Paxman Scalp Cooling Cap for prevention of Chemotherapy-Induced-Alopecia

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Project Description

This portfolio contains outputs from a collaboration with Paxman Coolers Ltd, which focused on the design of the Paxman Scalp Cooling cap, and the development of a novel manufacturing approach. Ultimately the project has generated an award-winning medical scalp-cooling cap, used to prevent chemotherapy-induced hair-loss. The cap is commercially successful in more than 54 countries, and has achieved extensive regulatory approvals, including FDA (USA) and Shonin (Japan).

Project Duration:

- 2012-2014: PHASE 1: Research collaboration established. Prototype produced in 2014.
- 2015 : PHASE 2: KTP commenced, initially focusing on rapid tooling for mass manufacture.
- 2016: Two patents were published.
- 2017: FDA Approval.
- 2017-2019: PHASE 3: Through the existing KTP global adaptation for Asian patients was addressed.
- 2019-present: Establishment of the World's First Scalp Cooling Research Centre, based at the University of Huddersfield, with commercial investment of £1M.

Funder:
TSB Grant for R&D (#4643, 2012-2014): Paxman awarded £229k with £55k allocated to the University of Huddersfield for prototype development.
KTP (#9863, 2015-2019): £181k For development of a mass manufacturing approach utilising rapid tooling and addressing global variations in head shape/size.

Research Partners, consultants, collaborators:
Paxman Coolers Ltd (Collaborator).

Research Aims & Objectives

Research Aims & Objectives:

- The aim of this research was to design a scalp-cooling cap for the prevention of chemotherapy induced alopecia, capable of mass manufacture, meeting all of the performance requirements and fitting a variety of head sizes and shapes.

- This research addressed this challenge and involved the design, development, prototyping and manufacturing optimisation of the Paxman Scalp-Cooling Cap.

- The cap design objectives included optimising cap heat-conductivity and coolant flow pattern, along with maximising cap fit, patient-comfort and ergonomics, and developing an easy-to-fit cap range which could adapt for variations in head shape/size.

- The cap design had to facilitate mass manufacture using CE/FDA approved biocompatible materials. The method for mass manufacture had to be developed, with the aim of reducing manufacturing cost and increasing production capability.

Research Context

Chemotherapy-induced alopecia (CIA)/hair-loss is recognised as one of the most traumatic side effects of cancer treatment, affecting annually 65,000 UK patients, and 3.12 million worldwide. Scalp-cooling is a preventative treatment for CIA, reducing scalp temperature limits scalp blood flow and minimises chemotherapy-induced damage to rapidly-dividing hair follicles. The concept of scalp-cooling has been widely recognised for >40 years, but presents significant challenges for manufacture. Existing manual scalp-cooling products included frozen gel/ice packs, which have limited effect due to lack of temperature control and patient discomfort. Machine-based scalp-cooling utilising continuous coolant-flow, provides a more comfortable and successful treatment option, but patient access was severely limited due to design and manufacturing constraints.

This research revolutionised the design and the manufacturing process of the Paxman scalp-cooling cap. The resulting award-winning product reduces/prevents patient hair-loss during chemotherapy treatment. Achieving regulatory approval internationally, including FDA (USA) and Shonin (Japan), the product is now available in >54 countries, dramatically increasing patient access to effective scalp-cooling treatment.

The research founded a strong collaboration between the University of Huddersfield's product design team, led by Dr E. Unver (1999-present, Principal Enterprise Fellow, Editorial Board Member for The Design Journal) and SME Paxman Coolers Ltd. Paxman was initially formed as a spin-off from a beer-cooling company, in response to a family member suffering chemotherapy-induced-alopecia. They installed their first prototype scalp-cooler in Huddersfield Royal Infirmary in 1997. Paxman saw steady growth and while the product innovatively addressed an unmet clinical need, design and manufacturing methods limited distribution and wider success, and scalp cooling remained an underutilized therapy that had the potential to prevent CIA. In order to overcome these growth-limiting factors, in 2012 Paxman sought the design and mass customisation expertise of Dr E. Unver, and the collaboration was established.

This portfolio brings together a series of outputs arising from this successful research collaboration, including two patents, two journal papers, a conference paper and multiple exhibitions.

Research Methods & Process

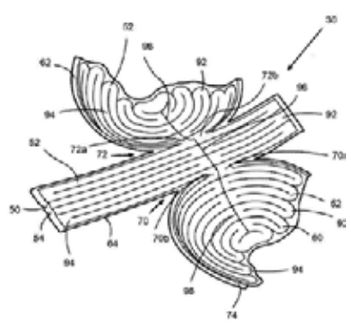
The preliminary research stage focused on prototyping utilising novel approaches with 3D-technologies, ultimately designing a single standard-size cap prototype. This cap was designed to integrate a close fit with uniform coolant circulation, whilst providing high levels of patient comfort and adhering to the US/EU medical product approval processes.

