OSLO METROPOLITAN UNIVERSITY
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Compliance Monitoring Orthosis

Project Description

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Requirement Specification

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1. Introduction

Orthoses assists the rehabilitation of a variety of musculoskeletal impairments. From broken bones to post-stroke neurological damage, orthoses are a valuable and effective tool in many types of interventions. Objective measurements for how long an orthosis have been used is crucial to identify the efficacy of interventions. In patient populations, receiving correct information about the compliance to intervention may be unavailable. To solve this problem the authors will develop an orthosis fitted with a temperature sensor, an accelerometer and a microcontroller equipped write an algorithm which determines, based on the sensor inputs, whether the orthosis is being worn at any given time. This paper described a project to develop sensor-enabled wrist hand orthoses. The described orthoses will be developed and tested over 10 weeks. The results and development will be documented in a written article.

2. Background & Literature Review

The Scopus (www.scopus.com) database was used to search for articles focused on WHOs.

2.1. Search Strategy

The search utilized the keywords as follows:

TITLE-ABS-KEY ("Orthoses") AND TITLE-ABS-KEY ("Upper limb" OR "Wrist" OR "Wrist hand" OR "Hand") AND TITLE-ABS-KEY ("Review" OR "Meta-analysis") AND PUBYEAR > 2013 AND PUBYEAR < 2025.

The search yielded 318 articles and the 240 most recent articles were included in the literature review. The articles were filtered by title and abstract for relevance, the remaining articles were then fully read.

2.2. Findings

Articles were filtered by reading titles and abstracts 38 articles remained after filtering for titles. 9 articles were chosen for full reading after filtering abstracts, not all were included in this paper.

2.2.1. 3D-printed Orthoses

Traditionally, orthoses are made using thermoplastic molds. This is a time-consuming process and requires skilled personnel to manufacture. With the rise of 3D-printing technology, 3D-printed orthoses are rapidly being adopted as a viable alternative to conventional methods of construction(Oud et al., 2021).

Demeco et al. (Demeco et al., 2023) identifies several problems with traditionally constructed orthoses: ventilation, hygiene, breathability, weight, moisture, lack of water proofing. All these factors may contribute to non-compliance in a patient, and thus worse patient outcomes.

Almost half of the studies review by Choo et al. (Choo et al., 2020) identifies 4 main attributes to explain why satisfaction with 3D-printed orthoses were higher than those made traditionally. Firstly, the contact surface is better aligned with the shape of the upper limb. Secondly, the strength of several filament materials for 3D-printing are stronger and more versatile than traditional molds. Thirdly, a better distribution of pressure results in a more comfortable orthosis. Lastly, 3D-printed orthoses are often lighter and thus more comfortable.

Oud et al. (Oud et al., 2021) notes that studies using 3D-printed orthoses often conduct for a shorter amount of time than usual for long-term orthopedic interventions. The faster development and iteration speed 3D-printing may cause the results to favor 3D-printing because of the short time spans of studied interventions. In a long-term intervention these effects may be smaller or negligible. Additionally, rehabilitation using 3D printed orthoses was found to vary greatly in both frequency and volume, normally 3-6 times per week where patients wore an orthosis for 30 minutes to 6 hours, and the functional outcome was assessed using a variety scale such the Fugel-Meyer assessment, manual function tests, and block tests.

2.2.2. Material

The most popular materials used for 3D printed orthoses are thermoplastic polyurethane (TPU) and polylactic acid (PLA). PLA is very widely used; it is composed of polymers and renewable agricultural raw products, making it non-toxic and harmless. At the same time, it is also biodegradable. (Schwartz & Schofield, 2023) PLA is known for its ease of use and being cheap, but they have a serious disadvantage as low temperature resistance. Temperatures around 50–60 °C may cause it to soften and thus deform (Górski et al., 2020).

