Investigation of a New Framework for Mass Customization Within Healthcare Orientated Human Head Data Collection for Healthcare Professionals

Jonathan R. Binder[1], Ertu Unver[1], Caterina Benincasa-Sharman[1], Yang E. Yee[2] and Aishwarya Bandla[2]

[1]University of Huddersfield, England, J.Binder@hud.ac.uk
[1]University of Huddersfield, England, e.unver@hud.ac.uk
University of Huddersfield, England, c.a.benincasa@hud.ac.uk
National University of Singapore, Singapore, yee.ye@nus.edu.sg
National University of Singapore, Singapore, aishwarya.bandla@nus.edu.sg

Corresponding author: Jonathan. R. Binder, J.Binder@hud.ac.uk

Abstract. This funded research investigates parameters within cranial anthropology to develop a new framework for generating tailored mass customizable scalp cooling caps through the assistance of healthcare professionals to prevent chemotherapy-Induced alopecia during chemotherapy treatments. The paper explores several data capture methods and a selection of cranial data parameters including manual and additive approaches to head data capture that could be used to 3D print wearable heat exchangers (Cold caps).

Keywords: Mass customization, 3D Scanning, Cranial Anthropology, 3D Printing, Chemotherapy-Induced Alopecia.
DOI: https://doi.org/10.14733/cadaps.2024.499-509

1 INTRODUCTION

This commercially funded research is in contribution to goals set out in the Paxman Research and Innovation Centre, for enabling the development of a novel, environmentally friendly ecosystem for customised 3D-printed cooling caps ready for mass production. Without treatment Chemotherapy-Induced Alopecia (CIA) affects 3.5 million patients worldwide and over 67,000 in the UK annually [1]. Scalp cooling is recognised as the only effective treatment for CIA prevention. Previous studies [2] show that the efficacy of this treatment relies on accurate cranial data so that designers can produce close-fitting scalp cooling caps. This research shows how a design research methodology can be adopted to meet the expectations of commercial partners.

Relevant papers [3] focused on the human head size data, had the most impactful influence on this study so the research team could initially categorise human head sizes. Recent research [2] demonstrated personalised 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. This research will establish a global data collection practice for industry 4.0 applicable Mass Customization (MC) practices for customisable wearable cooling technology utilizing human-centered parameters with a heavy focus on healthcare professional-orientated data collection. Earlier data was collected in the UK by the design teams [3,4]; this research collects data primarily from Singapore where protocols were developed to enable researchers beyond the design team to train healthcare professionals to lead this data collection in the design process for the first time. The results from this study are presented to validate the usefulness of this approach as a new method for designers to implement mass customisation through CAD of wearable devices.

In reflection, to achieve a better fitting cap, industry 4.0 methods must be employed, whereby a mass customization approach can be implemented into a business model for commercial viability. For this approach it was necessary to establish the most appropriate approach for healthcare professionally orientated human head data collection. In this study, three core approaches were explored that could be feasibly and viably implemented into a healthcare setting based on previous research [3, 4]. After establishing the most appropriate method, data has been processed using CAD packages with aims of generating flexible 3D printed cooling caps.

2 MASS CUSTOMISATION APPROACHES

An extensive literature review of over 175 papers evaluated human head size research. Existing research lacked the appropriate parameters to categorise and define head shapes for optimal fit on different head shapes [5,6,7,8], which are distinct across the world. Previous research often generalised nuances of head shape profiles. Designers require an approach that considers the parameters required to accurately design a cap to suit individual users, and which can be customised and rolled out within the healthcare industry.

Although it would be easy to assume that a designer could generate an optimally fitting cooling cap for individuals with time and resources, these commodities are typically in short supply. Mass customisation approaches must utilise human-centred methods to ensure an equilibrate approach to accuracy of design and efficiency of data collection. The literature review highlighted a gap in knowledge to create, test and identify a cranial measurement protocol for others to undertake without supervision to enable optimal design of scalp cooling caps.

