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CASE STUDY

Human head analysis for mass customisation in medical design: A pilot study

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SUMMARY
Scalp cooling is a clinically proven treatment for addressing chemotherapy-induced alopecia (CIA). Previous studies show that the efficacy of this treatment relies on accurate cranial data so that designers can produce close-fitting scalp cooling caps. The cephalic index is often used, but are that data still accurate? We conducted a pilot study to explore mass customisation of scalp cooling caps.

Key Words
Cephalic Index; chemotherapy-induced alopecia; scalp cooling; mass customization; cranial anthropology

ABSTRACT

We conducted a pilot study to investigate how human head shapes could potentially 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 to prevent chemotherapy-induced alopecia (CIA). The efficacy of the scalp cooling treatment depends on the close fit of the cap to the patient's scalp. The ability to access accurate cranial data is necessary to design and produce close-fitting caps. The cephalic index is often used for head size analysis in many medical conditions, but it is insufficient for applications of design. Eleven people participated in this pilot study, which used a selection of chosen parameters for gathering accurate human head data for the medical design process outlined in an extensive literature review on cranial anthropology studies.[1]

BACKGROUND

Without treatment, CIA affects 3,500,000 patients worldwide (67,000+ in the United Kingdom) annually. CIA negatively influences a patient's psychosocial wellbeing, self-esteem, body image, and quality of life.[2] Scalp cooling is recognised as the only effective treatment to prevent CIA; machine-based devices enhance patient comfort and treatment efficacy compared to traditional frozen-cap/packs. Forty-seven per cent of female patients consider CIA the most traumatic aspect of chemotherapy, and 8 per cent have indicated they would decline chemotherapy due to fears of hair loss.[3] Recent research demonstrated personalised cooling caps are essential to improve scalp cooling success rates/efficacy to over 80 per cent through perfect fit.[4]

Researchers study head sizes and shapes for various purposes, including developing face masks, assessing childbirth defects, for biological analysis, and race identification. There are a dearth of data about product development applications for designers and researchers focused on creating products worn on the head and which require a close fit to the scalp. In this pilot study, we evidence the relevance and need for accurate cranial data, with chemotherapy-induced alopecia (CIA) as the focus, with the Paxman scalp cooling cap. A literature review we conducted identified some groupings, but we found existing studies to be insufficient. Most studies focus on basic factors like head circumference. To achieve high levels of efficacy, our application requires a fit that closely mimicks the patient's scalp. Achieving a close fit requires a rich data set that incorporates many parameters, including head shape profiles.

Scalp cooling relies heavily on close fit to the patient's scalp for optimal efficacy.[5] In addition to safety and efficacy, other crucial parameters for the design process are properties attributed to the cap materials—namely, flexibility, tear resistance, ability to hold liquids at pressure, comfort, heat exchange capabilities, and regulatory requirements such as biocompatibility.

The cephalic index is commonly used to measure head size and shape. It comprises an equation of the maximum width of a head, divided by the maximum length x 100. This equation is one key parameter that helps to differentiate between different human races. However, because the cephalic index does not provide sufficient data to enable Industry 4.0 to adapt and introduce new methods for a head shape data collection infrastructure in medical design, a new data collection method is required. The design of products worn on the head relies on access to accurate anthropometric data, describing human head shapes and sizes.

Traditionally, the information available to designers has been based on mainly Western Caucasian data such as the research by Godil and Ressler.[6] Quantitative 3-D human head shape data analysis from CAESAR[7] and SizeChina[8,9] discuss anthropometric clustering, whereas Azouz's studies[10] explored automatic locating of anthropometric landmarks on 3-D human models. Comparatively, one is grouping data and the other attempts to automate data collection. Asian users have often experienced poor fit with products worn or used on the head. Human head geometry is complex, making traditional univariate data unsatisfactory to describe the form. It typically includes only numerical values for head length, width, and circumference. The inelastic nature of the head causes head-related products especially demanding in relation to nuances of shape.

The published literature is inadequate in terms of categorising head shapes for optimal fit on different head shapes worldwide. Previous research often generalises nuances of head shape profiles. Designers face challenges because they can neither easily nor seamlessly integrate numerical dimensions, spreadsheets, and unprocessed 3-D scans into sketching, model-making, rapid prototyping, animation, digitising, computer-aided design (CAD), tooling, and manufacturing.[11]

The reseach team is currently conducting a 5-year project as part of the Paxman Research and Innovation Centre, a £1 million interdisciplinary research centre created by Paxman and Huddersfield University. The Centre is exploring the new Industry 4.0 technologies and mass

customisation infrastructures. Additive manufacturing, which first emerged in 1987, along with newer, more sophisticated advances in technologies, such as projected light liquid printing, have enabled the investigation of new possibilities for scap cooling. These sophisticated advances in technologies require more data. The development of new products requires new methods to collect core data points, possibly even automated methods to streamline data collection as manual data collection may be too time-consuming in healthcare settings.

