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An Approach of Rapid Tooling for Scalp Cooling Cap Design

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Abstract. This Innovate UK funded research studies the design, development and integration of a replicable mass-manufacturable process for scalp cooling caps using 3D anthropometric human head data assisted by Selective Laser Sintered tooling (SLS), and implementation of Additive Manufacturing (AM) in silicone manufacturing for chemotherapy-induced hair loss prevention. This research also consists of how 3D digital technologies including 3D scanning, 3D modelling & virtual analysis, AM and Rapid Tooling (RT) can be effectively used in prototyping and low volume manufacturing of sheet silicone forming for creating complex geometry with channels where traditional tool making process cannot be applied.

Keywords: rapid tooling, additive manufacturing, medical design, scalp cooling
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1 INTRODUCTION

This research investigates the design, development and integration of a mass-manufacturable scalp cooling cap using 3D anthropometric human head data assisted by SLS RT, pioneering the implementation of AM in silicone manufacturing. Research also covers 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 in SolidWorks for assessing optimal flow performance analysis.

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 as stated by Brandes et al [3]. The use of scalp cooling or 'cold caps' is proven to be an effective way of combatting chemotherapy-induced hair loss' and can result in a high level of retention or completely preserve the hair. Scalp cooling can be used with all solid tumor cancers that are treated with chemotherapy drugs such as taxanes (e.g. docetaxel), alkylating agents (e.g. cyclophosphamide) and anthracyclines/DNA intercalating agents (e.g. doxorubicin). These drugs target rapidly dividing cells and the matrix keratinocytes, which results in hair loss [18].

This project covers design and development of scalp cooling caps using 3D technologies including 3D scanning, 3D modelling & virtual analysis, AM, sheet silicone forming and RT for creating complex geometry with channels (Figure 1b). Initially for product evaluations and testing then later for low volume manufacturing. Several design and 3D printed tooling iterations were

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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. The investigations in rapid tooling and CAD methodologies can help entry into a market such as sheet silicone manufacturing as shown in this research where patented design is currently licensed for use in over 42 countries worldwide including FDA, Ninsho, Shonin, BSI and Medical Device Single Audit Program approval. The project team also include medical & biology collaborative partnership from Applied Science department for studying the medical science of scalp cooling in preventing Chemotherapy-Induced Alopecia. The scalp cooling caps are designed to be soft, flexible and provide a snug close fit around the patient's head. Manufactured from high grade silicone which 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. These procedures are time consuming and require skilled full-time workers manually producing a limited number of parts. Quality, cost, repeatability, patient fit, device efficacy and regulatory requirements are subject to stringent controls were beyond the in-house expertise of the company.

Figure 1: System and cap on patient (a), Cooling cap on patient, adhering cap cover (b).

This research aimed to address all of the above issues as well the accurate fit for European and Far-East human head sizes and shapes. Aided by a Knowledge Transfer Partnership (KTP) initiative the project enabled investigation of these problem areas. The team investigated 3D scanning of a range of heads with volunteers, processing the acquired cloud data, 3D CAD models of Caucasian head shapes to produce human head NURBS surface data, 3D Rapid Prototype (RP), 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.

This study investigates how RT can be applied to develop a new silicone manufacture method where the cap can be designed, prototyped and manufactured in commercial environment. The complex 3D groves that a scalp cooling device consist of technical requirements, fit, functions indicated that traditional manufacture methods cannot be used for manufacturing of this product. The project aimed to 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 to create working prototypes and regulatory compliance within the testing phases.

During this project, we utilised the methodologies by the Design Council [8], Nigel Cross [6], Richard Buckminster Fuller [13] and Donald Schon [10]. An iterative process of 'discover, define, develop and deliver' [7] as stated by the double diamond process is core 'to develop technology-based solutions to important and relevant business problems' [12] as defined by the Design Science methodology. The evaluation and iteration within research projects has aided areas such as user-centered design iteration. The design thinking methodology by Nigel Cross has aided in

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‘user centered research for evaluating user wants and needs, to identifying and address the opportunities’ [6]. Lastly, utilizing Donald Schon’s reflective practice of learn by doing during the experimental innovative phases has enabled continuous improvement in all aspects.