The team conducted a small UK pilot study to investigate how human head shapes could be systematically measured and categorised for complex Industry 4.0 manufacturing applications with the help of a mass customisation infrastructure that would optimise scalp cooling. In this pilot study 11 people participated, which used a selection of chosen parameters (Figure 1) for gathering accurate human head data for the medical design process outlined in an extensive literature review on cranial anthropology studies. The pilot study evidenced that historical studies and preconceptions of parameters based on previous claims alone were outdated and inaccurate. For example, according to studies on cephalic index for head shape proportions, previous studies may generalize a Caucasian users as Dolichocephalic or Asian users as Brachycephalic, which is not the case. Critical literature assessed in determining the parameters presented in Fig 1, include comparisons in global head shape a size variation, methods for data capture in heads, cephalic head data studies, comparative studies for scalp cooling and more [9,10,11,12,13,14,15].

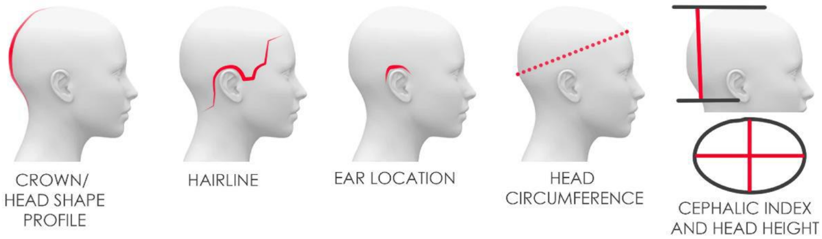


Figure 1: Initial proposed parameters for complex scalp geometry data collection.

2.1 Technical Considerations

There are two main considerations required for customised cooling caps. For regulatory purposes there will always be safety and efficacy, but with particular focus on the Generation of an approach to mass customization for scalp cooling, we must consider the usefulness of the data captured for Design (For generating a cap and making it fit well) and the usefulness of the approach for healthcare professionals (time, complexity, reporting, processing, cost).

The Paxman cooling cap shown in Figure 2 below, is a wearable heat exchanger. There are 6 cap shapes/ sizes available, used in over 60 countries worldwide, so it is essential that these caps utilize some level of flexibility to accommodate a plethora of global head variances including hair types and head shapes. Two of the most important technical considerations of this will be fit to the patients' head and heat extraction.

Figure 2: Current Paxman silicone cooling cap

Material selection was assessed on a selection of parameters. One of the more important factors for products interacting with users' skin for medical devices, is compliance with ISO 10993, Biocompatibility. Formlabs is a supplier of AM technology, prevalently used in healthcare, with both the machines and material (Some) being compliant with these standards. A plethora of material with specialist specifications required for this project is available. Some materials specifications required are flexibility (preferably 70A), ability to retain liquid at pressure, tear resistance, good chemical resistance, preferable clear/ transparent and the ability to operate at lower temperatures.

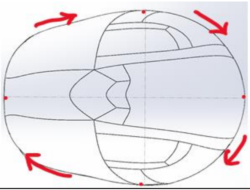
2.2 Anthropometric Data Collection

After the initial pilot study in the UK, the approaches were refined and extensively reviewed by ethics committees at the University of Huddersfield and the National University of Singapore. From the pilot studies, three approaches were proposed and conducted in the National University of Singapore's N.1 Institute of health [16]. 21 participants were evaluated of which 20 were Chinese, 1 Indian, 57% Female and 43% Male, ranging between 51 and 21 years old. Participants all came from a healthcare background, ranging from Clinicians, Healthcare Academics, Medical Students and Nurses.

