RAPID PROTOTYPING AND MEDICAL PRODUCT DEVELOPMENT─GETTING THERE FAST/FIRST

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ABSTRACT

When a patient is intubated during anesthesia it is very important that the Endo-tracheal (ET) tube remains in the correct place. If the tube deviates from the correct position it can cause one or both lungs to collapse and can be fatal.

The idea behind the product was to design and manufacture a product that held an ET tube in place in a more secure manner than currently. It is common for an ET tube to move and or become dislodged due to various extraneous reasons.

As with any new product, there was uncertainty about the design. Traditionally this meant the manufacturing of a hard tool and determining the right design by trail and error. Hard tooling allows for some small changes to be made, but if the changes are radical a new tool will have to be designed and manufactured. Prototyping revolutionized this process by simplifying the development iteration process, which means changes can be made quicker and easier, the costs will be lowered and the time-to-market is shortened.

1. RAPID PROTOTYPING AND PRODUCT DEVELOPMENT

Rapid Prototyping can be defined as a technique in which physical models are fully created from materials, provided in various forms, completely under the control of model data created within a computer aided design environment. More concisely, the term refers to the transformation of a manufacturer's concept into a three dimensional object in the shortest possible time.

Currently there are four main types of rapid prototyping technologies/ processes:

- **Curing processes,** where a photo-sensitive polymer is exposed to a light source in order to harden the polymer;
- **Sheet processes,** where thin sheets of a material are cut to shape and stacked on top of each other;
- **Dispensing processes,** where a material is melted and then deposited either as a hot filament or as individual hot droplets; and
- **Sintering processes,** where a powdered material is sintered together using a heat source, typically a laser beam [1].

Usage of prototypes in the development process can be divided in four categories:

- **Communication:** The existence of a prototype facilitates discussion among all the people with different skills and different concerns involved in the creation of a product. Without a prototype model it may be difficult to explain an idea to management in a manner which is likely to obtain their agreement to commencing or proceeding with the project.

- **Customer testing:** Prototypes enable a manufacturer to ascertain how well a design meets the requirements, expressed or perceived, of their expected customers. A prototype model can also help explain a company's requirements to its distributors and providers of packaging.
- **Platform for integration:** Functional Prototypes normally involve individual components rather than the entire product. Prototypes enable the integration of the components to be assessed, ensuring that the various designs are able to meet these constrains of assembly in the manufacturing process.
- **Project evaluation:** Prototypes are an extremely useful tool for allowing a company's management and/or customers to assess the progress of a project at various stages. Again, a model may convince management that a project is indeed progressing towards a marketable product. Since any project has cost implications, prototypes may be vital to its continuation [2].

2. OVERVIEW

2.1 Product Development Process

Most companies are not organized well enough to make a meaningful reduction in the product development cycle time. Last-mentioned is in general viewed as the heart of the information assembly line, and has tremendous potential for improvement. The use of technology, tools, process, re-engineering and new approaches all have a positive influence. Concurrent Engineering, Solid Modeling, Reverse Engineering, rapid Prototyping and other related processes may streamline the product development process. However, all of these factors need good management practices to produce results. Streamlining the product development process increases R&D efficiency and thereby lower the cost and time for a certain amount of work. Better processes lead to reduced scrap and rework, fewer prototype design cycles, and therefore shorter time to market. This in turn, influences the volume of sales and production.

To achieve dramatic reduction in development time, a total integrated product development approach, addressing all company structures, need to be followed. Factors such as planning and evaluation, goal setting, concurrent engineering, reduced bureaucracy, world class manufacturing and the use of computers in design and manufacturing, should be taken into account as well. [3]

2.2 Support of Rapid Prototyping Technologies

The design protocol for this case study was to develop a solid model of the product using Computer-Aided-Drawing (Solid Edge). Making a prototype of the product necessitates a solid model.

A prototype of the design can then be made by using various Rapid Prototyping options like SLA or SLS and then making a silicone mould (soft tooling) to cast limited quantities of the product. Various Rapid Manufacturing options like Vacuum Casting or the Reaction Injection Moulding (RIM) process can then be used to reproduce the prototype.

When the demanded volume of a product requires a hard tool, the manufacturing of the hard tool can commence, if you have the assurance that no alterations to the hard tool is necessary, when the customer is satisfied with the product or the product has been proven.

2.3 RP processes used in this development

2.3.1 Stereolithography (SLA)

Stereolithography is one of the oldest rapid prototyping technologies, and was released commercially in the mid1980s. SLA can be used to make parts with complex geometry and with a surface finish comparable to many conventionally machined components. SLA parts are often used as masters to produce silicon moulds for vacuum casting or reaction injection moulding.

