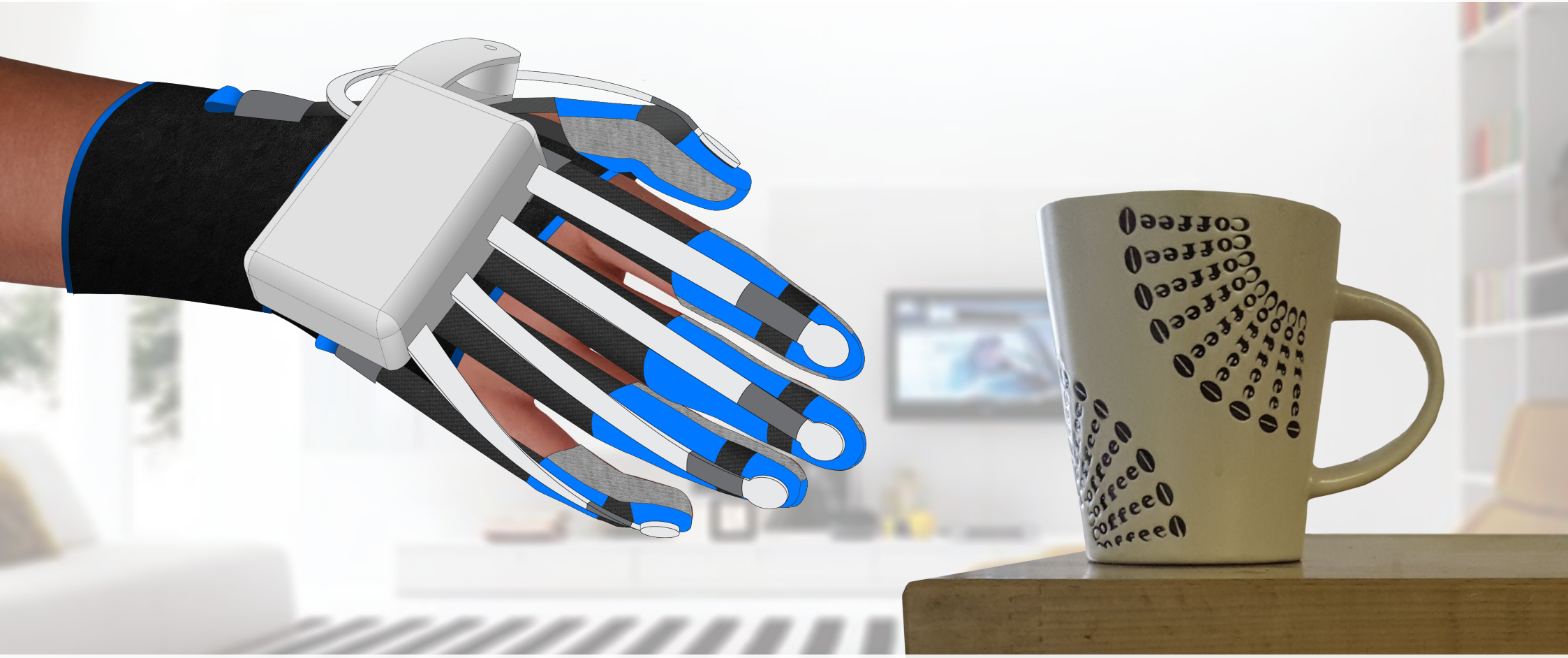
A smart brace to support spasticity management in post-stroke rehabilitation



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Adjuvo Motion

A smart brace to support spasticity management in post-stroke rehabilitation

By

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Special thanks goes out to Eelco Sengers, for being kind (and patient) enough to answer my questions and for allowing me to attend one of his physiotherapy sessions. I would also like to extend my gratitude to my fellow interns and graduates; Loes Schilderink, Dionne Peeters, Guus van Mastrigt and Jose Urra: Each of you have contributed to this project in your own ways, be it through lengthy discussions, the sharing of ideas or simply by humbling me in a game of ping-pong.

Glossary of Terms

Abbreviations

ARAT – Action-Reaction Arm Test
ADL – Activities of Daily Living
CVA – Cerebral-Vascular Accident
DoF – Degrees of Freedom
FMA – Fugl-Meyer Assessment
IMU – Inertial Measurement Unit
MAS – Modified Ashworth Scale
MTS – Modified Tardieu Scale
NSA – National Stroke Association
OT – Occupational Therapist
PT – Physiotherapist
RoM – Range Of Motion
RT – Recreational Therapist
SLP – Speech-Language Pathologist
USP – Unique Selling Point

Jargon

Active (Assist) Device
A device which moves the user's limbs for them through actuators.

Active (RoM) Exercise
Exercise where the patient moves their limb(s) by themselves.

Hemiparesis
One-sided weakness.

Hemiplegia
One-sided paralysis.

Hyper-extension
Extending a joint beyond the natural workspace.

Inpatient Care
Medical care or -treatment of patients whose condition require admission to a hospital or clinic.

M-Brace
A robotic brace that is being developed by Adjuvo Motion.

Outpatient Care
Medical care or -treatment that does not require overnight stay in a hospital of clinic.

Passive (Assist) Device
A device that cannot move the user's limbs, but offers resistance or compensation to a movement.

Passive (RoM) Exercise
Exercise where another person or device moves the patient's limb(s) for them.

Executive Summary

This report covers the design of a product to help stroke survivors who are suffering from chronic spasticity manage their everyday activities.

In the Netherlands alone, 44.000 people suffer from a Cerebro-Vascular Accident (CVA) each year. A CVA, more commonly known as a stroke, results in brain trauma with afflictions such as paralysis, fatigue and spasticity. It is possible to recover some, if not all, motor function though intensive physiotherapy, which requires long-term stay at a rehabilitation clinic in severe cases. Due to limited room and staff, only 12% of stroke survivors end up rehabilitating in a clinic. The remaining survivors are sent home, and will to travel to the clinic 3-5 times per week for therapy as part of the outpatient rehabilitation.

Adjuvo Motion, a young start-up, aims to improve the situation of stroke survivors by bringing the rehabilitation center to their home through the Adjuvo Platform, which allows them to perform exercises in the context of virtual tasks. They proposed an assignment to extend their product portfolio with a Range of Motion assessment device that is suited for those suffering from spasticity.

Spasticity occurs in roughly 60% of stroke survivors with varying degrees of intensity. It is caused by the damaged parts of the brain sending conflicting signals to the muscles, causing them to contract. This inhibits the survivor's ability to perform daily tasks, but can be solved temporarily with stretching exercises. A solution to compensate for these spastic forces using a passive-assist device was proposed at the start of this project.
The project was divided into four stages: Analysis, Synthesis, Embodiment and Evaluation.

During the Analysis stage, interviews with a Physiotherapist and stroke survivor and literature studies regarding anatomy, the state of the art and relevant technologies were used to create a framework for the design of a smart passive-assist glove. Looking at competing products, there is a demand for passive assist and Range of Motion assessment functionalities, yet a combination of these in a single device is not yet present in the market.

During the Synthesis stage, the design problem of the passive assist device was split into three groups: *Orthoses*; the connections to the body, *Passive Assist*; the compensation medium, and RoM measurement; the sensing mechanism(s). These three groups were further split into sub-problems, the solutions to which were compiled into a Morphological Chart. By combining the solution within this chart, three promising concept designs were created: One upgrade to the existing sensor glove, one full integration of sensing and passive assist, and one passive assist glove with removable sensors.

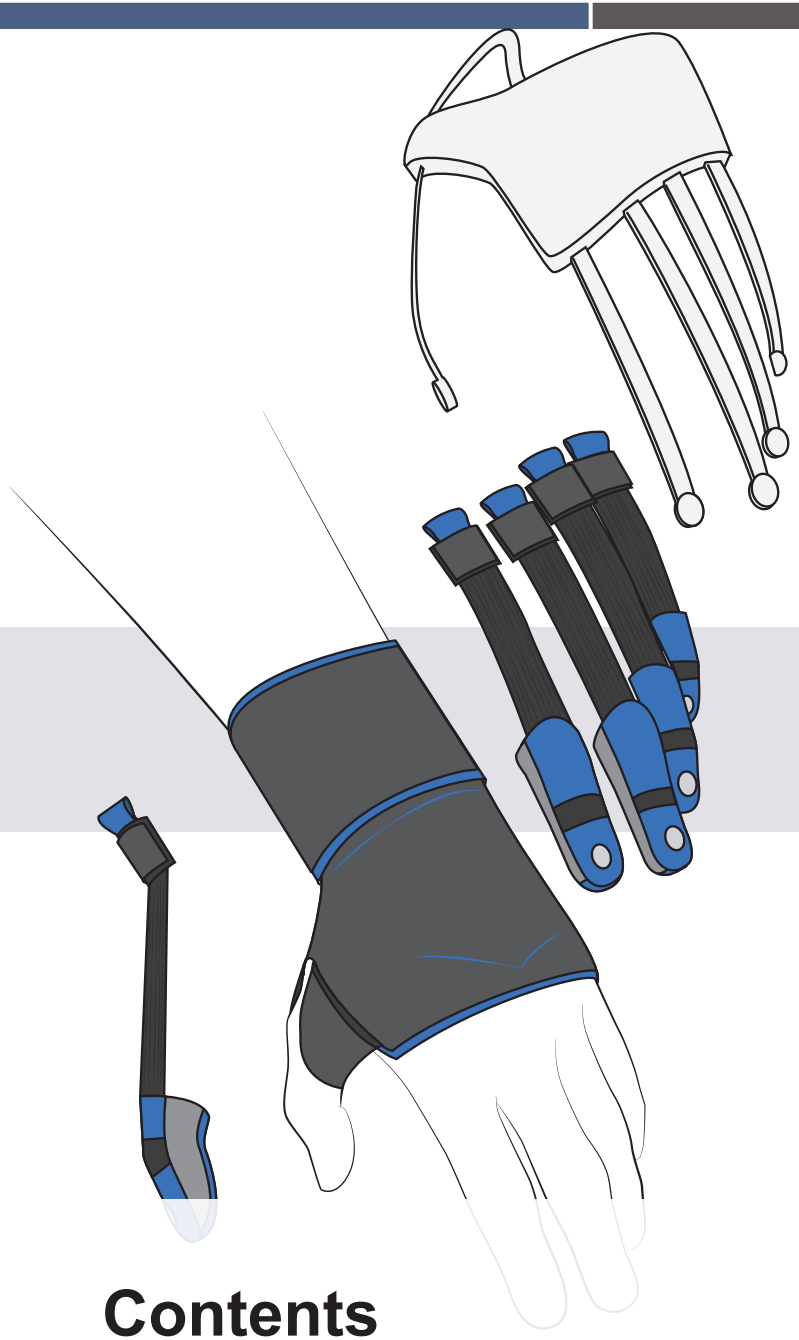
To evaluate these concepts, eight criteria were established and weighted with the help of a physiotherapist. In order to create an objective assessment, the criteria were kept strictly quantitative and the three designs were first scored against the *Raphael Smart Glove* by *Neofect* using early prototypes. These scores were then used to evaluate the designs relative to each other, which resulted in an overall higher score for the concept with separable electronics. Making the sensor part of the brace removable allowed the product to be used during daily life as well as physiotherapy exercises, and proved a key benefit in keeping the product clean.

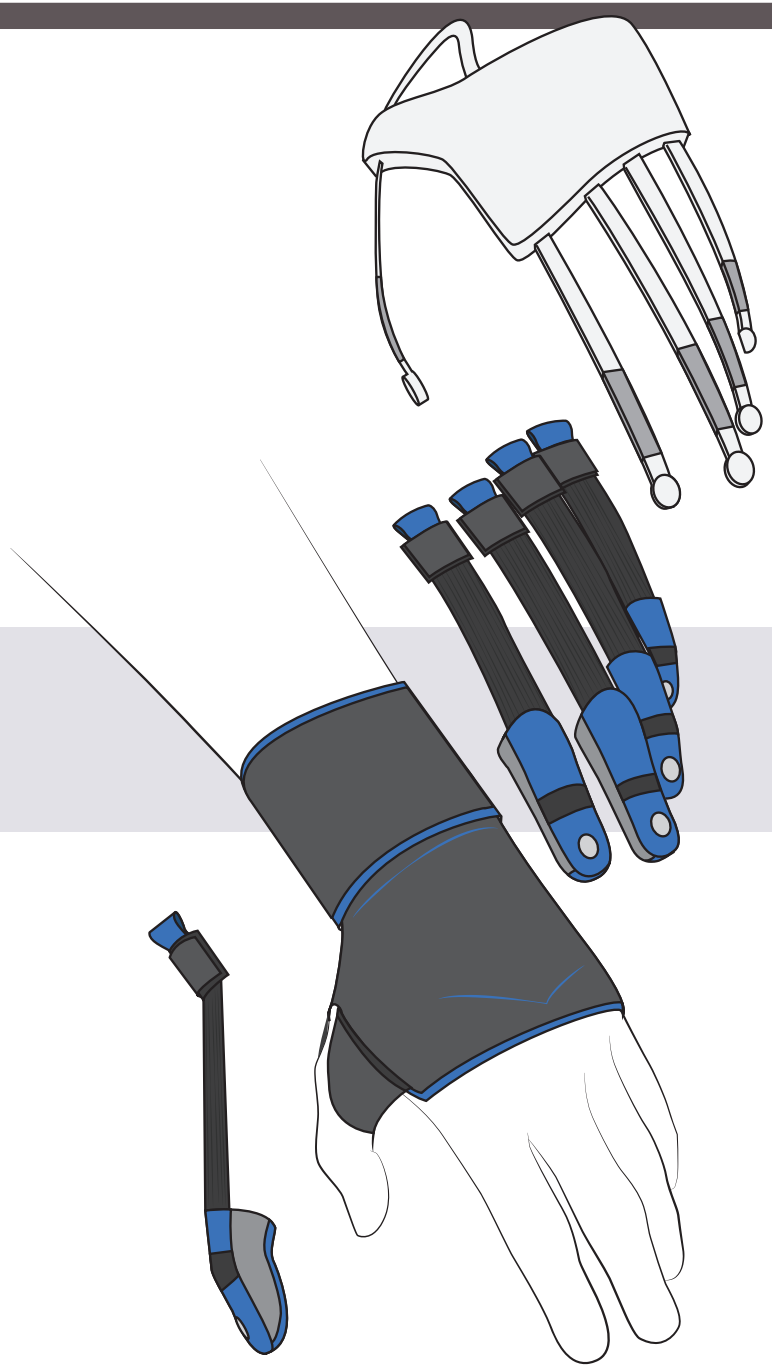
Based on the chosen design, four iterations of prototypes were made, which were tested with healthy subject. During this stage, it became clear that flex sensors are be best suited to create a range of motion assessment for spastic stroke patients, since it is less important to know how well they perform a task, and more important to know if they can actually perform it.

Based on a quantified use case, the four sub-assemblies; the *Wrist Wrap*, *Finger Modules* and *Sensor Module*, and their connections were materialized in the Embodiment design stage. When selecting production methods, the main challenge was a small batch size of 1000 units, which made conventional techniques for mass production, such as Injection Molding, less attractive. This stage ended in an assessment of the product's production price and durability: The product would cost €250 to make, and would last for 2.5 years before the Velcro connection on the Wrist Wrap would become too weak to sustain the spasticity forces.

In the Evaluation stage, the product was evaluated on the seven most important requirements established during the analysis stage. For several of these, a user test was performed, again with healthy subject. While the Adjuvo Auxilius passed most theoretical requirements, the user tests on healthy subjects could not be used to draw any conclusions regarding its effectiveness on spastic stroke patients. However, since the product's working principle is based on that of existing spasticity compensation products, the prediction is that the Auxilius will be an effective therapy supplement.

The result of this project is the Adjuvo Auxilius; a spasticity-compensation glove with modular sensors, which can be added to allow virtual (stretching) exercises through the Adjuvo Motion's platform. The results of these exercises are used to create a remote assessment of the patients motor skills, and to adjust the therapy if needed.





Contents

1. Introduction *1*
1.1 Company 3
1.2 Assignment 6
1.3 Approach 8

2. Analysis *10*
2.2 Context 12
2.3 The Human Factor 25
2.4 State of the Art 30
2.5 Conclusion 35

3. Synthesis *39*
3.1 Approach 40
3.2 Morphological Charts 41
3.3 Concepts 44
3.6 Evaluation 50

4. Prototyping *52*

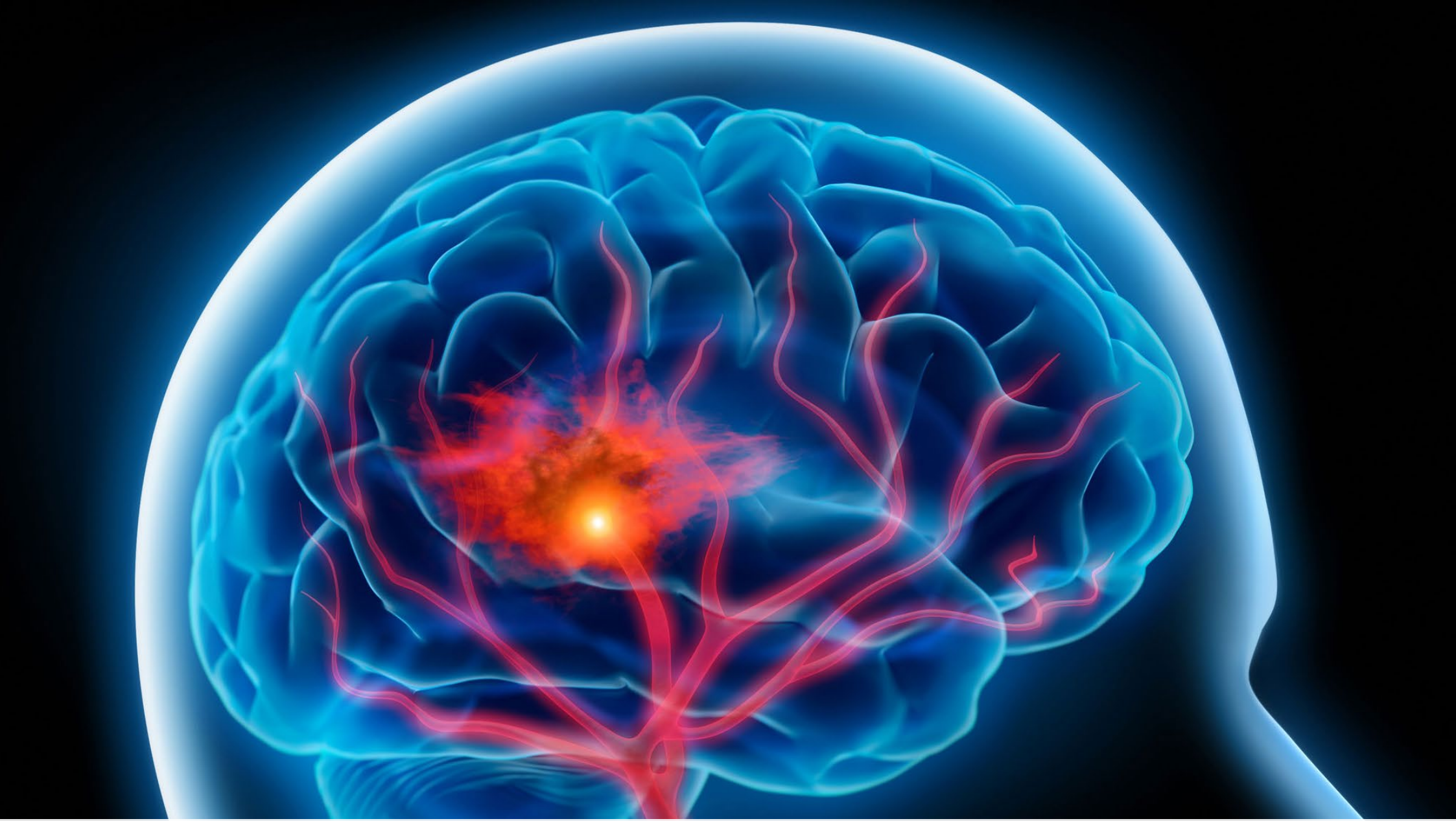
5. Adjuvo Auxilius *57*
5.1 Connections 59
5.2 Components 61
5.3 Auxilius Design 64

6. Embodiment Design *65*
6.1 Approach 66
6.2 Scenario 67
6.3 Material Selection 68
6.4 Production methods 72
6.5 Durability 74
6.6 Aesthetics 76
6.7 Costs & Pricing 77
6.8 Algorithms 79
6.9 Conclusion 80

7. Evaluation *80*
7.1 User Testing 81
7.2 Requirement testing 82
7.3 Design Improvements 84

8. Conclusion *87*
8.1 Process 88
8.2 Product 88

9. References *88*



1. Introduction

The global burden of stroke

Each year, 44 000 Dutch citizens suffer from stroke (Volksgezondheidenzorg.info, 2013), most of whom are left with impairments on one side of the body. These patients require intensive physiotherapy to regain the functionality of their affected arm and leg. With the aging of society, the amount of stroke survivors is expected to increase in the next few years, forming a greater burden on the healthcare system (WHO, 2011).

A stroke is a "brain attack", commonly referred to as a Cerebral-Vascular Accident (CVA). It can happen to anyone at any time, and occurs when blood flow to an area of brain is cut off. When this happens, brain cells are deprived of oxygen and begin to die (National Stroke Association, 2014a). A stroke can have different causes, as seen in figure 1.1, which affect the patient's post-stroke afflictions and their chances of survival.

Depending on the type of stroke, its severity and its location in the brain, survivors must deal with varying degrees of physical, cognitive and emotional impairments. The National Stroke Association (2014c) lists the following effects:

Physical Effects

- Weakness or Paralysis of limb(s)
- Stiffness of the limb(s) (Spasticity)
- Fatigue
- Difficulty Swallowing (Dysphagia)
- Foot drop
- Pain
- Seizures
- Vision impairment

Emotional Effects

- Depression
- Outbursts of crying / laughing.

Cognition Effects

- Aphasia
- Memory Loss
- Vascular Dementia

Not every stroke survivor will suffer from these effects, nor will they suffer them in the same degree as other survivors. In short; every stroke is unique.

Of all post-stroke side effects, patients have reported that paralysis, spasticity and fatigue are the most impactful in their daily lives (National Stroke Association, 2015). Fatigue may fade over time, but spasticity is a chronic problem that may lessen over time, but will always be present. Paralysis can recover over time through intensive physiotherapy.

According to Timmermans et al (2009), some of the brain cells that were damaged during a stroke can (spontaneously) recover in the acute stage. During later stages, Brain Plasticity causes function to return to the affected side of the body by re-assigning the lost motor skills to a different, adjacent part of the brain.

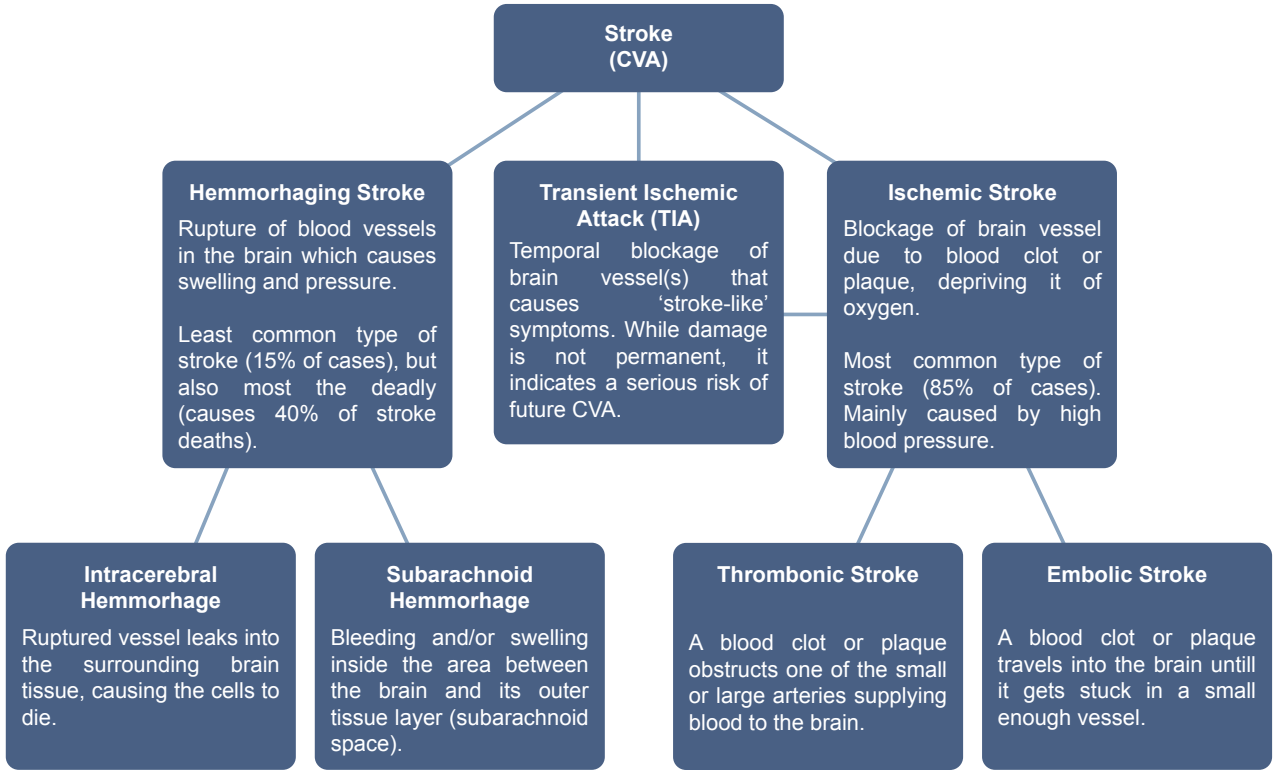


Figure 1.1 - Types of Cerebral-Vascular Accidents (CVA)

After a CVA, patients spend their first days in the ‘stroke unit’ of a hospital, where their condition is stabilized and the first steps of rehabilitation begin, often as early as 24 to 48 hours after the accident. The first steps involve promoting independent movement because many individuals are paralyzed or seriously weakened (National Institute of Health, 2014).

