An Approach for Industrial Designers to Accelerate Validation in Wearable Medical Devices Through Programmable Sensors

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Abstract. The application of CAD, 3D printing, sensor rig devices, and AI-assisted code generation to carry out testing during the new product development process would benefit SMEs. This research is an early application of how these testing methods are effectively developed and applied in commercial settings by Industrial Designers without employing professional experts. AI-assisted code generators and relevant tools can be integrated into the Industrial Design process to creatively generate many design iterations in the future, not only for concept generation but also for more regulated areas such as medical product development. In this research, Industrial Designers propose a new approach for producing a low-cost testing rig development method as part of a new medical product development process for Scalp Cooling as a case study.

Keywords: Wearable product design, Industrial Design, Software Programming, Sensor rig development, Rapid Prototyping, Human data collection.
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1 INTRODUCTION

The accelerating pace of technological advancement has opened new avenues for Industrial Designers to acquire specialist skills and deploy more multidisciplinary tools. This paper explores the challenges and opportunities in adopting multidisciplinary approaches, specifically in the context of Industrial Design, design engineering, and software engineering collaboration. While these skills are integral to the development of wearable technologies, they are often managed by distinct teams, leading to a significant learning curve for designers taking on new roles.

This study uses scalp cooling as a case study for wearable cooling, using Paxman Coolers LTD as the *Medical SME*. Recent studies [16] have shown links to improved clinical efficacy through closer fit to the patient's scalp. This Study presents the development of a programable pressure-sensitive test rig with the integration of 3D printing and sensor technologies to streamline the design and development of medical wearable devices for small and medium-sized enterprises (SMEs) by assessing contact variability for effective treatment. Benefiting from using Arduino and various software packages to accelerate the development process with objective-driven metrics to increase efficacy in a heavily regulated medical device market where the opportunity to change designs is limited.

The importance of fit [16] for this process drives the use of recent technologies required for this process to assess the closeness of the cap to patients' heads. The development of this sensor rig will assist the R&D teams at the *Medical SME* validate designs and verify the processes to avoid subjective results by simulating a controlled environment initially, rather than human participants who can often largely vary in cranial anthropology and thermoregulatory responses. Figure 1 below shows the *Medical SME* cap and cover used for scalp cooling treatment. These are used initially with this sensor rig development and some bespoke designs where mass-personalized 3D printed caps were made for this testing process.

Building testing systems (Rig development) traditionally relies on professional input, specialized knowledge, and expertise [18]. This research, however, focuses on the development of a low-cost testing rig where minimal external expert input is utilized. Testing of medical devices necessitates calibrated technical equipment, especially to ensure regulatory compliance [7,5]. While readymade testing rig systems are available for purchase [4,12,19], in some specialist applications, bespoke testing tools may be required. These rigs can be acquired through purchase, rent, or subcontracted to specialists for the development of a specific application. Developing in-house testing systems becomes crucial for reducing product development cycles, especially where the end design goal is unknown and customization is required. In such cases, low-cost, off-the-shelf parts can be integrated into new systems, such as sensors on a bespoke rig.

In traditional practice, an Industrial Designer is typically recognized for their creative and visual communication skills, with a background that does not typically involve coding. Traditionally, the industrial design process incorporates methodologies such as design thinking or the double-diamond design process [3]. These structured approaches provide a framework for problem-solving and innovation in product design and development. This study specifically investigates and illustrates how Industrial Designers can effectively leverage current technologies within their Design process in the absence of software engineers where the advantages and disadvantages of this approach will be discussed, defined by the design inputs and protocols for the application of scalp cooling.

Figure 1: SME silicone cooling cap & cover (left), personalized 3D printed cap (right).

2 LITERATURE: DESIGN CHALLENGES FOR SME INTEGRATION

The medical device industry has unique requirements, requiring considerable science and technology management, where extensive testing, clinical trials, regulatory hurdles, and prolonged development cycles are involved [7]. When addressing scientific and technical innovation within this industry, it is critical to have a clear understanding of the clinical need, market potential, and technical risks [5,7]. Companies must develop products that meet their target customers' diverse, individualized needs while maintaining low production costs and product development cycles [14]. Exemplified in the medical device development market as patient access (test subjects) are limited and can be controversial, and clinical trials are costly, time-consuming and resource-heavy [7]. Newer research suggests Industry 4.0 technologies could shift this paradigm by increasing designers' access to data and innovations that lead to improved product design quality [14].

