GYNAECOLOGICAL PRODUCT DEVELOPMENT FACILITATED THROUGH RP AND RAPID TOOLING

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ABSTRACT

Atkinson [(1)] distinguishes between four types of prototypes, categorised through its end-use:

- *Design or aesthetic prototypes*
- *Geometrical prototypes*
- *Functional prototypes*
- *Technological prototypes*

Shigley and Mitchell [(3)] define the design process according to the following six phases:

Recognition of need
Definition of problem
Synthesis
Analysis and optimization
Evaluation
Presentation

The Centre for Rapid Prototyping and Manufacture (CRPM) of the Central University of Technology, Free State was asked to assist in the development of a newly developed gynaecological cream applicator. Apart from needing a freeform fabrication system to give form fit and function to the very complex design, the product needed Rapid Tooling/Rapid Manufacturing support to enable a first batch production for medical trials and evaluation. The paper will describe the total product development process alongside prototype categories described by Atkinson [(1)] and design phases defined by Shigley and Mitchell [(3)] (including some iterations enabled through timeous prototyping, including various Rapid Prototyping (RP) Technologies, soft tooling and vacuum casting). More importantly, results from Rapid Tooling for limited run production (due to the complexity of the product the cycle time of the Prototype Tool is fairly long), as well as the economical impact made possible through the support of CAD/CAM and RP Technologies, will be discussed.

Keywords: Rapid Prototyping, Rapid Tooling, CAD Design, Functional Prototype

1. INTRODUCTION

The CPRM was requested by a gynaecologist to develop a vaginal cream applicator that could be used comfortably and without problems. Women who need to use this cream applicator are mostly pregnant or elderly, and need to get hormone supplement. In some cases woman with vaginal infection also need to use antibiotics cream. The product needs to apply a constant dosage of the cream where needed, without irritating the vaginal sides. The applicator must furthermore reduce the possibility of infection or transfer of organisms. Therefore the tip of the product should be formed in such a way that no sharp edges occur and that the least possible amount of cream or vaginal fluids are trapped in the opening at the front after application. The application bubble should not suck in any cream or air when it is released, and thus should be very thin. The shape of the product should be based on the shape of the opening of the vagina. The product had to be flexible so as to flex to a limited extent not to harm the user.

2. DESIGN BRIEF

Already practicing for 25 years, the gynaecologist had been confronted with bad designs of cream applicators. In explaining the use of the applicator to his patients, he recognised the need for a better-designed product.

The problem was defined by both the difficulty of use and the discomfort while using the existing product. A freeform design was needed to produce a product, acceptable and functional for the women needing it. In order to support the inventor's claim, it was necessary to design and manufacture a product that incorporated the required functionality. Product aesthetics played an important role, as if there would be resistance by the women using it the product was destined to fail.

The following requirements had to be met in the design:

- The applicator had to be fixed to the cream by screwing it onto the tube.
- It had to form an angle of 23° with the center-axis of the cream tube, to ensure easy access of the applicator into the vagina without any problems for the user. (This will ensure that pregnant and older women would be able to use it comfortably. The user can take the tube in her hand and the angle which the vagina forms with the centre of the body will then be the same.)
- A circular volume (ball) of which the cavity is equal to the volume of cream needed, had to be placed in front of the threaded collar. The side-walls of the ball was designed as thin as possible, so that when it is squeezed, it would remain in that position without sucking new cream out of the tube and into the applicator.

- The applicator-ball needed ribs on both sides to provide stability of the tube while inserting the shaft into the vagina.

- The applicator-shaft needed to be flex ble but also stable enough so that it does not fold or deflect when inserted.

- The channel through which the cream is injected must be thin enough to hold the smallest quantity of cream possible, but still accommodates free-flowing of the cream with as little as poss ble flow resistance.

3. DEVELOPMENT PROCESS

3.1 CAD design

The design was completed on CAD and analysed by the customer and his patients. The internal volume could be calculated, using the CAD data. A few minor aesthetic changes were made and applied to the design. A prototype was grown to enable better representation of the design. Figure 1 shows the completed design. Figure 2 shows the CAD of the core. The complexity can be seen in the design.

