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Research Paper

Ortho-Monitorizer: A portable device for quantitative monitoring of temperature and pressure in a 3D-printed upper limb orthosis

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ABSTRACT

Background: Adherence to wrist-hand orthoses in patients with musculoskeletal conditions, such as Carpal Tunnel Syndrome, is crucial for effective rehabilitation. However, objective methods for monitoring wear time and pressure distribution remain limited.
Purpose: This study presents the Ortho-Monitorizer, a portable 3D-printed sensor-integrated device designed to provide real-time, quantitative monitoring of temperature and pressure in upper limb orthoses. The objective is to evaluate the system's feasibility in detecting patient adherence and identifying critical pressure points.
Study Design: A descriptive and cross-sectional study was conducted to develop and validate the device, including sensor integration and data acquisition.
Methods: Using a 3D scanner and Fusion 360 software, the orthoses were customized and printed in thermoplastic polyurethane. Data from healthy participants (n = 55) and patients with Carpal Tunnel Syndrome (n = 2) were collected through the Ortho-Monitorizer's application, using six sensors (three temperature and three pressure sensors) placed at clinically relevant anatomical points. Data were acquired over five hand positions, and normal reference values were established.
Results: Mean temperature values ranged between 29.5°C and 32.5°C, while pressure values varied from 0.00 MPa to 0.08 MPa across different hand positions. One CTS patient exhibited pressure values above normal thresholds in specific positions, correlating with discomfort and numbness reports. The device achieved a System Usability Scale (SUS) score of 86.8% (healthy participants) and 92.5% (CTS patients), indicating high usability and acceptance.
Conclusions: The Ortho-Monitorizer provides a non-invasive, objective method for monitoring patient adherence to orthotic treatments. By offering real-time tracking of critical parameters, it enhances clinical decision-making and patient outcomes. Future research should explore wireless integration and long-term clinical validation to further optimize its applicability.

Introduction

Innovations in technology are providing real-time insights into the immediate impact of orthotic devices, not only on their fit and comfort but also on patient adherence to prescribed wearing protocols. Despite the increasing reliance on orthotic interventions, current monitoring methods are primarily subjective, limiting the ability of both therapists and patients to effectively track orthosis use and identify potential pressure points. At present, sensor-based monitoring solutions for upper limb orthoses, particularly in the forearm, wrist, and hand areas, remain scarce, underscoring the need for objective, real-time adherence assessment.[1]

Force, pressure, and temperature sensors have been the three primary types of sensors employed to evaluate adherence in orthotics systems. Pressure and force sensors measure the compressive forces exerted by the orthosis on the skin, offering precise information regarding the intensity of active use. Meanwhile, temperature sensors monitor fluctuations in the body region where the orthosis is applied, providing insights into potential regional tissue inflammation. This inflammations may result from the body's response to prolonged pressure – a risk associated with orthotic use – which increases blood circulation to the affected area.[2]

Temperature sensors were developed and tested to evaluate orthoses wear time for impairment of the shoulder, arm, or hand. These sensors

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were able to capture the transitional effects of putting on and taking off the orthosis by monitoring changes in temperature.[3] Later, a study was conducted to evaluate the contact pressure of a static Wrist-Hand Orthoses (SWHO), without thumb stabilization, equipped with twelve pressure sensors. Three critical pressure points were identified during the use of SWHO: the most prominent point of the *abductor digiti minimi*, the distal end of the radius and the distal end of the ulna.[4]

As an emerging technology, 3D printing technology promises alternatives to traditional methods of orthotic device fabrication, offering cost-effective and customizable orthotics for individual patients.[5] 3D-printed orthoses can be customized to address various medical conditions, including arthritic conditions, neuromuscular disorders, traumatic injuries, and nerve injuries.[6] For instance, a thermoplastic polyurethane (TPU) SWHO was 3D-manufactured for a Carpal Tunnel Syndrome (CTS) patient whose hand function improved significantly.[7]

Although 3D-printed and sensor-based orthoses have been tested in conjunction,[5] no device has yet been developed to quantitatively monitor patient adherence with the SWHO.

To address this need, the Ortho-Monitorizer project was initiated with the objective of developing a customizable device and an objective methodology for the simultaneous analysis of pressure and temperature parameters through the integration of sensors into orthoses. This initiative will facilitate the monitoring of patient adherence, allow healthcare professionals to adjust the orthotic treatment to meet the individual needs of each patient, and enable the identification of risk situations arising from fluctuations in pressure and temperature. For individuals with sensory impairments, this issue is particularly critical, as they may not be able to report discomfort until the damage is already done.[8,9]

The Ortho-Monitorizer device was developed in a co-collaboration methodology with Curry Cabral Hospital. The device was engineered to be lightweight and compact, ensuring portability, utilizing flexible, small sensors for enhanced comfort and efficiency, with wireless data transmission, and low power consumption.[8]

Following a comprehensive analysis, the device was engineered featuring an Arduino UNO R3, driven by the ATmega328P microcontroller. This setup includes three resistive force sensors (FSR-400) and three temperature sensors (B57164K0472J000 thermistors). Connecting the sensors to the Arduino exists a perforated plate with the necessary electronics, better detailed in the previous article.[8]

Data transmission utilizes the Bluetooth Low Energy (BLE) AT-09 module, with real-time display in an Android application and storage in a NoSQL database. Figure 1 provides an overview of the portable device implementation, which includes the aforementioned elements, a power supply designed to generate a negative voltage, and a powerbank for powering the Arduino.[8]

The mobile application associated with the Ortho-Monitorizer supports three types of users — patients, therapists, and administrators — each with access to distinct features tailored to their specific roles[8]:

- Patients: Can update their personal information, access usage and cleaning instructions for the orthoses, and connect via Bluetooth to the sensors to initiate data collection on pressure and temperature;
- Therapists: Can update their personal information, access a list of patients along with each patient's history, and edit personalized parameters for each individual;
- Administrators: Have access to both patient and therapist information and can be individuals overseeing healthcare professionals (such as lead therapists or clinical administrators) or app support technicians.

Even though it is still not available to therapists, this device has been recognized for its medical utility[8,9] and tested with conventional orthoses,[9] however several limitations remain to be addressed. Specifically, concerns include the need to integrate 3D-printed devices into the medical context, as this technology is cost-effective and increasingly adopted; the development of an appropriate fitting structure for the sensors in contrast to conventional orthoses; the lack of a normative database for sensor-collected data, particularly in the realm of 3D-printed orthotics; and the absence of testing in clinical context. In this regard, this work aims to address some of these gaps.

Aim and study questions

The primary goal of this project is to improve patient adherence to orthotic devices and enable continuous monitoring in high-risk situations. To achieve this, it is proposed the development of a simple, low-cost, and user-friendly 3D-printed device with embedded sensors that allow ongoing physiological monitoring. This approach aims to enhance the effectiveness of orthotic treatment and patient care by establishing risk thresholds based on the selected sensors and orthoses. As such, the following Study Questions (SQs) were posed:

1. Production: Are 3D-printed orthoses comfortable and feasible for sensor-based monitoring?
2. Production: Does the designed shape properly fit the sensors?
3. Patient interaction: What pressure and temperature values indicate patient adherence to orthoses?
4. Patient interaction: What are the normal pressure and temperature values?