Based on their recovery in the first weeks, patients are given a prognosis using evidence-based techniques, which determines their rehabilitation program. The prognosis gives an indication of whether or not the patient can make a full, notable or limited recovery of motor function, or if they will not recover at all (Verbeek et al, 2014). Patients with a ‘negative’ prognosis will have to work harder in order to regain their motor skills or otherwise learn to compensate for the loss of function. They require overnight stay in a rehabilitation clinic due to their dependency on caregivers. This type of treatment is referred to as ‘inpatient care’.

As seen in Figure 1.2, only 12% of stroke survivors are treated in the clinical environment. The remaining 88% of patients, especially those with a ‘positive’ prognosis, are sent back home, and will return to the clinic 3 to 5 days a week for treatment . In some cases, patients complete both an inpatient and outpatient care program before their treatment is over.

‘Inpatients’ have around the clock access to trained staff and have fixed day programs, while ‘outpatients’ access to these facilities is limited to their visits to the rehabilitation clinic. This sometimes leads to patients with a negative prognosis in inpatient care recovering more of their motor function that a patient with a positive prognosis in outpatient care. This difference is caused by the lack of available caregivers combined with the limited room capacity of rehabilitation clinics.

In the current situation, stroke patients in outpatient care are not receiving enough treatment (Ribbers, 2013): They need to travel to and from rehabilitation clinics for 15-30 minutes of physiotherapy per day, while 1,5 hour is considered optimal (EBRSR, 2013). The company *Adjuvo Motion* wants to change this situation.

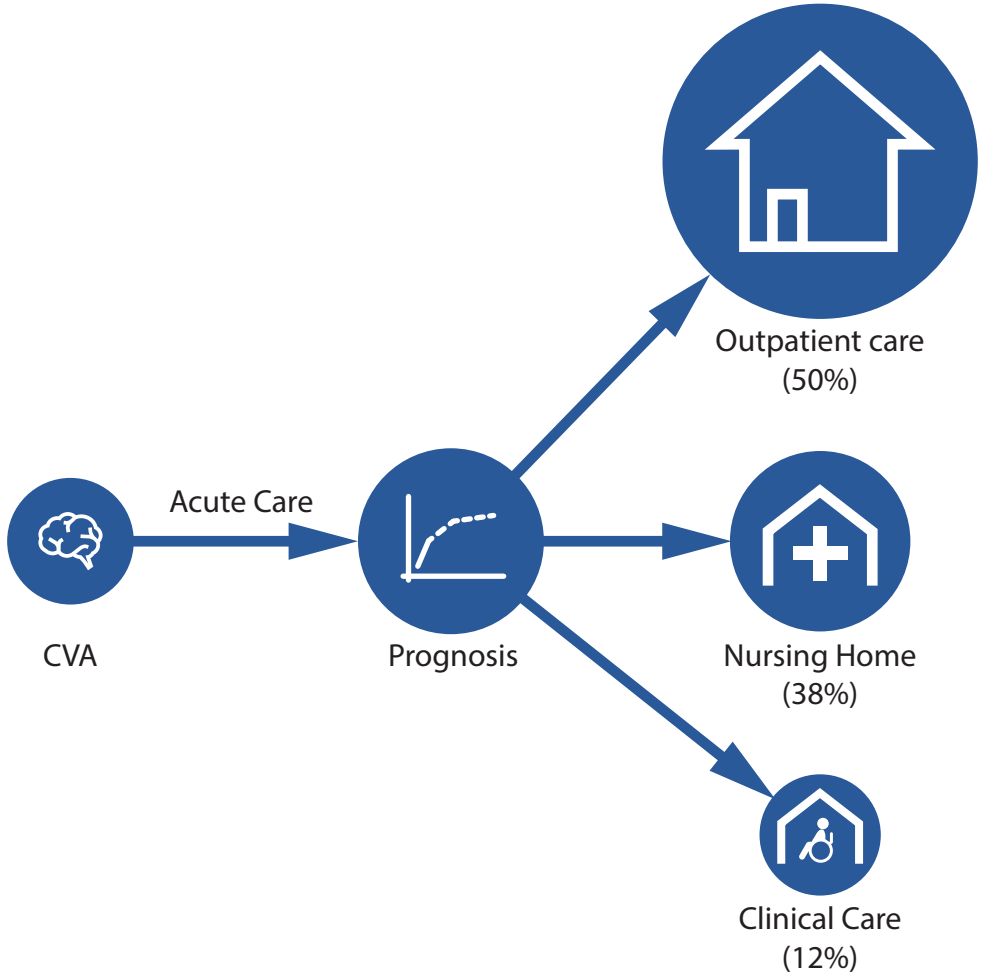


Figure 1.2 - In- and Outpatient care distribution after the Acute stage.

1.1 Company

Adjuvo Motion is a young spin-off from the TU Delft, founded by Johannes Luijten and Gijs den Butter in 2015. The company is developing the M-Brace seen in figure 1.3: A robotic brace for stroke patients to improve their upper limb rehabilitation in the home environment in combination with an e-health service. Timmermans et al, 2009 report that up to 85% of stroke survivors suffer from impairments of their upper limbs. This means that Adjuvo Motion can help a significant part of stroke survivors.

Rehabilitation robots have proven to be effective in post-stroke upper-limb physiotherapy (Klamroth-Marganska et al, 2013), and are currently seeing use in progressive clinics. However, the current products, such as the *ARMEO Power* created by *Hocoma*, are large and expensive, and therefore limited to the clinical environment.

In contrast, Adjuvo Motion is designing a compact robotic system that does not require a specialist to operate, which would allow stroke patients to rehabilitate at home with the aid of their family or caregiver(s). To supplement their rehabilitation, patients will perform exercises in a virtual environment, the results of which can be seen by their physiotherapist using an e-health service called the *Adjuvo Platform*. This platform will be used to evaluate the patient's progress remotely.

However, the development of the M-Brace is expected to take another 3-5 years due to the complexity of the project and the standards and certifications it must adhere to. Therefore, Adjuvo Motion has decided to first enter the market with a "sensor version" of the M-Brace which measures a patients upper limb Range of Motion (RoM). The sensor-only solution has significant overlap with the robotic brace in terms of development process and features; both solutions will send RoM data to the Adjuvo Platform, will be designed for the home context and will share similar components. The sensor version allows the company to test the value proposition of the M-Brace with physiotherapists and patients in a safe way, while reducing financial risk, development costs and certification levels.

This new product will focus on measuring the RoM of the lower arm, specifically that of the joints in the wrist, finger and thumb, which are most important in exercises for fine motor skills. Measuring these joints will provide a great range of potential 'positions' or 'gestures' to be used in virtual exercises in the Adjuvo Platform.

Adjuvo Motion has also expressed interest in allowing patients with spasticity to use the sensor brace. Spasticity is a common effect of stroke that inhibits patients from moving their joints due to stiff muscles which prevents them from fully benefiting from the exercises of the platform. Therefore, the brace must also be made suitable for spastic stroke patients.

Opportunities

- Develop a sensor glove to test the value proposition of the robotic brace with reduced risk.

Requirements

- Product is used for post-stroke rehabilitation.
- Focus on stroke survivors rehabilitating in outpatient care.
- Product makes use of the Adjuvo Platform.
- Product measures RoM of the lower arm.
- The product can be used by stroke patients suffering from spasticity.

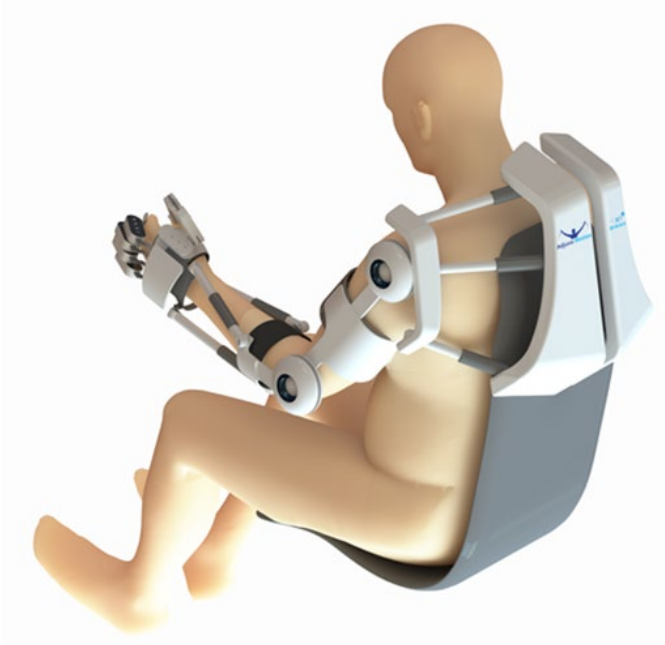


Figure 1.3 - Visualization of the M-Brace

1.2 Assignment

In stroke rehabilitation, “grasping” and “reaching” of the hand are some of the most important functionalities regain: Being able to perform these tasks means that the patient is not completely dependent on caregivers in their everyday life. A stroke patient suffering from spasticity, however, will have difficulty performing these motions and will be unable to complete Activities of Daily Living (ADL) by themselves.

Spasticity is an involuntary tightening of the muscles which is caused by the damaged parts of the brain sending conflicting signals to the muscles (Thibaut et al, 2013). These signals can activate the extensor and/or flexor muscles of the joints in the affected side, with different levels of severity. Figure 1.4 shows the manifestation of spasticity in the elbow, wrist and fingers. Because the problem of spasticity originates in the brain, it cannot be cured, only reduced, without surgery.

When locked in one position for too long, spasticity can cause shortening of the affected muscles (Bhakta, 2000). It is therefore important to frequently stretch these muscles through exercise or by fixing them using orthoses. Stretching exercises can decrease spasticity and increase a patient’s Range of Motion, but the effect only lasts a few hours. Oral medication is sometimes use to reduce spasticity, but this method cannot specifically target the stiff muscles. On the other hand, Botox injections can reduce the muscle tone in specific areas, but take time to start working and must be reapplied periodically. A last resort to treat spasticity is to surgically re-route the stronger muscles, thus balancing out the forces or, in the most severe cases; to cut the nerves which enervate the affected muscles, preventing the defective signals from the brain from reaching them entirely (Thibaut et al, 2009).

Over 40% of stroke patients suffer from some form of spasticity, ranging from just a little to severe spasticity (Sommerfield et al, 2012). Spasticity can develop in the first weeks after stroke, and is said to reach its maximum between 1-3 months after the event (Fellows et al, 1993). Conversations with therapists have revealed that the severity of spasticity can change slightly depending on the patient’s mental state: If the patient is in a calm state of mind, their spasticity can lessen. Therefore, a product that compensates for this should be adaptable for the patient’s current level of spasticity.

Severe spasticity occurs in 20-30% of patients (Sommerfield et al, 2012; Welmer et al, 2006; Watkins et al, 2002). These patients generally do not recover much of their motor function due to the high forces acting on their joints and the pain that comes with moving them. Furthermore, the treatment costs for people with severe spasticity are estimated to be four-fold higher compared to those without (Lundström et al, 2010).

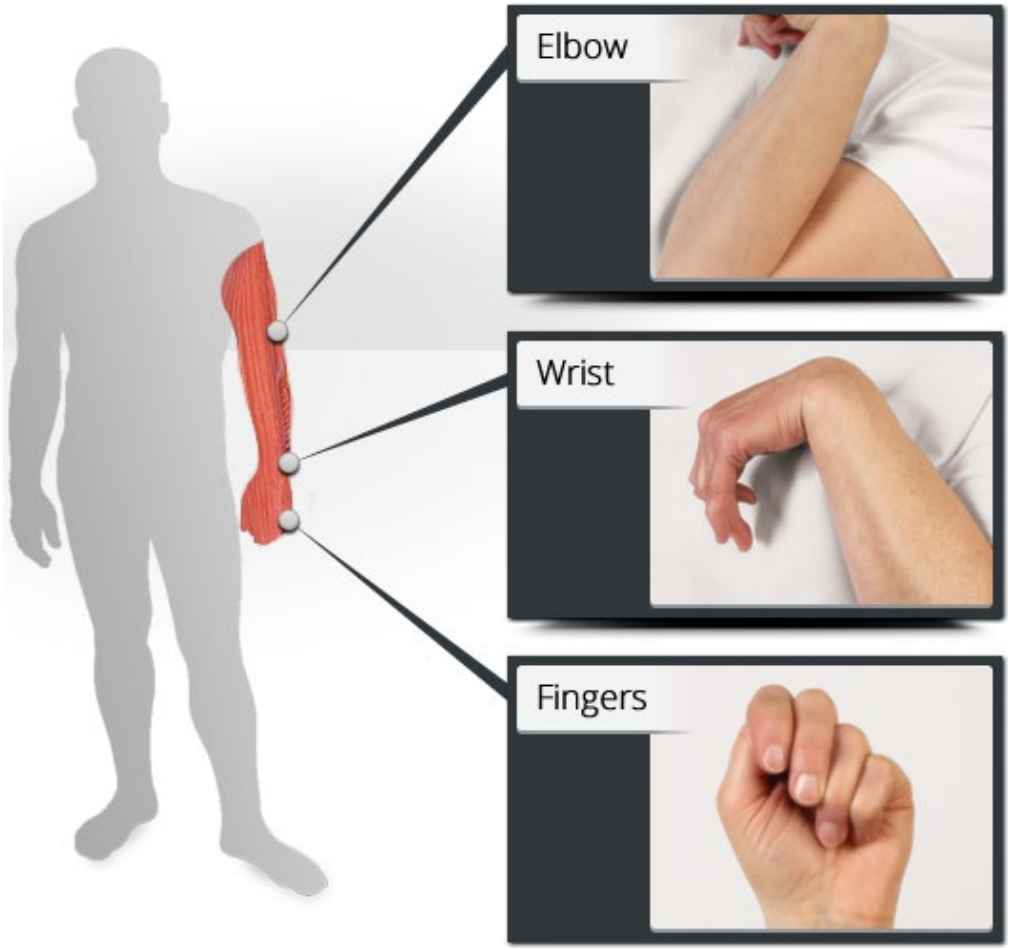


Figure 1.4 - Spasticity in the upper limb (Texas Neurology, n.d.).

1.2.1 Problem Definition

The problem of spasticity within the context of stroke rehabilitation and within the context of Adjuvo Motion can be formulated in the following problem definition, as per the guidelines of Roozenburgh and Eeckels (1998):

What is the problem?
Stroke patients in outpatient care do not receive enough treatment compared to patients in the clinical environment. Furthermore, 60% of all stroke survivors suffer from some form of spasticity, which limits them in their Activities of Daily Living.

Who has the problem?
This problem affects stroke patients suffering from spasticity, who have recovered some of the motor function in their arm and who are rehabilitating in outpatient care. The problem of spasticity is also present in other afflictions, such as Multiple Sclerosis or Spinal Cord Injury.

What are the goals?
Because Adjuvo Motion develops supportive products, not medication or surgical tools, the solution in this thesis is limited to a physical product. The goal is not to cure spasticity; which is impossible without invasive surgery. Instead, this thesis will focus on the design of a product that increases the Range of Motion (RoM) of spastic users through stretching exercises which will allow them to perform their ADL with greater ease and less pain, thus increasing their independence. The exercises will serve as a supplement to the physiotherapy that the patient normally receives, increasing the amount of treatment in the first months after stroke. Lastly, the product should give the patient and their therapist feedback into the progress of motor recovery, through the Adjuvo Platform.

Which options are open?
The first option that is open is to choose between an active device which moves the user's joints for them, and a passive device which cannot move joints, but rather offers resistance to the spastic muscle movement. Current products for lower arm spasticity use static or dynamic splints to keep the hand in a new 'open position'. One option is to improve on these mechanics by making them easier to put on and by integrating sensors to measure the user's RoM.

What is to be avoided?
The product should not make use of high forces to move joints, especially with patients suffering from severe spasticity: This will cause more pain and could potentially increase the spasticity reaction. If the product takes a long time to put on (>5 minutes), both patients and physiotherapists will be less inclined to use it (Dijkerset al, 1991): It will increase the threshold to use the product. Furthermore, the mechanism used to fulfill the desired goals should not hurt the stroke patient during use due to shearing mechanisms or unexpected movement. Lastly, the result of this project will be a product, not medication or a surgical procedure.

Requirements

- Must increase the Active Range of Motion (RoM) of the joints in the lower arm of spastic stroke patients.
- Provide feedback on the motor recovery of the stroke patient through the Adjuvo Platform.
- The product must not use 'high forces' to compensate for spasticity. 'High forces' must be defined.
- The product can be put on within 5 minutes.
- The level of spasticity compensation is adjustable.

Opportunities

- The Brace is also suited for patients with other afflictions that are paired with spasticity.

1.2.2 Assignment

RoM Measurement

The main reason of the sensor functionality is to interface with the Adjuvo Platform and to provide feedback on the motor performance over time through an objective assessment of the user's Range of Motion. The e-health service allows patient and professional to perform exercises and review results respectively. The RoM measurement can also be used to make the result of the stretching exercises tangible for stroke survivors, and motivate them to continue doing them.

Type of device

With a high number of stroke patients suffering from some form of spasticity (>50%), the decision to make the sensor version of the M-Brace compensate for this affliction allows Adjuvo Motion to reach a greater market share. Due to number of existing 'sensor glove' products, the addition of spasticity compensation will give Adjuvo Motion a Unique Selling Point (USP) over its competitors. The next step is deciding how to achieve the spasticity compensation:

In upper limb rehabilitation devices, a distinction is made between "active assist" devices and "passive assist" devices. Figure 1.5 shows the definitions of these types, together with their strengths and weaknesses. Adjuvo Motion's first product, the M-Brace, is an active device. For spasticity compensation, both types of assist would work.

Maciejasz et al, (2014) mention that there is a need for devices that assist in therapy and ADL. However, not many of these products have made it to the market yet due to "*technical & economic restrictions*" that seem to come mostly from the active devices such as battery life, safety and portability. A passive assist mechanism would not consume any electrical power, thus removing the problem of using (heavy) batteries that active devices require. Furthermore, it removes the need for complex control algorithms which makes the product better suited for long-term use in both therapy and ADL in the home environment. Due to the lack actuated components, a passive assist device also creates less risk for the patient. Furthermore, according to a small study by Park et al (2016), spastic muscles behave much the same as springs, with a linear in resistance during elongation.

It is because of these strengths that the decision was made to design a passive assist device, which is in line with Adjuvo Motion's earlier explorations. However, this decision means that the product will not be suited for patients that cannot move their limbs. Figure 1.6 shows how a passive assist device can place the spastic hand into a functional 'open' position by canceling out the forces of the spastic muscles. From this new position, it takes less effort to move the fingers in different grasping motion(s), much like how a desk lamp balanced by springs takes very little effort to move.

Conclusion

The assignment is to design a passive-assist hand brace for post-stroke rehabilitation suited for home-based therapy of spastic patients, which measures the joint Range of Motion and makes use of the Adjuvo Platform .

The result of this thesis is a design for a product, with a prototype to test its main functionalities.

Opportunities

- Make the results (benefits) of stretching exercises tangible for spastic patients to motivate them to keep exercising.

Requirements

- The product must not actively add kinetic energy to the body: It is a passive assist device.
- The product is not suited for patients suffering from flaccid paralysis.

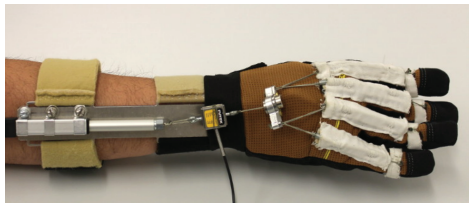
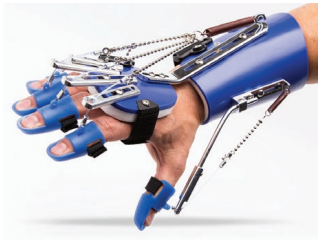
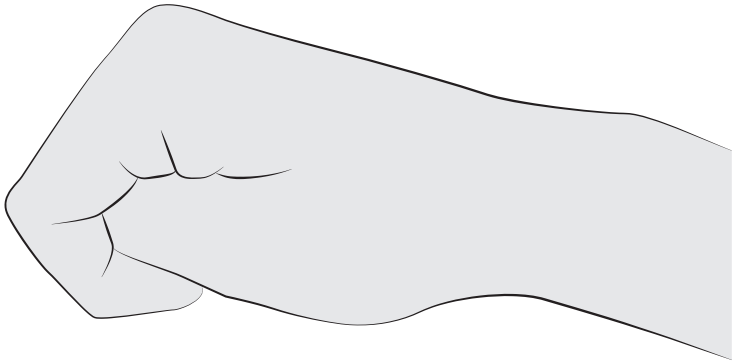
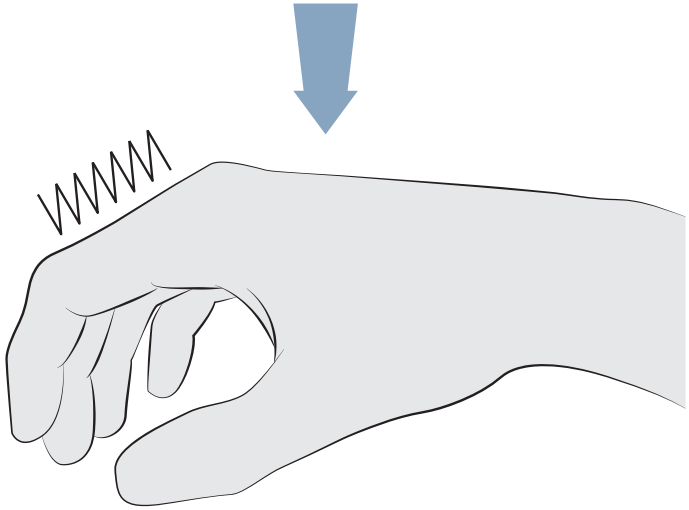
Active Assist Device	Passive Assist Device
	
A device that is able to move limbs through active actuators.	A device that cannot move limbs, but may resist movement when it is exerted in the 'wrong' direction.
+ Suited for both passive and active exercise support. + Different training algorithms and forms of assist are possible.	+ Fewer costs involved. + No control, this is all done by patient. + Lower risk for patient. + No batteries required.
- Requires batteries or access to (mains) power supply. - Greater risk for patient due to actively adding kinetic energy to the body. - Generally more expensive than passive assist. - Requires control loop / mechanism as part of safety. - Heavier due to actuators and batteries.	- Not suited for those without any function in the arm (flaccid paralysis). - Only suited for active exercise.

Figure 1.5 - Active vs. Passive assist devices.



Spasticity in the finger extensors and thumb abductor puts the hand into a fist, inhibiting its funtion. The extensor muscles are not strong enough to (fully) open the hand.