Within the 5-year project, researchers and designers have worked to achieve a closer-fitting scalp cooling cap. In Phase 1, the first Paxman cooling cap was hand-made; tubes were manually glued on a head-shaped jig. In Phase 2, Paxman and Huddersfield University collaborated to investigate scalp fit parameters that enabled the development of a mass production method using rapid tooling in sheet silicone thermoforming manufacture. This mass production method achieved much higher efficacy rates.[10] Phase 3 aims to achieve close to zero hair loss with near-perfect fit to the individual patient's head by using mass customisation infrastructures to develop an Industry 4.0 process for 3D-printed cooling caps. Tailoring using mass customisation requires much more data.

METHOD

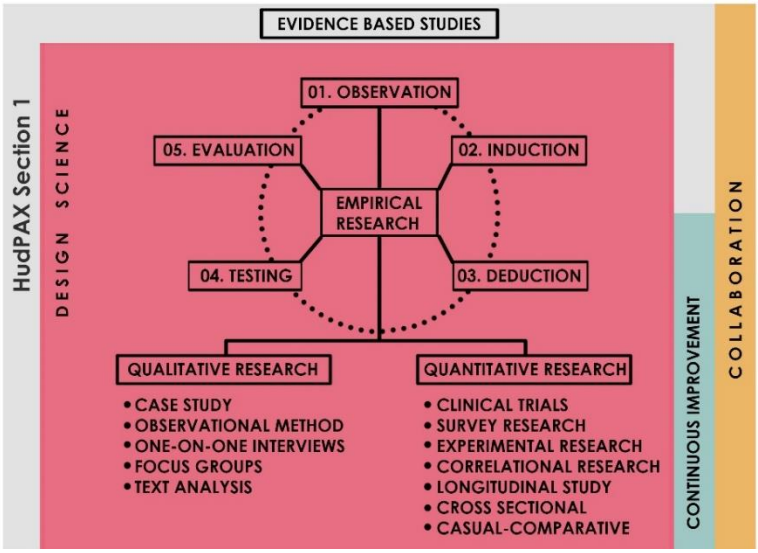
This pilot study used the HudPAX approach[11], a hybrid method that supports the delicate balance between the needs of medical device design, commercial feasibility, and stringent regulatory control. The HudPAX approach integrates the following established design research methods:

- The Double Diamond model by the Design Council, which is a strategic and incremental process encompassing four stages: Discovery, Define, Develop, and Deliver.
- Reflective Practice by Donald Schon, which promotes the reflection on our actions in design to engage in a process of continuous learning.
- Design Science, a evidence/outcome-based methodology to bridge the practice–academia divide by developing actionable knowledge that is grounded in evidence.
- Design Thinking, a user-based approach to investigate potential user wants and needs.
- Agile Waterfall method, a hybrid approach combining the Agile continuous iterative development and Waterfall methodologies for project management, promoting sequential development through distinct stages.

Developed in line with medical standards and design process, HudPAX ensures resulting medical devices are fully compliant with international regulations. ISO13485:2016, the quality management system for medical devices, provides a core element within the HudPAX process to which all other methods tether.

The HudPAX method could be applied to obtain 3D head shape data collection: it supports the delicate balance within the project between the distinct needs of medical device design, commercial feasibility, and stringent regulatory control. In addition, the HudPAX method ensures a comprehensive range of design inputs (user requirements) are successfully gathered and addressed through design outputs. Specifically, an evidence-based approach is applied using clinical evidence as the foundation for optimal efficacy (Figure 1).

Figure 1: Evidence-based studies using the HudPAX research methodology



We conducted a pilot study on 11 Paxman employees: participation was 45 per cent male and 55 per cent female, and included a selection of racial backgrounds to evidence variations in a global market. We explored the application of a hybrid method for data collection around crucial parameters highlighted in our extensive literature review.[1]

RESULTS

Our aim was to gather data of fit accuracy from different variations of users using a medium Caucasian cap. We collected anthropometric data from cephalic, circumference, and shape profiles to establish how accurate and viable each method was for gathering data against what we currently know from prior Paxman studies.[1,4,5,12] Fifty-five per cent of the pilot study participants reported poor fit in the crown area. This finding was unexpected given that 55 per cent of the participants are of Caucasian background, and they used a Caucasian style cap. Our data provide evidence of some overlap in variation as idiosyncrasies in head shape (lumps, bumps, hair thickness) where poor fit is experienced.The results of our sample show the racial variation in the cephalic index (Table 1).