Due to the stringent medical device design and development regulations of the MDSAP and ISO 13485:2016, a mixed methodologies approach has been used. In accordance with the regulatory process, methods such as the double diamond process are beneficial to incrementally assess, the feasibility, design inputs and outputs, validation, verification, design transfer and so on. Other crucial factors for medical design and development where safety testing and usability tests are considered in all aspects including but not limited to CAD where IEC 60601-1 is assessed for general requirements for basic safety and essential performance, ISO 14971 is assessed for applications of risk management to medical devices and IEC 62366 is assessed for applications of usability engineering to medical devices among other standards.

The following research is structured with some initial background research of Rapid Tooling and the silicone forming method, followed by research conducted on quantitative 3D scanning data collection and anthropometric analysis that aided in some of the evidenced concept generation. Post concept generation, Manufacturing processes are explored with this new innovative application of Additive Manufacturing Rapid Tooling in sheet-silicone thermoforming; some of the Design for Manufacture considerations required in Computer-Aided Design.

2 BACKGROUND OF RAPID TOOLING AND 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. The demand for quick, low volume tool solutions has resulted in a number of RT methods being developed worldwide with direct and indirect methods. Direct RT approach involves creating the actual core and cavity mould inserts and indirect method use RP master patterns to produce a mould. Although there are distinct advantages of using Metal RT or AM methods to create tools and final components that are infeasible 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 particles are combined to produce affordable SLS materials which can be used for RT.

Recent developments in Rapid Tooling (RT) have changed the design process and economic models for mass manufacture. With the advent of RT, the process can be divided into three segments. The first stage is Prototype or Soft Tooling where a mould is designed to test component functionality, appearance, size and fit. These tools produce only a few hundred parts, whereas in Bridge Tools tens of thousands of units could be manufactured. These tool stages facilitate the early introduction of new products to the market, prior to or during the fabrication of the Production or Hard Tool. By adopting RT methodologies, the manufacturer can gauge the volume of demand for the product before specification and investment in the production tool. RT can meet the needs of a customised market where an inexpensive (softer) tool is sufficiently robust to handle batch outputs.

Rapid tools either directly produces a tool with a rapid prototype system, or indirectly utilises a rapid prototype as a pattern for the purposes to produce the tool [15]. Chil-Chyuan Kuo [14] studied new methods to manufacture rapid tooling with different cross-sectional cooling channels to reduce the manufacture cost and manufacture time to market as substitute for conventional molds or dies to reduce cost and time to market. Chua et al states there are a variety of RT methods; be categorized as indirect tooling or direct tooling. Indirect tooling consists of creating a master pattern via rapid prototyping, which is then used to create the mold that may include, metal casting, resin casting, silicone rubber casting and 3D KelTool process. Thermal and mechanical properties of soft tool materials vary significantly from those of conventional steel tools, affecting the quality of the final product and tooling longevity as they are often made for short manufacturing runs [16]. The application of 3D printing for RT study Segal & Campbell [20] shows the issues of shrinkage of a tool was double compared to an aluminum

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studied. These differences in conventional RT are related to factors including cooling rates, mold-stress and thermal properties of the tooling materials. Nsengimana et al [17] investigates using AM SLS for Nylon and Alumide powders and ABS in FDM for post-processing methods on small samples involving tumbling, shot peening, hand finishing, spray painting, CNC machining and chemical treatment whilst discussing the benefits and negatives of these methods. Other research by Chimento et al [5] studied the use of RT molding for prosthetics manufacture process and its flexibility for fitting to patients using 3DP in the manufacturing process. Yih Lin Cheng [4] propose a new application of RT on customised nasal mask cushions for continuous positive airway pressure. The study claims the price-to-performance ratio of the customized cushion can be lower than the commercial ones if more than three cushions were made by a single rapid tool.

Although many researchers studied the use of RP, SLS and other 3D printing processes for RT particularly for injection moulding or other moulding techniques, we are not aware of any commercial or academic study who applied 3D printed RP technology to silicone sheet forming processes with complex grooves as investigated in this research for manufacturing of consumer products commercially.

3 DESIGN AND DEVELOPMENT

During the design and development of this medical cooling device the team complied with the medical device regulations particularly ISO 13485:2016, the design and development process must ensure that the design outputs meet the design input requirements. In the initial stages for investigating this project, some crucial design considerations were to evaluate the current production method using Computer-Aided Design to improve the manufacturability. Investigation of global ergonomics and anthropometric data to ensure a better tighter fit of the patients' head which is essential for preventing hair-loss and also the technical considerations for improving the efficacy of the device to improve operational performance such as flow rates, heat transfer, tear prevention, weight reduction, usability, user experience were the some of the considerations.