The product development process is often broken down into various tasks and processes and characterized by a clear division of labor where each activity is assigned to specific skilled staff and departments [5,8,16] such as engineers, designers, software developers, and quality officers. Industrial Designers work on various stages of product development, conceptualizing prototyping and final production. Combining artistic flair, business, and engineering to develop the concepts for physical manufactured objects, devices and products [3,8]. Various researchers point to Industrial Designers' strong ability to incorporate and employ multiple knowledge across multiple domains. In which the Industrial Designer can be interpreted as a jack of all trades, master of none [8] but oftentimes better than a master of one.

In the early stages of product development, project planning must deal with uncertainty to reduce the risk of project failure. Many researchers studied generic product development, testing and validation, including design analysis, modelling and simulation, physical tests, and analysis of test [17]. Early in the medical device development process, Industrial Designers must have a more comprehensive understanding of user needs, regulatory needs and mitigate significant risks posed to users and stakeholders [5] compared to generic product development. Traditionally Industrial designers collaborate closely with engineers and healthcare professionals to select relevant testing kits and sensors that align with the intended use and functionality of the medical product. Generally, larger enterprises have more resources at hand and a close collaboration between professions is not only desirable but necessary for the eventual success of a product [8]. However, an Industrial Designer operating within a small SME may take on various roles, further exaggerating the jack of all trades label. The challenge within SME's integrating industry 4.0 initiatives and high-level sensors are expensive, limiting some SMEs, from leveraging product design features [14].

Recent advancements in industry 4.0 and AI tools demonstrate their application across various stages of the design process, including idea inspiration, concept generation, evaluation, and design optimization, significantly contributing to the creative and decision-making processes in Industrial Design [22, 23, 24, 25]. Existing research raises questions about AI's influence on design and its role in fostering innovative solutions [23]. AI's support for knowledge-intensive activities has been shown to enhance productivity and innovation [23, 26]. However, as noted by Vocke et al. [2019], further research is needed to develop methodologies for identifying AI's application potentials and establishing new forms of human-machine interaction to enhance innovation processes [22].

The application of CAD and AI is evidenced in Yoo et al.'s study [26], where numerous 3D model candidates for a vehicle wheel were generated and collaboratively evaluated by engineers and industrial designers. Although this paper will not be addressing data interpretation, extensive research highlights AI's capability to analyze vast amounts of external data, significantly enhancing automated product design and development. Additionally, AI systems aid in creating design prototypes and iterations, enabling designers to refine and select the most promising concepts, thereby increasing efficiency and reducing time-to-market (Wang, Zhang, & Wang, 2019) [27]. The integration of AI in product design introduces a new era of adaptive and iterative design processes [25]. This iterative approach aligns with the practice based agile development methodology, where products undergo refinement through a series of incremental changes based on insights.

Although AI has numerous applications in Design, there are very limited studies where the Industrial designers themselves, with the help of AI integrate sensors, utilizing jigs, and leveraging 3D printing technologies to enhance the efficiency and effectiveness of the product development process. (Elahi et al., 2023). To address these challenges, this paper proposes the development of a 3D-printed programmable pressure-sensitive sensor test rig by Industrial Designers.

3 METHODOLOGIES

The Product design process is practice based, utilizes mixed methodologies such as Design Science and approaches like Agile [16] and Design Thinking [3] to help capture the evidence and feedback required to iteratively improve the medical device, whilst complying with regulations. Figure 1 highlights this, where user testing, validation and verifications make up the latter stages of each iterative loop.

