

Mass customisation for wearable design: A pilot study on Type 3–4 hair and female cranial data

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SUMMARY

Scalp cooling (SC) is a clinically proven treatment for addressing chemotherapy-induced alopecia (CIA). Previous studies highlighted parameters required for designers to develop products worn on the head for optimal SC. Among these, a lesser explored input was hair types and hairlines, particularly in usability (design thinking). Further exploration of hair type classifications could inform the design process to increase accessibility through the development of new SC caps using mass customisation. This research proposes customisation of wearable cooling products based on gender and hair type to improve efficacy for underrepresented users.

Key Words: Cranial anthropology; trichology; scalp cooling; medical design; mass customisation

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ABSTRACT

The close fit of the cap to the patient's scalp is a crucial factor affecting the efficacy of scalp cooling. Maximising the efficacy requires access to accurate cranial data necessary to design close-fitting caps. The research teams' previous studies^{1–3} hypothesised a set of crucial parameters to design optimal fitting head wearables, including hair type and hairlines. This study collected hairline and hair type data from 58 participants to inform the design process for improved usability. Scalp cooling (SC) is predominately female, and historically users with Type 3–4 hair have experienced lower efficacy with SC.⁴ The study uses the Paxman cap.

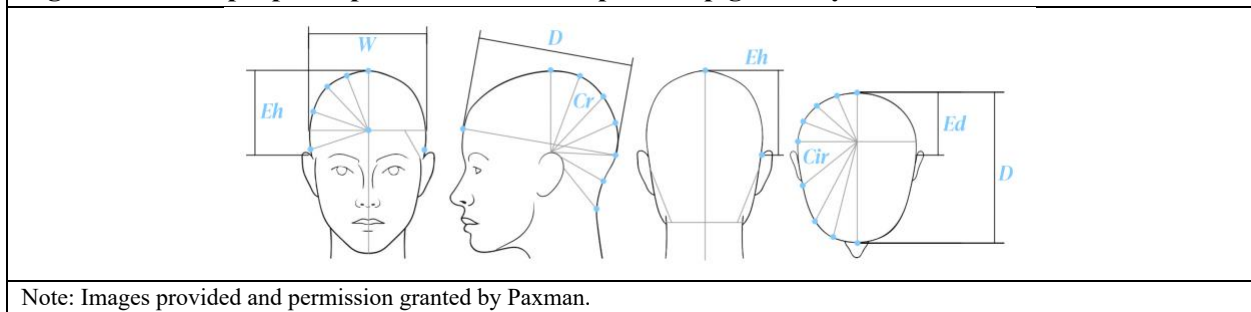
BACKGROUND

When designing products worn on the head, cranial anthropometrics is a crucial design input. Research has demonstrated that personalised cooling caps are essential to improve scalp cooling efficacy past 80 per cent through perfect fit.⁵ SC uses a wearable heat exchanger worn on a patient's head that allows coolant to be pumped around the surface of the head to extract heat energy, inducing vasoconstriction. Chemotherapy drugs typically work by attacking rapidly dividing cells in the body (like cancer cells); hair follicles are also considered rapidly dividing cells. The core function of SC caps is to slow down the metabolism of a person's hair follicles and prevent the chemotherapy drugs from attacking them.

Following the principles of Fourier's law, increased surface area, through means of closer fit, is crucial to this heat extraction. Hair types have varying levels of thickness and insulative properties, which can further reduce or increase heat extraction. A previous study² evaluated more than 175 published academic articles about cranial anthropology, and a case study¹ piloted a selection of parameters researchers concluded were

necessary or crucial parameters for generating optimally fitting caps for SC to prevent chemotherapy-induced alopecia (CIA) (Figure 1). This study explores usability within these scalp wearable products, specifically investigating the aspects of trichology (hairlines and hair types). Additional literature indicated that hair types have different characteristics, such as volume, individual hair thickness, resilience to hair damage in varying hair types, UV protection vs colours, and more.

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













This study uses Paxman, the leading global experts in SC as the subject, with a comparative assessment using the following: 1) Orbis (older version); 2) PSCS (current silicone cap); 3) current outer neoprene cap cover; and 4) new proposed outer cap cover (Figure 2).