The machine consists of a vat of photo-sensitive polymer that contains a platform on which the part is built. The platform can rise and fall within the vat. The platform moves until it is just below (0.1 —0.25 mm) the surface of the liquid polymer. A laser traces the cross-section of one slice of the part. Where the laser makes contact with the polymer it solidifies to become a solid. The platform then moves down the distance of one slice (0.1 —0.25 mm) of the part, the recoater moves from one side to the other and the laser draws the next slice on a fresh layer of liquid polymer. This slice of the part solidifies on top of the previous slice. When all slices of the part have been traced, the platform is removed from the vat and excess liquid polymer is cleaned off the completed part. The completed part is then finally cured in a ultra-violet oven [1]

2.3.2 Selective Laser Sintering (SLS)

Selective laser sintering allows rapid prototypes to be built in a variety of materials to directly produce semi-functional parts. Parts of complex geometry can be made from the powdered materials used. The fact that powder is used as the base material limits the quality of the surface finish of the final part.

A layer of powdered material is deposited on a platform. A laser beam traces the cross-section of one slice of the part. Where the laser beam makes contact with the powder, the affected particles fuse together (or sinter). Another layer of powder is then deposited on top of the previous layer using a roller mechanism, and another slice of the part is sintered onto the sintered material in the previous slice. The unsintered material in each layer can act as a support structure for the part itself. When the part is complete the unsintered material can simply be brushed off.

Table 1: Advantages and disadvantages of SLA and SLS [1]

SLA		SLS	
Advantages	**Disadvantages**	**Advantages**	**Disadvantages**
Good surface finish–can be sanded/polished to required surface finish	Models need support structures that must be removed as a finishing operation	No post-curing of the parts is needed, unless they are ceramic	Surfaces of the parts are porous, and surface finish can be poor
Complex geometry easily obtained	Parts can warp, especially with acrylate resins	Parts can often be built without additional support structures	Process machines can take a long time to heat up and cool down
Generally there is good accuracy of the geometry	Resins are hazardous and need careful handling Some types of resin parts more brittle	Parts in a range of materials can be obtained directly	Investment casting requires the surface of master parts to be sealed Parts can warp significantly

2.4 Rapid Manufacturing process used in Case Study - Vacuum Casting

Silicon tooling is the most common technique for part replication, and can be used to supply a wide range of material including resins, waxes and low melting point alloys. The main use for silicon or room temperature vulcanization (RTV) tooling is in the manufacture of cavities for two-part resin casting. However, irrespective of down-stream application the manufacture of silicon cavities relies on a master pattern from which copies are replicated.

The silicon tool is placed in a vacuum chamber with a two part polyurethane resin. The two-part resin is mixed and degassed before being poured into the silicon cavity. After pouring, the vacuum is released and the tool is removed to a post-curing oven for up to two hours depending on the tool size. Following an exothermic reaction of the two-part resin, the cavity is opened and a polyurethane part removed. The silicon cavity is then closed and the process repeated.

Vacuum casting resins are currently available to mimic a wide variety of production polymers including ABS, filled nylon, heat resistant acetyl and a simulation of rubber. Tool life is dependent of both the complexity of the cavity and the resin used in the casting process. A typical cavity may last between 10 and 20 replications before severe degradation of the silicon. This degradation occurs because there is a reaction between the casting resins and the silicon.

After a few castings the surface of the cavity inside the mould is so damaged that the part can not release and then a new mould must be manufactured [1].

Once the product design is evaluated and accepted, a single cavity injection mould is manufactured using the rapid mould manufacturing protocol. This mould needs to produce 30 000 products/month.

For this specific product, the total development consisted of a series of iterations entailing 10 CAD designs, six prototypes (grown with the SLA process), and six different silicone moulds made to cast the different products, with the vacuum casting process.

3. RESULTS

The first prototype was developed and trailed during October 2002, as discussed in the design protocol (Figure 1). This design did not meet the required standards of the product and a number of small design changes were made for the following reasons (Figures 2-5 explains the models developed through the iteration process):

- Patient comfort: The airway clamp rubbed on the patients gums
- More secure clamping was needed on the ET tube
- Design changes to make the manufacturing of an injection mould simpler and cheaper, and in parallel, to decrease the cycle time to make the unit price more competitive.

A final shape that met all of the design criteria was modeled (Figure 6). These changes lead to a more suitable configuration and a rubber prototype was remoulded through the mentioned design protocol (Figure 7). This model was successful and was used in patient trials [4].

The manufacturing process included the following steps:

- An injection mould was designed and manufactured in August 2003 for mass production of the product (Figure 8 and Figure 9). This was necessary because large quantities of the product were needed and latex-free moulding material was essential for an approved medical product.
- During the injection moulding process various materials were tested in different shore hardness and a suitable material was found.
- The final product as used during operations is shown in Figure 10.

