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FUNCTIONAL ANALYSIS FOR THE DEVELOPMENT OF BIO-MEDICAL PRODUCTS

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Abstract: *The engineer nowadays needs to possess knowledge that will enable the design of more diverse and cheaper products, but of higher quality, which reach the market faster, and do not pollute. These requirements are the effect of globalization, competition, reduction of the life-cycle of a product, managing the environmental issues, increasing computing power related to communication networks etc. The present paper proposes research applying technical functional analysis for the development of a surgical device manufactured from biocompatible silicone rubber. The vacuum surgical device is a treatment instrument for skin ulcers resistant to antibiotics and difficult to treat because of other connected diseases. The product is fabricated by open mould casting in a selective laser sintered (additive manufactured) mould, obtained after performing functional analysis. Functional analysis is applied to establish the optimum mould concept and the technological process of manufacturing it. Additive manufacturing is used for both the intermediary functional prototype production of the mould and the zero series mould.*
Keywords: *additive manufacturing; life-cycle analysis; bio-compatibility; functional analysis;*

1. INTRODUCTION

The vacuum surgical device (VSD) is a treatment instrument for skin ulcers resistant to antibiotics and difficult to treat because of other connected diseases. The existing product on the market (Figure 1) is designed and manufactured by a SME in United Kingdom. The vacuum device is used to repair the affected skin area, through local distribution of antibiotic and drainage of the wound liquid using a vacuum system. The client proposes the improved version of the product and provides the execution drawings to the working team. The final product will be injection moulded, from biocompatible transparent silicone.

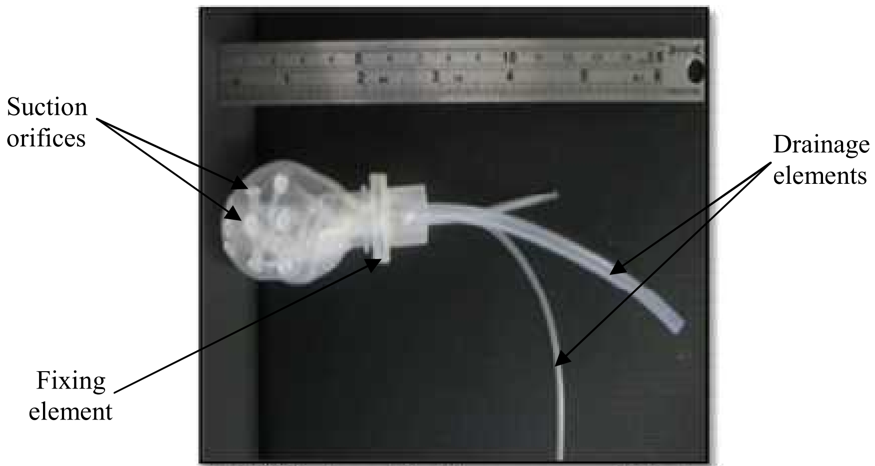


Figure 1: Original model of the vacuum medical device

Additive manufacturing technologies are used in this case to manufacture the mould for the initial testing batch. The client wished to manufacture an initial batch of 50 pieces, which would be used for preliminary testing of the vacuum device. Later, the zero series mould will be adapted to the real conditions for the series production. The aim is to design a mould on which the batch of 50 could be manufactured with a minimum cost for the initial investment. Functional analysis is applied to establish the optimum mould concept and the technological process of manufacturing it. Additive manufacturing is used for intermediary functional prototype production of the mould [1, 2].

2. FUNCTIONAL ANALYSYS FOR DEVELOPING THE ZERO SERIES MOULD

As a result of the research undertaken, the optimum procedure to obtain the mould for the initial series of 50 products is additive manufacturing (Table 1). The main selection criteria which determined this version were the process cost and delivery terms. From a surface quality point of view, product life expectation, maintenance and post processing operations, CNC processing obtained higher scores than additive manufacturing. But due to the clients' importance weighting, the adopted solution will be an application of additive manufacturing.

