Title:
**Application of CAD and Technical Testing for Developing Sustainable Textiles in Healthcare**

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Introduction:
Medical device manufacturing is a complex landscape that requires the harmonious collaboration of various disciplines [1]. Due to the complex and heavily regulated nature of medical devices, development leans on expertise from several disciplines. Particularly where the development of textiles is involved, the approach used in healthcare will significantly differ from the development of standard products such as jumpers. The developed materials must comply with ISO10993 biocompatibility testing, such as Cytotoxicity, for textiles that directly contact the skin, particularly for wearable designs. This framework utilizes a collaborative approach to the development of textiles with technical textile experts and medical designers.

In line with the UN's sustainable development goals, with responsible consumption and production [2], designers have an ever-growing demand to integrate more sustainable approaches to product development. Typically, in healthcare, thermosets and non-recyclable plastics such as Silicones and Neoprene are used based on their specific properties such as biocompatibility, infection control, and hydrophobicity that make them so suitable [3]. Paxman has undergone an Innovate UK-funded project to replace these plastics with recyclable, sustainable materials. Paxman manufactures scalp cooling caps for the prevention of Chemotherapy-Induced Alopecia. The wearable heat exchanger is worn on the head to induce vasoconstriction, limiting the delivery of drugs to hair follicles without causing scalp metastases. The caps are made of an inner cooling cap and an outer cover. The outer neoprene cap cover for scalp cooling is explored, and a new material is developed to replace the existing neoprene. Technical testing is applied in an iterative design approach, where certain parameters are applied that are typically not heavily used in the textile industry, such as heat extraction.

The textile and fashion sector in the UK is predominantly working towards imparting net zero and circularity [4]. To achieve a circular supply chain, industry standards are being altered, and the selection of eco-friendly and sustainable raw materials is being promoted. Technical textiles provide added value for specific technical applications in the fields of households, aerospace, automobiles, medicine, and geology [5]. Medical textiles deal with antibacterial textiles, scaffolds, bandages, high-sorption fibers, and drug delivery devices, which are needed during daily usage in healthcare [6-9].

An extensive literature survey and recyclability criteria of raw material production were used to select an alternative material to Neoprene, which is open-cell polyester polyurethane foam as the middle layer for the cap cover. Open-cell foams are readily available, low in cost, recyclable, and possess a high thermal insulation property due to their open-cell structure [10]. These types of foams are seldom used in the field of medical products. Huge progress has been made in medical textiles due to the demand for such materials. The testing phase related to medical textiles involves the evaluation of specific properties, including sorption behavior, wicking properties, thermal resistance, material strength and extensibility, and biocompatibility [11-12]. This article provides how CAD can be utilized to design a bio-compatible and eco-friendly medical textile that can be used for scalp cooling during chemotherapy treatment.

Methodology:

A mixed methods approach where iterative design [13] is used to integrate textiles and product development to produce a new approach that could be beneficial for researchers and medical design industries. This approach required a new method for implementing test procedures with CAD tools for knowledge exchange between the disciplines for new procedures, new devices, and testing kits. These approaches are important for the successful implementation of medical regulations and suitable engineering methods for wearable soft-good medical devices. These approaches can be applied to develop new approaches for new products to improve health worldwide.

Computer-aided design:

CAD packages were essential to developing prototypes in collaboration with textile experts to understand the composition of the materials so fabric patterns could exploit certain parameters such as directional stretch and natural compression. In this, software and CAD packages previously explored or already used by R&D teams at Paxman and Huddersfield University were explored to develop optimal cap cover designs. Textile design and pattern-cutting oriented CAD packages like Optitex and Clo 3D were analyzed [14]. For design and development, SolidWorks was used to generate DXF files for pattern cutting and technical drawings for manufacturing. Also, Blender is analyzed for educational purposes, where a more organic approach to modeling is used for rendering and animation for knowledge exchange between nondesigners. For this project, to bridge the gap between industry and Academia in an area the SME had little experience with, the R&D teams at Paxman had to investigate several CAD packages, Optitex, Clo3D, Illustrator, SolidWorks, and Fusion. Where samples were needed, laser cutting was the predominately used technology due to their accuracy and suitability with a plethora of various materials used. These machines used DXF files predominantly, and the chosen laser cutter was a Glowforge Pro, where the premium Glowforge software was used to cut out samples, as shown in Figure 4 below. In this project, the team used SolidWorks to generate the CAD and an exported DXF for use with the Glowforge Pro software for laser cutting.