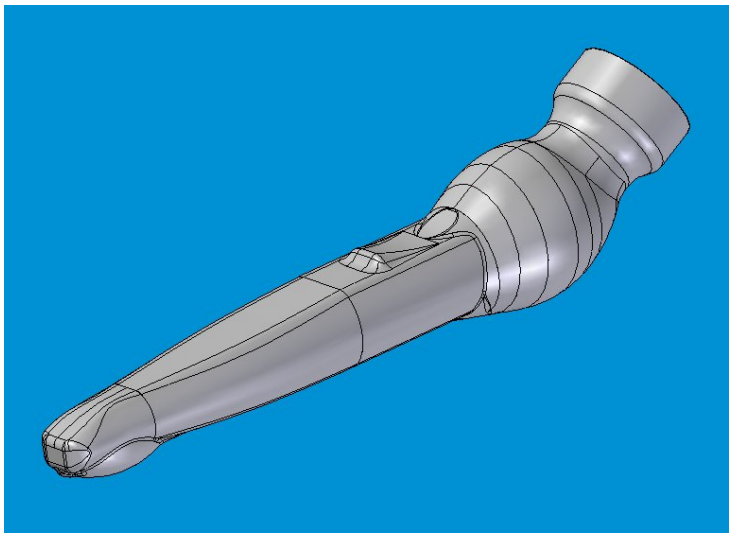


Figure 1: CAD design of cream applicator

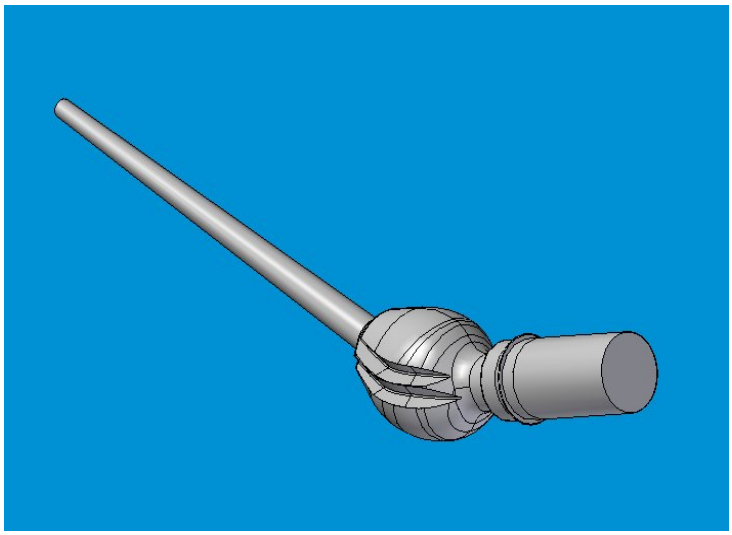


Figure 2: Design of the core

3.2 Prototyping of cream applicator

The design was grown on the Stereolithography (SLA) in Somos 9110 resin. The initial prototyping was done to ensure that the aesthetics are acceptable to the users.

Figure 3 shows an image of the completed SLA prototype.

Figure 3: SLA prototype

4. RESULTS

4.1 Evaluation of the prototype

The prototype was sent to the customer, who consulted other gynaecologists and patients (as poss ble consumers). A few minor design iterations were made and the design was approved.

4.2 Limited production tooling

For limited production quantities, vacuum casting and silicone tooling can be used. However, although initially only 50 parts were needed, it was decided to develop a prototype tool for injection moulding, supporting the following prototype testing and evaluation needs:

- In order to ensure that the dosage would be exactly 6g, a prototype had to be manufactured from a flexible material to measure the delivered dosage with an electronic scale.

- Clinical tests would only be allowed if the product was manufactured in the final Food and Drug Administration (FDA) approved injection moulded rubber. Therefore, it was decided not to manufacture a vacuum casting mould but to directly manufacture an injection-moulding tool.

