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# Design and Development of a Medical Product Using 3D Technologies: Scalp Cooling Cap Design Case Study

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**ABSTRACT:** Hair loss is a well-known side effect of many chemotherapy regimens, with many patients claiming it is the most traumatic aspect of their treatment. Scalp cooling provides the only real alternative to hair loss resulting in a high level of retention or complete hair preservation, improving patients' self-confidence and creating positive attitudes towards treatment.

The aim of the project was to redesign a scalp cooling cap so it fits patients better, it also had to be mass-produced and have an improved flow pattern of the coolant that cools the head. The new cap uses 3D printed tooling technologies and will pave the way for mass manufacture using lightweight silicone sheet so the scalp cooling cap is soft and flexible - providing a snug, comfortable fit during treatment moulding to all head shapes and sizes.

## 1 INTRODUCTION

Scalp cooling is a method used to reduce hair loss for patients undergoing chemotherapy treatment. Many patients experience great concern over the possibility of hair loss, which is a constant reminder of the disease to the patient, their family and in the wider social environment of work and leisure. Scalp cooling reduces hair loss with many prescribed chemotherapy drugs. It can result in a high level of retention or complete hair preservation which can improve patient's self-confidence leading to a positive attitude to their treatment and recovery. (Paxman 2015)

Benefits and Features of Scalp Cooling are:

- Greatly reduces the risk of hair loss,
- Preserves self-image,
- Allows continued social activities,
- Maintains the scalp at a constant temperature,
- Comfortable and pain free,
- High level of patient tolerance and acceptability.

The research team and Paxman group have been collaborating for over five years, primarily around the development of a unique product, namely a mass manufacturable scalp cooling cap using 3D anthropometric human head data. The research group initially worked on the chemical processes around the treatment which was explored through a previous KTP in the Biology Department, (Al-Tameemi et al, 2014) where the research helped deeper understand the science behind the treatment, leading to further

improvements in the globally-marketed cap. Initial research showed that there is a demand for a new cap which requires redesign of the cap shape to suit local anthropometric variances with improved cap production methods.

## 2 BACKGROUND OF MEDICAL RESEARCH ON SCALP COOLING

The Paxman Hair Loss Prevention System provides cooling for one or two patients simultaneously with each cap working independently during chemotherapy. The system consists of a small compact refrigeration unit containing a special coolant which is circulated at  $-4^{\circ}\text{C}$  through coolant lines to specially designed cooling caps. It is simple to operate and can monitor cooling parameters using a touch screen display.



Fig 1. Paxman Cooling Cap (Paxman.de, 2016)

### 2.1 Cooling Caps

The most important feature of the Paxman Hair Loss Prevention System is the specially designed lightweight cooling caps. The caps are soft, flexible and provide a snug, close fit around the patient's head,

the 5 different cap sizes in the range are colour coded and ensure most head shapes are catered. Coolant passes through the cap, extracting heat from the patient's scalp. Inline temperature sensors ensure the cap maintains the scalp at an even, constant temperature. (Paxman, 2015)

## 2.2 Procedure

Scalp cooling works by inducing vasoconstriction and reduction of metabolism. Vasoconstriction leads to reduced blood flow to the hair follicles in the period of peak plasma concentration of the relevant chemotherapy agents. In the past decades, scalp cooling has been achieved by a number of techniques, such as simple bags with crushed ice, frozen cryogel packs, and packs with an endothermic cooling reaction. Examples of precooled caps are ChemoCap™ (ChemoCap, Canada), Elasto-Gel™ Cold Caps (Southwest Technologies, Akromed Inc.) and Penguin Cold Caps (Medical Specialities Of California). Cooling machines that use liquid circulation are the systems of **Paxman** (PCS-1 and 2, Orbis) and **Dignitana** (DigniCap™), while **Amit Technology** (SCSII™) uses chilled air.