Approach 1 is manual, the cheapest, quickest, most simple but potentially not accurate enough. Approach 2 is a hybrid method which is manual, affordable, time consuming, and more accurate. The last is time-consuming, the most accurate but the most expensive. The first approach utilized a contour ruler tool and a neoprene cap cover with markers on it (Figure 3a, b). This method required the use of the contour tool to take impressions of the head on seven points of the head. This would be used to generate a wireframe structure in CAD based on the shapes of the impressions from the location points of the cap cover. The second approach utilized a refined version of the pilot study, whereby practiced methods were improved and utilised more accurate methods of data capture (using digital calipers). Followed by a questionnaire assessing the participants' parameters such as hair type. The third approach utilised a 'low cost' handheld 3D scanner (Sense 2) to scan the users head with a neoprene cap cover tightly compressed to the users' head due to hair being hard to scan and simulating the correct size of the cap when the users' hair is compressed. The first two approaches were manual and instructed, as they would be in a healthcare setting; each participant's heads were measured for the collection of a database of cranial data. Each participant measured the same researcher's head to assess consistency and accuracy of the approach by keeping the measuring subject the same but changing the data collector. Both collection processes were timed; an assessment of accuracy, simplicity, speed, and usefulness of the instructions was established.

Figure 3: Cap Cover with Markers on it Side (a – Left), Top (b – Right).

The first method, utilizing a contour ruler, had many problems as a form of data capture. As this was a basic measuring tool, which could latch shut, it was possible to press the contour tool into the users' head in the areas highlighted in Figure 3 above. However, with this manual approach it was possible to drastically affect the result by rocking side to side when pressing the ruler down, measuring at an angle, not pressing the pins fully to lock the teeth, lifting before locking the tool and so on. It could be possible to develop a tool for this purpose that could mitigate many of the operators' errors, though this reduces the adoptability of the technology and possibly increasing the cost of the tools needed, causing further hurdles for technology adoption. For method 2, a plethora of parameters as reasoned by the teams' previous research [3, 4], Table 1 below outlines the approach deployed for this second method.

Visual	*Parameter*	*Description*
	Circumference	A tape measure is run around the circumference of the head between the outermost part of the forehead, the Squamous Suture on either side, outermost part of the occipital bone, the squamous suture and then back to the forehead.

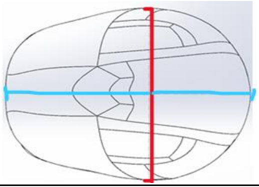
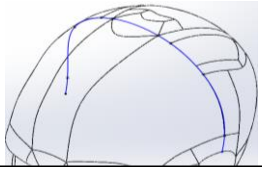
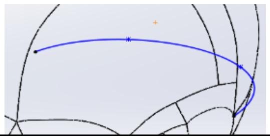
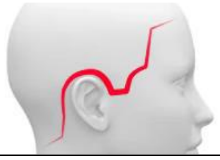
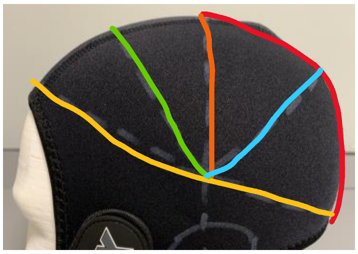
	Head width (Red) Head Depth (Blue)	Using digital head calipers measure between the outermost parts of the squamous suture on the left and right of the head. Repeat the above process, measuring between the outermost parts of the forehead and the occipital bone.
	Ear Height	Using a tape measure, measure above the top inside part of the ear across the head.
	Ear Depth	Using a tape measure, measure behind the inside of the ears across the back of the head.
	Hairline	Take a photo of the hairline (Front and side), peeling the hair back to expose the hairline if the hair is lone. These images will be imported into CAD.
	Hair Type	This is a visual assessment based on an existing chart.
	Crown shape (R1 – Red) Contour zone 1 (R2 - Orange) Contour zone 2 (R3 - Yellow) Contour zone 3 (R4 - Green) Contour zone 4 (R5 - Blue)	Use a contour measuring tool and imprint into the crown between the points located on the neoprene cap cover, using the markings for start and end points and relation of the measurements for R1, R2, R3, R4 and R5. Currently this is a manual method requiring recording of the shape onto paper to be scanned into CAD as an image for the various planes/ projections.