A spring-like material adds the extra extensor force needed to place the hand into a fuctional 'open' position, without using actuators. From this position, it is easier to manipulate objects and to perform stretching exercises.

Figure 1.6 - Changing a spastic fist into a functional 'open' position.

1.3 Approach

Adjuvo Motion already has a working, actuated prototype of the M-Brace hand module that can be used as a starting point for the design of a sensor glove. The company also has a sensor-only version of is robotic glove available, as seen in figure 1.7. The company also has an agreement with the Sophia center of rehabilitation in the Hague that allows them to involve staff and/or (ex-)patients in the development of its products.

The main challenges of this thesis is to identify and integrate the requirements from patients and staff, and the technological development of the assist- and sensor mechanism. To tackle these challenges, the project is divided into four stages: Analysis, Synthesis, Embodiment and Evaluation.

In the Analysis stage, literature studies into the context of stroke rehabilitation and spasticity will be performed to identify a desired functionality of the product. Expert interviews with a physiotherapist and an (ex-)stroke patient will be used to supplement this desired functionality and compile them into use scenario. Using further literature studies into the human anatomy and state of the art products and technologies, the desired functionalities are quantified so that they can be used to test concepts, prototypes and the embodied design.

During the Synthesis stage, solutions are generated for the three main design problems of the product: The passive assist mechanism, the Orthoses or connections to the body, and the sensor mechanism. To generate these solutions, each design problem will split into multiple sub-problems, for which individual ideas can be found. These ideas will be compiled into a Morphological Chart, from which a number of concept designs can be created. The most promising designs will be evaluated using early prototypes and compared by using the requirements found in the previous stage in a Weighted Criteria Method. The weights in this method will be determined with the help of a physiotherapist. This will lead to the solution that is best suited for the context. The chosen design will then be subjected to a number of design iterations that are prototyped and tested with healthy subjects on critical points, in order to identify the small details that will make of break the design. The results of this stage is a design for a smart, passive-assist glove that is embodied in the next stage.

With all components of the product know, the custom designed parts will be materialized in the Embodiment stage. Using data from the *Cambridge Engineering Selector*, materials will be chosen based on a quantified use case. Production methods were chosen based on the materials selected, and on a batch size estimation based on the analysis stage. Finally, a cost price estimation is made of each individual component and the total product. As pat of the embodiment design, the theory on how to transform sensor input into useful data is presented.

Lastly, the product is evaluated on the most important requirements established in the Analysis stage, several of which can be tested using theory only. For those requirements that must be judged in practice, a user test and prototype are designed to evaluate these requirements. Based on the results, of this test, a number of improvements are made on the design.

Finally, a conclusion can be drawn on how well the product functions within the context of spasticity and stroke rehabilitation, and which steps should be taken next to bring it to the market.

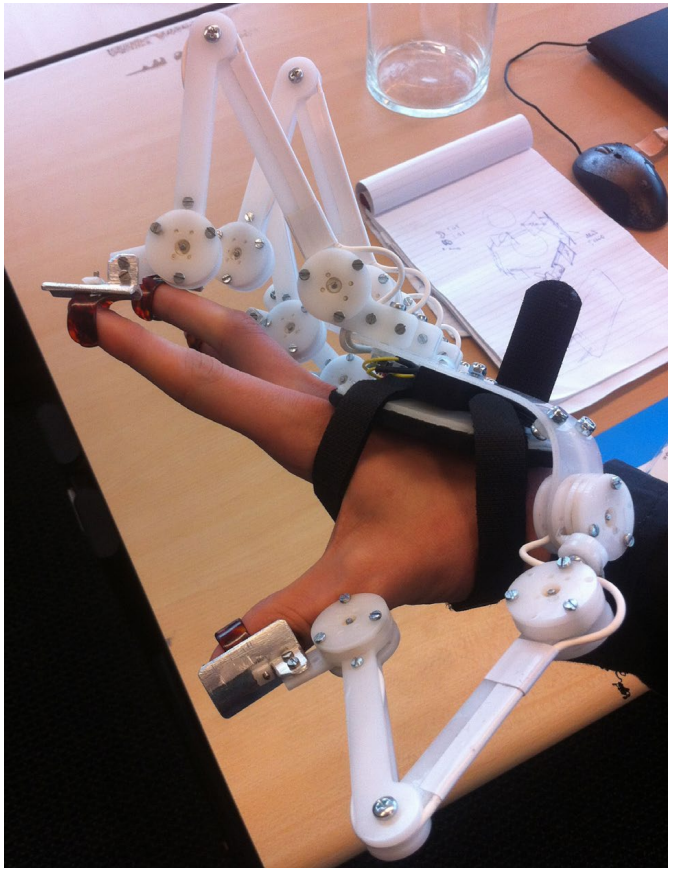


Figure 1.7 - The sensor-only prototype of the robotic glove

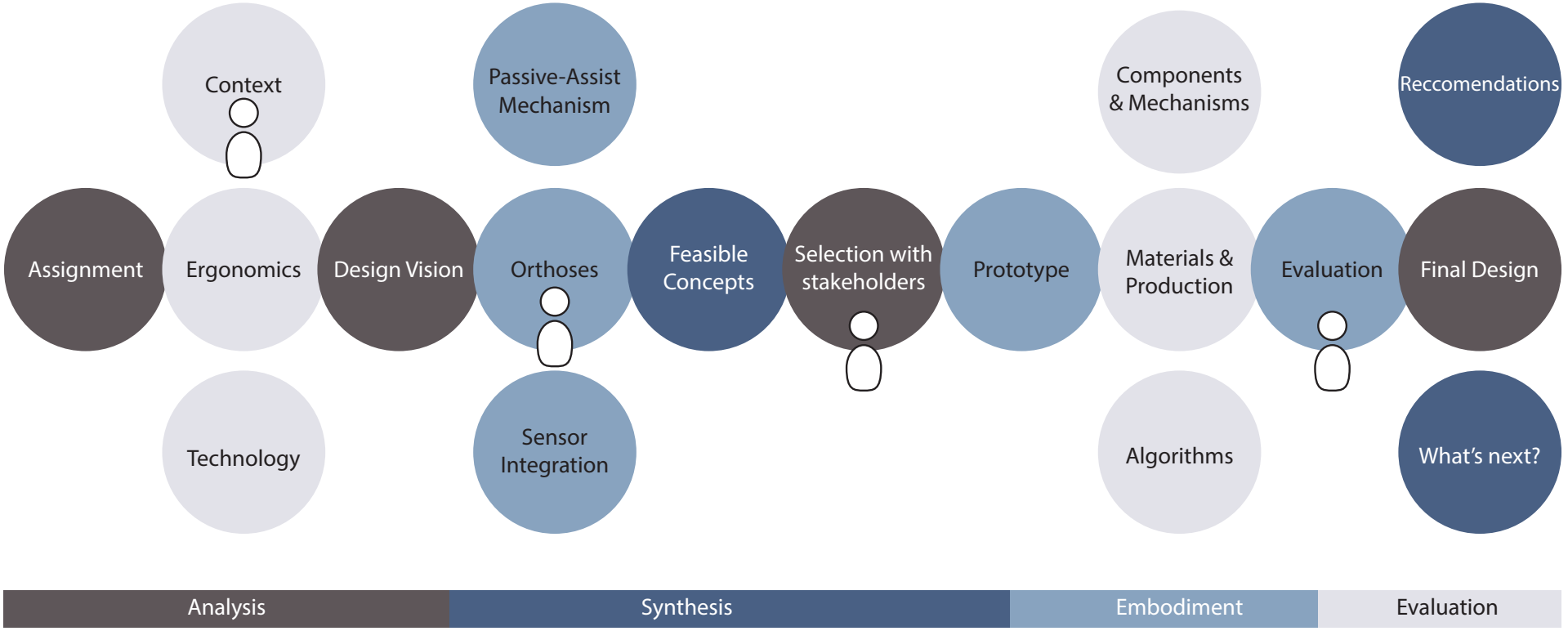


Figure 1.8 - Overview of the approach used in this thesis..

2. Analysis

The goal of the analysis stage is to find and quantify the underlying requirements that are implied by the assignment (Roozenburg & Eeckels, 1998). These requirements, combined with a reformulated problem definition, will provide a framework for the design of the passive-assist brace.

In this thesis, the Analysis stage is divided into three main fields: Context; where the needs of the stakeholders and ideal functionalities of the product are identified, Human Factors; where these requirements are quantified, and State of the Art; where the existing solutions are evaluated according the findings in the first two fields. These three fields are then combined into a reformulated design problem, vision and a list of requirements. In figure 2.1, an overview of how these different fields are interconnected is shown.

Refer to Appendix A for further elaboration on the tasks performed during the analysis stage, and how they influences the rest design of the product.

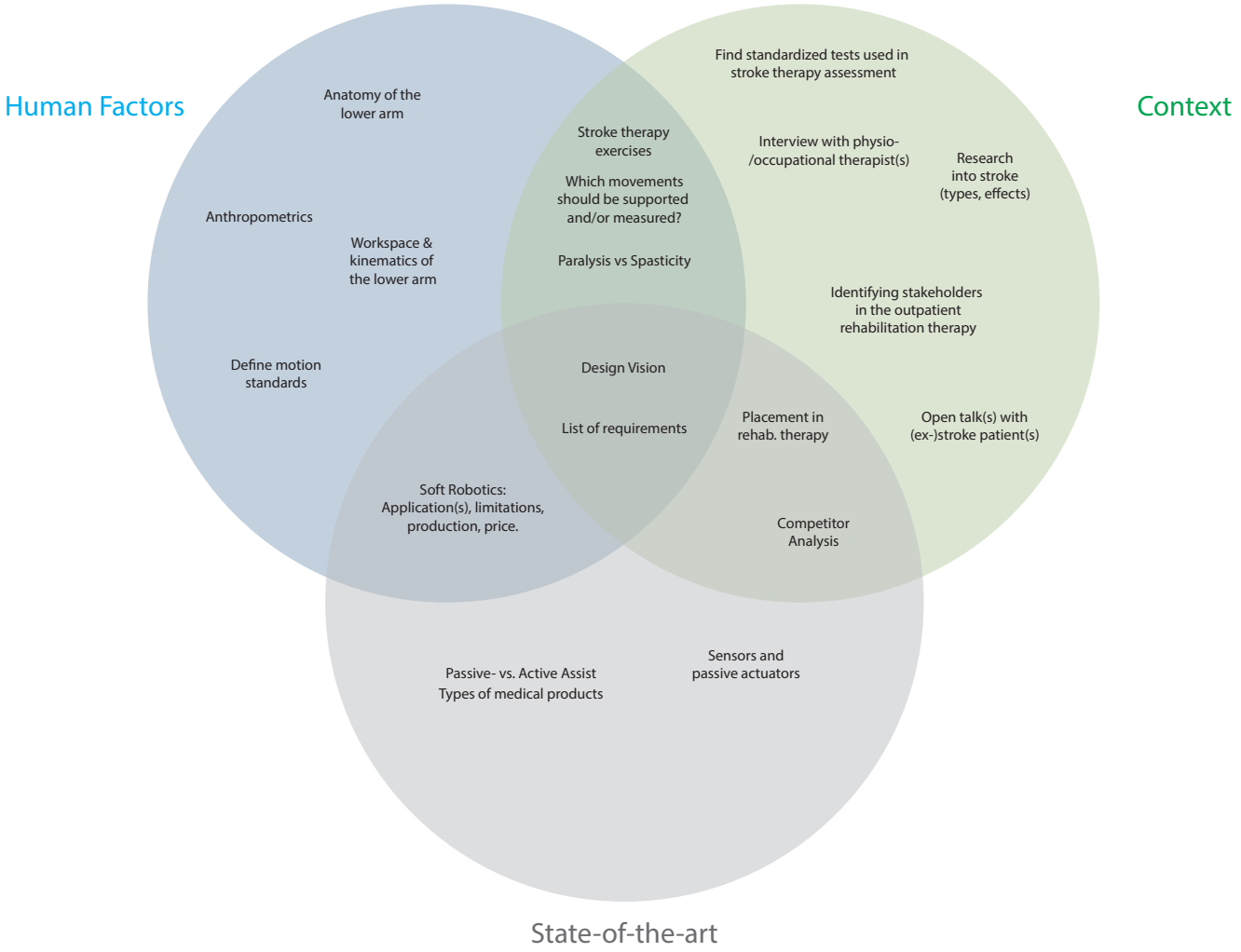


Figure 2.1 - Overview of the analysis stage

2.1 Context

Stroke recovery is separated into three stages: the acute (0-90 days), sub-acute (91-180 days) and chronic stages (180 days onward). In each of these stages, the goal and intensity of rehabilitation therapy is different.

Figure 2.2 shows which types of recovery occur during the different stages of motor rehabilitation. According to Timmermans et al (2009), motor recovery in the acute stage is commonly attributed to spontaneous recovery of the synapses, while "true recovery" in the later stages is mostly achieved through a reorganization in the functional brain map. Figure 2.3 shows the recovery process of 40 stroke patients, using a standardized test as an indication of motor performance. The generalized recovery process (A) is in line with the theory of Timmermans et al, and individual patient data (B) shows that the prognosis gives an accurate indication of the patient's eventual recovery.

Most of the recovery in the sub-acute and chronic stages is gained in the first 6 months after stroke through rehabilitation therapy (Kwakkel et al, 2004). The patient's prognosis and personal goals form the basis of a treatment plan that determines how the next 6 months can be used to regain the desired motor function.

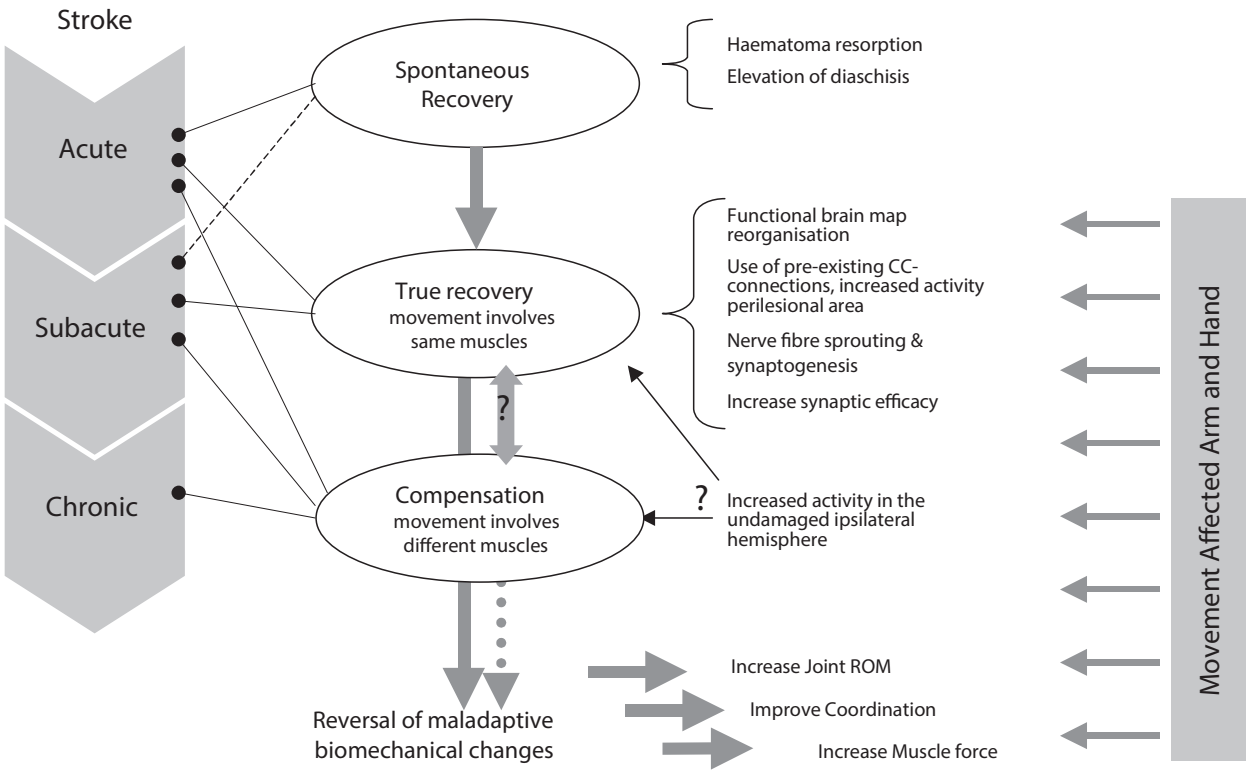


Figure 2.2 - Declarative model of motor recovery after stroke (Timmermans et al, 2009)

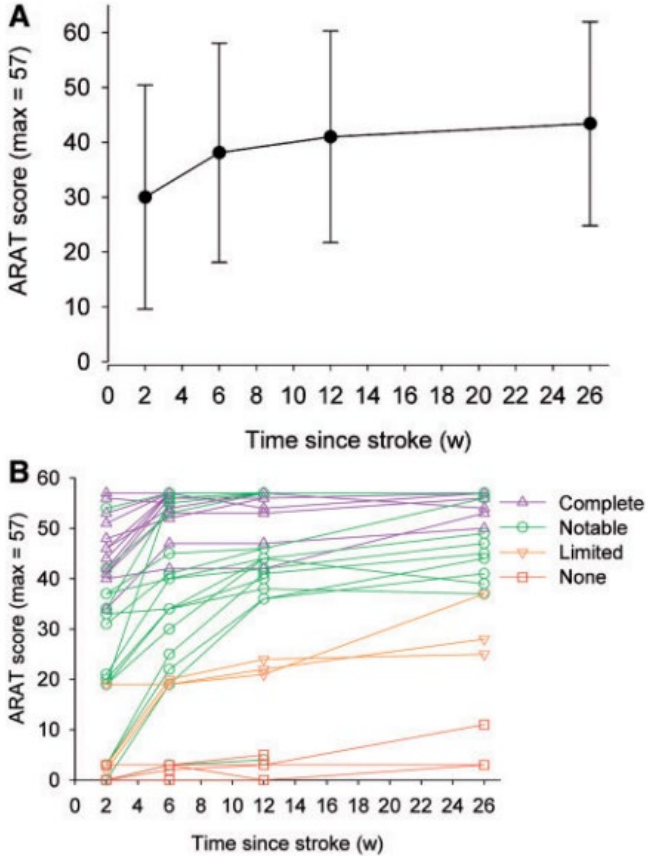


Figure 2.3 - Generalized recovery process after stroke, based on 40 patients (Stinear et al (2012).

2.1.1 Stroke Assessment

To assess a patient's recovery progress, therapists use many different evidence-based tests, that are performed multiple times during the rehabilitation process. Such tests, which focus on mental and/or physical performance, can take anywhere from 5 minutes to one hour, depending on the patient's ability and whether or not the tests are performed fully. (Stroke Engine, n.d.)

There is an opportunity to perform motor function tests at home using the sensors on the brace to save time during therapy sessions and to increase the accuracy of the effect of exercises. Therefore, a number of standardized tests were investigated with a focus on physical assessment of the upper limb. Appendix C contains a detailed list of all the standardized tests that were investigated in this project.

Prognosis

The patient's performance of finger extension and shoulder abduction in the acute stage are key indicators of their recovery in the next months (Stinear et al, 2012). In the Sophia Rehabilitation center, this SAFE test is performed every week during the acute stage to form a prognosis. Using the brace with its passive assist disabled, a therapist can accurately plot a patient's finger extension in the acute stage using the Adjuvo Platform, and use this result to determine a prognosis. However, the main focus of this thesis will remain on the sub-acute and chronic outpatient stage, not on the acute, clinical stage.

Motor Recovery Assessment

Some motor assessments are frequently mentioned in medical papers regarding stroke recovery: These are the Fugl-Meyer Assessment (FMA), the Action-Reaction Arm Test (ARAT) and the Nine Hole Peg Test (NHPT). These tests have good correlation between each other's results, which explains their use in journal papers. Some of these assessments incorporate RoM exercises as part of their evaluation, but always in combination with functional exercises, such as "move your hand up here" or "pick up this object". Because of the focus on the hand and wrist, the passive assist brace cannot be used to fully perform the most common assessments, but it can be used to perform parts of the tests, such as the FMA hand & wrist scores.

Spasticity Assessment

While the Modified Ashworth Scale is frequently used in clinical trails as inclusion/exclusion criteria for "spasticity", they acknowledge that its results are not a true indicator for spasticity. The Modified Tardieu Scale (MTS) improves upon the MAS by taking into account the speed component of spasticity. However, the MTS still relies on subjective data: A therapist must move the patient's joints at fixed speeds, which would be very difficult for a human to do consistently. There exists an opportunity to adapt the MTS into the brace to objectively assess a patient's level of spasticity. However, the demand for such functionality comes mostly from clinical researchers, and not from patients or therapists. Because spasticity assessment requires a second person to move the patient's joints at set speeds, this functionality is only suited for an active device. Spasticity assessment will therefore not be part of the passive-assist brace, but will be very interesting to incorporate into the M-Brace or a separate product.

Other

Some other assessments, such as the Functional Independence Measure (FIM) are based on self-reporting or observation. Such assessments would be interesting to include in the Adjuvo Platform though questionnaires, as part of the overall therapy.

Requirements

- Recognize functional tasks by measuring both finger and wrist movements.

Opportunities

- Using the sensors on the brace to determine a patient's prognosis in the acute stage, based on finger extension.
- Creating an objective assessment of spasticity, based on the Modified Tardieu Scale, using the M-Brace or another active device.
- Incorporating self-reporting tests into the Adjuvo Platform.

2.1.2 Adjuvo Therapy

Every stroke is unique, which means that stroke survivors have different needs which change throughout the recovery process. A passive assist brace is not suited for every patient: In order to benefit from active exercise, one must be able to move their limbs. Most stroke survivors start with flaccid paralysis; having little to no motor control and no spasticity (yet). As they progress through their rehabilitation program, a survivor may recover the functional control of their arm, and they may develop (severe) spasticity which may or may not recede over time. Each of these factors influence the type of therapy required and the needs of the patient at that time.

With the aid of Loes Schilderink, who has performed a number of interviews with patients and therapists for Adjuvo Motion, an attempt was made to determine which type of product is suited for a stroke survivor based on their level of spasticity and functional motor control, as seen in figure 2.4. One can argue that stroke survivors cannot be grouped using these parameters alone. However, it is spasticity and lack of motor control that Adjuvo Motion is trying to solve through its products. The focus of the categorization was therefore on these two factors.

As seen in the figure, there are three distinct therapy types which correspond to different products. There will be overlap between products as well, which represents a 'transition' between two therapy types, where a therapist and patient should determine which product is right for them. For example; A patient who recovers fully from their stroke without developing spasticity will need only robotic therapy at first, followed by virtual exercises once they can move their limb well enough by themselves. Should this patient develop spasticity in a later stage, they should switch to passive assist therapy.

There exist an opportunity to develop a modular product that can be used to perform all therapy types based on its configuration. Such a device must have a sensor glove as a base of which the functionality can be extended with 'passive' or 'active' modules. To a simpler, more feasible extent; both the passive-assist and virtual exercise therapy can be performed using the same product, if the passive assist can be fully removed, leaving only a sensor brace.

Using the standardized tests covered in the 'Stroke Assessment' chapter, the axes in figure 2.4 can be quantified by linking them to the scores of the Fugl-Meyer Motor Assessment (FMA - for functional control) and the Modified Tardieu Scale (MTS - for spasticity). These tests are chosen because they are the most detailed assessments for their respective post-stroke condition. However, it is possible to use other assessments to quantify this figure as well.

The FMA score ranges between 0-66 points for the upper limb, where 0 points represents hemiplegia (flaccid paralysis) and where 66 points represents full motor control. Of 66 points, 28 are associated with the RoM of the wrist and hand. The MTS score ranges from 0 (no resistance) to 5 (cannot be moved) for each joint. Considering the four fingers, thumb, wrist, elbow, and shoulder joints, the maximum score for the MTS in this figure would be 25, of which 15 are associated with hand and wrist movement.

Following the both the FMA and MTS assessment, the clinical inclusion criteria for the passive assist brace can be determined: Users of the brace should have at 7 out of 28 points on the hand and wrist scale of the FMA (half of the score for hand RoM) in order to use it effectively.
As mentioned in the *problem definition* chapter, patients suffering from high levels of spasticity in the hand and wrist (MTS > 10 out of 15) can not use the passive assist brace, as opening their hands would require high forces which could do more harm than good. Patients suffering from this much spasticity may be able to use the brace if they (temporarily) reduce their spasticity, either through medication or surgery.

