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Computer-Aided Design AND APPLICATIONS

Qualitative Data-Driven Generative Design for Personalized Wearable Scalp Cooling Devices

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Abstract. This research evaluates a qualitative data-driven approach where generative design is used to manufacture personalized wearable cooling caps capable of preventing chemotherapy-induced Alopecia. A plethora of CAD software is explored to transform human head data collected by healthcare professionals into usable CAD data through means of a generative design, where a simple algorithm is developed to modify a CAD geometry for individual patients. 3D Printed bespoke cap artifacts are produced and presented in this research as a proof of concept for the developed framework.

Keywords: Mass Personalization, Generative Design, Cranial Anthropology, 3D printing, Chemotherapy-Induced Alopecia.
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1 INTRODUCTION

Following an extensive research and development phase [1,2,3], in a funded project conducted over the past few years, personalized scalp cooling caps are developed with generative design tools using cranial data collected from healthcare professionals to provide an optimally fitting wearable cryotherapy device utilizing CAD packages and design tools.

Recent research [4] demonstrated personalized cooling caps are essential to improve Scalp Cooling success rates/efficacy to over 80% through perfect fit. Perfect fit requires extensive iterative research with multidisciplinary global healthcare professionals, scientists, and Designers. Following a study where cranial parameters were studied that could provide the optimal fit of head wearable designs, several pilot studies were able to prove a 93.8% accuracy rate against a control for human head data collection. Following this, collected data would be used to generate CAD models to be 3D printed, providing accurately fitting cooling caps that represented the measured patient's head with high precision. This approach utilizes a qualitative approach to mass customization whereby individuals' cranial data drives the generative design of CAD models for mass personalization.

Generative design applies algorithms to parameters to generate hundreds of thousands of design variations [5]. It is a powerful design tool that allows you to fully exploit additive manufacturing potential [6]. The Generative design process is largely viewed as a collaborative, interdisciplinary activity that is more flexible [7], allowing for multiple stakeholders to have their input in the design process to develop a more suitable product. Generative design has been used in mass customization for fully harnessing the design opportunities provided by advanced manufacturing technologies for improving user satisfaction [8]. Data driven design data-driven frameworks can be improved by integrating multiple types of data to improve the automation level, and performance, and boost design efficiency [8]. Similar approaches have investigated data-driven customization for ankle braces [9] and glasses [10].

Parametric design's ability to produce variations and bespoke products [11], combined with digital fabrication's ability to physicalize this variation, enables mass production of non-standard products [12]. Many companies are adopting parametric-oriented digital interfaces that allow the user to change design parameters to personalize a product.

2 ERGONOMICS & ANTHROPOMETRICS, MASS PERSONALISATION

An extensive literature review on over 175 papers evaluated human head size research. Existing research lacked the appropriate parameters to categorize and define head shapes for optimal fit on different head shapes globally [1]. In this mass customization approach, parameters have been piloted in several data collection studies with healthcare professionals in the UK [2], USA and Singapore [3] to provide an accurate representation of a global healthcare market. Below highlights the set of chosen parameters.

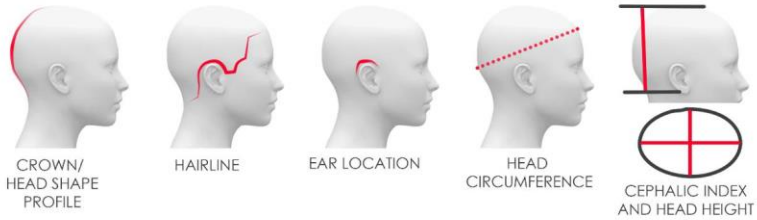

Figure 1: Parameters for cranial data collection [2].

This study explores one of the three approaches piloted, where previous investigations [1,2,3] evidenced the suitability of 2 of the three approaches. Though one of these utilized 3D scanning techniques, for ease of implementation globally with healthcare professionals, it is preferred that expensive and complex 3D scanning machines to gather accurate human head data are not required. Ultimately, the chosen approaches will be used by the layperson, where the products and services need to be used by nurses or patients, where measuring of the heads will not be conducted by trained engineers or designers. Therefore, in this study, a manual approach is explored more thoroughly and applied to a generative design approach as input parameters for the algorithm that will generate the bespoke cooling caps.