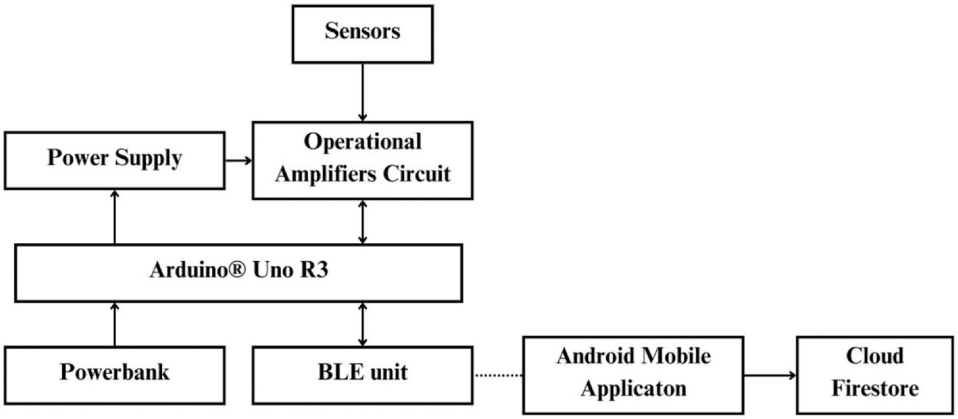


Fig. 1. Block diagram of the Ortho-Monitorizer system.

Methods

A descriptive design study was conducted to provide a detailed account of the Ortho-Monitorizer's data processing and the development and characteristics of the orthoses. Meanwhile, a cross-sectional design study was employed to establish a normative database, defining the pressure and temperature values for the sensors within the Ortho-Monitorizer system when integrated into 3D-printed orthoses.

The research focused on three main outcomes: pressure values, temperature values, and a final survey. These components were crucial for defining normal sensor values and assessing usability. To achieve this, the study was divided into three key phases: (1) 8-hour sessions without human hands, to establish baseline variability within the system; (2) sessions with healthy participants; and (3) sessions with 2 CTS participants.

The data collection involving participants was approved by the Ethics Committees of the NOVA School of Science and Technology and the Curry Cabral Hospital, *Unidade Local de Saúde de São José*. All volunteers signed an informed consent form, which was also approved by these committees.

3D-printed orthoses design, fabrication and sensor placement

The 3D-printed static orthoses model developed in this work were based on the conventional orthoses prescribed at Curry Cabral Hospital for patients with CTS.

Five main steps, schematized in Figure 2, are needed to create custom and personalized orthoses using 3D printing.

First, a 3D scan of the forearm and hand is performed. For that, the EinScan H scanner was used. This scanner is a handheld device featuring a wide scanning area and adjustable working distance, making it suitable for various types of objects. The scanning process takes approximately ten minutes when conducted in a dim, uniformly lit room. The final file can be exported and the next step takes place.

The modulation step was performed in Autodesk Fusion 360. The modulation of the orthosis is applied to the scan file, with the design featuring a Voronoi pattern for skin breathing, soft limits, and a specific shape for fitting the sensors, detailed in Figure 3.

The main structure of the orthosis is created with a 1.5 mm offset from the upper limb scan and has a 3 mm thickness. A thumb insertion hole is cut into the main structure, along with a posterior opening extending vertically from the fingers to the forearm. In planning for sensor placement, the cables were routed through the posterior opening and the sensors were positioned horizontally to minimize skin contact. The shape for the sensors, detailed in Figure 4, comprised an arch-topped rectangle, both internally and externally, at the three desired locations. Internally, it was designed to accommodate the sensors within the orthosis, while externally, it aimed to ensure minimal thickness for printing. The inner arc has a diameter of 10 mm, the outer arc has a diameter of 11 mm, and the rectangle extends as necessary to reach the opening. Vertical lines were perforated into the structure, serving as guides to facilitate the correct placement of the sensors. This sensor architecture allows for accurate sensor positioning without the need for self-adhesive fabric.

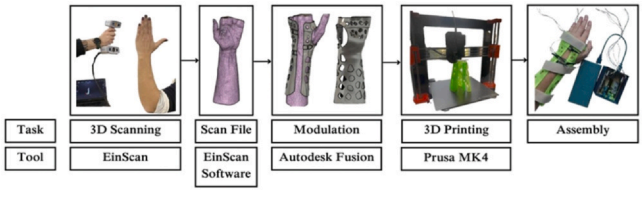


Fig. 2. Schematic of the orthoses development process with corresponding technologies.

When the temperature sensor is placed on top of the pressure sensor, both can be inserted into the orthosis until they reach the end of the cavity. The *Voronoi Sketch Generator* extension of Autodesk Fusion 360 facilitated the creation of the Voronoi pattern, where consistent design rules are applied to achieve a systematic arrangement of openings. The Voronoi burrow was applied, creating a larger texture for the forearm region, a smaller texture for the hand, and omitting the pattern in the wrist area to enhance stabilization and prevent flexion.

The orthoses were printed in TPU on a Prusa MK4 printer. TPU is a flexible material and has the higher deformation without fracturing, when compared to other materials commonly used for orthotic devices,[10] such as polylactic acid (PLA) and Low-Temperature thermoplastics (LTTPs), the latter of which is currently used in clinics. Furthermore, TPU is more cost-effective than the materials currently employed. Additionally, 3D-printed designs enable a variety of configurations, including the creation of perforations, which reduce material consumption and the overall cost of the device, without significantly compromising its durability.[10]

The 3D-printed orthoses were positioned vertically with supports limited to enforcers, optimizing printing time, material usage, and reducing overall costs. The manufacturer's recommended settings were employed in this study, as they were deemed most appropriate for the objectives of the research. The filament, with a diameter of 1.75 mm, printed at a temperature ranging from 200 to 230°C. The printing speed varied between 20 and 40 mm/s, and the bed temperature ranged from 50 to 60°C. The first layer was printed at the higher temperature to improve the adhesion of the material to the bed, preventing the orthoses from detaching or cracking.

Figure 5 illustrates the final stage of fitting the orthotic, where three Velcro straps are applied to increase stability and reinforce orthoses' primary function. The Velcro was applied to mimic the approach used in conventional orthotics.

This process was carried out twice. Two forearm and hand sizes were scanned from two volunteers, leading to the modulation, printing, and utilization of two orthoses to construct the normative database. The objective was to cover a broad range of hand sizes, ensuring a more inclusive dataset. Since TPU is a flexible material, and the Velcro closure system enables individual adjustments, no additional orthoses were printed. These two sizes were sufficiently different to accommodate a large number of individuals, an approach commonly accepted by therapists in clinical practice, where prefabricated orthoses are often available in a limited number of sizes to fit multiple hand dimensions.

