning and processing a passive foot prosthetic (Figure 11).

Figure 11 Passive foot prosthetic

By using scanning techniques and reverse engineering, the outer prosthesis shape can be customized for each individual patient as shown in [26].

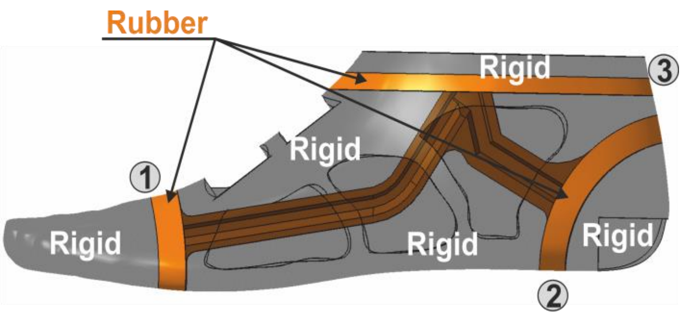

Figure 12 Prosthesis design

The designed prosthesis combines two materials: one rigid PLA and the other one elastic as shown in Figure 12. Zone 1 and 2 allow fixation of the prosthesis in a similar way to the natural movements of the foot (Figure 13).

Figure 13 Flexing the prosthesis

Zone 3 is an area that takes vertical shocks and whose thickness can vary depending on the weight of the patient and is a customizable element of the prosthesis.

The three areas printed with elastic material are connected by an elastic core whose shape has been optimized in order to increase the adhesion between the two materials (Figure 14).

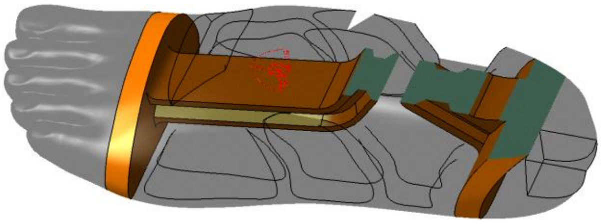

Figure 14 Connecting the flexible areas

Obtaining the prosthesis is possible using a printing equipment with at least two print heads, one for each material. The printing materials used are:

- PLA : 1.7mm, material density 1,24 g/cm^3, tensile strength 110 MPa,
- Rubber: 1.7mm, material density 1,21 g/cm3, tensile strength 40 MPa,
- A third material such as PVA can be used for the support which reduces manufacturing time by simplifying the removal of the support.

The printer used for prototyping is Leapfrog Creater XL (Figure 15).

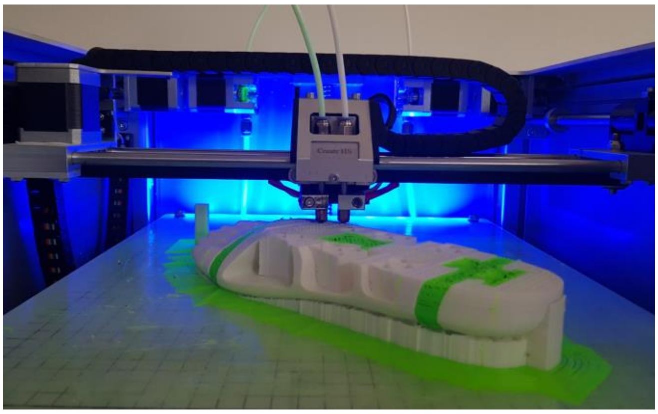

Figure 15 3D printing of prosthesis

In Figure 16 shows the printed prosthesis; represented in white/orange is the flexible material, this material represents about 30% of the total volume of the prosthesis.

Figure 16 Printed prosthesis

3. CONCLUSION

The paper presents the first phase of the development of a foot prosthesis. The innovation brought about by this prosthesis model consists in the use of two different materials, one solid and the other elastic, which were added in layers by means of using additive manufacturing equipment. The prosthesis will enter the test and validation phase when endurance and fatigue tests will be performed as shown in [27]. Also tests will be conducted in order to determine gait patterns on various terrains, (balance, on flat, uneven, sloped), stairs and walking speed [28].