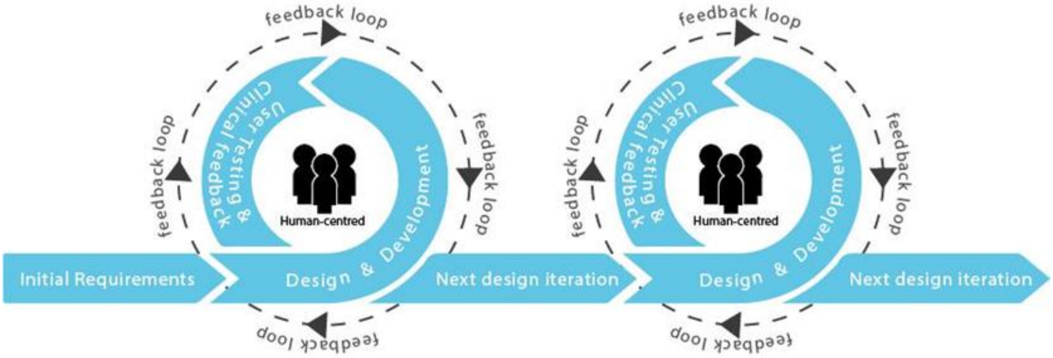

Figure 2: Iterative waterfall feedback loop.

4 BACKGROUND

This commercially funded research contributes to the goals set out in the Research and Innovation Centre of *the Medical SME*. The approaches developed in this research will streamline the assessment of feasibility, validation, and verification processes required for medical devices, particularly in wearable cryotherapy. Chemotherapy-induced alopecia (CIA)/hair loss is recognized as one of the most traumatic side effects of cancer treatment, affecting annually 65,000 UK patients and 3.12 million worldwide. CIA is considered one of the most traumatic factors in cancer patient care and occurs with an estimated incidence of 65% [16]. Hair loss negatively affects a patient's perception of appearance, body image, sexuality, and self-esteem [16].

Critical to the success of hair retention is the optimal fitting of the cap and its close contact with the scalp. Geographical variations in head shapes [1,16], as indicated by the cephalic index, further compound the challenges of achieving reduced hair loss globally. As a result, ensuring anatomical and ergonomic considerations becomes imperative. Patients are often required to wear a cap and its associated cover to provide optimal thermal management to the scalp. The cap comprises two aspects: the wearable heat exchanger and the outer insulating cover, as displayed in Figure 1 above. This outer cover prevents the dissipation of heat from the head. It is equipped with a fastening mechanism that allows for tightening the cap to ensure a snug fit over the scalp, thereby optimizing the heat transfer efficiency [16]. Patients often express discomfort with chin straps, attributed to most downward forces being anchored on the chin. Evaluating comfort, a sensor placed at the chin becomes a valuable method, offering a comparative assessment for wearable design iterations. The duration of treatment may extend up to five hours, presenting additional challenges to designers due to regulatory complexities and limited access to patient testing.

The Norwood/Hamilton scale for men [6] and Ludwig scale for hair loss for women can be used as a guide to outline seven anatomical scalp regions: Frontal, anterior mid-scalp, vertex, crown, occipital, temporal, and nape [6] in figure 3 below. Scalp cooling studies indicate hair loss is particularly pronounced in the crown region. This phenomenon may be attributed to anatomical and biological contraindications or issues related to the fit and design of the current cap.

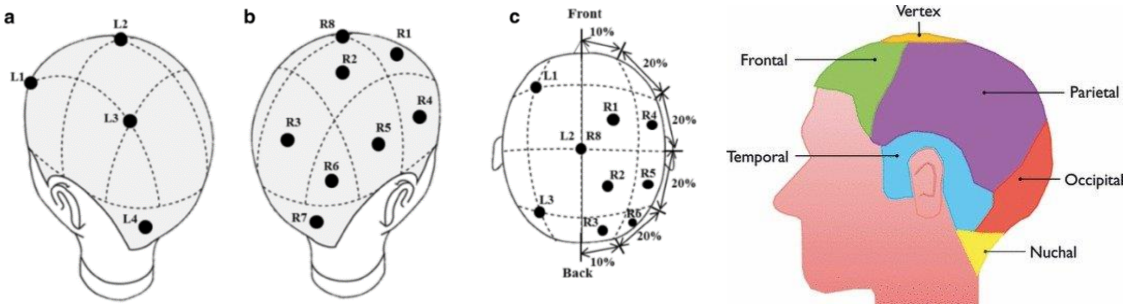

Figure 3: Measurement: regions on the scalp (left), Anatomic regions of the scalp (right) [6].

Figure 4 depicts an adaptation that integrates literature on scalp regions and background knowledge to identify 11 crucial regions relevant to the specific application of scalp cooling for pressure measurement.