Participants

A total of 55 healthy subjects between the ages of 18 and 63 participated in the data collection, seven of whom are therapists at the Curry Cabral Hospital. Their demographic specifics is detailed in Table 1 and includes age and sex (biological) details. In the context of this study, healthy participants were defined as individuals without any musculoskeletal, neurological, or sensory impairments affecting the hand, wrist, or arm. Participants with conditions that could impact sensory perception or motor function were excluded from the normative database to ensure that the collected data accurately reflected a reference population for comparison. Exclusion criteria also included individuals whose orthoses did not fit properly. This decision was based on the need to ensure consistent sensor placement and reliable measurements across individuals.

Despite the versatility of the two standard designs developed, there were certain individuals for whom none of the orthotics were customized. As a result, the sensors were not positioned correctly on their hands and forearms, preventing accurate data collection. For these individuals, additional 3D-printed orthoses in various sizes should be produced to ensure a proper fit.

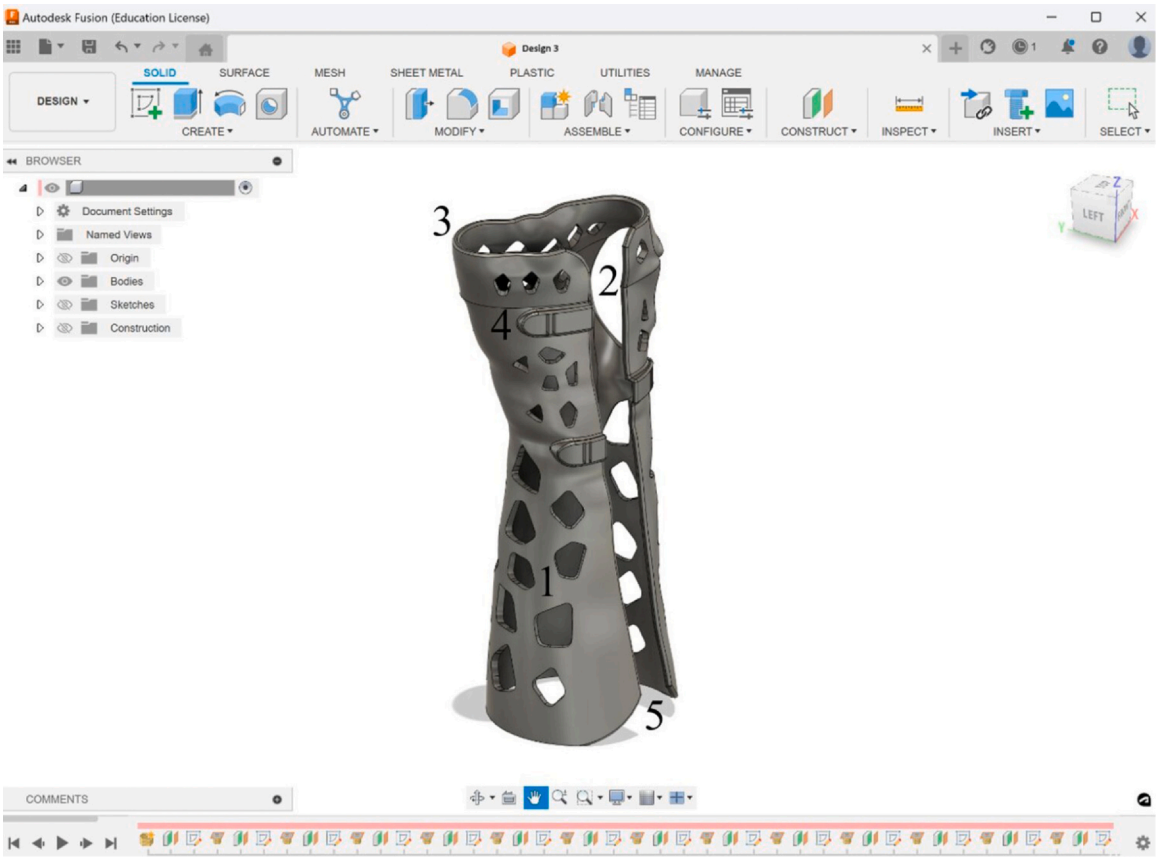


Fig. 3. Final Design 1. 1 – Voronoi pattern; 2 – Thumb insertion; 3 – Soft edges; 4 – Sensor shape; 5 – Posterior opening.

Data were collected from two individuals diagnosed with CTS through electromyography. The participants were 37 and 57 years old. Based on a clinical recommendation, CTS was selected for this study because patients with CTS often require SWHO for support and symptom relief.[11] It is also well-documented in clinical practice, with established protocols for orthotic use, making it a practical choice for evaluating adherence and comfort using sensor-based monitoring. Patient feedback is crucial for assessing the device's long-term comfort and usability in comparison to traditional options. Although this data was collected using the same methodology, it was not included in the normative database. Instead, it was utilized to evaluate the Ortho-Monitorizer system based on insights gathered from regular orthosis users.

Ortho-Monitorizer: Data collection and data processing

The Ortho-Monitorizer starts acquiring data from the sensors with the scan of the BLE device through the Android application. The sensors should be positioned in pairs — one for temperature and one

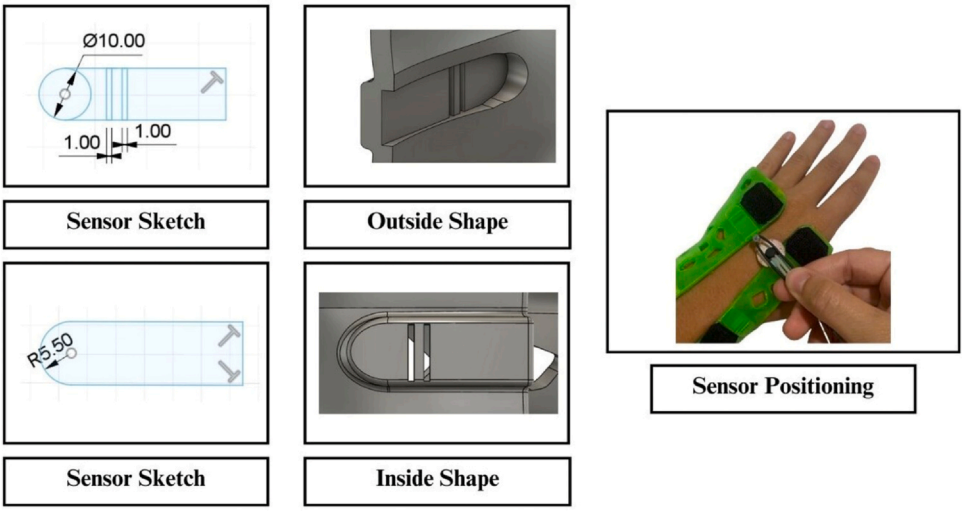


Fig. 4. Final sensor assembly within the orthosis.