Table 1: Decision matrix for establishing the optimum manufacturing technology for the mould fabrication

		Additive Manufacturing		**Casting**		**CNC Machining**		**Traditional Machining**	
Selection Criteria	**Weight**	**Rating**	**Weighted Score**	**Rating**	**Weighted Score**	**Rating**	**Weighted Score**	**Rating**	**Weighted Score**
Process Cost	20%	4	0.8	2	0.4	3	0.6	5	1
Product delivery terms	20%	5	1	3	0.6	5	1	2	0.4
Material cost	10%	4	0.4	2	0.2	4	0.4	2	0.2
Post-processing labour cost	8%	5	0.4	3	0.24	5	0.4	4	0.32
Quantity of used material	5%	5	0.25	4	0.2	3	0.15	2	0.1
Complexity	7%	4	0.28	5	0.35	4	0.28	3	0.21
Efficiency	5%	4	0.2	4	0.2	5	0.25	3	0.15
Surface quality	5%	3	0.15	3	0.15	5	0.25	4	0.2
Life span	3%	4	0.12	5	0.15	5	0.15	5	0.15
Maintenance	2%	4	0.08	5	0.1	5	0.1	5	0.1
Environmental impact	5%	4	0.2	2	0.1	3	0.15	3	0.15
Possibility of recycling	5%	5	0.25	4	0.2	4	0.2	4	0.2
Weight	5%	4	0.2	3	0.15	3	0.15	3	0.15
	Score	**4.33**		**3.04**		**4.08**		**3.33**	
	Rank	1		4		2		3	
	Selected Solution	YES		No		No		No	

The second part of the research, entails establishing the optimal concept of the VSD mould. Functional analysis (FA) starts with establishing the general need and identifying the main functions of the product. To accurately state the need, the "insect with horns" tool [2, 3, 6, 7] is deployed: "The mould prototype must ensure the fabrication of the zero series VDS batch, under the technical conditions imposed by the designer". FAST (Function Analysis System Technique) diagram is deployed for the "usage" state of existence, in order to logically identify the main functions [2, 3]. Ranking the established functions, allows evaluation of the importance order of each function that the product must perform. Weighting of the functions, prioritises this importance order by assigning "weights" in absolute or relative value, independent from technical solutions. After weighting of the functions, the following percentage values have been obtained: x_{F1} = 16.0%; x_{F2} = 40.0%; x_{F3} = 26.6%; x_{F4} = 18.0% [2].

For undertaking the FA process, a team must be put together, consisting of specialists in the considered research field. Economic dimensioning of the functions is the most laborious stage of the FA research, requiring a lot of information, data, research and calculations, fully testing the technical and economic competences of the FA

team members. Cost allocation has been done by the team members after considering medical and additive manufacturing specialists' points of view. The percentage values of the functions in the total costs are as follows: y_{F1} = 17.5%; y_{F2} = 32.5%; y_{F3} = 30.0%; y_{F4} = 20% [2].
Using the smallest squares method, the diagram in Figure 2 is plotted [6, 7]. Only the "fabrication" life stage is analysed, as it was established that there are no significant influences from the other life stages. In order to develop the injection mould prototype, the functions are: F1: ensure tightness; F2: ensure part precise characteristics; F3: maintains the material characteristics; F4: ensure part evacuation. For the VSD, the elements values calculated using the smallest squares method, are: y = 0.952x; a = 0.952; $\alpha = 43.6^0$; S = 72.024 and S' = 0. Figure 2 represents the diagram which allows the comparison value – cost. Functions whose values are above the line require redesigning, in this case the functions F1, F3 and F4.

