The Challenges of Implementing Design research within SME Based Medical Product Development: Paxman Scalp Cooling Case Study

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ABSTRACT: This paper examines a long-term study on patient experience to identify value generated through collaborative medical design research, in developing a scalp cooling device to prevent chemotherapy-induced alopecia (CIA)/ hair-loss. Developing a new medical device is long and complex, requiring a cross-platform multi-disciplinary team. User feedback is essential to ensure continuous development to improve efficacy. Qualitative and quantitative data was gathered from chemotherapy patients using scalp cooling in 9 different countries. Analysis of patient experience captures the impact design research has had for scalp cooling patients globally and guides continuous development, placing the patient at the centre of the design method, driven primarily by the aim of maximising treatment efficacy for all patients and promoting positive patient experiences. Overall, patient experience of scalp cooling using this device is highly positive and impacts significantly on five key areas of wellbeing. The outcomes will help develop an improved cap for global use.

Keywords: Design value, Medical design, Patient experience, Scalp Cooling, Chemotherapy-Induced Alopecia, Collaborative design.

Introduction

Identifying and assessing the value of design research is becoming ever more important, with governments and funding bodies increasingly concerned with measuring the impact of research (Rodgers, Mazzarella, and Conerney 2020). The impact and value of design research is often difficult to capture and quantify (Buchanan 2001). Specifically, with regards to medical design research, patient-centred approaches emphasise the importance of patient experience and feedback which is central to both the prospect, direction, and success of future developments (Bitkina, Kim and Park 2020).

Recent research (Unver, 2013) demonstrated personalised cooling caps are essential to improve Scalp Cooling (SC) success rates/efficacy to over 80% through perfect fit. For Paxman caps, the product must closely fit the scalp, requiring extensive research from users.

Our core goals in this study were to answer the following:

- Does User-centred design research bring value to the medical design process for an SME?;
- What are the main challenges and limitations of collaboration in a medical development project between an SME and Academia?

It is widely acknowledged that medical device design and development is a complex and high-risk process, with challenges including stringent regulation and commercial demands. SME's in particular face unique challenges implementing product development, due to limited resources & infrastructure, and lack of formalized development processes (Kangley, Barrans, and Newton 2019). Implementation of a multidisciplinary collaborative approach significantly enhances the prospect of success, by uniting a spectrum of essential expertise. The design and development of the Paxman Scalp Cooling cap is an example of one such multidisciplinary developments through backgrounds such as Designers, Oncologists, Engineers, Academics, Patients, Marketing and more. Funded through a TSB and KTP grant, the project brought together cross-sector expertise in a collaboration between The University of Huddersfield and SME Paxman Coolers Ltd., ultimately resulting in the development of the market-leading product for the prevention of chemotherapy-induced alopecia (CIA) (Paxman 2020). Paxman installed their first prototype scalp-cooler in an NHS hospital in 1997. While the product (**Error! Reference source not**

Figure 1: Paxman Scalp Cooling Cap, i. Initial design (Orbis/PSC model) ii. PSCS cap design.

found..i) addressed an unmet clinical need, the design and manufacturing methods limited treatment efficacy, production capability and the ability to meet the international regulatory demands. In 2012 Paxman sought the design and mass customisation expertise of the Product Design Team at the University of Huddersfield. The collaboration led to the establishment of the world's first Scalp Cooling Research and Innovation Centre in 2019.

This research investigates completion of Phase 1 of the long-term project, where the impact of the teams' design outputs are evaluated through patient feedback to quantify areas of importance and factors to ensure continuous improvement is achieved in the development process. Consequently, this user feedback will drive the next phases of the project to improve the design outputs with end goals of improved efficacy.

Chemotherapy-Induced Alopecia

CIA is an acquired form of hair loss which is frequently considered to be the most distressing physical side effect of chemotherapy treatment (Dua et al. 2017). CIA affects 65% of chemotherapy patients and occurs when commonly administered chemotherapeutic agents target rapidly dividing cells in the hair follicles. In addition to dealing with their cancer diagnosis and other chemotherapy-induced side-effects, including fatigue, nausea and vomiting, the hair loss experienced by patients with CIA has a considerable impact on their social relations and everyday lives, for both male and female patients (Hilton et al. 2008). CIA negatively influences patients' psychosocial wellbeing, self-esteem, body image and quality of life (Choi et al. 2014), and their changing appearance provides an unwanted outward indication revealing their health status to others which may have ramifications on employment, social and personal relationships. The fear of hair loss causes up to 8% of female breast cancer patients to consider declining the optimal and potentially life-saving chemotherapy treatment (Marks et al. 2019). The occurrence and severity of CIA is influenced by the chemotherapeutic agent and dose, with some regimens causing universal CIA.

The process of hair loss is traumatic, the hair can take a year to grow back and can have a different texture or colour, sometimes full regrowth does not occur. Patients with CIA adopt various coping strategies, some patients opt for total disclosure viewing their hair loss as a logical and inevitable consequence of the treatment (Hansen 2007), others choose to conceal hair loss with a wig and makeup and/or a head covering, providing patients with some degree of control over their appearance. Some patients proactively cut/shave their hair, putting them in control of when and how the hair loss occurs. Whilst methods to conceal hair loss aim to minimise the stigmatizing effects of CIA (Hansen 2007), in some cases such strategies can emphasise their cancer status, making it more visible to others with items that are symbolic of cancer treatment (Harcourt and Frith 2008). The importance placed on hair within society compounds the negative impact of CIA. Hair is often seen as essential to identity and represents an important social symbol which can generate perceptions of individuality, personality, age, sexuality and a sense of attractiveness. Traditionally considered a cosmetic concern (Marks et al. 2019) the

increasing appreciation for the significant psychosocial burden of CIA, for both male and female patients, has led to its growing recognition within the appropriate clinical context and increasing demand for preventative treatments.

