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10. Design and Prototyping for Disability. PROTIUM Case Study

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Abstract

The present paper introduces the methodology applied for the development of Protium, a low cost prosthetic foot for children assisted in the Sulaymaniyah Rehabilitation And Social Reintegration Centre of Emergency, in Iraq.

Nowadays in Iraq a high percentage of the population is affected by landmines and, in particular, children need a constant replacement of the prosthesis due to their growth, which impacts on the life quality and on the healthcare costs.

We have designed Protium in order to be made inside a rehabilitation center, where operators can replicate the prosthetic element with machinery and materials available at a low cost in Iraq, increasing the independence of the center in agreement with Emergency's ethics.

To guarantee the quality of the device, we have analyzed the users and walk's biomechanics with the support of experts from Emergency and Orthomedica; then we have examined low-cost prosthetic feet cases and some innovative projects. A further step was the focus on the materials, we analyzed the stress on elements in order to identify these materials with the best properties to accomplish our aim.

The result of the research consists of the design for a prosthetic foot for children, made with a low budget and an high level of efficiency. The production of the prosthetic element uses reusable appropriate materials and integrates the local potential. Moreover, Protium is designed to be an open source project that everyone can benefit on: all the steps of production can be reproduced easily, making it accessible to everyone.

Keywords: *Prosthetic Foot, Life Cycle, User Centered Design, Learning Experience, Design Open Source.*

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10.1 Introduction

The relevance of design contribution in the field of assistive technologies and the possibility to have an insight on the work done by the team of Emergency[1] in the centre of Sulaimaniya (Miccio, 2018), drove us to approach the problem of the production, customization and care of prosthetic elements substituting feet of amputees due to landmines in Iraq. Our research focused on how to make prosthetic elements more accessible. The methodology consists of a first phase of research to understand the psychological and physical problems caused by the amputation of the lower limbs. In addition, the way Emergency operates in the Iraqi rehabilitation centre and how prostheses are made has been studied. Secondly, the materials available in the area were studied to understand their technical characteristics and their possible use. Subsequently, the design of a low-cost children's prosthetic foot and the related production process was achieved. Finally, Protium was tested in order to verify the correct functioning and behavior of the materials with the help of expert technicians and biomedical engineers. The objective of the project is that these prosthetic feet should facilitate walking and be easy to make, with easily workable materials and waste materials available in the territory. With these aims, we have designed a low-cost product that is accessible to a larger number of people.

10.1.1 Production of Prostheses

It was necessary to analyse the different phases of prosthesis production in the Sulaimaniya centre in order to understand the process. It was essential to understand the needs for prosthetists and doctors in order to achieve these limbs, and it was crucial to know Emergency's willingness to make the different centers independent in order to teach local people to manage the center itself. The whole process does not differ much with the western production processes, still remains based on the experience and skill of the technicians, and involves handwork and crafting making it closer to artisanship than to industrial processes.

10.2 Methodology

For us the possibility of dealing with the issue of prostheses with the support of Emergency and the experience of the technicians at the center of Sulaimaniya has been an opportunity to face a purposeful design challenge: under-

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standing and improving the production of prostheses, using materials available in the area, being able to control production waste and making the product as economical as possible.

We had the opportunity to meet a doctor from this association who has worked in the area for many years and knows perfectly the difficult situation, and through this exchange he helped us to direct the course of the project. Our aim was therefore to make the centre independent from external suppliers, in order to remain in line with the values of Emergency, which promotes the independence of the premises. The element needs to be bought externally because of its complexity: the previous trials to product the element on site have been abandoned because the production was too expensive. Given these premises, the objective of the project is to design a prosthetic foot which can be made within the rehabilitation centre. The definition of the user was complicated by the impossibility of going to Iraq to know and see how the population lives.

However, a series of researches are made to understand the characteristics of the Iraqi population and the people affected by landmines within the area have been analysed. The data about hospitalised people (year, sex and type of amputation) from the centre have been taken into consideration in order to understand the target of the project. From the official data, it can be seen that in the last twenty years the largest number of people in hospital have been amputated in the lower limbs, especially in 2018 patients with amputation of the lower limbs are 232 against 102 of the upper limbs: this has allowed us to understand the area on which to focus. It should be noted that many of the hospitalized people come from the city of Mosul following the recent attacks by ISIS.

Further research has been conducted to understand trends, demographics and other epidemiological characteristics of patients injured by landmines.