The success of the treatment is affected by the degree of control in maintaining the scalp at a constant temperature. The machine is switched on and allowed to reach its operating temperature, which takes approximately 30 to 40 minutes. A cooling cap connected to the system is then placed on the patient's head. Pre-cooling of the scalp takes 20 to 30 minutes prior to drug infusion. This ensures the scalp is at the required temperature before chemotherapy is administered. Patient preparations can take place during the pre-cooling period. The cap continues to be worn throughout the administration of the chemotherapy drugs and for a period of time afterwards, depending on the drug regime being administered

## 2.3 Research into Effectiveness of Scalp Cooling

Chemotherapy in the treatment of cancer relies for its effectiveness on the ability of the drugs to attack rapidly dividing cells which may be both malignant and normal. Certain drugs, or chemotherapy may cause partial or total atrophy of the hair root bulb, causing the hair shaft to break off spontaneously. The hair may also be weakened, by a narrowing of the hair shaft adjacent to the scalp this has been suggested as associated most frequently with standard doses of chemotherapy. Measures to reduce or eliminate alopecia during chemotherapy have been investigated since the 1960s. There are few studies comparing different methods of scalp cooling, but one study has suggested that cold air circulation is more effective than cryogel packs, as a lower temperature can be maintained for a longer period. (Massey SM, 2004)

## 2.4 Scalp Cooling Clinical Trials

Paxman Scalp Cooling experiment in UK (1997-2010), observational study reports an 89% success rate following use of the Paxman System in breast cancer patients, with only 11% with severe hair loss requiring wigs. Patients reported high comfort and acceptability levels with low numbers of withdrawals from scalp cooling. 85% of patients reported they were comfortable, reasonably comfortable, or very comfortable during the scalp-cooling period. (Paxman, 2013). Netherland studies (2006 - 2010), involved 1411 cancer patients from 11 hospitals in the Netherlands, carried out in 2 phases, to determine the effectiveness and tolerance of scalp cooling. Randomized study in the Netherlands shows that a reduction in scalp cooling time to 45 minutes, did not reduce the effectiveness of the PSCS (Paxman Scalp Cooling System) in preventing hair loss in docetaxel treated cancer patients. (Van Den Hurk et al. 2012 & 2013)

Massey SM (2004) Research, studied to determine the efficacy and patient acceptability of scalp cooling using the Paxman Scalp Cooler. This was an open, non-randomized, observational study conducted at eight sites involving 94 patients. The study describes the use of Paxman scalp cooler and states that a scalp temperature below 15 to 22C is required for hair preservation. A pre-cooling time of 15– 20 minutes was recommended to allow time for an adequate reduction in scalp temperature. (Massey SM, 2004). Research by Komen et al (2011), provides an overview of the incidence and severity, presentation and impact of chemotherapy-induced alopecia (CIA), one of the most common and distressing side effects of cancer therapy. Prevention of CIA by scalp cooling is described, as well as suggestions for improvement of scalp cooling application and clinical research approaches. Scalp cooling is described as effective but not for all chemotherapy patients and it is recommended that scalp cooling should be available in every hospital, and every suitable patient should be given the opportunity. (Komen et al, 2011 & 2013)

## 3 EXPERIMENTS: DESIGN AND DEVELOPMENT OF THE SCALP COOLING CAP

### 3.1 Project Aims and Objectives

The aim of the project was to produce a working prototype cap to fit initially to a single UK head size to allow testing of performance, and then develop the new cap further to meet all the performance requirements but also to fit the variety of head sizes

and shapes for a global product. The cap must meet the following criteria:

- Improve Conductivity,
- Improve Cap Fit, Comfort & Ergonomics,
- Improve the Ability to Mass-Produce.

### 3.2 Application of Rapid Tooling for Silicone Forming

The term “Rapid Tooling” (RT) is mostly used for prototyping and rapid manufacturing whereas Rapid Prototyping (RP) is typically used for visual design evaluation or physical and functional verification. RP provides an effective communication between design, management and marketing teams. Additive Manufacturing (AM), mostly using laser sintering technology, has been also adopted in industries such as aviation and aerospace. (Durgun et al, 2016)

### 3.3 Medical Device Materials

The biocompatibility of medical devices can be defined as the ability of the device to perform its intended function without causing undesirable side effects. Biocompatibility will be dependent on physical properties of the device and its chemical nature, as well as the body’s reaction to the device that will affect its function. Common Medical Device Polymers include: Polyethylene, Polypropylene and Thermoset Elastomers—Silicone. (Medical Plastics, 2013)

Materials that the team could choose from was limited by current regulations from, UK, EU and FDA approval bodies, thus from analysis the team decided to use Silicone as unlike latex, most healthcare silicones contain no proteins and are non-allergenic. Unlike PVC, they contain no phthalates or other organic plasticizers which might leach out.