2.1 Generative Design, CAD

The study aims to integrate data-driven methods into the generative design-based mass customization process to improve patient satisfaction and clinical efficacy past 80% through improved fit. The main contributions are to integrate a qualitative data-driven approach to personalization through a developed framework tailored for the optimal design of scalp cooling caps gathered by healthcare professionals and exploiting generative design frameworks to improve the efficacy and attractiveness of the products based on individual needs.

A hybrid approach is integrated for the CAD modelling process to achieve this personalized wearable design that can be feasible, viable and desirable, whilst adhering to the list of regulatory demands. Initially a parametric design approach is utilized to modify an existing CAD to a tailored head geometry (from a patient). Following this, generative design tools are utilized through B-Rep modelling to generate structures inside the channels to improve the function of the cap. Initially, the team investigated Generative design for bespoke internal support structures inside liquid channels to remove the need for complex, timely, and costly post-processing requirements. Ongoing work is investigating how these generated structures can be designed to produce turbulent coolant flow and improve heat extraction potential efficacy.

Initial Generative CAD design approaches were applied in a section of tubing to iteratively develop a section of the approach rather than immediately integrating it into a full cap straight away. Using Rhino Grasshopper, various parameters were defined to generate the lengths, wall thickness, and diameter of the tubes, and further B-Rep modeling has been used to explore various lattice structures using the crystallin plugin to populate the inside of the liquid tubes with voxels, see Figure 2 below.

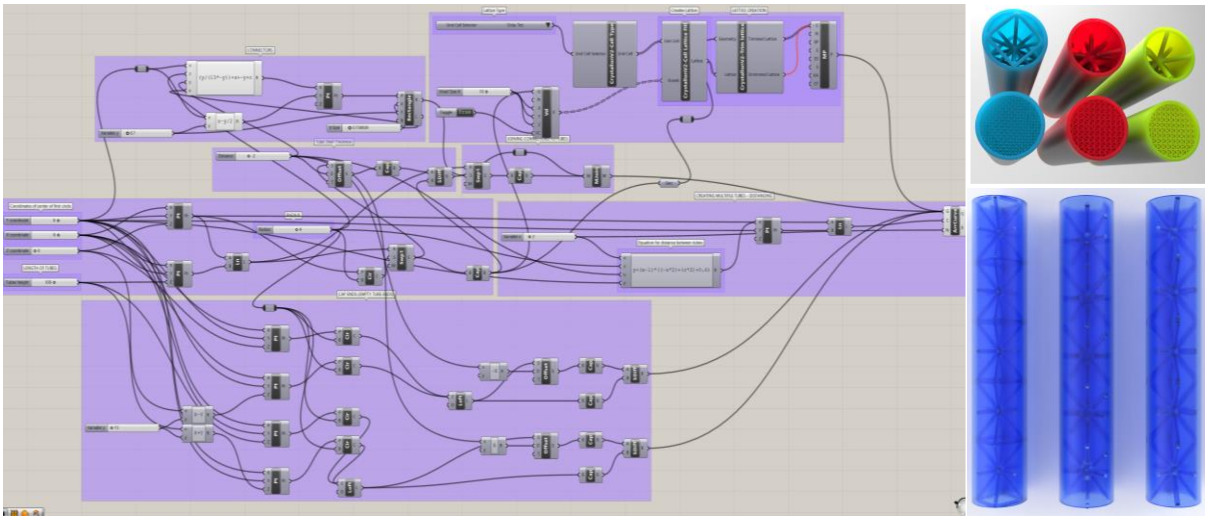

Figure 2: Grasshopper algorithm for basic turbulent lattice liquid tube (Left), Renders of various designs (Right).

Whilst evaluating various CAD packages for this approach, which previously included Blender, Grasshopper, and SolidWorks, the team also evaluated another AutoDesk software called Netfabb. In this similar approach, a parametrically modified CAD model will be utilized. However, for the B-Rep modeling, the liquid heat exchanger (Cap model) would be imported into the software without hollow channels and will utilize the Netfabb software to both hollow out the channels and generate an optimized lattice structure inside for optimized turbulent flow performance (seen in Figure 3 below). This is one of the two elements required to produce personalized cooling caps for patients. The second requires a parametric approach to tailor the geometry to the patient's qualitative data-driven inputs.

