

INTERNATIONAL CONFERENCE ON ENGINEERING AND PRODUCT DESIGN EDUCATION
4 & 5 SEPTEMBER 2014, UNIVERSITY OF TWENTE, THE NETHERLANDS

A CASE STUDY ON THE DESIGN OF A MODULAR SURGICAL INSTRUMENT FOR REMOVING METASTASES USING ENGINEERING DESIGN TOOLS

Preca G.¹, Farrugia P.¹ and Casha A.²

¹ Concurrent Engineering Research Unit, Faculty of Engineering, University of Malta

² Department of Anatomy, Faculty of Medicine & Surgery, University of Malta

ABSTRACT

Metastatic cancer is a form of cancer stemming from a primary tumour that propagates to different organs and/or to different sites within the same organ [1]. Studies have indicated that the chances of survival improve upon surgical removal of metastases [2]. The overall goal of this research was to develop a modular surgical instrument that would be easy to use and manipulate and hence facilitate resection of metastases. This research forms part of a final year project carried out by a mechanical engineering student in the four-year bachelors course at the University of Malta. The basic design cycle [3] taught in the third year of the course was employed to systematically generate the design of a novel modular surgical instrument. This was complemented by a number of hospital visits and various meetings with professionals and other stakeholders relevant to the field. Through this case-study, this paper shows how, even at a bachelors level project, the application of design tools and the continuous communication with typical end-users can lead to the development of a high-value added product which can be potentially commercialised. Other benefits of joint supervision are also discussed.

Keywords: basic design cycle, learn-by-doing, design iterations

1 BACKGROUND

Almost 90% of cancer deaths are due to metastases, making this a very dire problem [2]. Even when the primary tumour has been completely removed, there is no guarantee that the patient is in the clear, as the cancer may have already spread [1]. The excision of metastases can be challenging, hence there is a clear need for a novel surgical instrument to facilitate excision [4].

Lung parenchyma is the second most frequent site for metastases with 30%-50% of all cancer patients developing lung metastases. This led to the project being focused on lung metastases [5]. Currently, a pulmonary metasectomy is a procedure that can be performed multiple times as long as conservative resections are made [6]. Older instruments and techniques often led to patients with multiple metastases being labelled incurable due to extensive damage to the lung parenchyma [6]. Nowadays more novel state-of-the-art instruments have led to patients previously thought to be incurable being offered a cure [6]. Yet, a critical literature review of the state-of-the-art of surgical instruments revealed that such instruments do not satisfy all the attributes required by surgeons, in particular ergonomics, reusability, the ability to facilitate minimal invasive procedures and the capability of addressing metastases of varying size.

1.1 Introduction to the project

To this end, the overall goal of the research disclosed in this paper concerns the development of a modular surgical instrument for removing metastases. To systematically accomplish this goal, the basic design cycle BDC [3] was employed. A number of engineering design tools were employed in the different activities of the basic design cycle. This design methodology is commonly taught in various engineering design curricula, including the curriculum at the University of Malta, as described in [12]. The work was conducted by a mechanical engineering student in the fourth year of the bachelors course. This student had previous design experience during the third year of the course. As described in [12], during the fifth semester, students are taught the design methodology and the various tools available during the BDC activities. In the sixth semester, they are given a group project

during which they have the opportunity to apply these tools to design an innovative product. This project was a result of internal collaboration between the Concurrent Engineering Research Unit within the Department of Industrial & Manufacturing Engineering, Faculty of Engineering and the Department of Anatomy, Faculty of Medicine and Surgery at the University of Malta. As a result was supervised by one academic from each of the aforementioned departments. This enabled the student to get feedback on the evolving solution from an engineering design point of view and also from typical end-users' perspective through several meetings with local leading surgeons.

The structure of the rest of the paper follows the basic design cycle, covering the problem analysis, synthesis, solution analysis and evaluation (Sections 2 to 5). Conclusions and reflections are drawn up in Section 6.