The research commenced with a thorough scoping exercise; reviewing the scalp-cooling procedure, technical challenges, critical competitive analysis and patent reviews. The research process from concept to prototype is described in the peer-reviewed conference paper (Unver et al. 2016). A hybrid research methodology was applied using Design Science and Double Diamond product design and development by the Design Council.

Primarily, anthropometric data was analysed to establish head size/shape variance, and 3D laser scanning of an average size head was used to create a standard-sized 3D-head for 3D-CAD modelling. This was used for concept generation, with the aim of simplifying moulding and optimising fit. Incorporation of manufacturing simplifications was imperative to the design, paving the way for future mass manufacture.

Fig.1: Cap form concept

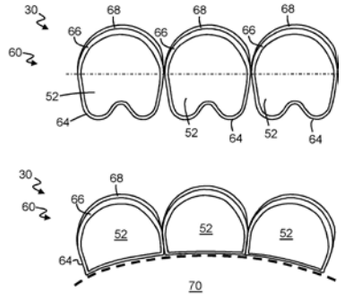
Fig.2: Final cap form as presented in patent



Various cap forms were evaluated. The final concept involved creating a flexible 3D folded silicon cap, for optimal fit the design consists of four 2.5D elements, which fold/join on assembly, forming a 3D cap (Fig.1 & 2). Healthcare silicone sheet was selected as the material for its non-allergenic, antibacterial qualities and its reliable wall thicknesses in the moulding process.

A novel, patented scalp-contact surface structure was designed to optimise scalp contact and provide a highly efficient medical heat exchanger. Specifically, the first patent (Heat Exchanger, WO/2016/046534) describes the design of the internal coolant channels which optimise scalp-contact. The channel design incorporates a novel arched-shaped scalp-contact surface. When in use, the arched-channel surface flattens under pressure of the circulating coolant, conforming to the scalp and maximising scalp-contact (Fig. 3). In addition, the channel pattern design dictates the flow-route of coolant fluid through the cap. The cap incorporates an innovative boustrophedonic/serpentine flow-route, designed to maximise heat-exchange.

Fig.3: Coolant channel design for maximising scalp contact, as presented in patent

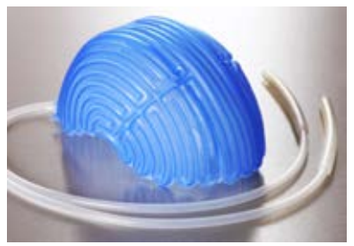


Traditional manufacturing technologies were unable to produce the complex geometry/forms required by the design parameters. Various technologies where investigated for creating the tools required, including utilising recyclable low-melting point alloy (Durgun et al. 2016).

Ultimately a revolutionary automated production method combining alumide 3D-laser sintering rapid tooling and twin-sheet silicone sheet thermoforming, was developed as described in Unver et al. 2019, and then implemented at a UK-based silicon manufacturer. This revolutionary patented manufacturing method initially produced the prototype (Fig. 4), and subsequently facilitated mass manufacture of the cap. A second patent (Heat Exchanger Cap WO/2016/046535) describes the overall design of the cap and its novel manufacturing and assembly methods.

Rapid-tooling enabled affordable iterative design modifications, required to meet medical testing procedures and adapt to global markets, at significantly reduced tooling costs.

Fig.4: Final prototype



Addressing global variations in head size/shape was a crucial step in generating an internationally successful treatment and product. Initially a product range (3 sizes) for Caucasian head shapes was developed. Global variations in cranial anthropometry (head size/shape) were then evaluated, generating a 3D-scan database, ultimately leading to the mass production of a further 3 cap sizes/designs tailored to more rounded Asian head shape.

Research Outcomes & Dissemination

Peer Reviewed Conference Paper:

Unver, E., Sorbie, C., Silkstone, R., Kagioglou, M., Paxman, R., Burke, P., (2016) Design and Development of a Medical Product Using 3D Technologies: Scalp-cooling Cap Design Case Study. In: International Conference on Sustainable Smart Manufacturing (S2M), Oct 2016, Portugal.