Being a prototype tool for limited production of parts, an existing bolster was used to accommodate the insert. It was decided to manufacture a hand-operated tool where the core will be manually pulled out of the product. The bottom and top half of the tool was manufactured from Aluminium by means of a three-axis CNC milling machine. Figure 4 shows a machined bottom half of the tool.

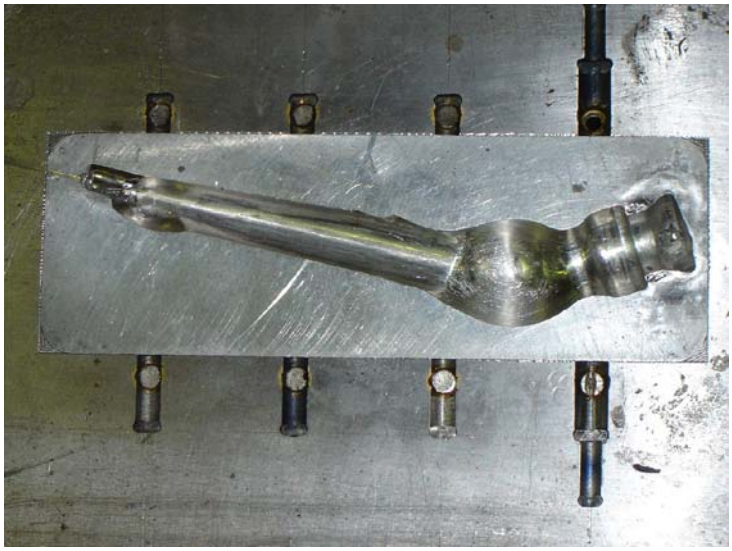


Figure 4: Machined bottom half of the tool

The shape of the product's corresponding core was very complex and needed five-axes CNC machining. Not having direct access to five-axes CNC machining, it was decided to grow a core with a DTM SLS 2000 machine, using ST-100 [(2)] steel. As seen from Figure 2, the design included a high level of complexity and detail, such as the ribs on the side of the ball, as well as a very thin and long shaft - all problematic for machining. By growing the core in ST-100, the product could be tested and the design (and corresponding core geometry) adjusted until the correct dosage was reached. Figures 2 and 5 show the core design and prototyped core in ST-100.

Figure 5: ST-100 grown core

4.3 Manufacturing of functional prototypes

Injection moulding was done through a single-cavity tool. The moulded part (including the core) had to be removed from the tool by hand, following the hand-removal of the core from the product. After each cycle the core had to be hand-placed in the tool again, before a next cycle could start. The cycle time of 135 seconds/product was lengthy, but was sufficient to manufacture the 50 products needed for clinical tests. Figure 6 and 7 show the completed prototype tool and the final part from the tool.

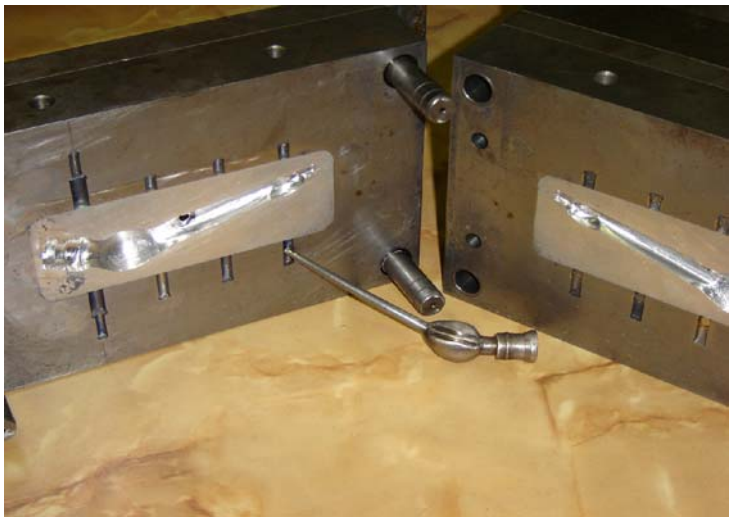


Figure 6: Prototype tool

Figure 7: Functional prototype

5. DISCUSSION

5.1 Economical impact of the Product Development Process

The gynaecologist was quoted R250 000 (32 000 euros) for a double cavity production tool. As the product was not proven yet (neither in terms of functionality, or accuracy of the dosage), the client could not consider manufacturing of the moulds, and thus had no way of proving the product.