Requirements

- There should be clear clinical inclusion and exclusion criteria of the brace: The product is used by stroke survivors suffering from little to mild spasticity (MTS score between 1-10 of max. 15) and with at least a small amount of motor control (FMA >= 7 of max. 28).

Opportunities

- Creating a modular device that can be adapted to the needs of 'active assist', 'passive assist' and 'sensor-only' therapy.
- Using the brace to treat non-spastic stroke survivors by making the passive-assist mechanism removable.
- Patients with high levels of spasticity can still use Adjuvo's products if they can (temporarily) reduce it's severity.

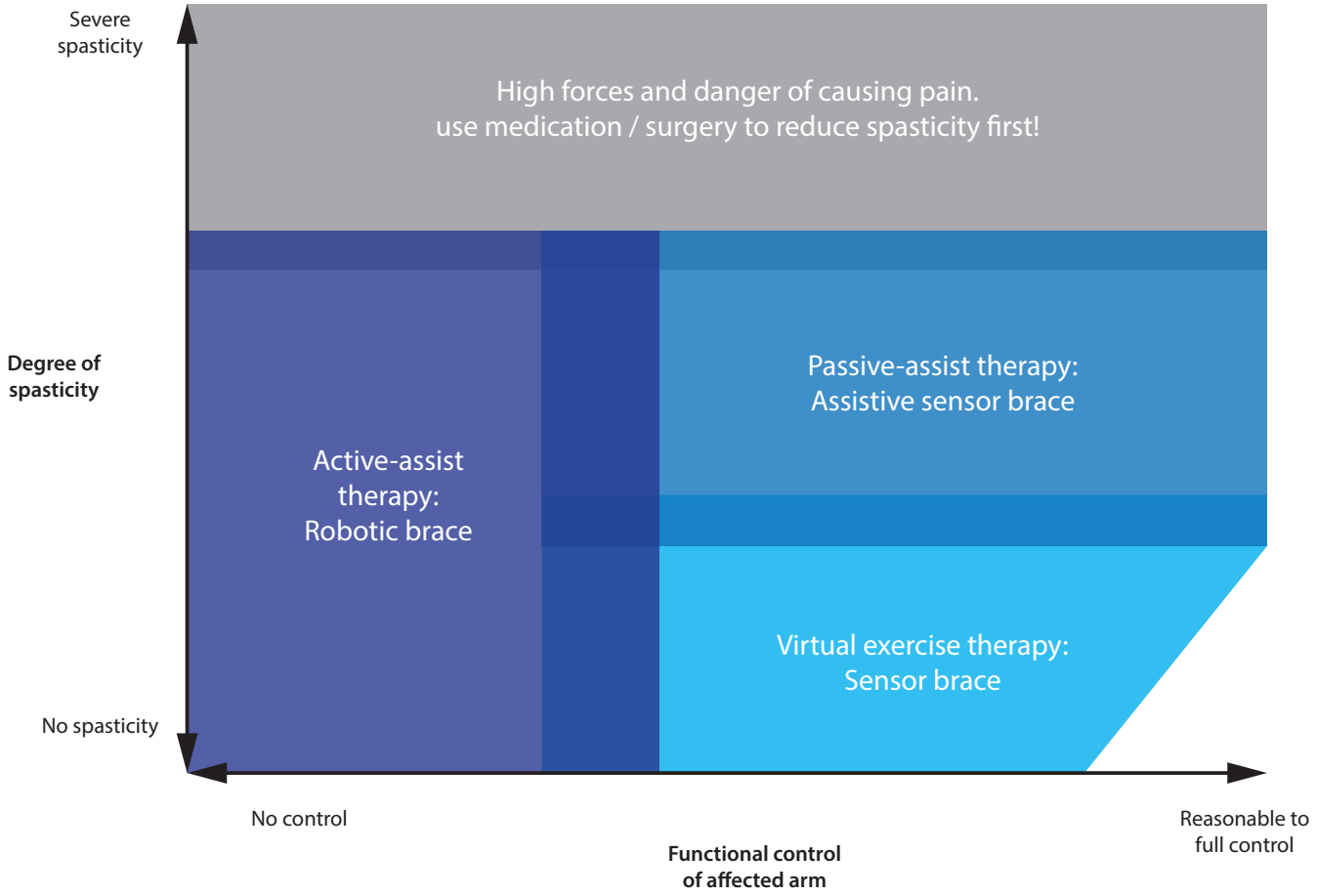


Figure 2.4 - Therapy type based on functional control and level of spasticity

2.1.3 Stroke Recovery Exercises

In stroke therapy, there is a distinction between “passive (RoM) exercise” and “active (RoM) exercise”. In passive exercises, a therapist or device moves the affected hand for the patient, which is especially effective when the patient suffers from flaccid paralysis. In active exercise, the patient moves their limbs themselves, although some assistance can still be given. To illustrate, Figure 2.5 shows the difference between passive- and active devices and exercises.

The key with passive exercise is that the (initial) movement is triggered by the patients themselves (Maciejasz et al, 2014), which allows them to increase their active RoM. However, a passive assist device is unable to provide the assistance needed for passive exercise, and is therefore not suited for patients without motor control. If the passive assist mechanism can be turned off or removed, patients suffering from only one-sided weakness would be able to perform the same exercises as spastic patients, using only the sensor-part of the brace.

Maathuis et al. (2015) have developed a home exercise guide for outpatient stroke survivors. This booklet is divided into three sections for patients with little to no motor function, limited motor function and near full motor function. In Appendix B, a few of these exercises, like the one shown in figure 2.6 are covered in greater detail. For spastic patients, it is ill-advised to put their fingers into hyper-extension, as this is said to trigger a contracting reflex which can damage the ligaments (Laidler & Campling, 1994).

	Device	Exercise
Passive	A device that cannot move a patient’s limb, but rather offers resistance.	Exercise where another person or device moves a patient’s limb for them.
Active	Moves the patient’s limb for them through actuators.	Exercise where the patient moves their limb by themselves.

Figure 2.5 - An explanation of active vs passive devices & exercises.

Requirements

- Patients using the brace must have some form of motor control.
- The mechanism must NOT put the fingers in hyperextension.
- The product must allow for individual finger movements.
- The palm of the hand must be kept unobstructed of mechanisms.
- Results from the exercises must be shown to the user and therapist in the form of RoM assessment.

Opportunities

- Performing exercises with the brace while seated at a flat surface, which will be used for calibration and to relieve the weight of the upper arm.
- Incorporating physical objects into the therapy with the passive assist brace.

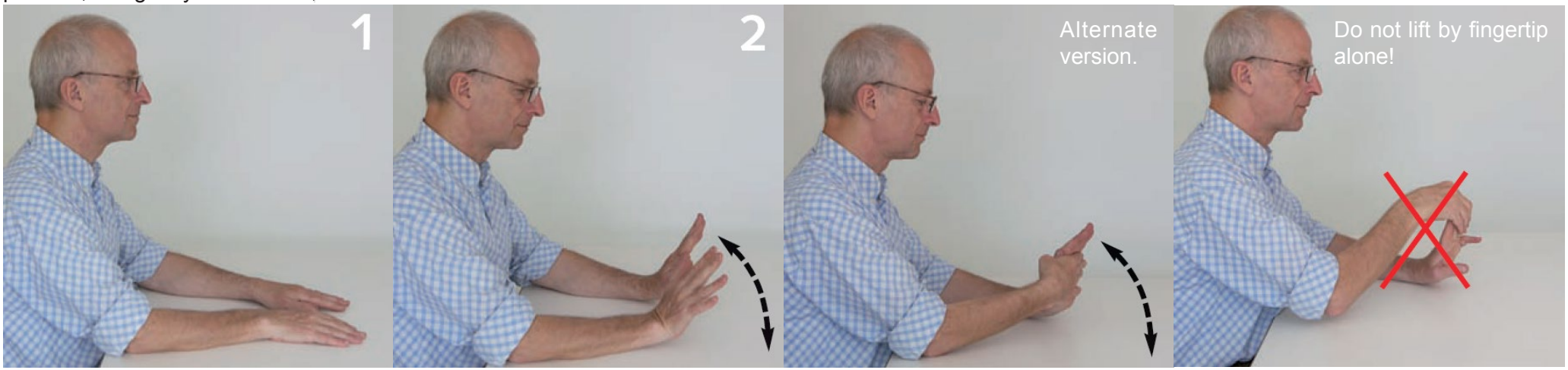


Figure 2.5 - Example wrist exercise from the fast-to-home exercise guide (Maathuis et al. 2015)

2.1.4 Stakeholders

The product should fulfill the needs of the key stakeholders with regards to RoM measurement and passive assist. In figure 2.7, an overview of all potential stakeholders in outpatient stroke rehabilitation is shown (National Stroke Association, 2006; Sophia Revalidatie, n.d.). These stakeholders are grouped by their availability to the patient, from directly available in the home environment to only available in clinical care, to those that are only available during specific parts of the rehabilitation process. The actual composition of the medical team varies depending on the impairments of the patient: For example, a stroke survivor afflicted with only a speech impairment has no need for a physiotherapist.

The focus of this thesis will be on the patient, physiotherapist, occupational therapist and caregiver. These stakeholders were chosen because they will have the most contact with the passive assist brace. The needs of Adjuvo Motion are also of a high priority, as they are the ones to bring the product to the market. The needs of other stakeholders are still presented as opportunities, but do not count towards the program of requirements. The full stakeholder analysis can be found in Appendix D.

Figure 2.7 - Stakeholders in outpatient stroke rehabilitation.

Outpatient

The outpatient is central to the rehabilitation process. For most of the week, they live at home, usually with their caregivers. Three to five times a week, the patient travels to the rehabilitation centre to receive treatment which helps them complete their main goal: To recover their motor function so that they can become independent again. The passive assist functionality should give spastic patients back the control of their hand and wrist by placing it in a new 'open' position through force equilibrium. From there, only a small amount of force is required to move the fingers, much like how a desk lamp compensates for gravity with springs. The patient will use the RoM measurement as input for virtual exercises, the results of which will be used to show them their motor recovery over time.

Family and Friends

Usually, the family of the patient become their caregiver, supporting their loved one emotionally and in daily tasks. When family is unavailable, a paid helper can support the patient instead, albeit for a limited time each day. Family members are normally not knowledgeable enough to help the patient, but the Adjuvo Platform might be able to put their minds at ease by educating them about stroke rehabilitation. The passive assist mechanism should allow the patient to be more independent, thus taking some of the burden off the caregiver. However, the patient might need help equipping the product. Family and friends will not directly use the RoM measurement, but could potentially help the patient during the exercises by co-operating with them in a virtual environment.

Physiotherapist (PT)

The PT helps the patient regain their movement, balance and muscle strength though exercise in order to re-learn walking, standing and fine motor skills. These skills build towards activities of daily living that Occupational Therapists teach. The passive assist mechanism will allow their patients to train more often, as a supplement to the training they already receive. The RoM measurement must be qualitative in order to give the physiotherapist objective feedback on their patient's progress, which means they can adjust the treatment if necessary. Through the Adjuvo Platform, the PT should be able to see the progress of all of their (active) patients.

Occupational Therapist (OT)

The OT teaches strategies to manage activities of daily life, such as eating and dressing. Their therapy focus is on functional tasks and exercises, as well as strategies to compensate for non-functional joints. The passive assist functionality is useful to OT's only if the patient can use it to assist them during their ADL: The occupational therapists cares more if a patient can perform a task, however possible. As the user regains more of their motor function, they could continue using the brace for ADL instead of physiotherapy.

Adjuvo Motion

This company is a new stakeholder in the outpatient rehabilitation process: They will supply the passive assist brace and will manage and maintain the Adjuvo Platform. They want the passive-assist product to require little service or replacement parts when out in the field, as to concentrate their efforts into the development of the M-Brace. They must also have at least a CE certification on the product to bring it to the market. As such, they will want the design of the product to be ready for commercialization. Adjuvo Motion will have access to the data from the patient's exercise, and it is their job to protect and process these results and show them in a clear, concise manner to both patient and therapist.

Requirements

- The product will be designed with a commercial purpose, not for research.
- The product must adhere to CE certification standards (See Chapter 2.3).
- The RoM measurement should be detailed enough for a physiotherapist to assess the patient's progress.
- The Adjuvo Platform should allow a therapist to see the progress of all their patients individually.

Opportunities

- Provide family members a chance to educate themselves about stroke through the Adjuvo Platform.
- Making the brace suitable for occupational therapy to increase its effective use.
- Using the available caregivers to help equip the product.
- Using challenging games in the chronic stages to train cognitive skills for recreation, or even using the platform as the recreation itself.
- Linking a patient's prognosis to one or more of Adjuvo Motion's products, as part of an insurance package.
- Incorporating more disciplines into the Adjuvo Platform: Dietitians (Find low-sodium recipes), Speech-Language Therapists (incorporate speech exercises) or Sexologists (allow patients to ask questions anonymously).

2.1.5 Use Scenarios

The results of the context analysis are summarized into two scenario's that take up the next four pages, which combine the conclusions from both literature and interviews into use situations. The goal of these use scenarios is to identify more detailed problems and requirements regarding the passive assist brace.

Figure 2.7, the first scenario, shows the current rehabilitation plan for an outpatient suffering from spasticity, while figure 2.8 shows the envisioned use of the passive assist brace in the same scenario.

Use Scenario - Current Situation

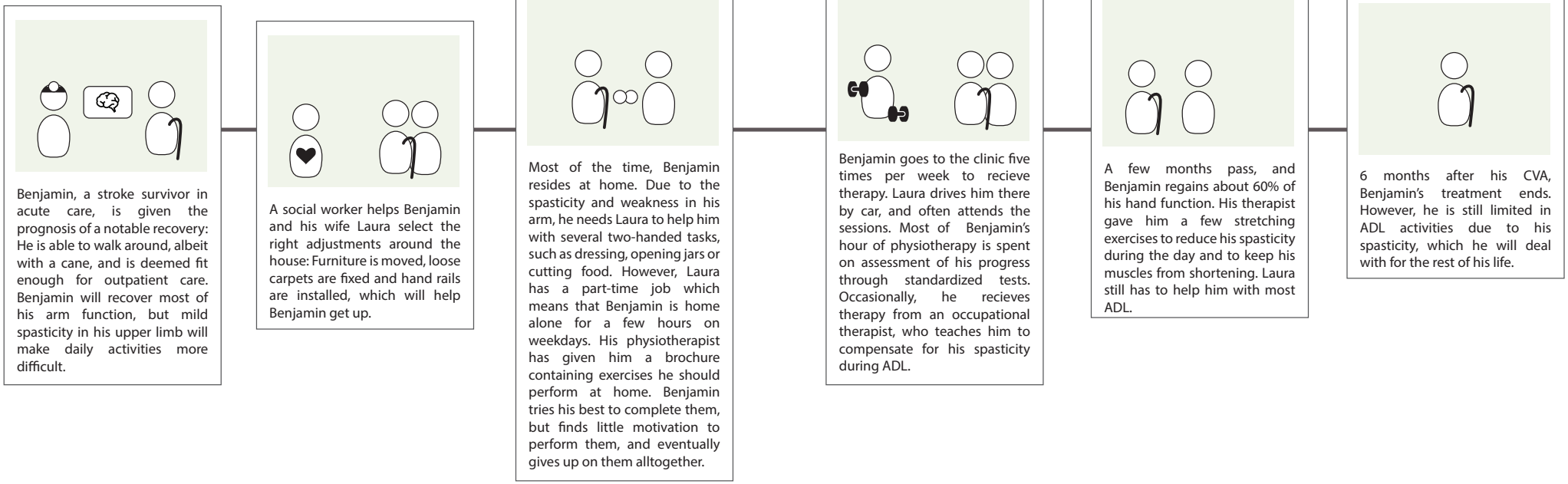


Figure 2.7 - Scenario of the current outpatient rehabilitation process.

Use Scenario - With Passive Assist Brace

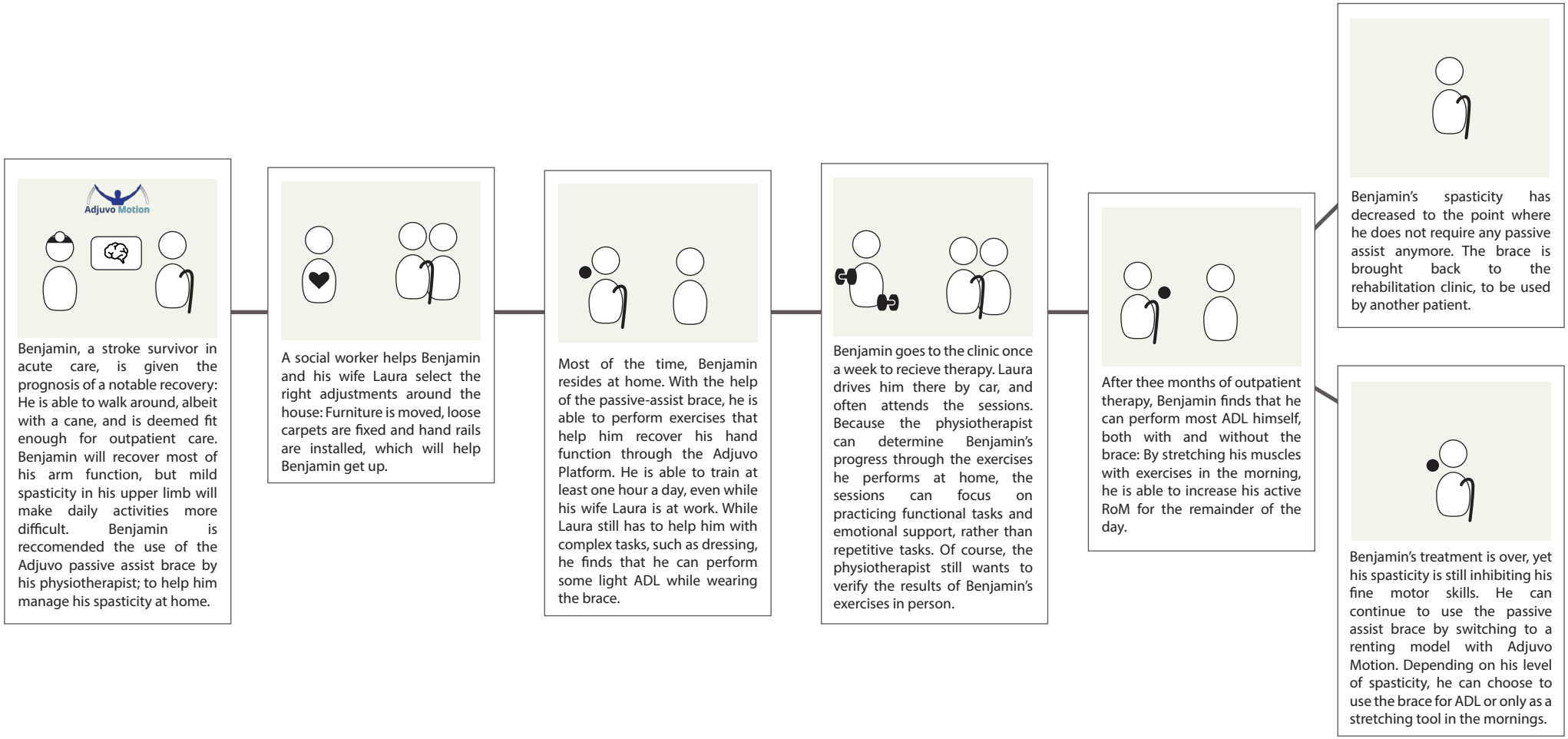


Figure 2.8 - Scenario of the envisioned outpatient rehabilitation process with the passive assist brace.

Conclusions use scenarios

Prescribing
The passive assist brace is 'prescribed' by either a physiotherapist of rehabilitation doctor. These stakeholders should be one of the first adopters of the brace before it sees a general use. There are two ways to achieve this; either a push-strategy (marketing towards physio's) or pull-strategy (demand comes from patients).

Equipping
The patient needs help putting on the brace, as they have only one fully functional hand due to the stroke. However, when their caretaker is absent no one can assist with donning and doffing the brace, limiting its use: The patient can only practice when their caretaker is present, and has to ask them for assistance every day. In order to lower the threshold of use, the user should be able to don the brace themselves.

If the product costs too much time to put on compared to the time that it is used effectively, neither patient nor therapist will use it. In a pilot study on the acceptance of robotic therapy, Dijkers et al (1991) concluded that many therapists will stop using devices if set-up takes more than 5 minutes. Adjuvo Motion wishes that the patient is able to don the brace within one minute.

Long-term use
Because spasticity is a permanent affliction, there must be a way for a stroke patient to use the product indefinitely, even after their rehabilitation process is over. The patient should be allowed to continue to rent the product from either the clinic or Adjuvo Motion.

Alternative Scenario
There is an alternative to the use scenario with passive assist brace, where the brace is used solely in the clinical environment (many different patients using it during the day). This scenario implies a heavier focus on donning and doffing of the product with the help of a therapist, and adjusting the spasticity compensation for each patient each session.

Compensation
The user and therapist should know at a glance which level of spasticity compensation is being used (e.g. Low, Medium or High compensation). This will serve as a rough indication of the patient's level of spasticity, as well as a way to quickly adjust the brace in between patients (clinical environment) or when replacing the passive assist at home.

Therapy vs. ADL
There are two different ways to increase a spastic patient's Range of Motion (RoM) through the passive assist brace: One way is for them to stretch their joints one or more times a day, using the brace and Adjuvo Platform to perform exercises and increase their RoM. Another is to wear the brace constantly during the day as an assistive device, and collecting data on the quantitative use. A device designed for one context could still be used for the other, and vice versa, at the cost of some performance. Both methods will change the way the passive assist mechanism is designed.

Requirements

- The brace can be donned by the user themselves.
- The brace can be donned within one minute.
- Should be clear (at a glance) which level of passive assist is used.
- Offer an option for patients to continue using their brace after their rehabilitation is over.

Opportunities

- Using the RoM measurement system to instruct the user which level of compensation is ideal for them.
- The therapist or rehabilitation doctor will be the ones to advise the use of the passive assist brace.
- The brace is able to make Activities of Daily Living much easier.

2.1.6 Conclusion - Context

Stroke recovery is an intensive process that takes months to complete. The stroke survivor is supported by a multidisciplinary treatment team, each with their own expertise and wishes regarding passive assist and RoM measurement.

The scenarios revealed an alternate use for the passive assist brace: Aside from using it for stretching exercises, the new ‘open’ position of the hand can be used to simplify Activities of Daily Living (ADL) through the increased RoM from the force equilibrium. While a device can fulfill both function, choosing which to focus on will significantly change the size and shape of the passive assist and measurement mechanism(s). This presents a choice of design direction for this project: Designing a device for physiotherapy exercises (therapeutic device) or a to assist in daily activities (ADL device)?

Figure 2.9 on the next page shows a summary of these directions, together with their advantages and disadvantages. The ADL device can greatly increase the effective use of the passive assist brace, and is especially suited for patients with chronic spasticity, for whom the stretching exercises are less effective. However, users are dependent on the ADL brace to perform their daily activities, meaning that they will need to continuously use it, even after their treatment plan is over. On the other hand, a therapeutic device can teach the user how to perform the stretching exercises themselves, and show their benefit through its more detailed RoM assessment. After their treatment plan is over, the stroke survivor can continue stretching without the brace, knowing the benefits it brings.

The strengths of a therapeutic device has led to the choice to continue development in this direction, which means that the product is designed for the context of a user sitting at a screen and performing stretching exercises. Therefore, the RoM measurement should be 'sufficiently accurate' and cover (almost) all joints in the lower arm, excluding the elbow. In the next chapters, such requirements will be quantified by comparing them to anthropometric data and competing products.

A passive assist device that supports users during their ADL could still be a valuable addition to Adjuvo Motion's product portfolio, especially if it can also interface with the Adjuvo Platform somehow.

Requirements

- The passive assist mechanism must be as small as possible.
- The RoM measurement should be sent to the platform without a cable.
- The product is used for 30-60 minutes at a time.

Opportunities

- Developing a different passive assist brace that supports users during their Activities of Daily Living with minimum sensors.