Inside the document “Landmine injuries at the Emergency Management Center in Erbil, Iraq” (Shabila, Taha and Al-Hadithi, 2010), data show that the average age of patients is 26.5 ± 13.2 years (range 6-71 years), 95.1% are almost 50% are between 19 and 35 years of age and 96.8% are civilians. About 72% of the victims suffered limb amputations; 58.6% of the lower limbs and 13.3% of the upper limbs of the total.

Emergency’s contact, who worked for a few months in the Sulaimaniya centre with some local technicians, highlighted also the frequent need for replacement in children due to their rapid growth as a common problem.

It was also considered useful to analyse the growth curves of children in general in order to have a comparison with data on children in war zones zones

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Tab. 10.1 - Details on limb amputations

Type of injury	No.	(%)	Remark
Upper limb amputation			
Below elbow	11	(3.9)	
Hand	25	(8.8)	
Fingers	2	(0.7)	
Total	**38**	**(13.3)**	
Lower limb amputation			
Above knee	16	(5.6)	
Below knee	87	(30.5)	
Foot	57	(20.0)	
Toes	7	(2.5)	
Total	**167**	**(58.6)**	

(Hosseini, Carpenter and Mohammad, 1998). For this reason, a wide range of growth curves of European males and females from 0 to 18 have been studied, based on data from the WHO (World Health Organization).

A further step was to identify the relationship between the size of the foot and the growth understood as an increase in kilos and variation in height. In order to do this, it was decided to analyze the size of the prosthesis in the current market, because, in many catalogues, including online, it is possible to set the weight of the patient and consequently obtain the specific size of the foot to be used.

10.2.1 Biomechanics of the Foot

It was considered necessary to study the biomechanics of the foot (Imeri and Mancia, 1979) in order to better understand the pace cycle, the functioning of the walk and the various joints (Hutton and Dhanendran, 1979).

The gait cycle during walking has as its purpose the movement of the subject, and in particular the locomotor apparatus performs some important functions:

- generation of a propulsive force;
- maintaining postural stability;

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- absorption of the shock caused by the impact with the ground;
- energy conservation during previous functions to minimize muscle effort.

For our project it was necessary to study:
- step cycle;
- support phase;
- oscillation phase;
- flexo-extension;
- the reaction forces on the ground.

10.3 Results

10.3.1 Prototype

The evolution of the project has been functional to the improvement of some aspects to respect some fundamental characteristics for the correct functioning of the prosthesis. This was also possible thanks to the comparison with Orthomedica, a company in Padova specialized in the production of orthopaedic aids, including lower limb prostheses. Thanks to the strength tests carried out on the model and thanks to the considerations, some aspects of the foot have been improved.

1. The apex of the curve of the underlying plate has been retracted in order to align with the knee as in the correct alignment of the present anatomy of the body.
2. On the back a nylon belt has been inserted that limits the deformation of the C curve at the time of the flexion of the walk.
3. On the back a nylon belt has been inserted that limits the deformation of the C curve at the time of the flexion of the walk.
4. In order to maintain greater adhesion between the sheets.
5. The heel has been slightly flared in order to accommodate more the flexion of the C.
6. On the lower part, the rubber parts have been inserted.

A low-cost 21 cm long children's foot was designed, which corresponds to about 36 cm.

Shared Materials/Instructions. In order to choose the material for the manufacture of the structure of our prosthesis, an analysis of the materials used during the manufacture of the prosthesis was carried out. The foot prosthesis

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must have sufficient rigidity to support the child's body weight during the entire cycle of steps, a certain elasticity, good resistance to atmospheric agents and the lowest possible weight. Many production techniques are considered inappropriate to the technology available on site have been discarded, for example 3D printing and carbon fiber (Mora and Mercedes, 2007).

Considering the materials analyzed on the basis of their strength, low weight, low cost, recyclability and availability in Emergency, Polypropylene was chosen as the material of manufacture of the structural part of the prosthesis. The low density of PP allows the production of lightweight products with a high elastic recovery capacity. It has high impact resistance, high rigidity and is easy to recycle and reuse.

The cushioning element, located in the heel of the prosthesis, consists of a sheet of Ethylene Vinyl Acetate (EVA). Its elastomeric characteristics allow it to absorb the impacts produced during activities such as walking or running.