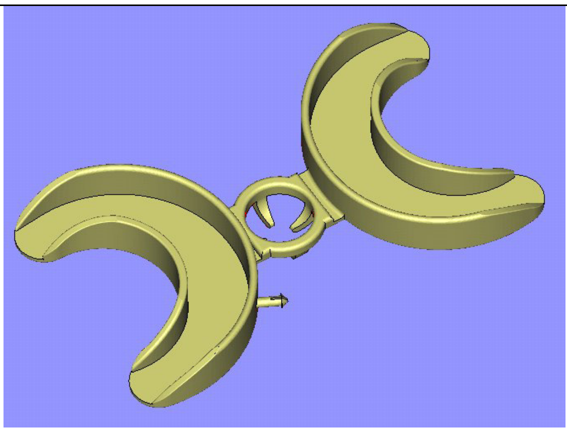
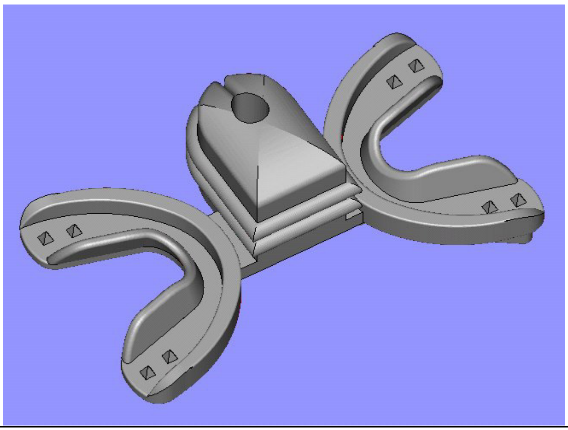
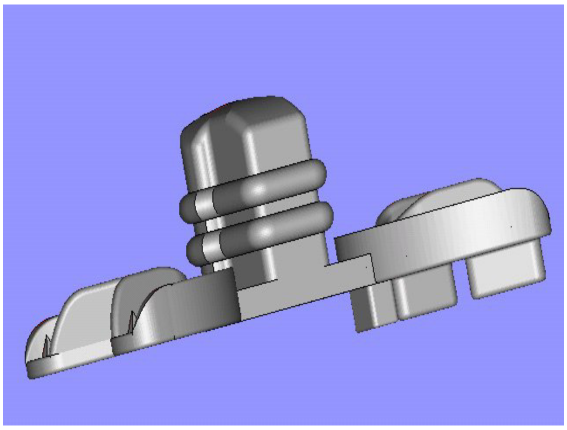
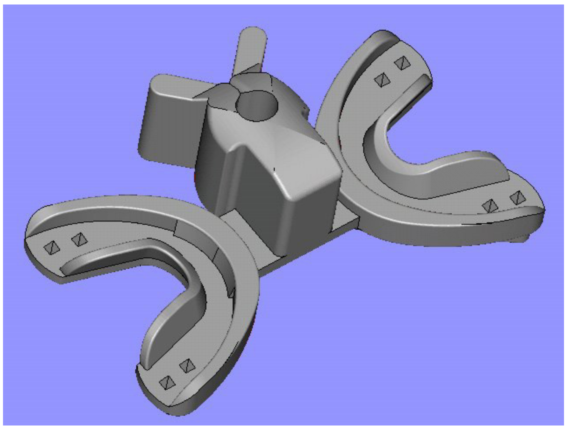
	

Figure 1	**Figure 2**
	
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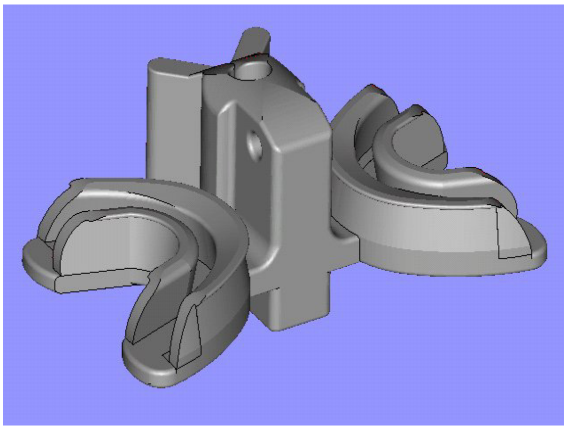	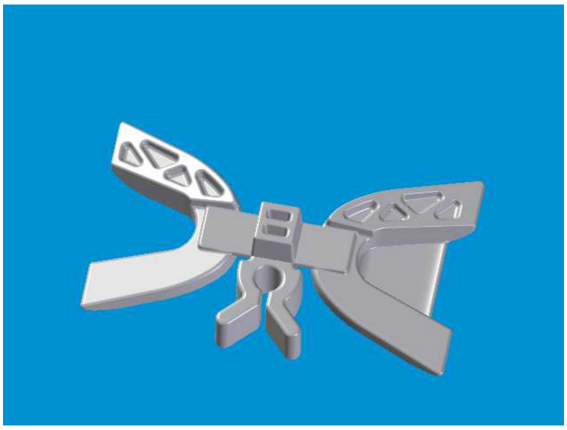
Figure 5	**Figure 6**