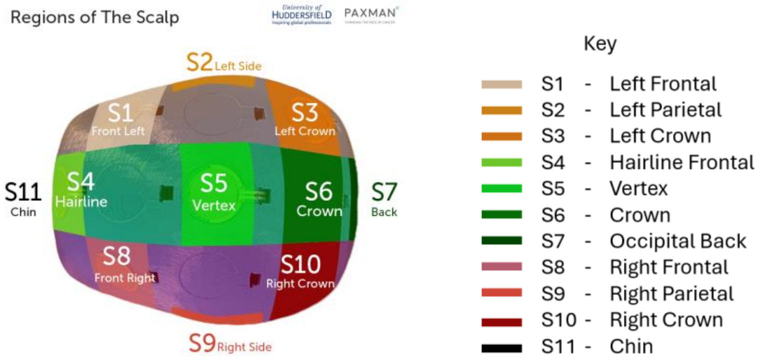

Figure 4: Adapted Measurement: regions on the scalp for sensor location placement

The scalp is complex in shape, and attuning to various global cranial anthropologies is a challenge. Research shows pressure sensors are used in sports science, therapeutic, and apparel industries. SMEs can implement this technology to develop their testing systems. Some applications exist in the medical industry but not for the proposed application. Research on military helmet comfort using a flexible pressure matrix for Asian head styles is evaluated [12]. Similarly, Tekscan uses flexi-sensors to aid in concussion detection by measuring linear and angular head accelerations impacting football helmets [21]. There are many applications of wearable foot pressure sensors for human gait analysis in the sports injury/physiotherapy industry [4]. Foot and body mattress mapping sensor pads to measure pressure distribution are used in medical mobility and diagnosis [19]. Other sensors and head pressure mapping rigs exist, such as TactileHead, costing upwards of $30K [20]

Other industries evidence the use of sensors for testing, though these sensors are overly expensive, with specialist teams working on their development, and in some industries require less in-depth specifications. Medical applications are limited due to regulatory constraints of bringing new devices to market and limited patient access. This could make it difficult for SMEs to justify expenditure for developing testing rigs on product designs that might not get to market. A new method is deployed for SMEs as resources and applications are limited to assist an industrial designer and need validations during the early phase of design and development. Also, a useful method later to support proof in technical files in medical design.

5 THEORY: TESTING SYSTEM (RIG) DEVELOPMENT

A test rig can be defined as a bespoke research and testing device designed for a specific application. It is a form of hardware prototype built for lab testing new ideas to collect data on set parameters and functionality [18]. Typically, off-the-shelf testing rigs and systems can be purchased or subcontracted to specialists for the development of a specific application. In this case, a pressure-sensitive testing rig has been developed. As an Industrial Designer, I underwent short basic training to familiarize myself with basic coding and interfacing with microcontrollers and sensors. Online tutorial training was undertaken utilizing university resources. The pressure-sensitive testing rig incorporates 11 strategically positioned thin programmable sensors on the head, complemented by a proprietary LCD screen for real-time readings (Figure 5), and connected to custom software developed to display live pressure data in a bar chart format. The sensors denoted as S1, S2, S3, etc., correspond to sensors based on specific anatomical locations shown in Figure 4. The device is constructed using an Arduino Mega, force sensing resistors assembled on a stripboard with jumper cables, and 3D-printed cranial heads and casing.

Figure 5: Testing wearable design combinations on Pressure Sensitive 3D Printed Head Rig.

Sensors are actuators capable of detecting changes in physical stimuli. Actuators encompass a broad spectrum, including light, sound, and more. In this context, the focus is on piezoresistive force-sensitive resistors (FSR). These sensors exhibit a variance in their resistance depending on how much force, pressure, or mechanical stress is applied. They can be interfaced and programmed with low-cost open-sourced microcontrollers such as Arduino or Raspberry Pi [9,11]. Within the programming framework, an Industrial designer implemented functions to decode and translate voltage values into human-readable and interpretable data. For SMEs, low-cost feasibility rigs may be required for early design validation prior to scaling up and higher investments into more expensive testing with external bureaus, such as regulatory testing for 60601 [5]

For the creation of the 3D human head, 3D scanning of medium western head styles is used to measure various parameters of the human head [2]. The mesh data is cleaned up, and the topology of the model is optimized in CAD [2]. Features are integrated with surface modeling in SolidWorks to attune to mesocephalic, brachycephalic, and dolichocephalic head styles [2], which were all printed using rapid prototyping facilities. 11 Sensors were placed on different anatomical scalp regions at the hairline, frontal section vertex, crown, occipital, temporal sides, and chin, following the adapted Norwood Hamilton Scale [6] shown in figure 4 and 6.

