MASTER THESIS

REDESIGNING AN ANTI-TREMOR ORTHOSIS FOR INCREASED WRIST MOBILITY

Graduation Project Integrated Product Design by Bob de Reus

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Master Thesis

Improve the mobility of a tremor suppression mechanism for the next generation of anti-tremor orthosis to be marketed in ~2024.

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ABSTRACT

People who suffer from tremor experience uncontrollable, involuntary movements. Depending on the underlaying cause, these movements occur during rest, or simultaneous with voluntary movements.
STIL is a YES!Delft based, med-tech startup that is developing a non-invasive, anti-tremor orthosis that helps people with tremors in their upper limbs. The current anti-tremor orthosis helps with the reduction of upper limb tremor. However, it limits the mobility of the user's hand and wrist. Motion in the Wrist Radial and Ulnar Deviation (WRUD) degree of freedom are limited due to the way the orthosis is designed.

By redesigning several parts of the orthosis, a new degree of freedom has been added to the device.
This increased mobility makes the orthosis more comfortable in daily use, and could even be beneficial to the suppression of upper limb tremor.

By integrating a small mechanical damper, the friction in the WRUD degree of freedom can be controlled.
A system of interlocking parts, supported by dampers ensure a durable and smooth rotation when the wrist is moved.
The fully functional prototype was manufactured and handed over to STIL bv for further testing, along with recommendations to optimize the design .

ABBREVIATIONS

- ADL – Activities in Daily Life
- DBS – Deep brain stimulation
- DOF – Degree of Freedom
- EFE – Elbow Flexion/Extension
- ET – Essential Tremor
- FPS – Forearm Pronation
- FVD - Fluid viscous dampers
- HIFU – High Intensity Focused Ultrasound
- MR dampers - Magnetorheological dampers
- NIOSH - National Institute of Occupational Safety and Health
- PD – Parkinson's disease
- PoR – Program of Requirements
- PoW – Program of Wishes
- RoM – Range of Motion
- SAA – Shoulder Adduction/Abduction
- SFE – Shoulder Flexion/Extension
- SIER – Shoulder Internal/External Rotation
- TRL – Technology Readiness Level
- VEM - viscoelastic materials
- Vim – Ventralis intermediate nucleus
- WFE – Wrist Flexion/Extension

READERS GUIDE

1: ASSIGNMENT AND APPROACH

The initialization and structure of the project are introduced. The client, product and problem are introduced and the research assignment is established.

2: ANALYSIS

General knowledge of tremor and its impact on people's life has been gathered by literature research. The 5W1H method is used to get a broad understanding of the context of the project

3: EXPLORATIVE RESEARCH

By engaging tremor participants with simple spit-model prototypes, a deeper understanding of the needs and want of the users is created. The gathered information is used to set the design scope.

4: IDEATION & CONCEPTUALIZATION

Different ideas that have come to light during the research are discussed and the most valuable ones are clustered into concepts. After testing the concepts, a design direction is chosen.

5: FINAL DESIGN

The development of the final design is explained. Based in the improvements of the chosen concept, a fully functional prototype was manufactured.

6: CONCLUSION & RECOMMENDATIONS

This report ends with several conclusions based on all the knowledge that has been gathered during the project. Recommendations are given for the further development of STIL's orthosis

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PART 1: ASSIGNMENT AND RESEARCH APPROACH

This part of the report discusses the initialization and structure of the project. The client company is introduced, as well as their product on which the project is based and the problem it is trying to solve. The design brief that was used as a starting point for the project is provided in summarized form. An overview of the methods and tools that have been used can also be found in this section.

INTRODUCTION

A tremor can be described as a rhythmical, involuntary oscillatory movement of a body part (Deuschl et al., 1998). People who suffer from tremor can experience difficulties in activities of daily life, such as eating, drinking, writing, cooking, reading a newspaper and much more (Bain et al., 1993).
The contractions of the muscles limit the ability to execute controlled motion with the affected body part. Apart from the physical discomforts, movement disorders that cause tremor are associated with higher than normal rates of depression (Miller et al., 2007) and social anxiety (Louis et al., 2015).

Tremors can occur due to many different conditions. However, the two most common ones that cause tremor in the upper limb are Essential tremor (ET) and Parkinson's Disease (PD) (Davidson & Charles, 2016).

Figure 1. The effect of upper limb tremor

STIL'S ANTI-TREMOR ORTHOSIS

This project is initiated by STIL. STIL is a YES!Delft based med-tech startup that is developing a non-invasive, anti-tremor orthosis that helps people with tremors in their upper limbs. The orthosis, also referred to as "The Beam", helps to cope with their condition by stabilizing their hands without surgery or medication. A patient wears this orthosis on its arm (see Figure 2). By mechanically dampening the motion caused by the contraction of different muscle groups in the arm, involuntary tremors have less impact on the overall movement of the limb. The STIL orthosis differentiates itself from other anti-tremor devices by being 100% mechanical and therefore not rely on sensors or other electronics to function. This allows for a sleeker and lighter product than competitors that offer for example weighted brace solutions, or electronically controlled dampers (see chapter: Anti-tremor devices).

At the moment of writing, the latest version of the STIL orthosis is in Beta-testing and has been clinically tested. The last steps are being taken for the first production run. Any and all proposed variations or redesigns to the design of the product in this report will only be considered by STIL for the next version of the orthosis.

DESIGN BRIEF ASSIGNMENT

The current anti-tremor orthosis helps with the reduction of upper limb tremor. However, it limits the mobility of the user's hand and wrist. This limitation in mobility can hinder the user in everyday tasks and this could lead to the user experiencing discomfort. The current design mounts to the upper arm and hand and due to its construction, the degree of freedom that is associated with Wrist Radial and Ulnar Deviation (WRUD) (see Figure 3), is locked. This means that movements like giving a handshake, drinking from a cup or using a computer mouse are obstructed by the orthosis.

Figure 2. A person wearing the STIL orthosis

The research can be condensed into the following assignment:

"Improve the mobility of a tremor suppression mechanism for the next generation of anti-tremor orthosis to be marketed in ~2024."

This research will be based on 3 subquestions

1. Is adding a degree of freedom to allow for WRUD desirable?
2. Is damping tremors in WRUD desirable from a user's perspective?
3. How could STIL best integrate wrist mobility in their anti-tremor orthosis?

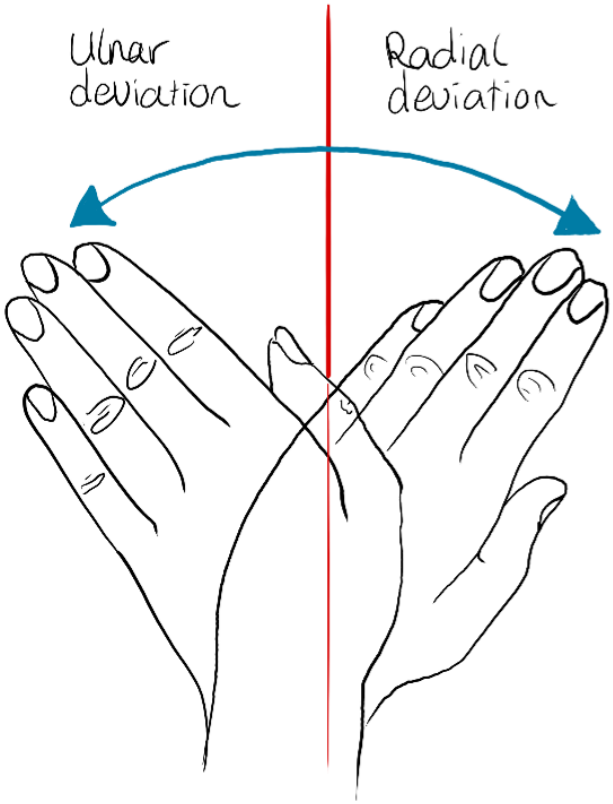


Figure 3. WRUD illustrated

PART 2: ANALYSIS

The analysis phase can be categorized using the Kipling method. The problem as stated in the design brief is tested by asking questions “How? Why? Where? What? Who? and When?” This method is also referred to as the “5W1H method” for this reason.

The problem as stated before is: The current anti-tremor orthosis helps with the reduction of upper limb tremor. However, it limits the mobility of the user’s hand and wrist.

The first part of this chapter; “How”, discusses how the device currently functions. How does the user wear it, and how does it suppress tremor?

“Why?” covers the different types and causes of tremor. To answer the question “Why do people suffer from tremor” some definitions and numbers are given.

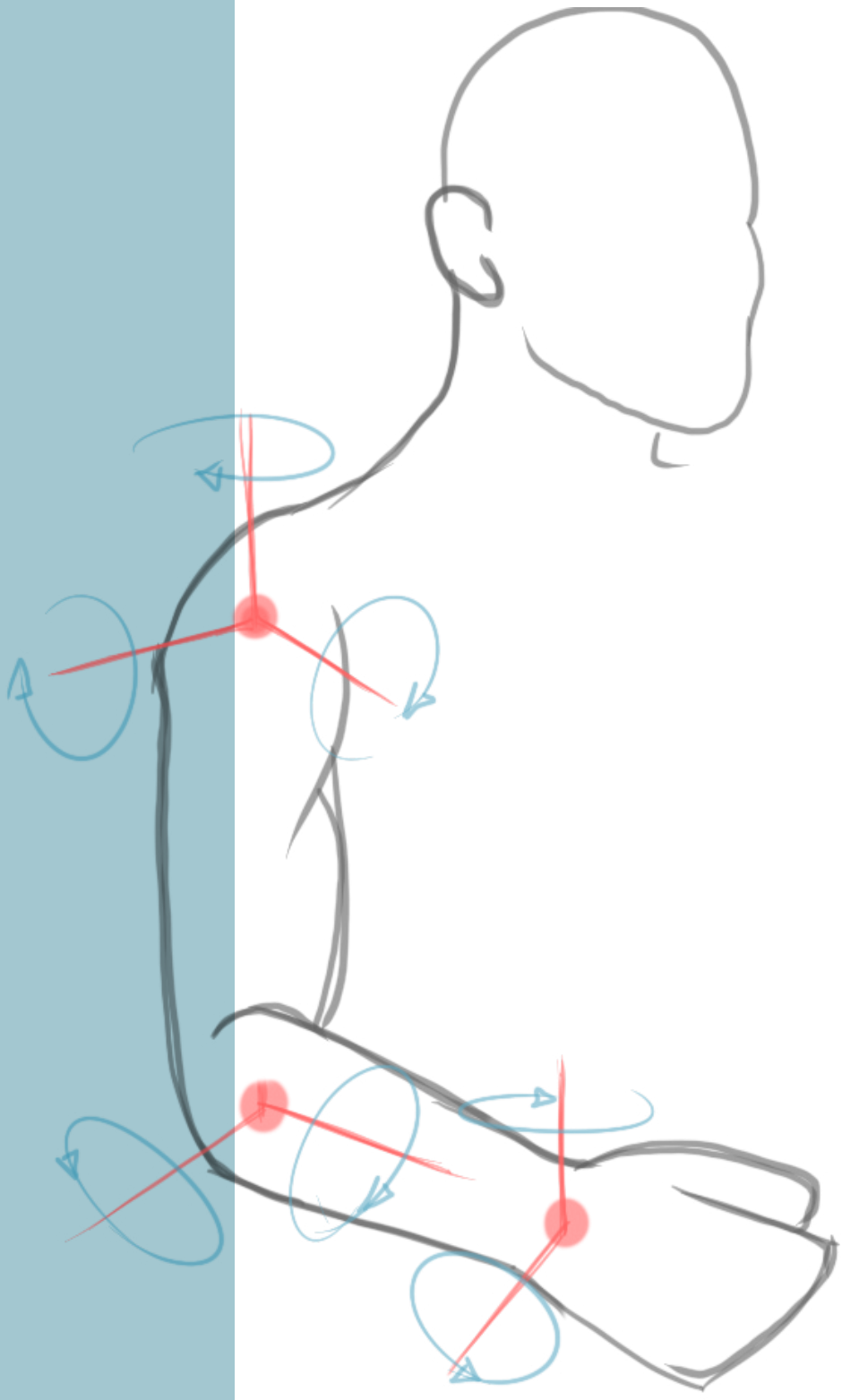
“Where?” zooms in on the mechanics of the tremor in order to answer the question: Where does the tremor take place? The knowledge of degrees of freedom in the upper limb help to understand the mechanics of the orthosis and is essential for understanding the literature and previous research regarding the involved types of tremors.

“What?” is aimed at collecting information regarding what is the status quo on tremor suppression. What are current treatments and what are other products that are currently on the market that suppress lower limb tremor?

The subchapter “Who?”, focusses on subjects regarding the target group and direct stakeholders. Who is the device designed for? Who is impacted by the design choices proposed in this report?

“When” forms the last chapter which covers the timing of this project in the greater timeline of the development of the entire STIL anti-tremor orthosis.

The findings that are collected in this part of the report are converted into design guidelines or requirements. The guidelines are accompanied by a (PoR...) number that refers to the corresponding line in the Program of Requirements, or a (PoW...) for wishes (Appendix 3: Program of Requirements)



HOW?

To answer how the orthosis functions, this chapter explains some of the working principles. It shows the different parts of the orthosis and explains how the user can mount it on its arm.

THE ORTHOSIS IN DETAIL

The device created by STIL is classified as an orthosis. This is defined as an external device (such as a brace or splint) for supporting, immobilizing or treating muscles, joint or skeletal parts which are weak, ineffective, deformed or injured by the Merriam-Webster dictionary. Orthoses are not to be confused with prostheses, which are artificial devices that replace a missing or impaired limb or body part.

The user mounts the Orthosis (Figure 4) on its arm and attaches the device securely using straps on the elbow cuff and the hand piece (2 and 3). A foam padding in the elbow cuff and a layer of soft fabric between the hand piece and the user's hand ensure a comfortable fit on the user's upper limb.

A combination of bearings, axles and dampers allow the user to keep a relatively high range of motion of the upper limb in most degrees of freedom. However, the dampers will resist some of the forces that are exerted on the device due to movements in specific directions and slow down these movements. This is concept of mechanical dampening is what helps to diminish the effect of the tremor.

The Orthosis can be configured for both left, and right arm, dependent on which arm is dominant and the severity of the tremor. Most users prefer to wear the orthosis on the dominant hand, but in some cases, it is the non-dominant hand that experiences the most tremor. If so, it could be more beneficial to wear the orthosis on this limb. Currently, the orthosis can be configured for left or right arm use without changing parts. It does however require some disassembly and reassembly.

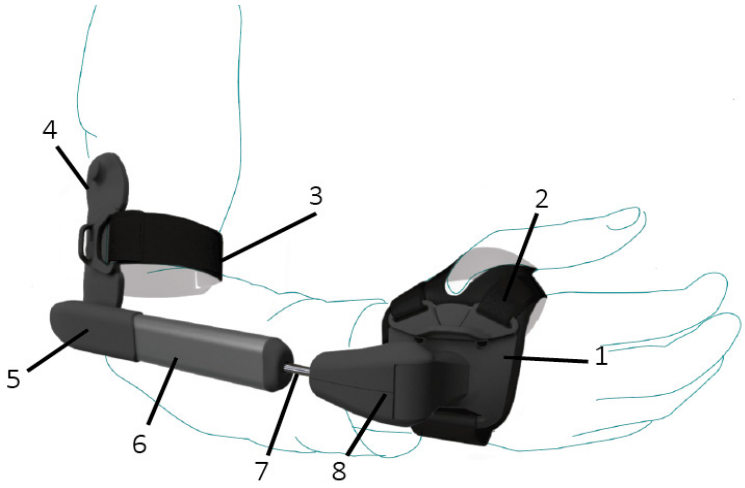


Figure 4. Orthosis by STIL

1. Hand piece
2. Hand piece fabric and straps
3. Elbow strap
4. Elbow cuff
5. EFE joint
6. Extension element
7. Extension axis
8. WFE joint

Design guidelines from this section:

- Orthosis must facilitate a high range of motion in the entire upper limb. (PoR 12.1)
- The orthosis must be able to withstand 1 Nm torque in WFE direction (PoR 12.2), and 1 Nm torque in FPS direction (PoR 12.3) (based on current damper specs with a safety factor applied suggested by STIL).
- Orthosis must be wearable on both left and right arm with minimal changes to the device. (PoR 22.1, 22.2)
- The parts of the orthosis should be as interchangeable as possible for left or right handed

WHY?

In order to find a solution, you must first know the cause of the problem. In this sub chapter some definitions can be found regarding tremor and tremor types. The most prominent causes of tremor are discussed in the section.

TREMOR DEFINITION

A tremor is an involuntary quivering movement in a person's body. Tremors are classified in several different categories by Anouti (1995), and are summarized in Table 1.

Table 1. Table 1. Types of tremor

TYPE OF TREMOR	SUBCATEGORY	DESCRIPTION
Rest		Occurs in a body part that is not voluntarily activated and is completely supported against gravity
Action	Postural	is present while voluntarily maintaining a position against gravity
	Kinetic	Simple kinetic tremor - This tremor occurs during voluntary movements that are not target-directed. Intention tremor - is present when amplitude increases during visually guided movements toward a target at the termination of the movement and the possibility of a position-specific tremor or a postural tremor produced at the beginning or end of a movement is excluded.
	Task-specific	Kinetic tremor that may appear or become exacerbated during specific activities.
	Isometric	Occurring as a result of muscle contraction against a rigid stationary object (for example, while making a fist or squeezing the examiner's fingers).

The current orthosis seems to be the most effective against action tremors. The mechanics of the device only achieve their intended goal of damping motion during larger movements of the upper limbs (more than a couple of degrees of rotation in the joints). In the case of an action tremor, these motions coincide with the propagation of the tremor. A resting tremor is also present when the limbs are stationary. Therefore, the focus lies on action tremor mitigation. Since the device only has an obvious mechanical advantage during motion of the hinges, kinetic action tremor is expected to be the most susceptible subcategory for using the orthosis. However, effectiveness on other categories cannot be ruled out. Essential Tremor is often characterized by action tremors (Louis, 2013), whereas Parkinson's Disease is usually associated with resting tremors (Baumann, 2012).

WHY DO TREMORS OCCUR?

Tremor can be triggered by something innocent like excitement or cold, withdrawal from alcohol or other addictive substances or it can be the result of diseases or disorders. The two most prevalent examples of disease related tremors are Essential Tremor and Parkinson's Disease. Essential Tremor is estimated to affect 4.6% of the population aged 65 and older. Parkinson's Disease is prevalent in 2% of the population above 65 years old. Out of all individuals affected, an estimated 50% of those who suffer from Parkinson's Disease will develop tremors while all of those affected by Essential Tremor will have to deal with tremors (Pigg, 2019). Combined, Parkinson's Disease and Essential Tremor are responsible for causing tremors in an estimated 1.1%, or 5.49 million individuals in the European Union alone (Fromme et al., 2019). In 65% of the cases, these tremors cause great difficulty with everyday activities like eating or drinking. This leads to at least mild depression symptoms with 48% of Parkinson's Disease and 34% of Essential Tremor patients (Fromme et al., 2019).

Anouti (1995) lists some of the main characteristics of Parkinson's and Essential Tremor. Essential Tremor is described as mostly effecting patient's hands held in posture, or during voluntary movements. Parkinson's disease can symptomize as rigidity, bradykinesia and (classically) resting tremor, but postural tremors are also known to occur.

Due to the way that Essential Tremor and Parkinson's usually present themselves, it seems that the orthosis will be most effective for people suffering from the former. Although the orthosis could very well be helpful to a portion of Parkinson patients, the developments during this project will focus on, and be scrutinized by people with Essential Tremor. In future research, it would be advisable to see if any alterations to the design impact the effectiveness for people with Parkinson's Disease.

So, why do people get tremor?
Tremor is not linked to a single cause, nor does it have the same characteristics in every person. Essential Tremor is the most common cause of tremor, followed by Parkinson's Disease. The STIL orthosis is expected to work better for action tremors that are common for ET than for resting tremors that are common for PD. Tremor can affect people of all ages, but the

prevalence does seem to increase with age. To made the orthosis suitable for as many users as possible, data from a p97,5 population has been used when applicable

Design guidelines from this section:

- The orthosis must be effective at suppressing Action tremors, caused by Essential tremor (PoR 1.4)
- When data is gathered from population datasets, a 97,5 percentile must be considered. (PoR 7.2)
- The orthosis should help against as much tremor types as possible (PoW 1)

WHERE?

To find out where tremor takes place, and where improvements can be made, some

MECHANICS OF TREMOR

In order to define which muscles are most important in causing tremors, Pigg et al (2020) classified seven degrees of freedom in the upper limb in which tremors can occur. Although a tremor often does not limit itself to a single degree of freedom, these degrees can be used to describe tremor activities in specific parts of the upper limb.

The seven degrees of freedom of the upper limb are illustrated in Figure 5. The numbers correspond with the labels in Figure 6 as well.

The orthosis is engineered to fit on the lower arm. This means that by wearing it. The degrees of freedom 4, 5, 6 and 7 are affected.

EFE (4) is made possible by a pivoting axis that connects the arm cuff to the extension element.

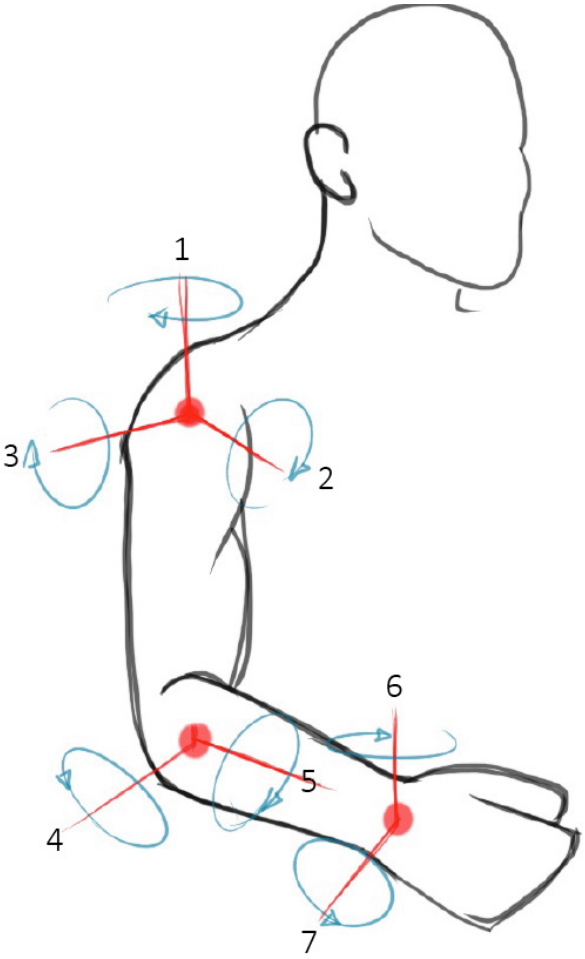


Figure 5. Degrees of freedom in the upper limb

1. Shoulder Internal/External rotation (SIER)
2. Shoulder Abduction/Adduction (SAA)
3. Shoulder Flexion/Extension (SFE)
4. Elbow Flexion/Extension (EFE)
5. Forearm Pronation/Supination (FPS)
6. Wrist Flexion/Extension (WFE)
7. Wrist Radial/Ulnar Deviation (WRUD)

FPS (5) can take place due to an axis that runs through the extension element. The rotational movement is dampened with a damper that is attached to the axis. This axis can also move in and out of the extension element to follow the movements of the lower limb.
WFE (6) is facilitated by a damper. This damper attaches the handpiece to the rest of the orthosis.
WRUD (7) is currently fixated by the orthosis. There is a range of motion of +/-10 degrees due to play in the soft fabric straps on the hand. However, this is not intended.

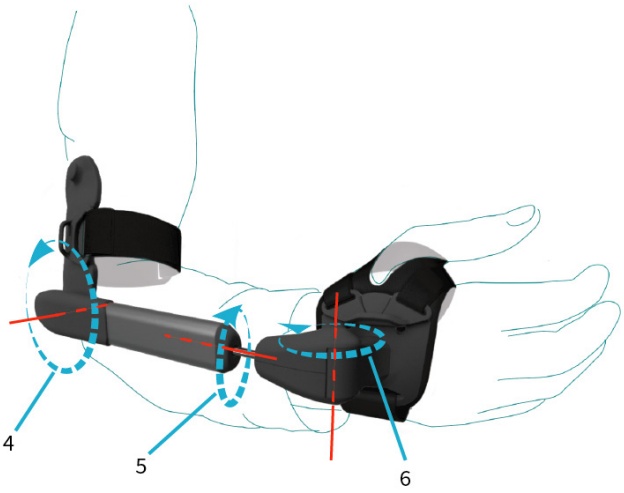


Figure 6. DoF's of STIL's orthosis

FOCUS ON WRUD

This project will focus primarily on the motion occurring in the WRUD degree of freedom. Pigg et al. (2020) have found that (kinetic) tremors are most powerful in FPS and WFE. Tremors in WRUD share the 3rd place with SIER in Pigg et all their tremor power ranking. WRUD tremors are currently dealt with by fixating the upper limb around this degree of freedom. This helps to diminish the tremors to a certain degree. However, fixation also brings discomfort to the user. In order to make the orthosis more comfortable, a simple hinge could be added in the WRUD DoF. However, the expectations is that this would reduce the effectiveness of the tremor damping of the orthosis. Too much freedom in the system could counteract the damping that is required in other degrees of freedom. Therefore, this research will focus on finding a solution that provides optimal comfort and suppression.
Patients do often present themselves with tremor in more than one degree of freedom. Hence, WRUD tremor cannot be considered as an isolated problem. The influences of changing the design on the functionality of the entire product have to be kept in mind.
Table 2 provides an overview of several Activities in Daily Life (ADL) that could benefit from more mobility in the WRUD DoF. These examples have been collected by watching archival video of participants who got to use an early version of the orthosis where WRUD is fixed

Table 2. Table 2. ADL hindered by limited WRUD mobility, as observed in STIL archival video

ADL, hindered by limited WRUD mobility
Drinking from a cup
Shaving facial hair
Using a computer mouse
Opening a door lock
Reaching for a high shelve
Polishing nails
Brushing your teeth

RANGE OF MOTION

Mashall (1999) identified that there is a statistically significant effect of forearm and wrist posture on the RoM of the wrist. However, the effect is small in magnitude (<5°) for the most parts. One combination of movements that did show profound effects on the RoM was radial deviation and WFE. Radial deviation was highest with the wrist is extended, and it decreased with more than 30% when the wrist was in flexion.

The anthropometric database of the TU Delft (DINED) contains measurements of different populations and can be used to find statistics on WRUD RoM The following datasets are consulted: “Dutch adults 20-30, mixed”, “Dutch elderly 50-54 mixed”, “Dutch elderly 75-79 mixed” and “Dutch elderly 80+, mixed”. Other databases did not provide information on WRUD RoM or were deemed not relevant. Table 3 shows the mean and standard deviation of all 4 datasets and the P97.5 data. P97.5 is selected as a threshold value since this is the population that STIL would like to be able to reach with their product. The numbers indicate the maximum RoM in WRUD.

(Upon closer inspection and based on the researcher’s intuition, it seems that the measures for ulnar and radial deviation have been swapped in the population Dutch adults 20-30, mixed. Contact has been sought with the staff of DINED but no confirmation nor denial that the data is mixed has been given so far. A quick round of measuring peers resulted in exclusively larger radial than ulnar deviations, strengthening the suspicion of a mistake in the data. The data from this population will be excluded as arguments for design decisions)

The largest radial deviation can be found in Dutch elderly, aged 50-54 with a value of 64 degrees for a P97.5. The largest ulnar deviation can be found in Dutch adults aged 50-54 and 80+ with a value of 36 degrees. From this we can conclude that there is no need for the device to facilitate more than 64 degrees of RD and 36 degrees of UD for RoM purposes (see Figure 7). It is not very likely that these extreme angles are often achieved while wearing the orthosis during ADL since this would be uncomfortable.
In order to minimize the risk of repetitive trauma injuries, postures or motions that place joints near the limits of their Range of Motion (RoM) should be avoided. The National Institute of Occupational Safety and Health (NIOSH) concluded in a survey of epidemiological studies that strong evidence exists to show a positive association between work that requires extreme postures and the prevalence of hand/wrist tendinitis (Bruce P. Bernard, 1997). Therefore, one could argue that it can be beneficial if the orthosis would limit RoM

Table 3. DINED P97.5 Max WRUD data

population	Dutch adults 20-30, mixed			Dutch elderly, 50-54, mixed			Dutch elderly 75-79, mixed			Dutch elderly 80+, mixed		
measures	Mean	SD	P 97,5	Mean	SD	P 97,5	Mean	SD	P 97,5	Mean	SD	P 97,5
Radial deviation (deg)	23	6	34	44	10	64	44	7	58	42	8	58
Ulnar Deviation (deg)	45	8	61	22	7	36	19	8	35	20	8	36

of the user to a value near their limit in order to prevent accidental overstretching, although this is not the original purpose of the device. This will therefore not be a direct goal in this research.

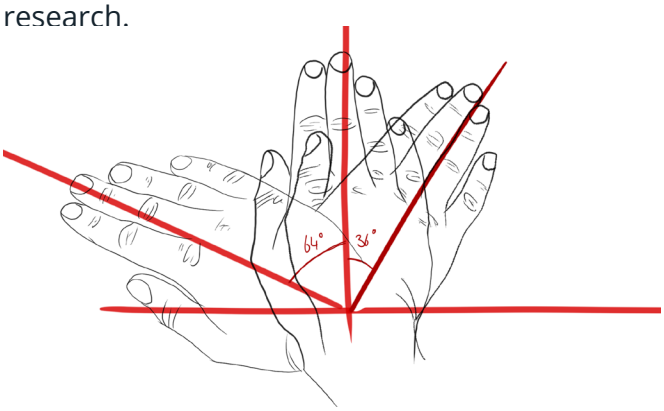


Figure 7. 64 degrees radial and 36 degrees ulnar deviation

LOCATION ON THE HAND

The center of rotation of WRUD influences the design decisions regarding the implementation of any sort of system that allows this mobility. Due to the intricate anatomy of the human hand, the center of rotation varies slightly between ulnar and radial deviation but is can be placed roughly at the lower center of the capitate metacarpal bone (see red dot in Figure 8 & 9) according Ayhan and Ayhan (2020) in the book Kinesiology of the Human Body. This means that in order to avoid unnecessary tension or discomfort, the axis of WRUD in the device should run as parallel as possible to this spot on the capitate.