Figure 2: Caps and covers used in the study, Paxman wearable heat exchanger products and covers



Hair types are one of the more prevalent parameters in studies that have investigated the characteristics that influence or affect SC. In a large multi-centre observational study in the Netherlands, Van den Hurk et al.⁶ concluded that SC was more effective in patients with Caucasian types of hair. Janssen et al.⁷ found that the thickness of the hair layer correlated with the scalp skin temperature during SC. This finding strengthens the hypothesis of lower SC efficacy in patients with thicker hair such as Black patients, who have thick layers of hair that acts as an insulating layer between the cooling cap and the scalp. Andre Walker⁸ created the universally used hair-type categorisation system, which includes four main hair types, each with sub-types as illustrated (Figure 3).

Figure 3: Andre Walker’s hair types classifications⁸

1		3b	
2a		3c	
2b		4a	
2c		4b	
3a		4c	

Note: Images provided and permission granted by Paxman.

In a recent study⁹, the authors investigated the development of a new framework using these parameters with healthcare professionals (the main audience for this approach) for collecting human head data for designers. As a case study the research team assessed how many instances of each hairline type and hair type would be observed in a random study of the public. The study, which comprised 58 participants, revealed that a mass customisation approach is necessary due to such broad variations found in the random study.⁹ The researchers also collected cranial data parameters for circumference and cephalic index; these were categorised based on existing size classifications of the Paxman cooling caps.⁹

Many SC studies find high efficacy for users with Types 1–2 hair^{10,11}, due in part to the lower insulative properties compared to Types 3–4 hair. Paxman outlines different hair preparation guidelines for Type 1–2 hair and Type 3–4 hair, supported by the widely explored varying haircare and preparation needs.¹² For Type 3–4 hair, users require longer cooling periods prior to infusion typically observed in Black ethnic groups due to hair thickness⁹ and formation.¹⁴ A study of Black patients concluded that SC may not be efficacious in preventing alopecia.⁴ Differences in hair thickness, hair volume, and limitations of cooling cap design are possible contributing factors. Araoye et al.¹³ explained that the effectiveness of SC may be affected by factors determined by hair type. Janssen et al.⁷ demonstrated that wetting the hair increased the conductivity of the hair layer, resulting in a further decrease in scalp skin temperature. Unlike the straight hair of Caucasian or Asian ethnicities that lays flat when it is wet, curly hair tends to become bulkier when it gets wet.¹³ Previously, hair preparation for Black patients was to wet their hair in preparation for cooling, which resulted in reduced efficacy.

METHOD

Supported by an extensive literature review comprising more than 175 articles between 2020 and 2021 in our previous publications^{1,2}, we conducted an in-person usability study was conducted on 58 volunteers in conjunction with an online survey with 52 participants. We collected data manually of head circumference, width, and depth, for cranial classification of participants. We conducted a survey in which participants tried on Paxman scalp cooling products to gather additional data on sex, ethnic background, hair type, and hairline. This data was collected at an exhibition at the University of Huddersfield, where volunteers participated in the study. Hence, we extended the study to a random audience of the public. The study used

a design thinking approach, whereby we evaluated human-centred design aspects to refine outgoing cap and cover designs within a live project with Paxman. The design thinking approach was closely centred around international standards (in particular, IEC 62366-1:2015) pertaining to the usability of medical devices.

RESULTS

In total, we recorded 58 online participants and measured 52 people in person. Of the 58 participants, 33 were male (56.9 per cent), and 24 were female (41.4 per cent). The study cohort comprised 15 Asian (25.9 per cent), 8 Black (13.8 per cent), 29 Caucasian (50 per cent), 5 other (5.8 per cent), and 1 Arab (1.7 per cent). Participants were aged 18–58.