2 PROBLEM ANALYSIS

The workflow of a surgical procedure is constituted of three main steps, namely incision into the patient, removal of metastases and sealing of tissues. This paper focuses on the second step. In addition as a research boundary, it was decided that the surgical instrument should facilitate open approach surgery, thus allowing digital palpitation of the lungs, as 65% of surgeons felt that this was essential in ensuring that all metastases were removed [7]. A clay model of the lung was constructed leading to a greater level of understanding of how metastases appeared in the lungs.

2.1 Communication with end-users through visits and surveys

A number of meetings were held with surgeons at the main hospital in Malta. The most crucial conclusions drawn from these meetings were that, firstly, metastases varied in size from 0.5-3cm and, secondly, they are usually perfectly spherical in shape and should be removed in one piece. A survey was also carried out with surgeons in order to understand their expectations from this surgical instrument. Results reveal that surgeons gave priority to their ability to operate the instrument with one hand, to good ergonomics and to having a rigid, robust product. The survey also highlighted the fact that the mode of operation of the instrument and the maintenance required were important and so a simple, easily assembled design provided the best solution. On the other hand having good aesthetics and no external power supply were aspects not valued very highly. A *quality function deployment* (QFD) exercise was also conducted with surgeons, from which it resulted that the most important technical parameters were mode of operation, cost, suitable choice of materials, size, weight and ergonomics of the instrument. A Product Design Specification was also drawn, in which the criteria on which to base the concepts in solution synthesis, were documented.

3 SOLUTION SYNTHESIS

The function of the instrument was disassembled into a number of sub-functions. Brainstorming and sketching were extensively used, giving rise to a number of working principles.

3.1 Morphological Chart

A morphological chart was drawn up as shown in Figure 1. Amongst the different means for each sub-function, seven potential paths were identified. These solutions were screened in order to find the solution that best embodied the design requirements; this was principle solution 1 that is characterised by a black line in Figure 1. The means (if any) selected for each sub-function are shown in Table 1.

4 SOLUTION ANALYSIS

Weak spots of the selected principle solution from the morphological chart were analyzed using a value analysis profile, as shown in Figure 2. The numbers 1-10 are the grading parameters in the evaluation chart, which are also listed in Figure 2. The principal solution selected was rated weak with regards to parameters 8 and 9. However, medical professionals did not consider these sub-functions as important to the final design. In addition, the parameter 'performs multiple tasks' (such as the ability of the instrument to coagulate and divide tissue) was not considered at all important by relevant stakeholders.

4.1 Physical Modelling to Test Ergonomics

Based on the selected principle solution, three clay models were fabricated, having different configurations as shown in Figure 3a. These physical models were evaluated with medical

professionals. This exercise was aimed primarily at addressing *Design for Ergonomics*. Demanding long surgeries make an ergonomic instrument design essential, as poor ergonomics causes a decrease in productivity and an increase in the number of operator errors [8]. Following the feedback received and in reference to anthropomorphic data, a new clay model (see Figure 3b) was fabricated. After consulting with medical staff, it resulted that the new configuration was more ergonomic. Other *DFX* tools were employed in order to further improve the evolving design solution.