### 3.4 Patent Search and Head Size Ergonomic Data

Patent research is key part of a product development process. There are number of patents covering various innovation in thermal head cooler exchange. As well as UK, EU and relevant American patents are investigated for initial design process. Intellectual Property office of UK also recently started offering Design Registration and Search functionality to their online facilities.

The research team evaluated where and what type of 3D Anthropometric data could be obtained. Databases such as the CAESAR project, the North American and the European edition (CAESAR, 2002) and the SizeChina Project (SizeChina, 2007) were investigated, all databases includes measurements from

approximately 2400 males and females and include both 3-D scans and traditional 1-D measurements.

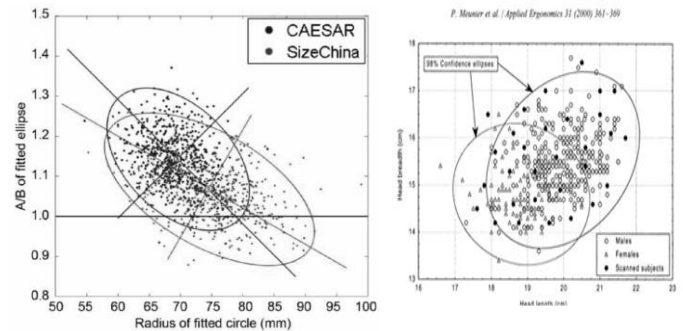


Fig 2. Comparison of European to Asian Head Sizes (Ball et al, 2010)

The design of consumer products that are worn on the head relies on the availability of accurate anthropometric information describing the shape and size of the human head and face. Historical anthropometric studies with univariate data have documented the existence of shape differences between Asian and Western head shapes, but the information available to designers has traditionally been based on only Western data. As a result, Asian users have often experienced poor fit in products used on the head. In addition, the geometry of the head is complex, making traditional univariate data unsatisfactory as a description for its form, as it typically includes only numerical values for head length, head width and circumference.

## 4 DESIGN AND DEVELOPMENT

The following are the considerations during the design and development phase:

**Patient Flexibility:** Due to the lightweight nature of the caps, patients should relax during the cooling process, engage in a number of activities and visit the bathroom without affecting their treatment.

**Nursing Flexibility:** The system and the cap must be simple to operate with easy to read digital displays. The equipment must be compact and maneuverable, nursing staff do not need to be in attendance with patients during cooling.

**Termination of Cooling:** On completion of cooling, a nurse should assist with the removal of the cap. The patient is then left to acclimatize before leaving the hospital.

Phase one of this project requires designing a new method for creating caps which will fit a selected individual better than the current standard model but also adjustable so cap size number will be reduced from five to three. The team decided to create middle size of the products which is the standard size. Having a standard size head, a staff volunteered to

be 3D scanned to create a 3D head as seen in the figure below.

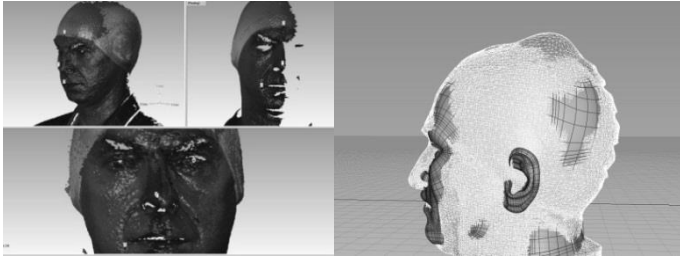


Fig 3. 3D Data from Paxman Staff (Unver, 2013)

The team then developed a manufacturing system for creating mass manufactured silicone cap. Some of these development phases are explained initially such as creation of 3D tubes around the head to demonstrate the idea of water flowing through the tubes.

This work proved that the channels can be created to fit the scan data. But the method to create a mould form sheet silicon was the first challenge. After this initial work the team met for a brain storming session, where a number of potential directions were discussed. First idea was to create the cap for the head from multiple smaller sections. But how to split the head shape to multiple sections that can be used to create mould(s) similar to the injection moulding process was the challenge.

