Title:

A Method for Accelerated Medical Product Design Validation by Industrial Designers Using Sensors and AI.

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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, where recent studies [1] 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 utilizing 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. Building testing systems (Rig development) traditionally relies on professional input, specialized knowledge, and expertise [2].

This research, however, focuses on the development of a low-cost testing rig where minimal external expert input is utilized. This research shows how Industrial Designers in SME teams can effectively implement such systems and processes, even in the absence of software engineers.

Challenges for Designers to integrate with medical device SME's:

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. 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 [3,4].

Industrial Designers work on various stages of product development, conceptualizing prototyping, and final production. Combining artistic flair, business, and engineering to develop physical manufactured objects, devices and products [5]. Early in the medical device development process, designers must have a more comprehensive understanding of user needs, product functions, prove technologies, assess risks introduced, regulatory needs and mitigate significant risks posed to corresponding stakeholders [3] compared to generic product development. Recent developments in AI

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tools showed that AI techniques can be used in one or more stages of the design process such as idea inspiration, concept generation, evaluation, and recently design optimization, and decision-making [6].

Literature shows that pressure sensors are used in sports science, therapeutics, and apparel. Research on military helmet comfort using a flexible pressure matrix for Asian head styles is evaluated Foot and body mattress mapping sensor pads to measure pressure distribution are used in medical mobility and diagnosis. Other sensors and head pressure mapping rigs exist, such as TactileHead costing upwards of $30K [7]. Other industries evidence the use of sensors for testing, though these sensors are overly expensive, with specialist teams working on their development. There are very limited studies where the Industrial designers themselves, with the help of AI, integrate sensors, utilize jigs, and leverage 3D printing technologies to enhance the efficiency and effectiveness of the product development process. To address these challenges, industrial designers propose the development of a 3D printed programmable pressure-sensitive sensor test rig.

Background:

This commercially funded research contributes to goals outlined in the Paxman Research and Innovation Centre, aiming to streamline feasibility assessment, validation, and verification processes for medical devices, particularly in wearable cryotherapy. Chemotherapy-induced alopecia (CIA), affecting 65,000 UK patients and 3.12 million worldwide annually, is a significant concern in cancer treatment. CIA, with a 65% [8] incidence rate, profoundly impacts patients' appearance, body image, sexuality, and self-esteem [8].

Effective hair retention relies on optimal cap fitting and close scalp contact, complicated by geographical head shape variations [9,8] compounds the challenges of achieving reduced hair loss globally. Patients wear a wearable heat exchanger cap and a cover for thermal scalp management. The cap includes a wearable heat exchanger and an outer insulating cover with a fastening mechanism for snug fitting, enhancing heat transfer efficiency [8]. 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 offers a comparative assessment for wearable design iterations. Treatment durations of up to five hours pose design challenges due to regulatory complexities and limited patient testing access.

The Norwood/Hamilton scale for men and Ludwig scale for hair loss for women [10] can be used as a guide to outline seven anatomical scalp regions: Frontal, anterior mid-scalp, vertex, crown, occipital, temporal, and nape [10]. Scalp cooling studies indicate hair loss is pronounced in the crown region.

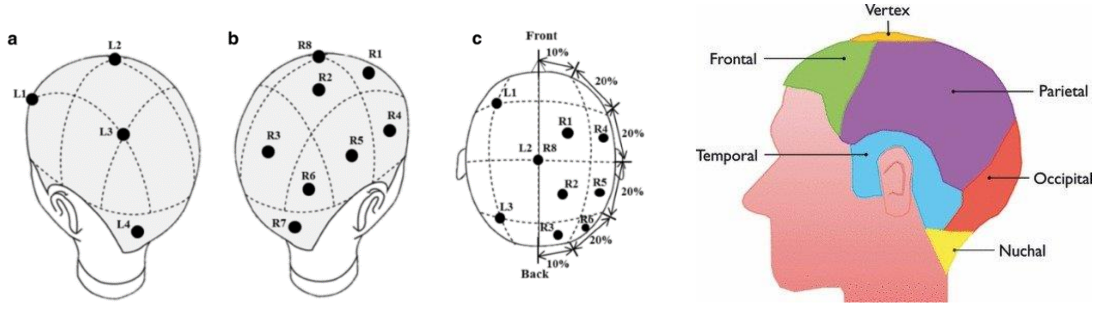


Fig. 1: Diagram of measurement regions on the scalp (left), Anatomic regions of the scalp (right) [10].