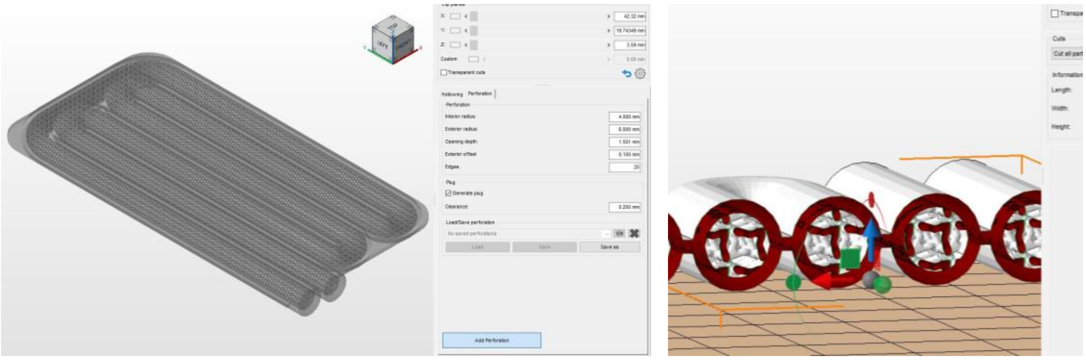

Figure 3: generic flat liquid channel heat exchanger in Netfabb with lattice inside (Left), close-up of cross-sectioned channels after B-Rep modelling completed (Right).

2.2 Parametric Design, CAD

Initially, existing cap models were rigged in a blender, where the skeleton of the CAD model for customization was determined by the parameters outlined in the previous studies highlighted in the above section. From this, cap models are manipulated for bespoke users. The team concluded that using a standard CAD model of a cap and manipulating it to each user's head is the best approach, as opposed to generating a new design for each patient. This will ensure the consistency of crucial factors such as the cooling channels' cross-sectional volume for flow, wall thickness, and technical parameters of the cap, which are maintained for safety and efficacy.

In Figure 4, a generic Scalp cooling cap CAD model is used. This was generated as a standard representation of the existing scalp cooling cap using SolidWorks Surface modeling tools into a solid body CAD file. A wireframe structure is generated around the cap, representing the required parameters for the personalization approaches explored. From this, the SolidWorks CAD models are exported as either STL, STEP or Parasolid models and imported into Blender and Grasshopper. For the Sculptor approach, no exporting is required.

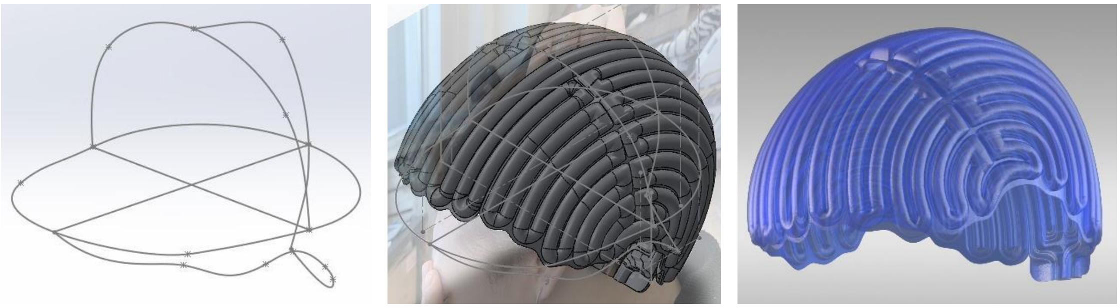

Figure 4: Path for skeleton rigging (Left), application to cap (Mid), cap CAD model (Right).

Blender is used in the first instance, though the intention is to assess SolidWorks Sculptor for a streamlined, simplified commercial approach and Rhino Grasshopper for a more technical engineering approach. Below is the process used where the SolidWorks CAD model is imported into Blender, where the rigging process is applied to enable the input of customized parameters such as head circumference, width, depth, ear height, ear depth, and crown shape profile.