Sketch dimensions of sensors were replicated in SolidWorks from technical data sheets and offset from the head geometry using a plane, determining sensor placement in regional scalp subdivisions (Crown, Nape, Temporal). Corresponding surface offset cuts from the head were cut using specific depth thickness for the sensors shown in (Figure 7). Ensuring a seamless fit while accommodating potential variations for Fused Deposition Modelling (FDM) tolerances. CAD geometry was mirrored, incorporating locator points in the CAD software for proper fitting of the STL on the printer's build plate. Although an 0.8-1mm nozzle could expedite printing time, the specifications were selected to preserve detail and dimensional accuracy for the integrated sensor cavity. Figure 6 shows the locations of the pressure sensors on a 3D-printed head.

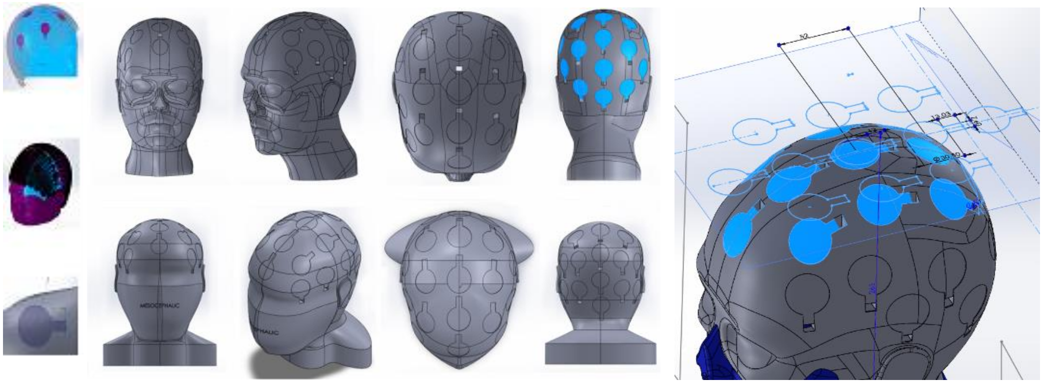

Figure 6: CAD geometry and pressure sensors.

The FSR30 sensor was chosen over alternative sensors, such as soft sensors, conductive textiles, or ink-based sensors, based on its ability to meet the necessary level of sensitivity required for the specific application, cost, time to integrate, and coverage of surface area to the anatomic scalp region. While these sensors are conventionally flat, the application should accommodate complex head geometries, necessitating a design capable of wrapping around curvature rather than adhering to a flat, linear plane shown in Figures 6-7. The sensor should not bend excessively, as this could result in voltage fluctuations and compromise the reliability of the data obtained. The Rig is optimized to incorporate a hollow design, allowing for the passage of wired cables internally, which connect to the Arduino analog inputs shown in Figure 7.

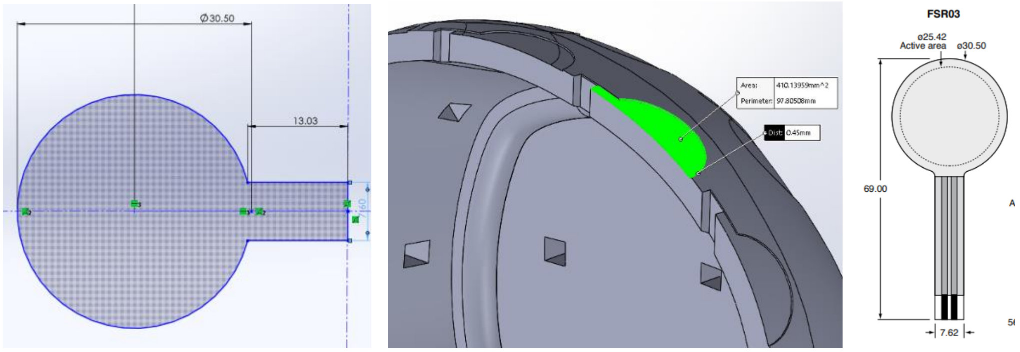

Figure 7: Linear and curved interface for the sensor.

