Title:

Investigation of Mass Customization within Healthcare Orientated Human Head Data Collection for Chemotherapy-Induced Alopecia Prevention

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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.

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, 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-centered 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 healthcare professionals to undertake without supervision to enable optimal design of scalp cooling caps.

Utilising this information, 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. The experimental study included 11 people participants, which used a selection of 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 literature showed 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 determine a Caucasian users as Dolichocephalic or Asian users as Brachycephalic, which is not the case.

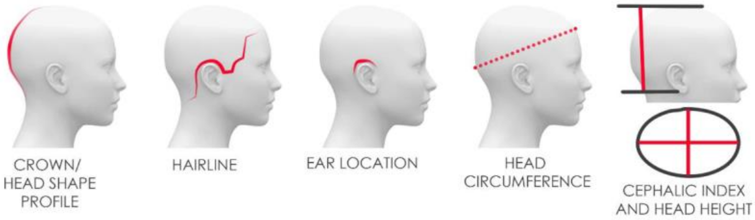


Fig. 1: Initial proposed parameters for complex scalp geometry data collection.

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).

Anthropometric Data Collection:

After the initial pilot study in the UK, the approaches were refined and extensively reviewed by ethics committees the UK and Singapore. From the pilot studies, three approaches were proposed and conducted in the National University of Singapore's N.1 Institute of health. 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, low-cost, time efficient, and simple. 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. 2a, 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 (i.e., using digital calipers). Followed by a questionnaire assessing the participants' measurements such as hair type. The third approach utilised a 'low cost' handheld 3D scanner (Sense 2 by 3D systems) 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.

The second approach collected the parameters in Figure 1. The data from the study is seen below in Table 1. 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). 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**

Tab. 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 L (81%) and M (19%); Large is correct. All bar 1 participants measured my head as B-UB Cephalic classification, with the one being 0.1 off B, 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.

3D Scanning and Concept Generation:

Previous 3D scanning studies [5] 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 04-3m 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. To ensure this 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 with an operating range of 0.35m-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. The 3D scanning approach utilised the above handheld scanner and a trained operator 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 2).

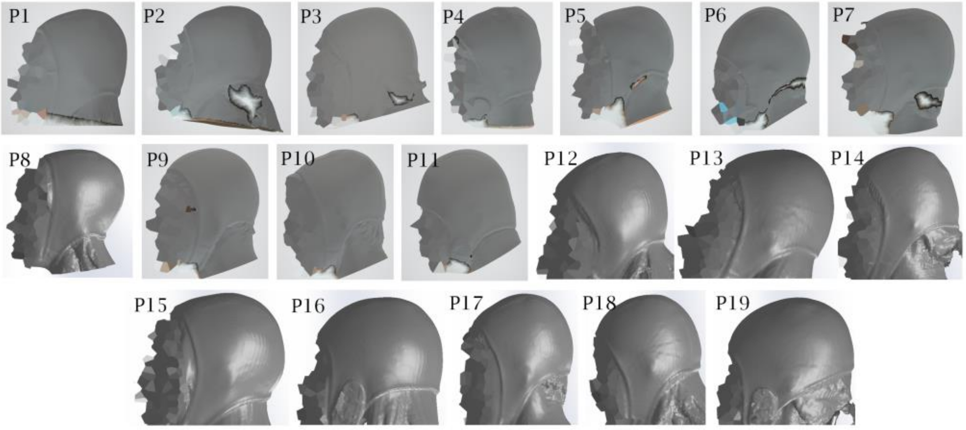
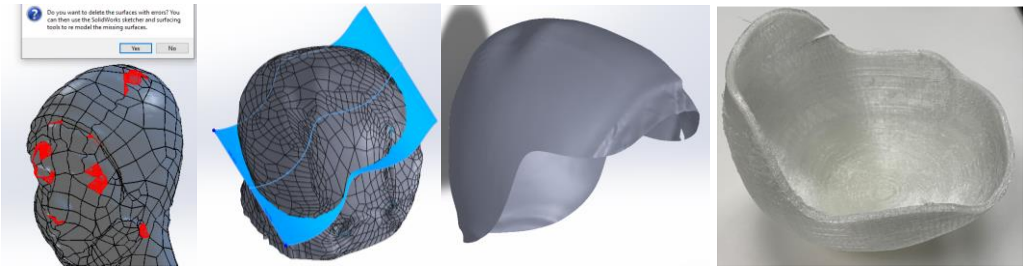


Fig. 2: Side profiles of collected human head 3D Scans.

After human head data is collected using the handheld 3D Scanner, the scanned head is then generated in the 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 unnecessary parts and fill gaps in the CAD data. OBJ files were then 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 3 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.



Do you want to delete the surfaces with errors? You can then use the SolidWorks sketcher and surfacing tools to re model the missing surfaces.

Fig. 3: ScanTo3D processing (a), processed data (b), SolidWorks cap (c), FDM TPU Cap (d).

Manufacturing Process, Additive:

The team has investigated several approaches to additive manufacturing for this project [6] 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.

Conclusions.

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.

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