Title:
An Approach of Rapid Tooling for Scalp Cooling Cap Design

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Introduction:
This Innovate UK funded research studies the design, development and integration of a mass-manufacturable scalp cooling cap using 3D anthropometric human head data. Scalp cooling is used to reduce hair loss for patients undergoing chemotherapy. For many patients their biggest concern is 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. Pioneering the implementation of Selective Laser sintered 3D rapid tooling additive manufacturing in sheet silicone manufacturing. Research includes developments in, global human head size analysis and technical requirements including heat transfer, fit, flow rates and user interaction using advanced 3D modeling and simulation technologies. The investigations in rapid tooling and CAD methodologies can boost entry into a market such as sheet silicone manufacturing. This patented design is currently used in over 42 countries worldwide with FDA, Sho-nin, BSI and MDSAP approval.

Using 3D technologies including 3D scanning, 3D modelling, virtual analysis, 3D Additive Manufacturing, sheet silicone forming and Rapid Tooling (RT) for creating complex geometry with channels. Initially, for product evaluations and then testing later for low volume manufacture. Several design and 3D printed tooling iterations were evaluated to improve the manufacturability of the chosen design before the final tooling and prototypes were created. The cap has been developed, made and globally marketed by Paxman ltd. Forming close ties with experts at the University for Design and medical science for scalp cooling in preventing hair loss during chemotherapy.

The cooling caps are designed to be soft, flexible and provide a snug close fit around the patient's head. Manufactured from high grade silicone ensures most head shapes are catered for; supplied in various sizes. Previously the caps have been manufactured by draping silicone tubes manually around a model wooden head and bonded using silicone glue. This time-consuming process requires skilled full-time workers manually producing a limited number of parts. The research requirements included European/Far-East human head sizes and shapes, 3D scanning volunteers, processing of the acquired cloud data, 3D CAD modelling of a single agreed UK head size from 3D Scans to produce NURBS human head surface data, 3D Rapid Prototype, printing of the model head to enable trials for fit & surface contact, produce a suitable replacement method of the cap design & construction using sheet silicone forming techniques. The final cap must meet the following objectives: Improved heat transfer, cap fit, patient comfort, ergonomics, ability to mass-produce with minimal cost, minimise the number of size options, identify optimal flow pattern within the cap design, detailed CAD models to create working prototypes and regulatory compliance with testing phases.

Anthropometric Data Collection:
The design of consumer products worn on the head rely on access to accurate anthropometric information describing the shapes and sizes of the human head. Historical studies with univariate data show the shape differences between Asian and Western heads sizes. However, the information available to designers has traditionally been based on mainly western Caucasian data such as the research by Godil & Ressler [3], on the retrieval and clustering from a 3D human database based on body and head shape based on caucasian CAESAR data. Enciso et al [2] discusses 3D head anthropometric analysis where as Azouz et al [1] studies automatic locating of anthropometric landmarks on 3d human models. Asian users have often experienced poor fit in products used on the head. 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. Because of the inelastic nature of the head, head related products are especially demanding in relation to nuances of shape.

Technical Consideration and Manufacturing Requirements:
Choosing the right material and correct manufacturing methods always the main challenge for any designer and manufacturer. From the analysis of approved materials used in medical industry and availability of manufacturer partner, the team decided to use Silicone for manufacturing of the caps. Although silicone materials are more expensive, their antimicrobial properties for medical purposes make it good choice for healthcare products despite the fact that recycling is not easy. In the past century, engineering plastics have progressed from novel invention to a major component in numerous industries penetrating markets once dominated by metals. Silicone is one of the most common and thoroughly tested biomaterials; are well known for their intrinsic biocompatibility, bio-durability, chemical stability, physical strengths, low surface tension and hydrophobicity. Silicone elastomer is a thermosetting material, capable of being processed by various moulding, dipping, and extrusion methods. They can usually be dry-heat sterilised. Because of this, silicones have been used extensively in medical products and in many demanding applications. In general, silicone is known to possess temperature stability potentially ranging from -115°C to 260°C, and to exhibit low shrinkage, low outgassing and low shear stress.

3D Scanning and Concept Generation:
After reviewing the head size literature, a staff member with mid-size Caucasian head volunteered to be scanned to create a 3D head as seen in Fig 1c below. 3D non-contact lasers are used to capture shapes by repeated scanning of the required objects from eight different angles to generate a point cloud data using the Minolta 910 laser to create a 3D CAD head model (NURBs) data using Autodesk's Alias and 3DS Max CAD packages alongside SolidWorks professional surface modelling for post-processing the scanned data as shown in Fig 1a, b, c and Fig 2a. Initial studies with the handheld Structure SDK sensor for 3D scanning with low quality and a range of 04-3m was not adequate. More high-quality scanners were investigated including the Eva Artec, Creaform 300 and FARO Freestyle, demonstrating the need for higher quality point cloud data for accurate designing of the caps.