Testing System (Rig) Development:

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. The pressure-sensitive device incorporates 11 strategically positioned thin programmable sensors on the head, complemented by a proprietary LCD screen for real-time readings. Connected to custom software developed to display live pressure data in bar chart format. The sensors denoted as S1, S2, S3, etc., correspond to sensors based on specific anatomical locations. 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.

For the creation of the 3D Human head, 3D scanning of medium western head styles is used combined with measuring various parameters of the human head [11]. The mesh data is cleaned up and the topology of the model is optimized in CAD [9]. Elements integrated complex surface modeling, where mesocephalic, brachycephalic and dolichocephalic head styles were prototyped 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 Norwood Hamilton Scale [10].

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). which will vary its resistance depending on how much force, pressure or mechanical stress is applied. Suitable for the application as a low-cost sensor suitable within SME's, operates at a high level of sensitivity to the specific application tolerances, and easily transferable to many open-sourced microcontrollers such as Arduino [12,13].

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 2). Ensuring a seamless fit. While these sensors are conventionally flat, the application should accommodate for complex head geometries, necessitating a design capable of wrapping around curvature rather than adhering to a flat, linear plane.

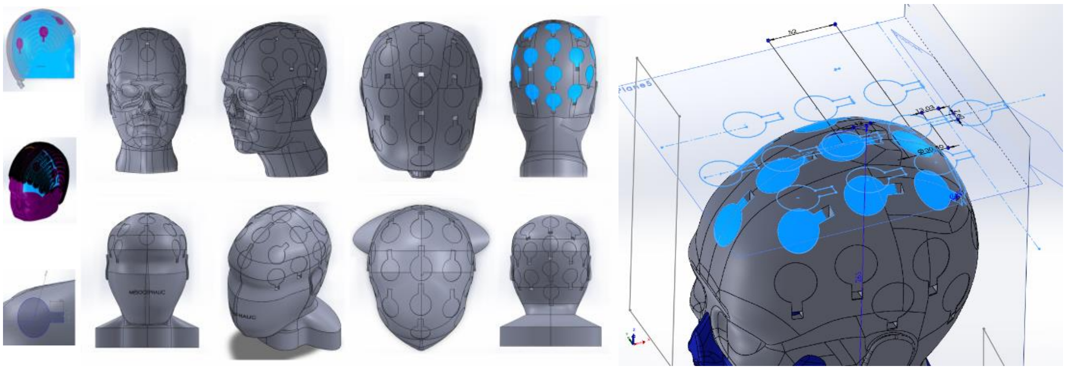


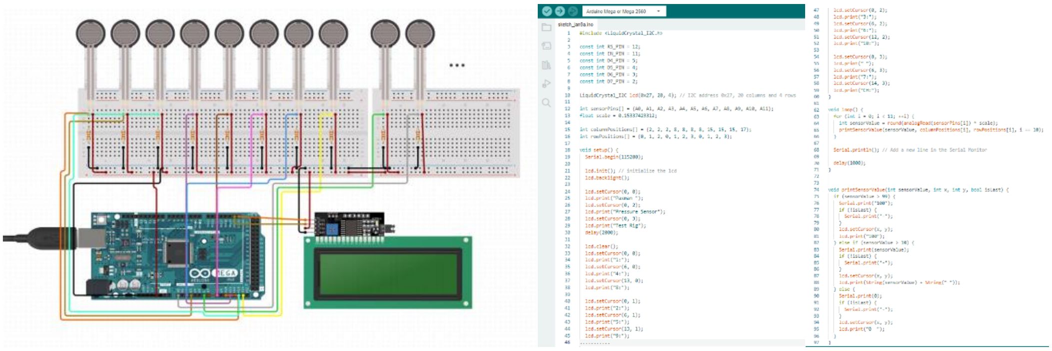
Fig. 2: Pressure-sensitive 3D printed head rig.