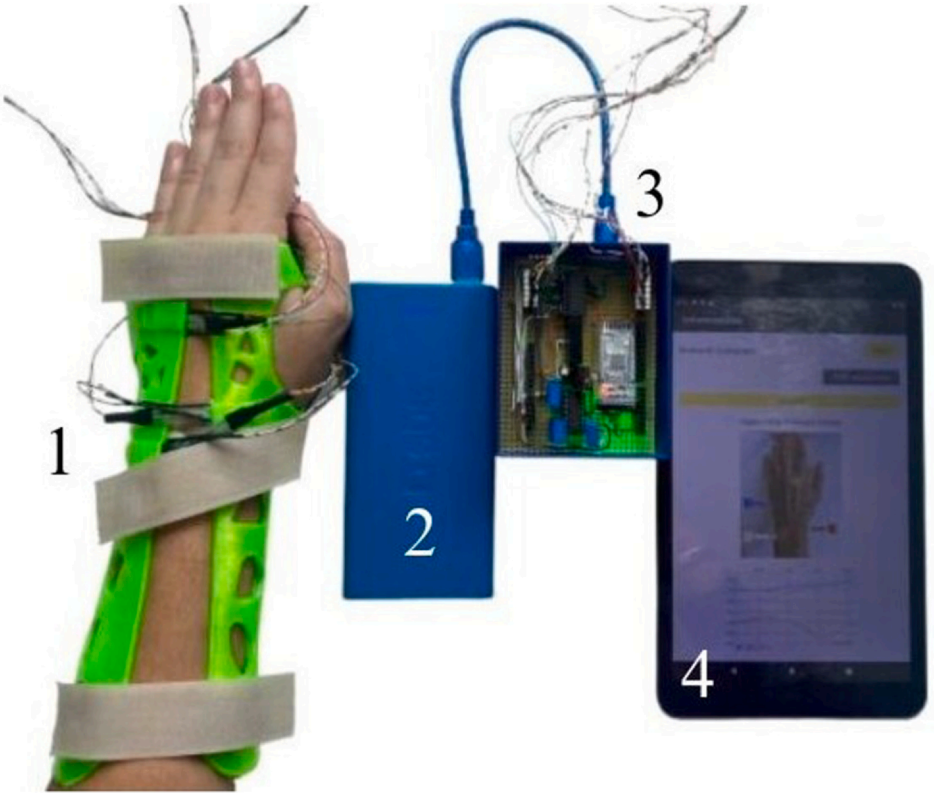


Fig. 5. Final assembly of the Ortho-Monitorizer device. (1) Orthosis with the integrated sensors and adjusted with Velcro; (2) Powerbank; (3) Arduino UNO R3 with its connections; and (4) The mobile application.

Table 1
Demographic information of the normative database participants

Participant	Age	Sex	Therapist	Participant	Age	Sex	Therapist	Participant	Age	Sex	Therapist
1	18	F	N	21	22	F	N	41	42	F	Y
2	19	F	N	22	23	F	N	42	43	F	N
3	19	M	N	23	23	F	N	43	46	F	N
4	19	M	N	24	23	F	N	44	47	F	N
5	20	F	N	25	23	F	N	45	48	F	N
6	20	M	N	26	23	M	N	46	50	F	N
7	20	F	N	27	24	M	N	47	50	F	Y
8	21	M	N	28	24	M	N	48	51	F	N
9	21	F	N	29	24	F	N	49	52	F	Y
10	21	F	N	30	24	M	N	50	53	F	N
11	21	M	N	31	26	M	N	51	53	F	N
12	22	F	N	32	26	F	N	52	53	F	N
13	22	F	N	33	26	M	N	53	55	F	N
14	22	M	N	34	27	M	N	54	60	F	N
15	22	F	N	35	28	F	Y	55	63	M	N
16	22	F	N	36	31	F	Y				
17	22	F	N	37	34	F	N				
18	22	F	N	38	34	F	Y				
19	22	F	N	39	35	M	Y				
20	22	F	N	40	40	F	N				

In the “Sex” column, “F” stands for female, and “M” stands for male. In the “Therapist” column, “Y” means the participant is a therapist, and “N” means they are not.

for pressure — at the three critical pressure points identified by Tan et al.[4] and represented in Figure 6:

1. At the most prominent point of the *Abductor Digiti Minimi* (Zone ADM), the Temperature Sensor in the *Abductor Digiti Minimi* (TADM) and the Pressure Sensor in the *Abductor Digiti Minimi* (PADM) are positioned;
2. The radial styloid process, at the Distal End of the Radius (Zone DER), houses the Temperature Sensor in the Distal End of the Radius (TDER) and the Pressure Sensor in the Distal End of the Radius (PDER);
3. Similarly, the ulnar styloid process at the Distal End of the Ulna (Zone DEU) is equipped with the Temperature Sensor in the Distal End of Ulna (TDEU) and the Pressure Sensor in the Distal End of Ulna (PDEU).

Once the sensors and orthosis are correctly placed, data acquisition can commence, providing real-time and continuous readings of temperature and pressure.

The Generic Attribute Profile (GATT) protocol provides a hierarchical structure of attributes, enabling efficient and structured

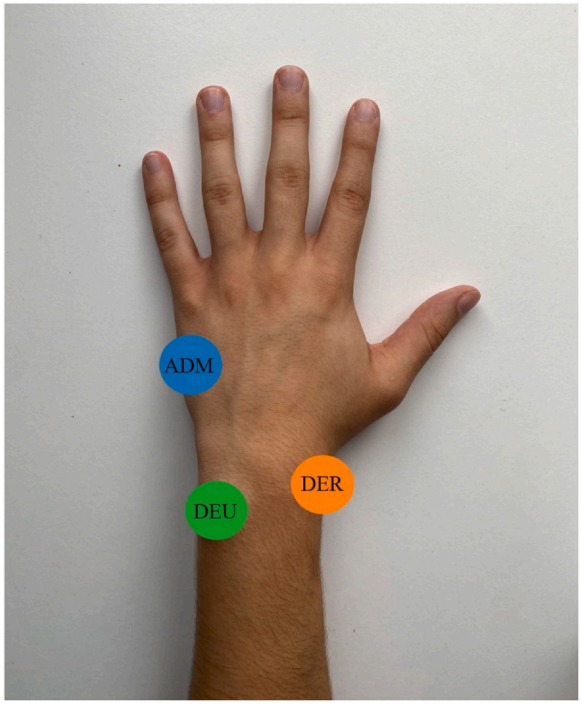


Fig. 6. Locations for sensor placement.
Adapted from Dinis et al.[9]

data exchange between devices. Characteristics are the attributes responsible for transmitting data through BLE. The sensor values are sent from the Arduino in volts via a characteristic with a maximum size of 20 bytes. These values are then converted within the application to celsius (°C) for temperature and megapascals (MPa) for pressure. Each processed value is subsequently sent to the Cloud Firestore – a noSQL database cloud, used for storing the values collected from the sensors – over the internet, where all user data and sensor history are securely stored. A more detailed explanation of the entire data transmission process is provided in Dinis et al.[9]

Acquisition protocol

The first step involved collecting sensor data over ten 8-hour sessions without participants to verify continuous data transmission and app reception throughout the night. This also helped identify patterns in temperature and pressure when the sensors were not attached to anyone. The device was placed indoors on a surface in an enclosed, non-air-conditioned space, avoiding direct sunlight. Bluetooth was connected and data acquisition was initiated via the app for each session, with breaks between sessions. Data were transmitted every 10 seconds.