Table 1: Cranial anthropology parameters for mass customization and processes of data collection.

The second approach collected the parameters in Figure 1. The data from the study is seen below in Table 2. Size and shape classifications are provided based on the gathered literature. AS (Asian Small), AM (Asian Medium), AL (Asian Large), S (Small), M (Medium), L (Large), UB (Ultrabrachycephalic), HB (Hyperbrachycephalic), B (Brachycephalic), MS (Mesocephalic), D (Dolichocephalic), HD (Hyperdolichocephalic), UD (Ultradolichocephalic), CI (Cephalic Index), E (Ear). Dimension presented are all in mm’s, except the Cephalic Index, which is a measure in and of itself. The results show that 76% are between Brachycephalic and Ultrabrachycephalic which is true of Cephalic index norms for Asian demographics. However, 19% are mesocephalic and 5% are Dolichocephalic. Strengthening the pilot study findings [4]. Although 20 of the participants are Asian, only 57% are classified under the Asian cap type based on Paxman's sizing guide. This strengthens the hypotheses for the pairings of parameters chosen for this study arm.

	Circum	*Size*	*Width*	*Depth*	*E-Height*	*CI*	*Type*	*E-Depth*	*Time*
P1	595	L	163.6	193.7	345	84.4	B	230	02:08
P2	610	L	158.3	198.1	360	79.9	MS	225	02:14
P3	580	M	162.8	193.4	360	84.2	B	240	02:04
P4	590	L	165.5	177.8	350	93.1	UB	230	01:47
P5	590	L	160.5	187.7	360	85.8	HB	250	02:06
P6	640	L	156.8	194.2	340	80.7	B	230	-
P7	590	L	161.5	193.8	360	83.3	B	230	01:57
P8	600	L	158.5	186.1	345	85.2	HB	218	01:56
P9	600	L	160.9	196.4	340	81.9	B	325	01:37
P10	595	L	162.3	186.4	340	87.1	HB	225	01:41
P11	580	M	161.1	187.2	330	86.1	HB	240	02:43
P12	580	M	160.9	191.4	360	84.1	B	270	01:26
P13	610	L	162.7	181.6	350	89.6	HB	230	02:07
P14	596	L	158.9	198.1	350	80.2	B	240	01:28
P15	596	L	156	190	340	82.1	B	270	01:43
P16	590	L	160.4	193	340	83.1	B	235	01:39
P17	590	L	163	193.9	360	84.1	B	240	03:47
P18	590	L	161.3	196.5	340	82.1	B	225	02:05
P19	580	M	162.7	192	355	84.7	B	230	03:41
P20	590	L	160.2	188.6	-	84.9	B	-	04:30
P21	590	L	165.3	178.4	325	92.6	UB	255	-
	594.4	**L**	**161.1**	**190.4**	**347.5**	**84.7**	**B**	**241.9**	**02:14**

Table 2: Head measures based on participant collection.

Each participant was given a brief sheet explaining the process and a quick demonstration of the tools (1 minute approximately). Given the minimal training the average time was 2:14 to complete the data collection compared to the 1:42 speed of the fully trained individual of this approach. The average size classifications were Large (81%) and Medium (19%); Large is correct. All except 1 participant measured my head as Brachycephalic – Ultrabrachycephalic classification, with the one being 0.1 off Brachycephalic, which is correct. Given the time, cost, and accuracy of this process from the results, it is safe to validate this as a highly feasible approach to mass customization for human head data collection.

The average head circumference recorded from the 21 participants on the subject head was 594.4mm +-15 (Large being 600mm), this is the correct classification. The average head width was 161.1mm +-4.5, average head depth was 190.4mm +-10 and the average height was 347.5mm +-15 (Across the head, ear to ear). This provides a cephalic index of 84.7, Brachycephalic (Which is the correct classification).