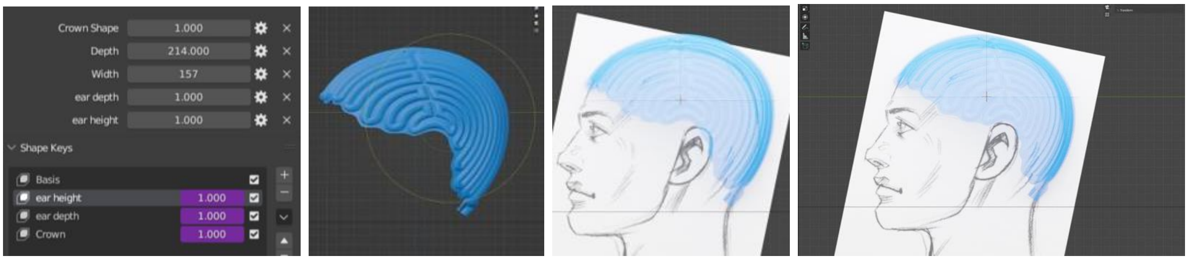

Figure 5: Blender and SolidWorks Sculptor CAD models.

Using Blender, custom properties are applied to a standard Cap model imported from a SolidWorks model. Properties such as float, integer, and max/min values are used as drivers to manipulate the imported models. In this application, the properties aid in the correct fitting of cap models for different head shapes with unique scales and shapes using shape keys in a properties panel. As shown in Fig. 5 above, reference images are used for reference to highlight changes based on anatomical locators for fit.

Further studies explored surface NURB modeling, where several iterations were manually modeled to explore a mass-customized approach (Seen in Figure 6). This approach defined a larger set of caps based on collected data where an alternative approach to customization could be achieved by an SME. From here, the three options can be converted into 21 options, and the human head data collected would help categorize which of the 21 caps the patients are best suited to.

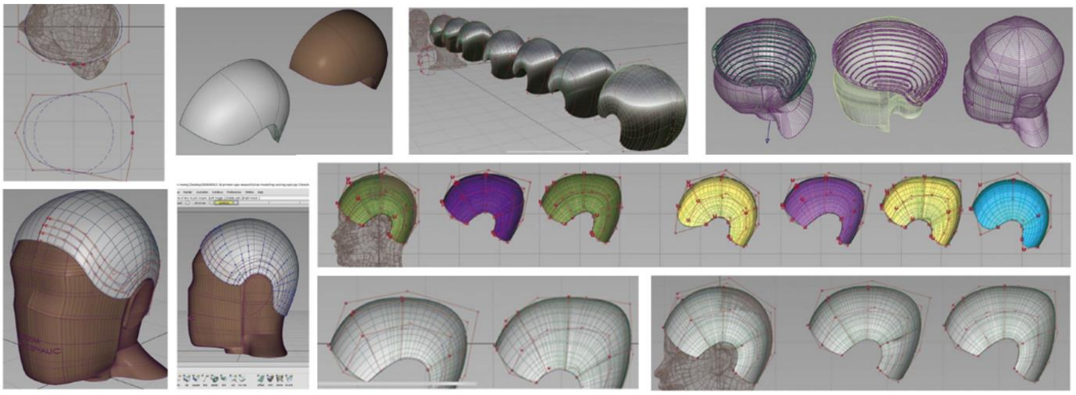

Figure 6: Surface NURB modeling iterative design.

Ongoing work is assessing SolidWorks Sculptor and Rhino Grasshopper for both a more accurate advanced approach and a simplified, easy-to-implement approach in a more standardized CAD package. Though there are several CAD packages that can be applied, it is important to consider the feasibility, viability, and desirability matrix for the chosen mass customization approach. For ease of implementation for a globally sold product, in simplifying the approaches used in CAD, it could be possible to roll out in other countries more easily through standardization of the CAD packages developed in this work or a similar. With this as a business model, simplifying the generative design process could enable 3D printing manufacturing hubs for cooling caps in several countries. For example, if approached correctly, there could be a scalp cooling cap printing manufacturing hub in Europe, the UK, Singapore, and the United States.

Initial studies explored Blender, where the generic proof of concept framework was explored in Figures 2-3 above based on the parameters of the initial phases chosen. For the next phase, exploration in Rhino Grasshopper is being explored using the framework needed for the generative design approach below (Figure 7).