The temperature and pressure values from the Ortho-Monitorizer sensors placed inside the orthoses on the upper limb were then used to construct a normative database. The system underwent performance and usability testing. Participants were required to register with the app, received instructions on its functionality, and selected the appropriate orthosis size from the two available. The instructions and follow-up were provided by the researchers, and the timing of position changes was recorded for subsequent data analysis. The orthosis was secured using three Velcro straps to ensure a comfortable fit.

Participants held five different forearm and hand positions, performed consecutively, for 3–5 minutes each to capture sensor data reflecting potential nighttime positions (which is complemented by Figure 7):

1. Forearm and hand supported with fingers extended;
2. Forearm and hand supported with fingers flexed;

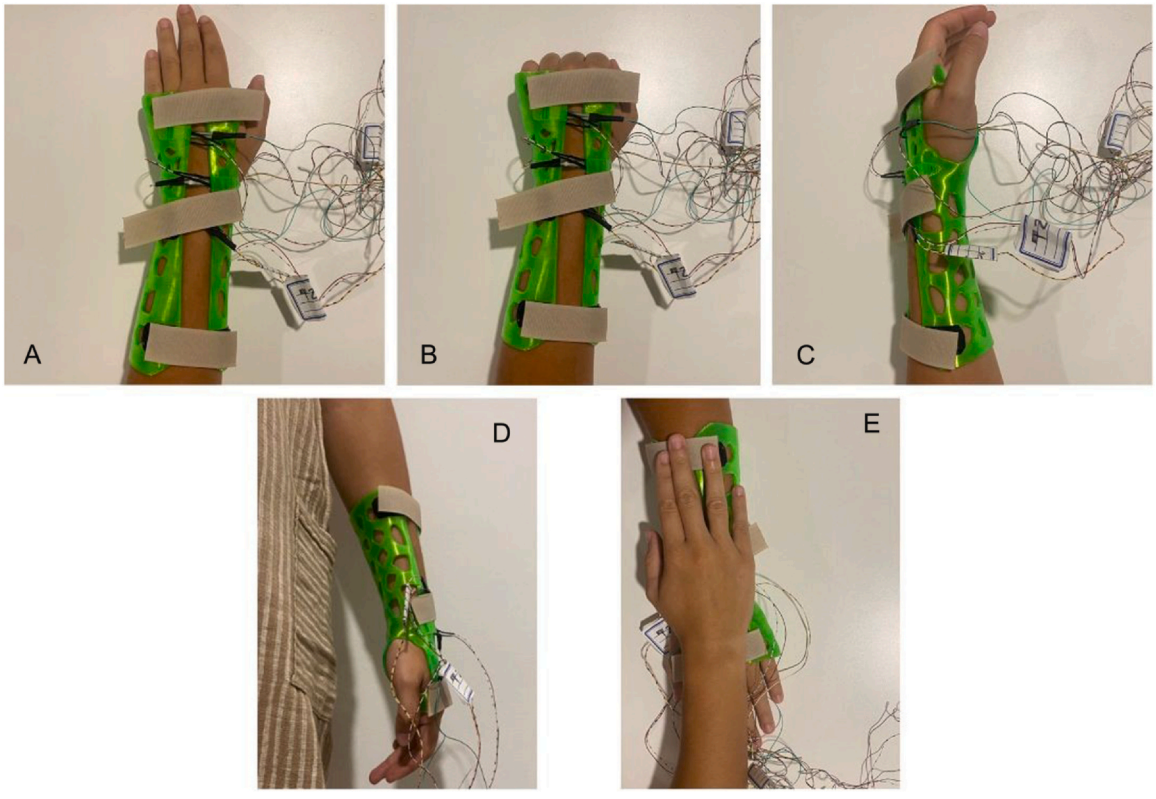


Fig. 7. Acquisition protocol. (A) Position 1. (B) Position 2. (C) Position 3. (D) Position 4. (E) Position 5.

Table 2
Data collected during 8 h acquisition without participants

Set	Start time	End time	Collection time	Data collected	Data expected	Percentage error (%)
1	12:04:00	20:04:50	08:00:50	2882	2885	0.10
2	20:05:30	04:06:16	08:00:46	2887	2885	0.08
3	04:06:40	12:08:40	08:02:00	2893	2892	0.03
4	12:09:10	20:30:06	08:20:56	3004	3006	0.05
5	08:57:19	17:02:06	08:04:47	2890	2909	0.64
6	17:03:14	01:55:28	08:52:14	2891	3193	9.47
7	01:56:01	10:29:57	08:33:56	3058	3084	0.83
8	10:31:18	18:31:51	08:00:33	2887	2883	0.13
9	01:09:17	09:10:57	08:01:40	2887	2890	0.10
10	01:45:26	10:02:28	08:17:02	2979	2982	0.11

3. Forearm positioned at the side, with the fifth finger resting on the table, the thumb facing upwards, and the hand relaxed;
4. Forearm and hand extended along the body;
5. Forearm and hand supported with fingers extended with the other forearm on top.

After completing the data acquisition, participants with and without CTS filled out a final survey. This survey was divided into two parts: the System Usability Scale (SUS)[12] and complementary questions, which are detailed in Appendix A.

The SUS is a reliable and cost-effective tool for evaluating usability. Scores range from 0 to 100, with scores above 70 indicating good usability and those below 50 highlighting significant issues. While it does not provide specific action steps, the SUS offered a quick overview of system usability.[12]

Data analysis

The temperature and pressure values from the six sensors were stored in real-time in a Cloud Firestore database, which allows continuous data synchronization and secure storage. These readings were then exported to an.xls file for further analysis. Each participant's data were compiled into a new Excel spreadsheet where automated processing was performed. The mean temperature and pressure values were calculated using all participants without pathology, along with their respective standard deviation (SD). The mean offers a clear representation of overall trends, while the SD provides valuable insight into data variation. The chosen metrics are simple, widely used, and together enhance the understanding of patient outcomes while informing clinical decisions.

Results

This section presents the results obtained and is organized according to the two data acquisition methods described.

Eight-hour acquisition without participants

In this acquisition, the Ortho-Monitorizer technology was tested using 8-hour recording sessions. Table 2 presents information about the acquisition sets, where the percentage error represents the discrepancy between the number of data points collected (uploaded to the Cloud Firestore) and the expected number.

For nine out of the 10 sets, the discrepancy was insignificant. Only in acquisition 6 was found a significant difference of 302 data points. The issue was caused by an internet failure, which prevented the data from being stored in the Cloud Firestore, leading to a gap in data uploaded.

The overall graphics for temperature and pressure mean values over 8 hours were analyzed. The temperature sensors, TADM, TDER, and TDEU, exhibit similar and consistent behavior, with respective mean values of (23.9 ± 0.6)°C, (24.1 ± 0.6)°C, and (24.1 ± 0.5)°C. All pressure sensors showed null values, as it was expected, since they were not being pressed.

Normative database

Table 3 shows the mean sensors values by position of all participants which is visually complemented by Figure 8. This figure presents a graphic of the mean temperature and pressure values collected for the 55 healthy participants while performing the five consecutive positions. During the data acquisition, none of the individuals reported experiencing pain or discomfort during de acquisition process.