Other characteristics of PLA material are rigidity and brittleness, whereas TPU is a semi-flexible material. TPU features excellent mechanical resistance to abrasion, as well as resistance to impact, tearing, and chemical resistance to oils and greases. (Venumbaka et al., 2020) TPU, as a material with many advantages, is also biocompatible and very popular in the medical field. For example, blood bags, surgical gloves, catheters, synthetic veins, and wound dressings all utilize TPU material.

From the results of a Tensile test, PLA has a high tensile strength but lacks flexibility. On the other hand, TPU demonstrates a lower elastic modulus but possesses low stiffness and good flexibility. (Venumbaka et al., 2020)

Another popular material is polyethylene terephthalate glycol (PETG) which is biocompatible (Vijayasankar et al., 2022). PETG is introduced by adding glycol to PET, resulting in greater flexibility and impact resistance. Due to its low shrinkage rate, it is easy to print. It also possesses high transparency, impact resistance, chemical resistance, and weather resistance, making it a recommended material for many highly durable applications (Al-Atroush et al., 2023). PETG has advantages such as durability, flexibility, high impact resistance, high chemical resistance, and low moisture absorption. Worth to note that when they are reinforced with carbon fibers, they become stronger and more elastic (Valvez et al., 2022).

Other available materials are acrylonitrile butadiene styrene (ABS) and nylon. Compared to PLA, ABS has higher impact resistance and is generally recognized as a tougher material. It also has good thermal stability and can withstand any temperature encountered in daily use. However, this paper states a serious issue that ABS is not skin friendly and needs to be sterilized before and after daily use. At the same time, it is not biodegradable like PLA, making it less environmentally friendly. (Górski et al., 2020).

Nylon, also called polyamide, is stronger and more durable compared to ABS and PLA. Other advantages include being lightweight, highly flexible, wear-resistant, and not easily broken. Recommended printing temperature between 210°- 260°, and bed temperature between 60° - 110° (Elliot et al., 2021). Nylon is a relatively expensive material with a higher production difficulty. As an elastic material, it can resist high temperatures and chemical elements, and it also has high bending strength, impact, and scratch resistance. Its ability to bear dynamic loads makes it a recommended material for wrist-hand orthoses. Lastly, it is relatively environmentally friendly. (Górski et al., 2020).

As a 3D printing material, ABS is more popular than PLA. This is not hard to imagine due to its better temperature tolerance and toughness, especially since orthoses should possess flexibility and bending strength. Through tensile and bending tests, ABS is a good choice if making a wrist orthosis (Kumar & Sarangi, 2022).

Material	Density [g/cm3]
PLA	1.24
ABS	1.04
PETG	1.27
NYLON	1.52
Flexible (TPU)	1.21

Table 1 shows density of different 3D printing materials.

2.2.3. Testing Paradigms

Manual function test, Fugl-Meyer Assessment, and block tests are common scales to measure functional improvement for upper extremities after orthopedic rehabilitation (Oud et al., 2021). Manual functions may include gripping tools, opening doors, and holding plastic cups. This review finds that orthopedic rehabilitation can provide better patient outcomes compared to non-orthopedic treatments.

2.2.4. Compliance Monitoring

Devanad and Kedgley (Devanand & Kedgley, 2023) investigated different methods of compliance monitoring in the literature. They identified 23 studies using sensors compliance monitoring: 6 used temperature sensors, 4 used step counters (pedometers), 6 used accelerometers, and 6 used pressure sensors. A few studies used a combination of sensors.

Temperature sensors achieve high accuracy, however climate and warm clothes can interfere with the results. Pressure sensors can achieve good results, but the calibration of thresholds is prone to errors. Step counters have the major drawback of not detecting time spent neither running nor walking. Accelerometers have high accuracy, but may give false positives during travel and other movements.

Thus, using a combination of temperature sensor and accelerometer a robust system for compliance monitoring may be possible. The sensors have complementary advantages and disadvantages. The accelerometer can give false positives during travel, but the temperature can invalidate those results. The temperature sensor can give false results when heavily clothed and climate changes, the accelerometer invalidate those results.