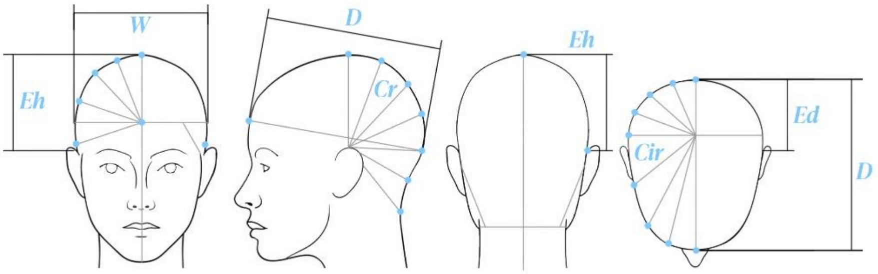

Figure 7: The framework for generative design algorithm in CAD is visually represented.

For this framework to be suitable, there is a list of changeable parameters based on mass personalization and a list of constant parameters that must not change regardless of the variable parameters input. The approach will use a standard cooling cap design, and the generative approach will use this framework to manipulate a CAD model. It will be important to ensure cooling channels are not closed off when the cap is stretched. Some examples of these parameters are shown in Table 1 below.

Fixed parameters	*Variable parameters*
Channel cross-section shape	Head width (*W*)
Channel wall thickness	Head depth (*D*)
Distance between channels	Ear height (*Eh*)
Thickness between cap and head	Ear Depth (*Ed*)
Patented inside channel profile	Head circumference (*Cir*)
Shore Hardness	Crown shape (*Cr*)

Table 1: Examples of Fixed and Variable generative design parameters.

2.3 Equation-driven CAD Modelling in SolidWorks

Following the parametric modeling completed in Blender, Excel-driven CAD modeling was evaluated where equations can define the geometry of the 'cap model' prior to conducting B-Rep generative CAD modeling. Initially, smaller sections of tubes are produced, followed by larger flat heat exchanger models. At this stage, these are proof-of-concept models to evaluate the best approaches for enabling the generative design of personalized scalp cooling caps. Below are some of the equations used to drive the models and how these can change to simulate different patient geometry being input (Figure 8).

This approach uses the Equations function in SolidWorks, where global variables are defined and applied to smart dimensions on the CAD file. Over 50 iterations of the CAD models have been produced, and 3D printing has been used to evaluate the repeatability of this approach with Industry 4.0 manufacturing applications to assess the repeatability of the industry using a generic heat exchanger model. 3D prints were produced on a Formlabs 3L liquid resin printer using the 50A

Flexible TPU resin shown in figure 8 above. Some of the equations used as global variables can be seen in Table 2 below.

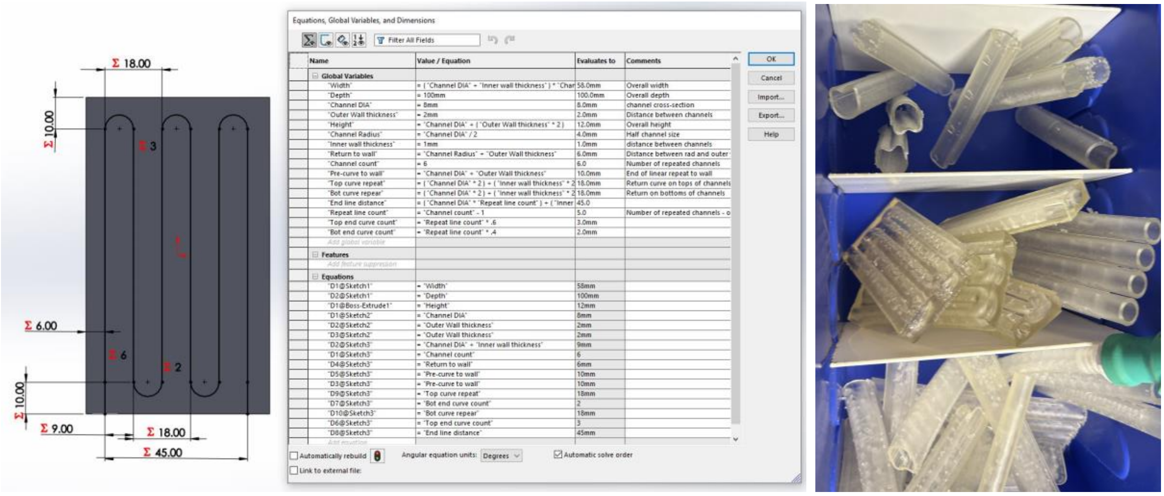

Figure 8: Excel Equation-driven heat exchanger model produced in SolidWorks (Left), 50A TPU 3D printed samples (Right).