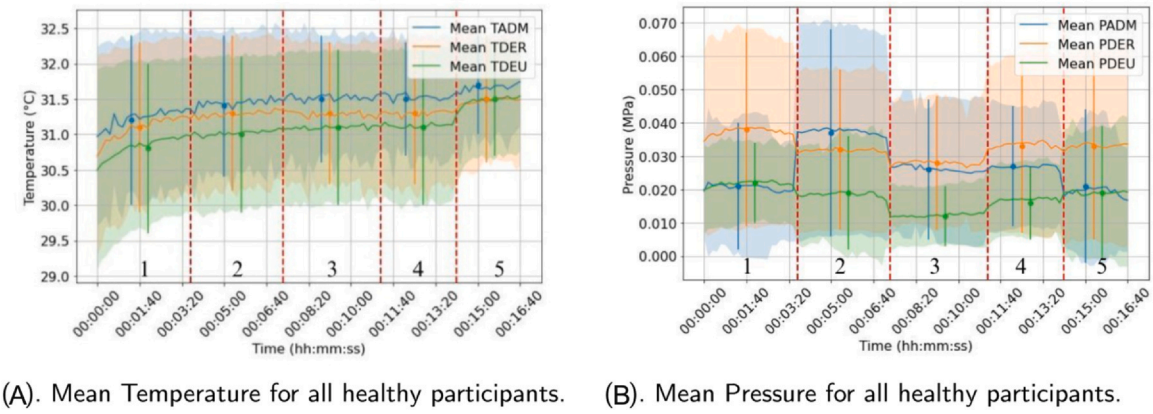
The temperature sensors presented a consistent and closely related pattern, with readings remaining between 29.5°C and 32.5°C. The temperature of all three sensors tends to rise over time, likely due to the confinement within the orthosis, which limits heat dissipation and causes passive warming of the skin. As expected, the mean temperature is highest in position five, where the other hand rests on top of the orthosis with the integrated sensors. Overall, PDEU is the sensor which pressure values are lower, while PDER shows the highest pressure, except at position 2. At this position, the fingers are flexed, which increases the hand's volume, thereby raising the pressure exerted by the orthosis on the hand.

Mainly for pressure sensors, visible in Figure 8(B), it is possible to identify when position changes occur, as the values shift automatically. For all pressure sensors, the readings remained between 0.00 MPa and 0.08 MPa.

Table 3
Temperature and pressure measurements by sensor location

Position	TADM (°C)	TDER (°C)	TDEU (°C)	PADM (MPa)	PDER (MPa)	PDEU (MPa)
1	(31.2 ± 1.2)	(31.1 ± 1.2)	(30.8 ± 1.2)	(0.02 ± 0.02)	(0.04 ± 0.03)	(0.02 ± 0.01)
2	(31.4 ± 1.0)	(31.3 ± 1.1)	(31.0 ± 1.1)	(0.04 ± 0.03)	(0.03 ± 0.02)	(0.02 ± 0.02)
3	(31.5 ± 0.9)	(31.3 ± 1.0)	(31.1 ± 1.1)	(0.03 ± 0.02)	(0.03 ± 0.02)	(0.01 ± 0.01)
4	(31.5 ± 0.8)	(31.3 ± 1.0)	(31.1 ± 1.1)	(0.03 ± 0.02)	(0.03 ± 0.03)	(0.02 ± 0.01)
5	(31.7 ± 0.7)	(31.5 ± 0.9)	(31.5 ± 0.8)	(0.02 ± 0.02)	(0.03 ± 0.03)	(0.02 ± 0.02)

The sensor locations are ADM, at the most prominent point of the Abductor Digiti Minimi; DER, Distal End of the Radius; and DEU, Distal End of Ulna.



(A). Mean Temperature for all healthy participants. (B). Mean Pressure for all healthy participants.

Fig. 8. Graphics of mean temperature and pressure values, and respective SD, over time, collected using the five-position protocol. Positions are identified by the number that identifies the order in which they were executed. The red dotted lines mark the moments of position changes. The dots represent mean values, and the vertical bars indicate the corresponding SD, recorded at each position by various sensors. The sensor locations are ADM, at the most prominent point of the *Abductor Digiti Minimi*; DER, Distal End of the Radius; and DEU, Distal End of Ulna.

Carpal Tunnel Syndrome patients data

The two case-study patients participated in a data acquisition session following a protocol similar to that of the normative database.

The first volunteer was a 37 years old patient with CTS – case 1. Figures 9(A) and (B) present the values of temperature and pressure, respectively, for this patient across the five positions data collection. The individual's values are compared to a shaded area representing the normal range, derived from participants without wrist-hand related pathology. Upon examining Figure 9, it is evident that the temperature and pressure readings remained within the normal range. The temperature values for both TDER and TDEU increase during the initial position as the sensors adapt to the skin temperature. In position 3 is possible to identify a slight drop in temperature, likely due to an increase in the distance between the orthosis and the skin in zone 2, caused by the position itself. The pressure readings are predominantly observed near the lower limit of the normative database and remain relatively consistent across the three sensors as well as throughout the acquisition period.

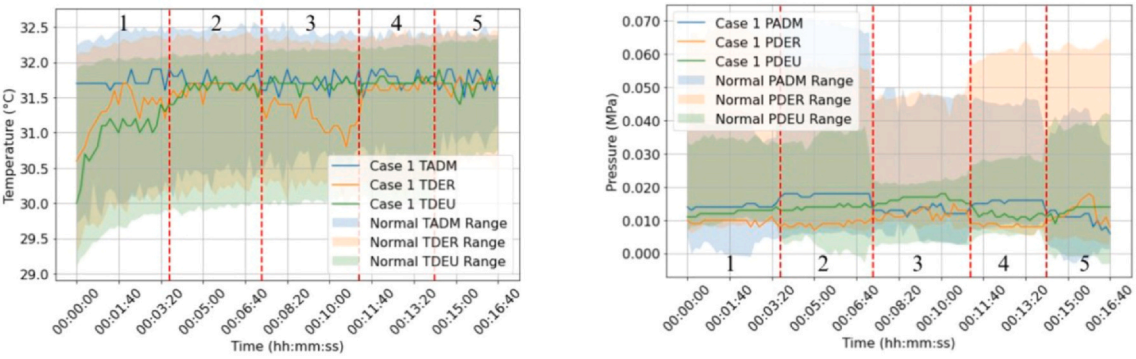
The second volunteer with CTS was a 57 years old individual – case 2. Position five was excluded rom the acquisition protocol due to the patient's accumulated discomfort. Similarly to the case 1 patient, Figures 10(A) and (B) display the temperature and pressure values, respectively, for this patient across the four positions, alongside the normal range established in this study. For the pressure values, PDEU exceeds the normal range at position one. Meanwhile, PADM exhibits values above the values observed in the participants without pathology, particularly in the second position. Values outside the normal range were linked to discomfort and numbness in the fifth finger, as reported by the patient. This allows for conclusions about various aspects of the Ortho-Monitorizer device's functioning.