	
Therapeutic Device	**ADL Device**
The brace is used twice a day for stretching exercises that (temporarily) increase the user's Range of Motion (RoM).	The brace is used during Activities of Daily Living (ADL) as an assistive device that collects less detailed data in the background.
Emphasis on gathering detailled data through exercises that can be used as a RoM assessment.	Emphasis on making the mechanism as small as possible, so as not to interfere with daily activities.
+ After the exercises, the hand is completetly free for ADL. + Can make the results of stretching exercises tangible, which motivates users to continue doing them. + The user is seated and can use the table as calibration and/or weight compensation. + Over time, users can learn to perform (stretching) exercises independent from the platform.	+ The user has an increased RoM for as long as they wear the brace: There is no work involved in gaining this increase. + Can remind patients to use their affected limb during daily activities. + The minimal mechanism makes the product easier to equip by oneself.
- The user must be motivated enough to perform the stretching exercises. - The increased RoM is temporary. - The complex mechanism makes the product harder to equip by oneself.	- Creates a 'dependance' on the product: Without it; ADL becomes difficult. - The data gathered is not as detailed due to limitations in digital memory, making it less suited for standardized stroke assessments.

Figure 2.9 - Therapeutic focus vs. ADL focus

2.2 Human Factors

The goal of the *Human Factors* analysis is to quantify the needs of the patient and physiotherapist through the study of anatomy, kinematics and anthropometrics. While it is highly important to understand how the human anatomy and anthropometrics shape spasticity and Range of Motion (RoM), these studies have already been performed countless times. Therefore, chapter 2.2 will focus on the aspects that are important to the design of the passive assist brace. The full study is available in Appendix E.

Figure 2.10 and 2.11 on the next pages set the 'Adjuvo Standard' for joint movements, to be used both in this report and in further communications by the company. These naming conventions are based on anatomical literature by Egmond et al (2006) and Snijders et al, (2004). It is important that a user should be able to perform most, if not all, of these movements while wearing the brace.

Each finger consists of three joints, each with their own DoF. When the abduction in each joint is neglected, the finger can be modeled as in figure 2.12: A series of beams, linked by 1 DoF hinges. Following Greubler's Equation for DoF in a 2D Plane, this system requires 3 variables to determine the position of the joints.

The thumb can be modelled in the same manner, albeit with a more complex model. If the abduction of the MCP and PIP joint are neglected, the system needs 5 DoF to solve, because the thumb twists around the CMC joint during opposition. However, the number of DoF required can potentially be brought down by assuming there is a connection between two or more of the joint angles.

Figure 2.12 - The finger and thumb as simplified kinematic chains.

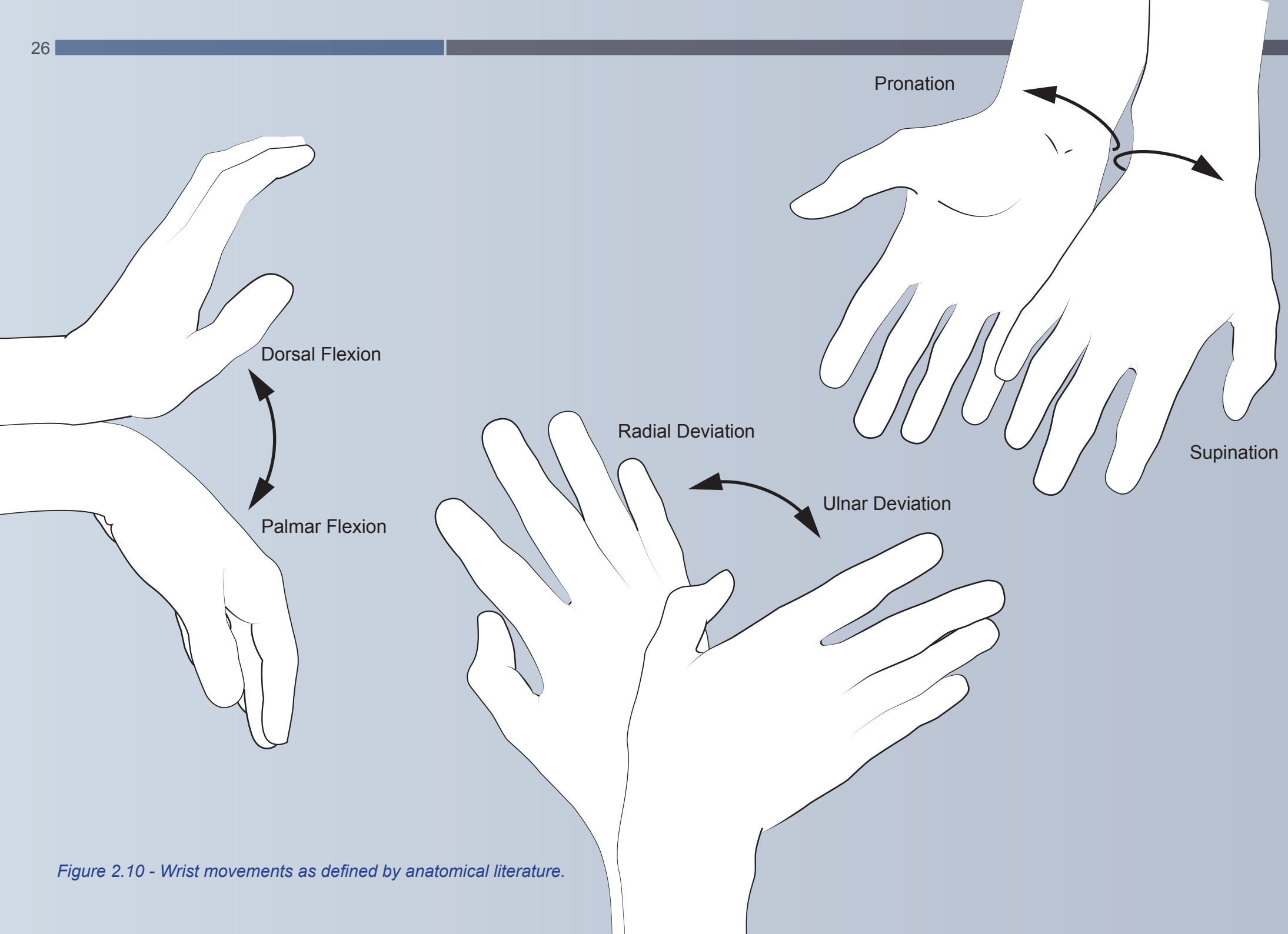


Figure 2.10 - Wrist movements as defined by anatomical literature.

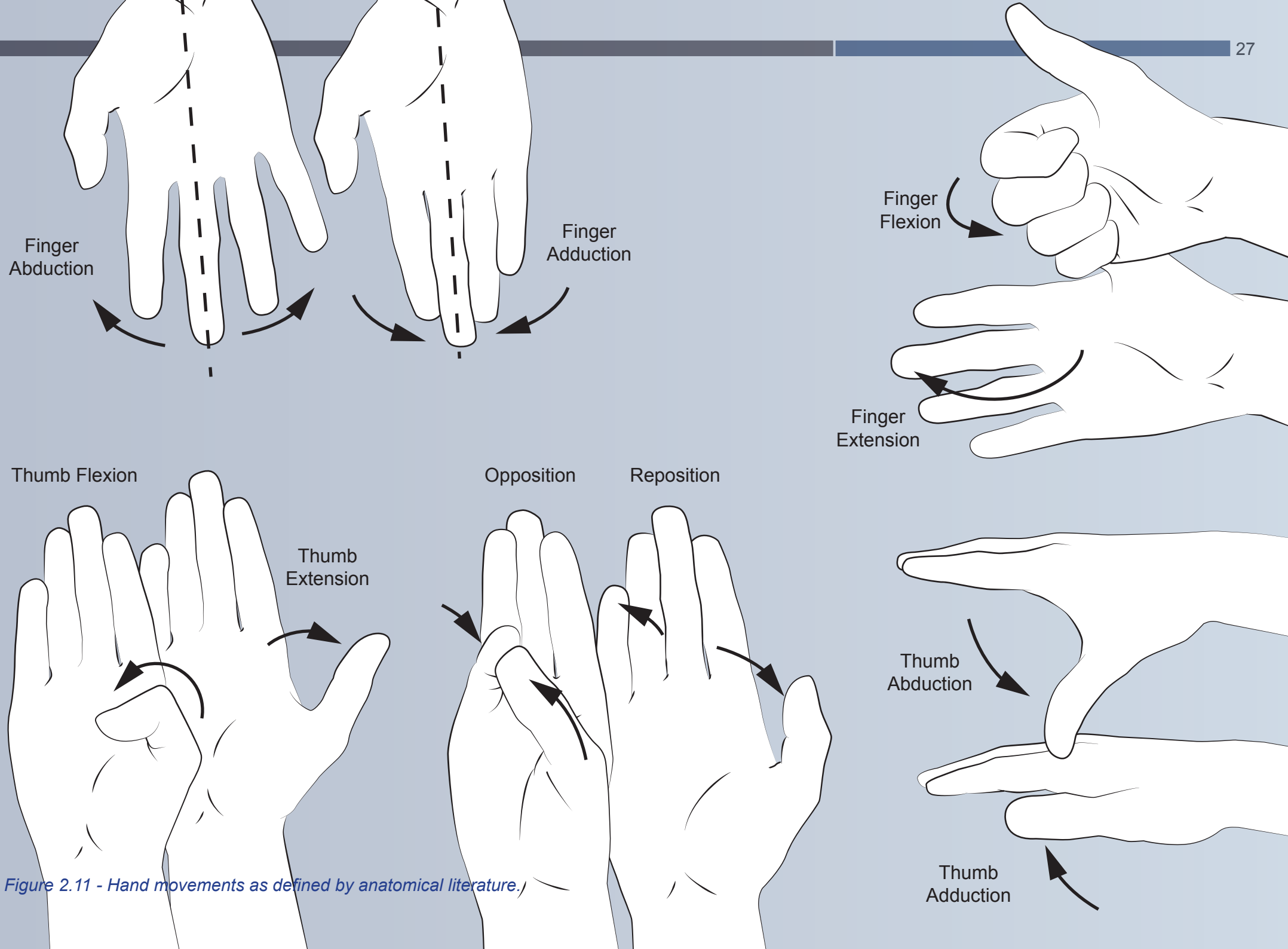


Figure 2.11 - Hand movements as defined by anatomical literature.

2.2.1 Opening a spastic hand

Physiotherapists have a specific method to open a spastic patient's hand, which uses knowledge of anatomy to minimize the muscle contraction. The importance of following this method increases when a patient suffers from severe spasticity. Figure 2.13 shows the steps to open the hand.

1) Placing the wrist in ±15° palmar flexion will decrease the distance between the finger flexor muscles and fingertips, as the tendons travel through the Carpal Tunnel on the palmar side. This releases some of the tension in the flexor tendons, allowing the fingers to move away from the palm with greater ease.

2) Extending the thumb: The thumb uses about half the muscles in the hand, so extending it will make it easier to open the fingers. One should take care to apply the force as close to the base of the thumb as possible, to minimize the risk of over-stretching

3) Applying a force to all fingers, as proximal (close) to the hand as possible. This again reduces the risk of over-stretching, to which the distal pahalange is most sensitive.

During these steps, it is important to move slowly to minimize the 'catch' of spasticity and to avoid touching the palm, which might activate the grasp reflex.

Requirements

- The passive assist force should be exerted as proximal to the hand as possible.

Opportunities

- The product keeps the wrist in ±15° palmar flexion to make the finger easier to open.
- The product follows the physiotherapy method of opening a spastic fist.

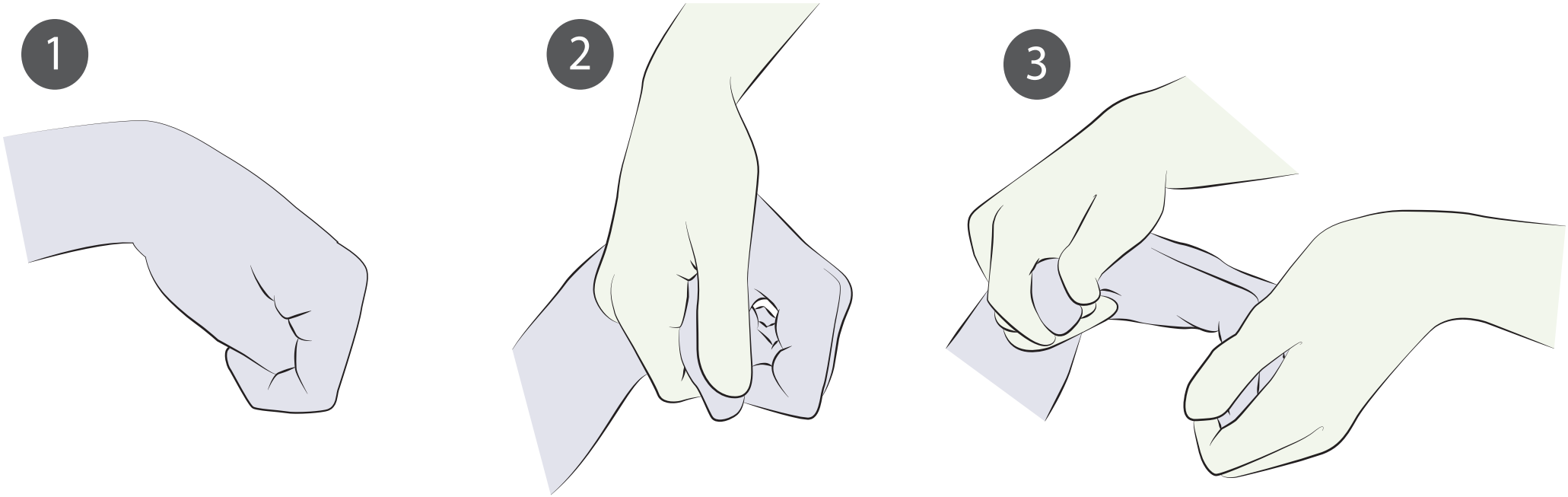


Figure 2.13 - Opening a spastic hand (illustrated)

2.2.2 Conclusion - The human factors

Spasticity in the fingers and wrist is caused by muscles outside of the hand; the so called extrinsic hand muscles, while spasticity in the thumb is caused by the muscles inside the hand; the intrinsic hand muscles. Studies performed by Park et al, 2016 indicate that a spastic muscle has a linear force-distance characteristic similar to that of a spring. From an anatomical perspective, the passive assist mechanism will add an additional set of extensor muscles to the fingers and thumb, to compensate for the increased tone in the flexor muscles.

The choice to incorporate functional grasps in the RoM measurement will make it easier to integrate the product in current evidence-based therapy, and will give physiotherapists a simple, familiar indication of the patient's progress. Therefore, the brace should be able to measure the finger motions in figure 2.14, with the exception of finger abduction / adduction, with at least 1 Degree of Freedom (DoF) to distinguish between the most common grasps used in standardized stroke assessments.

Measuring more Degrees of Freedom will allow the brace to determine individual joint RoM, which increases the level of detail and the number of grasps the brace can distinguish. Figure 2.22 shows which anatomical motions the passive assist should measure, and with what level of DoF. This table is also used to compare competing solutions.

Upper Limb Section	Movement	Maximum DoF	DoF to measure	Why is it measured / trained?
Forearm	Pronation / Supination	1	1	Used in many object manipulations: Opening doors, pouring liquids and turning keys.
Wrist	Ulnar / Radial Deviation	1	1	Used in tool manipulation (eating, vaccuuming).
	Palmar / Dorsal Flexion	1	1	Affects how easy it is to open the fingers. Palmar flexion should be trained for reaching.
Thumb	Thumb Flexion / Extenstion	3	1-3	Important to detect different types of grasps.
	Thumb Abduction / Adduction	1	1	Can be used to determine thumb twist / opposition.
	Opposition / Reposition	-	-	Is considered a combination of Thumb Flexion/Extension and Abduction/Adduction.
Fingers	Finger Flexion / Extenstion	3	1-3	Individual finger movements to determine grasps.
	Finger Abduction / Adduction	1	0	Deemed not important to measure.

Figure 2.14 - Which hand motions to support?

Opportunities

- The product keeps the wrist in 30° dorsal flexion, a functional position.

Requirements

- The brace must not compress the radial, ulnar or median nerve.
- A user wearing the product should be able to perform all movements in the lower arm.
- The brace measures finger and thumb flexion, thumb abduction/opposition, and Wrist flexions, deviations and pronation/supination.
- The brace must provide passive assist for each finger, or not at all.
- The mechanism must not obstruct the workspace of a healthy person (see figure F).
- The product can detect and distinguish between the Wrap-, Tripod-, (Lateral) Pinch-, Sphere- and Tool Grasps.
- The product must measure all anatomical finger motions, except for finger abduction, with at least 1 DoF.

2.3 State of the Art

This state of the art analysis investigates the latest developments in the area of stroke rehabilitation solutions, especially the products that use passive assist, RoM measurement or a combination of the two. The goal of this analysis is to find out what is required to bring a new product into this market, as well as finding ways to improve upon the existing solutions.

2.3.1 CE Certification

Before a product can be sold in Europe, it must first adhere to the Conformité Européene (CE) classification. A CE marking proves that the product has been assessed and meets the health and safety requirements of the EU. The CE marking is divides medical products into four categories: Type I, IIa, IIb and III medical devices, where Type I is associated with low risk for the patient, and type III products are associated with a high risk. The higher the risk for a patient, the stricter the rules and regulations of the CE become (NEN, n.d.). Type I medical devices can also fall under two sub-categories Im - measurement devices, or Is, instruments that require sterilization. Figure 2.15 shows each of the CE categories, with examples.

CE marked products of levels Im, Is, II and III should have technical documentation available, which includes:

- Design Records
- Product Description
- Results of Risk analysis.
- Test results.
- Clinical data.
- Labels / other certifications.

Products with a CE marking should display its logo and registration number as well.

An assistive brace that does not actively add kinetic energy to the body falls under CE category I (CE Tool, n.d.). However, because the device also has a measurement component, one that is used for a RoM assessment, it actually falls under the Im category instead (CE-Marking.com, 2015). A type Im medical product must be assessed by a notified body on its metrological performance, which includes the accuracy, reproducibility, and sensitivity of the device. It is therefore important that the device creates a consistent measurement. It is reasonable to assume that, for the envisioned RoM assessment, the device must be as accurate as the currently used solution: The Goniometer, which has a with a standard error of deviation of around 7° (Carter et al, 2009).

Certification Level	Risk for patient	Example Products	Remarks
I	Very Low	Plaster Casts	The Type I classification has two sub-classes: One for instruments that have to be sterile (Is), and one for measurement devices (Im).
IIA	Low	Injection needles	Devices of this level and onward must be certified by a notified body.
IIB	High	Anasthesia devices	-
II!	Very High	Pacemakers	This category is reserved for products that come into direct contact with the heart or central nervous system.

Figure 2.15 - CE certification levels of medical devices.

Requirements

- Design records of this product must be kept.
- A risk analysis of the product must be performed.
- The product must display an indication of its CE marking and registration number.
- The device must have a standard error of deviation between measurements of at most 7°.

2.3.2 Relevant Technologies

Soft robotics is a relatively new trend aiming to replace the rigid parts of robotics with 'softer' components such as elastomer. This field is inspired by animals such as octopus or starfish, whose gaspers are highly adaptive.

The adaptive nature of soft robotics lends itself well for the manipulation of unknown objects or contact with living things, such as the human body (IEEE, 2014). However, the modeling of non-linear actuator behavior is complex to pull off.

There are two approaches in robotics to provide the characteristic 'soft interaction': Either by controlling the stiffness of the robotic links through their actuators (Albu-Schäffer et al, 2008) or by having an intrinsic softness in the robot's body (Trivedi et al, 2008). While the principle of soft robotics is mostly suited for active assist applications, there is potential to apply it to a passive assist device through orthoses that can adapt to the user's hand.

Currently, Harvard University is working on creating a soft-robotic exoskeleton using Embedded Pneumatic Networks for people suffering from paresis due to stroke, spinal cord injury or muscular dystrophy, as seen in Figure 2.16 (Polygerinos et al, 2015). Their glove can be actuated closer to the skin compared to conventional robotics, due to the soft material and decreased risk of pinching. Harvard engineers must determine where the actuators will bend and/or twist, based on the composition of materials and air chambers. The location of the bends is dependent on the user's joint sizes, meaning that the product must be tailored to each user.

Parallel to Harvard, the Seoul University is also developing their own 'soft glove' for stroke rehabilitation (Kang et al, 2016). *The Exo-Glove Poly*, shown in figure 2.17, keeps its actuators away from the hand. Instead , the electrical components move the fingers by way of steel cables inside Teflon tubes. Not only does this method decrease the weight of the product, it also becomes easy to clean by simply rinsing the orthosis in water. Certain decisions, such as the use of magnets to connect some of the orthoses, are a result of Seoul University's design criteria:

- Hygiene
- Usability
- Simple Design
- Price
- Mass Production
- Wearability
- Appearance
- Safety

To gain a functional position in the hand, the thumb is held in place by a static orthosis, and only the index- and middle fingers are actuated. While this does reduce the complexity of the system, it raises the risk of creating a "learned non-use" in the index- and pinky fingers, which are neglected by the product. Functional control of only the thumb, index- and middle finger is enough to perform most precision grasps, though the lack of control in the last two fingers will hinder during (spherical) wrap or tool grip motions. Control of the Exo-Glove's "actuator unit" is currently done through a push button only, but there are plans to replace this alternatives such as EEG.

Opportunities

- Using soft robotics to create a comfortable, adaptive orthosis.
- Keeping the actuation away from the hand, making the wearable parts easier to clean.
- Using magnets to create a secure, yet easy to apply connection.

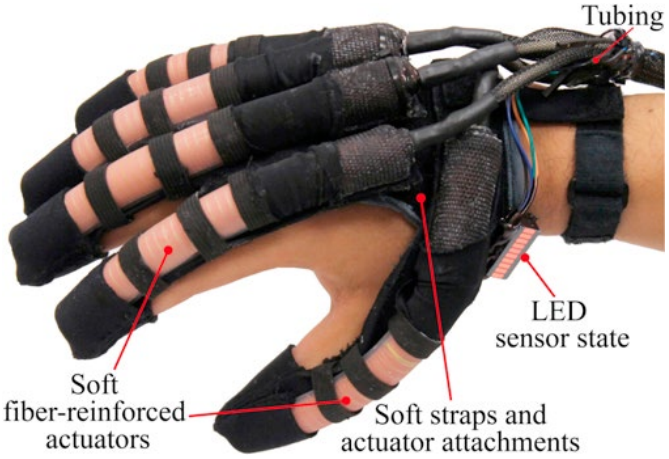


Figure 2.16- Harvard University soft robotic glove (Polygerinos et al, 2015).

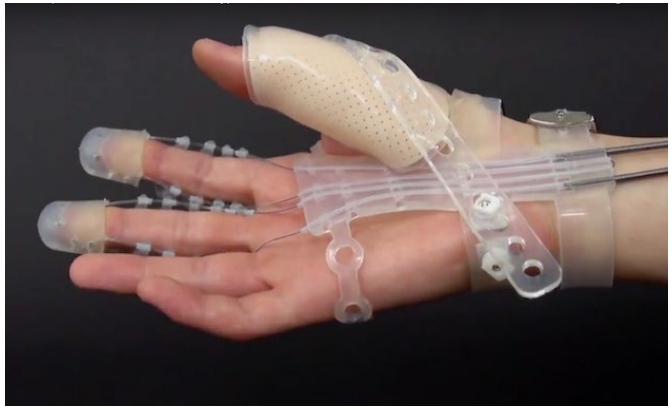


Figure 2.17 - Seoul University "Poly Glove"

2.3.3 Competitors

Competing products are analyzed in order to find gaps in the market and to gain inspiration from their materials & mechanisms. Figure 2.18 shows an overview of products that measure joint angles of the lower arm and products that provide passive compensation for spasticity. These products are grouped based on how well they fulfill the two functionalities. Appendix F covers the competing products in greater detail.

The most commonly used product for RoM measurement in stroke therapy is the Goniometer (8): It is a simple device that can measure one joint angle at a time, yet can be used for nearly all joint movements in the human body. It is a requirement for the new assistive brace to be at least as accurate as the traditional Goniometer; with a standard error of deviation of less than 7° (Carter et al, 2009).

Measurement devices become more expensive with each additional (joint) angle. Most of the advanced measurement products are designed for Virtual Reality (VR) applications and for users without physical impairments. These gloves are hard to put on for paretic and spastic stroke patients, who cannot extend their fingers enough to slide their fingers into a glove. However, there is one measurement product that is designed specifically for stroke patients: The Raphael Smart Glove (10). This glove measures finger flexion/extension and wrist movements and uses them as input for virtual exercises. Due to its focus on the stroke market, the product is relatively easy to equip for paretic and spastic patients. Early studies show patients using the Raphael for therapy recovering more of their hand function (Shin et al, 2016).