Technical considerations:

As this project investigates the development of new materials to potentially replace neoprene from an outer cap cover for scalp cooling, the Paxman neoprene cap cover is used as the case study. An outer fabric layer or sleeve is typically used to develop a wearable heat exchanger on the body. The main purpose of these garments is to insulate the heat exchanger, preventing unnecessary extraction of heat energy from the ambient environment, ensuring heat extraction is targeted at the subject, and reducing the unnecessary increase of coolant temperature caused by external heat.

Several crucial parameters are considered as inputs for the new selection process. The Neoprene cap cover consisted of three layers (Neoprene, polyester, and terry nylon, shown in Fig 1). The outer layer is for aesthetics and infection control, the middle layer is insulative, and the inner layer is biocompatible and comfortable for direct skin contact. The new cap cover prototypes were designed using materials that followed extensive research against the parameters outlined by the existing cap. In Fig 1 below, prototypes were manufactured from a bespoke open-cell polyester polyurethane foam consisting of three layers: open-cell foam at the center, polyurethane-coated polyester fabric, and brush nylon fabric at the top and bottom layers (Figure 1). The thickness of the open cell foam was varied to obtain prototype cap cover samples of varied thickness, which are 8, 13, and 18 mm. All the layers of the cap cover were flame laminated together to retain sustainability and to form a composite fabric, which was used for further testing.

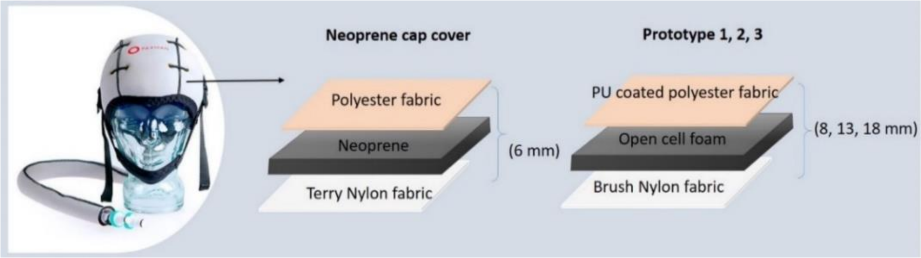


Fig. 1: Flow chart representing the cap cover samples of Neoprene and new prototypes.

Technical textiles testing:

2 main parameters crucial to the function of the cap are presented: thermal insulation and water vapor permeability (WVP), though a plethora of parameters have been evaluated. Utilizing the expertise and facilities in the Technical Textiles Research Centre at the University of Huddersfield, in collaboration with Paxman on an Innovate UK SMART project, the team was able to iteratively explore over 50 material types, blends, and grades of fabrics in over 200 prototypes. An interdisciplinary approach to wearable prototype development may include generic design processes to bridge the gaps in knowledge, as shown by the taxonomic classification of visual design representations [15]. However, 2D design still plays an important role in the fashion industry, where 2D CAD is predominantly used, though 3D CAD is still explored [16]. Testing methods for textiles and CAD are largely used, as seen in the University of Huddersfield [17], particularly in the Technical Textiles Research Centre.

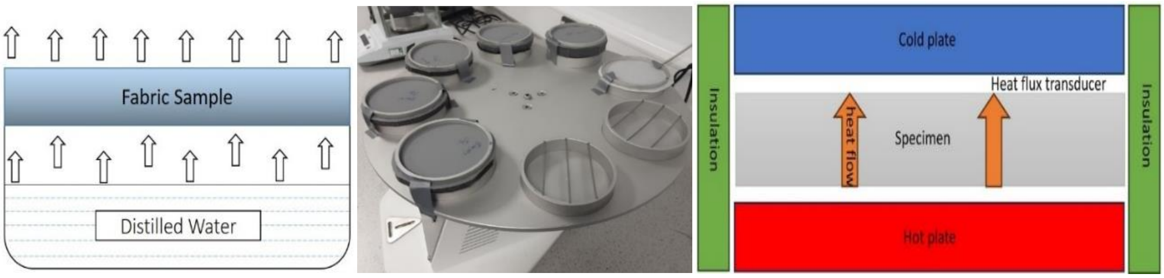


Fig. 2: Thermal conductivity testing and WVP testing machines.

All the cap cover fabric samples were tested for thermal conductivity following the ASTM C518 testing standard. 20x20 cm fabric samples were used for the evaluation of thermal conductivity. The testing was conducted on a thermal conductivity instrument (TA-Instrument-Waters LLC) which represented a heat flow meter. The conductivity of the samples was calculated at a temperature range of 10-40°C. The testing sample was placed between two plates of varying temperatures (10 and 40oC), and the heat flow was directed from the bottom plate to the top plate. The instrument generated the data for thermal resistance, which was further used to assess the thermal insulation of the fabric in TOG.