5.1 Software Development and Utilization of AI

In the realm of Industrial Design, the rapid progress in modern technology, including advancements in Artificial Intelligence (AI), empowers designers to equip more skills in their arsenal and can bring a revolution to working environments in various professions [15]. The explosion in large language models (LLM) such as ChatGPT, conversating on a wide range of topics, introduces the potential for a distinct workflow [15,12]. Preliminary insights indicate and have shown capability in teaching, providing explanations to technical queries, optimizing and diagnosing code [15] by offering valuable fixes and guided advice. This diminishes barriers to entry but also reduces the learning curve where basic knowledge may suffice. Particularly advantageous for designers in (SMEs), where access to individuals with specialized software skills can often be limited.

Within this process, the overall code was written with the Industrial designers' prior knowledge of coding and basic experience with Arduino and Python from online tutorial training and university recourses. For the rig, the program script is written to facilitate the transfer of sensor values through a serial USB COM port, displaying live readings on a graph, see Figure 9. The AI chatbot tool ChatGPT was used to produce, modify, and enhance certain aspects of the code. Writing scripts traditionally begins with reference to the programming language documentation and online tutorials easily accessible through search engines. With assistance of AI, an Industrial Designer does not require expertise in coding but needs to understand the basic Python skills for how to guide the code to design the device. Initially, the designer can prompt ChatGPT or any AI LLM chatbot as demonstrated: *"how to interface with FSR10 sensor?".* (figure 8) Which returns instructions alongside valid code to copy and paste into the Arduino IDE (Intergraded Development Environment). The project could also get started by searching GitHub's public repository for a boilerplate template of previous projects which interface with the same sensor module [13]. In this instance, picking up previous projects from GitHub was slightly favorable in getting a project started. However, both processes would suffice, and it would depend on the practical relevance for further studies.

ChatGPT, when prompted with less technical jargon, is still effective: "Explain *this code so I can add more sensors*." Ordinary Industrial Designers/students who may not have extensive coding experience can effectively utilize this approach to interface with computer software/device electronics. If a bug or error arises, traditionally, online community websites such as Reddit or Stack Overflow are commonly used to help developers learn and share their programming knowledge via questions and answers. ChatGPT can also be used to reduce the response/reply time and direct input from experts by prompting: "*This code is not working, please suggest changes" or "The IDE gives an error code XYZ123, please write a fix*". Further, it provides industrial Deisingers with accessibility to attaining multidisciplinary tools within their design and development process. Frequently, a solution would be found, but often, this would not be useful. Additional work was still required, and reference back to Stack Overflow, iterative testing, and a combination of previous knowledge would be required to fix the errors.

The technology setup involves an Arduino Mega, a 20x4 LCD, and jumper cables soldered to a stripboard. Using Arduino's Integrated Development Environment (IDE), the script reads the sensor resistance value at the Arduino analog pins A0, A1, A2…, and A12 then converts it to a "force" value. A loop function continuously updates the 11 analog inputs and prints their correlating values out of 100 on the 20x4 LCD Screen. Additionally, the script sends sensor values to the Serial Monitor, which can be accessed through the Windows terminal or the Arduino IDE. After design approval, the electronic schematics from a breadboard were transferred and securely soldered at each connection point, ensuring a robust fit. The schematics are shown in Figure 10.

5.1.1 Graphical User Interface (GUI)

The development of the GUI involves creating bespoke software written in Python and utilizing Matplotlib's comprehensive graph plotting library to create static, animated, and interactive visualizations. Matplotlib was preferred over alternative packages like MATLAB and Plotly. Its ease of adoption, open-source nature, and accessible documentation make it beginner-friendly, particularly for Industrial Designers possessing limited software programming skills.