Scalp Cooling for the prevention of CIA

Scalp-cooling is a preventative treatment for CIA, which involves reducing the temperature of the scalp immediately before, during and after infusion of the chemotherapeutic agent/s. Multiple biological mechanisms are proposed to be involved in the cryoprotective effect of scalp cooling. Scalp cooling induces vasoconstriction limiting scalp blood flow, cell metabolism is reduced, and cellular uptake of the drug is attenuated (Dunnill et al. 2020), ultimately minimising chemotherapy-induced damage to rapidly dividing cells in the hair follicles. Whilst multiple pharmacological agents have been evaluated scalp cooling remains the only available safe and effective option for CIA reduction/prevention (Dunnill et al. 2018).

Two types of scalp cooling devices are available- manual and machine-based. Manual devices are typically composed of an insulating outer-cap and a chilled/frozen gel-filled insert. The insert is initially very cold, but quickly reheats on application and requires regular changing throughout treatment, posing problems with patient discomfort, the risk of frostbite (Belum et al. 2016) and maintenance of a constant scalp temperature. On the other hand, machine-based devices utilise continuous flow coolant, integrating a refrigeration unit and silicone cap. Machine-based cooling does not involve such low temperatures as manual cooling, therefore enhancing patient comfort and maintaining a more constant scalp temperature without the need for mid-treatment changes, reducing nursing time-investment.

The efficacy of scalp cooling treatment has been analysed through clinical trials internationally. Overall, >50% (Nangia et al. 2017; van den Hurk et al. 2012) of patients keep at least half of their hair and do not require a wig/head covering. However, efficacy rates vary dramatically between chemotherapy regimens, with a success rate of 88% observed for breast cancer patients receiving taxane-only treatment (Vasconcelos, Wiesske, and Schoenegg 2018). Scalp cooling has also been seen to accelerate the rate of hair regrowth following chemotherapy treatment (Bajpai et al. 2020).

The concept of scalp-cooling has been recognised since the 1970's when ice packs and frozen gel caps were first used in Europe and Canada. The development of machine-based scalp cooling devices, together with mounting evidence defining the underpinning biological mechanisms (Dunnill et al. 2020; Dunnill et al. 2018) and demonstrating the clinical efficacy (Nangia et al. 2017; Rugo et al. 2017) and safety (Rugo, Melin, and Voigt 2017; Van Den Hurk et al. 2013) of scalp cooling, have contributed to the increased acceptance and implementation of scalp cooling internationally.

Scalp Cooling Cap Design Process

The initial focus of the collaboration was the design, development, and manufacturing optimisation of the Paxman Scalp-Cooling System: PSCS Cap (**Error! Reference source not found.**.ii). This patented cap design (Unver, Paxman, and Paxman 2016b, 2016a) has since achieved international regulatory approvals. The design research prioritised cap fit optimisation, which is crucial to successful scalp cooling treatment, as it maximises contact between the cap and scalp, hence ensuring scalp temperature is evenly and sufficiently reduced. Areas of sub-optimal contact can result in bald patches. The design also incorporated optimised heat-conductivity, enhanced patient-comfort and head shape/size variation adaptation.

Anthropometric data and 3D laser scanning were used to create multiple 3D heads for CAD modelling (Unver et al. 2016) concept generation. The final concept involved creating a 3D folded silicon cap (Figure 2), with a novel scalp-contact-surface structure (Unver, Paxman, and Paxman 2016b) and cap channel design to maximise scalp contact and heat exchange potential. Medical-grade silicone sheet was selected as the material for its non-allergenic, antibacterial qualities and its reliable wall thicknesses in the moulding process.

Figure 2: Final concept of the design construction.

Traditional manufacturing technologies such as injection moulding, were unable to produce the complex geometry/forms required by the design parameters. Tooling research ultimately demonstrated the technical capability of 3D laser sintering as the optimal tool-production method. This facilitated rapid tool generation, initially made from polyamides for prototyping and later in alumide for mass manufacture (Unver et al. 2020) . Rapid-tooling was combined with advanced manufacturing systems to develop a novel automated production method using twin-sheet silicon thermoforming (Unver, Paxman, and Paxman 2016a). This enabled affordable iterative design modifications, required to meet medical testing procedures and adapt to global markets, at significantly reduced tooling costs (Unver et al. 2016). To optimise cap-fit, global variations in cranial anthropometry (head size/shape) were evaluated, generating a 3D-scan database. Ultimately a product range of 6 sizes was developed with 3 Caucasian sizes and 3 brachycephalic/Asian head sizes. Global adaptation of the cap design improved treatment efficacy rates particularly for Asian patients, increasing patient access to effective scalp cooling particularly in Japan.

Design Impact: Increasing Patient Access

The new PSCS cap was launched in 2017, receiving international regulatory approvals including FDA (USA) and Shonin (Japan). The re-design and new cap manufacturing process significantly increased production rates and reduced production costs,

internationally increasing patient and clinical access to effective scalp cooling technology, now reaching patients in 59 countries (Paxman 2020). Until 2016, only manual caps were available in the USA, which are not FDA-approved. However, the PSCS cap is now widely accessible to USA patients and the USA's National Comprehensive Cancer Network® (NCCN) has subsequently updated the Clinical Practice Guidelines in oncology for breast cancer (V1.2019) and ovarian cancer (V1.2020) to include scalp cooling as a Category 2A recommendation (NCCN 2020).