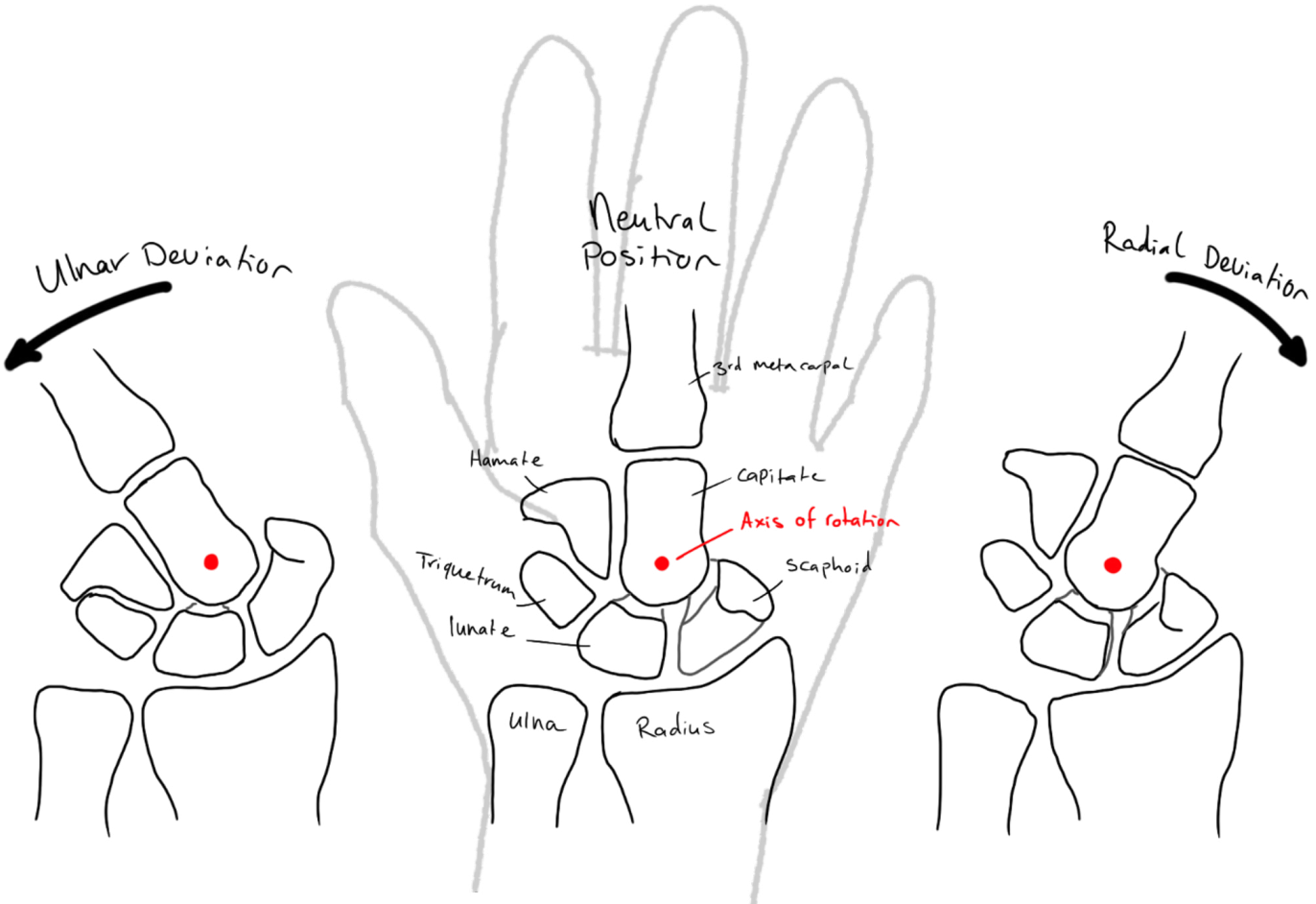


Figure 8. Axis of WRUD on anatomical representation of hand

The orthosis mounts to the hand with a connection that is located directly above the capitate (see Figure 8). This connection is called the WFE housing.
This part was expected to be the most obvious place to implement a system that facilitates WRUD

So where does the tremor take place?
Tremor can occur throughout the body. The most relevant tremor for this project is the Wrist Radial and Ulnar Deviation tremor. Often the tremor does not concentrate in one single degree of freedom. Therefore, it is important that changes made to the design of the product in favor of WRUD tremor suppression do not have negative influences on tremor suppression in other degrees of freedom. Considering a p97.5 dataset of the Dutch population, the maximal range of motion is 64 degrees radial, and 36 degrees ulnar deviation. The device should facilitate, but does not have to greatly exceed this range of motion.

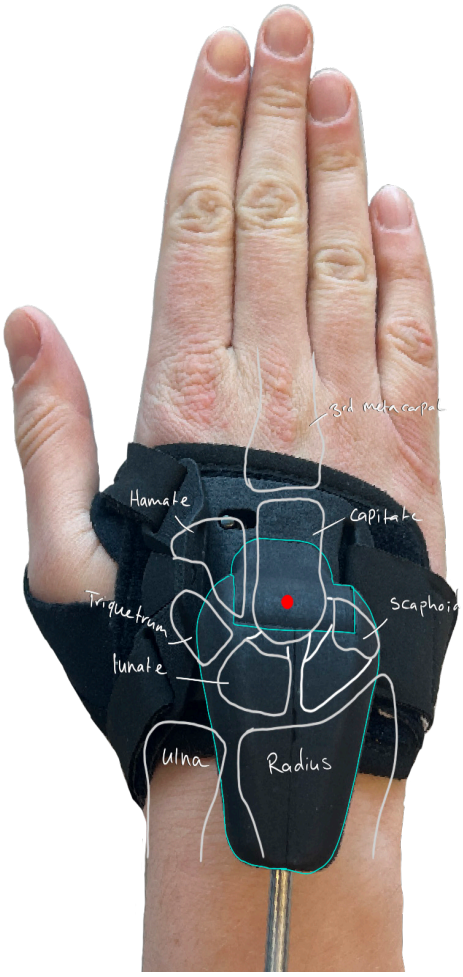


Figure 9. Orientation of WRUD axis and handpiece

Design guidelines from this section:

- The orthosis must include degrees of freedom for EFE, FPS, WFE and WRUD (PoR 1.5)
- The orthosis must have a Range of Motion of at least 64 degrees radial, and 36 degrees ulnar deviation. (PoR 7.1)
- The WRUD axis of the orthosis should center on the lower part of the capitate metacarpal (PoR 7.4)

WHAT?

What can we do against tremor? What are the unmet needs of people who suffer from Essential Tremor or Parkinson's Disease?

SURGICAL AND PHARMACEUTICAL TREATMENT

There are several ways of treating tremor. However, there is no permanent cure at this moment. The most effective treatment is dependent of several factors like age of the patient, progression of the disease and severity of the tremor. The treatments also differ in invasiveness for the patient. Medication can be preferred because it does not require the patient to undergo surgery. However, the medication can come with a plethora of side-effects and have varying mitigating effects on the tremors. Some patients respond well to medication and experience a rapid decline in tremor activity. Some others hardly notice any improvement at all. Alternatively, patients can undergo different types of brain surgeries.

Several methods have been developed to different types of brain surgery that are based on lesioning or stimulating the ventral intermediate (Vim) nucleus of the thalamus. The results of these surgeries are promising, but the procedure is highly invasive, not all patients qualify for this treatment and especially for Parkinson's Disease the effect on rigidity, gait and bradykinesia are lacking (Lozano, 2000). A nonpermanent surgical treatment that is available is Deep Brain Stimulation (DBS). Small electrodes are implanted in the brain and connected to a pacemaker-like device that is inserted beneath the skin of the patient (usually in the chest or stomach). Results are promising (40/80% reduction) but plenty of disadvantages remain. The treatment is expensive (+/- €33.000 per treatment), efficacy decays over time and the batteries need periodic replacement, requiring new surgeries (Davidson & Charles, 2016).

Then there is the problem that Essential Tremor and Parkinson's Disease are degenerative conditions, meaning that they get worse over time. None of the remedies that are effective at controlling tremors is therefore a guaranteed permanent solution (Case et al., 2013).

So, taking into account the side-effects, decaying efficacy, progressive nature of the diseases, financial aspects and invasiveness of the above-mentioned treatments, it is safe to say that surgical and pharmaceutical procedures cannot help everyone who suffers from Essential Tremor or Parkinson's Disease.

Table 4 lists procedures that form the main treatments for Essential Tremor and Parkinson's Disease.

TREATMENT GAP

If medication and surgery do not work, then what does?

In the 2015 study: "Defining the treatment gap", (Louis et al.) approached essential tremor patients with a questionnaire regarding their self-perceived, met and unmet needs. More than 1400 people responded and the results indicate that in general, Essential Tremor patients are not happy with the available care.

Table 4. Tremor treatments, taken from Lora-Millan et al. (2021) (1), Higuchi et al. (2017)(2), Lozano (2000)(3).

Category	Treatment	Description	Effectiveness *
Surgical	Conventional surgery	Drilling into the skull and causing lesion	
	Gamma knife	Use gamma beams to cause lesion	67-96% tremor reduction, (2)
	HIFU (ET)	Use MRI guided ultrasonic waves to cause lesion	55% amplitude reduction (1)
	DBS	Electrodes attached to the brain are controlled by a pacemaker-like stimulator	80-85% amp. Reduction, 2% eligibility (3)
pharmaceutical	Propranolol (ET/PD)	Blood pressure medication that also helps with tremors	
	Primidone (ET)	Alternative to Propranolol, heavier side effects	
	Levodopa (PD)	Replenishes dopamine	

**The exact effectiveness of many of the treatments is difficult to express in a percentage, since the effect is often temporary or dosage dependent. Therefore, the results in the "effectiveness" column should be interpreted as indications, rather than absolute truth*

Only 11.8% of respondents indicated that they were happy with their care.

One of the questions that Louis et al asked their respondents was: "What do you find lacking in the treatment of your tremor? What would you like to see happening during a doctor's visit that is not happening now?". The responses were clustered in 39 discrete categories. Some interesting categories are: "treatment is not effective enough" (16.1% of patients), "Need for more options and a feeling of being in control" (12.7%) and "A treatment approach other than just medication and surgery" (11.2%). Respondents were allowed to give multiple answers.

The variety of the responses indicates the individual nature of Essential Tremor patient's needs. However, the fact that 9 out of 10 patients indicate that they are unhappy with their current treatment does show that there is a need for new approaches to fight Essential Tremor.

ACTIVE VS PASSIVE DEVICES

A generally less invasive method of suppressing tremor symptoms than medication or surgery is by using an external device that influences the propagation of tremors. Many attempts have been made to create a device that can we worn or installed on a patient with the goal of suppressing tremors.

Devices can be active or passive. An active device requires a source of energy other than the human body, and acts by changing the density or converting this energy according to the MDR ("Regulation (EU) 2017/745 on medical devices," 2015). Devices that do not fit this description are not labelled as active, and

therefore are considered passive in this project. Anything that uses software, or electric motors for example is considered an active device. A system consisting of only mechanical dampers is considered passive.

STIL's current orthosis falls in the category "Passive device". This has benefits over active devices for both the producer and the user. Passive devices require less certification and testing, don't need any electricity or charging, and usually contain less vulnerable parts. Therefore, it was expected that any modification to the orthosis would be a passive one, unless the reason for implementation was exceptionally good.

ANTI-TREMOR DEVICES

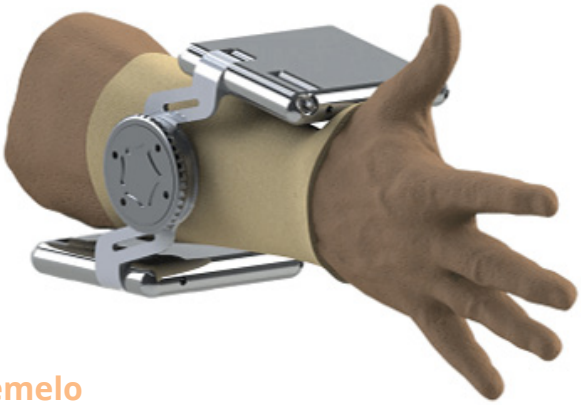
STIL is not the first company to try to get a device on the market that helps against tremors. A sample of some other products that are currently on the market is discussed below. This list is not exhaustive, but rather provides the reader with some context of the market for anti-tremor devices. These examples have been found by entering several search queries that describe "anti-tremor device" into google.

Liftware Gyro stabilized utensils

Working principle: Gyro stabilization
Summary: The spoon uses active motion cancelling. It moves in opposite direction of the tremor. This does not suppress any tremor, but rather mitigates the effect in the spoon itself.
Passive/active: Active
Price indication: €195
Website: www.liftware.com

CALA TRIO

Working principle: Electrical stimulation of the median nerve
Summary: A therapeutic, watch-like device that is worn on the arm. Patients should experience temporary tremor relief after a 40-minute wrist-worn treatment with the device
Passive/active: active
Price indication: prescription only, online forums mention a market price of €3200 combined with a monthly fee of €157. This price is not verified, since Cala does not list specifics on costs.
website: www.calatrio.com



Tremelo

Working principle: Mechanical tuned-mass-damper system

Summary: This system is worn on a sleeve on the forearm. 2 dampers cancel out the vibrations caused by tremor.

Passive/active: Passive

Price indication: €750

website: www.fivemicrons.com/tremelo

Steadi-Two

Working principle: Mechanical tuned-mass-damper system

Summary: This system is worn like a glove. The user can switch between two intensities of damping by turning a knob. A damper on the back of the hand suppresses the tremor.

Passive/active: passive

Price indication: €650

website: www.steadiwear.com

ATD

Working principle:
Nerve stimulation with vibration

Summary: The device transmits vibrations into the user's wrist in different patterns. Supposedly this helps with signal processing in the thalamus, which would decrease tremor symptoms.

Passive/active: active

Price indication: €340

website: www.antitremor.org

STIL's anti tremor orthosis

Working principle: Mechanical dampers

Summary: An orthosis is worn on one of the user's arms. By mechanically dampening the movement in several degrees of freedom, tremor should be suppressed

Passive/active: passive:

Price indication: No retail price yet, product is still in development. Expected retail price: €1500.

Website: www.stilwearable.com

So, what is the status quo of tremor suppression?
9/10 patients are not satisfied with their current treatment. The most common treatments against tremor include surgical and pharmaceutical procedures, but these can be ineffective, invasive and expensive. Anti-tremor devices could fill the treatment gap that patients experience.

Design guidelines from this section:

- The orthosis must remain a class 1, passive device according to the MDR (PoR 6.1)

WHO?

In previous sections some characteristics of the intended user of the orthosis have been covered already. By taking data from literature, some estimates have been collected in this section that illustrate the extent of the possible target group.

TARGET GROUP

As mentioned before in this chapter, the main target group for the STIL orthosis at this moment is people with Essential Tremor. The Netherlands will be the beachhead market, with plans to expand to neighboring countries like Germany once production, logistics and the market are ready.
A rough estimate of the size of the potential target group:

- (Song et al., 2021): Global prevalence of ET: 0.32% in the general population
  - (Ranging from 0.04% in people under 20 to 2.87% in those aged 80+)
- The Netherlands has 17.5 million inhabitants

17.5 million * 0.32%= 56.000 people in The Netherlands alone that have ET. Of course, only a selection of this group will experience tremor in the degrees of freedom that the STIL Orthosis can help with. However, this estimate shows that there is potential demand for the product. Especially since neighboring countries and other possible tremor patients like those suffering from Parkinson's are not even included. Also, ET is a disease that has an increased prevalence with increased age. Taking into account that the population of The Netherlands is aging, the ET prevalence of 0.32% is probably on the conservative side.
Some factors that are known to cause the orthosis to be less effective are:
Severe shoulder tremor, finger tremor, severely deteriorated hand or arm strength. Shoulder and finger tremor occur just out of reach of the orthosis, but can have a serious impact on the ability of the user to perform ADL. Deteriorated strength may cause the user to be unable to correctly mount the orthosis, or in severe cases experience fatigue quickly when wearing the device.

For people who suffer from upper limb tremor, activities that are usually experienced as pleasant and fulfilling can turn into embarrassing scenes. During the course of this project, several people who suffer from Essential Tremor have shared their problems and frustrations. Some examples can be found below:

- *You could imagine that eating a hot bowl of soup in the company of your family is not so comforting any more if your hand shakes uncontrollably and you spill soup everywhere.*
- *Being told to "Just take it easy" and "there is no reason to be nervous" all the time when you try to take your bank card out of your wallet to pay in line at the supermarket is very frustrating. Especially when you are not nervous, but rather have no control over the fine motor skills required to perform this every day task.*
- *Having to hold your wineglass firmly with two hands when you want to take a sip at a birthday party makes you look unmannered and draws attention, just when you don't want it.*

The feeling of disappointment and desire to return to a time before the tremor occurred was often tangible in the room when people shared these stories. Every participant was hoping to find a tool or method to, even if only temporary, do these seemingly mundane activities without the inconvenience of a tremoring limb.

So, who would use the product?

The 56.000 Essential tremor patients in The Netherlands are a good place to start. The device is not suitable for every one of these individuals. However, testing by STIL indicates that the orthosis can help a lot of people. Not much is known yet on the effects on Parkinson's disease, but the orthosis could be beneficial to those patients as well. Currently the focus lies on Dutch patients, but expansion to neighboring countries is a possibility is the product is a success.

Figure 10. AI generated impression of spilling soup due to tremor

Design guidelines from this section:

- The orthosis must be suitable for the Dutch market, and be in compliance with Dutch rules and regulations. (PoR 6.2)
- Preferably, the orthosis should conform to European rules and regulations to facilitate possible expansion to neighboring countries.

WHEN?

STIL is in the last stages before bringing the first version of the orthosis on the market. The design is frozen and only minor changes are made to facilitate production and logistics. The research done during this project will therefore not have an immediate impact on the first version available to the public. The reason that freedom in WRUD was not included in the current version was because of considerations regarding complexity, price and time available to put a product on the market.
The suggestions and advices in this report are relevant for a possible version 2 of the orthosis. Currently, version 2 is planned to be released somewhere in 2024.

Design guidelines from this section:

- The proposed improvements must be aimed at version 2 of the orthosis (PoR 10.1)
- The proposed improvements to the orthosis must be implementable by 2024 (PoR 10.2)

The insights collected through desk research in the previous chapters show that there is not a single, one-size-fits-all solution to relieve all tremors. However, STIL is developing a device that can help to regain control over one's hands when they are affected by upper limb tremor. In order to find a good balance between tremor suppression, and user comfort there are several variables that can be adjusted. It is likely that a compromise needs to be found between completely free, unhindered WRUD motion of the wrist and fixating WRUD in the orthosis. What is this compromise would look like and which mechanisms are involved will be investigated in the following parts of this report. The redesigned orthosis should increase the mobility without having a negative effect on the performance of the device in general. It should match the device's strong points, and contribute positively to the weak spots.

CONCLUSION OF PART 2

During the analysis phase, information was gathered and processed from many different sources. The findings are used to create guidelines for the redesign of the orthosis. These guidelines are included in the program of requirements for different concepts that have been developed.

REFLECTION ON DESIGN BRIEF

The problem that has been investigated in the analysis part has been: The current anti-tremor orthosis helps with the reduction of upper limb tremor. However, it limits the mobility of the user's hand and wrist. This limitation in mobility can hinder the user in everyday tasks and this could lead to the user experiencing discomfort.

The analysis proved that the initial assignment was accurate and interesting enough to continue the project. The main title remains: "Improve the mobility of a tremor suppression mechanism for the next generation of anti-tremor orthosis to be marketed in ~2024.".

The problem statement is backed up by literature and first hand experiences from people who have been contacted during this project.
The three sub questions have been reformulated in order to be more specific to the project and open ended.

Old sub questions:

1. Is adding a degree of freedom to allow for WRUD desirable?
2. Is damping tremors in WRUD desirable from a user's perspective?
3. How could STIL best integrate wrist mobility in their anti-tremor orthosis?

Reformulated sub questions:

1. How does adding a degree of freedom in WRUD affect the user of the STIL anti-tremor orthosis
2. How does adding damping to the WRUD degree of freedom affect the performance of the STIL anti tremor orthosis?
3. What is a good way to embody a system that optimally facilitates WRUD mobility in the STIL anti tremor orthosis.

PART 3: EXPLORATIVE RESEARCH

In this part of the research, sub questions 1 (How does adding a degree of freedom in WRUD affect the user of the STIL anti-tremor orthosis) and 2 (How does adding damping to the WRUD degree of freedom affect the performance of the STIL anti tremor orthosis?) are explored. Prototypes of the orthosis that include various degrees of WRUD freedom with and without dampers have been constructed. These prototypes have been used by people with tremor and their feedback is collected.

With this new knowledge, an educated decision could be made on the general design direction. Also, valuable experience was gained regarding working with the tremor patient demographic.

PARTICIPANT VALIDATON SESSIONS

Up to this point in the report, all research was based on the assumption that it would be beneficial for the user of the orthosis to have more mobility in their wrist. However, it was unknown how people would react to the orthosis with variable wrist freedom. More research was required to find out about both the physical implications (the effect on the tremor) and the experiential implications (how does the user reacts). In order to find out if freedom in WRUD helps to make the user feel less restricted by the orthosis, four versions of the prototype have been developed. These prototypes have varying degrees of dampened and undampened freedom of motion. Then they will be given to tremor participants for evaluation. These sessions will provide more insight on how the prototypes deal with the tremors, and how potential users value their properties. A full protocol for these sessions can be found in "APPENDIX 4A: FORMATIVE EVALUATION WRUD TESTING 1"

Two research questions were formulated on the topic:

1. How does adding a degree of freedom in WRUD affect the user of the STIL anti-tremor orthosis
2. How does adding damping to the WRUD degree of freedom affect the performance of the STIL anti tremor orthosis?

ETHICS

The four versions have been evaluated by STIL personnel first, to get an impression of how the variations are received by experienced users. All necessary precautions were taken to account for participant safety. See "Appendix 2: Ethics" for elaboration on ethical considerations.

EXPECTATIONS

The four cases that have been selected to validate with potential users are (see example with corresponding numbers in Figure 11):

1. Fixated WRUD (similar to the current orthosis)
2. Linear dampened WRUD (Friction damper)
3. Velocity dependent dampened WRUD (Viscous fluid damper)
4. Free WRUD (no damping in WRUD at all)

These four cases were translated into prototypes. A brief overview of the different characteristics of the four prototypes can be found in Table 5. A more elaborate explanation on the construction and details of the prototypes can be found in APPENDIX 4A: FORMATIVE EVALUATION WRUD TESTING 1

The difference between prototype 2 and 3 is based on the different types of dampers that have been used. For more information on these dampers see Appendix 5: Dampers.

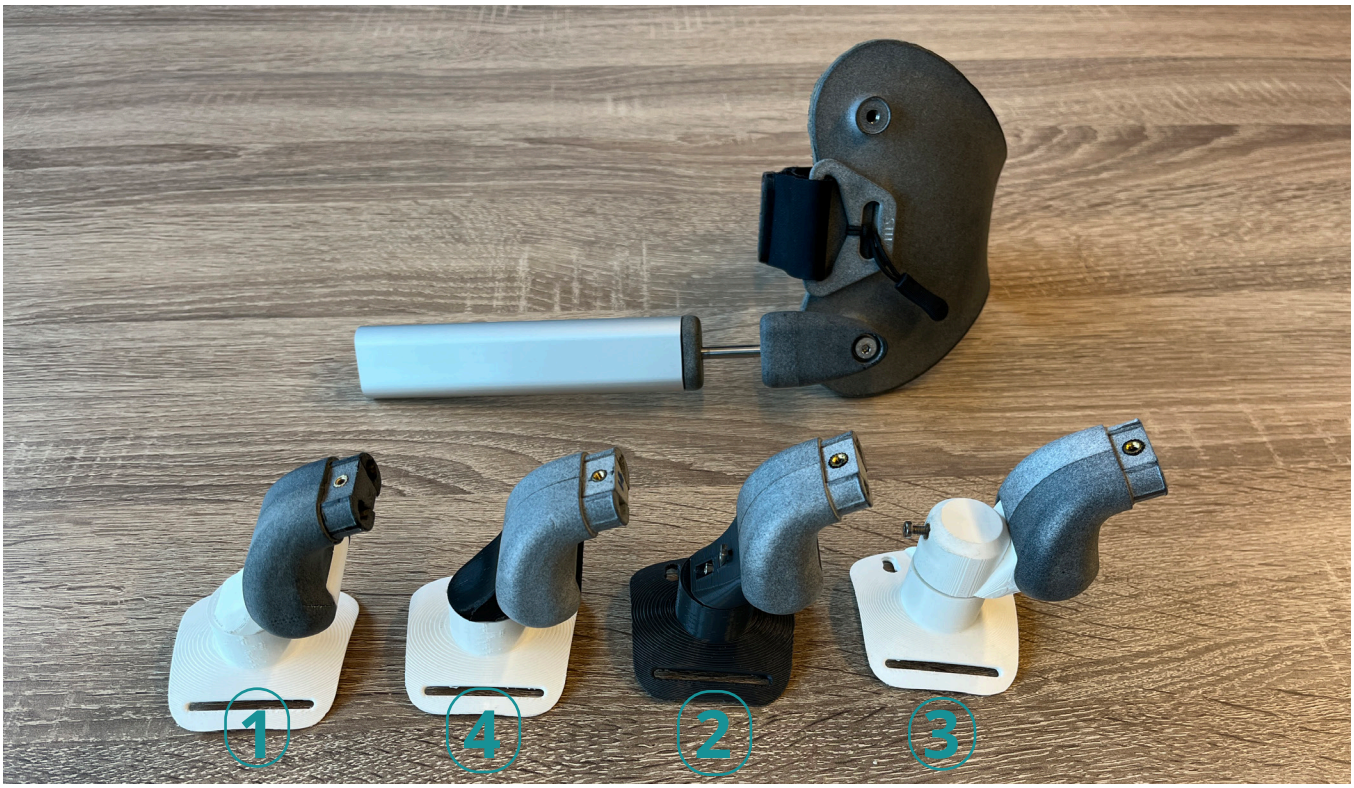
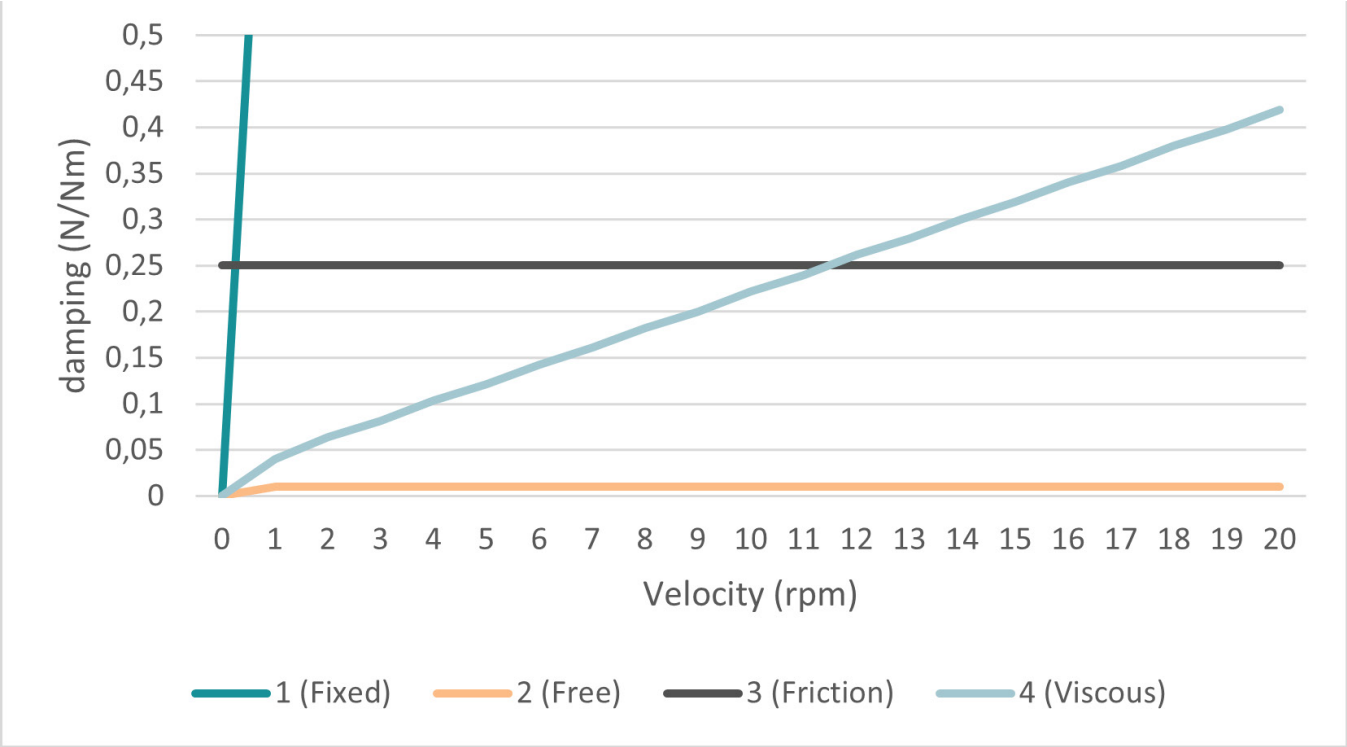


Figure 11. Prototype overview (1=fixed, 2= friction damper, 3= Fluid Viscous damper, 4= free)

Table 5. Characteristics of the four prototypes

	1	2	3	4
WRUD mobility	Fixed	Dampened	Dampened	Free
Type of damper	None	Friction	Viscous fluid	None
Expected damping	None	0.25 Nm	0.4 Nm (@20RPM)	<0.1 Nm

Graph 1. Damping characteristics of the four prototypes



Graph 1 gives an overview of the damping characteristics of these four different prototypes, dependent on the rotational speed of the wrist.