All the cap cover fabric samples were tested for WVP following the BS 7209:1990 testing standard. 9 cm circular fabric samples were used for the WVP tester (TESTEX). The samples were fixed on a disc containing water (measured by weight). The WVP index was calculated by observing the difference in weight of the amount of water that was left over after 24 hours. of the experiment. The water vapor transmission rate was calculated with respect to a reference sample according to the standard.

Discussion:

All the cap cover fabric samples were conditioned at 20±2°C and 65% relative humidity for 24hrs. before the testing. All the prototypes showed higher mean thermal insulation value compared to Neoprene fabric samples (Fig 4). The foams used in the prototypes are open celled which has hollow cavities in their internal structure. These cavities create air pockets which improves the insulation property of the material [18]. From Prototype 1 to 3 a gradual increase in mean thermal insulation with the increase in thickness of the sample (Fig 3). Thus, it can be confirmed that thermal insulation of the open cell foam prototypes is dependent on the thickness of the material. Therefore, the open celled foam can be used as a possible replacement for Neoprene.

All the prototypes show higher WVP compared to Neoprene fabric samples (Fig 3). As the thickness of the open cell foam prototypes increased the WVP also increased. This suggests that if condensation occurs the transfer of the moisture through the fabric will be quicker for a thicker fabric, suggesting the presence of micro-pores within the open cell foam which can aid in the diffusion of moisture through the fabric [13]. The WVP of Prototype 1 is comparatively closer to the WVP of Neoprene sample, which did not show any condensation during the 3hr cycle. Due to higher thermal insulation of Prototype 1, it has a higher tendency to maintain the temperature of the micro-climate of the wearer compared to the Neoprene cap cover. At the same time, the presence of micro-pores inside the open cell foams will make the material breathable, and the wearer will not feel any discomfort if condensation takes place. Thus, among the samples tested, Prototype 1 could be accepted as an optimized sample in terms of thermal insulation and WVP.

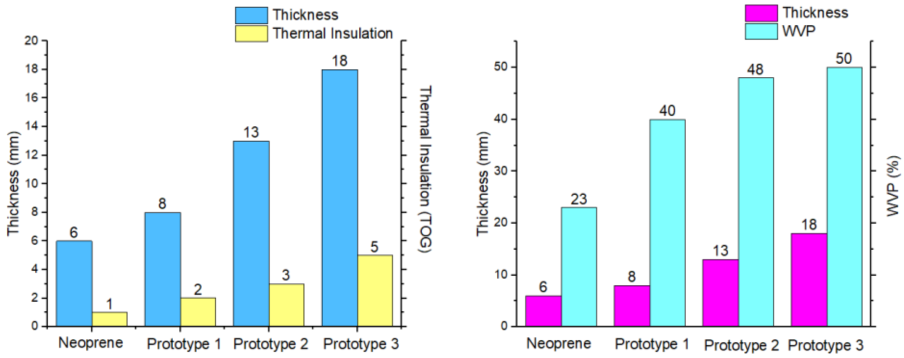


Fig. 3: Plots for thickness and thermal insulation (Left), Column plots for thickness, and WVP (Right).

Conclusions:

Paxman R&D teams understand the importance of multidisciplinary collaboration in the development of medical devices. For SMEs, it can often be difficult to justify investment into completely new areas or new CAD technologies and equipment for testing when it can be outsourced to academic institutions. Collaborations with academia are seen as essential, where you get access to not only state-of-the-art facilities and equipment but also skilled people and knowledge that are constantly being explored. In this project, the R&D teams at the University of Huddersfield and Paxman have collaborated with the technical textiles research Centre to successfully develop an alternative 3-layer solution to the existing Paxman scalp cooling cap cover. With this, extensive testing using various software and CAD packages outlined above not only streamlined the development process of materials but also the design process, enabling the design teams to exploit the properties of the materials explored and developed fully. From this, it has been possible to optimize designs in other areas by reducing parts through self-compressive properties, which improve the efficacy and sustainability of the cap.

Further collaboration with the Technical Textiles Research Centre will be used to investigate the Life Cycle Analysis of the existing (Neoprene) and prototype cap covers using the SimaPro software. This will provide a detailed comparative study of the environmental impact assessment of the cap covers and allow the R&D design team at Paxman to investigate various raw material, manufacturing, designing and process aspects to reduce the environmental impact of the cap covers thus opting for a sustainable and eco-friendly supply chain.

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