At this stage, a series of optimizations of the shape and proportion of the solid and the elastic material have been made, and other forms and material will be tested in the future. At this moment using the design shown in Figure 12 the prosthesis can be printed depending on printer performances in a time frame between 10 and 22 hours.

4. REFERENCES

1. Memorangapp.com. *Biomechanics - Swing Phase and Contact Period*. 2018 [cited 2018 June]; Available from: https://www.memorangapp.com/flashcards/182452/Biomechanics+-+Swing+Phase+and+Contact+Period/.

2. Americas, Ö. *Pro-Flex*. 2018 [cited 2018 May]; Available from: https://www.ossur.com/prosthetic-solutions/products/dynamic-solutions/pro-flex.

3. Freedom-innovations.com. *THRIVE™*. 2018 [cited 2018 July]; Available from: http://www.freedom-innovations.com/thrive-2/.

4. Group, M.B. *Transtibial Powered Prostheses* 2018 [cited 2018 June]; Available from: http://biomech.media.mit.edu/portfolio_page/powered-ankle-foot-prosthesis/.

5. Hernandez, M.S., Carranza, M.A.R., Nuno, V., West, J.C.H., and Castaneda, A.M., *Methodology for the manufacture of a transtibial prosthesis based on carbon fiber composite and epoxy resin.* Materia-Rio De Janeiro, 2018 Volume: **23** Issue: (2): p. 11 DOI: 10.1590/s1517-707620180002.0482.\

6. Chen, R.K., Jin, Y.A., Wensman, J., and Shih, A., *Additive manufacturing of custom orthoses and prostheses-A review.* Additive Manufacturing, 2016 Volume: **12** Issue: p. 77-89 DOI: 10.1016/j.addma.2016.04.002.

7. Yap, J. and Renda, G. *Low-cost 3D-printable prosthetic foot*. in *Proceedings of the 3rd European Conference on Derign4Health, Sheffield, UK*. 2015.

8. Pallari, J.H.P., Dalgarno, K.W., and Woodburn, J., *Mass customization of foot orthoses for rheumatoid arthritis using selective laser sintering.* IEEE Transactions on Biomedical Engineering, 2010 Volume: **57** Issue: (7): p. 1750-1756 DOI: 10.1109/TBME.2010.2044178.

9. Saleh, J.M. and Dalgarno, K.W. *Cost and benefit analysis of Fused Deposition Modelling (FDM) technique and Selective Laser Sintering (SLS) for fabrication of customised foot orthoses*. in *Innovative Developments in Design and Manufacturing - Advanced Research in Virtual and Rapid Prototyping*. 2010.

10. Jin, Y., He, Y., and Shih, A. *Process Planning for the Fuse Deposition Modeling of Ankle-Foot-Othoses*. in *Procedia CIRP*. 2016.

11. Deckers, J.P., Vermandel, M., Geldhof, J., Vasiliauskaite, E., Forward, M., and Plasschaert, F., *Development and clinical evaluation of laser-sintered ankle foot orthoses.* Plastics, Rubber and Composites, 2018 Volume: **47** Issue: (1): p. 42-46 DOI: 10.1080/14658011.2017.1413760.

12. Freeman, D. and Wontorcik, L., *Stereolithography and prosthetic test socket manufacture: A cost/benefit analysis.* JPO: Journal of Prosthetics and Orthotics, 1998 Volume: **10** Issue: (1): p. 17-20.

13. Rogers, B., Stephens, S., Gitter, A., Bosker, G., and Crawford, R., *Double-wall, transtibial prosthetic socket fabricated using selective laser sintering: a case study*. JPO: Journal of Prosthetics and Orthotics, 2000 Volume: **12** Issue: (3): p. 97-103.

14. Stephens, S., Crawford, R., Rogers, W., Gitter, A., and Bosker, G. *Manufacture of compliant prosthesis sockets using selective laser sintering*. in *11th Freeform Fabrication Symposium, Austin, TX*. 2000. Citeseer.

15. Faustini, M.C., Neptune, R.R., Crawford, R.H., Rogers, W.E., and Bosker, G., *An experimental and theoretical framework for manufacturing prosthetic sockets for transtibial amputees.* Ieee Transactions on Neural Systems and Rehabilitation Engineering, 2006 Volume: **14** Issue: (3): p. 304-310.