Software Development:

In industrial Design, the rapid progress in modern technology, advancements in Artificial Intelligence (AI), like the emergence of large language models (LLMs) such as ChatGPT can bring a revolution to working environments in various professions and [14] introduces the potential for a distinct. Preliminary insights indicate capability in teaching, providing explanations to technical queries, and optimizing and diagnosing code [14] by offering fixes and advice. This not only diminishes barriers to entry but also reduces the learning curve where basic knowledge may suffice. This is advantageous for designers in (SMEs), where access to individuals with specialized software skills can be limited.

Within this process, 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. The Ai chatbot tool ChatGPT was used to produce, debug, modify, and enhance certain aspects of the code. Writing scripts typically begins with reference to the programming language documentation, online tutorials or existing projects [15]. With the assistance of AI, an Industrial Designer requires less expertise in Python. Initially, the designer can prompt ChatGPT or any AI LLM chatbot: *"how to interface with FSR30 sensor?" or "this code is not working please suggest changes*". Which returns instructions alongside valid code to copy and paste into the Arduino IDE (Intergraded Development Environment). Often, the code success and validity rate vary depending on prompts provided and the level of complexity.

The technology setup involves an Arduino Mega, a 20x4 LCD display, and jumper cables soldered to a stripboard. Using the IDE, the script reads the sensor resistance value at the Arduino analogue pins A0-A12, then converts it to a “force” value. A loop function continuously updates the 11 analogue inputs and prints their values out of 100 on the LCD Screen. The script sends sensor values to the Serial Monitor, accessible through the windows terminal or the Arduino IDE.



```
#include <LiquidCrystal_I2C.h>

const int RS_PIN = 12;
const int EN_PIN = 11;
const int D4_PIN = 5;
const int D5_PIN = 4;
const int D6_PIN = 3;
const int D7_PIN = 2;

LiquidCrystal_I2C lcd(0x27, 20, 4); // I2C address 0x27, 20 columns and 4 rows

int sensorPins[] = {A0, A1, A2, A3, A4, A5, A6, A7, A8, A9, A10, A11};
float scale = 0.15337423312;

int columnPositions[] = {2, 2, 2, 8, 8, 8, 8, 15, 15, 15, 17};
int rowPositions[] = {0, 1, 2, 0, 1, 2, 3, 0, 1, 2, 3};

void setup() {
  Serial.begin(115200);

  lcd.init(); // initialize the lcd
  lcd.backlight();

  lcd.setCursor(0, 0);
  lcd.print("Paxman ");
  lcd.setCursor(0, 2);
  lcd.print("Pressure Sensor");
  lcd.setCursor(0, 3);
  lcd.print("Test Rig");
  delay(2000);

  lcd.clear();
  lcd.setCursor(0, 0);
  lcd.print("1:");
  lcd.setCursor(6, 0);
  lcd.print("4:");
  lcd.setCursor(13, 0);
  lcd.print("8:");

  lcd.setCursor(0, 1);
  lcd.print("2:");
  lcd.setCursor(6, 1);
  lcd.print("5:");
  lcd.setCursor(13, 1);
  lcd.print("9:");
...........
  lcd.setCursor(0, 2);
  lcd.print("3:");
  lcd.setCursor(6, 2);
  lcd.print("6:");
  lcd.setCursor(12, 2);
  lcd.print("10:");

  lcd.setCursor(0, 3);
  lcd.print(" ");
  lcd.setCursor(6, 3);
  lcd.print("7:");
  lcd.setCursor(14, 3);
  lcd.print("CM:");
}

void loop() {
  for (int i = 0; i < 11; ++i) {
    int sensorValue = round(analogRead(sensorPins[i]) * scale);
    printSensorValue(sensorValue, columnPositions[i], rowPositions[i], i == 10);
  }

  Serial.println(); // Add a new line in the Serial Monitor

  delay(1000);
}


void printSensorValue(int sensorValue, int x, int y, bool isLast) {
  if (sensorValue > 99) {
    Serial.print("100");
    if (!isLast) {
      Serial.print("-");
    }
    lcd.setCursor(x, y);
    lcd.print("100");
  } else if (sensorValue > 10) {
    Serial.print(sensorValue);
    if (!isLast) {
      Serial.print("-");
    }
    lcd.setCursor(x, y);
    lcd.print(String(sensorValue) + String(" "));
  } else {
    Serial.print(0);
    if (!isLast) {
      Serial.print("-");
    }
    lcd.setCursor(x, y);
    lcd.print("0  ");
  }
}
```

Fig. 3: Arduino circuit schematics Diagram (left), IDE interfacing code with sensors and LCD (right).