Design Research and Patient Experience for Continuous Development

The inclusion of designers in the process of conducting scientific experiments highlights the value that design as a method of enquiry can bring (Rust 2007). The overall aim of product and engineering design research is to develop knowledge which can improve the chances of producing a successful product (Bereiter 2002). For SMEs, it can be quite difficult to establish design inputs; usually don't always recruit Designers or researchers. Collaboration enables access to these resources that might be missing. Inclusion of Designers in this project were initially measured through a KTP collaboration. Design stimulates the creation of new knowledge by the production of artefacts to test ideas and deliver understanding; bringing this to the healthcare sector could bring benefits beyond the development of existing prototypes, and the beautification of medical devices. Design, as a practice/process, offers an opportunity to understand and address the complexities of users' needs for the delivery of health provision (Hagedorn, Krishnamurty and Grosse 2016). The understanding of user needs, and especially patient experience, provides a vital insight for successful continuous development of medical products. Scalp cooling users are at the core of the product development and include not only patients, but healthcare professionals. Using Paxmans established global network of the worlds best Oncologists and Healthcare professionals, data is usually gathered qualitatively as well as Quantitatively to guide these processes. The principal aim of a continuous product development of the scalp cooling cap is to perpetually improve treatment efficacy rates to maximise treatment success for all patients, while patient needs and feedback guides the design and development process accordingly, therefore, promoting an enhanced positive patient experience. Essential to the success of future medical device developments is the thorough understanding of current patient experience and determining the value previous design research has generated.

Design Thinking in Continuous Development

Design research is a critical step in creating the optimal user experience. It allows understanding of complex human behaviour and turns that into actionable insights to improve design artifacts (Bereiter 2002). Therefore, it focuses on the iterative improvement and development of ideas/solutions with the explicit intention of improving the user experience.

The design process begins with the rigorous study of the users and their context (Cross 2011; Design Council 2007; Sawyer et al.1996). This human centred approach to problem solving/design, emphasizes openness of mind, by challenging the existing constraints and the influences of behaviours and social structures (Pullin 2009). On the other hand, Design Thinking is understood as a complex and iterative creative thinking process that has seen the introduction of the design culture and its methods into fields such as business and healthcare innovation (Altman, Huang, and Breland 2018; Brown 2008; Kim, Myers, and Allen 2017). Design Thinking is an approach which prioritises developing empathy for the user across its core phases: Empathize, Define, Ideate, Prototype, and Test (Stanford d.school 2021). During the iterative design process, empathy and understanding of user's needs is continuously built through observation, prototyping, and reflecting on the feedback from patients themselves. The 'Empathise' stage focuses on patient and user-centred research. This aims at developing empathy and knowledge through direct observation and qualitative data to fully understand the behavioural, contextual and cultural aspects involved in the overall use of the medical device. Methods can include Secondary Research, through extensive literature review and data analysis, and Primary Research through ethnographic studies. Ethnographic research, such as user questionnaires, stakeholder focus groups and interviews allow the researchers/designers to observe and/or interact with patients and other stakeholders in their real-life environment to obtain insights into their needs and overall experience (Bichard and Gheraawo 2011).

Methodologies for Promoting Continuous Development

Commercially-led medical device product development has commonly utilized a Waterfall methodology for project management (FDA 1997; Royce 1970). The Waterfall method promotes sequential development through non overlapping stages, this method enables rigorous testing, but only at the beginning/end of the process, and thus the opportunity to implement recommendations from early findings is limited. On the other hand, Agile methodology promotes a continuous and iterative development, facilitating assessment throughout the product development lifecycle. The Agile method utilises rapid cycles, called sprints/iterations, with each iteration resulting in an incremental product improvement. Therefore, adding value to the final product with each iteration. Whilst the Agile method can typically lack the rigorous testing of the Waterfall, it enhances responsiveness, and allows simultaneous development and requirement gathering, potentially reducing costs and time to market. Furthermore, the Agile method facilitates the continual input from different stakeholders throughout the product development process. Consequently, allowing the product to be more attuned to the current time and market demands.

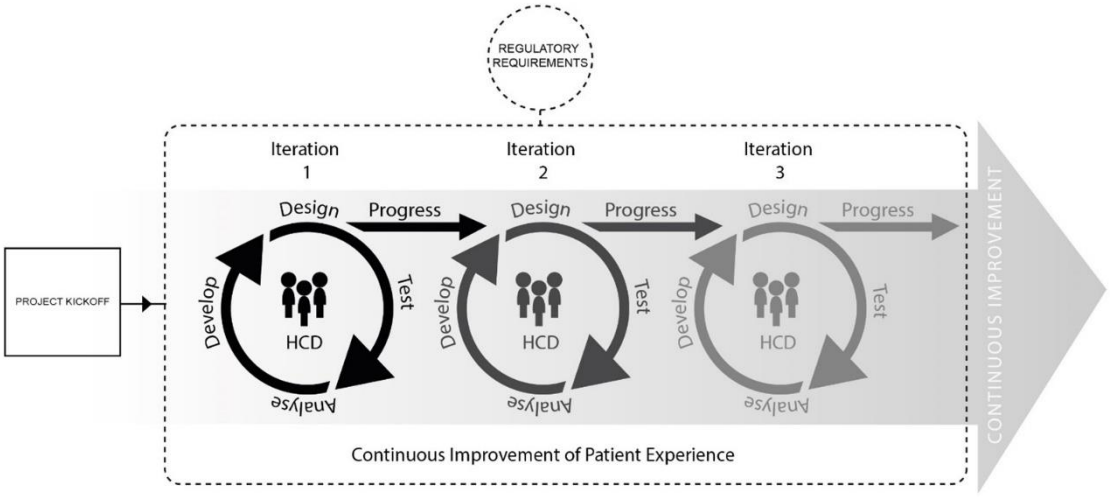

Figure 3: The WHAM method for continuous improvement

Methodology: Data collection

Based on extensive literature reviews and assessment in the first phased of this project, a summative assessment was built to validate earlier design decisions and guide future development. An extensive patient questionnaire was designed based on existing knowledge from literature review and secondary data. The questionnaire was composed of eight sections. Six sections were related to CIA and the patient's experience of scalp cooling, and the two final sections were related to the patient's awareness and experience of Chemotherapy induced Peripheral Neuropathy (CIPN). This paper addresses only the CIA related questions, which included an optimised mixture of 26 multiple choice, Likert-type scale and open-ended questions, gathering both quantitative and qualitative data.
The questions sought to establish details of the patient's: *1) demographic & cancer diagnosis details; 2) chemotherapy treatment received; 3) scalp cooling treatment received; 4) hair type and hair loss classification; 5) psychosocial impact of scalp cooling; 6) experience of scalp cooling.*