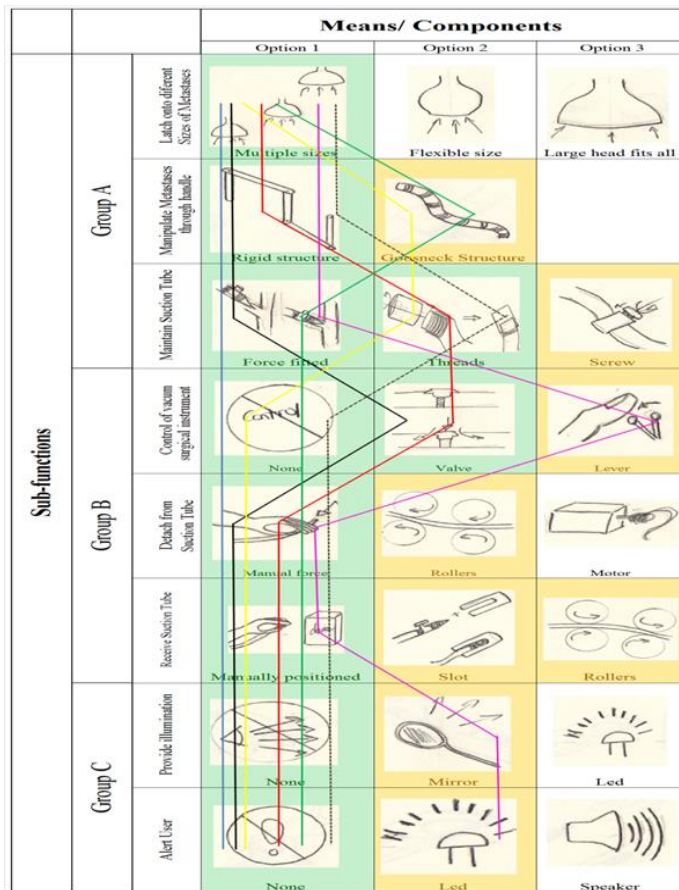


Table 1. Means for relevant sub-functions

Sub-Functions	Mean
Latches onto different sizes of metastases.	Multiple suction heads
Manipulates metastases through the handle	Rigid structure
Maintains the suction tube	Force fitted
The vacuum is controlled through the surgical instrument	Valve [user's finger]
Detaches from the suction tube.	Manually positioned
Receives the suction tube	Manually positioned
Provides illumination	None.
Alerts user	None.