Figure 7

Figure 8

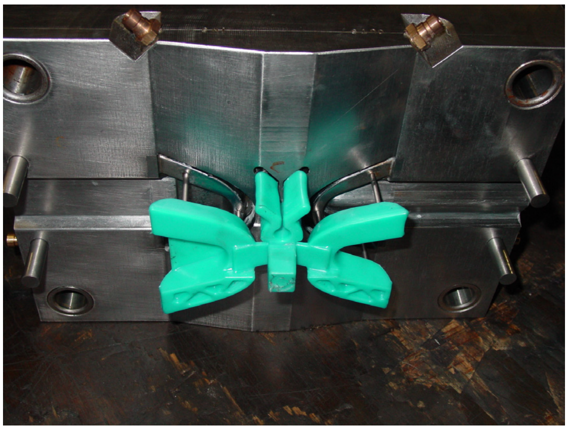

Figure 9

Figure 10

4. DISCUSSION

The total cost for the rapid prototype development phase amounted to R46 220, consisting of ten 10 CAD designs at R2 500 per design with two alterations allowed, six SLA prototypes at R2 500 each, six silicone moulds at R820 each and 26 cast components at R50 each of the different designs [5].

The conventional method of manufacturing an injection moulding tool would have amount to R45 000. The price to manufacture the product decreases dramatically once a hard tool has been made and one can only imagine what the cost and timeframe of development would have been if a decision was made to start directly with hard tooling. The cost of the injection moulded product was estimated to be R20 to R25, depending on the volume of the product.

Table 2: Cost comparison between the Rapid Prototype Development and Conventional Injection Moulding

Rapid Prototype Development Phase			Conventional Injection Moulding Manufacturing	
10 CAD Designs	R2500/design	R25 000	Design and Manufacturing of Injection Moulding Tool	R 45 000
6 SLA Prototypes	R2500/prototype	R15 000		
6 Vacuum Casting Moulds	R820/mould	R 4920		
26 Cast Components	R50/rubber prototype	R 1300		
Total		**R 46220**	**Total**	**R 45 000**

Table 3: Advantages and disadvantages of Rapid Prototype Development and Conventional Injection Moulding

Rapid Prototype Development Phase		Conventional Injection Moulding Manufacturing	
Advantages	**Disadvantages**	**Advantages**	**Disadvantages**
Inexpensive product alterations	Unit price of moulded part is high	Unit price of moulded part is low	Expensive product alterations
The more alterations the better the end product	Small quantities of the product can be produced	Large quantities of the product can be produced	Because of the cost implication many alterations aren't possible
Physical testing can be done before the end product			The end product must be produced for physical testing

From the above mentioned the advantages of rapid prototyping are clear. Even further advantages for implementing Rapid Prototyping and Tooling techniques can be divided into three areas:

Strategic advantages

- Time and cost savings in prototype production
- Enables rapid design and development changes to be made
- Reduced time-to-market
- Improved communication within and outside of the company

- Increased product improvement, customization and innovation

Production advantages

- Integration with CAD/CAM systems
- Rapid production of test prototypes
- Problems identified and rectified before tools are made and production process started
- Integrated production tools
- Reduction in number of test tools required.

Decision-making advantages

- Verifying the design
- Verifying the manufacturing process
- Verifying plans for production
- Verifying tool design and production
- Improved communication with suppliers
- Improved communication with sales and management departments [2]

During patient trials, the unit had a 100% success rate, with the ET tube staying exactly in place, for perfect ventilation of the patient. If the tube is grossly displaced (e.g. by somebody standing on a ventilator tube) the Secure Airway Clamp will be pulled out of the mouth and is easily noticed. This is not true for current methods of fixation. Even when one patient had a seizure on the operating table his airway remained secure. This is not normally the case during this type of episode using the old method of securing the tube.

Millions of operations are performed annually worldwide and if only a small percentage of market shares can be secured, with the possibility of substantial earnings and export.

This product has the ability to save lives and this will be paramount to the product's success.

5. REFERENCES

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