A full ethical assessment has been completed by the University of Huddersfield, School of Arts and Humanities Research Ethics and Integrity Committee before the research commenced.

Target population, access and data gathering

The questionnaire was created, in both English and Portuguese, in the Google Forms application. Responses were gathered from patients internationally, who had used, or were currently using, the Paxman Scalp Cooling system during their chemotherapy treatment. Access to potential respondents was facilitated through multiple channels, including launching the questionnaire through relevant social media channels, primarily a closed-access scalp cooling peer support group (600 members at questionnaire launch),

and shared directly by Paxman's international network of medical professionals with their patients. A database of responses was created, quantitative data was analysed statistically, and qualitative data was coded to identify recurring themes and their frequency.

Results: Data analysis and outputs

SME led research needs to be flexible to rapidly adapt to changing environments, markets, user requirements and feedback, therefore many SMEs utilise a combination of multiple methodologies. In this work, for the development of the PSCS cap, a WHAM method (Figure 3**Error! Reference source not found.**) was used. The WHAM method integrates both, Waterfall and Agile methodologies with a Human centred design (HCD) approach, alongside the stringent regulatory requirements for medical product development.

Profile of respondents

Between May and July 2020 150 respondents completed the questionnaire (Table 1). All respondents had received, or were currently receiving scalp cooling treatment during chemotherapy, with the Paxman Scalp Cooling system. Most respondents were female (97%), with an average mean age of approximately 47.9 years. Responding patients were located in 9 different countries, with 55% in the USA. The majority of respondents had received a diagnosis of breast cancer (88%) and had completed their chemotherapy treatment (69%).

Table 1: Profile of respondents (n=150)

Characteristic	Respondents (%)
Overall	150 (100)
Age (years)	
<20	0 (0)
20-34	16 (11)
35-44	42 (28)
45-54	57 (38)
55-64	25 (17)
65-74	8 (5)
75-84	0 (0)
>84	1 (1)
Undisclosed	1 (1)
Gender	
Female	146 (97)
Male	3 (2)
Undisclosed	1 (1)
Country of location	
USA	82 (55)
UK	44 (29)
Australia	12 (8)
Bulgaria	6 (4)
Others (5)	6 (5)
Diagnosis: Primary site of cancer	
Breast	133 (88)
Ovary	9 (6)

Endometrial/Corpus uteria	3 (2)
Uterus	2 (1)
Prostate	1 (1)
Other	2 (1)
Diagnosis: stage of cancer	
0	3 (2)
1	53 (36)
2	61 (41)
3	26 (17)
4	6 (4)
Status of chemotherapy treatment	
Complete	104 (69)
Ongoing	46 (31)

Patient Experience of Scalp Cooling

Reported Efficacy of Scalp Cooling Treatment

The hair loss experienced was self-assessed by respondents and graded on a scale of 0-4, as detailed in
Table 2.

Table 2: Self-assessed scalp cooling efficacy (n=150)

Hair loss grade (self-assessed)	Respondents (%)
0: No significant hair loss	17 (11)
1: Minor hair loss	34 (23)
2: Moderate hair loss: *not* requiring wig/head covering	62 (41)
3: Severe hair loss: requiring wig/head covering	36 (24)
4: Total alopecia	1 (1)

Scalp cooling is classed as successful when hair loss assessments are graded between Grade 0 and Grade 2. Scalp cooling was successful for 75% (113/150) of respondents who experienced ‘no significant’ to ‘moderate hair loss’ and did not require a wig/head covering.

Total alopecia (grade 4) was not reported by any respondents, who used scalp cooling for every cycle of chemotherapy. One respondent included in
Table 2, who had not used scalp cooling for the first cycle of doxorubicin and cyclophosphamide chemotherapy (due to their initial clinic not providing this treatment), consequently suffered total alopecia (Grade 4).

Patient Tolerability of scalp cooling

Respondents were asked to grade the tolerability of their experience of scalp cooling on a scale of 0-10, where 0 represented 'No discomfort' and 10 represented 'Agonising' (Figure 4). The mean tolerability grade response was 3.4, indicating that the average level of discomfort experienced was between 'Annoying' and 'Uncomfortable'. Almost half of the respondents (47%, 70) graded the level of discomfort experienced between 'No discomfort' (0) and 'Annoying' (2).

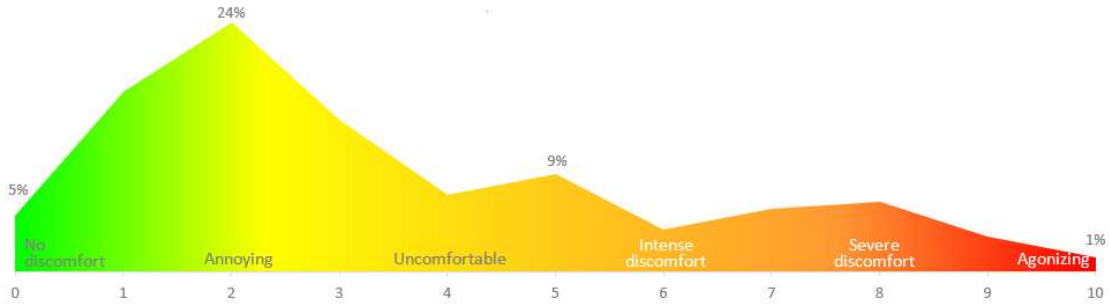

Figure 4: Scalp cooling tolerability grading response.