After some checks carried out during the meeting with Orthomedica, it was decided to place two metal plates (1 mm thick) between the heel and the heel of the prosthesis. The purpose of these plates is that the force exerted on the entire structure is evenly distributed over the entire heel of the prosthesis. In order to extend the service life of the prosthesis, a nylon strip has been inserted at the back between the upper plate and the lower part of the prosthesis, which limits the deformation of the polypropylene C – element of the central part.

The sole of the prosthesis is made with a tyre, in this case a motorcycle, which due to its ability to adhere to any type of soil or surface, allows the prosthesis to be used both inside a shoe and in any type of soil.

Fig. 10.1 - Protium and its components

Production. The aim of our project was that all the material used were all reusable, thus defining the production method and the end of life in order to

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recover some materials and to find a new life to the waste materials present in the area. In particular, production can be divided into two main phases: the recycling phase phase (Galvis Gutiérrez, 2014) and the production phase.

Tab. 10.2 - Material properties

Polypropylene (PP)	Melting point	160 °C
	Breaking strength	35,8 MPa
	Tensile modulus of elasticity	1600 MPa
	Compressive strength	12 MPa
Ethylene Vinyl Acetate (EVA)	Density	0,952 g/cm3
	Flexural modulus	10 MPa
	Shore A hardness	75
	Shore D hardness	32

Recycling phases:

1. shred the polypropylene with the Shredder;
2. extrude the PP bar;
3. cut the bar into smaller bars.

Production phases:

1. place the bars in the oven at 190 °C for 15 minutes;
2. insert the heated bars into the mould for 40 minutes;
3. pressing the mould;
4. open the mould;
5. stretch out the slabs and drill holes in them with a drill;
6. cutting and drilling the tyre;
7. cut the heel from a slab of EVA and shape it;
8. assemble the components with the belt inserted in the upper part;
9. complete the assembly with the bead and the part of the tyre behind.

The main feature of the project is the standardized and artisanal process. We decided to completely revise the production process of the foot elements in order to be able to make the prosthesis inside the prosthetic center.

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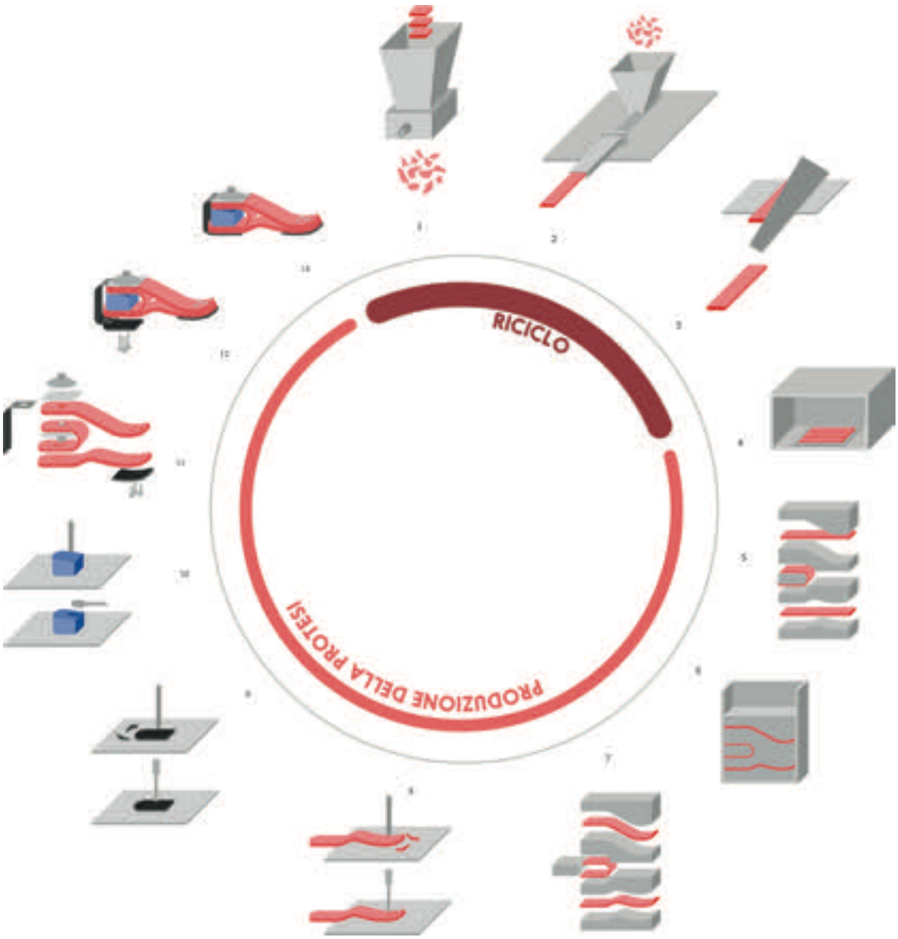