2.3 3D Scanning and Concept Generation

Previous 3D scanning studies [16] evaluated how low-cost 3D scanning can be used for capturing human-head data when handheld 3D scanners were in early development. Initial studies with the handheld Structure SDK sensor for 3D scanning with low quality and a range of 0.4-3m was not adequate. High-resolution scanners were investigated including the Eva Artec, Creaform 300 and FARO Freestyle, demonstrating the need for denser point cloud data for the accurate designing of the head models and related products.

There is a plethora of accurate and suitable handheld 3D scanners available to designers now. But for viability of applications, the team excluded professional scanners due to the costs and complexity associated. This project utilises a human-centered Design approach methodology including desirability, feasibility, and viability matrix. Therefore, to ensure that the application developed meets these needs, it must be affordable to be used in many hospitals around the world. The project utilised a Sense 2 handheld 3D scanner by 3D Systems with an operating range of 0.35m to 3m, perfect for localizing around the head. The resolution is between 0.9 and 1mm and cost approximately £400, which isn't accurate when compared to expensive scanners, but could be accurate enough when considering other parameters such as cap material flexibility. A structure light sensor handheld scanner was used with detail resolution of 1mm and spatial x/y resolution of 0.5-0.9mm. The 3D scanning approach utilised the above handheld scanner and a trained operator from Paxman scanned each person's head with a neoprene cap cover on. The cap cover ensures a successful 3D scan is captured, due to difficulties scanning hair; ensure the outer shape captured represents the size of the head when the hair is compressed. Each scan was timed to assess the viability of the process for time efficiency. This enabled the collection of 21 individual Chinese heads (Figure 4).

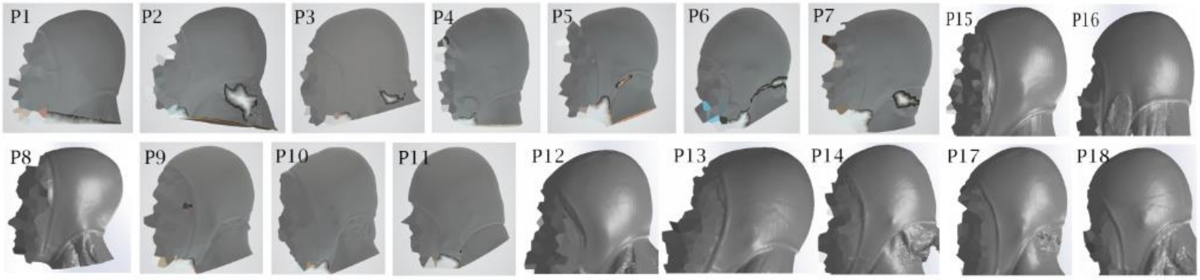


Figure 4: Side profiles of collected head 3D Scans, processed using 3D Systems Sense software.

After human head data is collected using the handheld 3D Scanner, the scanned head is then generated in the 3D Systems Sense, real sense software. This software will generate usable MTL and OBJ files. To clean these models up prior to use for Design, Autodesk Meshmixer was used to trim any additional or unnecessary parts and fill gaps in the CAD data. Once this is complete, OBJ files were imported into SolidWorks using the ScanTo3D add-in. This will import it as a Mesh, and this add-in can be used to correctly process the data as shown in Figure 5 Below. This add-in generates organic shapes, that could be used to produce NURBs surfaces allowing freedom to modify the 3D scan as a surface body. In Fig 5 below, the process shows as: raw scanned data, cropped and processed, imported Mesh in SolidWorks, processed ScanTo3D usable surface data.