Global variable	*Equation*
Top-end curve repeat	= (Channel diameter X2) + (Inner wall thickness X2)
Repeat line count	= Channel count -1
Top-end curve count	= Repeat line count X 0.6
Bottom-end curve count	= Repeat line count X 0.4
End line distance	= (Channel DIA X repeat line count) + (inner wall thickness X repeat line count).

Table 2: Examples of Fixed and Variable generative design parameters.

2.4 Technical Considerations

The next phase requires two main considerations required for producing 3D-printed personalized cooling caps from the generated CAD data, excluding the regulatory requirements at this stage as this approach falls under a feasibility study. The considerations include the material parameters to simulate a similar makeup of silicone, such as biocompatibility, flexibility, tear-resistance, and comfort, and secondly, manufacturability (which machine can make the cap in the chosen material).

Following an extensive material research phase, TPU (Thermoplastic polyurethane) was initially chosen for the additive manufacturing process. TPU is the industry's answer to silicone due to its enhanced properties, biocompatibility, sustainability, and improved thermal properties, all of which this project requires for successful implementation. Extensive research determined a minimum wall thickness required where throughout the model, no matter how much a cap was manipulated, it should not get thinner than 1000µm if 3D printed, for example. However, depending on what surface quality is used, that would affect how many layers each wall has. I.e., if FDM is used, where a 1000µm nozzle is used, then walls will only be 1 layer thick. If a 400µm nozzle is used, then walls will be 2 layers and only 800µm thick. These parameters have been implemented and considered in the Generative design approach.

TPU Is a readily available material that can be printed using various AM methods and has grown in popularity over the years due to the advancements in AM technologies, simplifying the associated complexities of printing flexible materials, which has also led to advancements in more complex and more varieties of flexible TPU's that can be printed.

With 3D printing, viability must be considered. Some 3D printing processes such as FDM generate a layered model, which often cannot be watertight if directly manufactured, requiring some additional coating perhaps which could inhibit costs, flexibility and pollute the plastics. SLA printing could be suitable, following a design for the manufacturing optimization phase to enable liquid to be flowed through a directly manufactured part in UV liquid resin.

In determining the efficiency of the wearable heat exchanger, the heat extraction calculation has been used. Using this calculation, a selection of variables will affect the output depending on the user which can be addressed in the final design to ensure a like-for-like efficacy based on the existing silicone cap to maintain the clinical efficacy already studied for regulatory retention. These are essential parameters that will affect the generative design approach. As a wearable heat exchanger, parameters such as the thickness of the walls interacting with the scalp will affect the amount of heat exchange. If we allow this to change from person to person, the heat extracted will vary. Therefore, the inner and outer walls must be constant, even if the internal channel walls vary. Other parameters, such as specific heat capacity, will be constant if the same material is used. The equation used in our calculations is Fourier's Law of heat conduction, where k is the thermal conductivity of the material, A is the heat transfer area, and dt/dX is the temperature gradients across the wall.

$$q = -kA\frac{dT}{dX}$$

3 ADDITIVE MANUFACTURING

In this section, a selection of additive manufacturing approaches is utilized on various machines such as Snapmaker for FDM and Formlabs 3L for liquid resin. For this project, a selection of materials and machines were purchased to enable a rapid prototyping and direct manufacturing pilot study phase to be completed. In Table 3 below, a selection of these materials are highlighted, all have been selected against the design input requirements for producing suitable 3D-printed cooling caps.

Material	*Specification*	*AM process*
1.75mm TPU filament	90A	FDM
1.75mm TPU Filaflex filament	70A	FDM
1.75mm TPU filament 500g	85A	FDM
1.75mm TPU filament 500g	82A	FDM
1.75mm TPU Filaflex filament	60A	FDM
Formlabs 50A Resin	50A	SLA
Formlabs 80A Resin	80A	SLA

Table 3: Flexible TPU materials used for the prototyping of bespoke caps.

Using the materials highlighted in the table above, a plethora of 3D printed caps were produced from both existing CAD models and new CAD generated from the mass customization approaches highlighted in this work. Various CAD models were prototyped using generative CAD tools to manipulate the CAD into different shapes and sizes in accordance with the parameters for mass personalization. Some of the prototypes can be seen in Figure 6 below. So far, over 20 different models have been made using various software, sizes, cranial data parameters, machines, and materials. Using an iterative design approach, ongoing work is being undertaken to explore the Generative design approach more, with more complex algorithm development and more advanced materials and manufacturing approaches.