The Psychosocial Impact of Scalp Cooling on Patient's Wellbeing

The impact of scalp cooling on patient's wellbeing was quantified, with respondents self-grading the level of impact according to the following Likert scale: *Very Significant Impact, Significant Impact, Some Impact, Low Impact, No Impact.*
Overall, 99% of respondents reported that scalp cooling had at least some impact on their emotional wellbeing, and 95% reported at least some impact on their social activities. A significant or very significant impact was perceived by the large majority of respondents on five key areas of wellbeing, including their emotional wellbeing, social activities, work activities, relationships with family and friends and their sporting/physical activities (Figure 5).

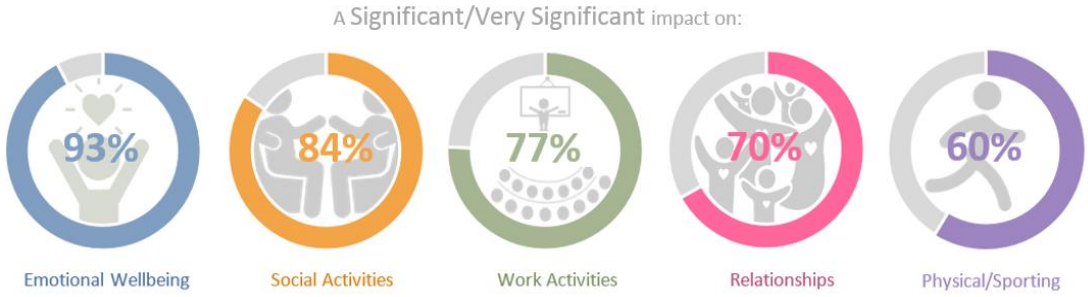

Figure 5: Impact of scalp cooling treatment on five wellbeing areas.

Qualitative data was also gathered from respondents relating to their experience of scalp cooling and what it meant to them personally, through open ended questions. Respondent's comments were classified according to the theme/themes they discussed. Five dominating key motivations for scalp cooling were identified, including: 1) Protect family/children; 2) Maintain normality; 3) Provide privacy; 4) Retain identity; 5) Retain control.

Product Design Feedback: Assessing Research Value and Guiding Continuous Development

Quantifying the impact of existing design developments

The linked nature of the data permits comparison between individual parameters, facilitating stratification and comparison of feedback for the different versions of the Paxman scalp cooling cap. This includes the latest version, PSCS (**Error! Reference source not found.**ii.) and previous versions, PSC/Orbis (**Error! Reference source not found.**i.). This allows the impact of the design modifications to-date to be identified/quantified.

Treatment efficacy and cap version: All respondents used a Paxman Scalp Cooling cap, with 85% using the latest PSCS Cap (**Error! Reference source not found.**ii.) and 12% using the original design of cap, Orbis/PSC version (**Error! Reference source not found.**i.), 3% were unsure which version they had used. The level of hair loss reported by the respondents through the self-assessed hair loss grading system (
Table 2) was compared between the caps versions.

The average grade of hair loss was 1.75 for the PSCS and 2.06 for the Orbis/PSC, where a grade of 1 = Minor hair loss and 2 = Moderate hair loss (not requiring a wig/head covering), indicating that the latest cap developments have significantly increased levels of treatment efficacy, with a 15% improvement in the average hair loss grade observed, increasing to 20% when analysing only respondents who had completed their treatment (69%, 104). A P value of 0.045 indicates a statistically significant improvement in self-assessed hair loss grade for respondents who had completed treatment using the PSCS cap compared to respondents who had completed treatment using the PSC/Orbis cap.

Tolerability and cap version: Tolerability of scalp cooling (Figure 4) has improved with PSCS cap, with average tolerability score of PSC/Orbis cap at 4.4 (Uncomfortable-Intense Discomfort) and 3.3 (Annoying-Uncomfortable) for the PSCS cap, indicating an 11% increase in tolerability on the tolerability scale of 0-10.

Cap Fit Parameters and Cap Version: Overall, respondents reported a positive experience with the fit of the cap, with 78%, responding positively to questions concerning cap fit, size selection and ease of putting cap on (Figure 6). However, when segregated for cap version, the cap fit parameter responses were notably more positive for the PSCS compared to the PSC/Orbis cap (Figure 6). Overall, responses to 'Cap fit was optimized' was 6% more positive for the PSCS than PSC/Orbis and 14% for the 'Cap was easy to put on'. The size selection process is significantly easier/more straightforward for the PSCS compared to the PSC/Orbis cap, with a 25% increase in positive responses observed.