3.1 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 [11]. In the retrieval and clustering from quantitative 3D human head shape data based on Caucasian CAESAR and Size China (shown in Figure 2 below), with approximately 2400 participants. Enciso et al [9] 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. The team scanned a number of selected Caucasian and Far East heads that were used in early design phase and during testing of the caps before the clinical trials. The gap between the head and inner surface is dependent on a few factors. Successful treatment is effected by the specified grouped head shapes and size categories (Small, Medium and Large) alongside other parameters including hair thicknesses and hair types of varying demographics. Patients with thicker hair will undergo a period of longer treatment due to additional insulation generated from thicker hair requiring longer to cool down the scalp.

3.1.1 Technical Consideration, Manufacturing Requirement and Regulatory compliance

Choosing the right material and correct manufacture methods are always a main challenge for any designer and manufacturer. From the analysis of approved materials used in medical industry and availability of manufacture partners, the team decided to use Silicone to manufacture the caps.

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Although silicone materials are more expensive, their antimicrobial properties for medical purposes make it a good choice for healthcare products despite the fact that recycling is not easy.

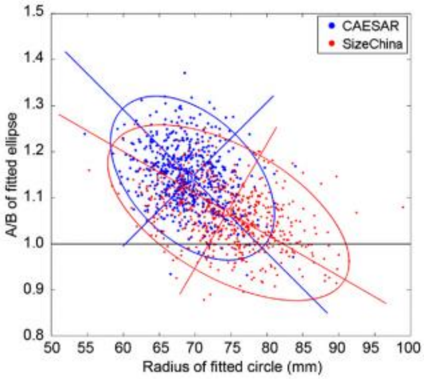

Figure 2: Clustering of quantitative 3D human head shape data based on Caucasian CAESAR and Size China [2].

In the past century, engineered plastics have progressed from novel invention to a major component in numerous industries to penetrate markets once dominated by metals. Silicone is one of the most common and thoroughly tested biomaterials; well known for their intrinsic biocompatibility, bio-durability, chemical stability, physical strengths, low surface tension and hydrophobicity. Silicone elastomer is a thermoset 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 high demand applications. In general, silicone is known to possess temperature stability that ranges from -115°C to 260°C, and to exhibit low shrinkage, low outgassing and low shear stress.

3.1.1 Design for regulatory compliance

Through this project, the collaborating company partner became the first company in the North of England to receive MDSAP approval, which allows the licensing of the medical devices with HC (Health Canada), FDA (Food and Drug Administration), ANVISA (Agência Nacional de Vigilância Sanitária/ National Sanitary Surveillance Agency), EC (European Commission), ATG (Australian Therapeutic Goods Administration) and PMDA (Pharmaceuticals and Medical Devices Agency).

Crucial regulatory compliance as part of the European directive 2017 in Medical design and development in addition to the stated management system ISO13485: 2016 where safety testing and usability testing is considered in all aspects including but not limited to Computer-Aided Design where IEC 60601-1 is assessed for general requirements for basic safety and essential performance, ISO 14971 is assessed for applications of risk management to medical devices and IEC 62366 is assessed for applications of usability engineering to medical devices among other standards.

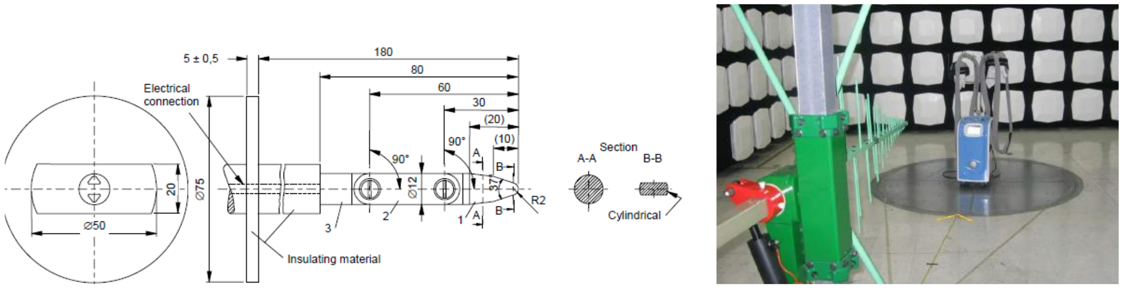

Figure 3: ISO 60601-1 Standard finger test (a), ISO 60601-1-2 Emissions testing (b).