In order to minimize the variables that could influence the participants, all prototypes were designed to have the axis of freedom at the same relative positions. Because of the addition of the dampers, this meant that the WFE axis had to be placed further away from the handpiece, causing the gap between the user's arm and the extension element to increase (see Figure 12) from approximately 40mm to 55mm. therefore all prototypes were adapted to have this same extension element-arm gap.

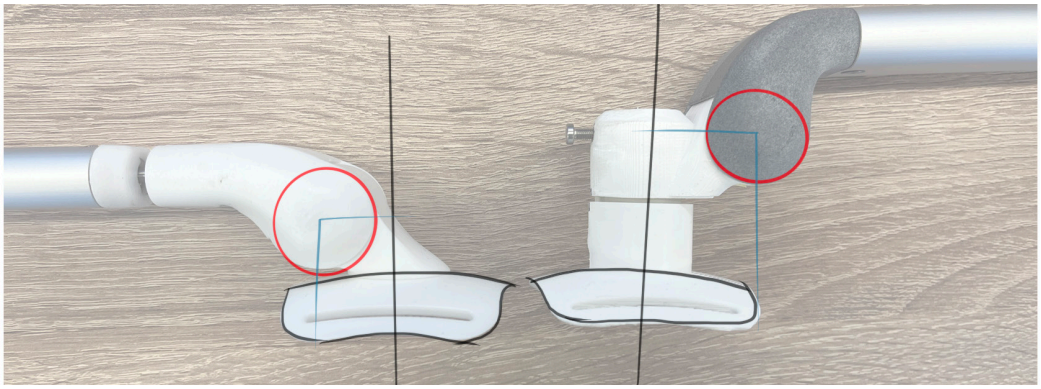


Figure 12. Orientation of WFE damper (left = current orthosis, right = prototypes)

Prototype 1

Expectations:

Should work similar to the current orthosis, since all of the functional parts have remained unchanged. However, it might be perceived as less comfortable due to the larger gap between the extension element and the user's arm ((comfort -2, ease of use 0, tremor suppression 0)

Figure 13. Prototype 1, fixed WRUD

Prototype 2

Expectations:

Works well for people who still have plenty of strength in wrists. Might be difficult to find the right damper value. If damper value is too high, people will not be able to rotate the wrist consequently which could be undesirable (comfort+1, ease of use +2, tremor suppression 0).

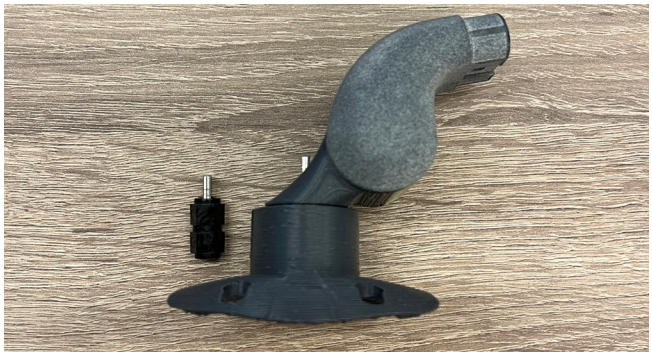


Figure 14. Prototype 2, Friction damper

Prototype 3

Expectations:

Works well for people with varying wrist strengths. Lack of strength can be compensated with slightly slower movements. Tremor is usually a faster movement than the voluntary one, so this could work well for tremor suppression. (comfort+2, ease of use +2, tremor suppression +1)

Figure 15. Prototype 3: Fluid Viscous damper

Prototype 4

Expectations:

The extra freedom could cause the user to move its arm in unforeseen ways. Tremor in WRUD and other DoF's that were previously suppressed could out themselves through this undampened axis. For users with mild tremors in general or no WRUD tremor this might be the most comfortable version since it allows the most unrestricted use of the wrist. However, it is also the most unpredictable version (comfort +3, ease of use-1/+2, tremor suppression-2)).

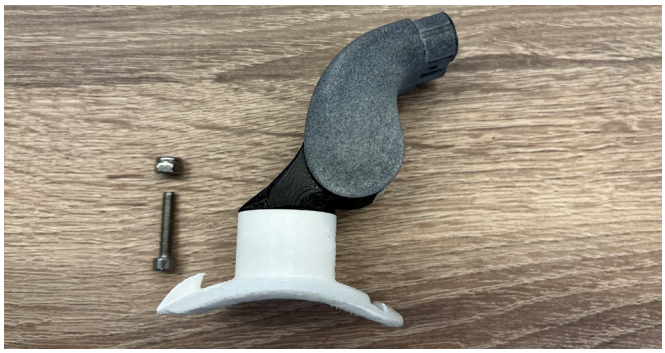


Figure 16. Prototype 4, Free WRUD

METHOD

To validate the expectations formulated at the beginning of this chapter, the prototypes are introduced to several people who are asked to use them during a prescribes list of activities. The full protocol for these sessions can be found in APPENDIX 4A: FORMATIVE EVALUATION WRUD TESTING 1

The sessions are designed to get validation of:

1. *The assumption that users want more freedom of motion in their wrist.*
   a. *Perceived comfort - Does additional freedom of motion in the wrist make the orthosis more comfortable to use? Does the user experience a certain variety in their range of motion as pleasant?*
   b. *ADL activities - How much is this freedom required in daily life? Does it help the user to have WRUD freedom when performing ADL?*
   c. *No detrimental results for other DoF's - How does adding a degree of freedom influence the tremor suppression performance of the device in other DoF's? Will extra RoM increase the expression of tremors that were suppressed in earlier versions?*

2. *Is damping of WRUD desirable?*
   a. *Perceived comfort - Does damping the WRUD movement make the orthosis more comfortable to use? Does the user notice the difference with undampened versions? Which one is preferred?*
   b. *ADL activities – Does damping the WRUD movement help with suppressing tremors in WRUD, FPS and WFA?*

PARTICIPANTS

The evaluation has taken place with the help of tremor participants and non-tremor participants. Recruitment of tremor participants will take place using STIL's database of interested tremor patients that signed up to help with the development of the product. Non-tremor participants (or "healthy" participants) prototype evaluation have been STIL personnel.

ACTIVITIES

The activities that have been performed by the participants are described in Table 6.
It was expected that "Computer use" (3) would be the easiest task to perform. It involves limited degrees of freedom of the upper arm, allows the participant to (partially) rest its arm on the table, and tremors do not cause very visible "mistakes" of any kind.
"Drinking" (1) and "key in lock" (4) were expected to be slightly more difficult. They both involve combined movements in at least 4 degrees of freedom. "Drinking" could add the mental hurdle of not wanting to spill, whereas "key in lock" has some extensive motion that pushes the participant to move towards the extremes of their achievable range of motion.
"Writing" (2) could be the most difficult task to perform since this requires very fine motor skills. Also the result of each individual tremor is highly visible, which could exacerbate the tremor.

PROCEDURE

During testing, participants have been asked to evaluate the devices while doing the activities mentioned in Table 6. The healthy users will be asked to perform the same activities as the tremor participants. Their results have been used to get a baseline on perceived comfort and ease-of-use and to pilot the sessions.

Table 6. Activities performed during sessions

Activity	Description	details	Involved DoF's
1	Drinking water from a cup	Bringing a cup (8 cm tall, filled with water to 1 cm from top) from the table to the mouth to drink water.	SIER, EFE, WFE, WRUD
2	Write with pen on paper	participant is asked to copy an Archimedes spiral using a ballpoint pen that approximately fills an A6 sheet of paper (Figure 7). The lines of the spiral should be approximately 1.3 cm apart. The pen should be held in such way that no part of the limb touches the table. After that the participant is asked to write 1 sentence with at least 4 words with the same pen and paper.	WFE, FPS, WRUD
3	Using a computer with mouse	Use a computer mouse to do a 30 second cursor accuracy test on a laptop. Specifically for this test: https://mouseaccuracy.com/	SIER, WRUD
4	Closing or opening door with key	Participant is asked to stand in front of a door. Using the hand with the orthosis, take the key out of the lock and remove it 30 cm horizontally from the lock, reinsert it and fully open and close the lock. A minimum of 360 degrees of rotation of the key is required	EFE, SFE, FPS, WRUD

The order of prototypes has been set from least to most wrist mobility. The rationale behind this is that it might allow the researcher to find a point where the patient indicated that this would be the "sweet spot" between freedom and damping.

PROCEDURE WITH THE NON-TREMOR PARTICIPANTS

This test forms the pilot for the tremor participants. The participants were asked to perform the same activities as planned for the tremor participants. Their input on safety and logistics of the procedure are used to optimize the test with tremor participants and to verify the safety and usability of the prototypes.

PROCEDURE WITH THE TREMOR

The participants will be observed during all activities while wearing different the four prototypes. Their performance is rated on a scale of 1 to 5 where 1= not influenced by tremor at all, and 5 means that the participant is completely unable to perform the task at hand due to their tremor.
The recorded video has been analyzed to see what the effects are of freeing WRUD on tremor propagation. Participant's comments were used to analyze perceived comfort. A list of questions was used to guide the feedback sessions, when necessary, but there is also room for spontaneous conversation.

PARTICIPANT VALIDATION SESSION RESULTS

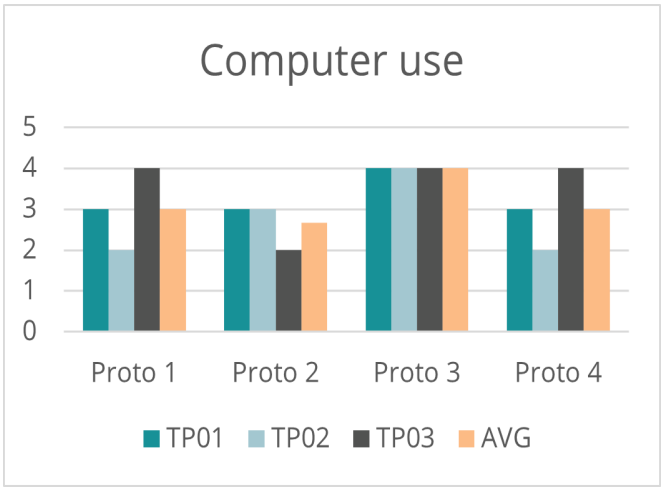
OBSERVATIONS WITH NON-TREMOR PARTICIPANTS:

- Participants are used to a sleeker version of the orthosis
- Participants generally respond very positive to increased WRUD mobility
- The difference between WRUD damping in prototype 2 and 3 is not picked up on by the participants themselves unless told what to pay attention to
- The damper values are quite low for the participants. They experienced little resistance or damping. Non felt like they had to push very hard to move their wrists.
- Prototype 4 was preferred over the rest. All indicated this one as their personal favorite. This was expected because these participants have no apparent benefit from damping their motion.
- Participants all indicated that the range of motion in WFE was limited due to the design of the prototype.
- By placing the WFE hinge higher and closer to the elbow piece, their ability to fully flex and extend their wrists was clearly reduced.

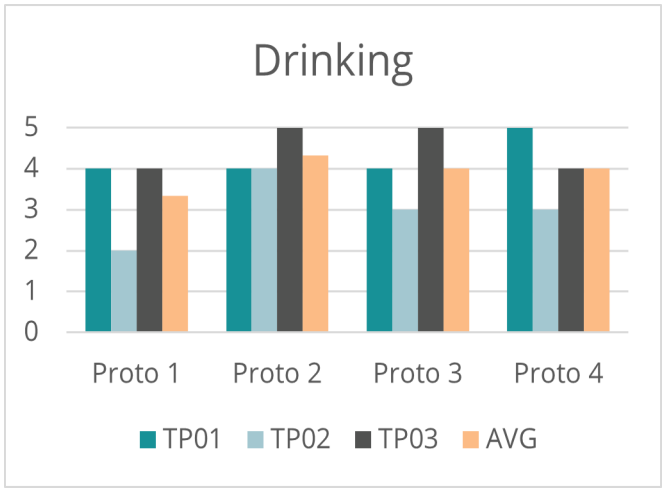
OBSERVATIONS WITH TREMOR PARTICIPANTS:

- All research with tremor participants took place in the participant's own home, so conditions were not 100% the same. However, the setup was kept as similar as possible with the tools available.
- The results from the session with these participants varied much more than the results with non-tremor participants.
- Markings on the WRUD axis of the orthosis made it possible to confirm that all participants displayed WRUD during testing, even though often they would not notice themselves.
- Only 1 participant indicated that he clearly felt a difference between all four prototypes
- There was a noticeable difference between the scores that participants gave themselves throughout the session, and the scores that the researchers gave the participants.
- Two participants did not seem to notice that tasks were performed with more fluency or accuracy by themselves.
- The third participants was more aware of this

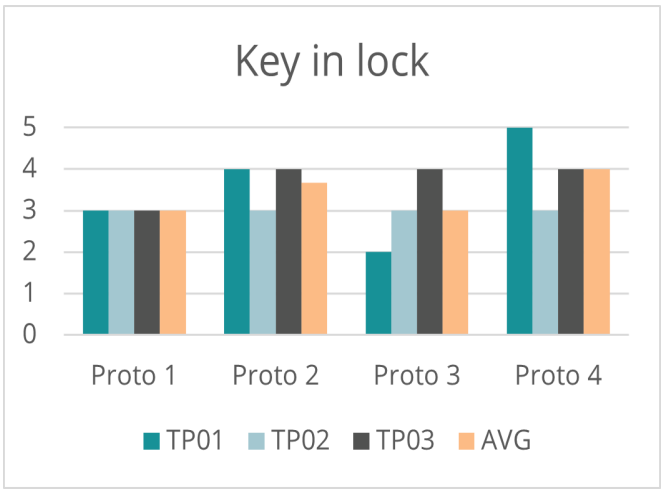
Graph 2. *Scores "computer use"*



Graph 3. *Scores "Drinking"*



Graph 4. *Scores "Key in lock"*



Graph 5. *Scores "Writing"*

Scores per activity

The scores of the participants with tremor are grouped per prototype, per activity. The AVG bar represents the average score of the 3 participants in Graph 2 to Graph 5. These graphs show that there is a large variety between the performance of the different activities. This can be explained by at least two factors: The complexity of the activity, and the tremor characteristics of the individual.
It turned out that “computer use” was not as easy as expected. The stress of the countdown timer made the tremor worse, and the participants seemed to avoid using a computer mouse in their daily lives.
“Drinking” and “key in lock” performed relatively similar when the averages are compared for prototype 1, 2 and 4. Prototype 3 scored better in drinking than locking a door.
“Writing” did seem to be the most difficult activity with all the prototypes.

No clear pattern could be discovered that shows that increasing WRUD mobility has a big influence on the performance of ALL

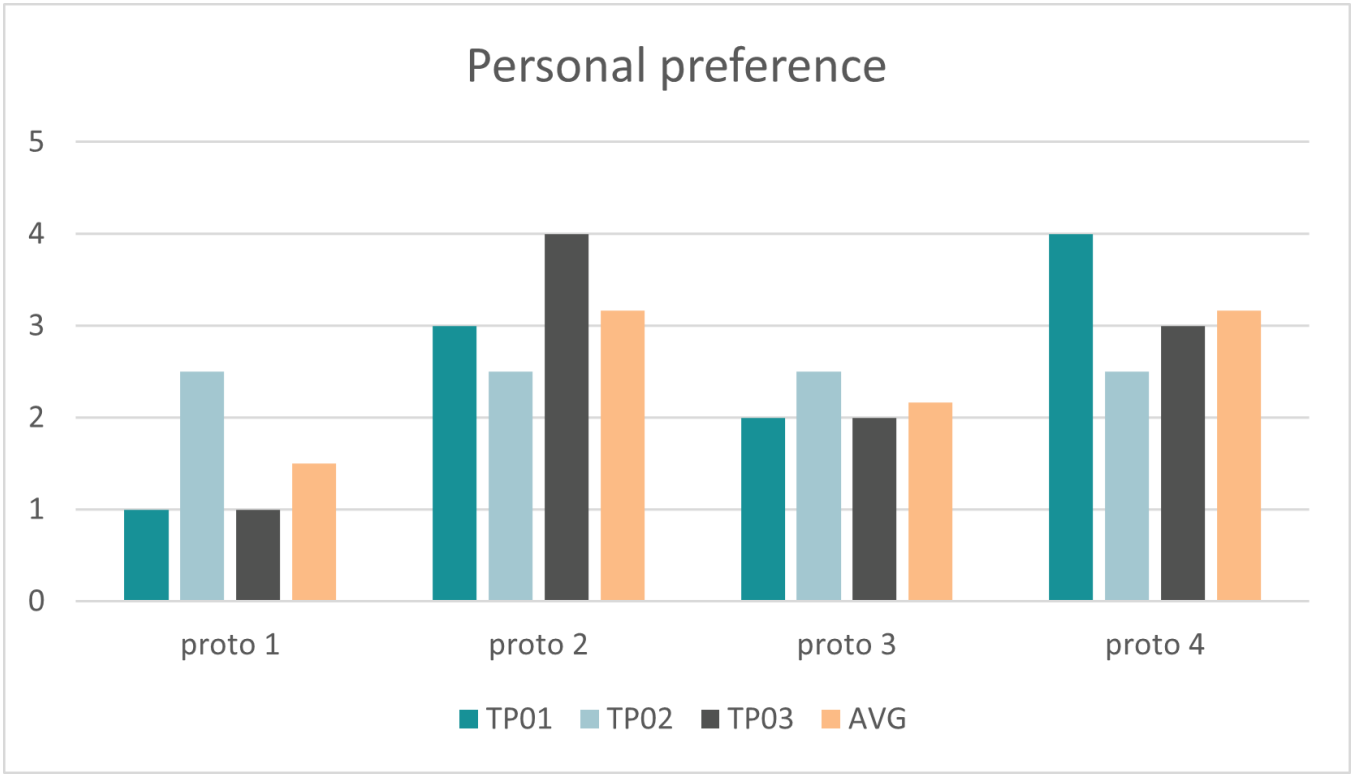
participants. The data varies per person. However, with the exception of prototype 2 during computer use, prototypes 2, 3 and 4 performed as good or even better at the tasks as prototype 1. This at least indicated that adding WRUD mobility does not seem to have

Personal preferences

After the activities, the participants were asked which prototype was their favorite. They did not have to give a logical explanation. A gut feeling was enough. The favorite prototype receives 4 points, the second favorite 3 points, and so on.
One of the participants indicated that there was no personal favorite. This has been interpreted as an average score of 2.5 for each prototype. The scores of all three participants, and their averages are shown in Graph 7.

Remarkable is that, without specific knowledge of the differences between the prototypes, the versions with increased WRUD mobility all scored higher averages than prototype 1 with fixed WRUD. Even though the performance of the prototypes varied a lot, the preference data does seem to imply that WRUD mobility is desired. Another interesting observation is that proto 2 (friction damper) and 4 (free) did better than proto 3 (FV damper).

Graph 6. Personal preferences of tremor-participants after sessions



CONCLUSION

The performance data suggests that in most cases (except for one), adding WRUD mobility does not affect the performance of the orthosis in a bad way. There was not a clear best method to implement this extra mobility noticeable yet.
The personal preference data shows that, even without knowing why, 2 out of 3 people have a preference for the versions that allow more WRUD mobility. The third person did not have a preferred prototype.

DISCUSSION

The sessions were hosted for only 3 tremor participants due to lack of time and availability of includable participants. This means that numbers should be taken with a grain of salt. They serve as an indication that there is merit for further investigation of the researcher's expectations.
The session with non-tremor participants were performed with STIL employees. They have plenty of previous experience with the orthosis to notice changes. They also noticed the limitation in WFE strongly and this might have played a role in the overall judgment of the prototypes.
The order in which the prototypes are provided to the participant might have an effect on how they experience the mobility of the wrist. It was expected that the participants would pick up on the increasing wrist mobility. However, only 1 out of 3 did. Perhaps if the order is changed, or the participants are guided more in what to pay attention to, the results would have been more outspoken.

PARTICIPANT VALIDATION DESIGN IMPLICATIONS

The most rudimental observation during the participant sessions was that every participant showed greater WRUD motion when using a prototype that allowed rotation in the WRUD joint. There was no evident relation between maximal range of motion and type of damping. This was expected, since there is no mechanism that provides a permanent counterforce or other limiting factor. One of the participants pointed out that the fixed WRUD orthosis caused shoulder pain. One possible explanation for this phenomenon could be muscle cramping due to unnatural movements of the upper limb to compensate the limited WRUD. Once this participant wore the orthoses with rotating WRUD joints, the pain subsided. The added range of motion was not always noticed by the participants during testing. However, the fact that the new added range of motion was actively being used during most activities indicates that a WRUD joint increases the usability of the orthosis. This observation might feel obvious but it confirms one of the main assumptions that this research is based on: "The user benefits from increased WRUD range of motion"

- The orthosis should have a mechanism that allows WRUD. (PoR 1.5)

By comparing fixed, dampened and undampened joints, insight was gained on the influence of restricting the WRUD. Damping was experienced differently by individual participants. Some noticed the damping

immediately; some never noticed it at all. In general, the participants did seem to perform slightly better with the dampened versions than with the free or fixed ones. Although definitive conclusions could not be drawn from the absolute test scores of the participants since n was only 3, observing the activities did give the researcher the confidence that some sort of damping in WRUD can be beneficial to decrease tremor in the upper limb. The exact type of damping has had only limited influence in previous testing.

- Damping of the WRUD joint could be beneficial to reduce upper limb tremor. The orthosis should have a mechanism that applies a damping force on WRUD. (PoR 8.2)

The method of using dampers to suppress tremor is applied on the WFE and FPS degree of freedom in the orthosis already. This first round of testing gave some promising results that damping the WRUD degree of freedom could also be beneficial. Therefore, it is included in further research in this report.

- The gap between the extension element and the arm should be kept as small as possible. The orthosis should keep a low and sleek profile. (PoR 7.3)

One of the aspects that all participants disliked was the increased space between the extension element and the lower arm (see Figure 12). This higher profile was perceived as more obstructive and less aesthetically pleasing than versions with a lower profile. It prevented the user from wearing the orthosis under a sleeve and could cause the user to bump into objects easier or even get entangled.

- Changes to the design cannot have negative influence on the functioning of existing features. (PoR 8.1)

The prototypes that have been used in these sessions were designed mainly with WRUD in mind. Not much attention was paid to the impact of the added mechanism on other degrees of freedom. During testing all the participants noted that their range of motion in WFE direction was more limited than they would like. The participants were more observant about new limitations than about new possibilities. If a new design implementation is detrimental to another feature of the product, the user focuses on the negative impact rather than the positive.

- Being able to vary the damping intensity is expected to be beneficial (PoW 4)

The fact that the responses to the prototypes varied a lot per participant shows the diversity of symptoms and level of distress that tremor can cause. On top of that, the intensity of tremor often changes over time in a single individual. It seems that it could be difficult to find a single, one-size-fits-all solution. During these sessions, test have been done with different types of dampers. However, no tests were done with varying damping force of one type of damper.

DESIGN SCOPE

This section concludes the research that has been done in support of this project. It is a subchapter that marks the transition from gathering information to the creation of new ideas.
The findings in the analysis and exploration yielded interesting background information and definitions on topics that have been crucial for this project. It also generated several design requirements. This list has been expanded throughout the project, hence the odd numbering in the overview below.

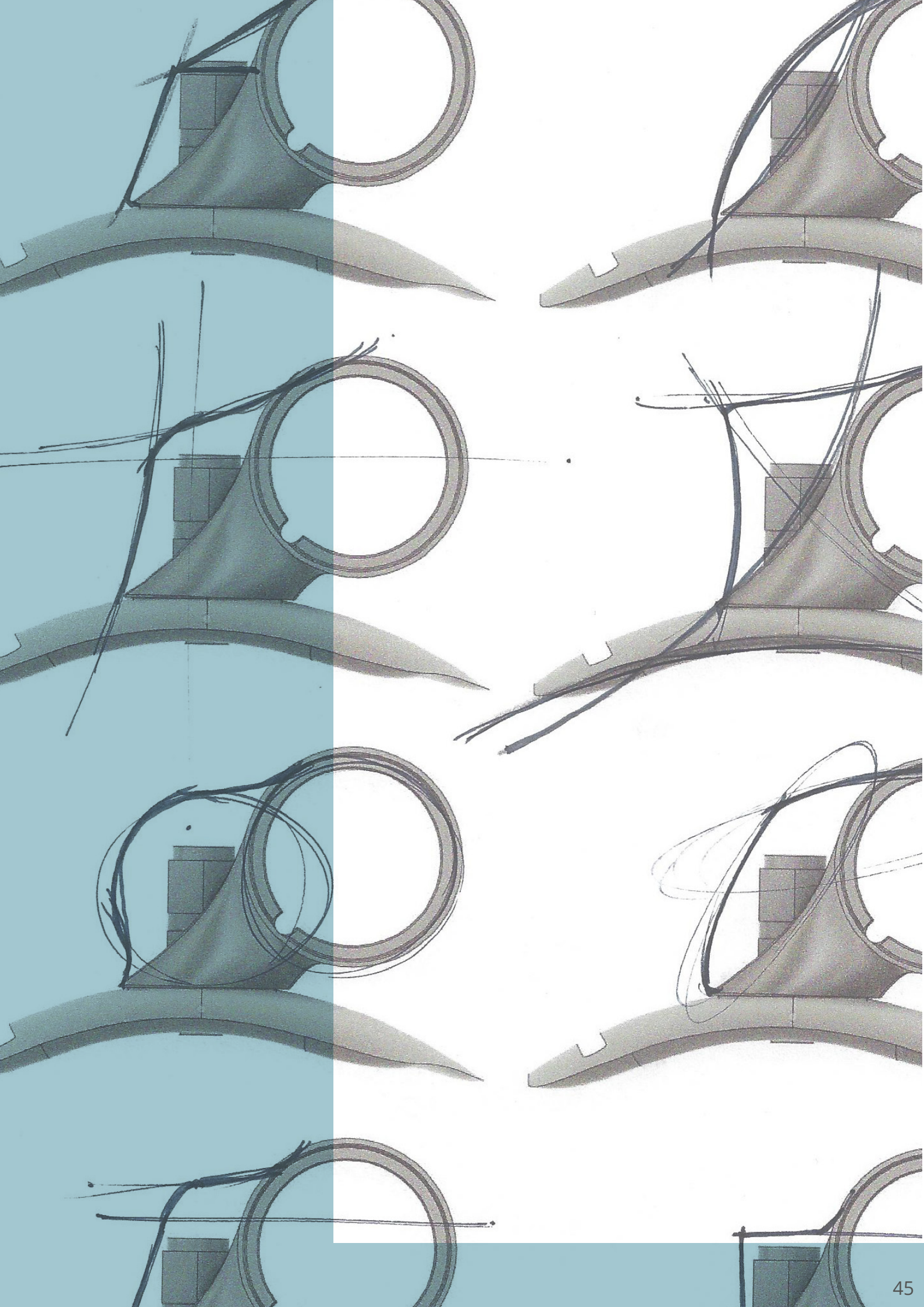
Requirements:

1. Performance
1.1. Product must facilitate a high range of motion in the entire upper limb.
1.2. Product must be able to withstand 1 Nm torque in WFE direction
1.3. Product must be able to withstand 1 Nm torque in FPS direction
1.4. The orthosis must be effective at suppressing Action tremors, caused by Essential tremor
1.5. The orthosis must include degrees of freedom for EFE, FPS, WFE and WRUD
2. Standards, rules and regulations
2.1. The orthosis must remain a passive device according to the MDR.
2.2. The orthosis must be suitable for the Dutch market, and be in compliance with Dutch rules and regulations.
7. Ergonomics
7.1. The orthosis must have a Range of Motion of at least 64 degrees radial, and 36 degrees ulnar deviation
7.2. When data is gathered from population datasets, a minimal p97,5 selection must be used.
7.3. In the neutral position, the gap between arm and extension element must not be bigger than 5 cm
8. Testing
8.1. The product should perform similar or better in comparison to the current (1.7) orthosis by STIL on TETRAS
10. Product policy
10.1. The proposed improvements must be aimed at version 2 of the orthosis
10.2. The proposed improvements to the orthosis must be implementable by 2024
11. Installation and initiation of use
11.1. The product must be wearable on both left and right arm.
11.2. The product must be reconfigurable between arms in less than 5 minutes.

These requirements will be used to test new ideas and concepts to make sure that they are realistic and valuable for all parties involved.

PART 4: IDEATION & CONCEPTUALIZATION

In this chapter, the different ideas that have come to light during the research are discussed and the most valuable ones are clustered into concepts. These concepts have been prototyped and introduced to a panel of potential users with tremor. During interactive sessions, the potential users got to experience the prototypes by performing several activities of daily life. Their performance was scored using the validated TETRAS essential tremor assessment instrument. Personal preference of the participants is also taken into account. The results of these sessions will be used as guidelines for a final design.



IDEAS/VARIABLES

During the research several design variables have been identified. The ideation for redesigning the orthosis is based on analyzing different approaches to these variables and combining the most promising options into design ideas. First the variables and their most promising options are discussed.

VARIABLE: WRUD MECHANISM

This variable deals with how to achieve a system that allows for the movement of the wrist in radial and ulnar direction. Desk research has been done into different "off the shelve" hinges and ways in which rotation is allowed in everyday objects. The most relevant ideas are:

Rotation axle

The idea is as old as the invention of the wheel. Perhaps older. A single, central axle that allows multiple parts to rotate independently, but on the same rotation axis. by creating a smooth and circular contact surface, friction and vibration are kept minimal.