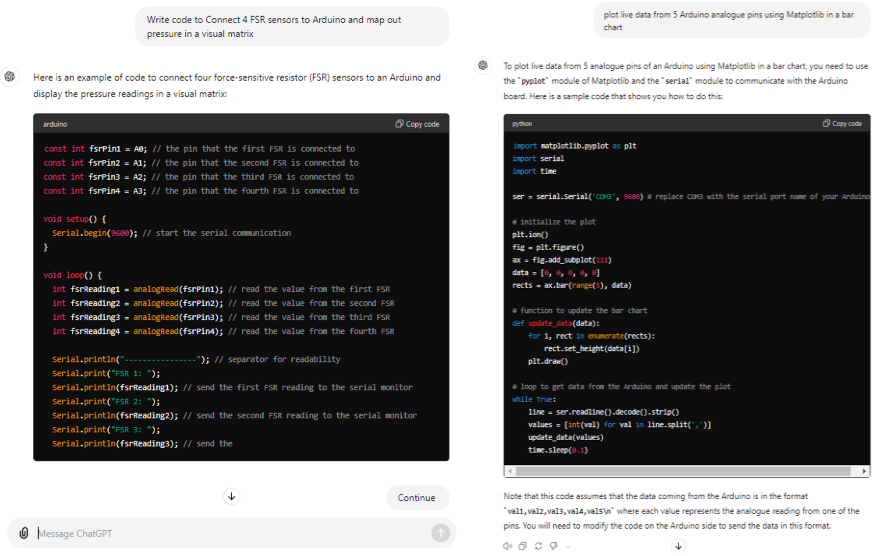

Figure 8: ChatGPT Prompts and code response for programming the Arduino and software.

Figure 9: Pressure Sensitive 3D Printed Head Rig.

In contrast, MATLAB, not being open source, presents additional barriers. Plotly, while powerful, is more convoluted and suited for sophisticated and elaborate visualizations. These factors were crucial for its suitability and adoption within an SME. Plotting is accomplished using matplotlib with a function invoked within the script. The figures are continuously updated in a loop as new data is read from the serial port. The baud rate and port name of the Arduino serial connection are written to be automatically identified through the script. A data decoder function to convert the received data to plottable values. A bar chart function to plot the data in the form of a live bar chart. GUI can be seen in Figure 5 above on the laptop screen.

6 DISCUSSIONS

A ubiquitous tool such as CAD remains beneficial for designers as it facilitates the creation of precise and detailed product designs. A comprehensive evaluation was conducted on the pressure-sensitive head rig, involving the testing of over 200 prototypes of wearable designs. These prototypes encompassed a diverse range of patterns, materials, shapes, and other design elements, aiming to assess and achieve the optimal fit and comfort for patients undergoing treatment. The results revealed variations of contact across different wearable designs, demonstrating a level of sensitivity difficult for human senses to acknowledge and, therefore, effectively mitigating subjectivity in user feedback and perception.

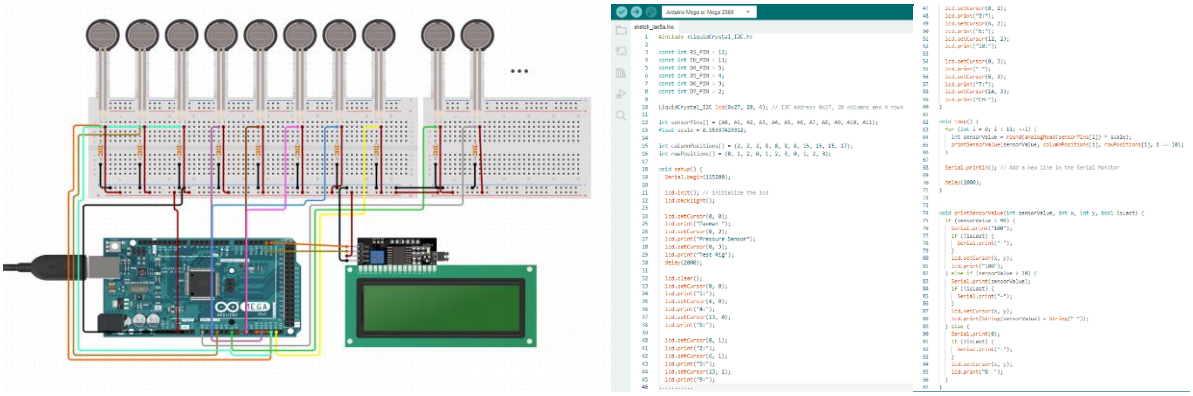

Figure 10: Arduino circuit schematics (left), IDE interfacing code with sensors and LCD (right).