Few of the passive assist products can be equipped by a single stroke survivor, largely due to conflicts with their fingers: Both spastic and paretic patients lack the extension in the fingers required to equip a 'closed' glove. Designing the passive assist brace to be equipped by the stoke survivor themselves will give it a competitive advantage over the existing solutions. The *Raphael Smart Glove* and the *Harvard soft robotic glove* for the previous chapter solve this problem by connection only to the fingertips. However, this method raises the risk of placing the last digit in hyper-extension if a passive assist force is guided along the dorsal side of the finger.

The most successful passive-assist competitor, the Saebo Glove (1), is sold for €500, from which a rough production price of €200 can be derived. Combining the same level of passive assist with RoM measurement is estimated to place the production price of the new brace between €200 to €300. The product is successful due to its relatively low price, its appealing aesthetics and adaptability to different levels of spasticity. Studies show that the passive SaeboFlex, similar in function to the SaeboGlove, benefit conventional therapy (Rickards et al, 2015).

The competitor analysis shows a clear gap: There are few products that can combine the measurement of joint angles with spasticity compensation. It is clear that there is a demand for both functionalities, and a combination of both functions into one product can provide Adjuvo Motion with a Unique Selling Point (USP). However, a combination alone will not guarantee success.

A robotic device for hand rehabilitation after stroke, the *Gloreha*, provides up to 5N of active force on each finger, which the developers consider to be a *"reasonable level of strength"* based on clinical suggestions (Glohera, n.d.). Using these forces, the Gloreha is suited for patients suffering from spasticity, up to a Modified Ashworth Score of 3 (see chapter 2.2.3). Since Gloreha target the same levels of spasticity as the passive assist brace, it is reasonable to assume that the passive assist brace needs to provide up to 5N of force along the finger as well.

Requirements

- The device will have a production price of €200-€300.
- The standard error of deviation of measured angles should be <= 7°.
- The patient should be able to put on the product by themselves.
- The palm of the hand should be left free of mechanisms.
- The device compensates for up to 5N of force per finger.

Opportunities

- Create a Unique Selling Point through a product that combines RoM measurement and spasticity compensation.
- Entering the VR market with the RoM part of the product.

Figure 2.18 - An overview of competitors

2.3.4 Conclusion - State of the Art

The *Raphael Smart Glove* and the *SaeboGlove*, shown in figure 2.19, represent the most well designed competitors in RoM measurement and passive assist respectively. Both products are designed specifically for stroke rehabilitation and have had at least one study that shows an increase in motor recovery when using the product during the overall treatment. A new product can create a Unique Selling Point (USP) by combining the functionality (and benefits) of these two competitors.

Most wearable competing products (both passive and active) require the help of a caregiver to put them on. Designing a brace so that the patient can equip it themselves will give it a competitive advantage, in addition to lowering the threshold to start using it, as concluded form the context analysis.

Opportunities

- Creating a Unique Selling Point by allowing the user to equip the brace by themselves.

Figure 2.19 - Combining the Raphael Smart Glove and SaeboGlove

2.4 Conclusion

Spasticity is a common disability for stroke survivors that may lessen over time, but can also ‘plateau’ at one level, resulting in a chronic problem that inhibits a patient’s independence. While it is not possible to cure spasticity through physiotherapy, a common practice in stroke therapy, it is possible to gain a temporary increase in Range of Motion (RoM) through stretching exercises that act as a supplement to the physiotherapy that the patient already receives. The increase in RoM makes it easier for patients to perform Activities of Daily Living (ADL) without the need for medication or invasive surgery.

To facilitate such exercises, an equilibrium must be created to cancel out the forces from the spastic muscles using a device with a ‘passive assist’ mechanism. This device will move the hand in a new ‘open’ position, from which it is much easier to move the fingers. The level and location of spasticity is different for each patient. It is therefore necessary for the mechanism to be adjustable, with clear indication of the level of compensation.

The stretching exercises will be facilitated by the Adjuvo Platform, which creates an environment in which the stroke survivor uses the sensors on the brace to perform task-oriented exercises that are designed to stretch their muscles. The user’s RoM performance is compiled into an assessment that can be used by their physiotherapist to give feedback on the effectiveness of therapy. The RoM measurement can also be used to show the benefits of stretching exercises.

Currently, there are many products that offer ways to compensate for spasticity, some of which have shown that training at home with passive assist increases the effectiveness of their therapy. On the other hand, there are a number of sensor-glove solutions available, which are designed for people without hand impairments. However, no combination of these two exists. By combining the spasticity compensation with sensor glove technology, Adjuvo Motion can fill a gap in the stroke rehabilitation market that will adhere to a CE marking for a category Im medical product.

Interviews with patients and physiotherapists also indicate that there is a need to make this device easy to put on, so that no help of another person is required. Not only will this lower the threshold to start using the product, it will also create a competitive advantage over existing solutions.

These conclusion can be compiled into a Design Vision, which is used as the starting point for the synthesis design stage.

*“Helping spastic stroke survivors regain their independence through a **passive assist** brace that **measures** and **increases** the **Active Range of Motion** of their lower arm, that is adjustable to the user’s current level of spasticity and can be **equipped by a single person**.”*

*“The product supports the user during **stretching exercises** that lighten spasticity, and by assisting them in their everyday activity. This combination is used to help stroke survivors manage their spasticity well after treatment is over.”*

There are two main challenges contained within this vision: First, to design a mechanism that combines the RoM measurement and passive assist. Second, to create this mechanism in such a way that it can be equipped by a singe stroke survivor suffering from spasticity.

In addition to these challenges, the design must adhere to a number of requirements and wishes have been identified in the analysis stage.

2.4.1 Requirements

The requirements found in the analysis stage have been ordered from *most important* to *least important* to *wishes* ('nice-to-haves'). Overlapping requirements were combined into one. The *most important* requirements are those that are clearly quantified, and can therefore be used to test the embodied design. This evaluation will be covered in chapter 7.

Several findings from the analysis are merely the result of the chosen context and/or design directions. While they do not contribute to the list of requirements, these findings provide a helpful recap of the context in which the product is designed.

Most Important

1. The brace can be donned by the user themselves.
2. The product can be put on within 1 to 5 minutes.
3. The device compensates for up to 5N of force per finger.
4. The level of spasticity compensation is adjustable.
5. The mechanism must NOT put the fingers in hyperextension.
6. The brace measures finger and thumb flexion, thumb abduction/opposition, and wrist flexions, deviations and pronation/supination.
7. The product can detect a Large Diameter-, Tripod-, (Lateral) Pinch-, Sphere- and Tool Grasps.
8. The device increases the Active Range of Motion (RoM) of the joints in the lower arm of spastic stroke patients through stretching exercises.
9. The device will have a production price of €200-€300.

Important

1. The product must not actively add kinetic energy to the body: It is a passive assist device.
2. The passive assist force should be exerted as proximal to the hand as possible.
3. The brace must provide passive assist for each finger, or not at all.
4. The product must allow for individual finger movements.
5. The RoM measurement should be sent to the platform without a cable.
6. The brace must not compress the radial, ulnar or median nerve.
7. The product must not obstruct the workspace of the user. As a reference, the workspace of a healthy person is taken.
8. The palm of the hand must be kept unobstructed of mechanisms.

Less Important

1. Provide feedback on the motor recovery of the stroke patient through the Adjuvo Platform.
2. Results from the exercises must be shown to the user and therapist in the form of RoM assessment.
3. The RoM measurement should be detailed enough for a physiotherapist to assess the patient's progress.

4. A risk analysis of the product must be performed.
5. The product must display an indication of its CE marking and registration number.
6. When used for assessment the device must have a standard error of deviation between measurements of at most 7°.

Wishes

1. The passive assist mechanism must be as small as possible.
2. It should be clear (at a glance) which level of passive assist is used.
3. The product keeps the wrist in ±15° palmar flexion to make the finger easier to open OR keep the wrist in 30° dorsal flexion, a functional position.
4. The brace is also used as an assistive device to make Activities of Daily Living easier.
5. Keeping the actuation away from the hand, making the wearable parts easier to clean.
6. Using the RoM measurement system to instruct the user which level of compensation is ideal for them.
7. Incorporating physical objects into the therapy with the passive assist brace.
8. Using the brace suitable for non-spastic stroke survivors by making the passive-assist mechanism removable.
9. The brace is also suited for patients with other afflictions that are paired with spasticity.
10. Make the results (benefits) of stretching exercises tangible for spastic patients to motivate them to keep exercising.
11. Using the sensors on the brace to determine a patient's prognosis in the acute stage, based on finger extension.

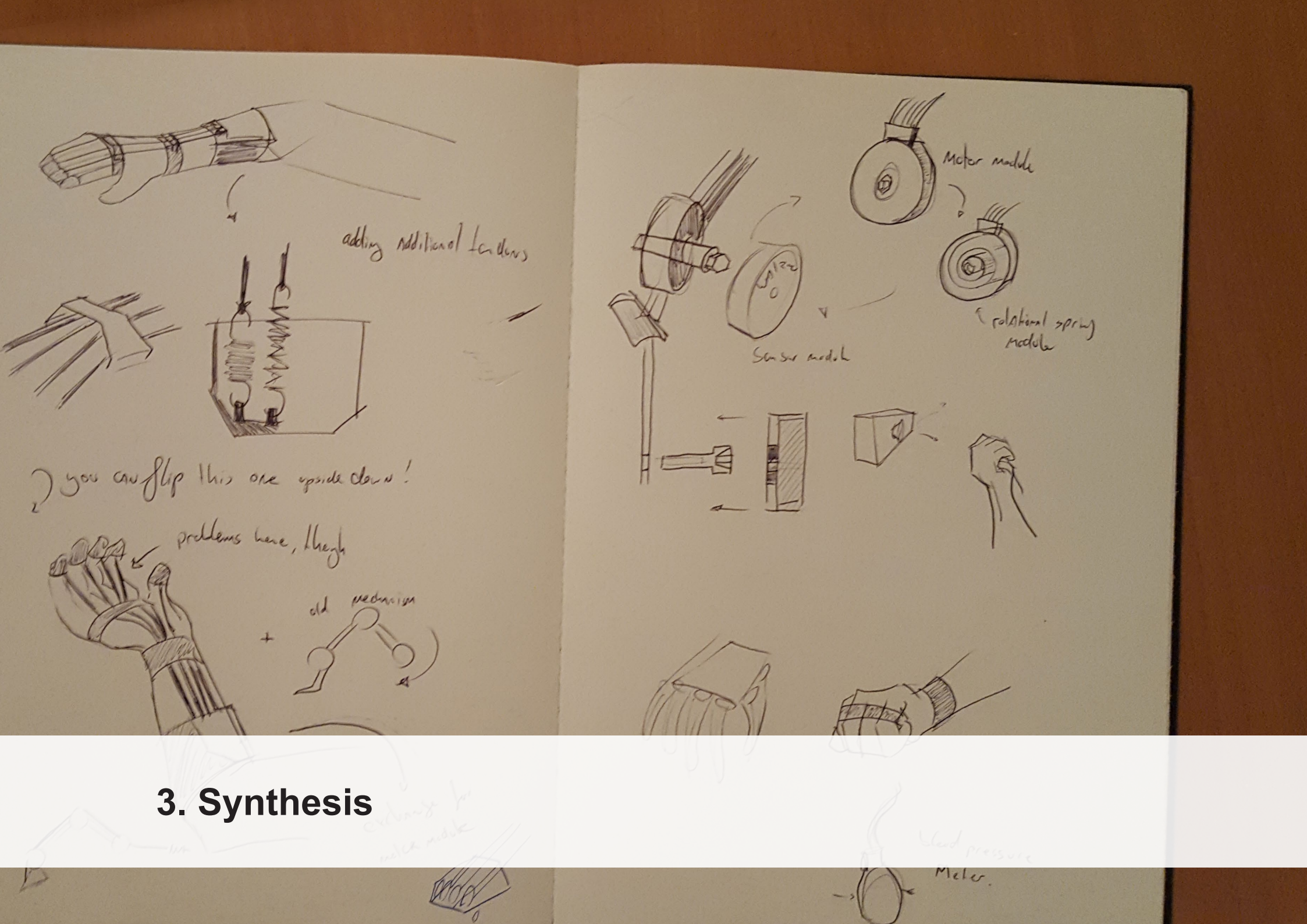
Context Related

1. The product is designed for stroke survivors rehabilitating in outpatient care.
2. Part of the product will be a sensor glove to test the value proposition of the robotic brace with reduced risk.
3. The device makes use of the Adjuvo Platform
4. The product will be designed with a commercial purpose, not for research.
5. The product is not suited for patients suffering from flaccid paralysis.
6. The product is used for therapy, 30-60 minutes at a time.
7. The therapist or rehabilitation doctor will be the ones to advise the use of the passive assist brace.
8. The Adjuvo Platform should allow a therapist to see the progress of all their patients individually.
9. The available caregivers can help equip the product.
10. Patients will be performing exercises with the brace while seated at a flat surface, which will be used for calibration and to relieve the weight of the upper arm.
11. Patients with high levels of spasticity can still use Adjuvo's products if they can (temporarily) reduce the severity of their spasticity, using medication.
12. Create a Unique Selling Point through a product that combines RoM measurement and spasticity compensation.
13. The product can be used by stroke survivors suffering from little to mild spasticity (combined MTS score between 1-10 of max. 15) and with at least a small amount of motor control (FMA >= 7 of max. 28).

2.4.2 Opportunities

Alongside requirements and opportunities for the passive assist brace, the Analysis stage revealed a number of opportunities that, while not directly applicable to this project, are interesting for the company, Adjuvo Motion.

1. Creating an objective assessment of spasticity, based on the Modified Tardieu Scale, using the M-Brace or another active device.
2. Incorporating self-reporting tests (ex. Functional Independence Measure) into the Adjuvo Platform.
3. Creating a modular device that can be adapted to the needs of ‘active assist’, ‘passive assist’ and ‘sensor-only’ therapy.
4. Provide family members a chance to educate themselves about stroke through the Adjuvo Platform.
5. Using challenging games in the chronic stages to train cognitive skills for recreation, or even using the platform as the recreation itself.
6. Linking a patient’s prognosis to one or more of Adjuvo Motion’s products, as part of an insurance package.
7. Incorporating more disciplines into the Adjuvo Platform: Dietitians (Find low-sodium recipes), Speech-Language Therapists (incorporate speech exercises) or Sexologists (allow patients to ask questions anonymously).
8. Offer an option for patients to continue using their brace after their rehabilitation is over.
9. Developing a different passive assist brace that supports users during their Activities of Daily Living with minimum sensors.
10. Using soft robotics to create a comfortable, adaptive orthosis.
11. Entering the VR market with the RoM part of the product.


adding additional tendons
? you can flip this one upside down!
problems here, though
old mechanism
+
Motor module
rotational spring module
Sensor module
Meter.

3. Synthesis

3.1 Approach

The synthesis stage started with the design vision established at the end of the Analysis stage. For the idea generation, the functionality of the brace was split into three sections: Orthoses - the connection(s) to the body, Passive Assist - the method(s) of spasticity compensation and Sensing - the medium(s) used to measure the RoM of the hand. These main sections are composed of multiple sub-functions, each associated with a design problem. The solutions to these design problems are compiled into a Morphological Chart.

Combinations of solutions were made, until three distinct, feasible concept directions remained. These concepts were further embodied with the aid of quick prototypes, until they could be compared using a Weighted Criteria Method. The weights in this method are determined by the analysis results, aided by a physiotherapist. Based this evaluation, the most suitable design was chosen. The process is visualized in Figure 3.1.

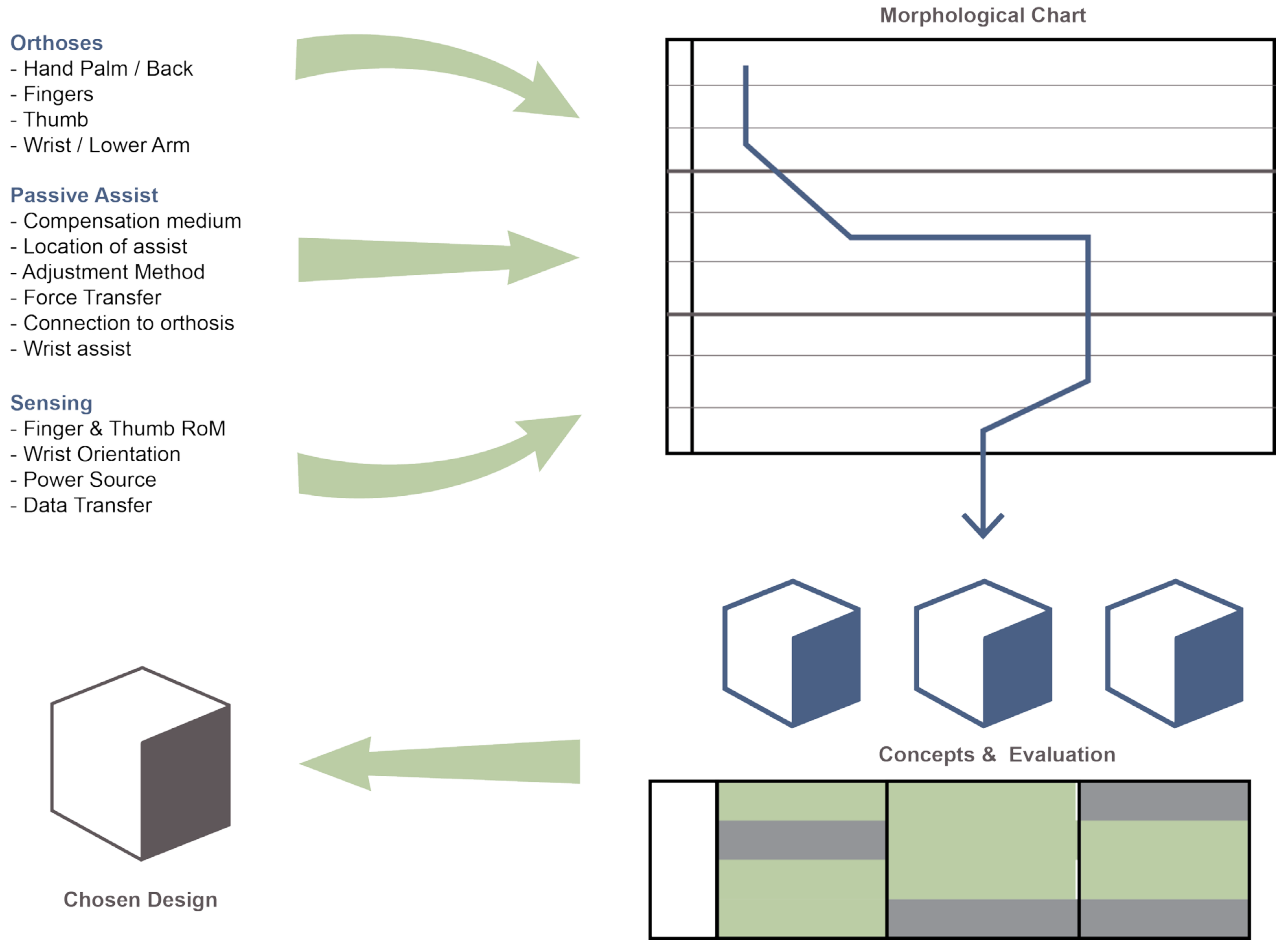


Figure 3.1 - An overview of the synthesis stage

3.2 Morphological Charts

The Morphological chart is a method to generate ideas in a systematic manner, by splitting the various functions of the product into sub-functions, each with their own design problem, for which independent solutions can be generated. These solutions were combined into concepts, which were tested with (quick) prototypes. The result of these charts are combinations of sub-functions that work well together and which form the concept directions in the next chapter..

3.2.1 Orthoses

The orthoses are what connect the brace to the body. It greatly influences how easy or difficult the product will be to equip, and how the passive assist forces are distributed over the lower arm. The solutions to the sub-problems related to orthoses are visualized in figure 3.2.

Hand Palm/Back

Design Problem: Provide a fixation point for the finger & thumb orthoses (as well as an optional wrist orthosis).

Fingers

Design Problem: Transfer compensation force to open the fingers.

(Wrist / Lower Arm)

Design Problem: Optional connection for wrist-hand orthoses, sensing peripherals or passive assist mechanism.

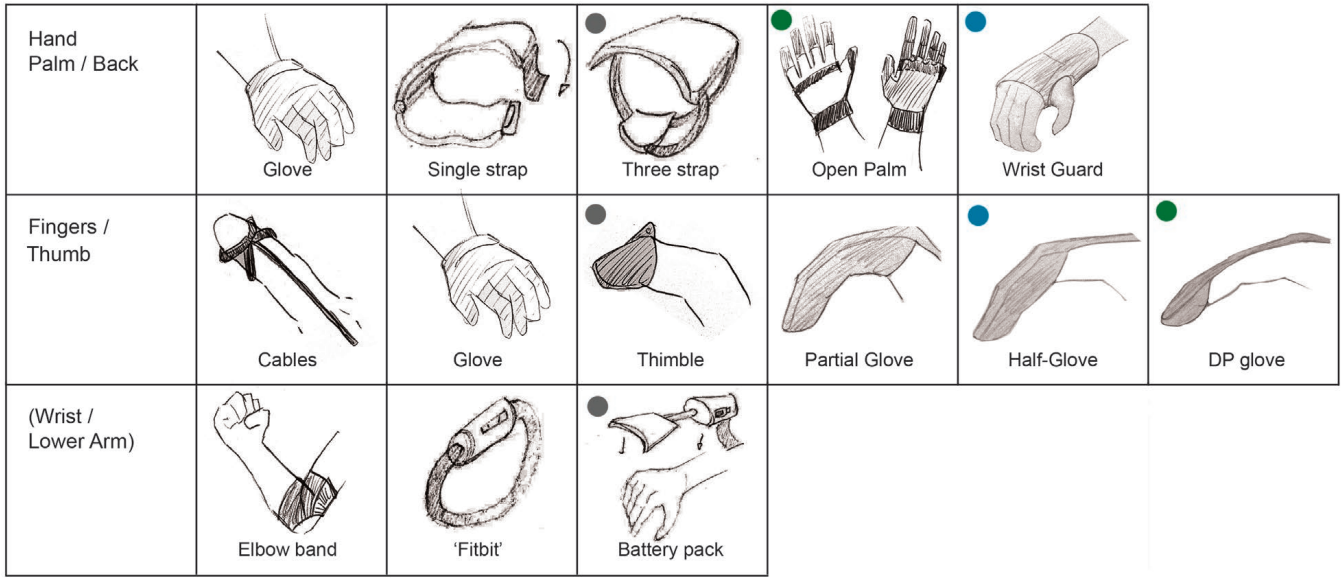


Figure 3.2 - Morphological chart - Orthoses

3.2.2 Passive Assist

The passive assist mechanism compensates for the spastic forces in the fingers, and must be adjustable to match the spasticity level of the user. The solutions to the design problems related to passive assist are visualized in figure 3.4.

Compensation Medium
Design Problem: Which medium is used to store / provide passive force / energy?

Location of Assist
Design Problem: Where on the body is the passive energy stored/released?

Adjustment Method
Design Problem: How can one adjust the level of compensation?

Connection to Orthoses
Design Problem: How is the mechanism connected to the orthoses?

Force Transfer
Design Problem: Can the mechanism be decreased in size and/or complexity by moving the passive assist (away from the hand)?

(Wrist-to-hand)
Design Problem: An optional connection to keep the wrist in the functional position of 30° dorsal flexion.