In the random study, we observed a broad range of results (Table 1). Popular size classification was evenly spread, with Caucasian large being the most observed size. We know from previous research that the anatomy of males is larger than females, on average.² As females are the main market for SC, excluding male results, the most common size observed is Cap 2 Small and Medium, which is 53–55.5 cms, vs the Cap 1 Large, which is 59–62 cms. These are Paxman’s smallest and largest cap sizes. If only female results are observed, for head shape proportions, according to results gathered on the cephalic index, the most common shape type was mesocephalic (round head), or predominantly brachycephalic (broad headed) (Table 2).

Table 1: Results of cap size according to circumference, Paxman sizing guidelines, and cephalic index

Size	No.	%	Cephalic classification	No.	%
Cap 1 Small	6	11.5	Dolichocephalic	3	5.8
Cap 1 Medium	11	21.2	Mesocephalic	18	34.6
Cap 1 Large	12	23.1	Brachycephalic	15	28.8
Cap 2 Small	8	15.4	Hyperbrachycephalic	12	23.1
Cap 2 Medium	11	21.2	Ultrabrachycephalic	4	7.7
Cap 2 Large	4	7.7			

Table 2: Female participant specific results of cap size according to circumference, Paxman sizing guidelines, and cephalic index

Size	No.	%		No.	%
Cap 1 Small	2	10.0	Dolichocephalic	0	0.0
Cap 1 Medium	4	20.0	Mesocephalic	7	13.5
Cap 1 Large	2	10.0	Brachycephalic	10	19.2
Cap 2 Small	6	30.0	Hyperbrachycephalic	2	3.8
Cap 2 Medium	6	30.0	Ultrabrachycephalic	1	1.9
Cap 2 Large	0	0.0		20	

Regarding cranial proportions, females largely fit either mesocephalic or brachycephalic and are typically more uniform in proportions in general with smaller heads. Comparatively, males are much more varied

with dolichocephalic (long skulled) only observed in males and the extremes of ultra and hyper brachycephalic predominantly occurring in males (Table 3).

Table 3: Cranial proportion extremes vs gender

	Male	%	Female	%
Dolichocephalic	3	100	0	0
Hyperbrachycephalic	10	83.3	2	16.7
Ultrabrachycephalic	3	75	1	25

We show the results observed from all 58 participants, male and female, for hair types and hairlines (Table 4). The most common hair type observed was Type 2, and the most common hairline was rectangular, closely followed by the “M” shape profile. We separate our results to show female only, followed by further investigation of ethnicity to establish a greater understanding of trichology stereotypes, with the intention of enhancing overall awareness of problems for accurate design solutions.

Table 4: Hair types and hairline types observed

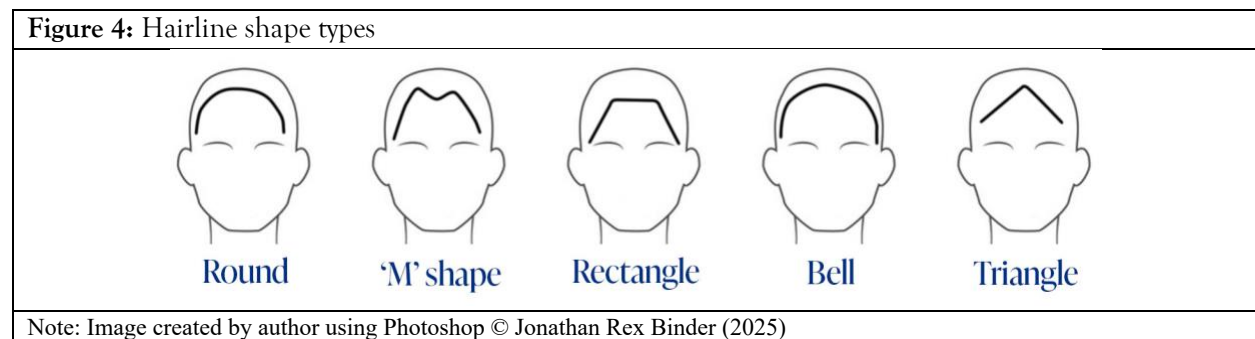
Hair Type	No.	%	Hairline Type	No	%
Type 1	16	27.6	Round	11	19
Type 2	28	48.3	M shaped	16	27.6
Type 3	8	13.8	Rectangular	21	36.2
Type 4	6	10.3	Bell shaped	6	10.3
			Triangular	4	6.9

Of the 58 participants, 14 were Type 3–4 hair (24 per cent), and the remainder (44: 76 per cent) were Type 1–2. The most common hairline type was rectangular, though the results show a broad range of hair types and hairlines. There are increased challenges associated with scalp cooling for Type 3–4 hair types. Results are split to show the variations within the participants with Type 3 and Type 4 hair. In this study, just over half were Black and the remaining participants were, in order, Caucasian, Asian, and other.