The first model produced utilized a simple outer shell of a participant's head generated in SolidWorks using data collected from the outlined parameters. Following a successful recreation of a participant's exact head with a close fit, a standard scalp cooling cap model for the existing Paxman cooling cap was added into SolidWorks and modified manually. After, a completely new CAD model was generated for this specific approach, whereby the channel arrangement would limit the complexity of generative design and reduce the potential risks of failing when adjusted. This is seen on the right of Figure 9 and was made bespoke to the person shown in the image.

Figure 9: 3D printed generic outer shell (left), standard printed cooling cap (left, mid), Customized cap (right mid), bespoke CAD customized cap (right).

4 DISCUSSION

New methods of design validation are being explored in a study working in tandem with this project. As the scalp has complex, varying geometry, where a personalized approach brings further challenges and considerations, a new method is required to verify the outputs' effectiveness. The next phase of this study will utilize a new head validation rig suitable for verifying the closeness of the fit in a controlled environment. A bespoke cap will be produced to demonstrate the mass personalization method for producing scalp cooling caps based on the head rig, and a validation process, in accordance with the quality management system ISO-13485, will document the results.

Following a validation and verification process conducted in a controlled and simulated environment in a lab with calibrated sensor equipment, a follow-up usability trial and subsequent clinical trials may be required, depending on the needs of the regulatory bodies, to gain approval for market sale. These studies will provide evidence of a level of efficacy, which will determine the product's effectiveness through hair retention. Compared to traditionally designed products, the head is not straightforward due to the globally varying parameters highlighted in this research; therefore, a perfect fit is used to prove efficacy.

Based on the research of parameters used in the generative design approach, a strategically mapped taxonomy is deployed, where sensors are subsequently located to measure closeness. Our studies evidence poorer fit in certain areas of the geometry such as the scalp, which is a largely varying profile. From this, the team will be able to map out varying tolerances based on areas that experience poor or good fit typically (i.e. ±0.2,0.5,1mm).

Although future projects will enable the required trials and further development of the validation sensor rigs, this study will initially utilize in-house validation methods for the prototyping stage. At this stage, these parameters have not yet been investigated and explored, though the following parameters will be crucial for the testing phase: liquid flow (ml/s), pressure (psi), temperature (°C), Heat extraction (watt/hrs.) and other usability factors.

5 CONCLUSIONS

This research has presented an expansive evaluation of potential CAD packages that can produce personalized scalp cooling caps (wearable heat exchangers) for the purpose of preventing chemotherapy-induced Alopecia, utilizing a mix of parametric and generative design approaches in various software. Utilizing these approaches will enable a world-first scalp cooling cap that could significantly improve the cooling efficacy of scalp cooling caps for cancer patients. The CAD tools evaluated have the potential to not only personalize caps to individual patients' heads geometry but also use generative CAD tools to optimize flow and material usage and optimize structural integrity alongside flexibility.

At this stage, the variables associated with like-for-like efficacy are not considered as this is a feasibility study and not preparation for market readiness. Therefore, variable wall thicknesses are considered but not applied to adjust the heat extraction based on Fourier's law. The team has been able to successfully generate mass personalized cooling caps based on collected cranial data from a set of chosen parameters. From this, it is possible to assume that personalized cooling caps could be manufactured using direct manufacturing approaches (3D printed), from bespoke human head data collected by healthcare professionals. However, there are still many variables that must be explored in the future stages.

Up to this stage, only one side of the feasibility study has been proven, which is, can bespoke cranial anthropology data collected by healthcare professionals be used in a mass customization approach to generative design for making 3D printed cooling caps? The second part requires an extensive technical testing phase where the liquid will be pumped around the 3D-printed caps to test for heat removal or extraction from the cranial according to liquid pressure, volumetric flow rate, and failure testing to ensure the cap can perform as intended.

The next phase of this research requires a way of evaluating and benchmarking the new outputs against the current silicone cooling cap. Although mass personalization is great, and offers benefits for the patients and user, regulatory requirements state the product needs to perform with similar efficacy as its predicate (the current cap). Bespoke caps may function differently, and if the new outputs perform better as heat exchangers, further optimization work packages would be required.

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