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

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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 a 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 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 exploit additive manufacturing potential [6] fully. 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 to fully harness the design opportunities provided by advanced manufacturing technologies to improve 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.

Ergonomics & Anthropometrics, mass customization:
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 is the set of chosen parameters.

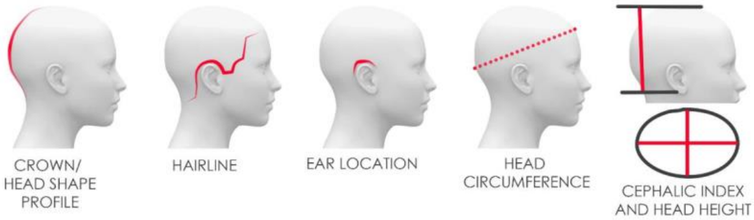

Fig. 1: Parameters for cranial data collection [2].

<u>Generative design, CAD:</u>

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.

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, 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.

Below, 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 modelling 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.

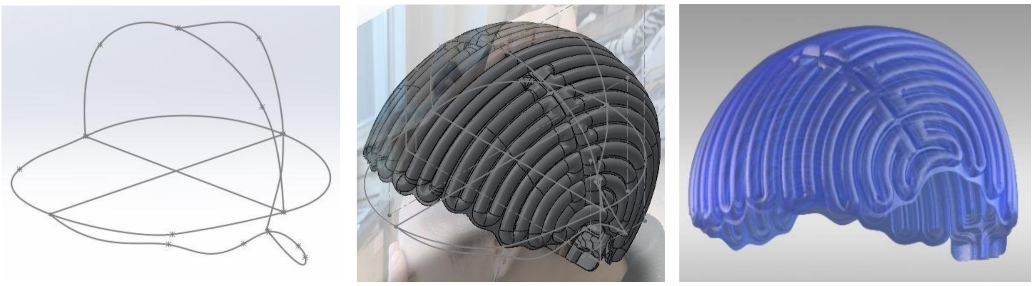

Fig. 2: Path for skeleton rigging (Left), application to cap (Mid), cap CAD model (Right).

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

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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.

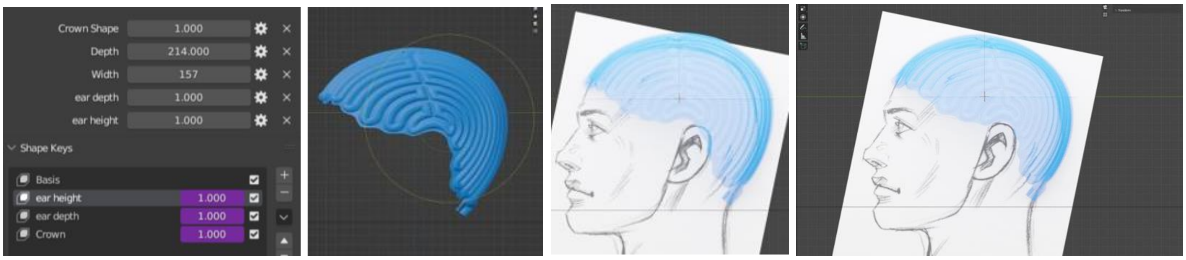

Fig. 3: Blender and SolidWorks Sculptor CAD models.

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 3 above, reference images are used for reference to highlight changes based on anatomical locators for fit.

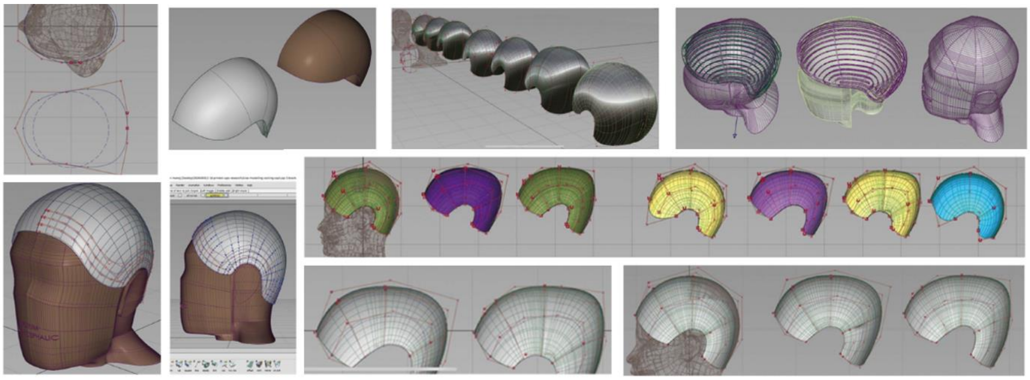

Fig. 4: Generative design CAD models in Alias.

Ongoing work is assessing SolidWorks Sculptor and Rhino Grasshopper for both a more accurate advanced approach and a simplified easy to 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, simplifying the approaches used in CAD could make it possible to roll out in other countries more easily through standardization of the CAD packages. 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 printed manufacturing hub in Europe, the UK, Singapore, and the United States.

<u>Technical considerations:</u>
The next phase requires 2 main considerations 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 materials parameters to simulate a similar makeup of

silicone such 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 and flexibility and pollute the plastics. SLA printing could be suitable, following a design for the manufacturing optimization phase to enable liquid to flow through a directly manufactured part in UV liquid resin.

Heat extraction calculation was used to determine the efficiency of the wearable heat exchanger. 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 heat exchange. If we allow this to change from person to person, the heat extracted will vary. Therefore, 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 Heat transfer (Energy) = thermal conductivity (specific heat capacity)/ material thickness x area x dT (temperature in - temperature out).

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 1? Below, a selection of these materials is 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

Tab. 1: 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 project. Various CAD models have been prototyped using generative CAD tools to manipulate the CAD into different shapes and sizes in accordance with the outlined parameters for mass personalization. Some of the prototypes can be seen in Fig 5 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 Fig 5 and was made bespoke to the person shown in the image.

Fig. 5: 3D printed generic outer shell (left), standard printed cooling cap (left, mid), Customized cap (right mid), bespoke CAD customized cap (right).

Conclusion:

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 that cranial anthropology data collected by healthcare professionals can 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 extraction, pressure, flow, and failure testing to ensure the cap can perform as intended.

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