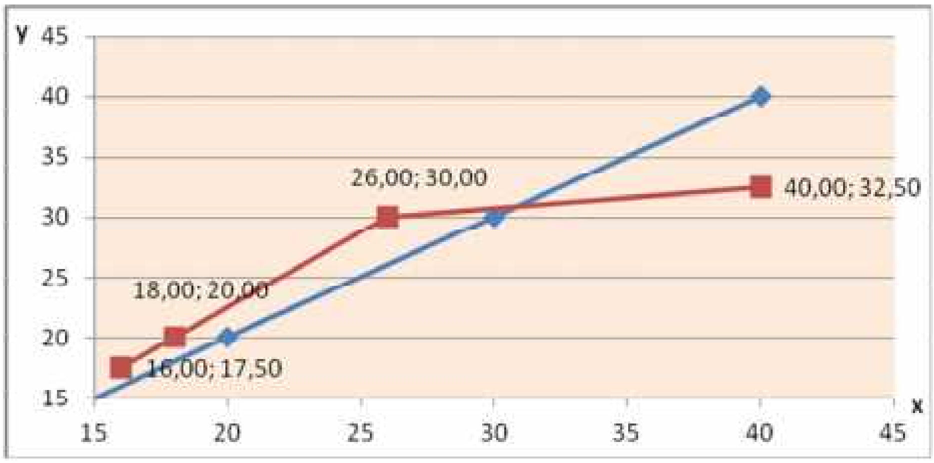
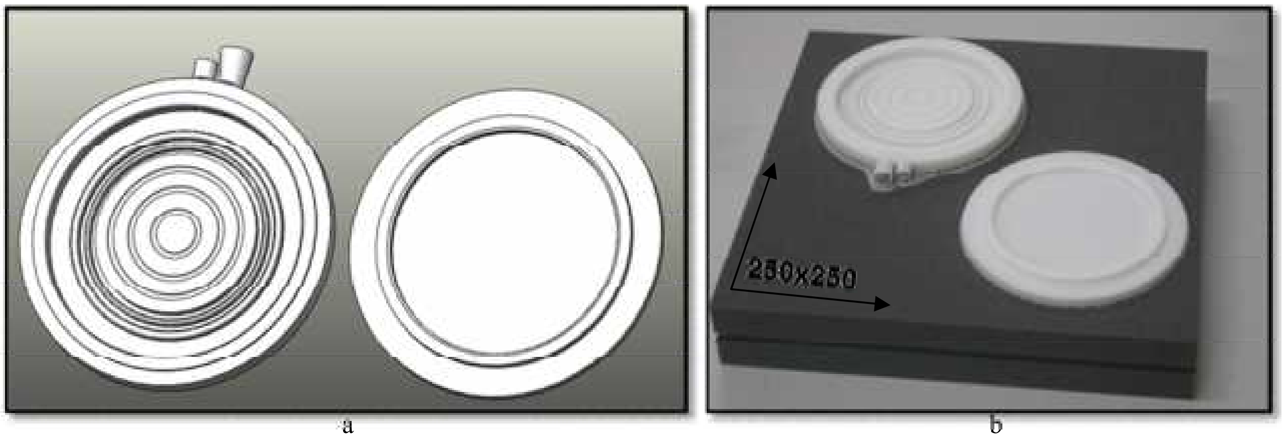


Figure 2: Weighting of the functions in value and cost – vacuum surgical device

3. RESULTS AND DISCUSSIONS

With the clients' approval for the VSD mould prototype, fabrication and testing (Figure 3) of the proposed model must be undertaken. The upper disk insert mould is fabricated using fused deposition modeling (FDM) technology, to validate the methodology and establish the main stages for manufacturing the zero series batch.



a b

Figure 3: a) CAD model of No 1 mould prototype; b) FDM No 1 mould prototype

The stages for manufacturing the VSD mould prototype are detailed as follows [2]: 1. The fluid volume is determined using the Flow Simulation module from SolidWorks, to establish the exact material quantity for the injection process; 2. The precise quantity of silicone rubber and hardener are measured, using the Polycraft GP-3481-F case set; 3. The mould prototype is clamped in the injection position; 4. The silicone rubber-hardener mix is injected into the mould; 5. The product is left to set and harden for 3 to 6 hours, depending on the injected mix, in this case the VDS insert was set in 3 hours. The VSD insert is presented in Figure 4 and some of the flaws are identified in Figure 5.
At the edge of the product and injection channels, respectively ventilation channels, an occurrence of bubbles and a thinning of the material appears (Figure 5). Also, tearing of the silicone rubber in the areas with thin

material, takes place when evacuating the VSD insert from the mould prototype, thus affecting the final shape of the insert. Due to the surface roughness of the functional face on the FDM mould, the silicone rubber permeates through its pours, resulting in an inconsistent insert surface roughness. The current mould injection process failed and the product is rejected.