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ISO 60601-1 considerations such as Mechanical strength where the device is placed in an oven for 7 hours, bearing test, Electric tests (Single fault condition) and the standard test finger as shown in Figure 3a above wherein a mechanical finger is used all over the device to ensure that a user cannot put their fingers into the device as a matter of safety.

For medical devices containing an electric interface, programming, software or similar, the standard ISO 62304 contains the considerations for software to ensure areas like bugs or defects are addressed. The commercial partner offers healthcare at home; subsequently it has been necessary to address ISO 60601-1-11 which is the standard that is concerned with Home Use and all the considerations that must be addressed. The medical devices not only have to be assessed for how users and patients will interact with them, but also how they will interact with or affect other machines. ISO 60601-1-2 is the standard for emissions testing (Figure 3b). This is to ensure that this device won't interfere with devices such as life-support units. Radio frequencies. Class A software (the lowest severity) and also so other devices don't interfere with ours. Other considerations include ISO 10993 Biocompatibility, Clinical Evaluation, Clinical Risk, Essential Requirements and Overall Safety (Device Specific).

RT and AM have facilitated the iterative development and enabled the modifications required for appropriate regulatory bodies. The methods used for validating and verifying the designs iteratively has been crucial for the SME's. Clinical trials are very expensive; without this method it is unfeasible to invest without feeling confident in the validation of a design prior to moving to hard tooling.

There are many stringent processes that must be addressed especially in the design and development of a medical device prior to sale on different markets. In relation to the design and development procedures, the cooling cap is approved by ISO 13485:2016 (UK), FDA (USA), Ninsho (Japan).

Amongst the stringent design and development procedures for a medical device, clinical trials are crucial for design validation and design verification. Utilising Paxmans international network of medical experts and medical professional clinical trials are conducted. For instance, in the regulatory proceedings for obtaining FDA approval, clinical trials to allow for licensing to distribute the Paxman medical devices in America.

3.2 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 4c 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.

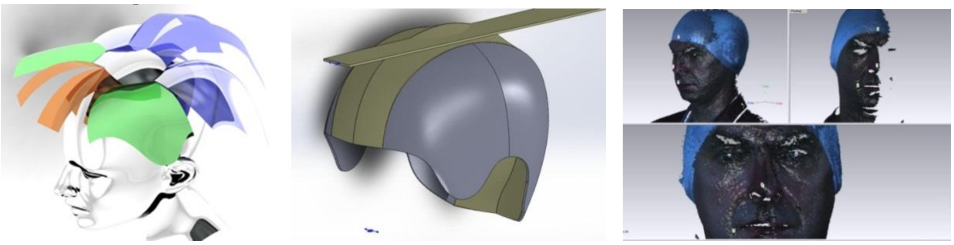

Figure 4: Cap design and ideation, multiple sections (a), shape (b) wireframe processing (c).

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) shown in Figures 4a and 4b. One of the important features is to consider continuous fluid flow in each section, therefore design

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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 Figure 5b.

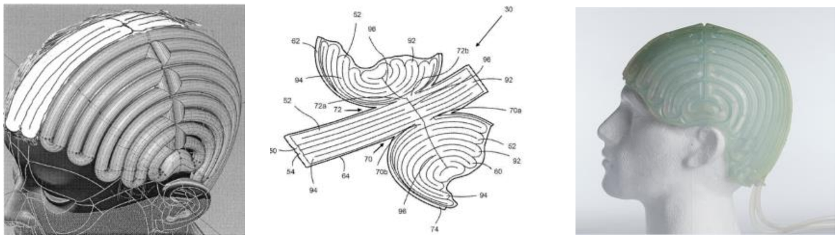

Figure 5: Cap manufacturing consideration, mid section (a), flat pattern (b) and prototype (c).

A flat middle section design was considered to simplify the moulding process (Figure 4b). The surface data is taken to a solid modelling package to evaluate how and where the mould could be generated (Shown in Figure 5a). Figure 5b 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 (Figure 5c). Different layouts could be explored, however for manufacture feasibility this pattern was chosen.