Figure 1. Morphological Chart

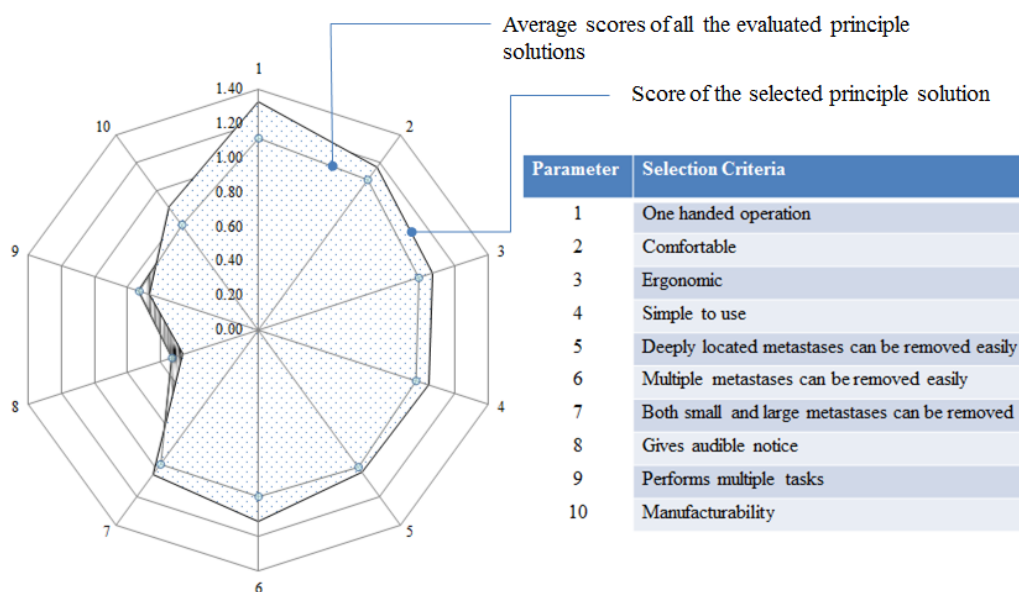


Figure 2. Value analysis profile of selected principle solution

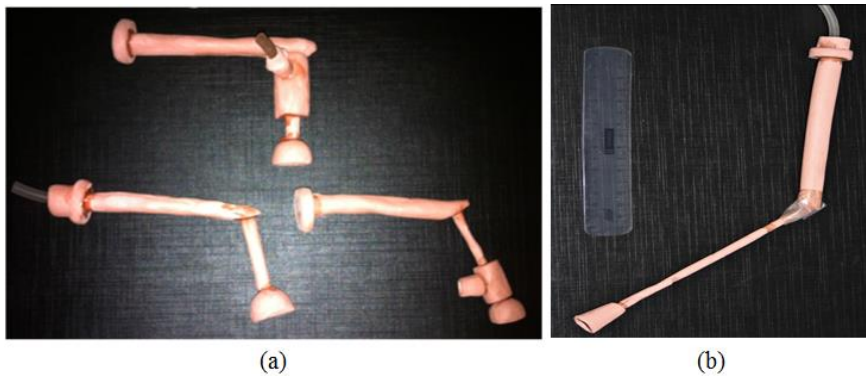


Figure 3. Clay models of (a) preliminary (b) final device configuration

4.2 DFX

Since the product would be re-usable and would be sterilized repeatedly, it was essential that the sterilization process be kept as simple as possible. Thus guidelines from the U.S *Food and Drug Administration* (FDA) were adhered to by avoiding valves regulating flow and by designing a device could be disassembled [9].

Through rigorous re-design following *Design for Assembly* (DFA) principles, a significant improvement of the instrument was achieved. The initial and final designs are illustrated respectively in Figures 4(a) and 4(b). Moreover, *Boothroyd and Dewhurst* tables [10] were used to quantify the DFA results achieved as shown in Table 2.

It must be noted that a library of biocompatible materials capable of undergoing sterilization procedures was compiled, and then using material indices, the materials for all 5 components illustrated in Figure 4b were selected. To manufacture the device, two fabrication processes are required – injection moulding of the suction head (including cup and snap fits), plastic processing utilizing *APEC 1745* resin and machining processes to fabricate the link, suction tube and handle utilizing *Stainless Steel 316L*. The suction tube assembly was analyzed in detail through the use of tables found in [11]; resulting in a 20.7% savings in the total cost of machining. Through the use of *Moldflow* simulation software and general injection moulding guidelines, the suction heads achieved 100% fill-ability as shown in Figure 5a. It must also be mentioned that detailed calculations were carried out to establish the forces acting on the snap fits and the dimensions of the suction cups.

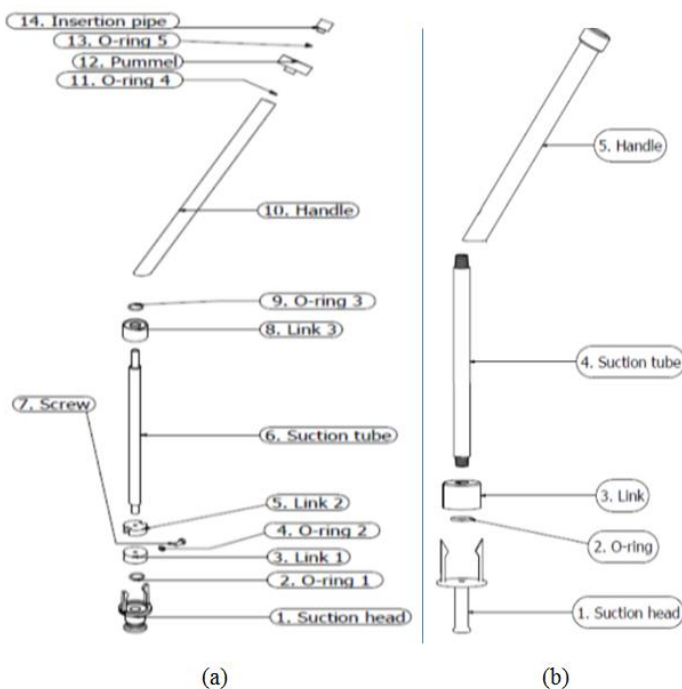


Table 2. Quantified DFA results [10]

	Initial design	Final Design	% Change Improvement
No. of parts	14	5	64.3%
Assembly time (s)	123.6	28.58	76.9%
DFA efficiency index %	12.6	35.2	279.5%