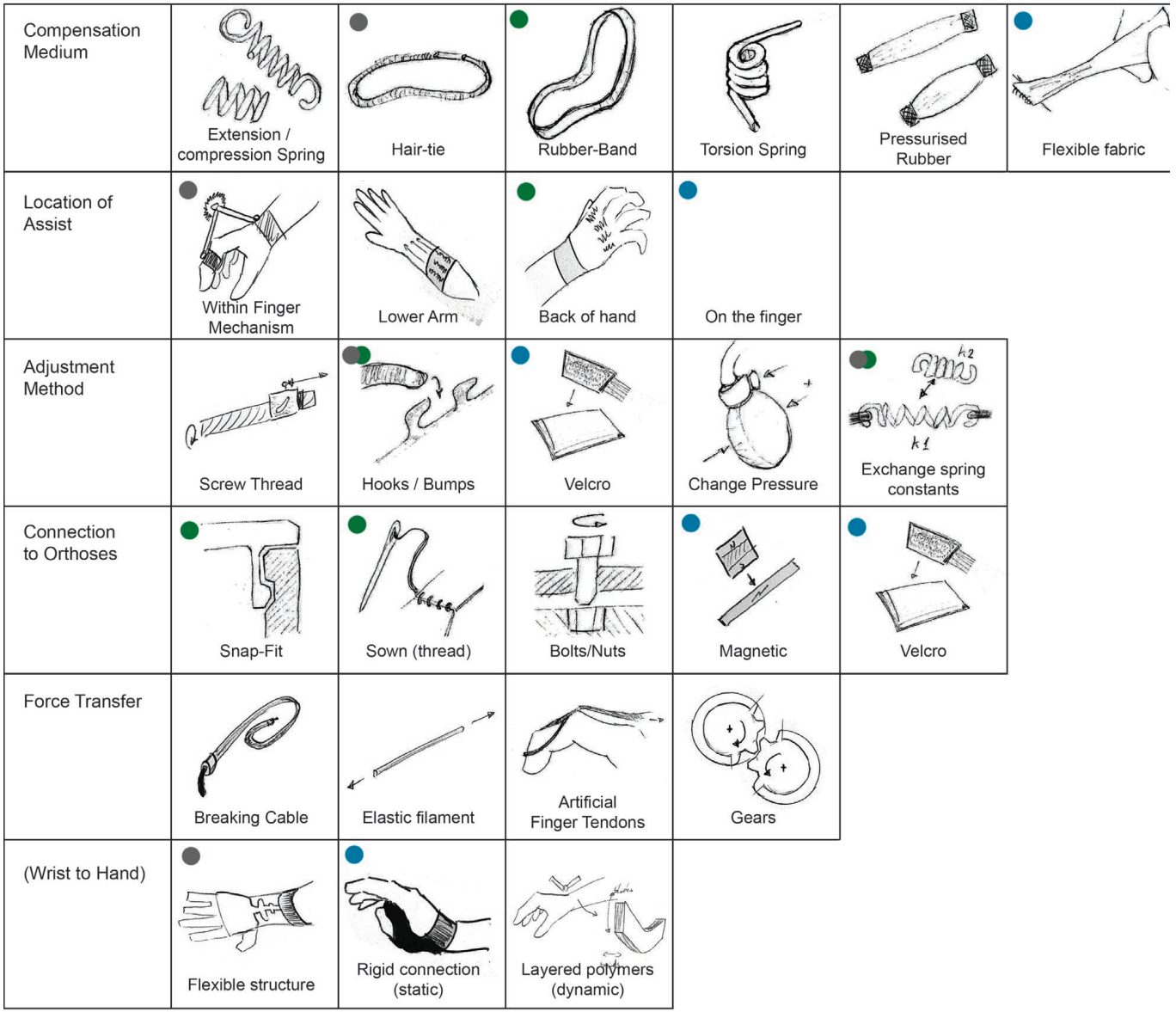


Figure 3.4 - Morphological chart - Passive Assist

3.2.3 Range of Motion Measurement

The brace measures the user's range of motion and uses these as input for virtual exercises. The solution to the design problems related to RoM measurement are visualized in figure 3.5.

Finger RoM

Design Problem: Measuring the Range of Motion of the MCP, PIP, DIP, and CMC joints.

Wrist Orientation

Design Problem: Measure the wrist movements: palmar-/dorsal flexion, radial-/ ulnar deviation, and pronation/supination.

Power storage

Design Problem: Provide power to the sensing mechanism.

Data Transfer

Design Problem: How to send the measured RoM data to the Adjuvo Platform?

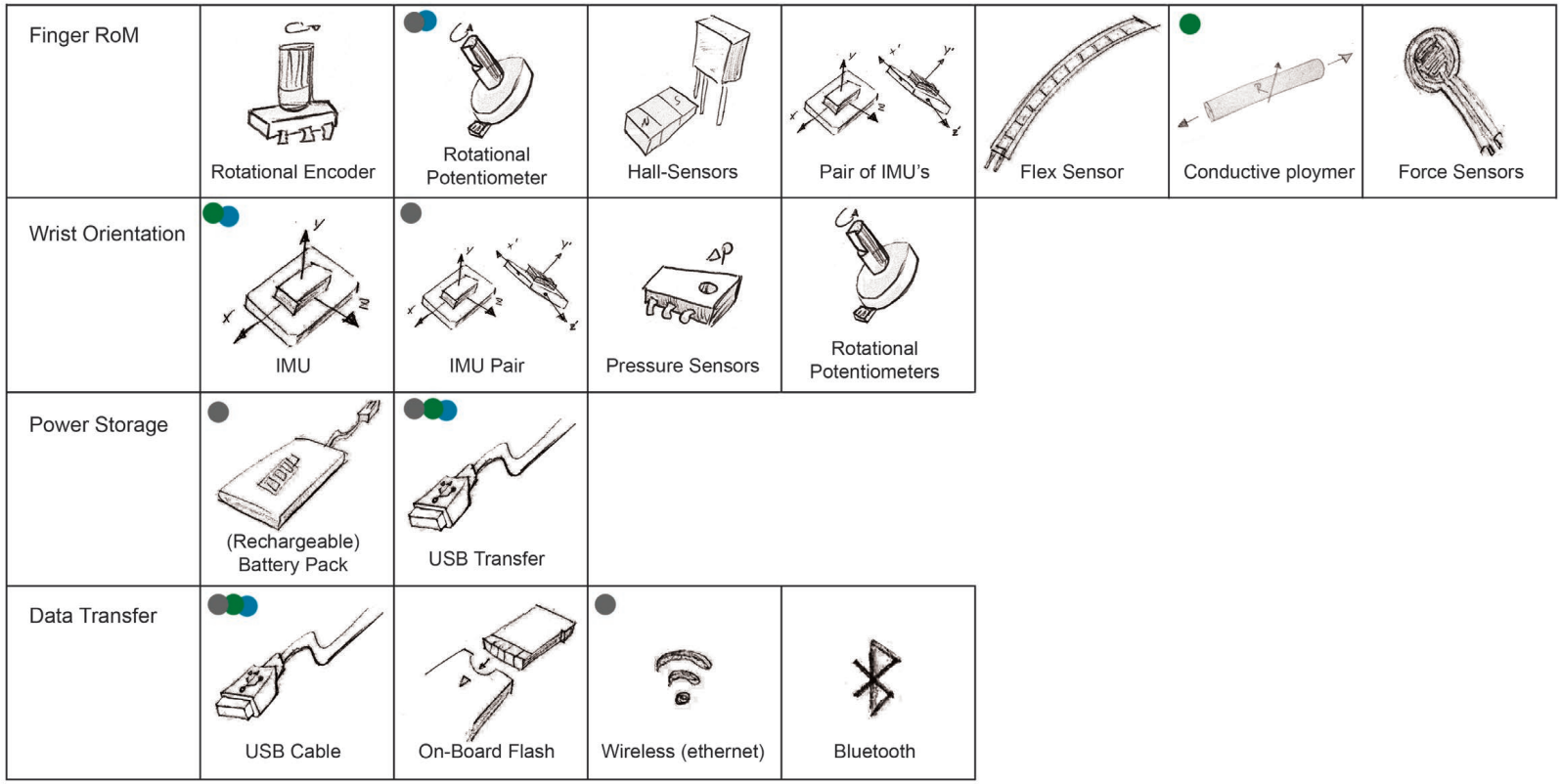


Figure 3.5 - Morphological chart - RoM measurement

3.3 Concepts

This chapter covers the three concepts created using the Morphological Charts. They are named after the methods they use to combine the passive assist and sensing.

3.3.1 Upgrade

“A direct upgrade from the Adjuvo Motion sensor glove”

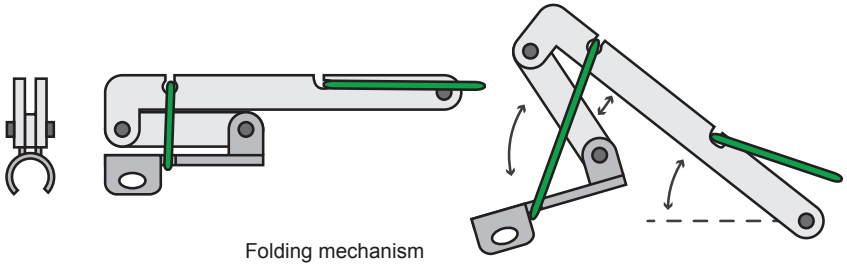
Adjuvo Motion has been working on a first and second iteration of a sensor glove, which includes a sensing mechanism that measures the hand Range of Motion using two rotational potentiometers for each finger and three potentiometers for the thumb. An Inertia Measurement Unit (IMU) is used to determine the wrist movement. The second iteration of this sensor glove uses integrated springs and a folding mechanism to minimize the size of the sensing mechanism, which was perceived as being too large in the first iteration. A comparison between these iterations is seen in figure 3.6.

The first concept, visualized in figure 3.7, represents a direct upgrade to the second iteration of the Adjuvo Motion sensor glove: The Upgrade concept uses the folding mechanism of the second Adjuvo sensor glove, but the passive assist medium was changed from springs to a material similar to hair-ties (An elastic material wrapped in a flexible fabric). This new passive assist medium connects on the outside of the mechanism, allowing for an easier adjustment to different levels of spasticity. The hair-ties also vary in size and thickness, allowing for even more adjustment options.

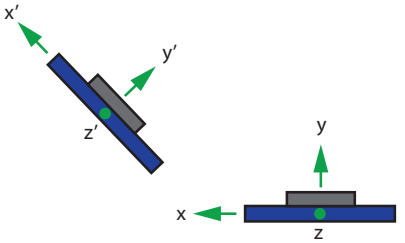
A second IMU was added on the dorsal side of the wrist, which allows the glove to measure wrist movement relative to the lower arm, regardless of it’s orientation. This extended functionality allows much more freedom of movement for the user, which makes an added wireless functionality that much more important. Both the second IMU and wireless chip are combined into a separate ‘module’. This module can be worn independently from the larger sensing mechanism and worn during the day. Using the IMU, the module can detect if a stroke patient is using their hand in daily tasks and, in case they are not, remind them to use it.

Although it is an upgrade, the concept is still far from finished: The connection of the mechanism to the fingertip, which is necessary to capture each joint movement, is currently created using thin metal ‘thimbles’, which can be bent to fit a user’s fingers. However, these thimbles are still unreliable, having a tendency to slide off during finger extension. Furthermore, while the passive assist is fully customizable, the usability could be improved by reducing the amount of hair-ties needed.

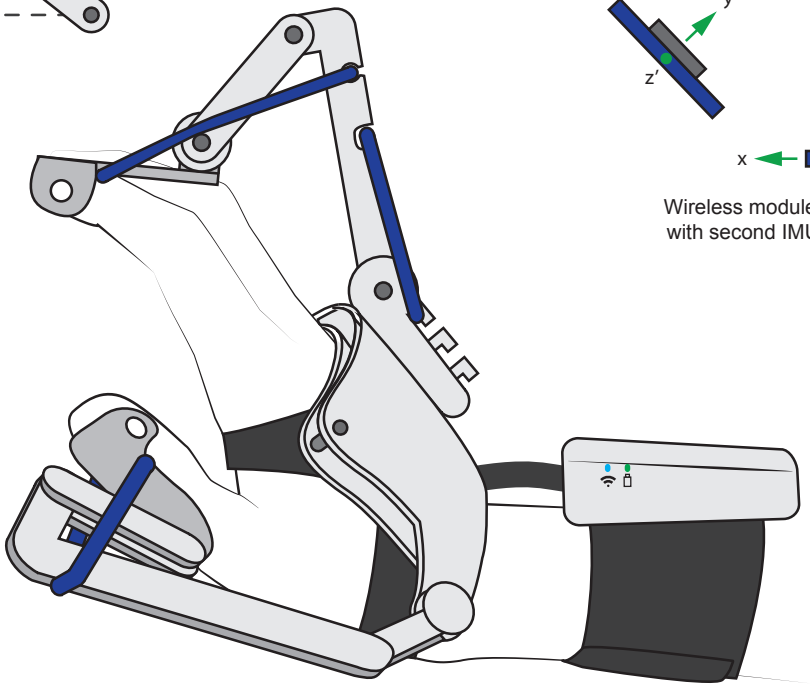
Figure 3.6 - Iterations of the Adjuvo Motion Sensor mechanism.

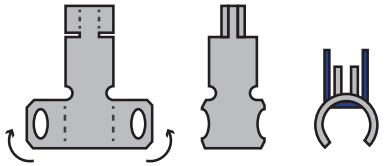


Folding mechanism
to minimize size



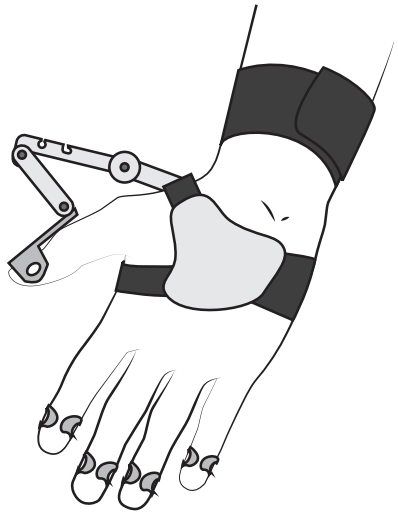
Wireless module
with second IMU





Bendable metal thimbles
which form a secure,
yet adjustable connection

Different options
for Size / Length of bands



‘Three strap’ orthosis.

Figure 3.7 - Upgrade Concept - Overview

3.3.2 Integrate

“A full integration of the passive assist and the sensing medium”

The Integrate concept is based on the principle that the resistance of an electrical wire is dependent on it’s length and thickness: According to (Shetty & Kolk, 2012), the resistance of a wire (R [Ω]) can be calculated by multiplying it’s resistivity (ρ [Ω/m]) with its length (L) and diving this by Its cross-sectional area (A [m^2]). Using conductive silicone bands which change these variables as they are stretched, this relatively small change in resistivity can be used to create a medium that both measures and compensates (see figure 3.8). The the conductive silicone is spanned between two opposing metal hooks to create a consistent contact for the electrical signal while still allowing one to switch to a higher or lower level of compensation.

The design of the passive assist mechanism, seen in figure 3.9, is based on that of the SaeboGlove, which uses regular hair-ties. The Integrate concept presents an improvement over this competitor by adding a Range of Motion measurement. Unfortunately, the Integrate concept’s unique feature is also its greatest weakness: The conductive rubber bands are highly variable, with an unknown change resistance depending on repeated stretching, creep and the level of adjustment. Therefore, this concept requires a calibration step each time the user makes a change to the level of spasticity compensation.

While the individual joint support allows the device to measure up to 15 finger joint angles, only those of the thumb, index finger and middle finger are covered, as these three fingers are used during all grasps that are important in daily tasks. This results in ‘only’ 9 measured joint angles, which reduces the electrical complexity of the product. It also opened up discussion about not supporting all fingers with physiotherapists.

Wrist movement is measured by a single IMU: Due to the small mechanism, exercises can be performed with the lower arm on a flat surface, much like the Raphael Smart Glove. Due to its minimal size, the glove can be used during daily life, and assess or remind the stroke patient using 9 joint angles and the less accurate wrist movement.

In order to bring this concept closer to completion, several tests need to be conducted in order to verify the working principle of the conductive polymers. Furthermore, the metal hooks need to be iterated upon to ensure a consistent electrical connection from which the resistance of the conductive bands can be measured.

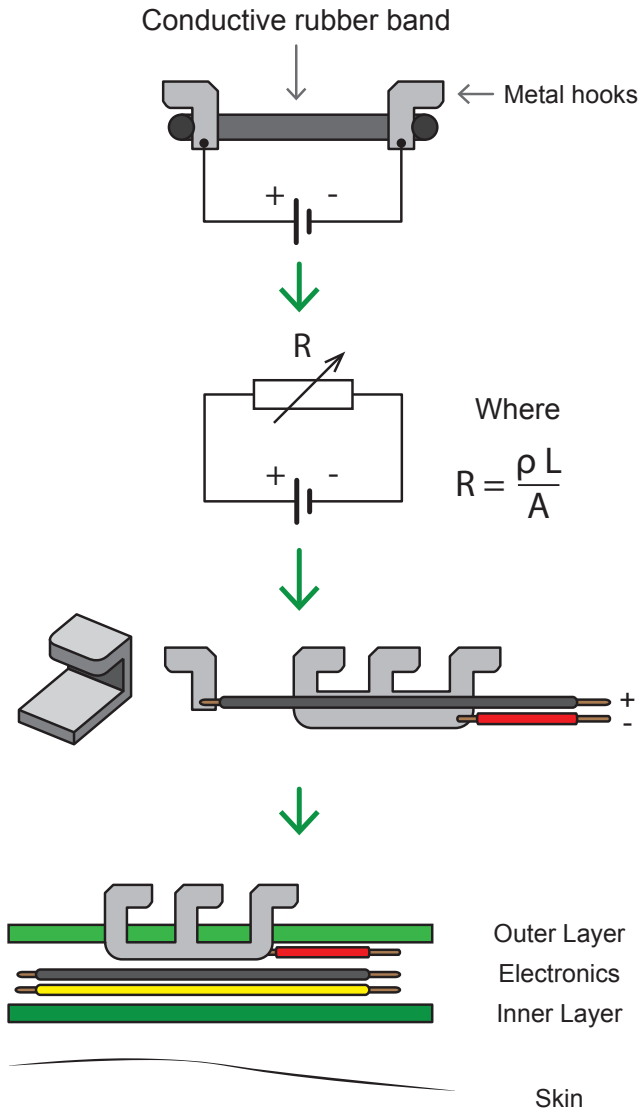


Figure 3.8 - Working principle of the conductive silicone as sensors.

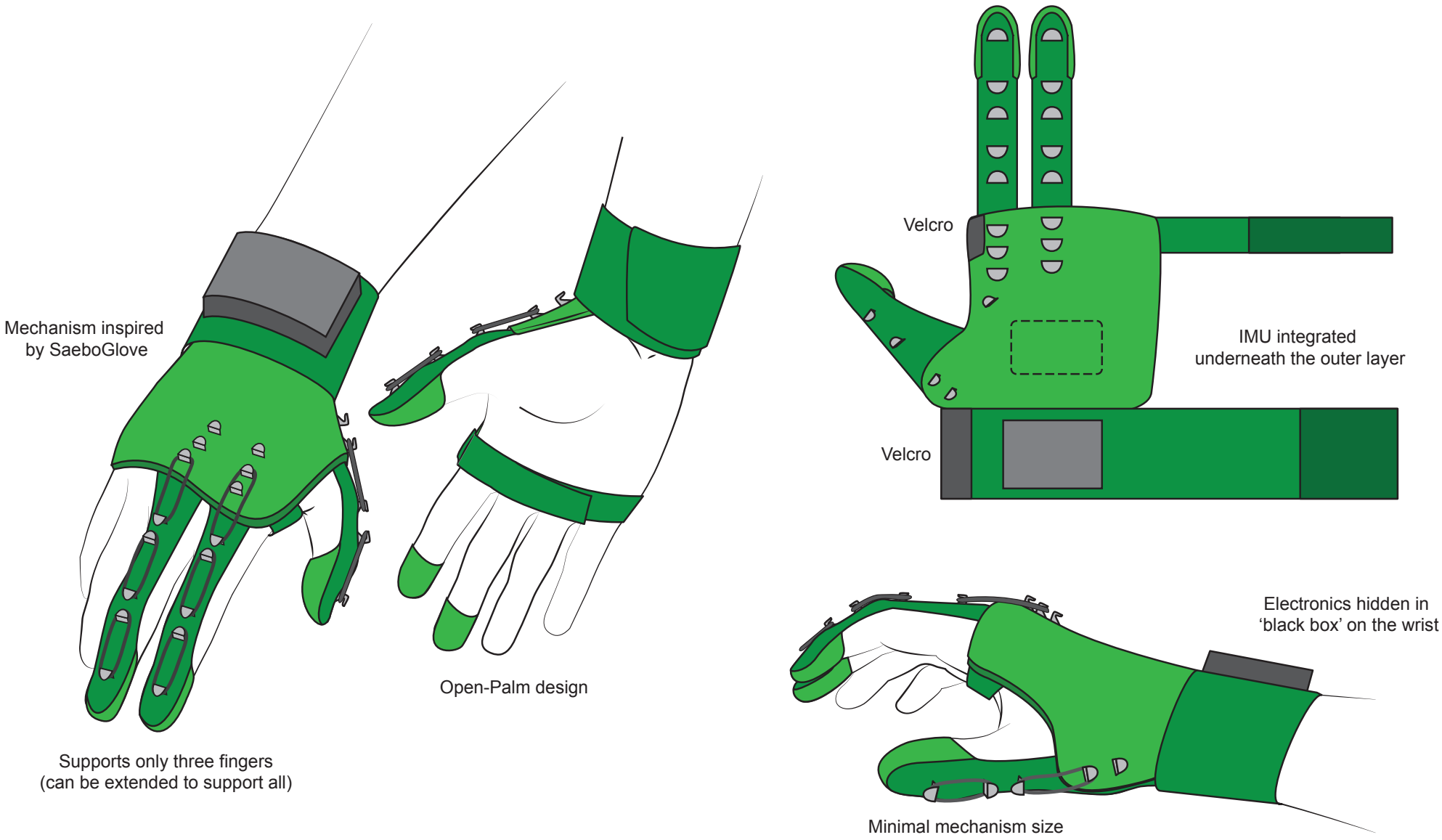


Figure 3.9 - Integrate Concept - Overview

3.3.3 Separate

“Separating the sensing and assist function into different components”

As a complete opposite of the Integrate concept, the Separate concept aims to split the passive assist and sensing mechanism into a modular product. The first part of the product is a simple passive assist glove that can be used to make Activities of Daily Living (ADL) easier. The passive compensation is provided to each finger by a stretchable fabric that spans between the Medial Phalanx and the back of the hand. These ‘finger units’ are fixed to the back of the hand using Velcro. The hand orthosis of this glove is similar to that of a wrist guard used in skateboarding, complete with a hard component that keeps the wrist in a functional position of 30 degrees dorsal flexion for ADL. Being completely free of electronics, the wearable parts of the concept, seen in figure 3.10, can be tossed in a washing machine.

The second part of the product consists of the sensor module, which uses a mechanism similar to the first iteration of the Adjuvo Motion sensor glove (seen in figure 3.6). As part of the envisioned use case, the user will first equip the ADL glove, placing the wrist and fingers into a functional position. This will make it easier to connect the sensor mechanism to the fingers, as seen in figure 3.9. Because the assistive forces of up to 5N are on the glove and not the mechanism, the connection between the fingertip and sensing mechanism becomes easy remove. In this case, the choice was made for magnets due to their near automatic alignment and the small forces required to remove them again.

In order to make this concept feasible, a consistent connection between sensing mechanism and fingers must be created, as a difference in placement of the sensors between sessions also means a difference in output. The magnetic connections between the mechanism and finger units must be revised, as early prototypes lost this connection at higher speeds.