16. Faustini, M.C., Crawford, R.H., Neptune, R.R., Rogers, W.E., and Bosker, G., *Design and analysis of orthogonally compliant features for local contact pressure relief in transtibial prostheses.* Journal of biomechanical engineering, 2005 Volume: **127** Issue: (6): p. 946-951.

17. Herbert, N., Simpson, D., Spence, W.D., and Ion, W., *A preliminary investigation into the development of 3-D printing of prosthetic sockets.* Journal of rehabilitation research and development, 2005 Volume: **42** Issue: (2): p. 141.

18. Rogers, B., Bosker, G.W., Crawford, R.H., Faustini, M.C., Neptune, R.R., Walden, G., and Gitter, A.J., *Advanced trans-tibial socket fabrication using selective laser sintering.* Prosthetics and orthotics international, 2007 Volume: **31** Issue: (1): p. 88-100.

19. Rogers, B., Bosker, G., Faustini, M., Walden, G., Neptune, R.R., and Crawford, R., *Case report: Variably compliant transtibial prosthetic socket fabricated using solid freeform fabrication.* JPO: Journal of Prosthetics and Orthotics, 2008 Volume: **20** Issue: (1): p. 1-7.

20. Montgomery, J.T., Vaughan, M.R., and Crawford, R.H., *Design of an actively actuated prosthetic socket.* Rapid Prototyping Journal, 2010 Volume: **16** Issue: (3): p. 194-201.

21. Sengeh, D.M. and Herr, H., *A variable-impedance prosthetic socket for a transtibial amputee designed from magnetic resonance imaging data.* JPO: Journal of Prosthetics and Orthotics, 2013 Volume: **25** Issue: (3): p. 129-137.

22. Doubrovski, E., Tsai, E.Y., Dikovsky, D., Geraedts, J.M., Herr, H., and Oxman, N., *Voxel-based fabrication through material property mapping: A design method for bitmap printing.* Computer-Aided Design, 2015 Volume: **60** Issue: p. 3-13.

23. Gao, C.Q., Guo, L.M., Gao, F.L., and Yang, B., *Innovation design of medical equipment based on TRIZ.* Technology and Health Care, 2015 Volume: **23** Issue: p. S269-S276 DOI: 10.3233/thc-150962.

24. Wang, F.K., Yeh, C.T., and Chu, T.P., *Using the design for Six Sigma approach with TRIZ for new product development.* Computers & Industrial Engineering, 2016 Volume: **98** Issue: p. 522-530 DOI: 10.1016/j.cie.2016.06.014.

25. SOLCAN, S., NEAMTU, C., GHINEA, R., and Stefan, B., *Using TRIZ method for support innovation in developing plastic parts.* ACTA TECHNICA NAPOCENSIS-Series: APPLIED MATHEMATICS, MECHANICS, and ENGINEERING, 2015 Volume: **58** Issue: (4).

26. Buhăţel, D., Buna, Z., Campian, R.S., Ilea, A., Moga, M., Ţărmure, V., and Neamţu, C., *Using Laser Scanning to Measure the Difference between Classical Individual*

Custom Trays and 3D Ideal Individual Custom Trays in the Totally Edentulous, in *International Conference on Advancements of Medicine and Health Care through Technology; 5th – 7th June 2014, Cluj-Napoca, Romania*, S. Vlad and R.V. Ciupa, Editors. 2014, Springer International Publishing. p. 155-158.

27. Prost, V., Olesnavage, K.M., Johnson, W.B., Major, M.J., and Winter, A.G., *Design and Testing of a Prosthetic Foot With Interchangeable Custom Springs for Evaluating Lower Leg Trajectory Error, an Optimization Metric for Prosthetic Feet.* Journal of Mechanisms and Robotics-Transactions of the Asme, 2018 Volume: **10** Issue: (2): p. 8 DOI: 10.1115/1.4039342.

28. Burger, H., Vidmar, G., Zdovc, B., Erzar, D., and Zalar, M., *Comparison between three types of prosthetic feet: a randomized double-blind single-subject multiple-rater trial.* International Journal of Rehabilitation Research, 2018 Volume: **41** Issue: (2): p. 173-179 DOI: 10.1097/mrr.0000000000000286.