It is important to note that the objective measurements of compliance may not indicate a patient’s non-compliance; in many patient situations the patient themselves is not responsible for the compliance. Additionally, some patients may find the measurements intrusive, thus hindering compliance.

2.1. Lecture by Head of OT Department at Sunaas Hospital

The authors participated in a lecture about orthoses by Anne-Marthe Sanders, head of the Occupational Therapy department at Sunaas Rehabilitation Hospital. The lecture introduced the field of orthoses and gave insight into practicing clinician’ experience working with them. The following statements are some of the authors’ key takeaways from the lecture.

Hand function is an important part of quality of life and being able to participate in society.

A dynamic orthosis has some sort of active helping function that aids some sort of hand function.

A non-3D printed orthosis takes a lot of time and skill to get right and is difficult to alter once it's made. There can be no "pressure" inside the orthosis because a painful orthosis may disturb sleep and cause lesions.

An orthosis should preferably be visually appealing to increase patient compliance, especially for pediatric patients.

It would be beneficial if the orthosis assists the patient in using it correctly, a lot of people with this upper-limb impairment also have cognitive impairment.

Improving upon an orthosis made at Sunaas can enable the occupational therapists to spend more time on patients rather than producing orthoses.

The clinicians need objective time tracking for the usage of orthoses. Assessing the efficacy of orthoses can be difficult without accurate information of how it has been used.

2.2. Previous Works

The previous students who attended the ACIT4730 course developed orthoses and wrote articles documenting their work.

Three articles were written, each primary focusing on a different type of sensor and actuators. The sensors included: a temperature sensor, accelerometer, and a pressure sensor. The temperature was calibrated to display 26 degrees when the orthosis was not worn, and 27 degrees when it was worn.

The temperature sensor was meant to monitor a patient's temperature inside the orthosis for a physician to monitor and intervene before any problems arose. The temperature reading was sent to a server across Wi-Fi and then displayed on screen.

The pressure sensor was implemented together with two light emitting diodes (LED). The system lit the LEDs according to pre-calibrated force measures from the pressure sensor. The goal was to inform the patient wearing the orthosis to if the pressure was too tight and impaired blood flow to the hand / wrist.

The accelerometer was neither implemented nor tested. It's potential usefulness is mentioned but not elaborated on further. None of the implementations conducted testing of their solutions.

3. Method

The authors will design and implement a static orthosis with integrated compliance monitoring. Meaning the orthosis will detect at what time it is being worn. This will be accomplished by utilizing a temperature sensor and an accelerometer. This project will improve upon the lack of testing as described in the previous section and conduct a thorough test of the compliance monitoring.

The following section describes the methodology that will be used to develop a compliance-monitoring static orthosis. The timeline for the method described in this section is covered in section 4. The requirement specification for this methodology can be found in Appendix A.

3.1. Scanning & Printing

One of the authors' arms, hand to elbow, will be scanned by a 3D-scanner. The scan yields a 3D-model, and it is likely to be noise with imperfections and therefore will be modified and cleaned in a 3D-software package like Blender or Fusion360. Once a clean mesh is achieved, the orthosis design process will start. The starting point of the orthosis is an extrusion of a subset of faces from the mesh. Neither the design nor print is expected to be satisfactory during the first attempt, therefore iterative design a planned and several different versions are expected to be printed over the course of development.

3.2. Sensors & Actuators

A temperature sensor and accelerometer will connect to a microcontroller. The temperature sensor will measure the temperature inside the orthosis and close to the skin. The accelerometer will measure the acceleration of the orthosis. The microcontroller receives input from both sensors. A compliance-algorithm will be developed which determines whether the orthosis is being worn, based on the inputs from the sensors. The results of the algorithm will be stored in the microcontrollers storage.

3.3. Material

Some of the key requirements include the orthosis being biocompatible with human skin, which is the most important factor. Additionally, the lighter the orthosis, the more comfortable it is likely to be. Furthermore, the orthosis must be strong enough to withstand spasms and hits.