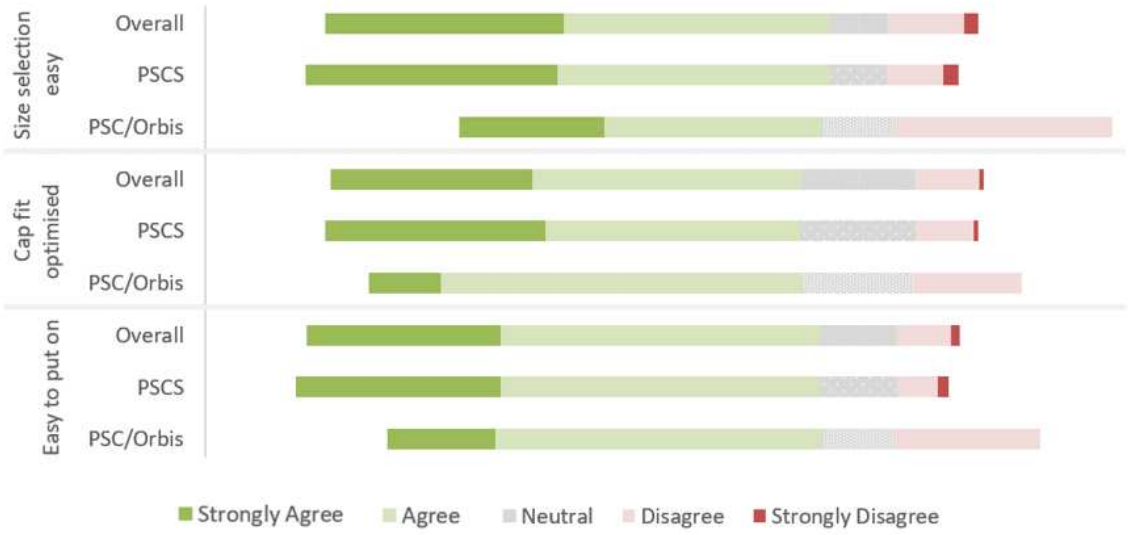

Figure 6: Cap fit parameters comparison

Feedback for Continuous Design and Development

Cap comfort and design

Most respondents found using the cap comfortable (62%), with both the coldness bearable (89%) and weight of the cap comfortable throughout the duration of treatment (87%) (Figure 7). Responses to specific aspects of the cap design emphasise the need for development, including the comfort of the chin strap, for which 53% of respondents provided a negative response. In addition, 70% of respondents agreed that the integration of sideburn cooling coverage would be beneficial.

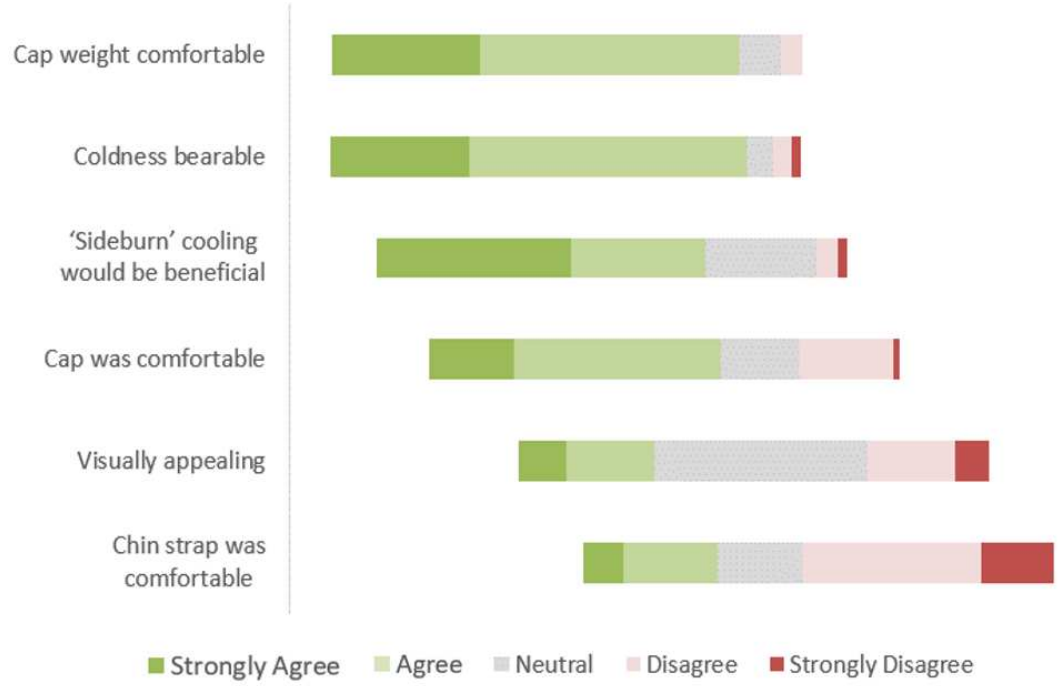

Figure 7: Cap comfort and design responses for all cap models.

Unlike cap fit (Figure 6) generally, the perception of cap comfort parameters was not significantly different between cap versions. This includes perception of overall comfort, coldness, cap weight and chin strap comfort. The perception of the cap's visual appeal was 27% more positive for the PSCS version, compared to the PSC/Orbis version, suggesting that patients appreciate, to an extent, the updated look of the cap.

Discussion

The Value of Design Research

Patient responses have been utilised in this paper to identify the value conferred through the design collaboration to-date and to establish a thorough understanding of current patient experience to promote successful continuous development.

Enhanced performance through Innovative Design

Comparison of responses between patients who had utilised the PSCS cap and the previous models (Orbis/PSC) evidence the value of iterative design improvements, and demonstrate that the design research has enhanced efficacy, patient tolerability, cap fit parameters and overall patient experience. The patented channel design promotes scalp contact, enhancing cap fit and consequently efficacy, with a 15% improvement reported in average hair loss for the PSCS. Utilisation of a softer more flexible silicone contributes to the enhancements in patient tolerability of scalp cooling treatment for PSCS users, which can ultimately affect a patient's willingness to continue scalp cooling treatment.