Advantages:

Simple construction, durable and strong. Can take radial loads very well. Can be found in the current orthosis in the connection between the elbow piece and the extension element. Is also the basic mechanism behind most friction dampers.

Disadvantages:

Does not usually carry axial loads. Moment loads could cause uneven wear, which can have a negative influence on durability and performance. It does require some sort of end stop to keep the part from sliding off the axle. Prolonged radial loads could cause friction and wear if not lubricated properly.

Conclusion:

Simple, reliable mechanism. Likely needs a system to dissipate moment forces so they do not cause uneven wear.

Bearings

A mechanical part that reduces friction between surfaces and constricts movements. Different types of bearings are required for different loading scenarios (radial/axial/combined loads)

Advantages:

Usually cheap and readily available. No extra measures need to be taken to reduce friction in the intended loading case (Radial/axial/combined).

Disadvantages:

If not loaded properly, friction can wear down the internal parts, which can have a negative influence on durability and performance.

Conclusion:

Can serve as a friction reduction part which facilitates smooth rotation for a long period of time. Not all bearings are suitable for all applications so the right type of bearing needs to be selected for the specific load case.

Threads

Similar to the rotation axle. However, the addition of threads on this axle could prohibit axial displacement or sliding on the shaft. This would require the object that rotates around the axle to have a threaded contact surface similar to the axle.

Advantages:

Simple nut and bolt systems make use of

threads to keep objects in place. It is easily producible and can be found as fastening system throughout the orthosis

Disadvantages:

Using a thread and nut type connection will cause the nut to climb up and down the thread during rotation.

Conclusion:

A (partial) thread on the axle could be used to hold an object in place. If the entire part is threaded, the part will climb up and down which would cause design complications.

Flexible parts

By making use of flexible materials, the orthosis might not need individual moving parts to facilitate WRUD. If parts can bend without failure, they might provide the required range of motion.

Advantages:

No moving parts, so no friction and less parts in general.

Disadvantages:

Bending or twisting materials induces stresses and strains. This can lead to fracturing and failures in the material. Prediction of which material is applicable for the intended use can be time consuming and not always accurate. Small manufacturing deviations can cause unpredictable materials. The characteristics of the parts are greatly influences by the size and shape so design freedom is limited.

Conclusion:

The idea of a flexible part that is shaped in such a way that it forms a compliant mechanism is interesting. However, with the time constrain and plethora of challenges to solve this method is deemed unlikely to be very suitable for this project.

Ball (and socket) joint

A type of joint where a spherical stud or ball is enclosed in a cup shaped depression or socket.

Advantages:

It allows for both rotation and pivoting between the two connection parts. Attaching the two parts can be achieved via different methods like force-fitting or a locking mechanism

Disadvantages:

Complete freedom in movement is not desirable in the orthosis since it would render for example the WFE damper useless. In order to limit the movements to the desired degrees of freedom, physical barriers need to be built in that block the motion. This type of joint brings difficulties for rapid prototyping due to the required strength of the materials. It is also expected to be difficult to reliably dampen if that would be required.

Conclusion:

Ball and socket joints offer a wide range of motion. Perhaps a bit too wide for this project. Combined with the fact that they might be difficult to dampen, they do not seem like the appropriate method for this design.

Conclusion WRUD mechanism

Apart from the flexible parts and the ball and socket joints, all proposed ideas have potential to be used in the concepts. A combination of these methods can be used to counter the disadvantages of the individual ideas.

VARIABLE: DAMPER TYPE

Damping as a physical phenomenon can be described as reducing a vibrating or oscillating motion by extracting energy and dissipating this. Below you will find an overview of the different types that have been researched during this project. Because of their importance to both the performance and user-experience of the orthosis, a more in-depth analysis of these dampers can be found in Appendix 5: Dampers. The results are summarized below.

Viscoelastic material damping (VEM)

As the name suggests, viscoelastic materials (VEM) show both viscous and elastic characteristics when they are deformed. An elastic material will resist deformation and change shape when a force is applied. When the force is released, it returns to its initial shape. Pure elastic materials convert all their stored elastic potential energy back into kinetic energy, no energy is lost due to heat

Advantages:

VEM dampers are usually relatively simple and cheap block of compressible material. Depending on their application, they have decent form freedom

Disadvantages:

They are often used to dampen small amplitude vibrations. Damping a motion with a range of motion as large as is required for WRUD is difficult to do with a small VEM damper.

Conclusion:

Ideal for small amplitude vibrations. Unfortunately, not likely to be suitable to provide continuous damping that is required for WRUD

Fluid Viscous Dampers (FVD)

An FVD uses a viscous fluid that is forced through an orifice in a confined space. The viscous fluid's resistance to moving through a small orifice is what creates a counterforce. FVD's come in rotary and linear capacity. Opposed to the normal force of for example a spring, the damping of a FVD is velocity dependent.

Advantages:

Velocity dependent counter torque rather than force dependent. They come in linear and radial types and can be tunable to a certain extend.

Disadvantages:

The dampers are relatively complex to manufacture. They are also relatively large, heavy and expensive.

Conclusion:

These dampers are velocity dependent rather than force dependent, but are somewhat heavy and big.

Friction dampers

Friction dampers are a very basic type of damper. Their working principle is the friction between two surfaces. Once enough force is applied to the damper to overcome the static friction threshold, the damper will provide a constant counterforce.

Advantages:

The dampers can be small, cheap and reliable. They have been proven to be effective in the orthosis and are used to dampen the FPS motion. They are highly customizable and have relatively high form freedom as well.

Disadvantages:

If used to create relatively large damping forces, the friction between the two materials could wear out. This has a negative impact on the

performance of the damper.

Conclusion:

Friction dampers are a good option for this project due to, amongst others, their size and damping properties. The forces that are applied on them are well within range of that the dampers can handle and they are available for prototyping.

Magnetic/eddy current dampers

When a magnetic field is crossed by a non-ferromagnetic conductor, an eddy current, or electric field is induced. A resulting magnetic field then is induced by these eddy currents which opposes the motion of the conductor (Cadwell, 1996).

Advantages:

Accurately tunable by varying the magnetic field.

Disadvantages:

Bulky and complicated, prone to interference from external magnetic fields. They are relatively expensive as well.

Conclusion:

Due to their price and level of complexity, these dampers are not suitable for this project.

Magnetorheological (MR) dampers

MR dampers use fluids that carry microscopic magnetic particles. If a magnetic field is applied to this fluid, the particles will align and transform the behavior of the fluid into a plastic or even semi-solid state. This makes it possible to influence the damping characteristics in milliseconds by introducing a magnetic field to the damper.

Advantages:

Accurately tunable by varying the magnetic field.

Disadvantages:

Currently mostly used in combination with an electromagnetic field. This requires electronics, making it an active solution rather than passive. Passively controlling the damper is theoretically possible but this has not been applied outside academic context much at the moment.

Conclusion:

This method was thought to have great potential at the beginning of this project. However, the technology is not developed far enough to be applicable within the time constrains.

Conclusion damper type

Based on the criteria listed in Appendix 5: Dampers, and the advantages and disadvantages discussed above, only two types of dampers are deemed suitable for this project. Friction dampers are cheap, small and easy to use. Fluid viscous dampers have the advantage of being velocity dependent rather than speed dependent. However, they are bulkier and more expensive and their damping properties are not yet proven to be as beneficial for WRUD as for WFE.

VARIABLE: APPEARANCE

The appearance of the orthosis is highly influential for the perceived level of comfort and purchase decision of potential users according to previous marketing research by STIL. Potential users preferred sleeker and less bulky designs that would draw less attention and perhaps could be worn under their clothes. Some strategies to add the least bulk to the orthosis are:

Change part orientations

By rotating and moving parts around, trying to find how everything fits together as neat as possible. This applies to the orientation of the damper, as well as changing the layout of current parts of the hand piece and WFE joint.

Advantages:

It forces the researcher to approach the design with a fresh set of eyes and not take the previous design as a given. Perhaps new parts require a new way of putting the device together.

Disadvantages:

The current design has been optimized and tested during the last years. By changing too much, it could negatively impact the aesthetics or performance of the entire orthosis.

Conclusion:

The current design should not limit the possibilities so much that there is no room for change. However, every major change in orientation will likely cause changes in appearance and needs to be justifiable to the design department of STIL.

Minimize part size

focus on the package size of individual parts. Try to find the smallest components or fabricate them in-house to reduce size.

Advantages:

Smaller parts add less bulk to the appearance. If there is a choice to be made between two equally good alternatives, size can be the decisive factor.

Disadvantages:

Smaller is not always better. Some parts are a much better option than their smaller alternatives.

Conclusion:

Size matters, the amount of space available is limited and the area of the orthosis that will be redesigned is in a visible spot. The performance does have to be kept in mind as well, which sometimes might mean that some bulk needs to be added.

Streamline shapes

By streamlining shapes, they could be perceived as less bulky even though their volume remains unchanged. This also helps with making sure that the orthosis does not get snagged by clothes or other objects during use.

Advantages:

By creating a design that “flows”, bulk can be hidden. This gives some extra design freedom and can be used to camouflage added parts without making the device look clumsy.

Disadvantages:

The aesthetics do have to match the rest of the orthosis. If the redesigned part has a very distinct look, the rest of the orthosis needs to be redesigned to match it.

Conclusion:

Streamlining parts does help to hide added

volumes, but it can only help so much. Parts still need to fit the entire design of the orthosis.

Leave out damper

Adding a damper requires space. Since the current orthosis is designed to have minimal obsolete volume, it is likely that adding a damper means adding volume to the orthosis. If adding a damper can be avoided, this would be beneficial to the appearance of the redesign.

Advantages:

Less parts, less bulk, less material.

Disadvantages:

Could harm the performance of the orthosis.

Conclusion:

Only if there is clear indication that this degree of freedom does not benefit from damping, this strategy can be considered. It is easier to remove the damper and scale down the design than the other way around. Therefore, this strategy has not been applied now.

Conclusion Appearance

The different ideas regarding the appearance of the prototype are not mutually exclusive. It is likely that a combination of these ideas will be most effective. As a starting point, minimizing part size, changing part orientation and streamlining shapes can be used. Leaving out damper has larger influences on the design than just the aesthetics. This direction can only be taken if it has been proven that the damper is not required.

VARIABLE: DAMPING CUSTOMIZABILITY

Because of the progressive nature of tremor and the various ways it expresses itself in individuals, the damper value that is ideal for one person might not be ideal for the next. In order to design an orthosis that is beneficial to as much people as possible, it makes sense to allow for some variation of damping force. The current orthosis is only available in a single damper setup. However, STIL did indicate that they are interested in variable damping. This subject is right on the edge of the scope of this research, but the researcher has included it out of curiosity. Some possible options for damper customizability are:

Swappable dampers

By keeping the damper accessible and universal, it might be possible to swap dampers of the same category for variations with different damping forces.

Advantages:

A fitting session at the moment of purchase or simple service appointment could help to tailor the device to the specific needs of the user. It could also make the orthosis effective for a longer period for the user. Perhaps the user could even do the swap at home.

Disadvantages:

Setting up an infrastructure for damper customization makes the initial fitting more time consuming. It also could lead to doubt for the user if they have the right damper. It also requires that the orthosis would be build to be assembled and disassembled multiple times in its life. It also requires dampers in the same size but with different damping specs.

Conclusion:

The idea of being able to swap out the damper for one with different damping specs is interesting. Especially because essential tremor effects people with different levels of strength. Also, the strength in the upper limb can deteriorate as the disease progresses.

Adjustable dampers

By using a damper that is adjustable on its own, the damping could be personalized by something as simple as a set screw.

Advantages:

It allows the orthosis to be fine tuned to the specific need of the user at that specific moment. One damper can be used for a longer time. One type of damper can be used for different people.

Disadvantages:

Only a small selection of damper types is adjustable, and an even smaller selection is small enough to be considered for the orthosis.

Conclusion:

An adjustable damper seems to be a perfect solution to personalize the damping specifications of the orthosis. Unfortunately, it seems that they right one is simply has not been made yet. It is not impossible to make, but would require much more time than available in this project.

Manipulating a mechanical advantage

Damping is expressed in the moment of a force. By changing the distance at which a force is exerted, the damping could be experienced as less or more than in the original situation.

Advantages:

It allows for adjustable damping without changing anything on the damper itself.

Disadvantages:

It requires intricate mechanics and moving parts.

Conclusion:

Changing the damping experience by manipulating the mechanical advantage can be a substitute for a complicate adjustable damper. It does require more moving parts and complication outside of the damper.

Change pressure/friction

By increasing or decreasing the tension in a system, the (friction) damping can be influenced.

Advantages:

This can be applied on multiple levels, either within a damper, or on different moving parts of the orthosis.

Disadvantages:

Based on the same principle as the friction damper, not easily compatible with other damper types. Increased friction can cause to higher wear on the contact surfaces.

Conclusion:

Implementing a system that allows different friction settings could simulate an adjustable damper. Executing this in a reliable and durable way is difficult.

Conclusion damping customizability

Some damper types are easier to customize than others. For now, the choice of damper type has priority over the customizability of the damper. Some of the above mentioned ideas are not depending on the type of damper that is used. Their additional complication to the mechanism has to be evaluated to see if the idea still makes sense.

MORPHOLOGICAL OVERVIEW

All the options from the chapter above have been mapped in a morphological overview (Figure 17). It serves as an overview of the results of the research and helps to keep all options in mind and not skip any obvious combinations. The two concept directions have been plotted in red (concept 1) and blue (concept 2) lines.

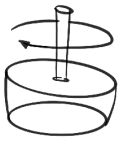
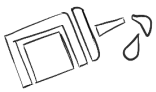
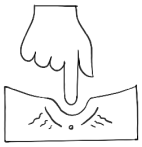
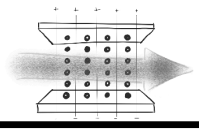
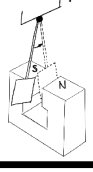
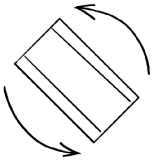
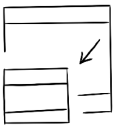
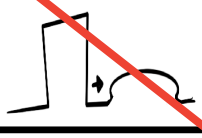
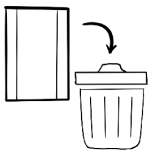
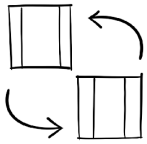
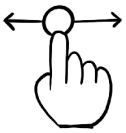
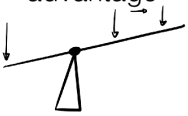
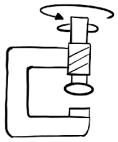
How to enable WRUD	Rotation axle 	Bearings 	Flexible 	Thread 	Ball joint 
Damping methods	Viscous damping 	Friction damping 	Visco-elastic damping 	M.R. damping 	Magnetic damping 
How to keep a discrete profile	Change part orientation 	Minimise part size 	Streamline shapes 	Leave out damper 	
How to ensure correct damping	Swappable dampers 	Adjustable dampers 	Manipulate mechanical advantage 	Change pressure/friction 	

Figure 17. Morphological chart

CONCEPTS

CONCEPT 1: SLEEK AND DISCRETE

This concept focuses on keeping the changes in appearance of the orthosis to a bare minimum, while still enabling WRUD mobility.

WRUD mechanism: Rotation axle
Damper type: Friction damper
Appearance: Minimize part size
Damping customizability: Swappable dampers

The rotation is facilitated by using a small friction damper (Figure 21) as rotation axis. These dampers have a height of 20 mm and diameter of 8 mm excluding the variable protruding metal shaft. The shaft of the damper is fixed to the hand piece (Figure 18, A). The hexagonal body that encases the shaft is attached to the WFE damper housing (Figure 18, B). Figure 19 illustrates the envisioned orientation of the damper in the hand piece.

The damper does not fit neatly in the existing WFE housing. Some modification is required to create a WFE housing that has enough space for the damper. Different form factors were explored (Figure 22) and several iterations were 3d printed to find a design that was both functional and matching the aesthetics of the rest of the orthosis. Figure 20 shows a section view of a modified WFE hinge which fully encases the damper.

Figure 19. Orientation hexatorq with original orthosis WFE hinge and hand piece

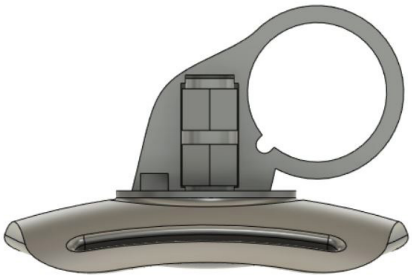


Figure 20. Orientation hexatorq in modified WFE hinge and hand piece

Figure 21. Close-up of hexatorq friction damper by KATO fastening systems

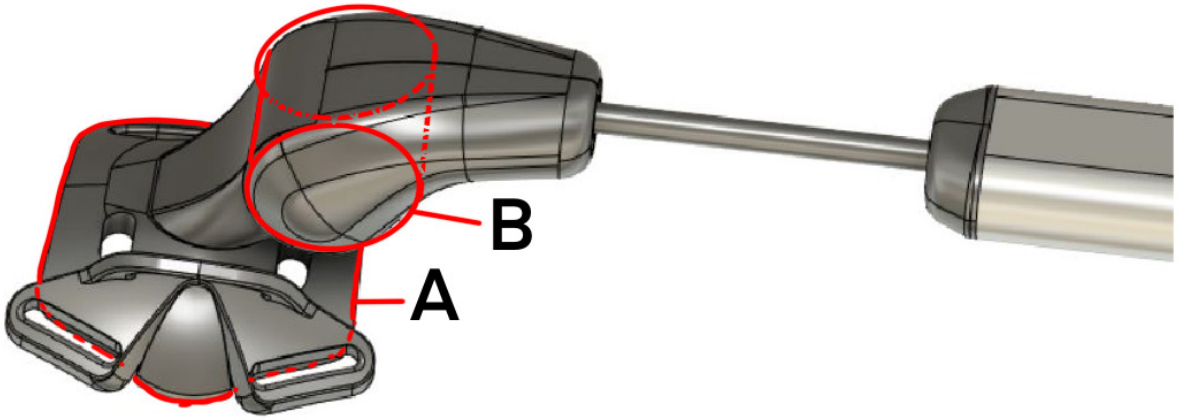


Figure 18. Hand-extension element joint of STIL's current orthosis (A= Hand piece, B = WFE damper housing)

In order to form fit the damper securely in the WFE housing, one of the possible solutions was to split the housing in two. The damper can be placed inside and the two halves are joined together and mechanically fastened with a clip on the bottom and the WFE damper on top (Figure 23). No glue should be used so that the damper could be replaced if different damper specs are required.

Several different options were explored, 3d printed and tested to see if their respective design could be developed into proof of concepts (Figure 24). With every attempt, the same major flaw in the design proved to be difficult to overcome. By relying on the damper as the central axle that keeps the design together, the damper would be exposed to forces that it simply could not take for a longer time. The axial forces would cause the shaft to release from its housing and the different moment forces would cause wear on the inside of the housing, changing the damper specs. Because of the time constrain on the project, it was decided to focus on the development of the second concept rather than dealing with these concerns first.

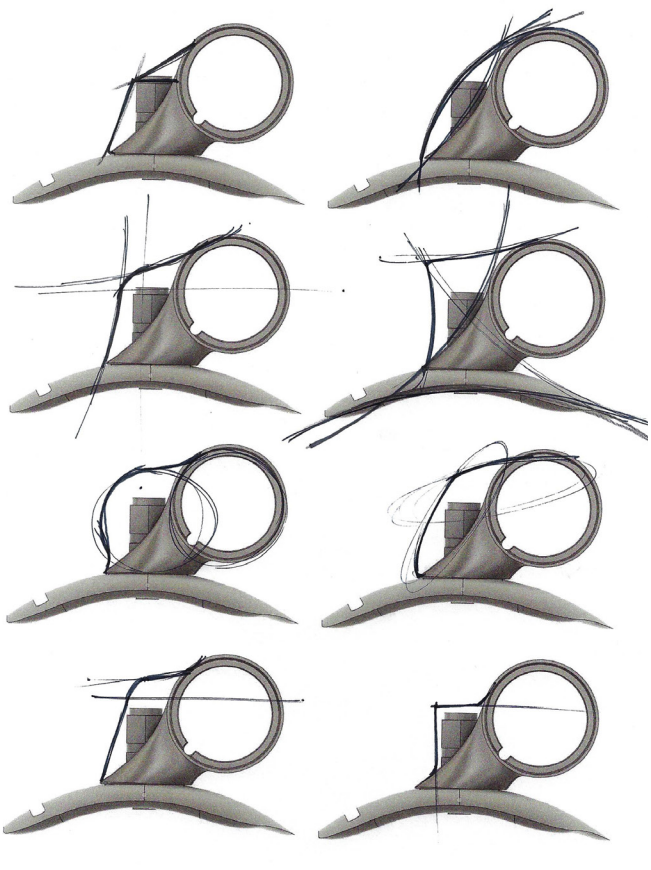


Figure 22. Shape exploration

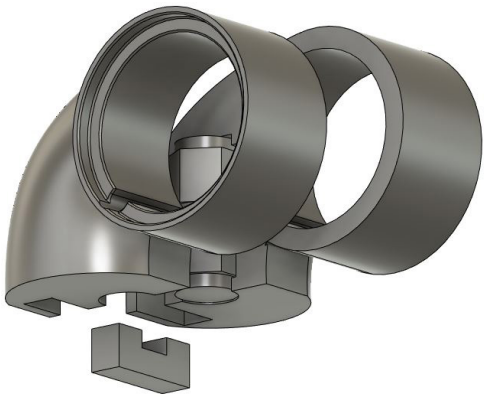


Figure 23. Split WFE joint with clip

Figure 24. Iterations on concept 1 prototype.

CONCEPT 2: FORM FOLLOWS

The second concept is more performance based. Some important aspects that were considered are wear and tear, force distribution in daily use and assembly of the product.

WRUD mechanism: Bearings

Damper type: Friction damper

Appearance: Streamline parts

Damping customizability: Change pressure/ friction

The forces that will apply on the hand piece during normal use occur in the degrees of freedom WRUD, WFE and FPS (see Figure 25). Typically, dampers are only designed for a single moment load case. This means that to ensure the optimal lifetime of the dampers, the only force or moment that applies on the damper should be in the direction of rotation of the damper axis. In other words, moments caused by WFE or FPS should not apply on the WRUD damper.

A concept version 1 (Figure 26) was made where a damper was to be placed inside an opening that runs through the center of a central axis (A), or shaft in the hand piece (C). This way the damper (D) remains at the center of rotation, allowing it to operate in the most straightforward way. The moment caused by the WFE damper (E) and FPS moments apply on the shaft rather than on the damper. A ring (B) that is secured to the hand piece with bolts keeps all parts together. In order to slide the ring (B) over the shaft of A, the lower flange of part A is threaded and can be removed. With the flange attached to part A, and B and C bolted together, you get 2 interlocking parts that are free to rotate.

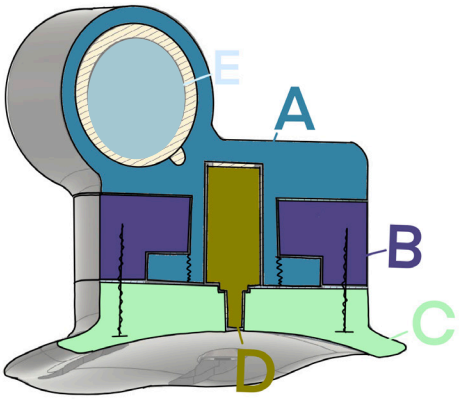


Figure 26. Cross section of concept 2 version 1

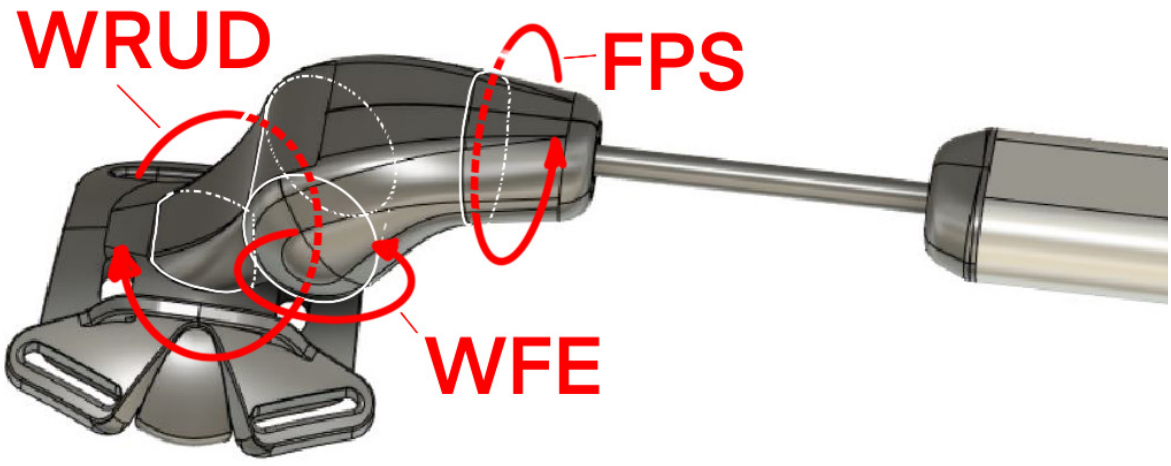


Figure 25. Moment forces applied on current orthosis

One of the issues that emerged was friction between rotating parts. During combined WRUD, FPS and WFE motion, plastic parts of A, B and C rub together and could start to heat up or wear out.
Therefore, choice was made to create a version 2 of this concept (figure 27) . Bearings (F) were added to the design to ensure smooth operation in the long run. Brainstorm sessions with several STIL employees resulted in some ideas on how to design an efficient bearing stack and which bearings to use. The bearings that were selected are AXK2035 thrust needle bearings (Figure 28). These are designed to dissipate large axial thrust forces in relatively small volumes. The bearings are placed between two metal washers to avoid direct contact between the rolling pins in the bearing and the plastic parts.
With Parts B and C are attached together using bolts that are inserted through extrusions that run from the bottom of part C, up through metal inserts that are placed in part B. This secures B and C while still allowing A and B to rotate individually from each other to allow the WRUD motion. This rotation is now fully supported by the two bearings (F). The damper housing is form fitted in part A. The end of the damper shaft is form fitted in part C. This way only the forces in the WRUD degree of freedom are applied on the damper.
For this prototype the decision was made to use the KATO friction damper (see Figure 22) because of its small volume, availability and ease of use. It took a few partial prototypes and iterations but a redesigned hand piece for the orthosis was completed that functioned well enough to serve as a proof of concept (Figure 29).

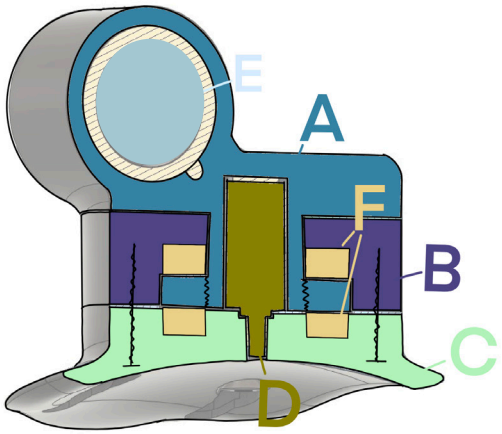


Figure 27. Cross section of concept 2 version 2

Figure 28. Thrust needle bearnings

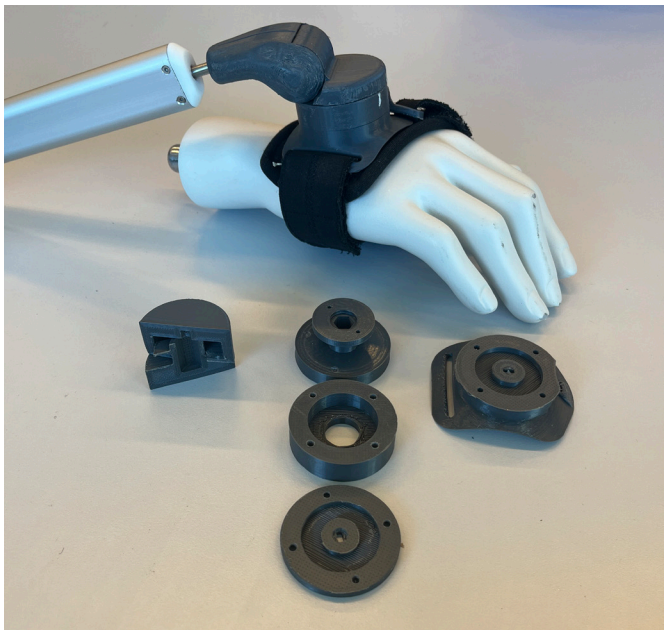


Figure 29. Fully assembled concept 2 prototype (top), several partial prototypes (bottom)

CONCEPT SELECTION

During the development of the two concepts, it had become clear that concept 1 was going to be the least invasive option for the design of the orthosis. However, it was unlikely to withstand the forces applied over a longer period. The biggest issue was the durability of the dampers due to the applied forces when it was in use in the long term. In order to evaluate the concepts fairly, a new requirement topic was added to the PoR:

5: Product life span

5.1: The product must withstand at least 1 year of daily use

5.2: The product must withstand 100.000 cycles

Initial testing of concept 1 showed that gaps and wear marks on plastic parts started to appear after manually moving the hand piece assembly 100 times (only fraction of the 100.000 cycles that STIL expects the orthosis to endure in 1 year). The prototype did pass all other requirements.

Concept 2 showed no signs of wear after the same 100 cycles, and also passed all other requirements. This lack of performance of concept 1 posed a serious threat to its viability. However, it was decided to continue the comparison between the two concepts. If concept 1 turned out to be clearly outperform concept 2 on all other levels, it was worth taking another shot at making the mechanism more durable. If concept 2 showed more promise, no more time was wasted on fixing the flaws of concept 1. The durability will be taken into

To decide between the two concepts, they were scored on five weighted criteria. The scores were given based on the researcher's experiences while wearing the prototypes and discussions with STIL.