3.3 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. The basic steps in the process are outlined in Figure 6. Temperature control, vacuum and pressure are important factors for this process. The ability to control heating in individual areas of the sheet is vital to prevent 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 glues or adhesives [19].

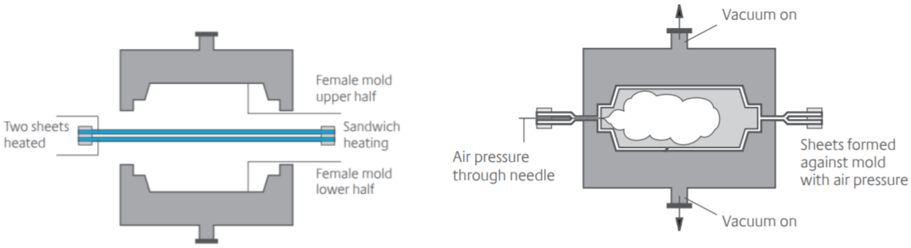

Figure 6: Sabic Twin Sheet Forming for Lexan Manufacturing [19].

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. An adopted method of this process has been explored but cannot be disclosed due to confidentiality.

3.4 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

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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 [23]. 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 1.

	Alumide (SLS)	*Ultem FDM*	*Nylon 12 (SLS-PA2200)*	*PEEK FDM*
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.

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

4.5.1 Cooling Channels Design

Initial testing of grooves as seen in Figure 7a proved that male and female moulding halves can be created and applied to this process. This patented idea as shown in Figure 7b 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.

Images above show the unique patented groove creation with max surface contact. As stated in the patent [21], 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.

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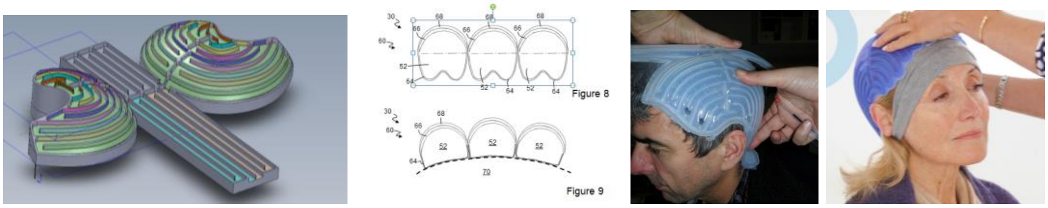

Figure 7: Initial tool & groove design (a) channel section (b) initial prototype (c) Cooling cap (d).

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 [22] gaining this product 6 international awards received; currently commercially sold in over 42 countries.

4 CONCLUSION

This study proved that the investigation of AM methods such as SLS can be effectively utilised for RT in the sheet silicone thermoforming in a commercial environment to develop medical silicone products. Using this method, new medical cooling caps have been designed, developed and produced from these AM RT tools to address Chemotherapy-Induced Alopecia. Enabling SME's to integrate iterative continuous improvement during the design and development for low-volume manufacturing to their business model. This design freedom and rapid aspects allow faster entry into a market and to meet medical regulatory standards. But design for AM is currently being studied by many academics and commercial bureaus, where limitations, best practices and feasibility are being explored. Each investigation considers a different approach to the AM methodologies that encounter variable problems to different products. This Method has allowed for design validation through different product sizes in different materials. Because of the many routes available for RT, part properties, process parameters and available materials, mechanisms need implementing to control the quality of the outputs produced. This research showed that even the same 3D printing bureau producing large (450x470x200mm) SLS RT tools using Alumide can generate varying qualities of outputs where reliability is required for generating consistent batches for low-volume production. This research identified that some RT Alumide tools can produce up to 3 times more products than others RT tools from the same specification as explored by Mendible, Rulander & Johnston [16]. Some considerations for using SLS for Alumide consist of specified wall thicknesses, can be hollow or solid for pressure and heat-transfer, warpage, surface finish, layer resolution, tolerances and design for post-processing.

The close fit of the cap to the user's scalp is a crucial aspect to prevent hair loss. Every person has an individual head shape and size, but this research has enabled the identification of head size categories and shape profiles. The use of RP in tool making in the last few years has reduced costs and expanded the boundaries of current manufacture methods. 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 evaluated to establish

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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.

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