Increased Patient Access through Innovative Design

A continuous development framework with strong regulatory requirements (i.e. WHAM) can accelerate the product development process while meeting FDA and other regulations, saving time and avoiding delays by receiving early feedback before starting full-scale development. The majority of respondents in this study were based in the USA (55%), where access to machine-based scalp cooling treatment has only been available since 2016 with the FDA approval of the DigniCap®, followed by Paxman PSCS in 2017. Prior to this only manual, non-FDA approved, caps were available. The FDA approval of two machine-based continuous flow scalp cooling devices has been followed, in the USA, with a sudden growth in scalp cooling awareness and acceptance, amongst both healthcare professionals, patients and the general public. This trend is being reflected globally and has been part of a larger social shift in cancer discourse, with increased awareness and honest discussion about cancer within the media. Podcasts, blogs and video diaries by media personalities, cancer bloggers and influencers, document their chemotherapy treatment, including their scalp cooling experience and have been accessed by millions worldwide. Complementary to this is the gradual shift of medical approaches towards Whole Person Care, a more human centred and empathetic approach which considers a patient's overall support needs, as opposed to just treating the illness. Furthermore, while traditionally considered a cosmetic concern (Marks et al. 2019), CIA is increasingly being recognised in the appropriate clinical context due to its impact on patient wellbeing. The research leading to the innovative design and revolutionary manufacturing approach was a central factor allowing the surging international demand for effective scalp cooling treatment to be met.

Patient Experience of Scalp Cooling Treatment

This study identified that overall, the patient experience of scalp cooling is predominately very positive. Hence, it can be suggested that design as a human centred approach promotes the improvement in patient’s scalp cooling experience (Kim, Myers, and Allen 2017). Expectation of extreme discomfort caused by the low temperature and sensation of scalp cooling is a key reason that some patients decline scalp cooling treatment.

However, this study has identified that discomfort is generally ranked relatively low on a tolerability scale of 0-10.

Scalp cooling to prevent/reduce CIA has an overwhelming positive impact on patients' psychosocial wellbeing. This impact is particularly significant in five key wellbeing areas including, in order of significance, *emotional wellbeing, social activities, work activities, relationships with family/friends and sporting/physical activities*.

- Emotionally, patients feel empowered by their choice to scalp cool, providing them with a degree of control over their treatment, helping them to retain their sense of identity, encouraging a positive attitude towards their treatment as a whole and allowing them to keep their diagnosis and chemotherapy treatment private.
- Socially, patients report feeling able to retain their self-confidence and desire to socialise, allowing them to maintain important social relationships and wider support networks.
- Patients frequently feel more able to continue their work activities and maintain usual interactions with colleagues/clients, due to the level of privacy afforded by scalp cooling treatment, potentially minimizing the financial burden by reducing work loss.
- Maintenance of a patients 'usual' appearance is seen as important particularly for the purpose of shielding children/grandchildren from the realities of chemotherapy treatment, and to maintain balanced relationships with family/friends to avoid their condition dominating their interactions.
- Furthermore, the privacy afforded by scalp cooling treatment, allows patients to feel more able to continue sporting activities including group and gym classes, promoting healthy lifestyle choices.

Patients' opinion of hair loss has been considered the best method to assess the efficacy of scalp cooling (Komen et al. 2018). Using a self-assessment hair loss grading system, the overall efficacy rate reported by patients in this study was 75%. Whilst this is higher than some clinical studies (Nangia et al. 2017; Rugo et al. 2017), an extensive number of factors influence efficacy rates which have not been controlled for in study.

An empathetic approach to understanding the patient's experience during treatment is a crucial aspect in continuous development. Unsuccessful scalp cooling treatment has been seen to cause additional distress to patients (van den Hurk et al. 2010), certain respondents to this study concurred with this, with one commenting: *"It meant a lot to me, so was even more devastating that it did not succeed."* Despite this, previous research has indicated that 38% of patients with unsuccessful scalp cooling treatment would want to use scalp cooling again if they needed chemotherapy in the future (Breed, van den Hurk, and Peerbooms 2011).

Continuous Research & Development

The primary aim of continuous research and development of this scalp cooling cap is to maximise treatment efficacy and to further promote positive patient experiences, to ensure that the considerable benefits to wellbeing conferred by successful scalp cooling treatment reach as many patients as possible (Freedman 1994; Rosman 2004).

The extensive patient experience data gathered in this study is utilised through the WHAM method as an insight to unveil patient needs, highlight problems and strengthen solutions to known issues. This method for continuous development supports the delicate balance in a complex compilation of design inputs where the patient is at the core of the development. Design inputs include feedback from other users, biological/clinical evidence, stringent regulatory requirements, manufacturing constraints and SME commercial feasibility, which all combined set the boundaries for design development

The constant collection and analysis of patient experience data provides a tool for continuous improvement when utilised through the WHAM method. The method promotes an iterative design approach that facilitates a constant communication loop between the users/patients and product developers. The WHAM method embraces a patient centred approach and challenges assumptions to generate innovative solutions. Whilst mitigation processes are employed to minimise reports of anomalies/user error, the user-centric nature of this method ensures that prevalent patient experience findings result in correlated areas of improvement, influencing the direction of the research and further design developments.

An example of this process, which initiated with user insights, ultimately led to the development and commercialisation of the new generation of cooling cap designed for Asian demographics. Patient and clinical feedback highlighted the suboptimal fit and regional hair loss issues specifically faced by Asian patients. Subsequent design research addressed the anthropometric variations between Dolichocephalic head shapes (Caucasian) and Brachycephalic head shapes (Asian), through volunteer-based pilot studies, collaboration with Japan-based clinicians and iterative development (Unver et al. 2020). The implementation of user feedback increased the range of cooling cap models (Dolichocephalic/Brachycephalic) and sizes available; enhancing cap fit, and consequently treatment efficacy, for more patients.

Examples of challenges highlighted through this patient experience study includes:

- Emphasising the comfort of the chin strap for the patient, whilst maximising the pressure applied and scalp contact of the cap on the crown of the head to minimise regional hair-loss.
- Further increasing patient tolerability of scalp cooling by minimising cold discomfort, whilst optimising coolant and scalp temperatures to maximise efficacy.