Usability questionnaires

The SUS questionnaire evaluating the orthoses with integrated sensors reported a mean score of 86.8% for participants without pathology and 92.5% for patients with CTS, indicating a high level of usability. The lowest scores were given to questions 4 – "I need the support of a technical person to be able to use the Ortho-Monitorizer" - and 10 – "I needed to learn a lot of things before I could get going with the Ortho-Monitorizer".

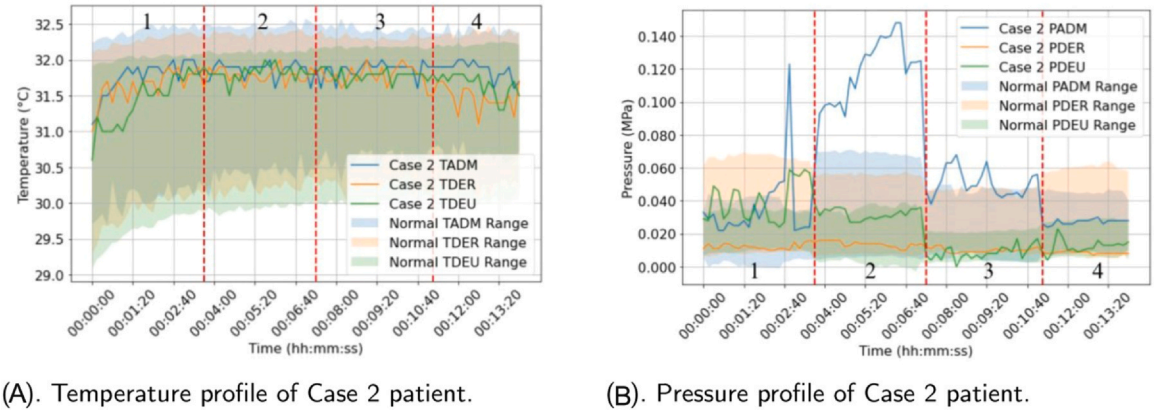
In contrast to participants and individuals with CTS, who would be required to wear these orthotics daily, the seven therapists gave the Ortho-Monitorizer an average final score of 58.5%.

The Ortho-Monitorizer received an overall rating of 9.13 out of 10 from all participants in the study for its pertinence in monitoring



(A). Temperature profile of Case 1 patient. (B). Pressure profile of Case 1 patient.

Fig. 9. Graphic of temperature and pressure over time comparing Case 1 patient values against normal reference values. Positions are identified by the number that identifies the order in which they were executed. The red dotted lines mark the moments of position changes. The sensor locations are ADM, at the most prominent point of the *Abductor Digiti Minimi*; DER, Distal End of the Radius; and DEU, Distal End of Ulna.



(A). Temperature profile of Case 2 patient.

(B). Pressure profile of Case 2 patient.

Fig. 10. Graphic of temperature and pressure over time comparing Case 2 patient values against normal reference values. Positions are identified by the number that identifies the order in which they were executed. The red dotted lines mark the moments of position changes. The sensor locations are ADM, at the most prominent point of the *Abductor Digiti Minimi*; DER, Distal End of the Radius; and DEU, Distal End of Ulna.

adherence with orthotic treatment. A score of 4.8 out of 5 characterized the TPU material as comfortable.

Out of 57 volunteers (55 healthy individuals and two with CTS), 42 reported marks left by the orthosis. Most of these marks were located in the sensor area and were attributed to the pressure sensors. However, five participants noted marks left by the edges of the orthosis on their forearms.

Final feedback from participants emphasizes the necessity for a more portable device with fewer wires.

Discussion

This study aimed to evaluate the feasibility and usability of the Ortho-Monitorizer, a sensor-integrated orthosis designed to monitor adherence and pressure distribution in patients using upper limb orthoses. The evaluation process involved the collection of sensor data followed by an assessment of usability through a final survey. By analyzing normative data from healthy participants and preliminary data from CTS patients, this study provides insights into the potential of real-time sensor-based monitoring for optimizing orthotic interventions.

The values obtained in this study provide valuable insights for both therapists and patients regarding the use of SWHO, primarily contributing to real-time data monitoring and improving patient adherence. The Ortho-Monitorizer application successfully displayed values collected via Bluetooth, with no failures during the 8-hour acquisition period. However, like in acquisition 6, the application could not recover the data lost during the internet disruptions. Even though continuous data appears in the mobile application's patient menu, the reliance on internet connectivity presents a problem, as it compromises data transmission to Cloud Firestore and hinders therapists' access to the data. This, in turn, undermines the real-time data monitoring device's intended objective.

Regarding the acquisition involving 55 healthy participants, it was possible to establish normal patterns for pressure and temperature values. The findings enable the definition of adherence thresholds and critical values for patients using orthoses. Specifically in data collection for constructing the normative database, participants did not report any pain or discomfort.

When the sensors are integrated into the orthosis and placed on the upper limb, temperature readings typically rise above 29.0°C. It is important to note that the observed transient increase in temperature at the beginning of the acquisition is likely due to the sensor's initial adaptation to skin contact. While this effect could potentially be minimized if patients were given time to acclimate to the orthosis prior to testing, it is not expected to be an issue during normal wear, as the system will reach equilibrium over time. Since the primary goal of temperature monitoring is to assess patient adherence rather than detect rapid temperature fluctuations, these transient effects do not impact the core functionality of the device.

Temperatures exceeding 29.0°C and pressures above zero indicate that the sensors are correctly positioned inside the orthosis and are properly placed on the forearm. Conversely, if the temperature is below this threshold, it suggests that the orthosis may not be properly positioned or is not being used at all. Based on this results, adherence can be established when temperatures exceed 29.0°C across all sensors and pressures exceed 0.00 MPa in at least one pressure sensor.

Normal patterns were established as planned, allowing for the determination of maximum normal values for each sensor. Values exceeding these thresholds can be identified as excessively high, falling outside of normal ranges, and potentially posing a critical or damaging risk to tissue. A threshold for unusually high pressure can be set at 0.08 MPa and for high temperature can be set at 33.0°C. Values above this limits triggered audible alerts in the application because of their possible link to alarming situations.

The Ortho-Monitorizer provides healthcare professionals with quantitative data on SWHO use while alerting patients to potential risks. As the results from this study serve as guidelines for therapists, an option to set personalized critical values for each patient has been included in the therapist/administrator menu. An initial reading, taken in the presence of a healthcare professional, helps establish the patient's baseline temperature and pressure levels. While some patients may initially view these tracking as punitive, the device is also a tool for guidance and reassurance, promoting proper use of the orthosis. It offers clear instructions on usage, cleaning, sensor placement, and abnormal sensor values, while empowering patients to monitor their own data and adjust the fit for improved comfort and autonomy.

3D-printing technology allows for lightweight, customized devices that reduce costs, with soft materials that don't require internal protection. Sensors are positioned within the design without extra attachment materials, but TPU's flexibility, while providing ease of movement, can cause variations in sensor placement and compression, affecting data accuracy. For instance, the PDEU sensor, located at the styloid process of the ulna, was expected to be at a high-pressure point but ended up closer to the posterior opening, where there was less material to secure it. In contrast, the PDER sensor, positioned deeper inside the orthosis, was more securely placed, demonstrating the challenges of sensor accuracy due to TPU flexibility.