Table 5: Female hair types and hairline results observed (left); Type 3 and Type 4 hair split for ethnicity and hairline types (middle and right)

Hairline Type	No.	%	Ethnicity	No.	%	Hairline Type	No.	%
Round	4	7.8	Black	8	57.1	Round	3	21.4
M-shaped	6	11.8	White	3	21.4	M-shaped	3	21.4
Rectangular	4	7.8	Asian	2	14.3	Rectangular	4	28.4
Bell-shaped	4	7.8	Other	1	7.1	Bell-shaped	3	21.4
Triangular	3	5.9						

Hair lines can be split commonly into five categories (Figure 4), which provides additional levels of tailoring for mass customisation. The hairline is an important metric, representing the boundary of a cooling cap, to ensure targeted cooling addresses all the hair, unless it falls out in areas not covered. The hairline must be covered to prevent direct skin contact with the cooling cap. Although round or bell-shaped hairlines are commonly observed in the Black ethnic group, due to the broad range of ethnicities in this study, we observed an almost even split in hairlines between these groups (Table 5).



DISCUSSION

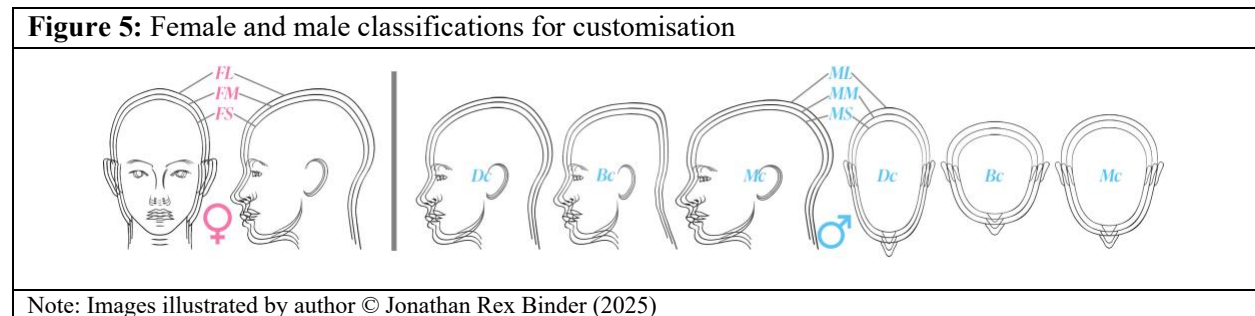
As hairline is such an important metric for SC, almost all participants had reported that they have never considered what their hairline type was before. Only those participants who had noticed receding hairlines—particularly in men with M-shaped hairlines—had actively observed their hairlines before. This finding highlights a tendency in men to be more self-conscious of their hairlines or anxiety about natural hair loss.

Historically, studies have evidenced the design of wearable head products being biased towards Western, Caucasian head types. Such study data often generalises both male and female results, however, our research indicates a predominantly female demographic for SC. Lower SC efficacy in the crown areas could be associated with the uniform broad skulls observed in females, where designs cater to male and female, posing a longer cap design that could leave gaps. In these instances, female users may experience tighter fit on the sides than in the crown area. It is also possible to assume in these cases that if the wrong type of cap is chosen, then the caps designed for longer heads may compress the sides of females' heads more, leading them to choose a larger cap, ultimately leading to a larger gap at the back of the head, resulting in more hair loss at the crown.