Comfort (weight 5)

One of the most important criteria is that the proposed redesign should increase the comfort of the orthosis. Attention is paid to impairment of motion of the wrist, and overall sensation on the arm while wearing the orthosis.

Rubric:

- 1/4: The prototype feels much less comfortable than the current version of the orthosis
- 2/4: The prototype feels somewhat less comfortable than the current version of the orthosis
- 3/4: The prototype feels slightly more comfortable than the current version of the orthosis
- 4/4: The prototype feels much more comfortable than the current version of the orthosis

Both concepts felt like a big improvement of the current orthosis. The increased range of motion allows for less cramped movements and makes the presence of the orthosis less noticeable. There was not a clear preference for either concept. Therefore, both scored full points.

Concept 1: 4/4

Concept 2: 4/4

Durability (weight 5)

Since the orthosis will be worn during ADL, it must be able to withstand several hours of daily operation for at least two years (PoR 5.1). It can be expected that the device will bump into

other objects from time to time and wear and tear should be minimal.

Rubric:

- 1/4: The prototype develops serious wear and tear or damage during short term handling
- 2/4: The prototype develops some wear and tear or damage during short term handling
- 3/4: The prototype develops no significant and tear or damage during short term handling
- 4/4: The prototype develops no significant and tear or damage during short term handling and is likely to outperform the current version of the orthosis

Concept 2 feels much more durable than concept 1. Even after several attempts to get the tolerances right, concept 1 developed noticeable play between parts that should be attached securely. Concept 1 seems to be much more vulnerable to impacts and wear and tear like mentioned before. The added degree of freedom in concept 2 actually reduces the stress on the connections in the hand piece and WFE joint of the orthosis which potentially makes it less likely to fail over time.

Concept 1: 1/4

Concept 2: 4/4

Tremor (weight 4)

Although the prototypes have not been tested on their actual performance on damping tremor, a best estimate should be made on the performance. Attention is paid to the sensation of damping, the weight and feel compared to the other dampened degrees of freedom in the orthosis.

Rubric:

- 1/4: The prototype is expected to have a negative impact on the tremor
- 2/4: The prototype is expected to have no impact on the suppression of tremor
- 3/4: The prototype is expected to have some positive impact on the suppression of tremor
- 4/4: The prototype is expected to fully suppress the tremor.

Both concepts use the same damper. However, a slight difference is noticed by the user. Concept 1 is lighter and in pure WRUD motion the damper seems to run marginally smoother. Once more complicated wrist motion occurs, concept 2 feels better. It absorbs the forces from other degrees of freedom better and therefore feels smoother. The damping in both concepts feel similar to the damping in other degrees of freedom. Therefore, both concepts get a 3/4 score, but more testing should be done to get a more confident performance score for the final product.

Concept 1: 3/4

Concept 2: 3/4

Innovativeness (weight 3)

This category deals with the perceived originality and originality of the concepts. How much value could the concept bring for STIL? Does the design present the expected complexity and ingenuity?

Rubric:

- 1/4: The prototype uses the same parts and systems as the current orthosis in similar ways as the current version
- 2/4: The prototype uses 1 new or redesigned part or system as the current version of the orthosis
- 3/4: The prototype uses 2 or more new

parts or systems as the current version of the orthosis in addition to the current ones in the orthosis

- 4/4: The prototype uses only redesigned parts and systems compared to the current orthosis

Concept 1 is much simpler that concept 2. For some aspects this can be a big advantage (assembly time, cost of parts etc.). However, in a device that is based on finding clever mechanical solutions, this approach, some extra consideration can be put into creating a high-end product.
Concept 1: 2/4
Concept 2: 3/4

Looks (weight 2)

The aesthetics or appearance of the device could have an influence on how willing people are to purchase and use the orthosis. Any redesign should take into account that it does not make the device bad or funny looking. This criterium is weighed the lowest since it is both quite arbitrary and not completely set in stone at this stage of the project.

Rubric:

- 1/4: The prototype does not resemble the rest of the orthosis in any way and requires a redesign of the entire orthosis to form a coherent product
- 2/4: The prototype has some visual coherence with the current orthosis, but requires some redesigning to form a coherent product
- 3/4: The prototype integrates well with the current orthosis
- 4/4: The prototype complements the current orthosis and increases the coherence of the design

Due to its smaller volume and more form freedom, concept 1 scored a bit better than concept 2. Concept 2 must be bulkier due to the bearing stack that is inside. The looks of concept 2 can likely be improved slightly, but the added volume seems to be unavoidable.
Concept 1: 3/4
Concept 2: 2/4

Table 7 contains an overview of the scores of both concepts. Concept 2 outperforms concept 1 on multiple criteria. It resulted in a score of 49/76, or 64% of the maximum for concept 1 and a score of 65/76 or 86% percent for Concept 2. Concept 1 only scored higher on looks. The scores have been visualized in a Harris profile in Figure 30. Concept 2 has its “center of gravity” much further in the top right corner than concept 1. This confirms the superiority of concept 2 regarding the five discussed criteria.

Concept 2 has been selected for further development. To optimize the design, extra attention needs to be given to the looks of this concept, since this is its weak spot.

Table 7. Weighted scores of concepts1 and 2

Criteria	Weight	Score C1	Weighted score C1	Score C2	Weighted score C2
Comfort	5	4	20	4	20
Durability	5	1	5	4	20
Tremor	4	3	12	3	12
Innovativeness	3	2	6	3	9
Looks	2	3	6	2	4
Total (out of 76)			49		65
In % of total			64		86

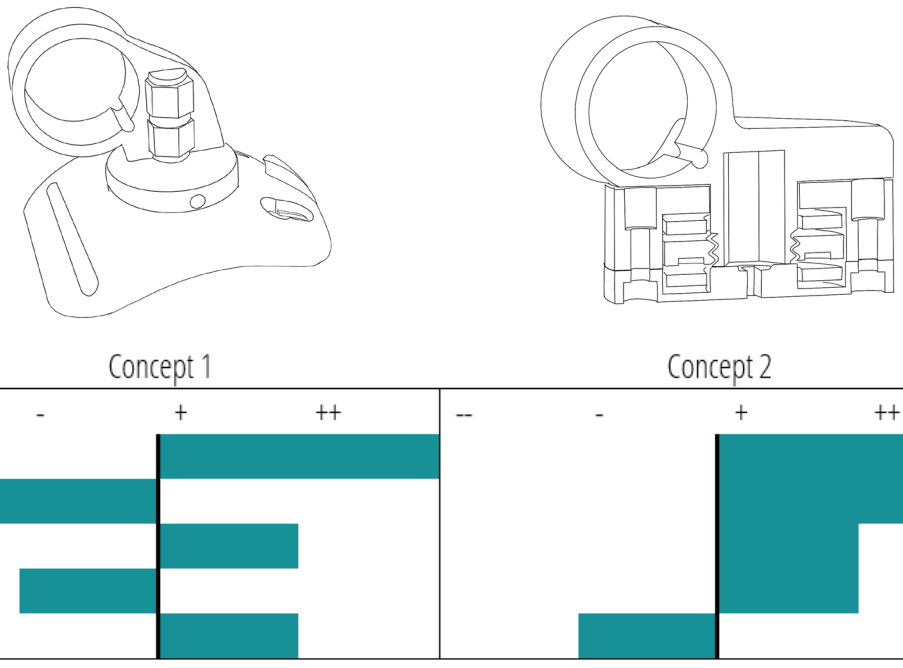


Figure 30. Harris profile concept 1 and 2

CONCEPT EVALUATION

Now that a concept direction was chosen, some more testing was due to see how the design would work for tremor patients. Five tremor participants were selected by STIL from their database based on WRUD tremor prevalence and their availability. Three versions of the prototype were developed; The concept with bearings and a damper was compared to a version without the damper, and a version where the WRUD degree of freedom was fixated. They were evaluated during interactive user sessions with the tremor patients. The main goal of the evaluation is to find out if the changes made to the design of the orthosis translate into increased perceived comfort by the user, without compromising the effectiveness of the device against tremor. Also, the current design is heavily influenced by the assumption that a damper is needed to suppress WRUD tremor. This assumption will also be evaluated.

The researcher expected that a device that allows freedom of movement in WRUD would be preferred by the user over one that fixates WRUD. Also, it was expected that damping WRUD would help to mitigate tremors in WRUD better than undampened WRUD.

The full evaluation protocol can be found in Appendix 6A: Concept 2 evaluation protocol

METHOD

Materials

Based on the design of concept 2, the three required prototypes were produced. The three versions look identical from the outside (see Figure 32 for an example). This is done on purpose as to not bias the participants that wear them in any way. However, with small modifications, different behaviors could be achieved.

Figure 31 shows a cross section of the model that all three prototypes are based on. The parts have been named for easier reference.

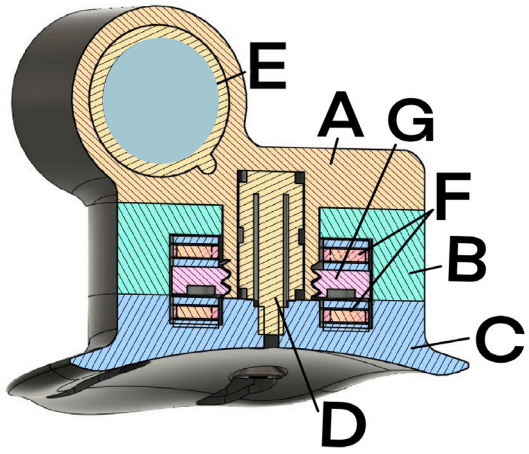


Figure 31. Concept 2 cross section with labels

A: Upper body
B: Mid body
C: Lower body
D: WRUD Damper (KATO friction damper, same as in Figure 22)
E: WFE damper
F: Bearings
G: Central nut (flange described in Concept 2 as being part of the central shaft)

Prototype 1:

In order to create a prototype without the possibility to move the wrist in the WRUD degree of freedom, the upper body and mid body are stuck together using double sided tape. No WRUD damper has been fitted, since WRUD motion does not take place in this prototype. Bearings have been included to distribute the FPS and WFE moment forces, but they did not rotate. They could also be replaced with washers or solid bodies of the same shape. This allows for an experience similar to the current orthosis where WRUD is not possible (or WRUD is fixed) when wearing the orthosis.

Prototype 2:

This prototype has been constructed as concept 2 is intended. WRUD damper and bearings are fully operational, allowing dampened WRUD to be accomplished when wearing the orthosis.

Prototype 3:

This prototype is an exact copy of prototype 2, except no WRUD damper is fitted. This allows for undampened (or "free") WRUD when wearing the orthosis

The redesigned parts were 3D printed and assembled on current STIL Orthosis orthosis (see Figure 32).

Participants

Five participants have been selected to evaluate the redesigned product. An attempt was made to find patients with tremor in their lower arms only. Preferably only the FPS, WFE and WRUD tremor participants are selected, but the progressiveness of the disease, difficulties in diagnosis and limited time forced some lenience into the selection process. A certain degree of tremor in other body parts or degrees of freedom was accepted.

Setup

Participants sit at a table across from the researchers, either at STIL's office or at participant's house. The location must provide a safe and private environment that allows the participant to feel at ease. Nervousness can have an influence on the severity of tremor. The researcher needs to make sure that the participant experiences as little nervousness or anxiousness as possible under the circumstances. The location must also have a table, at least 3 chairs, a table and wall sockets to power equipment.

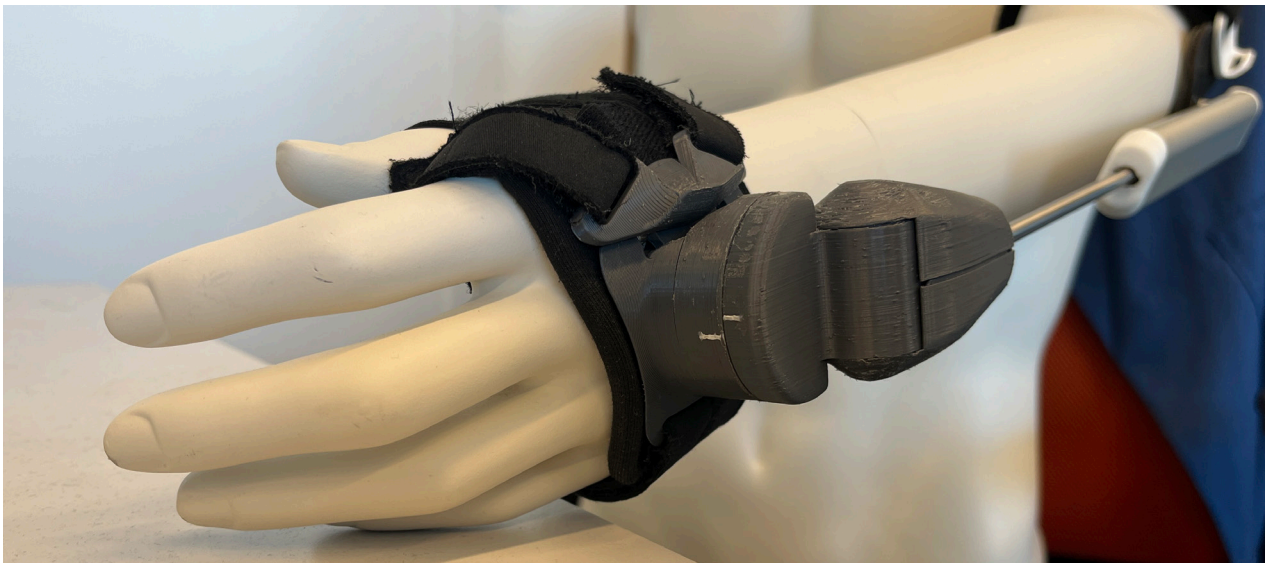


Figure 32. *Concept 2 prototype*

Procedure

The participants execute several prescribed actions that have been selected from “The Essential Tremor Rating Assessment Scale”, better known as “TETRAS”. This is a commonly used, validated method in the field of tremor research. Four tasks are selected from TETRAS and are executed by the participants while wearing the different versions of the orthosis. The participants are asked which version they experienced as most comfortable and easy to use. This preference is compared to their respective TETRAS scores which are assigned during the activities by the researcher according to the prescribed ranking system.

Data analysis

The TETRAS ranking is given in consultation with a clinical researcher from STIL. Video recordings are made during each task. This can later be used to back up rankings or explain observations. When specific consent is given by participants, the recordings could also be used for presentations and publications.

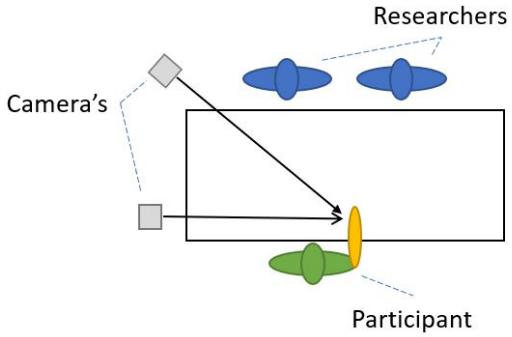


Figure 33. Room setup for evaluation sessions

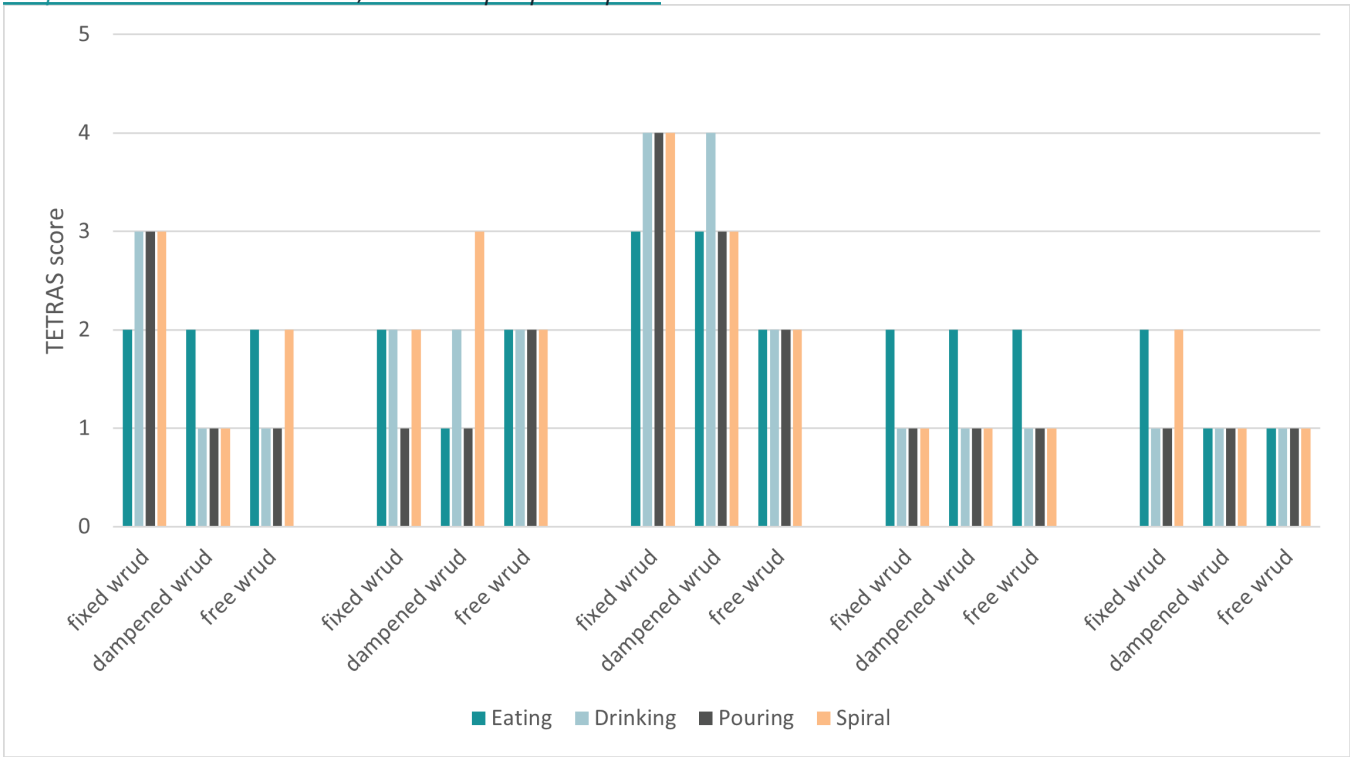
RESULTS

Data TETRAS

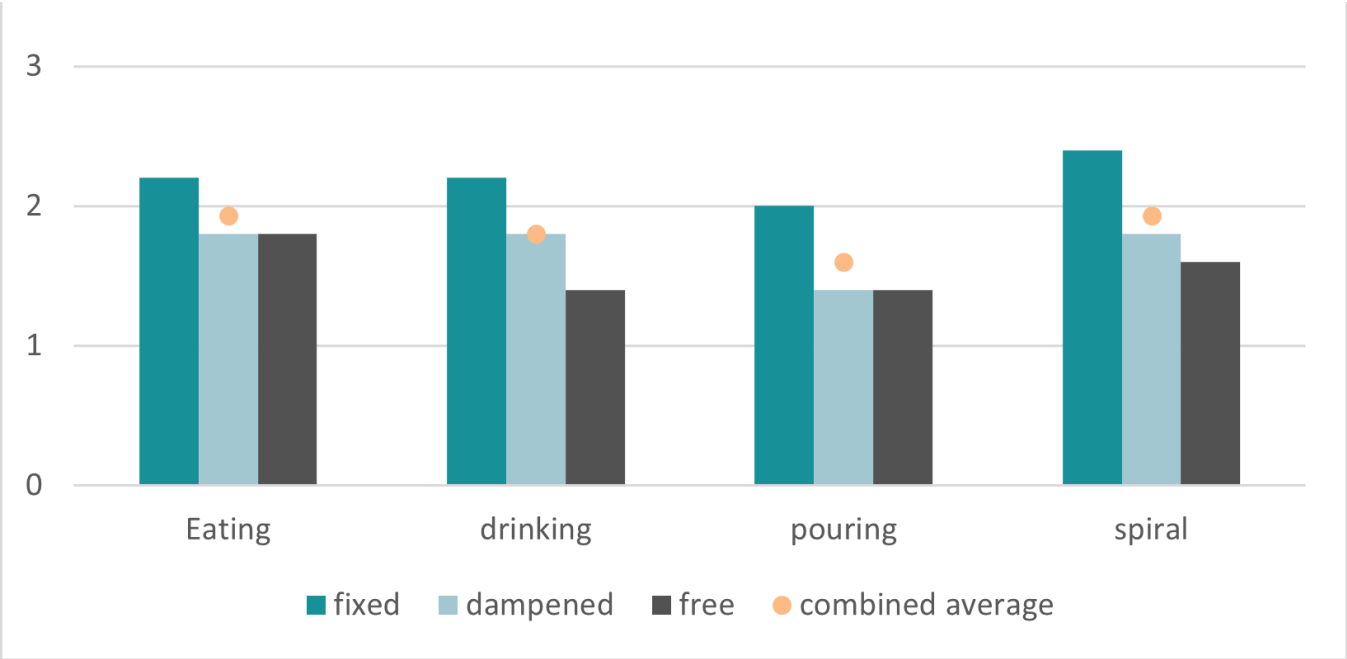
The TETRAS data that has been gathered during the five participatory sessions has been plotted in Graph 7.
Some first impressions *(remember: higher TETRAS= more tremor):*

Participant one experienced a visible reduction when doing “drinking”, “pouring” and “spiral”. However, none of the orthoses seemed to help with eating
Participant two was the only participant that actually scored worse at any activity when comparing the fixed WRUD to both dampened and free WRUD.
By globally scanning the bars, you could quickly conclude that the third participant suffered from the most severe tremor overall. This participant scored better every time the mobility was increased.
The fourth participant scored the exact same score with all three different prototypes. There was no noticeable difference in tremor activity between the 3 versions at all.
Participant five had some difficulties performing the “eating” and “pouring” activities. This seemed to decrease as soon as the WRUD DoF was freed.

Graph 7. TETRAS scores, clustered per participant



Graph 8. Average TETRAS scores of all exercises



Graph 8 shows the average of the TETRAS scores of all the participants. These averages are grouped per activity. Combining the averages within each exercise can give an indication on which activities are the easiest to perform for all participants, and which ones are the hardest. As indicated by the "combined average" dots, the activities "Eating" and "Spiral" generated the highest average TETRAS score of 1.9. "Drinking" was slightly easier with an average score of 1.8, and "pouring" was the easiest of all 4 tasks with an average of 1.6. These four average scores are quite similar with a difference of only 0.3 point on a 5 points scale.

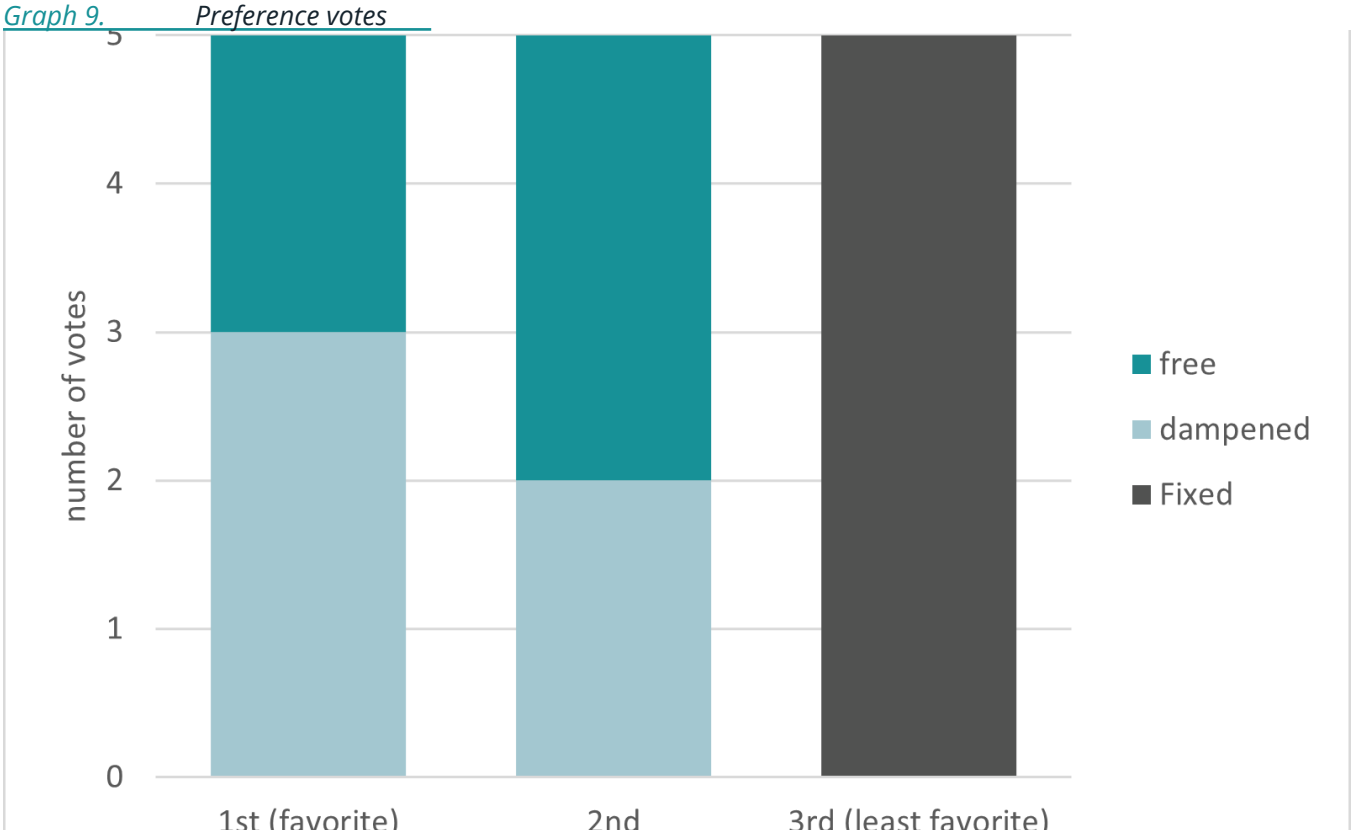
Something else that is remarkable in Graph 8, is the comparison between the "fixed" scores and the not fixed ("dampened" and "free") scores. In every activity, the TETRAS score is at least 0.4 higher for the fixed version. This indicates that having more WRUD mobility is actually beneficial for the performance of the orthosis. A somewhat unexpected result is that the "free" prototype on average, outperforms the dampened prototype in two out of 4 activities. In the other 2 activities they score the same average. The scores of "dampened" and "free" are relatively close to each other in comparison to the "fixed" version.

Personal preference

The participants were asked which prototype they preferred, which one came second and which came third. The results of these "preference votes" are shown in Graph 9. The columns indicate the amount of votes each prototype received for 1st, 2nd and 3rd place.

The "fixed" prototype was voted last by every participant. This shows that every participant would rather have some sort of WRUD mobility than not being able to move their wrist in that direction. First and second place were a close call with only one vote in preference of the "dampened" prototype. This was a much closer result than expected before the testing.
When asked to explain their choices, 4 out of 5 participants had no single, definite answer. Some reasons that were mentioned as possible reasons are: "The fabric of the hand piece might feel a bit better on this one" (hand piece fabrics were identical). "The shape of the bottom of the hand piece is better adapted to the shape of my hand" (all bottoms of hand pieces are identical) but most often "I don't know, it just feels better".
Only 1 participant figured out the increased WRUD mobility during the activities. All others had to be told afterwards. This was participant number four with the identical TETRAS scores. He/she preferred the dampened version over the free version.

Graph 9. *Preference votes*



CONCLUSION

This evaluation aimed to determine two things: first, whether users perceive the redesigned orthosis as more comfortable without compromising its performance, and second, whether adding the WRUD damper improves the overall orthosis experience.

The results of the evaluation indicate that participants had a clear preference for the orthosis with the option to move the wrist in the WRUD direction. There were no indications that adding this mobility had a negative impact on the orthosis's performance. In fact, performance appears to be better with increased WRUD.

The second question had a less clear answer. Damping the WRUD did not have the same effect on every user, and most participants did not even notice the increased mobility or damping until late in the session. The prototype without damping scored slightly better on average on the TETRAS scores, but the difference was not significant, particularly when compared to the prototype with the fixed WRUD. Once informed about it, a slight majority of participants expressed a preference for the dampened version. However, these results did not fully align with the TETRAS performance.

In summary, the evaluation suggests that adding mobility to the orthosis in the WRUD direction does not harm its performance, and that most participants prefer this option. The effect of damping on the WRUD is less clear, with mixed results across users and metrics.

DISCUSSION

Although the results were not entirely as predicted, this evaluation session proved to be a valuable test of the viability and desirability of the concept. Feedback from potential users provided insight into the performance of the prototypes, and overall, participants liked the concept. The conversation between the researcher and participants during the evaluation also proved invaluable for gaining intuition regarding designing for people with tremors. With every session, the researcher was able to observe the challenges, frustrations, coping mechanisms, and personal experiences of people with essential tremors. This was a learning experience on an educational, professional, and personal level.

However, it should be noted that the evaluation session only involved five participants, and there were significant differences in the amount of tremor each participant experienced. It would have been more informative if each individual had set a benchmark score before wearing the orthoses, but this was not realized until after the sessions were completed. With a benchmark, a better analysis could have been made, which would have been more conclusive about the performance of the orthosis.

Having a larger participant pool could also have affected the results. For now, five participants were considered sufficient to draw some conclusions about the concept, but if the development were to continue, a lot more participant sessions would need to be hosted to get definitive statistical backup for the design choices.