Figure 4. Number of parts (a) before (b) after DFA exercise

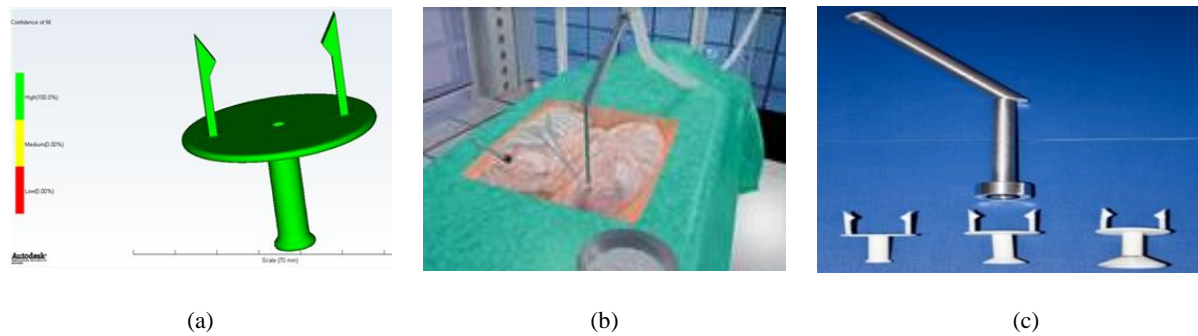


Figure 5. (a) Moldflow simulation results (b) MAYA 3D animation (c) physical prototype including three suction head sizes

4.3 3D Animation of the Device & Functional Physical Prototype

A 3D animation using *MAYA* was created depicting the tumour being supported whilst blunt dissection was used to remove the tumour, as illustrated in Figure 5b. Detailed 3D CAD models and their corresponding drawings were used to manufacture a functional prototype depicted in Figure 5c. CNC milling and turning were used to fabricate the stainless steel 316L suction tube assembly, whereas *Fused Deposition Modelling* (FDM) was employed to fabricate the three suction heads from ABS.

5 EVALUATION

A questionnaire based on the PDS requirements was prepared with the three different users in mind, in particular, the surgeons, the scrub nurses and the sterilization technicians. The 3D animation of the instrument and the working prototype illustrated in Figures 5b and 5c respectively were used in the evaluation. It must be mentioned that the aim of this evaluation exercise was to gather qualitative data rather than quantitative data, the key findings being:

1. The surgeons (n=2), felt that the instrument accomplished its primary objective, i.e. that of facilitating excision of lung metastases. One surgeon went as far as to say *“This is an important device because current instruments, which are not tailor made for this procedure, can cause fracturing of a metastasis”*.
2. The nurses (n=4) were impressed with the device and felt the modularity of the device would *“reduce surgery time therefore being beneficial to the patient”*.
3. All technicians (n=4) agreed the instrument could be easily sterilized.

6 CONCLUSIONS AND REFLECTIONS

It has been shown, that by the careful use of design tools, it is possible to navigate through the design cycle efficiently and effectively, resulting in a desirable surgical instrument useful to the relevant stakeholders in practice. Continuous communication with end-users throughout the different activities of the basic design cycle proved crucial in understanding what is expected from such an instrument. The novel characteristics of the developed surgical instrument included the use of snap fits to mount the suction head with the tube, thereby facilitating instrument sterilization and the fact that surgeons could choose different suction heads, depending upon the size of the metastasis.

As mentioned in section 1, this project was a result of internal collaboration between the Faculty of Engineering and the Faculty of Medicine and Surgery at the University of Malta. Certainly, joint supervision was of great benefit to the student as he managed to get the best of both worlds; in particular feedback on the application of engineering design tools and the accessibility of leading local surgeons at different activities of the design cycle. Such an internal collaboration led to the application of design tools to develop a high-value added product. A working prototype of the instrument was also fabricated and evaluated with a range of typical end-users; the promising results attained reflect that the instrument can be potentially commercialised. This pedagogic approach correlates with the *‘Design Theory to Practice’* (DT2P) model (see Figure 6), whose goal is to allow design theory, in the form of a range of systematic methods, to result in design solutions/concepts that can be readily taken up by industry [12].