For females, hairline should be a considered parameter for mass customisation as designers cannot address all demographics with a limited selection of caps. In addition, almost all parameters observed were varied and broad, further supporting a potential to increase overall efficacy through a mass customised approach.

Evidence in these studies points to female heads being more uniform, which means it could be possible to integrate male- and female-specific customisation options. Based on these results, we suggest a uniform shape (mesocephalic, round skulled), with small, medium, and large sizes for females. For males, a more varied range with brachycephalic, dolichocephalic, and mesocephalic, all with small, medium, and large types. For women we present these options: female small (FS), female medium FM, female large (FL)

(Figure 5). For men we present these options: dolichocephalic (DC), mesocephalic (MC), brachycephalic (BC), male small (MS), male medium (MM), and male large (ML).



This study presents findings on 58 randomised participants, evaluating cranial data to improve existing products commercially sold at Paxman. We collected the data in the early phases of the design process with further data collected on fit and function for feasibility prototypes produced by an R&D team in a separate live project. Our intention was to assess feasibility and usability of the new devices and quantify these against historic studies conducted by the research team to measure design improvement. Unforeseen findings emerged from the study that could be input back into the design process to improve wearable scalp cooling products for females and users who previously experienced lower efficacy due to their hair types.

The findings presented sufficient evidence for regulatory procedures to inform further design iteration in the early feasibility stages, where further design iterations can be informed by design thinking. We determined that a mass customisation approach might be useful for future design iterations. To customise caps, the following modifications should be explored:

- Address different hairlines (where cap versions only cover the hair, not cooling the skin, currently covered by a head band).
- Investigate approaches for cooling and designing of caps for various hair types. This could be designed mechanisms that penetrate through varying volumes or thicknesses of hair.
- Consider hair thickness vs ethnicity.
- If a predominately female market is pursued, a more uniform shape profile could be suggested, where additional customisation can come from hair-related aspects.

LIMITATIONS AND FUTURE RESEARCH

The study results led to observations that require individual study and experimentation before drawing firm conclusions to be validated in larger studies. After inputting the data into the design process, researchers can evaluate future iterations of the proposed designs initially in pilot studies; they can reframe the scope of the data collection. Suggested areas of study include, but are not limited to, how to address the different hairlines and hair types using a mass customised approach, and how to accommodate SC for different hair types, thicknesses, and volumes.

CONCLUSION

Previous studies have explored cranial anthropology and hair types, though these topics application to the design of products worn on the scalp is less explored. Individuals with Type 3–4 hair experience less success with SC, however, the teams at Paxman are working to improve this through hair-related research for inclusive design development for SC. Research such as this study can enable design teams to approach the design of SC caps from ergonomics and usability perspectives as design inputs for improving wearable products. It is crucial to consider these design thinking approaches for usability because conventional engineering approaches focus mainly on the performance of devices.

Our research underscores the importance of defining a patient's distinct ergonomic and anthropometric criteria for a mass personalised wearable design. The research team's prior studies indicated that SC caps require the following parameters: circumference, width, depth, height, hairline, hair type, and crown shape. This study shows that female heads vary much less than male heads in nuance of shape and size; therefore, a female-only market could be easier to design for with fewer products, though other parameters still necessitate a customised approach. Although the market for SC is smaller for males comparatively, there are still male users, whose needs must be considered.

We proposed additional parameters for a mass-customised approach for designing wearable head products. For gender-based parameters, we recommend a gender-based customisation approach where female customisation is more uniform and for males is broader. We suggest three types for females and at least nine types for males. A layer of customisation can be added with these size classifications to allow for features that treat hair types, where either Types 1–4 are the levels of adjustment, or clustering of Types 1–2 and Types 3–4 together, respectively. This research has contributed to the understanding of how to develop more inclusive designs that have increased efficacy in wearable SC products used for chemotherapy-induced alopecia prevention.

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PEER REVIEW

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CONFLICTS OF INTEREST

The authors declare that they have no competing interests.

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ETHICS COMMITTEE APPROVAL

We conducted this study under the Limited Risk, Form B procedure from The University of Huddersfield approved by the School of Arts and Humanities Ethics committee.