A major challenge in developing SWHO in this study was the printing time, which can currently take up to half a day, as well as the post-processing tasks, such as polishing and cleaning, necessary to ensure patient safety. These steps can add both complexity and time to the production process. However, a more pressing challenge lies in acquiring accurate data that demonstrates how 3D-printed SWHO devices can outperform conventional ones. Moreover, there is a need to modify existing infrastructure to accommodate 3D-printed devices and to educate healthcare professionals on these new technologies. Notably, the growth of 3D printing technology has been exponential, fostering hope for both improved printing times and greater ease of learning.

The data acquisition for CTS patients was conducted in a controlled environment with standardized positions, so no inflammatory processes or elevated pressures were expected. However, pressure values outside the normal range for the second patient highlighted the device's ability to detect clinically relevant pressure variations that are associated with negative SWHO use. Positive feedback from both patients and healthy participants emphasized the device's high usability, although lower scores in some questions indicated a need for initial guidance. Therapists tend to be more critical when evaluating devices for their patients, particularly when they identify limitations. The overall feedback cited the system's complexity and challenges with sensor positioning, especially for overnight wear. Sensor marks left on the skin from required pressure application remained a challenge. While the orthosis design accommodated the sensors, evaluating the intensity of SWHO use revealed that some pressure had to be applied to the sensors. However, these marks were not a complaint made by the participants, they may impact patient comfort, specifically for those with sensory modifications. Despite these issues, the comfort of the TPU material was recognized as a viable alternative to traditional materials due to its softness and lower cost.

This work proposed a novel approach in the realm of sensors integration in orthotic devices, allying 3D-printing to patient monitoring. Although initially designed to benefit individuals with CTS, Ortho-Monitorizer's application could extend to a broader range of patients, thereby making a meaningful impact across various rehabilitation contexts.

Ortho-Monitorizer and study limitations

As with any research, the developed device and the study itself are subject to certain limitations that must be acknowledged. These limitations may have influenced the final results and should be considered in future investigations.

The Ortho-Monitorizer, being a sensitive technological device, required rigorous testing of its sensors and wires, as occasional issues arose necessitating replacements. In some instances, installation errors led to immediate transmission failures to the application, though these issues were easily detected and could be addressed promptly. Therefore, it is strongly recommended that thorough testing of the sensors be conducted prior to use to ensure the accuracy and reliability of the data. Another restriction pertains to the reliance on internet connectivity for data transmission, which may present challenges in clinical settings where internet access may be unstable or limited. Furthermore, the complexity of the sensor cable system proved to be cumbersome, especially during nighttime use, when the system's intricacies made it more difficult to operate effectively.

The entire process of the study design was conducted in a controlled environment, which may not fully capture the variability encountered in real-world patient use. Additionally, the Ortho-Monitorizer was tested only with specific orthotic designs, and further evaluation across a broader range of orthoses and patient pathologies is necessary to determine the device's generalization and reinforce the values found in this study. Moreover, differences in hand and forearm structure, as well as the fit of the orthosis, likely influenced the results, and such factors must be considered when interpreting the findings.

Despite the challenges these limitations present, they offer valuable insights that can inform the refinement of both the device and the study methodology.

Future work

Several key considerations for future work could enhance the effectiveness and usability of the Ortho-Monitorizer system, while also refining the study's conclusions and increasing their reliability.

Enhancing the sensor integration and improving device portability will be essential for increasing patient compliance. A smaller microcontroller, housed within a compact enclosure integrated into the orthosis, could help streamline the design. This would reduce bulk and improve comfort, with cables routed through small, attached tubes leading to the microcontroller.

Additionally, creating a buffer to store data when internet connectivity is unavailable would be beneficial. This feature would allow the device to continue collecting data, which could then be uploaded to Cloud Firestore once the internet connection is restored, ensuring uninterrupted operation.

Expansion to different orthotic designs is also a priority. Future work should explore adapting the system to a broader range of orthoses and developing additional sizes of 3D-printed orthoses to meet diverse patient needs. Another important area to investigate is how the transient response of the SWHO might affect the detection of temperature changes, potentially influencing the accuracy of readings.

Further research should aim to test the system with a larger cohort of CTS patients to validate the findings. Expanding the system's applicability to other patients with musculoskeletal, neurological, or sensory impairments affecting the hand, wrist, or arm would also be valuable, broadening its use for various patient groups. Additional information could be collected from participants, such as their professional occupation. This is an important metric to consider, as many wrist and hand pathologies develop due to repetitive movements in occupational settings.

Finally, more work is needed to assess long-term adherence to the device and evaluate how real-time feedback may influence treatment outcomes. Understanding the impact of continuous monitoring and immediate feedback will be crucial in optimizing the system for improved patient care.

By addressing these next steps, the Ortho-Monitorizer will be strengthened, further enhancing its potential to improve patient care and assist therapists in decision-making for SWHO treatment.

Conclusions

This study confirms the feasibility of the Ortho-Monitorizer for real-time quantitative monitoring of adherence and pressure distribution in CTS patients. In addition to potential improvements, the results from two CTS patients offer valuable preliminary insights, indicating that the device has potential for supporting the management of CTS. There was a consensus among participants, therapists, and patients on the relevance of the Ortho-Monitorizer for monitoring patient adherence with SWHO, with participants expressing comfort when using the 3D-printed orthoses. The pressure and temperature values established in this study serve as initial guidelines for detecting adherence and preventing potential complications, providing a solid foundation for future research in this area. However, further research with larger clinical samples is necessary to fully assess its effectiveness and ensure its broader applicability in clinical settings.

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CRediT authorship contribution statement

Matilde Antão: Writing – original draft, Software, Resources, Methodology, Investigation, Formal analysis, Conceptualization. **Inês Rodrigues**: Validation, Resources, Methodology, Conceptualization. **Carla Quintão**: Writing – review & editing, Resources, Methodology, Formal analysis, Conceptualization. **Cláudia Quaresma**: Writing – review & editing, Resources, Methodology, Formal analysis, Conceptualization.

Declaration of Competing Interest

None.

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Appendix A. Final Survey: SUS and complementary questions

SUS regarding the Ortho-Monitorizer:

1. I think I could use the Ortho-Monitorizer daily.
2. I found the Ortho-Monitorizer unnecessarily complex.
3. The Ortho-Monitorizer is easy to use.
4. I need the support of a technical person to be able to use the Ortho-Monitorizer.
5. The various functions in the Ortho-Monitorizer were very well integrated.
6. There are too many inconsistencies in the Ortho-Monitorizer.
7. Most people would learn to use the Ortho-Monitorizer very quickly.
8. The Ortho-Monitorizer is too difficult to use.
9. I felt very confident using the Ortho-Monitorizer.
10. I needed to learn a lot of things before I could get going with the Ortho-Monitorizer.

Complementary questions:

1. On a scale of 0 to 10, how would you rate the relevance of this technology in monitoring patients using orthotics.
2. The orthosis material is comfortable (1–5)?
3. Did I get marks on my arm from the orthosis or the sensors (Y/N)?
4. In your opinion, what features could be improved or added to the device.

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