Fig. 10.2 - Production process of the prosthetic foot

In particular, the recycling phase was inspired by the Precious Plastics project (Hakkens, 2018), which promotes the recycling of plastics through the construction of hand-made machinery for recycling in an open source project.

Customization. We wanted to make the prosthesis customizable, because it was interesting to see how each child is able to customize their own prosthesis. To customize the prosthesis we decided to modify the plastic itself: through the insertion of elements, such as wire meshes, it is possible to create a texture on the surface by pressing the mold.

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Structural analysis. It was decided to apply forces (placing a load of 700 N) on the points where the maximum load is applied during the walk, it was simulated the deformation of the material both at the level of stress and displacement, thus finding that the prosthesis supports the forces applied.

Cost analysis. Considering the cost of raw materials directly from suppliers, the material cost for the prosthesis is €3.66, a sum that can be reduced if waste or recycled products are used for EVA, steel, nylon and tyres.

In addition to the materials, the cost of the machinery that will be purchased for the realization of the recycling phase of the prosthesis has been considered.

The possibilities of purchasing Precious Plastic machines are:

- the purchase of already assembled machines for a total cost of 3400 €;
- the purchase of equipment for the assembly of the machine on site for a total cost of about 100 + 250 = 350 €, without considering the labor.

The cost of the machinery is then amortised on a forecast of 250 prostheses (lower limb prostheses produced in 2018): 13.60 € cost of the machinery for each prosthesis.

It is also necessary to include the cost of labor working on the project, assuming an hourly rate of 7 euros and a time of 3 hours for the production of each prosthesis: 21.00 € is the cost of labor for each prosthesis.

At the end of the first year, the cost of the machine will be covered, from that moment on the final cost of the prosthesis will be lower.

The prosthetic foot has been compared with those on the market and with those already used by Emergency. Protium is a foot with lower costs than those of current prostheses, offering significantly higher efficiency than the classic wooden foot currently in use.

Tab. 10.3 - Table with cost of the prosthesis

	Final cost of the prosthesis in the first year	Final cost of the prosthesis after the first year
Raw materials	3,66 €	3,66 €
Machinery	13,60 €	-
Labour	21,00 €	21,00 €
Total	**38,26 €**	**24,66 €**

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10.4 Conclusions

Protium is a prosthetic foot for children that is made at a lower cost than the cheaper prosthetic feet, but offers the same efficiency as the mid-range prosthetic feet. It has been designed to accompany the user's walk as much as possible and the relative distribution of forces during the step cycle.

The design choices were all made with a view to circular economy: the materials to be used are easily available at low cost or can be waste materials. The evaluation of the materials was in fact dictated by the desire to use materials that can be reused and adapted to the possibilities of the Iraqi territory, but also efficient and adequate in terms of mechanical properties. In this way, the design of a prosthetic foot has been achieved, which over time will come at a very low cost. Protium was therefore designed within a logic of circular economy to avoid waste and waste as much as possible and, since one of the objectives is the possibility of production on site, the prosthetic foot is easily assembled and reproducible. These two characteristics make it possible to insert this project within an open-source logic and therefore to share information. In order to do this, the entire production method of this prosthetic foot has also been studied: all the manufacturing phases of the individual components have been standardized in order to simplify production as much as possible, which is so serial. Therefore Protium is a prosthetic foot for children that can be assembled in a few steps, reproducible, inexpensive but still very efficient.

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Notes

[1] EMERGENCY is a non profit organization founded in 1994, recognized as an NGO partner of the United Nations and that remains independent and neutral. It was founded to offer free, high quality medical and surgical care to victims of war, landmines and poverty. Emergency has been present in Iraq since 1995, when

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the programme was launched, and since then 941,116 people have been treated. The active programmes on the territory are different. In Sulaimaniya there is a rehabilitation and social reintegration centre to offer assistance and a self-sufficient life to people amputated by landmines. www.emergency.it.

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Contents

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