Table 1 below presents comparative methodologies for testing designs, aiding decision-making within the development process. The table displays a comparison of different combinations of wearable inner cooling cap designs and outer cap cover prototypes tested on the pressure-sensitive rig. The aim is to assess the differences and determine which combination offers the best and most uniform fit with new prototype designs compared to the current product. The product was tested following the *Medical SME* fitting techniques and instructions. 10x repetitions were performed, noting down the sensor values 1-12 at each specific scalp region to gather a mean average value. The aim is to eliminate bias introduced by individual fitting preferences by ensuring tests are conducted with two individuals to ensure comparable results for a more objective and reliable assessment of the wearable design's performance.

Inner Cap	*No Cover*	*Current Cover*	*Sample 1 cover*	*Sample 2 cover*
Current (A)	10	53.3	34.4	..
Current (B)	15	67.1	68	72.7
Sample (C)	22	52.2	49.2	...
Sample (D)	16	67.1	69	69

Table 1: Mean average sensor values comparing wearable designs 1 (current product) vs 2 & 3 on a pressure-sensitive head rig.

Assessing fit for this application is limited because of the complexity of head shapes, hair types, material properties, and access to the patient pool. Currently, the process of determining the good fit of the wearable is inducted manually, where trained nursing staff would check for even contact distribution and limited gaps. This assessment of fit involves a tactile examination by hand followed by visual inspection, supplemented by feedback from the patient once the cover is tightened. The process, mainly relying on previous user experience and training, is not quantifiable or repeatable, and a measurement model is not able to support technical file documentation for regulatory requirements within an SME. The proposed prototype offers an alternative non-subjective approach while demonstrating how non-experienced Industrial Designers can use CAD, integrate coding, and use low-cost technological means, especially during the early design and development phase, to accelerate the assessment of fit and validate product function, as opposed to relying solely on subjective user feedback.

7 CONCLUSIONS

Throughout the development cycle of a new product redesign, over 200 wearable prototypes were meticulously evaluated, and each iteration was tested on the pressure-sensitive head rig. Engaging in an iterative cycle that explored various patterns, seams, sizing, materials, and other factors. The overarching goal was to accelerate the development cycle in finding a design combination to achieve the best possible fit and comfort for patients undergoing treatment.

The feasibility study has validated only the main facet of the extensive research conducted. The Industrial Design process typically follows the iterative double-diamond process whilst collaborating with more departments & stakeholders within medical device development. This study reveals a promising prospect for Industrial Designers to seamlessly integrate 3D printing and programmable, flexible sensors, significantly expediting the testing and aiding the decision-making processes in the development of new products, especially within the demanding landscape of the medical device market for SMEs.

It is important to acknowledge the persisting challenge of an individual mastering these multifaceted skills. This research opens new pathways for more professionals as technology evolves, indicating that we have not yet reached the fully integrated possibilities but are steadily progressing toward it. Nonetheless, developing in-house capability by designers will play a vital role in the future. There is still a place for industrial designers to acquaint themselves with these tools, which are useful in the early stages of reducing risks. Perhaps the role of the future Industrial Designer could be likened to a 'middleman,' connecting technology to humans via emerging technologies [8] or a vessel for change. Moreover, embedded knowledge is essential for a comprehensive understanding of wearable device development.

This study illustrates how an industrial designer has successfully developed a low-cost testing rig for wearable medical devices through programmable sensors to inform early-phase design and how an SME can benefit from the use of ID to carry out the testing process within their development process. A range of tools, including AI-assisted code generation, have been used to support this process.

Though this approach accelerates development while keeping costs low, this research shows it is still not a straightforward process due to the nature of Industrial Design. The work still requires a relatively long learning curve. Personal interest, whilst ongoing training and skill development are still necessary in several topics such as sensors, AI, and programming in a brief period of time. There still lies a gap in AI, automation, and adaptability to simplify the process further.

For future advancements and consistency, SMEs could establish a knowledge hub where sensor testing and similar activities could be conducted at a reduced cost, with researchers engaging in knowledge exchange to mitigate risks and expand networks. This hub could function akin to a research center dedicated to medical validation testing and wearable development.

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