Of course, because it is a medical device, there are regulatory processes and clinical investigations that have to be completed before the technology can be made available on the market. Due to the restricted

timeframe, the student did not have the time to delve into the business aspect of the instrument. However, the positive feedback which he received coupled with the potential market of this high-value added product, motivated the student to pursue a taught M.Sc. in *Integrated Product Development* (IPD), offered by the University of Malta. In this course, students have the opportunity to acquire knowledge on the business pillar of product development, which lacks in the bachelors four year mechanical degree course. This can be perceived as another spin-off benefit resulting from engineering design related projects which are conducted jointly between relevant faculties.

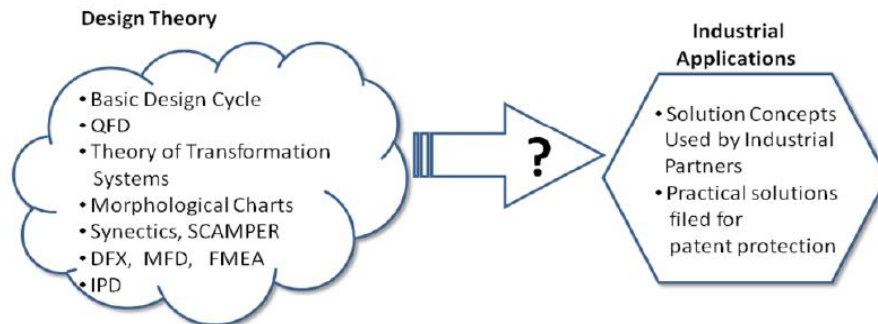


Figure 6. Underlying principle of the DT2P model of design education [12]

ACKNOWLEDGEMENTS

The authors are grateful for the input provided by all the persons who volunteered in the evaluation. Special thanks go for Mr. Alex Manche for his expert medical advice and for always finding time to answer questions. The input of all academic and technical support staff at the University of Malta towards the realization of this project is also appreciated.

REFERENCES

- [1] Life Extension. *Cancer Surgery*. Available: http://www.lef.org/protocols/cancer/cancer_surgery_01.html [Accessed on 2013, 22 November], (2013), 22 November.
- [2] Patient resource. *Metastatic Disease*. Available: http://www.patientresouce.com/Metastatic_Disease.aspx [Accessed on 2012, 30 November], (2012), 30 November.
- [3] Roozenburg N. F. M. and Eekels J. *Product Design: Fundamental and Methods*, 1995 (Wilshire, John Wiley & Sons Ltd).
- [4] S.A. Eccles, *Metastastasis: recent discoveries and novel treatment strategies*, *The Lancet*, 19(369), May 2007, pp. 1742-1757.
- [5] Zhu J.C., Yan T.D. and Morris L.D. *A Systematic Review of Radiofrequency Ablation for Lung tumours*, *Annals of Surgical Oncology*, 15(6), June 2008, pp. 1765-1774.
- [6] Venuta V. *Techniques used in Lung Metasectomy*, *Journal of Thoracic Oncology*, 5(6), June 2010, pp. 145-150.
- [7] Hoetzenecker K. et al. *Pulmonary metasectomy*, *European Surgery*, 43(5), March 2011, pp. 262-269.
- [8] Pheasant S. *Anthromorphic Data in Body Space Anthropometry, Ergonomics and the Design of Work*, UK: 2003, pp. 174-176 (Taylor and Francis e-Library).
- [9] Food & Drug Administration. *Medical Devices Standards*. Available: <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/ucm2005756.htm> [Accessed on 2014, 4 March], (2014), 4 March.
- [10] Boothroyd G., Dewhurst P. and W.A Knight. *Product Design for Manual Assembly*, in *Product Design for Manufacture and Assembly*, 3rd Edition. 2011, chapter 3, pp. 73-131 (USA: CRC Press).
- [11] Swift K.G. and J.D Booker. *Machining Processes*, in *Process Selection From Design to Manufacture*, 2003 pp. 131-150 (Oxford Elsevier).
- [12] Borg J.C. and Farrugia P. *Mapping Design Theory Into Industrial Applications: Best Practices From Malta*, in *Proceedings of the DesignEd Asia Conference 2011*, Hong Kong, December 2011, pp. 281-293.