One potential factor that may have influenced the data is a "learning effect." The orthoses and activities were always presented to the participants in the same order. By the time the participants reached the last activities, they may have become more accustomed to wearing the orthosis, and therefore their results may have been skewed. To mitigate this effect, in future research, it would be advisable to randomize the order of the prototypes and activities. The same is applicable for potential tiredness of the participants. In some cases, people with tremor can tire relatively fast. Tiredness can have an impact on the severity of their tremor, and therefore the results of the later activities could be influenced more than the early ones due to fatigue.

One final point of discussion is the influence of tremors in other degrees of freedom, such as shoulder or finger tremors, on the TETRAS scores. The selection of participants focused on finding those without shoulder or finger tremors, but during the activities, some tremor activity was seen above or below the reach of the orthosis. In reality, a large portion of essential tremor patients will experience some form of shoulder or finger tremor, but in order to keep the tests as representative as possible, they should be avoided as much as possible.

PART 5: FINAL DESIGN

This chapter discusses the development of the final design. Lessons learned from the evaluation of concept 2, and new insights that have been gathered throughout the process, have been used to fine tune and optimize the design of the concept 2 prototype. The final design has been professionally 3-d printed and manufactured to match the specifications and looks of the production version of the current STIL orthosis.

DESIGN DETAILS

In the final design, concept 2 was taken and refined into a fully functional product. The new parts have been manufactured using the same techniques as STIL uses for their production parts. They were fitted on the latest version of the STIL orthosis. Figure 34 and 42 show the results.
This device is fully operational and can be used as a demo model, or for further testing with tremor patients. The important design choices are elaborated on next.

Figure 34. *Final design in action*

The main difference between Concept 2 and the final design is the application of the bearings. The concept of using two bearings has remained unchanged in the final design. However, the implementation has been changed slightly. During testing some slight friction was noticeable. By taking concept 2 apart, it was found that the upper body (A) and mid body (B) showed small signs of wear. It turned out that during use, the moments caused by WFE and FPS caused pressure between the horizontal surfaces of A and B, rather than C and G. This rendered the bottom bearing useless. Therefore, the lower bearing was removed from between B and C, and replaced by a similar, but slightly larger AKX2035 needle bearing. A slight gap was left open between C and G to make sure that these surfaces would not make contact. Parts B and C (and A slightly) were modified to fit this new bearing setup. The rest of the model is similar to concept 2. An explanation of the forces that apply on the dampers can be found in Appendix 7: Analysis of forces on the hand piece.

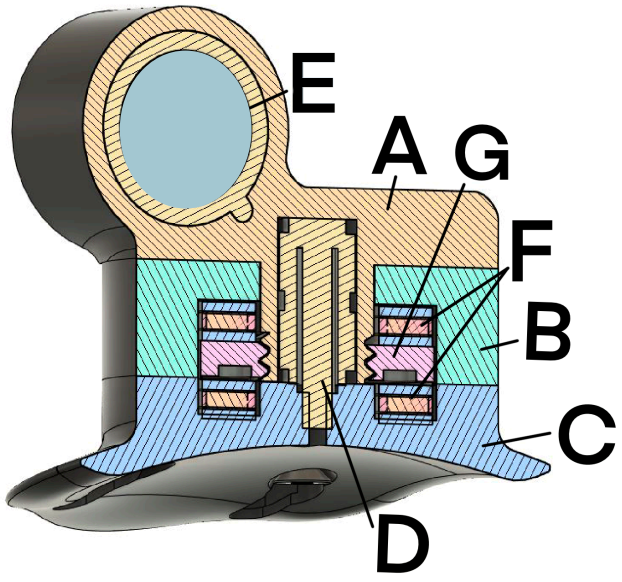


Figure 35. Concept 2 cross section

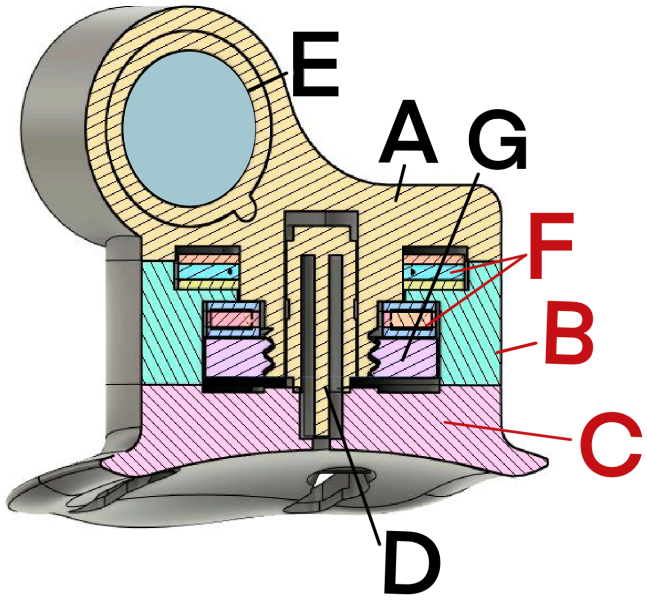


Figure 36. Final design cross section

A: Upper body
B: Mid body
C: Lower body
D: WRUD Damper
E: WFE damper
F: Bearings
G: Central nut

IMPLICATIONS OF BEARING POSITION

Changing the location of the bearing made it possible to fit a bearing with a larger diameter (F2). Figure 37 shows a diagonal cross section of the final design to show the location of the bolts (H). The diameter of the bearing was limited by the space that remains within the four bolts (H) that attach B to C. The new position of the upper bearing (F2) was above the bolts, and therefore only limited by the circumference of parts A and B. A wider bearing reduces potential play in the overhanging parts and is therefore more desirable.

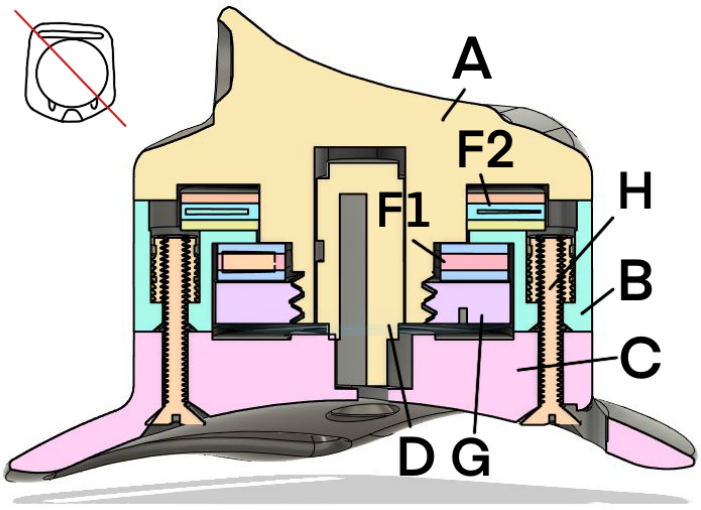


Figure 37. diagonal_cross_section_final_concept

A: Upper body
B: Mid body
C: Lower body
D: WRUD Damper
E: WFE damper
F1: Lower bearing (AKX1528)
F2: Upper bearing (AKX2035)
G: Central nut
H: Bolts and inserts

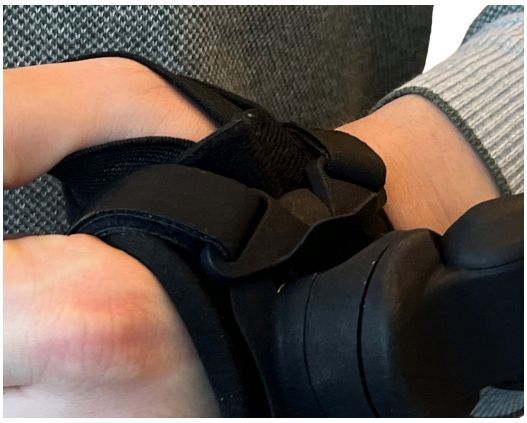


Figure 38. Close-up of hand clip attached to the hand piece

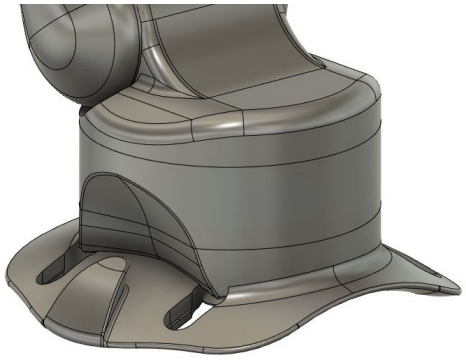


Figure 39. Hand clip notch without clip

HAND CLIP

The orthosis is secured on the hand of the user with two fabric straps around the hand. In order to make donning and doffing (putting the orthosis on and off your arm) as easy as possible, the user adjusts the sizes of these straps with a Velcro patch the first time. All consecutive times, the user only has to snap a clip into place to open or close the straps (see Figure 38 and Figure 39).
During the tests of concept 2, participants had difficulties with opening and closing this clip. In the final design, the notch that is cut out of the lower and mid body was made deeper and wider to allow more space for the hand clip. This made donning and doffing much easier. This is essential since the user often struggles with operations that require finer motor skills due to their tremor.

AESTHETICS

The volume of the redesigned hand piece is largely decided by the components it houses. The circular shape has been chosen so that all bodies align no matter in what direction the wrist is turned. One way to have some influence on the shape is by playing around with the top surface of the upper body. The ring that contains the WFE damper had to remain constant. Also, not too much volume could be taken off the part. It needs some material to remain strong enough. Three options were designed (Figure 40).

The first option features a simple, filleted edge. This is the same shape as concept 2.
The second option was designed to mimic the more organic, flowing shapes that can be found in other parts in the orthosis. Multiple fillets with varying radii are applied. This is the version that was used to manufacture the demo model of the final design.
Lastly, a version was designed inspired by some modern, minimalistic and sleek designs (see Appendix 8: Mood board “Modern sleek design”). These designs often featured a shallow, wide chamfer leading up to a flat, horizontal surface. This has been incorporated in the top surface of the upper part as well.

Design 2 was chosen for now, because it was the best match with the current orthosis. Option 3 was received well by STIL, and could serve as inspiration for future designs. However, it was considered to be too much of a different style to be implemented in this version.

Figure 40. Three different aesthetic choices for upper body

COMPARISON WITH CURRENT ORTHOSIS

Figure 41 shows the redesigned and current orthosis side by side.
The comparison makes it quite clear that the new version does have more volume than the current orthosis. Due to the size of the damper and the bearings that have been used, this was unavoidable. If the friction damper can be replaced by a damper with similar specifications but in a smaller, or more convenient size, the total volume of the mechanism could be more freely adjustable. Also, a version without a damper could be made a lot smaller too. In some cases, WRUD damping might not be necessary but WRUD mobility is appreciated. Generally speaking, the distance between the arm and the metal extension element has only increased by 1 or 2 centimeters. The researcher estimates that this could be reduced some more. Due to the time constrain, this has not been achieved in this project.

Figure 41. Comparison of redesigned (top) vs. current (bottom) orthosis

COSTS

The exact added costs of the new device are highly dependent on manufacturing method and batch size.
The off-the-shelves components that have been used in the design are the bearings and the damper.
The bearings used for the final design added up to €7.95 (low volume, no scale discounts). The price of the friction bearing is approximately €4. Currently the plastic parts are 3D printed. In the future, these parts will likely be injection molded. Therefore, the price of the plastic parts is not taken into consideration for now.

REQUIREMENTS CHECK

The final product passes all criteria that can be tested short term. A few criteria have not been tested yet due to the time constrain. These untested criteria are 5.1 (The product must withstand at least 1 year of daily use) and 5.2 (The product must withstand 100.000 cycles) of the Program of Requirements. All parts have been designed in such a way that it is likely that these criteria will be met. However, it is advised to do endurance testing to

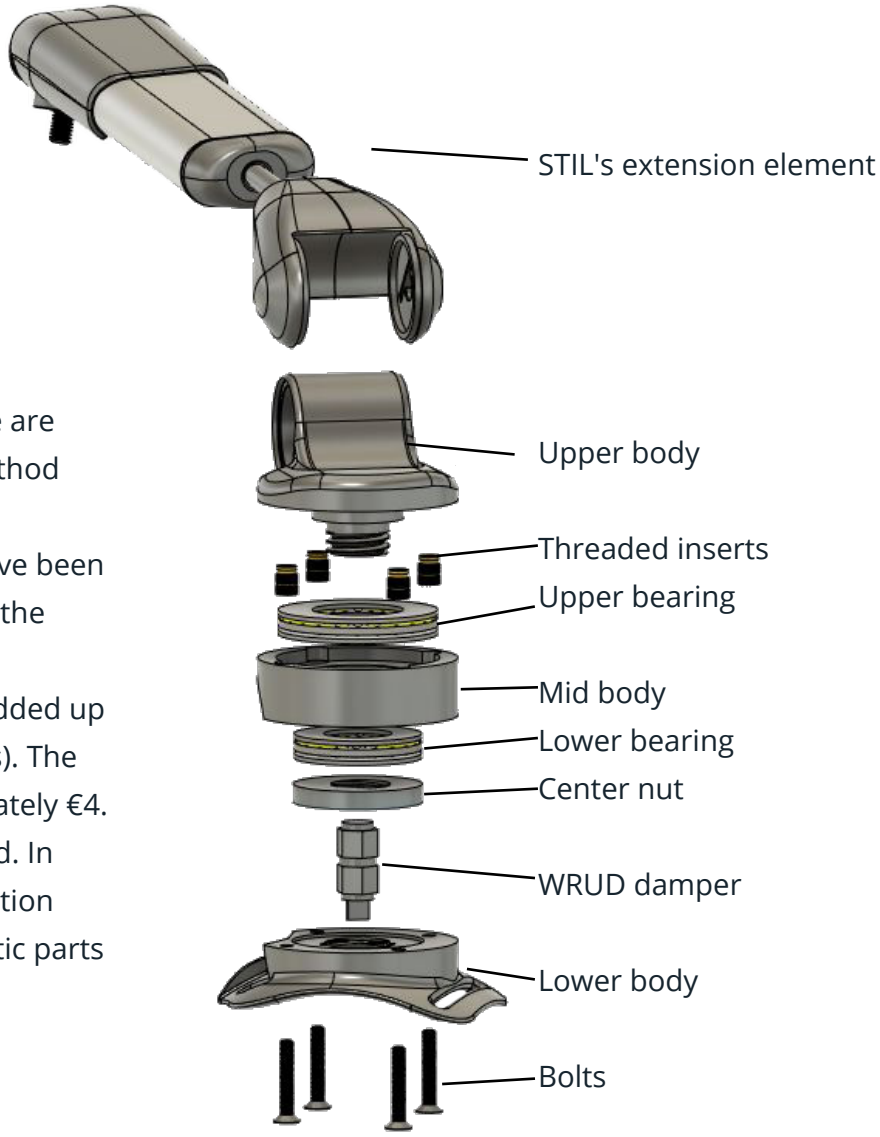


Figure 42. Exploded View final design

PART 6: CONCLUSION AND RECOMMENDATIONS

Based on the lessons learned throughout this project, conclusion have been drawn regarding the research assignments and the research questions were answered. The researcher has formulated several recommendations for the further development of STIL's anti tremor orthosis.

CONCLUSION

This research aimed to improve the mobility of the next generation anti-tremor orthosis by STIL, specifically in the wrist radial and ulnar deviation (WRUD). To achieve this, three primary research questions were addressed.
First, the desirability of WRUD mobility was explored through literature research and exploratory sessions with tremor participants. The addition of WRUD mobility was found to be beneficial and more comfortable, as indicated by evaluations with tremor participants. The prototypes that allowed for WRUD mobility scored higher in tremor suppression than the current STIL orthosis that does not allow WRUD.

Secondly, the use of dampers was explored to suppress tremor in the WRUD degree of freedom. The dampened and undampened prototypes had similar scores in tremor suppression, possibly due to the amount of damping force that was tested, the relatively small number of participants, or the testing method. However, three out of five participants preferred the dampened prototypes. Therefore, the development of a dampened WRUD mechanism was continued for further testing in the future.

Finally, the integration of the mechanism that enables (dampened) WRUD into the design of the current STIL orthosis required a small, durable, and comfortable mechanism. This involved the redesign of several parts of the orthosis and the addition of new components. The outcome is an assembly of multiple interlocking bodies that rotate smoothly with the aid of bearings, while an off-the-shelf damper provides a reliable counterforce against tremor activity.
After six months of research, including split-models, user testing, and analysis, a near production-level demonstrator prototype was created. This prototype combines parts from STIL's current orthosis with custom components made specifically for this project. It is now ready for long-term testing and serves as a worthy showcase of how WRUD can be made possible in the next generation of STIL's products.

RECOMMENDATIONS

Based on the experience gained in this project, the researcher has several recommendations for further research to make the next version of the STIL orthosis as successful as possible.

Include a mechanism that allows WRUD mobility.
Based on this research, adding WRUD seems like the next logical step to improve the orthosis. STIL formulated this assignment with the expectation that adding this degree of freedom would increase the perceived comfort of the device. This research confirms this, and adds that the extra mobility improves tremor suppression.

Expand research on the damping of WRUD motion.
Although not all tests indicate a unanimous preference for dampened WRUD over undampened WRUD, enough data is gathered to suggest that damping can be beneficial to a substantial part of the users of the orthosis. By testing a larger group of tremor patients short- and long-term, the necessity of a damper can be better evaluated. More research needs to be done to find out if the benefits that are experienced by one part of the users outweigh the preference of no damper of the other part. Using the TETRAS method can provide anchored data to prove the effect of the damper.

Develop custom damper
The current friction damper that has been used in the final design is an off-the-shelve component that is being used in the current orthosis as well. By using the same principles of friction between two materials, there are possibilities to create a custom damper in different shapes and with different damping forces. Due to the time constrain, no attempt was made to create such a custom damper in this project. However, the form freedom and its implications on the shape and volume of the mechanism show great potential to improve the design. Perhaps it would even be possible to create a range of damper with varying damper torques in order to provide the best specifications for each user. It is advisable to co-engineer a new damper with a company that specializes in this area.

Test the design for long term operation.
Since the new design features load-bearing and moving parts, the durability should be confirmed in long-term testing. Critical parts like the dampers are rated as durable enough by the manufacturers, but STIL should confirm that no significant wear and tear occurs when the device is used daily. Some factors that require special attention are the form-fittings of the friction damper, the tolerances required for different manufacturing processes and the water- and dirt-proofing of the device.

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Improve the wrist mobility of STIL's anti tremor orthosis — project title

Please state the title of your graduation project (above) and the start date and end date (below). Keep the title compact and simple. Do not use abbreviations. The remainder of this document allows you to define and clarify your graduation project.

start date 10 - 10 - 2022 — 10 - 04 - 2023 end date

INTRODUCTION **

Please describe, the context of your project, and address the main stakeholders (interests) within this context in a concise yet complete manner. Who are involved, what do they value and how do they currently operate within the given context? What are the main opportunities and limitations you are currently aware of (cultural- and social norms, resources (time, money,...), technology, ...).

A tremor is an involuntary quivering movement in a person's body that can be triggered by something innocent like excitement or cold, or it can be the result of diseases or disorders.
The two most prevalent examples of disease related tremors are Essential Tremor (ET) and Parkinson's Disease (PD). ET is estimated to affect 4.6% of the population aged 65 and older. PD is prevalent in 2% of the population above 65 years old. Out of all individuals affected, an estimated 50% of those who suffer from PD will develop tremors while all of those affected by ET will have to deal with tremors (Pigg, 2019). Combined, PD and ET are responsible for causing tremors in an estimated 1.1%, or 5.49 million individuals in the European Union alone. (Fromme, 2019). In 65% of the cases, these tremors cause great difficulty with everyday activities like eating or drinking. This leads to at least mild depression symptoms with 48% of PD and 34% of ET patients.
Currently, tremors are mostly treated with either medication or surgical intervention. Medical treatment is effective in only half of the ET cases. The medication prescribed for PD is known to cause motor fluctuations and dyskinesia itself after prolonged use (after 4-10 years) (American Parkinson Disease Association, 2019). Another option is surgical intervention where one of the most effective procedures is Deep Brain Stimulation (DBS). DBS has greater effectiveness than most pharmaceutical approaches. However, this is a highly invasive method with an associated high risk of intracranial haemorrhage (4%) or secondary psychiatric effects. Besides, the eligible patient rate is quite low (1.6-4.5% in PD) (Lora-Millan et al., 2021).
This project is initiated by STIL. STIL is a YES!Delft based med-tech startup that is developing a non-invasive, anti-tremor orthosis that helps people with tremors in their upper limbs. The orthosis helps to cope with their condition by stabilising their hands (see images on next page) without surgery or medication. A patient wears this orthosis on its arm. By mechanically dampening the motion caused by the contraction of different muscle groups in the arm, involuntary tremors have less impact on the overall movement of the limb. The STIL orthosis differentiates itselves from other concepts by being 100% mechanical and therefore not rely on sensors or other electronics to function. This allows for a sleeker and lighter product than competitors that offer for example weighted brace solutions, or electronically controlled dampers.
A good tremor orthosis must not only function as expected, there is also the matter of comfort. The final product that STIL is aiming for will be a wearable that the user will have close interaction with all day long. This means that small irritations like pressure points or hindrance during everyday activities can add up quickly, resulting in nonuse (Fromme, 2019). Therefore it is important that a close eye is kept on ergonomics and ease-of-use of the design. This means that any newly proposed solution to a technical problem should be thoroughly analysed regarding comfort as well.

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Initials & Name R.G. de Reus Student number 4379241

Title of Project Improve the wrist mobility of STIL's anti tremor orthosis

introduction (continued): space for images

image / figure 1: Closeup of current version of the orthosis. Green circle indicates focus area

image / figure 2: Current version in use, green arrows indicating wrist abduction/adduction

PROBLEM DEFINITION **

Limit and define the scope and solution space of your project to one that is manageable within one Master Graduation Project of 30 EC (= 20 full time weeks or 100 working days) and clearly indicate what issue(s) should be addressed in this project.

A significant problem with the current design of the STIL orthosis is that it does not allow the user to move its wrist in all directions. This limitation in mobility can hinder the user in everyday tasks and this could lead to the user experiencing discomfort. The reason that the user is limited in its mobility has to do with the way in which the orthosis suppresses tremors. In order to achieve mechanical damping of involuntary movements, several degrees of freedom of the upper limbs are partially constrained or cushioned by a device that mounts to the user's upper limb. The current prototype of the device mounts to the user's upper arm and hand and is attached securely with a strap. The core of this problem lies in the design of the part of the orthosis that mounts to the hand. Due to its design, the degree of freedom that is associated with Wrist Adduction/Abduction (WAA) (as seen in image 2), is fixed. This means that movements like shaking hands, drinking from a cup or using a computer mouse are made more difficult while wearing the orthosis. STIL has identified this issue with their design and offered this subject as a research topic for a graduation project. During this project it is expected that a student will research several aspects surrounding the issue in order to get a clear image of the problem. Then this new knowledge is to be used to create a redesigned version of the orthosis which should deliver a better experience for the user. The redesign should be tested with potential users to verify that the envisioned improvement is also experienced as better than the previous version.
One more important aspect to note is that the redesign has to integrate properly with the rest of the orthosis. This means that any change in design can not have a negative impact on the functioning of the orthosis as an anti-tremor device, but it also has to match the aesthetic qualities and ease of use of the current design.
The problem can be summarised in 3 research topics:
- Is adding a degree of freedom to allow for WAA desirable?
- Is damping tremors in WAA desirable from a user's perspective?
- How could STIL best integrate wrist mobility in their new version of their anti-tremor orthosis?

ASSIGNMENT **

State in 2 or 3 sentences what you are going to research, design, create and / or generate, that will solve (part of) the issue(s) pointed out in "problem definition". Then illustrate this assignment by indicating what kind of solution you expect and / or aim to deliver, for instance: a product, a product-service combination, a strategy illustrated through product or product-service combination ideas, ... In case of a Specialisation and/or Annotation, make sure the assignment reflects this/these.

Improve the mobility of a tremor suppression mechanism for the next generation of anti-tremor orthosis to be marketed in ~2024.

The focus of this project will be to increase the user's mobility while wearing a STIL anti-tremor orthosis.
In order to successfully finish this assignment the embodiment of the orthosis is expected to be researched and redesigned.
First a thorough analysis of the problem will be done. This will involve a literature study regarding the medical aspects of tremors, desk research on how tremors are dealt with and interviews with potential users of the orthosis will be conducted to find out what the extent of the problem truly is. Once enough information is gathered, new embodiments of the orthosis will be prototyped and tested. This will be done by researching technical possibilities and experimenting with implementing them, starting with lo-fi prototypes and resulting in a (min. TRL level 4) functional prototype that can be validated with potential users.
For the final prototype, factors like safety,perceived comfort, cost, aesthetics and performance should be considered.

In the end STIL should be able to use the findings of this research and the design of the prototype to decide how they want to approach wrist mobility in the nes version of their orthosis.

Initials & Name R.G. de Reus Student number 4379241

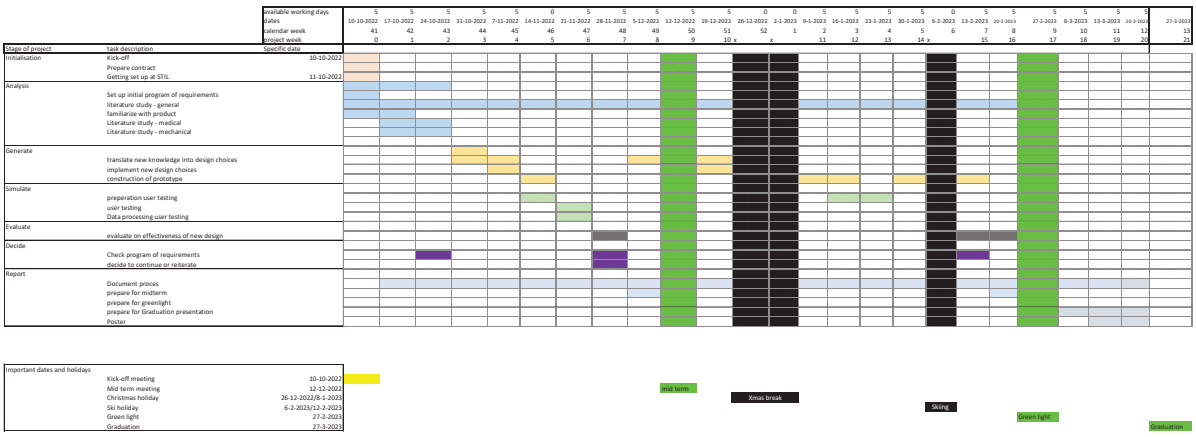
Title of Project Improve the wrist mobility of STIL's anti tremor orthosis

PLANNING AND APPROACH **

Include a Gantt Chart (replace the example below - more examples can be found in Manual 2) that shows the different phases of your project, deliverables you have in mind, meetings, and how you plan to spend your time. Please note that all activities should fit within the given net time of 30 EC = 20 full time weeks or 100 working days, and your planning should include a kick-off meeting, mid-term meeting, green light meeting and graduation ceremony. Illustrate your Gantt Chart by, for instance, explaining your approach, and please indicate periods of part-time activities and/or periods of not spending time on your graduation project, if any, for instance because of holidays or parallel activities.

start date 10 - 10 - 2022

10 - 4 - 2023 end date



The Gantt chart above shows an estimate of what I think my graduation will look like. Different colours indicate different stages of the design process as described in a basic design cycle. The downward sloped shape of colored blocks as can be seen in week 1/8 can be repeated multiple times if necessary. This visualises a full design iteration. Some parts may be left out, or the exact order may be changed depending on the impact of the changes made to the design per iteration.
The blacked out columns are holidays. I plan to keep these time slots empty. The bright green columns indicate important deadlines.

During the project I expect to be working at STIL on a daily basis. This way I can keep close contact and be involved in the development of the product as a whole.
Meetings with chair and mentor are expected to be on a weekly or 2 weekly basis. Especially during the first half of the project, weekly contact is preferred.

Important (proposed) dates:
kick-off meeting: 10-10-2022
Mid term meeting: 12-12-2022
Green light meeting: 27-2-2023
Graduation presentation: 27-3-2023

Initials & Name R.G. de Reus Student number 4379241

Title of Project Improve the wrist mobility of STIL's anti tremor orthosis

MOTIVATION AND PERSONAL AMBITIONS

Explain why you set up this project, what competences you want to prove and learn. For example: acquired competences from your MSc programme, the elective semester, extra-curricular activities (etc.) and point out the competences you have yet developed. Optionally, describe which personal learning ambitions you explicitly want to address in this project, on top of the learning objectives of the Graduation Project, such as: in depth knowledge a on specific subject, broadening your competences or experimenting with a specific tool and/or methodology, ... Stick to no more than five ambitions.

I have chosen to take this project on because it combines all the parts of my education that I like the most and it resembles what I would see myself doing in a professional career after graduating. I really wanted to do a graduation project at either a well known design company or at a (med)tech startup. What really appealed to me in the description of the assignment was first of all the fact that I would be dealing with a tangible, physical product that people would interact with on a daily basis. Secondly, the project would benefit from physical prototyping which would involve workshop hours and 3d printing designs that can quickly be tested with the intended user.
I enjoy this kind of hand-on approach and I am looking forward to applying it in an innovative environment with likeminded people.

Some of my personal ambitions are:
-To improve my prototyping skills.
-To gain experience in designing in a professional environment with a real client and product.
-To improve my skills in planning (and executing) a big design project on my own.
-To learn more about the extra challenges regarding designing medical devices.

FINAL COMMENTS

In case your project brief needs final comments, please add any information you think is relevant.