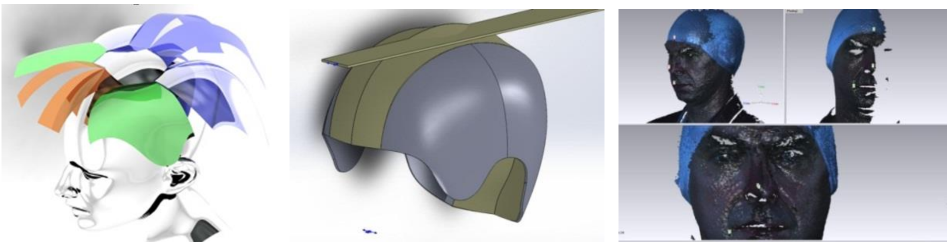

Fig. 1: Cap design and ideation, multiple sections (a), shape (b) wireframe processing (c).

The first idea was to create the cap from multiple smaller sections, challenged by how to split the head shape to multiple sections that can be used to create mould(s) Fig 1a, b. One of the important features is to consider continuous fluid flow in each section, therefore design should consist of minimal folding but also the fluid flow should not be restricted when folded. Therefore, although other folding shapes were considered and simulated, the team decided to produce the shape shown in Fig 2b.

A flat middle section design was considered to simplify the moulding process (Fig 1b). The surface data is taken to a solid modelling package to evaluate how and where the mould could be generated. Fig 2a shows the cap is divided in to three sections where the top could be moulded as flat and the side of the face sections could be constructed from the side panels. The team used a chosen concept to work on a method of creating surfaces which could be converted in to a tool where hollow channels could be created to produce a silicone cap (Fig 2c).

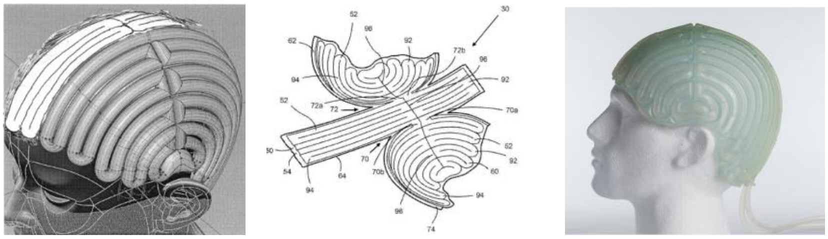

Fig. 2: Cap manufacturing consideration, mid section (a), flat pattern (b) and prototype (c).

Manufacturing Process, Thermoforming:

Twin sheet forming is a variant method of vacuum forming whereby two sheets are formed at the same time producing an application with a hollow sealed section. Temperature control, vacuum and pressure are important factors for this process. The ability to control heating in individual areas of the sheet is vital for preventing sagging. Hot-air is often used to keep the two sheets from touching each other. This process commonly used for producing hollow sectioned parts typically luggage boxes, air ducts, roof domes and roof hatches. The connection joint between the two parts is obtained by a combination of melting of the two materials and the exposed pressure of the molds without additional glue or other adhesive [4]. Lexan, Merlon, Makrolon (polycarbonate resin thermoplastic) is commonly used for thermoforming & twin sheet forming. In this research, twin sheet forming methods have been applied to the manufacturing of silicone materials, traditionally used for hollow parts such as lexan.

Cap manufacturing and Tool Design:

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. The demand for quick, low volume tooling solutions has resulted in a number of RT methods being developed worldwide including direct and indirect methods. D*irect RT* approach involves creating the actual core and cavity mould inserts and i*ndirect* method use RP master patterns to produce a mould. Although there are distinct advantages of using Metal RT or AM methods for creating tools and final components that are impossible to manufacture with other conventional methods, the high cost currently prevents its use for wider applications. Recently 3D printer manufacturers introduced mixed materials such as Polyamide and Alumide where the nylon and aluminum dust particles are combined to produce affordable laser sintering materials which can be used for RT.

Rapid Tooling Consideration for Silicone Forming:

Factors such as operational requirements can dictate important design inputs in design for manufacture. Three crucial considerations for rapid tooling due to the method of processing the sheet silicone include Thermal conductivity, Glass Transition Temperatures (GTT)/ Heat deflection and Yield stress (Pressure applied). PAEK, PEEK, PEI has up to 250˚C GTT. ULTEM materials for fused deposition modelling (FDM) as seen in Table 1, have 160˚C+ GTT. These materials have been bought with aims of implementing procedures into place for high temperature additive manufacturing particularly using in-house FDM 3D printer.