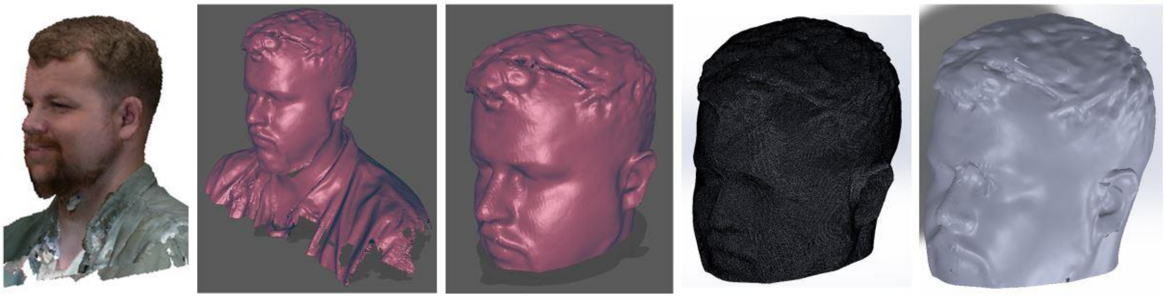


Figure 5: 3D scans processed from 3D Systems sense software to ScanTo3D in SolidWorks.

Once the data has been processed in SolidWorks, some CAD work will assist in transforming this into a cooling cap. Ideally the use of an algorithm that could tether a generic design with a pre-determined channel arrangement onto the individuals head geometry could be generated in Rhino Grasshopper. Without the use of an algorithmic approach to customization, a substantial amount of individual CAD/ Designer input is required to turn the process scan data into a usable cooling cap. Figure 6 below indicates a generic approach to transforming the processed data into a cap outer shell (Similar to a swimming cap), but this lacks detail of channel arrangements and design to transform it into a heat exchanger with channel patterns like the Patented cap design that is required [17,18,19].

The current methods available for converting CAD are not 100% accurate. There are varying levels of quality that can be achieved when converting the scans with these software's. In this approach a medium-low quality is presented to minimize the processing time and complexity, including potential face failures in the CAD models. Figure 6 below shows red face failures, where only a medium-low quality is used. Though the team proposes a new bespoke algorithm is required for this application where head geometry requires a complex network of fluid channels tethering to it, whilst maintaining a level of quality and consistency of cross-sectional volume for fluid dynamics and wall thickness for structural integrity. It is possible to work with a tolerance of +-0.5mm in some areas, whereby the flexible nature of the material used to produce a cap i.e., a lower shore hardness Silicone or TPU can accommodate for a broad range of idiosyncrasies in patient variances regarding nuance of shape.

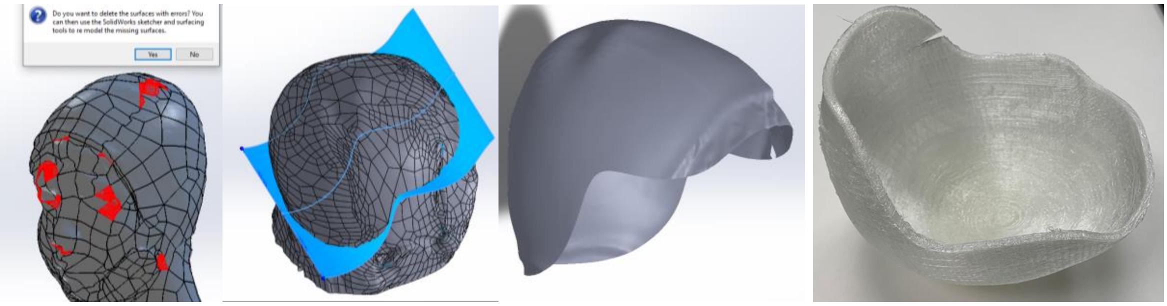


Figure 6: ScanTo3D processing (a), processed data (b), SolidWorks cap (c), FDM TPU Cap (d).

2.4 Additive Manufacturing Process

The team has investigated several approaches to additive manufacturing for this project [20] from SLS powder-based rubbers, FDM TPUs and Photopolymer flexible resins with SLA and DLP. The cap needs to be manufactured from a flexible material; as AM has become exponentially more sophisticated in its applications and materials available over the past decade, the project teams have identified that the technology now exists to enable the 3D printing of efficacious cooling caps. The team evaluated a range of technologies and materials and identified the biocompatible medical grade resins and machines manufactured by Formlabs were appropriate.