Graphical User interface (GUI):
The development of the GUI involves creating bespoke software written in Python and utilizing Matplotlib's graph plotting library. This comprehensive open-source library facilitates the creation of static, animated, and interactive visualizations suitable for data collection and algorithm implementation. Alternative data visualization software packages, such as MATLAB and Plotly, were considered for adaptability and suitability within a medical SME. Plotting is accomplished using a matplotlib function invoked within the script. The figures are continuously updated in a loop as new data is read from the serial port. The script is written to automatically connect the Arduino to the correct port number and baud rate. A data decoder function converts the received data to plottable values. A bar chart function plots the data in the form of a live bar chart. The GUI can be seen in Figure 4 on the laptop.

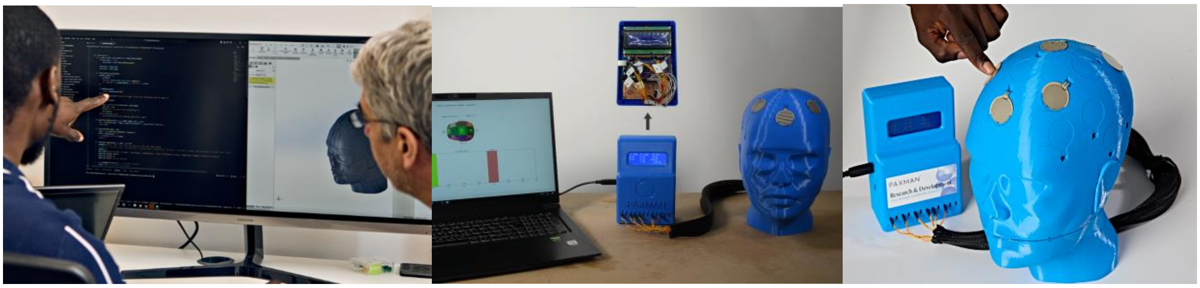


Fig. 4: (a) Back-end code, (b) Device GUI, (c) Pressure sensitive 3D printed head right.

Discussion:

A ubiquitous tool such as CAD remains beneficial for designers as it facilitates the creation of precise and detailed product designs. Over 200 prototypes of wearable designs were tested on the pressure head rig. These prototypes included 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.

Table 1 below provides comparative methodologies to test designs, assisting decision making within the development process. The product was tested in use following the proper fitting techniques and instructions. 10x repetitions were performed to gather a mean average value.

Assessing fit for this application is limited because of the complexity of head shapes, hair types, materials and access to patient pool. Currently, fit determination relies on manual inspection by trained nursing staff, supplemented by patient feedback after tightening the cover. The Process is not a quantifiable measurement model. The proposed prototype revealed variations of contact across different wearable designs, demonstrating a level of sensitivity difficult for human senses to acknowledge. This method offers an alternative approach, demonstrating how non-experienced designers can use low-cost means, especially during the design and development phase compared to subjective user feedback to assess fit to validate product function.

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

Tab. 1: Mean average sensor values comparing wearable designs 1 vs 2 vs 3 on a Caucasian head rig.

Conclusion:

Throughout the development cycle of a new product redesign, over 200 wearable prototypes were rigorously evaluated, each iteration tested on the pressure sensitive head rig, exploring various patterns, seams, sizing, and materials. The aim was to accelerate the development cycle in finding a design combination to achieve the best possible fit and comfort for patients undergoing treatment.

The Industrial Design process typically follows the iterative double-diamond process whilst collaborating with more departments and 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. There is still a place for industrial designers to acquaint themselves with these tools, which are useful in the early stages of reducing risks.

An industrial designer has successfully developed a low-cost testing rig for wearable medical devices using programmable sensors to aid early-phase design, with AI tools assisting in the process. Yet, the complexity of Industrial Design necessitates ongoing training and skill development, highlighting a gap in AI's ability to simplify the process further.

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