Using RT for printing, a production tool requires a printer big enough to achieve the desired size; it is industrially known that most SLS machines have relatively limited build volumes. Accuracy and tolerances are also crucial, particularly for tooling as any discrepancies or overhang can mean the tool won't mate correctly or cause a crash/ collision which can mean a broken or damaged tool. Knowing this will mean that tolerances can be designed into the CAD work prior to production (Design for Manufacture DFM). Knowing a machines resolution will aid in these areas, but will also dictate whether post-process will be necessary on a tool to prevent unwanted surface patterns or defects in the silicone forming process.

Considerations of a materials tensile strength will identify its capability to withstand the processing pressures during forming process. During manufacturing, tools can be heated and cooled intermittently where constant expanding and contracting, shrinkage, deformation, break-down factors must be factored to prevent failure and ensure a high-yield per print [7]. Upon the initiation of this project, 3D printing had limitation in the capability of material choice. Ultem and other highly engineered FDM materials weren't widely available; as such initial prototyping was carried-out with Nylon 6 (PA2200). This moved to Alumide blending the characteristics of fusing a polymer with a material of high heat-transfer co-efficiency, Aluminium. Later advancements in this industry sector years-on meant the discovery of engineered polymers and composite FDM filaments with increased properties to deflect heat for RT and rapid prototyping shown in Table 2.

	Alumide	Ultem	Nylon 6 (PA2200)	PEEK
Tensile Strength [MPa]	48	138	48	75
Heat transfer co-efficiency [W(mK)-1]	0.5 - 0.8	0.21	0.127 - 0.144	0.25
Glass Transition Temperature [˚C]	150	250	163 Vicat softening	130-150 type1 260-290 type 2.

Tab. 1: 3D printed material properties for tooling consideration.

Tool Design with Cooling Channels:

Initial testing of grooves as seen in Fig 3a proved that male and female moulding halves can be created and applied to this process. This patented idea as shown in Fig 3b where one side comprises of a thinner silicone wall with a double arced outer surface; both arcs are configured for contact with the head. The second side is comparatively thick and non-deformed in shape, using a single arcuate outer surface. External surfaces include an insulation layer encapsulating the silicone wall. When pressurised the internal groove channels become flattened therefore increase the surface contact to the scalp. Due to complexity of the surfaces channel cross-sectional area is set to 75mm2 and appropriate width and height parameters for optimal manufacturing.

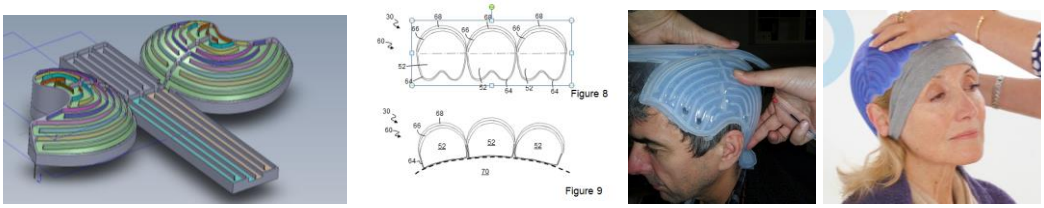

Fig. 3: Initial tool and groove design (a) channel section (b) initial prototype (c) and current cap (d).

Images above show the unique patented groove creation with max surface contact. As stated in the patent [6], the cooling cap is defined as a heat exchanger, and method of manufacture configured to be placed into contact with a human head to regulate the temperature. The cap comprises of a formed layer of material creating a passage through which a heat transfer fluid flow. A secondary layer has contact with the skin; and the opposing side which, in use, will face away from the head. The first side has a relatively high coefficient of thermal conduction. Comparatively, the second side has a relatively low coefficient thermal conduction.

Using the PA2200 material on the EOS 3D laser sintering machine with a layer thickness of 0.15 mm is used for prototyping of the moulding tool. Thermal and yield stress properties are the main factor for choosing this material as well as surface quality, print size, minimal thickness & fine details. This tool was used by a UK based manufacturing partner where silicone forming create the new cap. This process showed that the method is feasible and can be used for cap prototyping and manufacturing. Due to nondisclosure agreement, details of the manufacturing process and parameters cannot be discussed. Then cap is then used for clinical trials in various countries, including the UK, USA, Japan before commercially available to ensure compliance with different countries regulatory aspects. The cap is then exhibited in a number of trade shows and exhibitions [5] gaining this product 6 international awards received; currently commercially sold in over 42 countries.

Conclusion:

The close mimicking fit of the cap to the users scalp is a crucial aspect of preventing hair loss. Every person has an individual head shape and size, but research has enabled the identification of head size categories and shape profiles. 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 a few years ago. In this research, high temperature and high thermal conductivity materials were used for generating large scale rapid tooling for producing scalp cooling cap in a commercial environment. Tensile strength, the heat transfer co-efficiency and GTT characteristics needs evaluating for establishing optimal material parameters in RT tooling. This research confirms that non-metallic RT can be used for operating under heating and cooling parameters for producing low volume medical devices.

Acknowledgements:

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