Journal Papers:

Durgun, I., Kus, A., Unver, E., Jagger, B., Doruk, E. Findik, F. (2016) Experimental Investigation of Sheet Metal Forming Using a Recyclable Low Melting Point Alloy Tool. Materials Testing Journal, 58(5). pp.475-480. ISSN 0025-5300

Unver, E., Binder, J., Kagioglou, M., & Burke, P. (2020). An approach of rapid tooling for scalp cooling cap design. Computer-Aided Design and Applications, 17(2), 337-347

Exhibitions:

Unver, Ertu, Sorbie, Chris, Kagioglou, Mike and Paxman, Richard (2016) 3D printing for Medical Product Development: The Advantages of Additive Manufacturing to Reduce Cost of Design and Development in the Medical Industry: Paxman Case Study. In: Medtec Europe, New Medical Technology Device Events & Exhibitions, Stuttgart Germany.

Unver, Ertu, Swann, David and Paxman, Richard (2015) Exhibition Narrative: Scalp Cooling Cap 2015 MedTech Exhibition,Ireland.

Unver, Ertu (2015) Exhibition Narrative "Design, Development and Manufacturing of Scalp Cooling Cap" at 2015 Medica/Compamed Exhibition, Dusseldorf – Germany.

Unver, Ertu (2016) Exhibition of Design, Development and Manufacturing of Scalp Cooling Cap. Arab Health, Dubai.

Patent 1:
Granted in UK and Japan.
Published in Europe, USA and China.

Heat Exchanger: Unver, E., Paxman, G. A. & Paxman, N., 2016.

Patent Office	Publication Date	Publication No.	Link
WIPO	31.03.2016	WO/2016/046534	https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2016046534
UK	30.03.2016	2530496	https://patentscope.wipo.int/search/en/detail.jsf?docId=GB160582217
Europe	02.08.2017	3197407	https://patentscope.wipo.int/search/en/detail.jsf?docId=EP201411662
USA	18.08.2017	107072808	https://patentscope.wipo.int/search/en/detail.jsf?docId=CN204732692
Japan	12.10.2017	2017530327	https://patentscope.wipo.int/search/en/detail.jsf?docId=JP274717300
China	24.08.2017	20170239082	https://patentscope.wipo.int/search/en/detail.jsf?docId=US203342534

Patent 2:
Granted in UK.
Published in Europe, USA and Japan.

Heat Exchanger Cap: Unver, E., Paxman, G. A. & Paxman, N., 2016.

Patent Office	Publication Date	Publication No.	Link
WIPO	31.03.2016	WO/2016/046535	https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2016046535
UK	27.01.2016	2528512	https://patentscope.wipo.int/search/en/detail.jsf?docId=GB154525720
Europe	02.08.2017	3197405	https://patentscope.wipo.int/search/en/detail.jsf?docId=EP201411660
USA	24.08.2017	20170239083	https://patentscope.wipo.int/search/en/detail.jsf?docId=US203342535
Japan	05.10.2017	2017529155	https://patentscope.wipo.int/search/en/detail.jsf?docId=JP274717306

Conclusion

This research revolutionised the design and the manufacturing process of the Paxman scalp-cooling cap. The resulting product has achieved regulatory approval internationally (including FDA in USA and Shonin in Japan), and has been commercially successful in over 54 countries. Awards include, 2015 Medtech World Awards: Exhibitor Innovations Winner; 2015 Medilink Innovation Award; 2016 Medilink UK Awards: ‘Partnership with Academia Award’ and the 2018 BritishAmerican Business TransAtlantic Growth Gold Export Award, amongst others.

The impact of this research has been broad and significant, the central impact being the dramatic increase in clinical and patient access to effective scalp-cooling treatment, internationally. Achieving regulatory approval internationally and increased production capacity allows Paxman to now meet the needs of the global market and continue to supply an increasing number of the world’s largest healthcare markets. Furthermore, by enhancing treatment efficacy and patient experience, through design enhancements, global impacts on patient wellbeing have resulted. Paxman patients report positive impacts of scalp-cooling treatment on their mental, social and physical wellbeing, with 99% of patients reporting a positive impact on their emotional wellbeing. Awareness of hypenate scalp cooling, both clinically and generally, has increased. Commercially, as a result, SME Paxman are now recognised as the global leader in scalp-cooling, dominating the market with an 80% share and continued global growth, with turnover quadrupling between 2015 (£1.7M) to 2019 (£9.35M).

This successful collaboration has also led to the establishment of the World’s First Scalp Cooling Research Centre, based at the University of Huddersfield, with commercial investment of £1M.

Paxman map reflecting the cap distribution and market size.

Output Type:
Conference contribution, journal articles, solo exhibitions, contribution to collaborative group exhibitions, patents

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