In order to market the idea to pharmaceutical companies, clinical trials are needed, which in turn required products manufactured from FDA approved materials. Furthermore, products in the FDA material are required to test the dosage, and if not correct, to use the results for design iteration. This could lead to series of redesign and remanufacturing to get to a final proven stage.

In terms of normal risk analysis, there were too many unanswered decision making factors, leaving no other answer as that no economical solution was poss ble – also leaving pharmaceutical companies and poss ble venture capital firms no other option as to decline the product or deny it development support.

Using the different available technologies and stages discussed, the client invested/spent R32 000 (4000 Euros) on the product. Taking a decision to place an order for the production tool, subjected to possible redesign or tool changes, could have resulted in production costs exceeding one order of magnitude higher than was spent.

The technologies as used resulted in final products, which could be used to market the product to pharmaceutical companies without spending money on the production tool, prior to having orders. Final orders will enable a decision to support the manufacturing of a suitable size production tool according to the magnitude of orders placed.

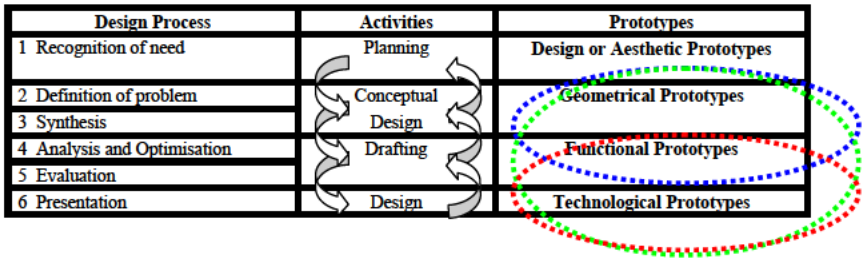
6. CONCLUSIONS

Shigley and Mitchell [3] define the Design Process as an interactive procedure consisting of six phases, namely recognition of need; definition of problem; synthesis; analysis and optimisation; evaluation and presentation. The first step arises from a specific need, or identified problem. Step two defines the boundaries in which the designer/design team should operate, and may predict the expected or required outcomes. The boundaries set out in the definition should indicate the constraints and criteria to be met with the design or development, and should ultimately be applicable for evaluation of the product. Such criteria should set out the parameters, which could be used to evaluate the design. Following the definition of the problem, synthesis, analysis and optimisation (the next three steps) are iterative processes, and are performed in conjunction with each other, as part of the optimisation process. A design is created to meet all constraints (synthesised) and then analysed to determine

whether the set of criteria has been met. Analysis of results, which indicate that the criteria have not been met, or even suggest that some criteria can be improved, will lead to modification of the design, and hence, further analysis.

During the analysis of the design, the need for physical prototypes to verify aesthetics, do form, fit and function analysis or perform technological tasks, becomes evident. This gradual movement from virtual prototypes or designs (which lend themselves to mathematical analysis) to physical prototypes, resembles the activities involved in the design process, and acts as interface to the types of prototypes defined by Atkinson [(1)]. Using the four types of prototypes, together with the activities involved in the design process, it is clear that an overlap of prototyping activities will be found in product design and development. The model as developed below, represent the various steps followed during the case study and related product development and depicts the overlap and grouping of activities in RP applications, alongside the design process. Table 1 show the overlap and grouping of activities that took place in this project.

Table 1: Overlap and grouping of activities in RP applications, alongside the design process



In addition to physical prototypes, virtual prototypes must be seen as an important extension of these capabilities to influence and support concurrent product development. If employed correctly, virtual prototyping has the ability to shorten the product development process even more. Each cycle or phase on which time can be saved, will ultimately have a cumulative effect on the acceleration or economics of the Product Development Process.

7. REFERENCES

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3. J.E. Shigley, L.T. Mitchell, Mechanical Engineering Design, McGraw Hill, New York (1983)