Table 1: Racial variation in cephalic index–sample

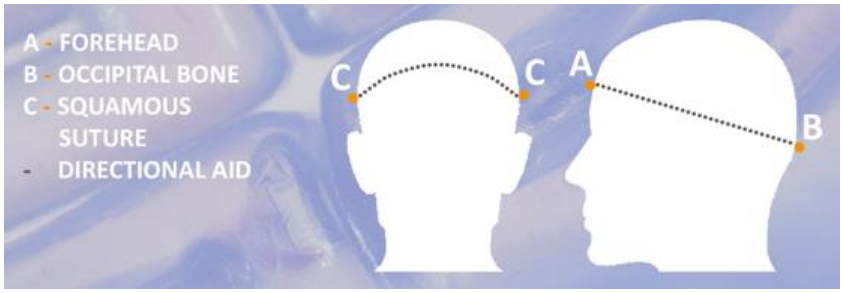
	Width	Depth	Circumference	Cephalic Index	Cephalic Category	
White British	139.5 cm	171.5 cm	53 cm	81.3	Brachycephalic	Europe
White British	140.3 cm	190.1 cm	56 cm	73.8	Dolichocephalic	Europe
White-mixed Caribbean	154.3 cm	204.1cm	62 cm	75.6	Mesocephalic	Europe
Indian	152.2 cm	182.2 cm	56 cm	83.5	Brachycephalic	Asia
Korean	141.7 cm	187.7 cm	56 cm	75.5	Mesocephalic	Asia
Eastern European	146.1 cm	186.4 cm	57 cm	78.4	Mesocephalic	Europe

We also captured the cephalic index data (Table 2), to analyse the efficacy of using it to gather necessary data accurately compared to other key parameters like circumference, fit, and shape profiles (Figure 2).

Table 2: Head classification according to the cephalic index[13]

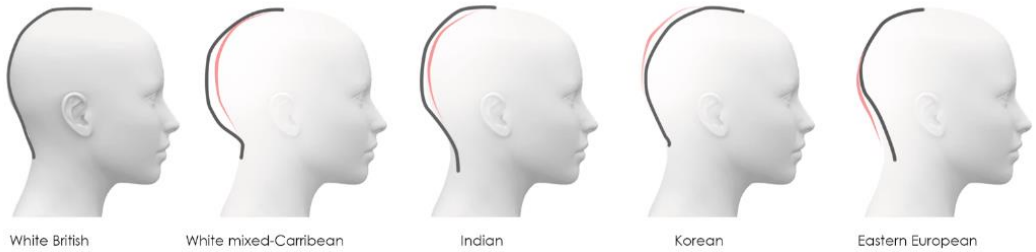
Cranial index (Cephalic index)	Max width/Max skull length x 100
Ultradolichocephalic	X – 64.9
Hyperdolicocephalic	65.0 – 69.9
Dolichocephalic	70.0 – 74.9
Mesocephalic	75.0 – 79.9
Brachycephalic	80.0 – 84.9
Hyperbrachycephalic	85.0 – 89.9
Ultrabrachycephalic	90.0– X

Figure 2: Reference points for circumference and cephalic measure points



Regarding nuance of shape, from data collected in our study, we highlight the vast variation in shape profiles (Figure 3). Even in one category of Brachycephalic, for two similarly proportioned skulls, the variations in occipital bone formation can result in patches of hair loss should the method rely on the cephalic index alone. The cap design requires an extremely close fit to a patient's head; gaps a little as a few millimetres could result in hair loss. The red lines highlight the deviation of cranial side profiles from that of a White British Caucasian shape as reference.

Figure 3: Different racial head shape profiles sample



Drawing from our extensive literature review[1] and the data we gathered in our initial pilot study, we are developing HudPAX Cranial Index methods to compliment where the cephalic index cannot be used as a standalone measure.

DISCUSSION

The pilot study results underscore the limitations of conventional ways to measure head size and shape. It also highlights the challenges and limitations of using conventional measures like the cephalic index in medical design. This pilot study strengthens our hypothesis that there is a severe lack of human head data available for product designing, and it is not always possible to categorise a person's cap shape based on race or gender (ie, determining an Asian user as Brachycephalic shape), though collection of this data set has proven useful for determining individual head characteristics and highlighting their shape profiles and proportions. Further studies will add more layers of complexity, including more of the hypothesised required parameters. This pilot study has trialed a selection of hypothesised parameters and provided evidence regarding the importance of combining the parameters shown in Figure 3, for accurate mass customization frameworks for scalp data collection. Future studies may benefit from applications of the more refined approaches developed using this study.