Initials & Name R.G. de Reus Student number 4379241

Title of Project Improve the wrist mobility of STIL's anti tremor orthosis

APPENDIX 2: ETHICS

Delft University of Technology
HUMAN RESEARCH ETHICS
CHECKLIST FOR HUMAN RESEARCH
(Version January 2022)

IMPORTANT NOTES ON PREPARING THIS CHECKLIST

1. An HREC application should be submitted for every research study that involves human participants (as Research Subjects) carried out by TU Delft researchers
2. Your HREC application should be submitted and approved **before** potential participants are approached to take part in your study
3. All submissions from Master's Students for their research thesis need approval from the relevant Responsible Researcher
4. The Responsible Researcher must indicate their approval of the completeness and quality of the submission by signing and dating this form OR by providing approval to the corresponding researcher via email (included as a PDF with the full HREC submission)
5. There are various aspects of human research compliance which fall outside of the remit of the HREC, but which must be in place to obtain HREC approval. These often require input from internal or external experts such as Faculty Data Stewards, Faculty HSE advisors, the TU Delft Privacy Team or external Medical research partners.
6. You can find detailed guidance on completing your HREC application here
7. Please note that incomplete submissions (whether in terms of documentation or the information provided therein) will be returned for completion **prior to any assessment**
8. If you have any feedback on any aspect of the HREC approval tools and/or process you can leave your comments here

I. Applicant Information

PROJECT TITLE:	**Adding 1 degree of freedom to an anti-tremor orthosis without compromising existing functions** **Design a solution for finger tremor patients**
Research period: *Over what period of time will this specific part of the research take place*	**10-10-2022 until 25-3-2023**
Faculty:	**IDE**
Department:	**SDE**
Type of the research project: *(Bachelor's, Master's, DreamTeam, PhD, PostDoc, Senior Researcher, Organisational etc.)*	**Master graduation Project**
Funder of research: *(EU, NWO, TUD, other – in which case please elaborate)*	**TU Delft**
Name of Corresponding Researcher: *(If different from the Responsible Researcher)*	**Bob de Reus** **Anna Starkenburg**
E-mail Corresponding Researcher: *(If different from the Responsible Researcher)*	**bdereus@tudelft.nl** astarkenburg@student.tudelft.nl
Position of Corresponding Researcher: *(Masters, DreamTeam, PhD, PostDoc, Assistant/ Associate/ Full Professor)*	**Masters**
Name of Responsible Researcher: ***Note:** all student work must have a named Responsible Researcher to approve, sign and submit this application*	**S. Ghodrat**
E-mail of Responsible Researcher: *Please ensure that an institutional email address (**no Gmail, Yahoo, etc.**) is used for all project documentation/ communications including Informed Consent materials*	**S.Ghodrat@tudelft.nl**
Position of Responsible Researcher : *(PhD, PostDoc, Associate/ Assistant/ Full Professor)*	**Assistant Professor/Project Chair**

II. Research Overview

***NOTE:** You can find more guidance on completing this checklist here*

a) Please summarise your research very briefly (100-200 words)

What are you looking into, who is involved, how many participants there will be, how they will be recruited and what are they expected to do?

Add your text here – (please avoid jargon and abbrevations)
The planned sessions are part of 2 different graduation assignments instigated by STIL B.V. Bob de Reus is researching adding degrees of freedom in the current design. Anna Starkenburg is doing exploratory research regarding finger tremors. See appendix 1 for a more elaborate explanation on the researches. STIL B.V. is developing passive, non-invasive anti-tremor solutions and is very experienced in running human participant research sessions in cooperation with (including the current generation, 30) interns and graduating students. Different participants will be invited to join a series of consecutive input sessions during varying stages of the project. Depending on what stage the research is in, participants will be invited to be interviewed or asked to wear and evaluate different variations of prototypes on their upper limbs. The goal of the sessions is to gain insights about redesigns and get an indication of the user's requirements and desires. Participants can for example be asked to

evaluate the current design, give feedback during the design process by trying out prototypes and evaluate late-stage concepts to validate research findings or indicate a need for redesigns. The input session, could include small physical tasks like picking up light objects. By default, sessions will take place in a dedicated space for user testing at STIL's office. This space is designed with participant safety and privacy in mind. If participants do not feel comfortable about travelling to the company, we will offer the possibility to have a session at the participants home.

Between 3 and 20 participants will be selected from a database that is managed by the client company STIL. Participants who are in this database suffer from tremors and have given permission to be approached for research by STIL. The selection will be based on suggestion of participants by the client company and selection criteria set up to suit the need of the specific interaction.

b) **If your application is an additional project** related to an existing approved HREC submission, please provide a brief explanation including the existing relevant HREC submission number/s.

Add your text here – (please avoid jargon and abbrevations)

c) **If your application is a simple extension of, or amendment to,** an existing approved HREC submission, you can simply submit an HREC Amendment Form as a submission through LabServant.

III. Risk Assessment and Mitigation Plan

NOTE: *You can find more guidance on completing this checklist here*

During the graduation project, different types of interactions with human participants are to be expected. In some cases, a risk is only relevant for certain types of interactions. In order to clarify to what type of interaction we attribute these risks, the following abbreviations can be found in the "Yes" column:

- EM – Expert Meeting (informative interview with "an expert in the field").
- PPE – Participant Prototype Evaluation (session where participants are actively using a prototype)
- EI – Explorative Interview (a session where participants like potential users are asked for opinions or information)

			If YES please complete the Risk Assessment and Mitigation Plan columns below.		*Please provide the relevant reference #*	
ISSUE	**Yes**	**No**	**RISK ASSESSMENT – what risks could arise?** *Please ensure that you list ALL of the actual risks that could potentially arise – do not simply state whether you consider any such risks are important!*	**MITIGATION PLAN – what mitigating steps will you take?** *Please ensure that you summarise what actual mitigation measures you will take for each potential risk identified – do not simply state that you will e.g. comply with regulations.*	**DMP**	**ICF**
A: Partners and collaboration						
1. Will the research be carried out in collaboration with additional organisational partners such as: • One or more collaborating research and/or commercial organisations • Either a research, or a work experience internship provider[1] [1] *If yes, please include the graduation agreement in this application*	**Yes** EM, PPE, EI		Conflicting interests, profit over science, data sharing with other parties	Graduation contract is based on template provided by TU Delft ensuring protection of both student and company. A Non-Disclosure Agreement (NDA) is signed by the faculty Industrial Design and the client company STIL B.V. In addition to this document, the graduation agreements between the researchers and the client company are included.		
2. Is this research dependent on a Data Transfer or Processing Agreement with a collaborating partner or third party supplier? *If yes please provide a copy of the signed DTA/DPA*		**No**				
3. Has this research been approved by another (external) research ethics committee (e.g.: HREC and/or MREC/METC)? *If yes, please provide a copy of the approval (if possible) and summarise any key points in your Risk Management section below*		**No**				
B: Location						
4. Will the research take place in a country or countries, other than the Netherlands, within the EU?		**no**				
5. Will the research take place in a country or countries outside the EU?		**no**				
6. Will the research take place in a place/region or of higher risk – including known dangerous locations (in any country) or locations with non-democratic regimes?		**no**				

			If YES please complete the Risk Assessment and Mitigation Plan columns below.		*Please provide the relevant reference #*	
ISSUE	**Yes**	**No**	**RISK ASSESSMENT – what risks could arise?** *Please ensure that you list ALL of the actual risks that could potentially arise – do not simply state whether you consider any such risks are important!*	**MITIGATION PLAN – what mitigating steps will you take?** *Please ensure that you summarise what actual mitigation measures you will take for each potential risk identified – do not simply state that you will e.g. comply with regulations.*	**DMP**	**ICF**
C: Participants						
7. Will the study involve participants who **may** be vulnerable and possibly (legally) unable to give informed consent? (e.g., children below the legal age for giving consent, people with learning difficulties, people living in care or nursing homes,).		**no**				
8. Will the study involve participants who **may** be vulnerable under specific circumstances and in specific contexts, such as victims and witnesses of violence, including domestic violence; sex workers; members of minority groups, refugees, irregular migrants or dissidents?		**no**				
9. Are the participants, outside the context of the research, in a dependent or subordinate position to the investigator (such as own children, own students or employees of either TU Delft and/or a collaborating partner organisation)? *It is essential that you safeguard against possible adverse consequences of this situation (such as allowing a student's failure to participate to your satisfaction to affect your evaluation of their coursework).*		**no**				
10. Is there a high possibility of re-identification for your participants? (e.g., do they have a very specialist job of which there are only a small number in a given country, are they members of a small community, or employees from a partner company collaborating in the research? Or are they one of only a handful of (expert) participants in the study?		**no**				
D: Recruiting Participants						
11. Will your participants be recruited through your own, professional, channels such as conference attendance lists, or through specific network/s such as self-help groups	**Yes** PPE, EI		Unpleasant experiences during session could translate into negative association with STIL.	In this research only individuals who have previously been contacted regarding the development of STIL's product will be approached for participation. This means that their suitability for the research has been predetermined and approved by the client company. The researchers will provide a safe and comforting experience.		
12. Will the participants be recruited or accessed in the longer term by a (legal or customary) gatekeeper? (e.g., an adult professional working with children; a community leader or family member who has this customary role – within or outside the EU; the data producer of a long-term cohort study)		**no**				
13. Will you be recruiting your participants through a crowd-sourcing service and/or involve a third-party data-gathering service, such as a survey platform?	**Yes**		The database that will be used to select participants from, consists in entries made by people who	In this research only individuals who have previously been contacted regarding the development of STIL's		

			If YES please complete the Risk Assessment and Mitigation Plan columns below.		*Please provide the relevant reference #*	
ISSUE	**Yes**	**No**	**RISK ASSESSMENT – what risks could arise?** *Please ensure that you list ALL of the actual risks that could potentially arise – do not simply state whether you consider any such risks are important!*	**MITIGATION PLAN – what mitigating steps will you take?** *Please ensure that you summarise what actual mitigation measures you will take for each potential risk identified – do not simply state that you will e.g. comply with regulations.*	**DMP**	**ICF**
	PPE, EI		responded to an online survey. In this survey people had to indicate the severity of their tremor themselves. In previous research, the client company has learned that self-diagnosis is not always accurate. Relying only on this data can lead to misjudgment of risks and unreliable research results.	product will be approached for participation. This means that their suitability for the research has been predetermined and approved by the client company. The selection of participants will be discussed and managed by a clinical researcher at the client company		
14. Will you be offering any financial, or other, remuneration to participants, and might this induce or bias participation?	**Yes** EM, PPE, EI		The participants, who travel to the office of the client company in Delft, gets a travel fee. Participants could be joining with the expectations of getting discounts, early or free access to the final product when it hits the market.	Participants will be made aware that participation is voluntary and there is no compensation that is dependent on their participation or completion of the session other than their travel expenses when applicable.		
E: Subject Matter *Research related to medical questions/health may require special attention. See also the website of the CCMO before contacting the HREC.*						
15. Will your research involve any of the following: • Medical research and/or clinical trials • Invasive sampling and/or medical imaging • Medical and *In Vitro Diagnostic Medical* Devices Research	**Yes** PPE,		The device that is being developed will be a medical device. The device will be a class I medical device according to standards set by the European Commission in their classification of medical devices. This indicates a non-invasive device with relative low risk to the user	The research that is conducted will not involve any type invasive or treatment related activities. Activities will not require any change in lifestyle or health management by the participant. The device to be developed is a Class I medical device supporting users in daily life activities (compensation for a disability) and is not aimed at treatment.		
16. Will drugs, placebos, or other substances (e.g., drinks, foods, food or drink constituents, dietary supplements) be administered to the study participants? *If yes see here to determine whether medical ethical approval is required*		**No**				
17. Will blood or tissue samples be obtained from participants? *If yes see here to determine whether medical ethical approval is required*		**No**				
18. Does the study risk causing psychological stress or anxiety beyond that normally encountered by the participants in their life outside research?	**Yes** EM, PPE, EI		Participating in research in itself could create minor stress or anxiety for some participants, whom are not used to being observed while using a product and being interviewed and asked for their opinion or experience about the products/services.	At the start of the session participants will be welcomed at ease and receive an explanation about what the session entails. Also, they will be informed that they can end the session at any time in case they feel uncomfortable and that they should not feel obliged to answer a question if they are not comfortable about this.		

			If YES please complete the Risk Assessment and Mitigation Plan columns below.		*Please provide the relevant reference #*	
ISSUE	**Yes**	**No**	**RISK ASSESSMENT – what risks could arise?** *Please ensure that you list ALL of the actual risks that could potentially arise – do not simply state whether you consider any such risks are important!*	**MITIGATION PLAN – what mitigating steps will you take?** *Please ensure that you summarise what actual mitigation measures you will take for each potential risk identified – do not simply state that you will e.g. comply with regulations.*	**DMP**	**ICF**
				If participants indicate that they do not feel comfortable with coming to the client company's office, they are given the option to do the evaluation at their home. This is a situation they already know and can eliminate potential stress by the participant.		
19. Will the study involve discussion of personal sensitive data which could put participants at increased legal, financial, reputational, security or other risk? (e.g., financial data, location data, data relating to children or other vulnerable groups) *Definitions of sensitive personal data, and special cases are provided on the TUD Privacy Team website.*		**No**				
20. Will the study involve disclosing commercially or professionally sensitive, or confidential information? (e.g., relating to decision-making processes or business strategies which might, for example, be of interest to competitors)	**Yes** EM, PPE, EI		The study will be conducted with a prototype of a product that is likely to be patented in some form in the near future. Therefore, there is a risk of participants sharing sensitive information with other people, obstructing the possible patent application.	To reduce this risk, participants are made aware of the sensitivity of the information they receive. The ICF that the participant signs will oblige the participant to keep confidential information to him/her self for 2 years.		
21. Has your study been identified by the TU Delft Privacy Team as requiring a Data Processing Impact Assessment (DPIA)? *If yes please attach the advice/ approval from the Privacy Team to this application*		**No**				
22. Does your research investigate causes or areas of conflict? *If yes please confirm that your fieldwork has been discussed with the appropriate safety/security advisors and approved by your Department/Faculty.*		**No**				
23. Does your research involve observing illegal activities or data processed or provided by authorities responsible for preventing, investigating, detecting or prosecuting criminal offences *If so please confirm that your work has been discussed with the appropriate legal advisors and approved by your Department/Faculty.*		**No**				
F: Research Methods						
24. Will it be necessary for participants to take part in the study without their knowledge and consent at the time? (e.g., covert observation of people in non-public places).		**No**				

			If YES please complete the Risk Assessment and Mitigation Plan columns below.		*Please provide the relevant reference #*	
ISSUE	**Yes**	**No**	**RISK ASSESSMENT – what risks could arise?** *Please ensure that you list ALL of the actual risks that could potentially arise – do not simply state whether you consider any such risks are important!*	**MITIGATION PLAN – what mitigating steps will you take?** *Please ensure that you summarise what actual mitigation measures you will take for each potential risk identified – do not simply state that you will e.g. comply with regulations.*	**DMP**	**ICF**
25. Will the study involve actively deceiving the participants? (For example, will participants be deliberately falsely informed, will information be withheld from them or will they be misled in such a way that they are likely to object or show unease when debriefed about the study).		**No**				
26. Is pain or more than mild discomfort likely to result from the study? And/or could your research activity cause an accident involving (non-) participants?		**No**				
27. Will the experiment involve the use of devices that are not 'CE' certified? *Only, if 'yes': continue with the following questions:*	**Yes** PPE		Product failure during use causing harm to participant. Another risk could be the unforeseen failure when a prototype is used for a longer time, for example during multiple sessions. If participants are not properly briefed on how to use a prototype this could lead to misaligned expectations and possible product failures.	The client company is ISO10993 certified, meaning they have experience and are capable of constructing safe prototypes. Experimentation will only take place after client company has approved the prototype. The researcher will check and quick test the prototype after every participant. Participants will sign an ICF explaining the potential risks involved. HSE officer will be contacted to see if further approval of prototypes is necessary		
• Was the device built in-house?		**No**				
• Was it inspected by a safety expert at TU Delft? *If yes, please provide a signed device report*	**Yes** PPE		A potential risk is that the prototype will not be inspected by a qualified authority. The product isn't safe and harm the participant.	IDE's HSE expert will be contacted to find out if inspection is necessary		
• If it was not built in-house and not CE-certified, was it inspected by some other, qualified authority in safety and approved? *If yes, please provide records of the inspection*		**No**				
28. Will your research involve face-to-face encounters with your participants and if so how will you assess and address Covid considerations?	**Yes** EM, PPE, EI		Infection with COVID	Individuals showing symptoms that can be related to covid will be asked to refrain from participating in face-to-face sessions. Additionally, contact areas in the research space and prototypes should be disinfected between participants.		
29. Will your research involve **either:** a) "big data", combined datasets, new data-gathering or new data-merging techniques which might lead to re-identification of your participants **and/or** b) artificial intelligence or algorithm training where, for example biased datasets could lead to biased outcomes?		**No**				
G: Data Processing and Privacy						

			If YES please complete the Risk Assessment and Mitigation Plan columns below.		*Please provide the relevant reference #*	
ISSUE	**Yes**	**No**	**RISK ASSESSMENT – what risks could arise?** *Please ensure that you list ALL of the actual risks that could potentially arise – do not simply state whether you consider any such risks are important!*	**MITIGATION PLAN – what mitigating steps will you take?** *Please ensure that you summarise what actual mitigation measures you will take for each potential risk identified – do not simply state that you will e.g. comply with regulations.*	**DMP**	**ICF**
30. Will the research involve collecting, processing and/or storing any directly identifiable PII (Personally Identifiable Information) including name or email address that will be used for administrative purposes only? (eg: obtaining Informed Consent or disbursing remuneration)	**Yes** EM, PPE, EI		Data of participants could leak which could put both the participant, the researcher and client company in unfavorable circumstances.	Personal data will the kept on the ICF and linked to a participant number. All other data will be linked to this number only. ICF's will be stored separately from all other data to promote anonymity.		
31. Will the research involve collecting, processing and/or storing any directly or indirectly identifiable PIRD (Personally Identifiable Research Data) including videos, pictures, IP address, gender, age etc and **what other Personal Research Data** (including personal or professional views) will you be collecting?	**Yes** EM, PPE, EI		Not complying with regulations regarding PII/PIRD. Failure to protect personal data against loss/misuse	All PIRD will be stored on a secure and private on drive partition at the client company. Any data that will be published elsewhere will be anonymized completely (see DMP)		
32. Will this research involve collecting data from the internet, social media and/or publicly available datasets which have been originally contributed by human participants		No				
33. Will your research findings be published in one or more forms in the public domain, as e.g., Masters thesis, journal publication, conference presentation or wider public dissemination?	**Yes** EM, PPE, EI		Client confidentiality, Personal data leaks	Adhere to regulations and standards regarding data as described above and in DMP and ICF		
34. Will your research data be archived for re-use and/or teaching in an open, private or semi-open archive?	**Yes** EM, PPE, EI		Client confidentiality, Personal data leaks	Adhere to regulations and standards regarding data as described above and in DMP and ICF		

H: More on Informed Consent and Data Management

NOTE: *You can find guidance and templates for preparing your Informed Consent materials) here*

Your research involves human participants as Research Subjects if you are recruiting them or actively involving or influencing, manipulating or directing them in any way in your research activities. This means you must seek informed consent and agree/ implement appropriate safeguards regardless of whether you are collecting any PIRD.

Where you are also collecting PIRD, and using Informed Consent as the legal basis for your research, you need to also make sure that your IC materials are clear on any related risks and the mitigating measures you will take – including through responsible data management.

Got a comment on this checklist or the HREC process? You can leave your comments here

IV. Signature/s

Please note that by signing this checklist list as the sole, or Responsible, researcher you are providing approval of the completeness and quality of the submission, as well as confirming alignment between GDPR, Data Management and Informed Consent requirements.

Name of Corresponding Researcher (if different from the Responsible Researcher) (print)

Signature of Corresponding Researcher: Bob de Reus

Date: 19.10.2022

Signature of Corresponding Researcher: Anna Starkenburg

Date: 19.10.2022

Name of Responsible Researcher (print)

Sepideh Ghodrat
Signature (or upload consent by mail) Responsible Researcher:

Date:19.10.2022

V. Completing your HREC application

Please use the following list to check that you have provided all relevant documentation

Required:

- **Always:** This completed HREC checklist
- **Always:** A data management plan (reviewed, where necessary, by a data-steward)
- **Usually:** A complete Informed Consent form (including Participant Information) and/or Opening Statement (for online consent)

Please also attach any of the following, if relevant to your research:

Document or approval	Contact/s
Full Research Ethics Application	After the assessment of your initial application **HREC will let you know if and when you need to submit additional information**
Signed, valid Device Report	Your Faculty HSE advisor
Ethics approval from an external Medical Committee	TU Delft Policy Advisor, Medical (Devices) Research
Ethics approval from an external Research Ethics Committee	Please append, if possible, with your submission
Approved Data Transfer or Data Processing Agreement	Your Faculty Data Steward and/or TU Delft Privacy Team
Approved Graduation Agreement	Your Master's thesis supervisor
Data Processing Impact Assessment (DPIA)	TU Delft Privacy Team
Other specific requirement	Please reference/explain in your checklist and append with your submission

APPENDIX 3: PROGRAM OF REQUIREMENTS

Requirements

1. Performance
   1.1. Product must facilitate a high range of motion in the entire upper limb.
   1.2. Product must be able to withstand 1 Nm torque in WFE direction
   1.3. Product must be able to withstand 1 Nm torque in FPS direction
   1.4. The orthosis must be effective at suppressing Action tremors, caused by Essential tremor
   1.5. The orthosis must include degrees of freedom for EFE, FPS, WFE and WRUD
2. Maintenance
   2.1. All fabrics must be removable for washing
   2.2. No planned maintenance should be required on the internal mechanism for at least 1 year
3. Aesthetics, appearance and finish
   3.1. The demo model must be produced in the same material and finish as the production model of the current orthosis for fair comparison.
4. Materials
   4.1. The product cannot contain materials that are not biocompatible on the surface
   4.2. The product must be made out of materials that are water resistant
5. Product life span
   5.1. The product must withstand at least 1 year of daily use
   5.2. The product must withstand 100.000 cycles
6. Standards, rules and regulations
   6.1. The orthosis must remain a passive device according to the MDR.
   6.2. The orthosis must be suitable for the Dutch market, and be in compliance with Dutch rules and regulations.
7. Ergonomics
   7.1. The orthosis must have a Range of Motion of at least 64 degrees radial, and 36 degrees ulnar deviation
   7.2. When data is gathered from population datasets, a minimal p97,5 selection must be used.
   7.3. In the neutral position, the gap between arm and slider must not be bigger than 5 cm
   7.4. The WRUD axis of the orthosis should center on the lower part of the capitate metacarpal
8. Testing
   8.1. The product should perform similar or better in comparison to the current (1.7) orthosis by STIL on TETRAS
   8.2. The orthosis must be able to be fitted with a WRUD damper
9. Safety
   9.1. The product can not contain gaps or sharp edges that can damage skin or clothes
10. Product policy
    10.1. The proposed improvements must be aimed at version 2 of the orthosis
    10.2. The proposed improvements to the orthosis must be implementable by 2024
11. Installation and initiation of use
    11.1. The product must be wearable on both left and right arm.
    11.2. The product must be reconfigurable between arms in less than 5 minutes.

Wishes:

1. The parts of the orthosis should be as interchangeable as possible for left or right handed orientation
2. The orthosis should help against as much tremor types as possible

3. The orthosis should be as “low profile” as possible to make it easy to fit under clothes
4. Damper specs should be variable in some way

APPENDIX 4: FORMATIVE EVALUATION PROTOCOL

Formative evaluation protocol WRUD initial testing

1. Introduction

Wrist Radial and Ulnar Deviation is not possible in the current version (1.6) of the Beam. In order to find out **if** freedom in WRUD helps to make the user feel less restricted by the orthosis, four versions of the prototype have been developed. These prototypes have varying degrees of dampened and undampened freedom of motion. Verification of these prototypes will be done using an old version of the Beam with the slider attached on the wrist side. This makes quicker changes of hand pieces possible. The four versions will be evaluated by STIL personnel to get an impression of how the variations are received by experienced users. Then they will be given to tremor participants for evaluation. These sessions will provide more insight on how the prototypes deal with the tremors, and how potential users value their properties.

2. Purpose

The main goal of the testing is to find out **if** adding freedom in WRUD would be beneficial, and **how much and which type** damping would be desirable. The following topics are of interest for these sessions.

verification of:

3. The assumption that users want more freedom of motion in their wrist.
    a. Perceived comfort - Does additional freedom of motion in the wrist make the orthosis more comfortable to use? Does the user experience a certain variety in their range of motion as pleasant?
    b. ADL activities - How much is this freedom required in daily life? Does it help the user to have WRUD freedom when performing ADL?
    c. No detrimental results for other DoF's - How does adding a degree of freedom influence the tremor suppression performance of the device in other DoF's? Will extra RoM increase the expression of tremors that were suppressed in earlier versions?
4. Is damping of WRUD desirable?
    a. Perceived comfort - Does damping the WRUD movement make the orthosis more comfortable to use? Does the user notice the difference with undampened versions? Which one is preferred?
    b. ADL activities – Does damping the WRUD movement help with suppressing tremors in WRUD, FPS and WFA?

Not directly relevant:

1. Size and shape
    a. How does it look
    b. Fit under clothes
2. Slider orientation
3. color

3. Method overview

3.1. SUBJECT RECRUITMENT

The evaluation will be done with a combination of tremor participants and non-tremor participants. Recruitment of tremor participants will take place using STIL's database of interested tremor patients that signed up to help with the development of the product. Non-tremor participants (or "healthy" participants) prototype evaluation will take place using STIL personnel.

3.2. INCLUSION AND EXCLUSION CRITERIA

Tremor participants will be selected using the inclusion and exclusion criteria (as defined in 6. Test Participants). Non-tremor participants must be employees at STIL. This is to make sure that they are familiar with the device and can give feedback based on earlier experience. This is a group that is easy to approach and is always available. Also, this way it is unlikely that they have conflicting interests, or that sensitive information falls into the wrong hands.

3.3. INFORMED CONSENT

Before any test can commence, participants will be informed about the protocol and the device to be tested. Participants must be given the opportunity to ask questions and deny participation. After agreement, Participant and investigators will sign two copies of an informed consent form. One for the researcher and one for the participant to keep. The session has been approved by the Human Research Ethics Committee of the TU Delft. A template of the Informed Consent form can be found in Appendix XXX.

3.4. USER TESTING

Participants will evaluate four prototypes with different degrees of wrist mobility. Participants can stop testing at any given moment, without any given reason.

3.5. DATA ANALYSIS

Tremor Participant data will be pseudonymized and stored using the unique identifier participants were given in STIL's database. Non-tremor participants will be pseudonymized as well, but their participant number will not correspond to STIL's database. Data analysis will be based on comparison of the 4 prototypes and their respective scores given by the participants. Storage and handling of data will be in compliance with methods as described to, and approved by TU Delft Human Research Ethics Committee (See file: HREC approval).

4. Test Materials:

Prototypes Used:

- fully assembled slider (reversed, one that attaches to wrist side), preferably in S, M and L.
- fully assembled versions of 4 different stages of WRUD freedom wrist pieces (see table below)
- different sizes of elbow pieces

Table 7: Prototype overview

	A	B	C	D
WRUD freedom	Fixed	Fixed damping	Variable damping	Free
Type of damper	x	Friction	Viscous fluid	x
Expected damping	x	0.25 Nm	0.4 Nm (@20RPM)	<0.1 Nm

Assumptions and expectations about the performance of the prototypes are discussed in part 11 of this document.

Equipment and materials used:

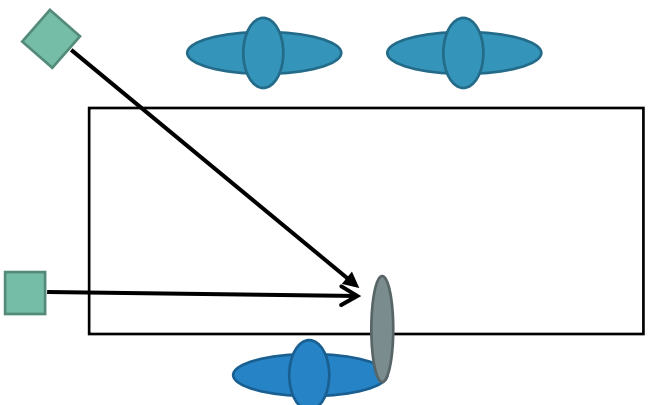
- Laptop with mouse
- Stopwatch (app)
- Camera + accessories (extra battery)
- Cups
- Water bottle
- Pen and paper

Printed documents

- Archimedes spirals
- Informed consent forms (2/participant)

5. Test Environment

STIL's office or at participant's house. The location must provide a safe and private environment that allows the participant to feel at ease. Nervousness can have an influence on the severity of tremor. The researcher needs to make sure that the participant experiences as little nervousness or anxiousness as possible under the circumstances. The location must also have a table, at least 3 chairs, a door with a key lock and wall sockets to power equipment. A rough sketch of a preferred setup can be found below in figure 1. Note that the cameras (gray boxes) should be placed on the opposite side of the arm where the orthosis (orange ellipse) is worn by the participant (green person). The researchers (blue persons) sit at the table (black box) in front of the participant in order to be able to observe the participant optimally.



6. Test Participants

Tremor participants must fit the following inclusion and exclusion criteria for participation in this evaluation.

6.1. Inclusion criteria

- Participants must have essential tremor
- Participants must have at least mild to severe FPS or WFE tremor

6.2. Exclusion criteria

- Mild to severe SIER tremor
- Open wounds on the arm
- Tendon inflammation on the arm
- Bruises on the arm
- Covid?
- Size S,S,S

6.3: preferred characteristics

- WRUD tremor
- Normal to high wrist mobility (WRUD min -20/+20)
- Size M in all parts of orthosis

Table 8: Participants

Participant	Quantity
Non-tremor	3
Tremor	3

Other factors could Influence the outcome of the result but are only controllable in limited amounts in the time permitted for this research. The researcher strives for an optimal spread of these factors but cannot guarantee even distributions. Factors that should be considered in this category:

- Age
- Sex
- Education and experience with human research procedures
- Experience with previous versions of the orthosis
- Elapsed time since tremor diagnosis
- Medication use
- (Un)diagnosed medical conditions other than E.T.
- Level of skill in tasks that are performed

7. Test personnel

The sessions could be done by a single researcher, but two are preferred. The first researcher can interact with the participant and give instructions. The second researcher operates the cameras, takes notes and can observe. Since the main researcher (Bob de Reus) has limited experience with evaluation sessions with tremor participants, it is expected to be helpful to have a more experienced researcher present for support.