The solutions offered by the work team for diminishing, even eliminating the flaws found, can be stated as follows: undertaking the injection moulding process in a vacuum chamber; using a smaller amount of hardener, thus allowing the air bubbles to reach the ventilation channels more quickly; redesigning the shape and positioning of the ventilation channels and of the mould, allowing a wider surface for the elimination of the air bubbles.

The first proposed solution is too costly, requiring the acquisition of a vacuum chamber machine. The second option is inconvenient due to the large period of time needed for the part to harden. As the zero series fabrication batch consists of 50 parts, the client rejects this option due to excessive timescales. The most satisfactory solution is to redesign the injection and ventilation channels, whilst all other process parameters are kept constant. Thus, VSD mould prototype No 2 is obtained, by FDM technology (Figure 6).

Figure 4: Upper VSD insert from silicone rubber manufactured in No 1 mould prototype

Figure 5: Flaws after the mould injection process

a b c

Figure 6: a) Upper VSD insert mould prototype No 2 on fabrication platform; b) Modifying the injection channels and the separation plane; c) Adding the liquid drainage channels.

In order to stop the silicone rubber permeating the mould surface, a different additive manufacturing technology is proposed for the fabrication of the zero series mould. Using SLS technology, an improved surface finish will be accomplished, thus the material will not infuse into the active surfaces of the mould [8, 9, 10]. The second VSD mould is used again for testing, thus FDM is used to manufacture it and a cheaper solution is adopted to prevent the infusion phenomenon. SLS technology will be used only for manufacturing of the zero series mould, after previous client validation and the approval of mould prototype No 2.
The previously described injection process is performed and the product from Figure 7 is obtained.
After analysing the product obtained, air bubbles are still identified. By changing the shape of the channels, a larger area must be post-processed, leading to visible uneven functional surfaces on the final insert. These inconveniences lead to a new stage of mould redesign. The process is changed from injection moulding to open mould casting. This solution allows a much wider surface for eliminating the air bubbles and the need for injection and ventilation channels becomes unnecessary, thus the external cylindrical surface remains unmodified. The product in this case is approved (Figure 8) and the client decides to manufacture the VSD mould using SLS technology. The mould for the lower insert is manufactured using SLS as well, adopting the same design [4, 5, 8, 9, 10].

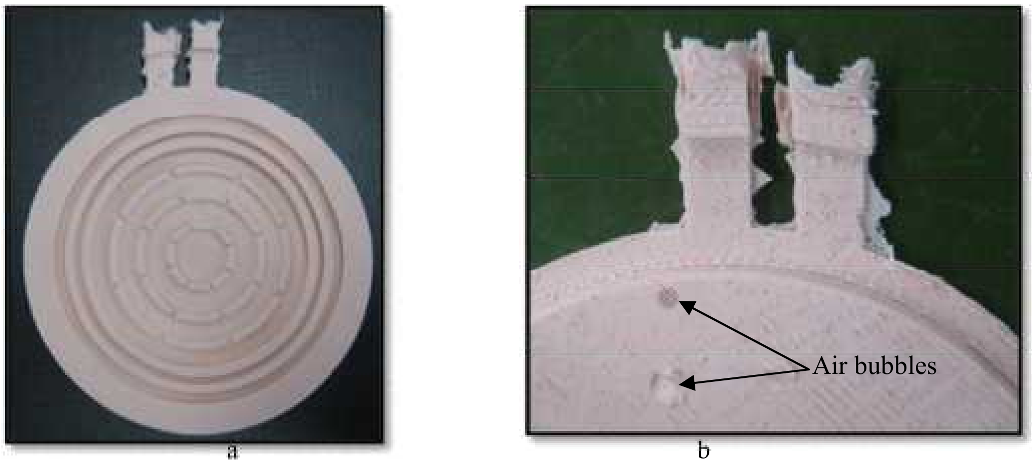


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Figure 7: a) Upper VSD insert on mould prototype No 2; b) Flaws – air bubbles.