Based on these considerations, TPU would be our top choice. First, TPU is biocompatible, many types of TPU are used in medical applications, indicating their suitability for direct skin contact.

And density of TPU material is around 1.21 g/cm3 which is the second lightest among the five materials introduced.

In addition, TPU has good flexibility which is essential for a hand orthosis. It needs to conform closely to the patient's movements while providing the necessary support. And its elasticity can also help in reducing discomfort during prolonged use.

Furthermore, TPU is known for its excellent wear resistance, which means the orthosis will be durable and capable of withstanding daily use without significant degradation. Choosing TPU offers a strong foundation for the primary structure.

Nylon also seems to be a good candidate. It offers great elasticity and flexibility, but compared to TPU, it has a higher humidity absorption rate and may not provide the same level of comfort as TPU. Additionally, it is more expensive.

3.4. Design

A plethora of different designs for orthoses exists. Some are in 2 pieces and closed with straps, and some are a single piece with flexibility allowing it fit. The design of the orthosis will be done in a 3D-design software such as Blender or Fusion360.Precise measurements of the components will be taken. The measurements will be used to implement slot-like section of the orthosis for the components to be attached to.

3.5. Testing

The testing of compliance monitoring will primarily be done by the authors wearing the orthosis for a period and then comparing to the output with manual time measurements. The parameters of the algorithm are unlikely to yield accurate results immediately and will therefore be tuned accordingly during testing. Additionally, the sensors will be exposed to their weaknesses as described earlier, such as warm clothes, rapid changes in climate, traveling, and more. Both sample rates and thresholds will likely be tuned during the testing. The following table is an example of a test procedure.

Challenge	**5 / 30 Hz -23C**	**20 / 100 Hz-34C**	**50 / 250 Hz**	**100 / 500 Hz**
Wintercoat	OK	x	x	x

In backpack	X	OK	X	X
Outside	OK	OK	X	OK

Table 2 shows an example of testing procedure.

3.6. Article

The methodology and results will be documented in a written article.

METHOD -> 3D scanners are not safe for eyes and must therefore must be accounted for.

Check the specifications for each 3D scanner, is it nesccary to use the large one when we can just use the small one? -> Reason for it in the article

4. Timeline

The proposed sensory/actuator enabled orthoses will be developed and tested over 10 weeks, starting from 28.02.2024. The article will be continually written throughout the entire development.

4.1. Week 9

In week 9 this paper is being delivered and the authors are presenting the project to the course/project supervisors.

4.2. Week 10

The arm and wrist of one author will be 3D-scanned and the results will be processed further according to the methodology described previously. Both the temperature sensor and accelerometer will be connected to the microcontroller, not attached to the orthosis.

4.3. Week 11

Using the hand-mesh design the orthosis and make 3D model and a first iteration will be printed, this will be rapidly tested and iterated on to start a new print. The compliance algorithm will be implemented.

4.4. Week 12

A new iteration of the orthosis is likely to be printed, and the components will be attached.

4.5. Week 13

The final iteration of the orthosis is completed, and the testing is started.

4.6. Week 14

Testing continues and the algorithm is finalized.

4.7. Week 15

Article is finalized. Presentation of the project for oral examination will be created.

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Appendix A: Requirement Specification

3D-printer: Capable of printing with TPU filament.

Filament for printer: 0.5-1kg TPU.

3D-scanner

USB Memory stick with minimum 1 gigabyte capacity.

Temperature Sensor:

Min / Max Temperature: -20 / 50 C

Accuracy: +/- 1C

Weight: < 50 gram

Voltage: 1-5 V

Accelerometer:

Min / Max Acceleration: -2 / 2 g

Sensitivity: > 10 kg/s

Weight: < 50 gram

Voltage: 1-5 V

Microcontroller:

Storage: 1 megabyte on chip or expandable storage (flash).

Voltage: 3-5 V

Weight: <150 grams.