This small study conducted at Paxman shows that the Indian participant is Brachycephalic; according to our studies that is accurate. However, with the White British participant, who is also Brachycephalic evidence that the cephalic index alone cannot provide accurate data required. As Figure 3 shows, head shape side profiles were captured from this sample; between Participant 1 (White British) and Participant 3 (Indian), the category and cephalic size are very close proportionally, but the shapes are different. When asked participants to try on a cooling cap, between the two, one had issues with conformity to the crown and the other did not. This finding provides evidence that there are other crucial and integral factors to include alongside circumference, cephalic proportions, and shape profile.

Paxman manufactures cooling caps based on two distinct categories: Caucasian and Asian style caps. Our research provides evidence of how markets such as Japan, originally perceived to be Mesocephalic, are now predominantly Brachycephalic. Paxman's Asian style caps cater to the Brachycephalic indices in line with our clinical trials study in the Japanese market called "The Hope Study".[14] This shape choice is supported by and confirms Macgowan and Hester's[15] theory of the paradigm shift in progressive round-headedness. Although our other studies[12,16–18] and confidential market data demonstrate the hypothesised paradigm shift for head shapes globally, there are other considerations. In countries such as the United States, high levels of migration are causing more variation anthropometrically. In addition, Gayer's theorems were conceptualised in the 1800s and revised in the mid-1900s when access to technology such as flight, accurate anthropometric measuring tools, and computer-aided design were less prevalent. Migration was much less common at that time, whereas now countries have become more diverse. As a result, it is more crucial now for continuous improvement in medical devices used on the scalp, that anthropometric data available to designers be as broad, univariate, and up-to-date as possible to ensure high levels of accuracy. A broad market presence increases the complexity of data capture and accuracy as a global and multidisciplinary approach is necessary to enrich the data pool.

Because clinicians and Paxman are aiming for the highest levels of clinical efficacy, more accurate data are required to generate better fit. Since Paxman cooling caps are used in more than 60

countries, existing data are not sufficient to achieve consistent levels of efficacy globally. Countries such as the US, UK, and Japan collect more data, and that data are available to designers, thus their designs would be more accurate and treatment efficacies could be 80%+. Comparatively, less explored countries such as Spain may experience lower efficacy levels from generic data. Varying global markets mean that some countries adopt technologies at different levels and some countries will have higher needs (ie, more users). Neither a medical professional nor a designer can feasibly collect extensive data in over 60 countries. A more effective approach may allow for mass cusotmisation using individual user data.

CONCLUSION

Current methods for anthropometric data collection are time-consuming and complex to conduct: they require teams comprising many researchers and numerous participants to be accurate. A new method, yet to be developed, must be useful for healthcare professionals. Their limited time and resources are the main factors to ensure a data collection method balances optimal data collected for best scalp fit, versus simplicity and speed. The goal is to create a usable process that can be collated in a timely manner and enable data processing by a design team. Data analysis is the final limiting factor for feasibility. Once the data have been captured, it must be processed into a usable CAD data; this processing could be achieved via an algorithm in a program. In many countries manual processing would not be feasible for global applications for thousands of patients. This study's results suggests a larger study is needed to establish a valid solution for data collection.

FUTURE RESEARCH

Future research could include a larger group of participants from different counties to elaborate on the currently limited data. Further studies are required to ensure that the data we have on the existing generations of caps are and remain up-to-date. Global research efforts are required to gather univariate and broad data to support the development of more accurate cap classification for CIA. The impact of developing an infrastructure to enable global head measurement analysis has many other applications alongside medical design, including cranial reconstruction or swimming caps design with hair-type considerations. Additional reseach will facilitate the creation of a method to easily collect and process data to streamline complex head data analysis in scalp product design and to address unmet needs where currently univariate and insufficient data exist.

For Paxman, additional data was previously not needed as caps could be manufactured using traditional methods. Although continuous improvement is always at the forefront of development, the technology for customised cooling caps is not yet sophisticated enough. The research team is currently investigating 3D-printing methods and other smart manufacturing to be evaluated and tested in the next stages of this project where head capture tools and systems will be developed to enable customisation.

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CONFLICTS OF INTEREST

The authors declare that they have no competing interests.

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ETHICS COMMITTEE APPROVAL

Ethics approval has been granted from University of Huddersfield School of Arts and Humanities Ethics Committee before the research was started.