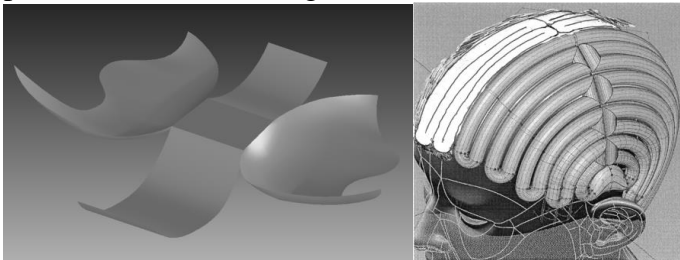


Fig 4. Tool shape and Tube Ideation (Unver, 2013)

The team then decided to evaluate the design using a flat middle section to simplify the moulding process. The surface data is taken to a Solid modelling package to evaluate how and where the mould could be generated. The final concept for creating the 3D folded cap where two side surfaces are shaped to fit the side of the head and the top surface when flattened will be folded on to the head.

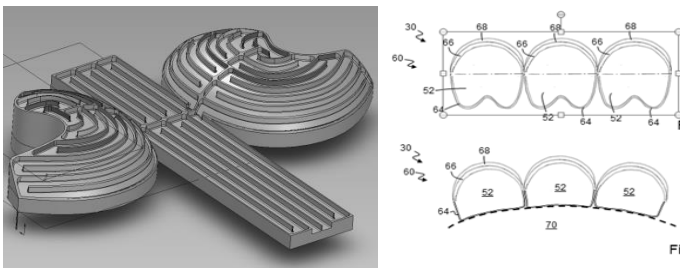


Fig 5. Tool and Patented Tube Design (Unver, 2013)

Initial testing of grooves as seen above proved that two parts of the moulding can be created and apply to this process. After modelling the male part of the mould as seen above, the female mould is created

using the male for reference. The two parts are assembled to produce the channels with 1.0mm dividers for minimal space between each cooling channel. Although the width of the channels are varied, it is calculated to achieve the same section area therefore same volume of the channels along the surfaces.



Fig 6. Tool Printed by EOS (Unver, 2013)

The EOS 3D laser sintering machine with PA2200 Polyamide material is chosen for tooling as the Laser Sintering Machine is available at the University. EOSINT P systems with recommended layer thickness is 0.15 mm.

Thermal properties of the 3D printed tools are one of the main reason for choosing this material as melting temperature of PA 2200 is around 180C where silicone is heat treated just over 100C during the moulding process. Although this was the one of the main factors, the required surface quality, print size, required minimal thickness value and details, and material specification required for heat and pressure was another important reason for choosing this laser sintering method. This tool was then used by the manufacturing partner (Primasil, 2016) where Silicon moulding machines used to create the new cap as seen in the images below. the moulded silicone showed that the method is feasible and can be used for cap manufacturing.

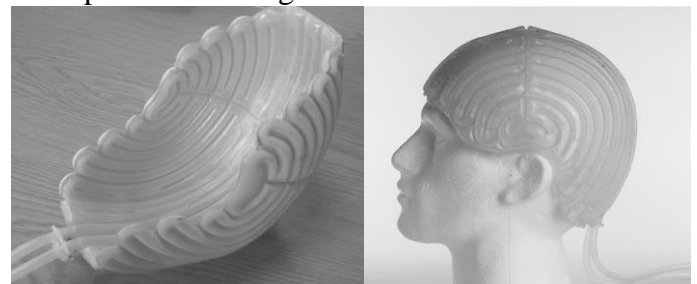


Fig 7. Completed Next Generation Cooling Cap (Unver 2013)

## 7 FINDINGS AND CONCLUSIONS

It is clear that the collaboration between Paxman and the research team has resulted an excellent product, not only achieving the company's requirements but also the needs of the patients as well. This project has shown that the use of RT is the potential future of design and development, proving that the tool can easily be reprinted and changed at low cost to provide the best design outcome where low tolerance tooling is acceptable.

The ability to use Rapid Prototyping in tool making in the last few years has enabled the boundaries of current manufacturing methods to expand, while reducing costs. This process has enabled the creation of innovative designs, which were impossible to manufacture in few years ago. Designers now can create new innovative products using additive manufacturing with not following core engineering design and manufacturing methods.

The new cap which is undergoing clinical trials in the UK, the US and Japan and has seen very positive results in terms of hair retention and patient acceptability. The new cap has also been awarded multiple awards, for both the innovation of the design and for the collaboration between the company and the universities design team, showing that the new technologies provided by universities, KTP's and other available funding can pave the way for new product developments and other innovative methods not currently available to SME's and other businesses that cannot get access to these technologies.

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