8. List of Tasks

The list of tasks in based on previous user tests that STIL has performed while testing versions of the device. All participants will be asked to perform the same tasks. Non-tremor participants results will be used to find out if the range of motion is experienced as pleasant. The tremor participants results are used to see how tremors influence the performance of the different prototypes, and to confirm or deny the findings of the non-tremor participants

The order of prototypes has been set from least to most wrist mobility. The rationale behind this is that it might allow the researcher to find a point where the participant indicated that this would be the “sweetspot” between freedom and damping.

8.1. Initiation test

Before testing with the user, the device is set up to the right configuration for the intended participant. The following checks are performed:

- Check if device is clean and all components are included
- Check if the right prototype hand pieces are mounted on the device
- Check for any abnormal play between components
- Check if straps are loosened
- Check if damping feels as expected

8.2. Introduction talk

At the start of the session, the participants will be explained what the session is about, and what the rules and regulations of the session are. This introduction should include, but not be limited to:

- Informed consent
    - Allow the participant plenty of time to read and ask questions about the form they have been presented
    - When all issues have been addressed to the researcher and participants satisfaction, both will sign
- NDA
    - Part of the provided informed consent covers confidentiality. The researcher will put emphasis on the sensitivity of the information that the participant will get, and explain that the participant is not allowed to share any details about the session with anyone for at least 2 years
- Safety
    - Explain that the participant should always indicate if any part of the session makes him/her uncomfortable. The participant is free to stop the session at any time.
- Purpose
    - The researcher will explain that the results found during the session will contribute to the graduation project of the researcher, and might help STIL to improve their product.

8.2. Non-tremor participant evaluation

The testing will take place at STIL's office. The participants are aware of what the research is about. However, they will be informed about the specifics of this session. The participants and researcher sign the Informed consent form.

Once all questions of the participant have been answered and the forms are signed the following activities will take place:

1. Wear proto A for 2 to 5 minutes while doing the activities described in the table below
2. 2 to 5-minute feedback conversation with researcher
3. Switch to proto B and wear for 2 to 5 minutes while doing the activities described in the table below
4. 2 to 5-minute feedback conversation with researcher
    a. Focus in perceived differences between step 1 and 4
5. Switch to proto C and wear for 2 to 5 minutes while doing the activities described in the table below
6. 2 to 5-minute feedback conversation with researcher
7. Switch to proto D and wear for 2 to 5 minutes while doing the activities described in the table below
8. feedback conversation with researcher
    a. Which was favorite?
    b. What was the difference?

8.3. Tremor participant evaluation

Assuming that the testing is combined with testing of STIL's current prototype of the Beam, participants will have worn a version with a fixated WRUD joint just before this test. The researcher will ask the participants to do the following steps:

Baseline testing:
Establish a baseline of participant's reach envelope and tremor by filming their arms (without orthosis) in the following ways:

- FPS: arm stretched towards the diagonal camera, hand in neutral position (hold 10 seconds). Move to max pronation (hold for 3 seconds). Move to max supination (hold for 3 seconds)
- WFE: Arm stretched out forwards, perpendicular to the 90 degrees camera, wrist pronated 90 degrees (hold for 10 seconds). Move wrist to max flexion (hold for 3 seconds). Move to max extension (3 seconds).
- WRUD: elbow at 90 degrees, hand neutral (hold 10 sec). max ulnar deviation (hold 3 sec). Max radial deviation (hold 3 sec)

Prototype testing:

1. Put on orthosis prototype version A
2. Repeat reach envelope and tremor baseline tests from the baseline testing while wearing the orthosis.
3. Perform the following activities (elaborated version in table 3):
    a. Using a computer with mouse
    b. Drink water from a cup

    c. Open a door with a key
    d. Write with pen on paper
4. Take off the orthosis
5. Answer the researcher's questions regarding the prototype.
6. Repeat with other versions of the prototype

Overall performance comparison

All prototypes are placed in front of the participant in order of testing. The participant is asked to place them in order of his personal preference. The researcher will instigate a dialogue on why the participant chose this ranking. The participant will be asked if the ranking would change if he would only rank on attributes like: Ease-of-use, comfort and tremor suppression.

Table 9: Elaboration on required actions

Activity	Description	details
1	Drinking water from a cup	Bringing a cup (8 cm tall, filled with water to 1 cm from top) from the table to the mouth to drink water.
2	Write with pen on paper	participant is asked to copy an Archimedes spiral using a ballpoint pen that approximately fills an A6 sheet of paper (Figure 7). The lines of the spiral should be approximately 1.3 cm apart. The pen should be held in such way that no part of the limb touches the table. After that the participant is asked to write 1 sentence with at least 4 words with the same pen and paper.
3	Using a computer with mouse	Use a computer mouse to do a 30 second cursor accuracy test on a laptop. Specifically for this test: https://mouseaccuracy.com/
4	Closing or opening door with key	Participant is asked to stand in front of a door. Using the hand with the orthosis, take the key out of the lock and remove it 30 cm horizontally from the lock, reinsert it and fully open and close the lock. A minimum of 360 degrees of rotation of the key is required

9. Data collection

Data collected when appropriate:

- Video and audio
- (digital) notes
- Participant's written results, preferences and input

Additional data gathered from tremor participant evaluation

- Video capture of all activities
- Digital and analog notes taken by researcher
- Digital scoring sheets of activities, filled in by researcher during session

10. Data Analysis

Research with the non-tremor participants:

This part of the research will not be analyzed for the development of the product. The procedures are carried out to pilot the sessions and to see if the procedure is safe and logical for participants with tremor. No data will be stored.

Research with tremor participant:

WRUD measurements will be taken from paused frames in the baseline video. These are used to see if participant data is comparable to a healthy population. This could confirm the usability of WRUD values found in DINED for example. Video will be further analyzed to see what the effects are of freeing WRUD on tremor propagation. Participant's comments will be used to analyze perceived comfort. A fixed list of questions will guide the feedback sessions with these users, but there is also room for spontaneous conversation.

11. Assumptions/expectations

The sessions are designed with some assumptions and expectations in mind. Some of these are listed below.

Assumption: The orthosis will be perceived as more comfortable by users when there is more wrist mobility.
The researcher expects that fixing WRUD motion can have a negative impact on the ease of use and comfort during tasks that require the user to move the wrist. IF tremor is left out of the equation, it is expected that the prototypes are ranked D,C,B,A in order most to least comfortable since this corresponds to the order of least to most resistance to movement.

Assumption: Dampening is required to mitigate tremor
When WRUD tremor is added to the equation, it is expected that a dampened version is preferred over the non-dampened ones. Therefore, comfort might be ranked as follows: BC>AD.
Tremor in FPS or WFE alone are expected to have little influence on the before mentioned ranking, since their motion happens perpendicular to the range of motion of WRUD. However, as soon as there is a combination of multiple tremors, there might be a need for dampening.

Assumption: User will prefer viscous damping over friction damping
The amount of force that can be applied can fluctuate between different users. Therefore, it might be difficult to find a friction damper with a fixed damping force that would suit all users. If the friction is too low, no effect will be noticed. If the friction is too high, the uses will not be able to overcome the threshold force and cannot move the hand. The researcher expects that that the variable damping force that is associated with the viscous damper will be preferred. Even if the user has very little strength in the wrist, slow movement will still be possible with prototype C.

The prototypes are all based on the hand piece of the current orthosis. The CAD models have been adapted so that variations in WRUD mobility were possible. Next, the newly designed hand pieces were 3D-printed. Assembly was done by form fitting the dampers, in combination with hardware like brass inserts and bolts.

Every hand piece is attachable to the slider of the orthosis using a single countersunk bolt that keeps it in place (Figure 43). Only a limited number of orthoses are available for testing. This is why a quick-change mechanism was used instead of producing four fully independent prototypes

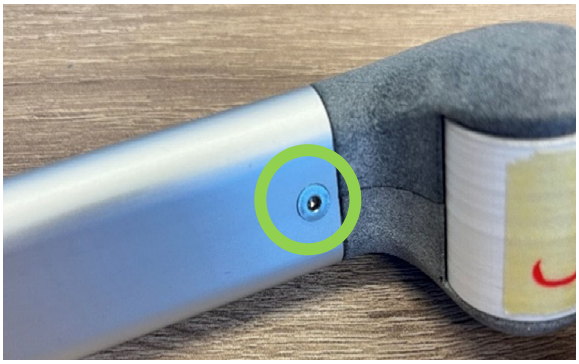


Figure 43: single bolt attachment

The textile cushioning that connects the 3D-printed parts with the user's hand are quickly interchangeable with a combination of 2 snap fasteners and some Velcro (Figure 44).

Figure 44: attaching the fabric parts

The intuitively estimated performance regarding comfort, ease-of-use and tremor suppression is given on the following scale: -2= much worse, -1 = a bit worse, 0= neutral, 1= a bit better, 2= much better, all compared to the current (STIL) version of the orthosis.

APPENDIX 5: DAMPER RESEARCH

In the section below, a brief description of different damper types is given. The section ends with a selection of two damper types that are used for further development.

Damping

Damping as a physical phenomenon can be described as reducing a vibrating or oscillating motion by extracting energy and dissipating this. The reason that a chapter is dedicated to this phenomenon, is because it is the main working principle of the orthosis.

Methods of damping

Damping can be achieved using a number of different principles. Below some of the common or interesting methods are described based on (amongst others) the paper from Johnson (1995). This list is not exhaustive, but does provide some insight into the world of damping.

Viscoelastic material damping

Working principle:

As the name suggests, viscoelastic materials (VEM) show both viscous and elastic characteristics when they are deformed. An elastic material will resist deformation and change shape when a force is applied. When the force is released, it returns to its initial shape. Pure elastic materials convert all their stored elastic potential energy back into kinetic energy, no energy is lost due to heat. Viscous materials, according to material science, are defined as materials that provide resistance against a force linearly to the time that this force is applied. They do not convert stored energy back as opposed to elastic materials. A material that combines these two characteristics can be used to dampen vibrations. The vibration's energy will deform the material, some of this energy is used to convert the material back to its original shape. The rest is dissipated into heat.

Typical application:

An example of a VEM damper is rubber vibration absorbing feet under a washing machine.

Fluid viscous dampers (FVD)

Working principle:

An FVD uses a viscous fluid that is forced through an orifice in a confined space. The viscous fluid's resistance to moving through a small orifice is what creates a counterforce. FVD's come in rotary and linear capacity. Opposed to the normal force of for example a spring, the damping of a FVD is velocity dependent.

Typical application:

An example of a FVD is the soft close system of closet drawers or toilet seats.

Friction dampers

Working principle:

Friction dampers (or Coulomb dampers) dissipate energy by dry contact between 2 surfaces (Gagnon et al., 2020) and might be the best known type of damper. Their commonality could be explained by their simplicity and effectiveness and examples of these dampers can be found throughout history. Friction dampers do not require an external power source and perform relatively temperature independent.

Once enough force is applied to the damper to overcome the static friction threshold, the damper will provide a constant counterforce.

Typical application:

These dampers are used for example in laptop hinges.

Magnetic/eddy current dampers

Working principle:

Magnetism can also be used to dampen a force. When a magnetic field is crossed by a non-ferromagnetic conductor, an eddy current, or electric field is induced. A resulting magnetic field then is induced by these eddy currents which opposes the motion of the conductor (Cadwell, 1996). This opposing force can be used to dampen the motion of the conductor.

Typical application:

This technique can be found in balancing scales and is used to quickly bring the scale into equilibrium without causing friction that could influence the measurement.

Magnetorheological (MR) dampers

Working principle:

MR dampers are similar to the beforementioned VEM dampers, but they use fluids that carry microscopic magnetic particles. If a magnetic field is applied to this fluid, the particles will align and transform the behavior of the fluid into a plastic or even semi-solid state. This makes it possible to influence the damping characteristics in milliseconds by introducing a magnetic field to the damper.

Typical application:

These dampers have been applied in for example high-end car suspension systems

Damper selection

In order to find the most interesting dampers, each damper type is ranked by its perceived performance using three criteria. Not all information and specs are known of the damper types so the scores are more “guesstimates” than hard, evidence-based categorizations. The device with the highest total amount of points should be most interesting for further development.

These dampers have been subjected to the following criteria:

1: Size.
The damper needs to be available in the right size range with the right damping specs

The required damping torque is estimated to be between 0.2 and 1 Nm, based on the current damper specs of the orthosis. Often dampers can be tuned by changing size and shape of their components. For this criterion, the damper needs to be small enough at this certain torque range to be incorporated in the design of the orthosis. The dampers are rated by perceived changes required to integrate them in the design.

- 1 point – Large impact, design requires significant change
- 2 points – Medium impact, some change required, but design could remain similar
- 3 points – Small impact, hardly any change to the orthosis required

2: Price.
The damper needs to be affordable

The dampers vary widely is price, and these prices also vary with order size. Some dampers would even need to be customized before they could be applicable. Higher part prices result in higher consumer prices.

- 1 point - >€50
- 2 points - €5-€50
- 3 points - <€5

3: Durability.
The damper needs to be reliable and have a long life-span

Since the orthosis is a product that is used on a daily basis, the components need to be reliable and durable. This will be ranked on the amount of cycles the damper can handle without maintenance or replacement. Since this is the most difficult criteria to estimate, and is most dependent on decisions within the category, only half of the points can be earned.

- 0.5 points – 0-50.000 cycles
- 1 point – 50-100.000 cycles
- 1.5 points – 100.000 + cycles

Table 10: Damper selection - scores per criterium

	1: Size	2: Price	3: Durability	total
VEM	2	3	1	6
FVD	2	2	1.5	5.5
Friction	3	3	1	6
Magnetic	1	1	0.5	2.5
MR	1	1	1	3

Conclusion dampers

Based on the three criteria, VEM, FVD and Friction dampers appeared to be much more promising than the magnetic and MR dampers. [redacted] VEM could potentially be interesting to use in the device. However, durability can be an issue, especially when the damper is not applied to counter small amplitude vibrations. High stress and strain can cause failures is the material. Therefore, it is a method that can be difficult to control and predict. For these reasons VEM has been excluded for this research. FVD and friction dampers are left as the most promising options and have been used in prototypes.

APPENDIX 6: CONCEPT 2 EVALUATION PROTOCOL

1. Introduction

Wrist Radial and Ulnar Deviation is not possible in the current version (1.6) of the Beam. In order to test if the proposed changes to the design of the beam improve the user's experience, a prototype has been made. This will be compared to the current version (and a sham???). By using a part of the validated TETRAS method, the different devices will be scored and compared

Purpose

The main goal of the testing is to find out if the changes made to the design of the orthosis translate into increased perceived comfort by the user, without compromising the effectiveness of the device against tremor.

Hypothesis

The researcher hypothesizes that a device that allows freedom of movement in WRUD is preferred by the user over one that fixates WRUD. Also, damping WRUD will help to mitigate tremors in WRUD better than undampened WRUD.

Assumptions/expectations

The sessions are designed with some assumptions and expectations in mind. Some of these are listed below.

Assumption: The orthosis will be perceived as more comfortable by users when there is more wrist mobility.
The researcher expects that fixing WRUD motion can have a negative impact on the ease of use and comfort during tasks that require the user to move the wrist. IF tremor is left out of the equation, it is expected that the prototypes are ranked D,C,B,A in order most to least comfortable since this corresponds to the order of least to most resistance to movement. However, previous sessions showed that in these short interactions, the increased mobility is not always noticed. Especially if other elements of the design also change.

Assumption: Dampening is required to mitigate tremor
When WRUD tremor is added to the equation, it is expected that a dampened version is preferred over the non-dampened ones.
Tremor in FPS or WFE alone are expected to have little influence on the before mentioned ranking, since their motion happens perpendicular to the range of motion of WRUD. However, as soon as there is a combination of multiple tremors, there might be a need for dampening.

2. Methodology

Method	Semi-structured interview Observation of user TETRAS scoring
Participants	3-5
Incentives	Travel expenses reimbursement
Length	1-1.5 hour
Prototype versions	Beam 1.6 orthosis Beam 1.6 – Dampened WRUD orthosis Beam 1.6 – Free WRUD orthosis
Data collected	Video of participants Written observations/Quotes TETRAS scores

Table 11: Summary of methodology

SUBJECT RECRUITMENT

The evaluation will take place with participants who are affected by tremor. Recruitment of tremor participants will take place using STIL's database of interested tremor patients that signed up to help with the development of the product. Preferably a minimum of 5 patients participates in the research.

Methods

The participants will execute several prescribed actions that have been selected from "The Essential Tremor Rating Assessment Scale", better known as "TETRAS". This is a commonly used, validated method in the field of tremor research. Four tasks are selected from TETRAS and are executed by the participants while wearing the different versions of the orthosis.

The participants are asked which version they experienced as most comfortable and easy to use. This preference is compared to their respective TETRAS scores which are assigned during the activities by the researcher according to the prescribed ranking system.

INFORMED CONSENT

Before any test can commence, participants will be informed about the protocol and the device to be tested. Participants must be given the opportunity to ask questions and deny participation. After agreement, Participant and investigators will sign two copies of an informed consent form. One for the researcher and one for the participant to keep. The session has been approved by the Human Research Ethics Committee of the TU Delft. A template of the Informed Consent form can be found in Appendix 2: Ethics.

DATA storage

Tremor Participant data will be pseudonymized and stored using the unique identifier participants were given in STIL's database.

Storage and handling of data will be in compliance with methods as described to, and approved by TU Delft Human Research Ethics Committee.

Test Materials:

Equipment and materials used:

- Laptop with mouse
- Stopwatch (app)
- Camera + accessories (extra battery)
- Cups
- Water bottle
- Pen and paper
- 3 prototypes (fixed WRUD, dampened WRUD and free WRUD)

Printed documents

- Archimedes spirals
- Informed consent forms (2/participant)

Test personnel

The sessions could be done by a single researcher, but two are preferred. The first researcher can interact with the participant and give instructions. The second researcher operates the cameras, takes notes and can observe.

Test Environment

STIL's office or at participant's house. The location must provide a safe and private environment that allows the participant to feel at ease. Nervousness can have an influence on the severity of tremor. The researcher needs to make sure that the participant experiences as little nervousness or anxiousness as possible under the circumstances. The location must also have a table, at least 3 chairs, a door with a key lock and wall sockets to power equipment. A rough sketch of a preferred setup can be found below in figure 1. Note that the cameras (gray boxes) should be placed on the opposite side of the arm where the orthosis (orange ellipse) is worn by the participant (green person). The researchers (blue persons) sit at the table (black box) in front of the participant in order to be able to observe the participant optimally.

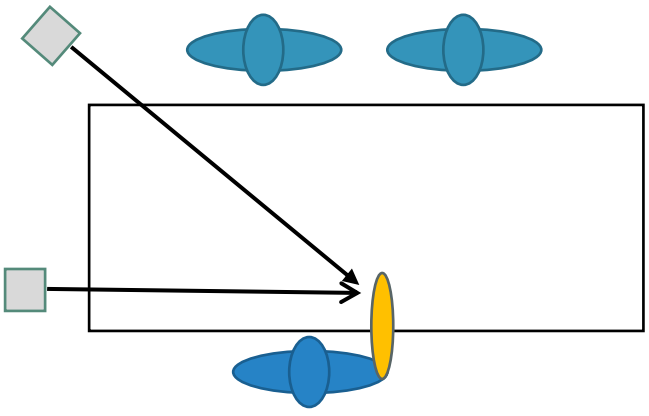


Figure 49: session location setup

4. Test Participants

Tremor participants must fit the following inclusion and exclusion criteria for participation in this evaluation.

Inclusion criteria

- Participants must have essential tremor
- Participants must have at least mild to severe FPS or WFE tremor

Exclusion criteria

- Mild to severe SIER tremor
- Open wounds on the arm
- Tendon inflammation on the arm
- Bruises on the arm
- Covid?
- Size S,S,S

preferred characteristics

- WRUD tremor
- Normal to high wrist mobility (WRUD min -20/+20)
- Size M in all parts of orthosis

Other factors could Influence the outcome of the result but are only controllable in limited amounts in the time permitted for this research. The researcher strives for an optimal spread of these factors but cannot guarantee even distributions. Factors that should be considered in this category:

- Age
- Sex
- Education and experience with human research procedures
- Experience with previous versions of the orthosis
- Elapsed time since tremor diagnosis
- Medication use
- (Un)diagnosed medical conditions other than E.T.
- Level of skill in tasks that are performed

5. Activities during session

TETRAS

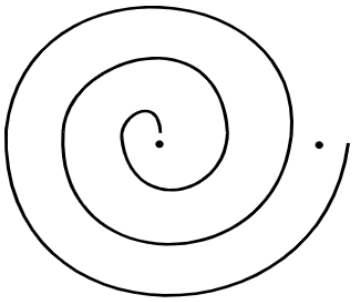
The following tasks are selected from the Activities of Daily Life and Performance sections of TETRAS:

Eating with a spoon: Using a spoon to bring M&M's of similar shaped food from a bowl on the table to the mouth. This is an adaptation from TETRAS, as it usually does not specify which solids or liquids must be used to assess eating with a spoon.
0 = Normal
1 = Slightly abnormal. Tremor is present but does not interfere with feeding with a spoon.
2 = Mildly abnormal. Spills a little.
3 = Moderately abnormal. Spills a lot or changes strategy to complete task, such as using two hands or leaning over.
4 = Severely abnormal. Cannot feed with a spoon.

Drinking from a cup: Bringing a cup (8 cm tall, filled with water to 1 cm from top) from the table to the mouth to drink water.
0 = Normal.
1 = Slightly abnormal. Tremor is present but does not interfere with drinking from a glass.
2 = Mildly abnormal. Spills a little.
3 = Moderately abnormal. Spills a lot or changes strategy to complete task such as using two hands or leaning over.
4= Severely abnormal. Cannot drink from a glass or uses straw or sippy cup.

Pouring: Pouring a water filled plastic cup (8 cm tall, filled with water to 1 cm from top) into another cup (8 cm tall) that is unsupported on the table.
0 = Normal.
1 = Slightly abnormal. Tremor is present but does not interfere with pouring.
2 = Mildly abnormal. Must be very careful to avoid spilling but may spill occasionally.
3 = Moderately abnormal. Must use two hands or uses other strategies to avoid spilling.
4 = Severely abnormal. Cannot pour.

Archimedes spiral: Demonstrate how to draw Archimedes spiral that approximately fills ¼ of an unlined page of standard letter paper (4-5 complete revolutions). The lines of the spiral should be approximately 1 cm or 0.5 inch apart. Test and score each hand separately. Use a ballpoint pen. The pen should be held such that no part of the limb touches the paper or table. Secure the paper on the table in a location that is optimal for the patient. Score the tremor seen in the drawn spiral, not the movement of the limb.
0 = no tremor
1 = tremor is barely visible (< 0.5 cm)
1.5 = tremor is visible, but less than 1 cm
2 = tremor is 1- < 3 cm amplitude
2.5 = tremor is 3- < 5 cm amplitude
3 = tremor is 5- < 10 cm amplitude
3.5 = tremor is 10- < 20 cm amplitude
4 = tremor is > 20 cm amplitude



Scoring is 0 – 4. For most items, the scores are defined only by whole numbers, but 0.5 increments may be used if you believe the rating is between two whole number ratings and cannot be reconciled to a whole number. Each 0.5 increment in rating is specifically defined for the assessment of upper limb postural and kinetic tremor and the point approximation task.

Overall performance comparison

After TETRAS activities, all prototypes are placed in front of the participant in order of testing. The participant is asked to place them in order of his personal preference. 1st place meaning their personal favorite, last place the least favorite.

The researcher will instigate a dialogue on why the participant chose this ranking. The participant will be asked if the ranking would change if he would only rank on attributes like: Ease-of-use, comfort and tremor suppression.

6. Session script

Initiation test

Before testing with the user, the device is set up to the right configuration for the intended participant. The following checks are performed:

- Check if device is clean and all components are included
- Check if the right prototype hand pieces are mounted on the device
- Check for any abnormal play between components
- Check if straps are loosened
- Check if damping feels as expected if applicable

Introduction talk

At the start of the session, the participants will be explained what the session is about, and what the rules and regulations of the session are. This introduction should include, but not be limited to:

- Informed consent
    - Allow the participant plenty of time to read and ask questions about the form they have been presented
    - When all issues have been addressed to the researcher and participants satisfaction, both will sign
- NDA
    - Part of the provided informed consent covers confidentiality. The researcher will put emphasis on the sensitivity of the information that the participant will get, and explain that the participant is not allowed to share any details about the session with anyone for at least 2 years
- Safety
    - Explain that the participant should always indicate if any part of the session makes him/her uncomfortable. The participant is free to stop the session at any time.
- Purpose
    - The researcher will explain that the results found during the session will contribute to the graduation project of the researcher, and might help STIL to improve their product.

Introduction to the device

At this moment the participant will be asked to put the device on its dominant arm. This must also be the arm that is affected by tremor. The participant will get a few minutes to try to figure out how to put it on themselves. If this proves problematic, the researcher will help out.

Once the device is on the dominant arm, the researcher tests if the device is mounted correctly and the straps are tightened properly.

Start of the data gathering

1. Start questionnaire/video software
2. Ask participant to demonstrate maximum WFE, WRUD and FPS
3. Let participant complete TETRAS activities
    a. Researchers assign scores to each individual activity
    b. Researchers note down relevant comments and observations during the activities.
    c. Researcher ensures that the actions are caught on video
4. Repeat 2 and 3 with all prototypes
5. Ask participant for personal preference

7: Data Analysis

Research with tremor participant:

Video will be further analyzed to see what the effects are of freeing WRUD on tremor propagation. Participant's comments will be used to analyze perceived comfort. A fixed list of questions will guide the feedback sessions with these users, but there is also room for spontaneous conversation.

The TETRAS data is entered in an excel sheet and individual scores are added up to find out how well the new prototypes score compared to the current version of the orthosis.

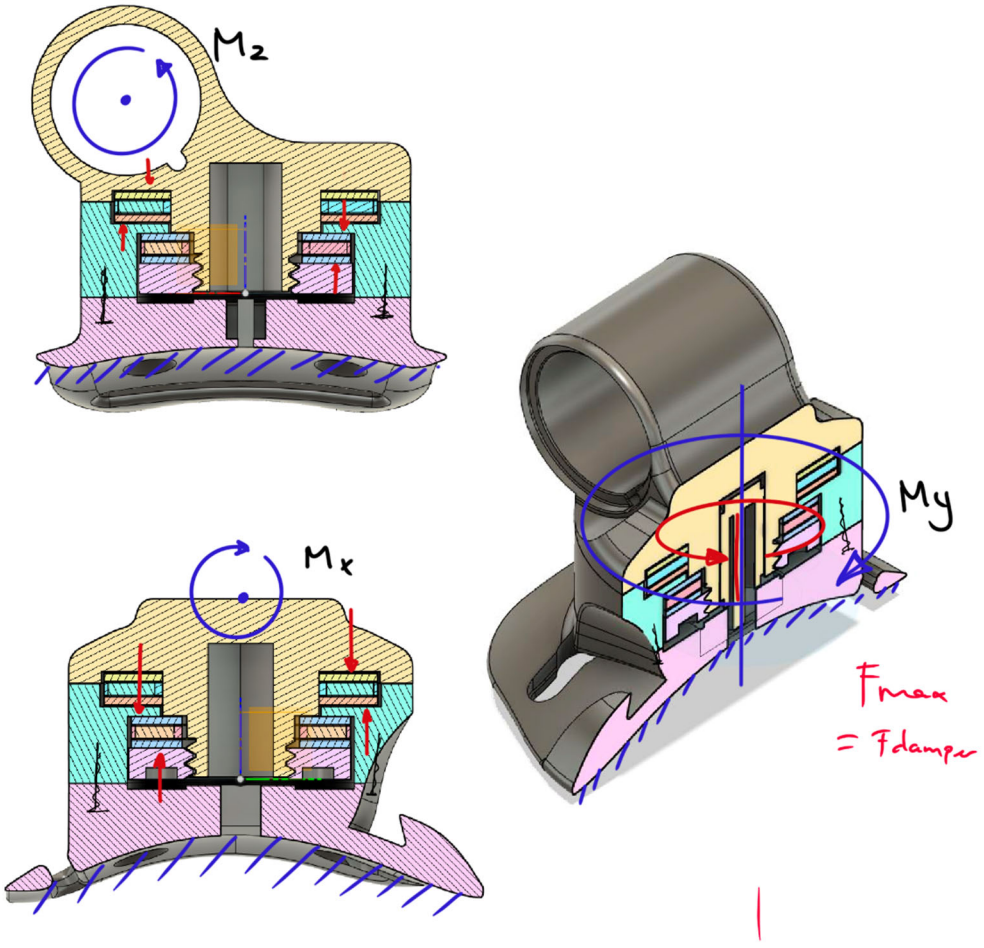
The ranking of personal favorites is used to determine of people perceive the new prototypes as more comfortable of easy to use.

APPENDIX 7: ANALYSIS OF FORCES ON DAMPER

Mz= moment caused by damping of WFE motion. Results in a pinching force on the bearings by the upper and mid body. Bearings take the load of the central axis, making sure that the damper does not experience resulting forces from Mz.

Mx= moment caused by damping of the FPS motion. Similar to Mz, the bearings take the load of the damper.

My = moment caused by damping of WRUD motion. Bearings reduce friction between upper body, mid body and central nut so that all damping friction is caused by the friction damper. Upper body form fits around the housing of the damper, the lower body form fits around the shaft of the damper.



APPENDIX 8: MOODBOARD "MODERN AND SLEEK"