- Emphasising the visual appeal of the cap as a consumer product, for the single-user markets, balanced with stringent regulatory requirement parameters, e.g., easy cleaning for hygienic repeated use, especially important for multi-patient markets.

Continuous Development allows these challenges to be addressed, since early stages of the creative process. If not perfect, an early exploration of such challenges allows the designer to get an insight into probable solutions. This process is initiated with an iterative ideation phase with the aim to explore diverse and innovative solutions. Figure 8 illustrates an example of the ideation phase exploring cap coolant channel design for optimised scalp contact, and outer cap design to minimise chin strap pressure whilst promoting close cap fit.

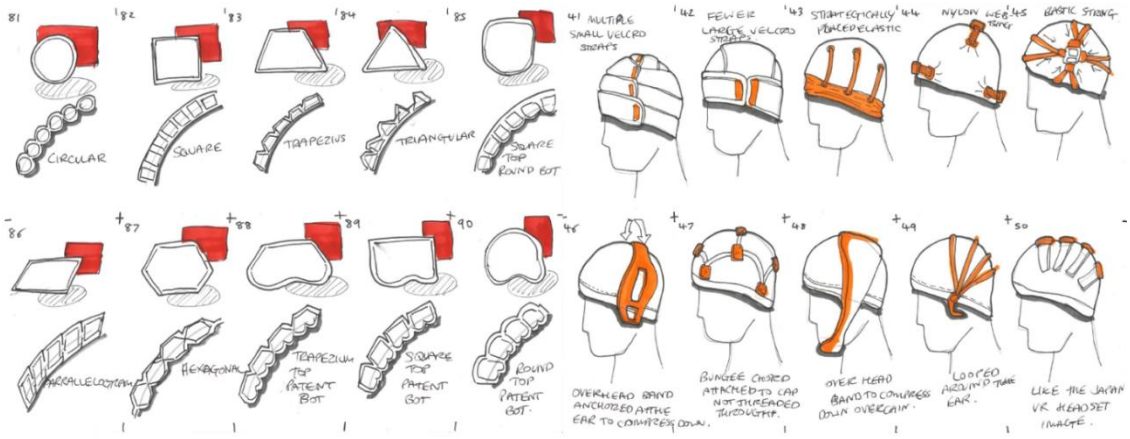

Figure 8: Ideation Example: Morph board for channel design and outer cap

The designer's approach to problem solving has an important role in new medical device development, it brings a systemic, integrative, and holistic view into the project management to build innovation capability (Kleinsmann, Valkenburg, and Sluijs 2017). Creativity and design have been recognised to be essential in tackling complex problems, where the systems and processes are difficult to untangle without adversely affecting the whole (Buchanan 1992). Design and creativity do not require all the answers to keep moving forward, instead they move forward by engaging with users/stakeholders in a collaborative effort to imagine new futures or possibilities (Kolko 2010). This abductive thinking is at the core of innovative design research through all stages of development, from problem discovery to solution delivery. Consequently, this process of organizing and filtering data in the context of a design problem, to produce information and knowledge, allows an innovative and diverse range of potential solutions. These solutions are then iteratively optimised into a finalised solution to balance user requirements and feedback, function, performance, regulations, aesthetics, manufacturability, and commercial feasibility.

Conclusion

Regulatory standards in Medical Design are typically very strict and regimented. Enabling flexibility in the design method from a rigid infrastructure is achieved in our research; with potential for other SMEs to adopt, including non-medical SMEs. The importance of patient experience for both identifying design value and directing the continuous development of medical products is emphasised in this study which evidences the highly positive psychosocial impact that access to effective scalp cooling treatment has for chemotherapy patients. Five key areas of patient wellbeing are significantly impacted, with 99% of patients confirming an emotional wellbeing impact- and 93% stating that this impact was significant/very significant. Furthermore, the patient experience data identifies and quantifies design value relating to increased patient access, increased treatment efficacy and tolerability, because of the design research.

The understanding of patient experience represents a powerful tool for continuous development in medical design. A human centred design methodology that prioritises empathy, through constant patient insight promotes continuous improvement. The adaptable nature of the WHAM method affords SME-led research the flexibility required to incorporate the strict regulatory requirements whilst remaining responsive to changing market needs and patient experience.

This study emphasises the value of design research and cross sector collaboration through a project which has had international reach and significance. The importance of funding initiatives, such as KTPs, to trigger successful SME-led academic design collaborations, is demonstrated, reducing the barriers for SME development, and leading to long-lasting research partnerships which contribute significantly to future innovative development, IP generation and commercial/economic growth.

One of the limitations to publications in industry-academia collaborative projects can be IP of Design outputs. Though these can be outputs in themselves and can be used to validate the importance of a project (Such as patents and Design registrations), ownership limitations from direct financial contribution can limit data shared from the project. This can be negotiated before a project starts, but other related outputs/ design solutions and benefits can become high-impact REF Case studies. As this research centres around Cancer treatment, this often-sensitive research can be difficult to disseminate and share. For public use such as publications, for obvious privacy and confidentiality reasons there are restrictions on what can be shared from personal experiences unless otherwise explicitly permitted. Our new methods explore how it is possible to quantify the data in a confidential way to protect our patients and ensure data collected is valuable to the design processes. Often also, these live projects with academia, enable placements for Students, post-graduate study such as master's or PhD; directly impact society through economic growth and wealth of contribution to a knowledge base which establishes a rich knowledge transfer.

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Declaration of interest statement

Paxman Coolers Ltd. provided access to their established network/channels for the purpose of this study, however all data was independently gathered and analysed from the company.

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