3 DISCUSSION AND COMPARATIVE RESULTS

This research is a follow-up study based on pilot studies conducted with UK participants [3,4], in those papers, a thorough literature review assessed available data for human head data capture, including mass customisation methods, apparatus used and protocols for various applications. The literature review concluded that there was a gap in the knowledge for cranial anthropology that hinders the optimal design of scalp cooling caps. Current methods for anthropometric data collection are time-consuming and complex to conduct, requiring teams of individuals and many participants to be accurate [3]. From that a follow up pilot study investigated a selection of parameters that would enable the optimal design of scalp cooling caps. These parameters provided a foundation for data capture in the pilot study and after this, the approach was refined and tested with healthcare professionals in Singapore's N.1 Institute of Health.

Though an algorithm is not yet developed, the team is investigating one for future work, where the parameters of this research will act as a precursor to determining parameters required as inputs for the algorithm. This includes tolerances, ear location, exact parameter start and end points, restrictions and other rules for a rule based data input approach towards mass customisation. Though some existing approaches may be suitable for wearable design that have been explored [21], wearable medical design and development is not as flexible and will require a stricter approach (i.e., scalp cooling requires a much closer fit); therefore, a rule-based approach will be necessary.

This approach presents a new opportunity where third-party healthcare professionals can collect the data required for designers to enable a customisable wearable medical device. Previously other approaches would require large amounts of designer input or teams of individuals to collect, monitor and process the data. These previous approaches wouldn't be a suitable model to use. This new approach will present a framework with the ability to integrated 3D scanning and or manual data capture alongside 3D printing into a healthcare setting for generating customised cooling caps.

We are in the initial phases of developing a programmable mass customisation framework to turn the processed scan data into a tailored cooling cap that could be 3D printed straight from data collected by healthcare professionals in hospitals. The team has explored other papers that investigate mass customisation [21], though as mentioned these are not suitable for more stringent medical applications. In these papers, several approaches are explored such as photogrammetry, which the team investigated, but due to the tight tolerances required, these were unsuccessful. Rough data is not suitable for medical design, accuracy is more important for improved efficacy.

4 CONCLUSION

Of the approaches trialed in this study, approaches 2 and 3 could be suitable for the application of mass customization with healthcare professionals for applications of 3D data collection methods to generate 3D shapes/heads. The data collection of the second process is simple, and time/ cost effective for gathering necessary data. To be useable for generating a cooling cap, this would still need a large input from a designer to convert into CAD data or of an admin team to input the collected parameters into an algorithmic software e.g., Grasshopper would benefit the mass customisation processes. However, the approach of data collection for healthcare professionals for gathering data to generate mass customised wearables has proven to have high accuracy, low cost, and simplicity. The processing of the 3D scan data with software and developed technologies currently is relatively simple and cost effective. However, to convert this to a usable design would require an algorithm to tether an existing cap design to the surface of the scanned users head (as shown in figure 3 Above) to be useable. As an approach to collecting human head data however, both manual and 3D scanning are suitable and accurate enough to collect necessary data to generate a cooling cap from. Further work would be needed to prove its viability for commercial applications, finalising the development of configurable 3D cap generation software semi automatically.

5 ACKNOWLEDGEMENTS

The authors would like to thank Paxman Coolers Ltd for their continued support; Paxman Scalp Cooling Research and Innovation Center at the University of Huddersfield Co-funded by the University of Huddersfield; and Paxman Coolers Ltd. Special thanks also to the Ethics team and the project team at the National University of Singapore including The N.1 Institute of Health.

Jonathan R. Binder, https://orcid.org/0000-0001-9413-2466
Ertu Unver, https://orcid.org/0000-0002-9031-6353
Caterina Benincasa-Sharman, https://orcid.org/0000-0001-5854-7170
Yang E. Yee, https://orcid.org/0009-0005-1277-8279
Aishwarya Bandla, https://orcid.org/0000-0002-6705-1318

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