Figure 8: Upper VSD insert from mould prototype No 3

4. CONCLUSIONS AND FUTURE RESEARCH

Using FA, the most appropriate manufacturing techniques to produce the zero series mould were identified. The optimum constructive characteristics which allowed a minimum initial investment from the client were chosen. The additive manufacturing technologies presented the advantage of fast prototyping and testing of the intermediary mould models in few days.

a) b)

Figure 9: a) SLS moulds for the VSD; b) CAD model of the final VSD upper insert mould

The whole development process took a week, from the initial contact with the client until the zero series mould was ordered. Information flow between the team members and the client was made in an organised and structured fashion.. The precise and easy to put into practice concepts were the result of correct FA deployment and accurate function identification.
The zero series moulds were manufactured using SLS technology (Figure 9).
As future research, the manufacturing of the 50 vacuum devices will follow and the testing of these in real conditions. The next step will be the design of the drainage elements and establishment of the final materials which will be used in the mass production. Using Flow Simulation from SolidWorks, the liquid flow inside the vacuum device mould will be simulated, establishing the process parameters and the shape characteristics of the internal channels. After establishing the products final shape, the injection mould used for large series manufacturing will be designed. Complete studies over the injection process characteristics will be made using CadMould Software.

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REFERENCES

[1] Wohlers T., Wohlers Report 2011: Additive Manufacturing State of the Industry Annual Worldwide Progress Report, Wohlers Associates, Inc., Colorado, USA, 2011.
[2] Lupeanu M.E., Cercetări privind aplicarea analizei funcţionale tehnice la dezvoltarea de noi produse realizate prin tehnologii neconvenţionale de fabricare aditivă [Research regarding the application of technical functional analysis to the development of new products fabricated with unconventional technologies of additive manufacturing], Doctoral Thesis, Politehnica University fo Bucharest, Bucharest, Romania, 2012.
[3] Lupeanu M., Rennie A., Neagu C., Additive Manufacturing Technologies and Functional Analysis used in Product Development Optimization, Proceedings of the 12th Rapid Design, Prototyping & Manufacturing Conference, CRDM Ltd, High Wycombe, Editors: Rennie A.E.W., Bocking C.E., Lancaster, United Kingdom, ISBN 978-0-9566643-1-0, 2011.
[4] Lupeanu M., Neagu C., Sindilă G., Neacsu A., An overview on the basic principles of industrial design optimization guided by Functional Analysis, TEHNONAV Conference, Ovidius University Annals of Mechanical, Industrial and Maritime Engineering, Volume 12, No. 1, Indexata CNCSIS B+, Cod CNCSIS 603, pg. 144 – 149, ISSN-1223-7221, Constanţa, 2010.

[5] Smith PC, Lupeanu ME, Rennie AEW, Additive Manufacturing Technology and Material Selection for Direct Manufacture of Products Based on Computer Aided Design Geometric Feature Analysis, Int. J. of Materials and Structural Integrity, Inderscience Publishers, ISSN 1745-0055, 2012.
[6] Miles L.D., Value Methodology: A Pocket Guide to Reduce Cost and Improve Value through Function Analysis. GOAL/QPC Publish, ISBN 1576811050, 2008.
[7] Ungureanu I., Analiza funcţională [Functional Analysis] Piteşti University Publishers, 2007.
[8] OPRAN C., BIVOLARU C., MURAR D., VLASE A., Research concerning the behavior at impact of the polymeric composite sandwich structures with the simulation of finite element analysis, Academic journal of manufacturing engineering, vol8, issue 1, Romania, 2010.
[9] Peek N., Rapid prototyping of green composites, Massachusetts Institute of Technology, Dept. of Architecture, Program in Media Arts and Sciences, Massachusetts Institute of Technology Publishers, 2010.
[10] Kumar S., Kruth J.-P., Composites by Rapid Prototyping Technology, Materials and Design, Volume 31, issue 2, p. 850-856, ISSN: 0261-3069, Elsevier Science, February, 2010.