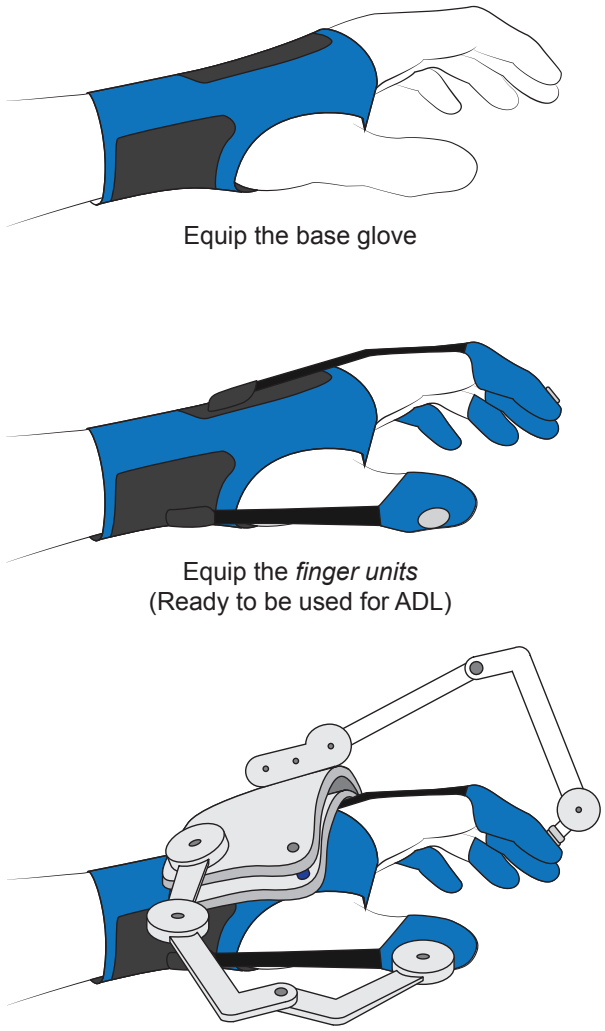
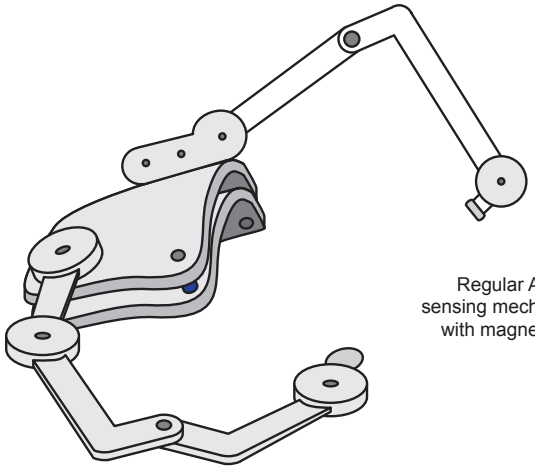
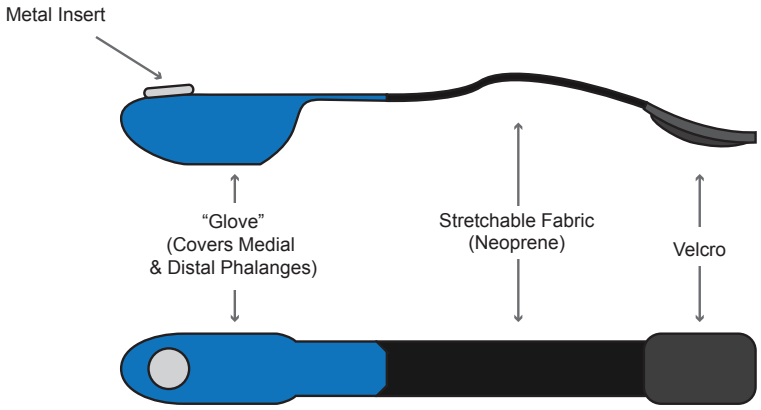


Figure 3.9 - Steps to start using the Separate Concept.

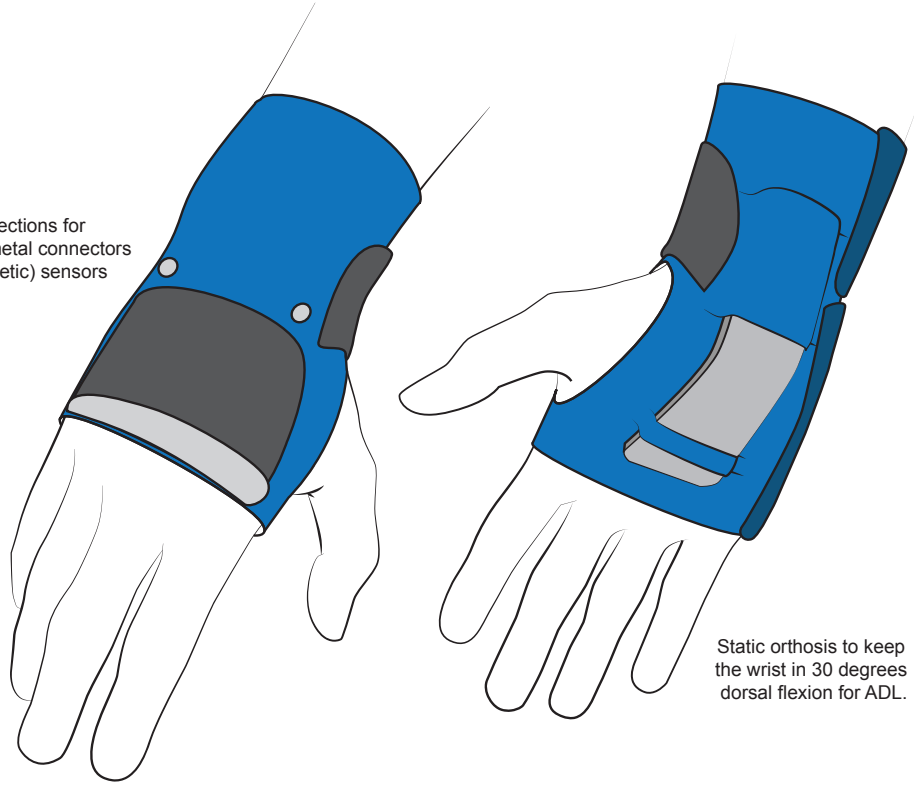


Regular Adjuvo Motion sensing mechanism, extended with magnetic connections

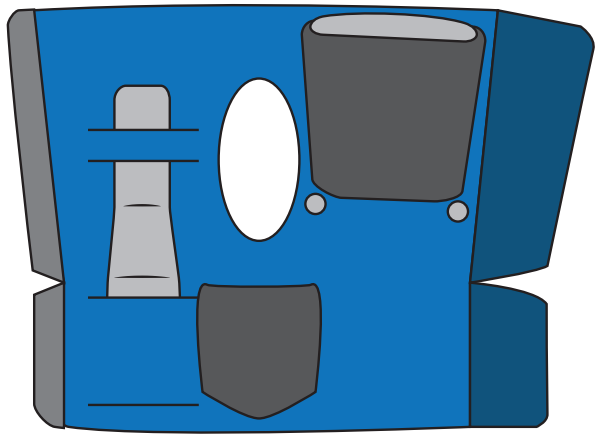


Finger Units

Velcro connections for passive assist, metal connectors for the (magnetic) sensors



Static orthosis to keep the wrist in 30 degrees dorsal flexion for ADL.



Base glove similar to a wrist guard.

Figure 3.10 - Separate Concept - Overview

3.4 Evaluation

The *Upgrade*, *Integrate* and *Separate* concepts were evaluated using a Weighted Criteria Method, using the following criteria:

Steps to put on - Weight: 20
The amount of steps required before one can use the brace. Assessed by setting up use scenarios and counting the number of steps it takes before the brace is ready for use.

Time to put on - Weight: 15
The amount of time required before one can use the brace. Assessed by timing oneself putting on prototypes at a reasonably slow pace.

Hygiene - Weight: 15
How many steps does it take to clean the (worn parts of the) product? Assessed by another use scenario where the products are either dis-assembled until they can be put in a washer or until they are cleaned by hand.

Data resolution - Weight: 10
The amount of joint angles measured. Determined by the number of joint angles that can be measured by the device, both with and without assumptions.

Passive Assist - Weight: 10
Similar to the data resolution, this criteria score is determined by the amount of possible joint angles that receive passive assist.

Weight - Weight: 10
How much do all components weigh together? Assessed by weighing early prototypes using a kitchen scale.

Complexity - Weight: 5
The total amount of components used to create the product. Assessed by setting up a list of components for each concept.

Price - Weight: 5
Manufacturing costs of all components. Assessed by a rough estimation based on similar products and / or components.

The weights of these criteria were based on priorities set by a physiotherapist, as well as the requirements of the Analysis stage.

Each concept was first scored individually against the *Raphael Smart Glove* by *Neofect*; a competing product that is easiest to put on and which represents a large number of (VR) measurement devices that are currently available. These scores were then normalized between concepts to create a score between 0 and 1. Evaluation was done for both a ‘worst case’ and ‘best case’ scenario to cover a range of possible scores, rather than a single number. Refer to Appendix G for a full breakdown of the scoring in the Weighted Criteria Method.

The final scores for each concept are visualized in figure 3.11 as a range between the best and worst case. Based on the criteria and weights used in this evaluation, the *Separate* concept scores higher than the others. This can be explained by to how easy the product is to clean due to the separation of the sensitive electronics. It is also both the easiest and hardest to put on of all the concepts, which depends on if the user is already wearing the ADL part of the concept, which makes the equipping steps much simpler. As seen in Appendix G; even when shifting the weights the *Separate* concept remains the strongest contender.

It was for these reasons that the separation of passive assist and sensing was chosen as the best suited solution for spastic patients rehabilitating in the home context. To supplement its design, a few elements from the other concepts were integrated into the Separate concept: The more compact mechanism and wireless functionality used in the Upgrade concept are integrated into the sensing part to make it easier in its use. The open palm glove from the *Integrate* concept was also incorporated in the final design, as it creates a platform on the back of the hand for the user to attach the finger units without needing to open the hand first. This integration between concepts is visualized in figure 3.12, and was given a name to reflect its function; the *Auxilius*; derived from the Latin word *Auxilia*, meaning *aid* or *help*.

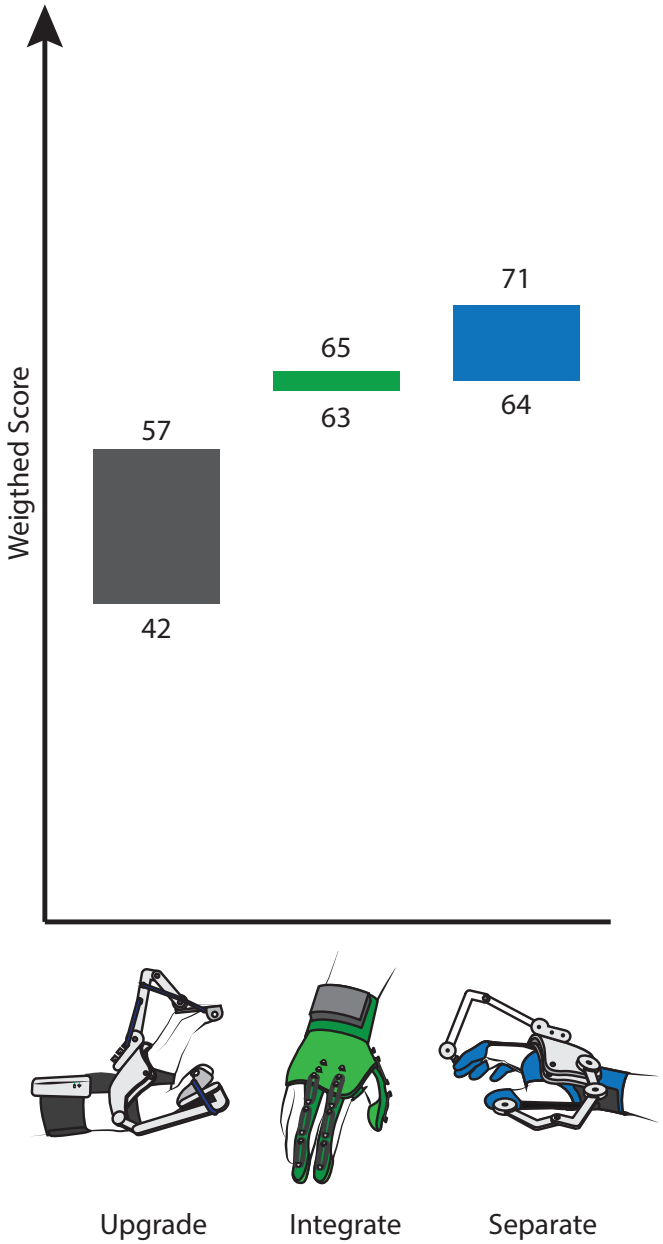


Figure 3.11 - Evaluation Results.

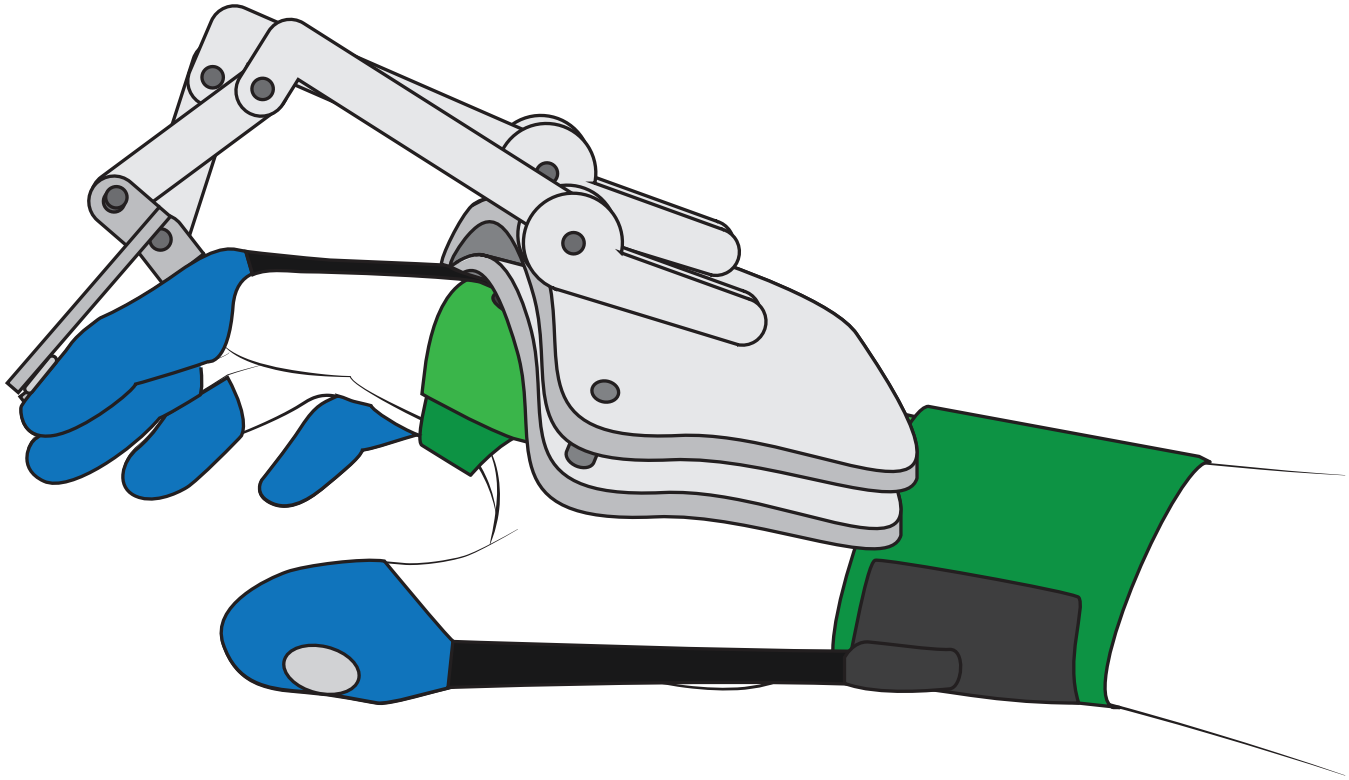


Figure 3.12 - A quick representation of the chosen concept.

4. Prototyping

Based on the chosen concept design, a number of iterations were made to find the right solutions that would make the Auxilius easy to equip and comfortable to wear. The goal of this stage was to test variations on the chosen design in terms of performance and comfort, while gaining insight in the production and materials of each component. These variations were tested by healthy subjects using prototypes. Based on this evaluation, a 'final prototype' was created for the more rigorous evaluation covered in chapter 7.

To streamline the design process, a focus was placed on four critical points, shown in Figure 4.1, that would make or break the concept:

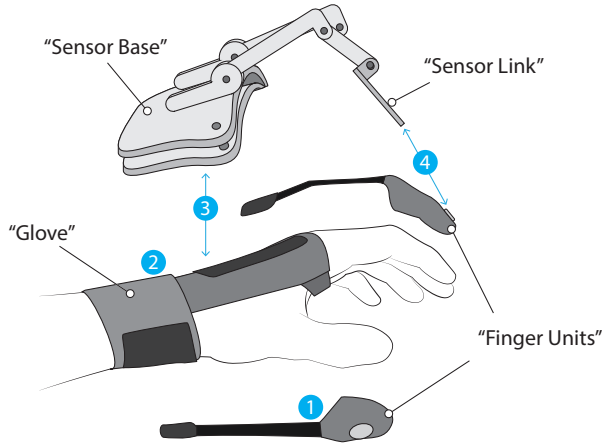


Figure 4.1 - Critical points in the design

1) Equipping the finger modules to a spastic fist / finger.
This is the biggest challenge to the product: The user should be able to wrap the finger modules around a flexed finger that has little to no extensor function, using only their unaffected hand.

2) Creating a stable glove that can be equipped with one hand, onto which one can add the sensor- and finger modules.
An unstable base will influence the accuracy of the RoM measurement. This glove part is also the first thing the user equips, and sets the tone for the rest of the 'equipping experience'.

3) Creating a consistent connection between the sensor module and glove which is easy to remove, and does not interfere with the passive assist.
Differences in placement of the sensor base will influence the consistency of the measurements between therapy sessions.

4) Creating a consistent, secure connection between the sensor links and finger modules.
The last links of the sensor mechanism must connect to the fingertips in order to measure the full RoM of each finger. It must have a consistent placement in between measurements, and remain connected during exercises.

In total, 4 prototypes were created and evaluated, an overview of which can be seen in figure 4.2. Figure 4.3 on the next page shows an impression of the prototyping stage, while figure 4.4 shows the evaluation of each iteration. This evaluation is fully elaborated in Appendix H- Iterations on the chosen design.

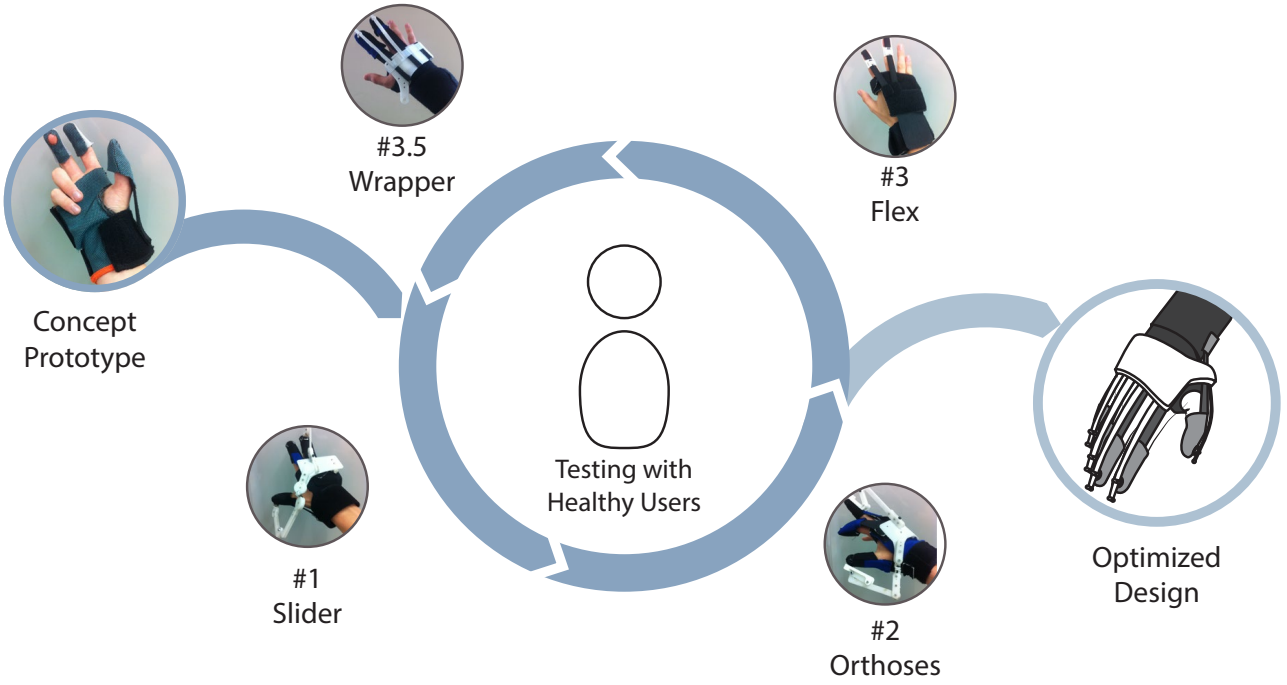


Figure 4.2 - An overview of design iterations.

Figure 4.3 - Impressions of the prototyping stage

During the prototyping stage, a critical look was taken at the chosen design for the sensing mechanism. Both the traditional- and folding sensor mechanism were considered to be 'too large and bulky', which made the product look too complex and intimidating. An attempt was made to reduce the size of the sensor mechanism using flex sensors, which are common among competing products.

Flex sensors only measure the bending of the fingers with 1 DoF, which is enough to recognize most functional grasps covered in Appendix E. Switching to the less accurate flex sensors makes the creation of a consistent sensor placement less important, since the sensors will require calibration when equipped.

From conversations with a physiotherapist of the Sophia Centre of rehabilitation, it became clear that there were two scenario's where an integration of passive assist and RoM measurement would be beneficial for spastic patients, as visualized in figure 4.5:

1) At the onset of spasticity, repeated training of the extensors could prevent the development of a tight fist, and 2) During the chronic stages of spasticity, the passive assist could be used to assist in ADL and/or stretching exercises. Another important factor was that: "as the spasticity increases, the accuracy becomes less and less important".

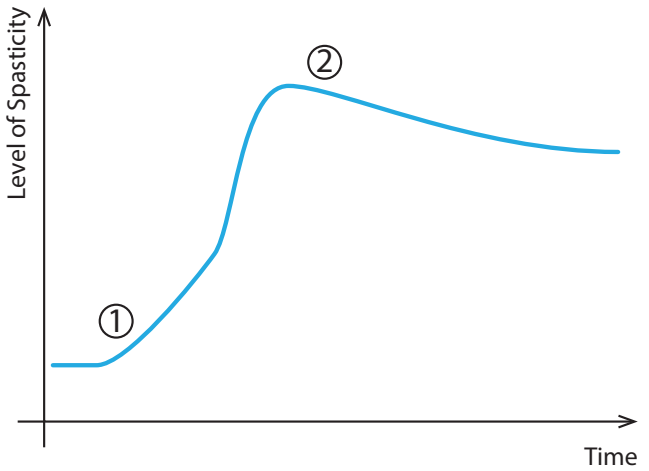


Figure 4.5 - When to use a smart passive-assist glove?

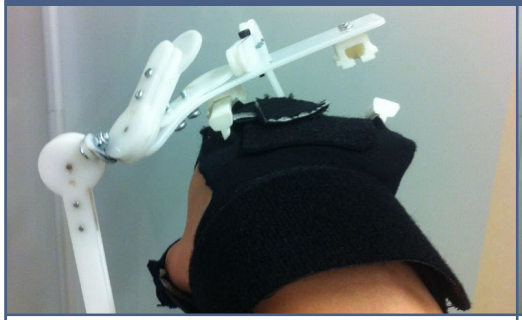
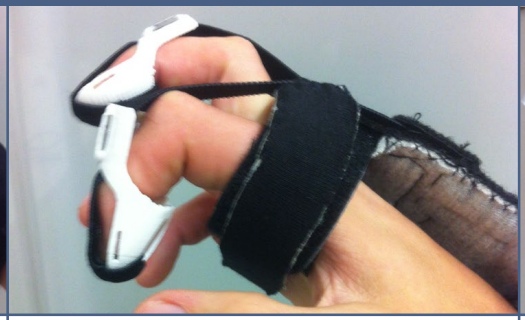
#1 - Slider	#2 - Orthosis	#3 Flex	#3.5 - Wrap
			
This is the first version of the design, which uses a sliding mechanism to create a consistent placement of the sensors, while still being removeable in one motion. Unfortunately, the sliding mechanism tends to get stuck due to friction, and gets in the way of the placement of the finger units. This type of connection will also not fit when someone has a different curve on the back of the hand, and must be replaced. The magnets on the sensor mechanism proved too strong for the metal rings on the outside of the finger module: The rings were ripped off the module after a few tries.	Improving upon the first iteration, several 3D printed orthoses were added as a way to facilitate equipping the glove. While the glove did in fact become easier to equip, those with larger or smaller hands were hindered by the orthoses instead. The sliding connection as replaced with a magnetic one, which could adapt to different hand sizes. Due to the magnetic connection, the sensor module was easy to equip and remove. However, a similar magnetic connection could not be achieved with the folding sensor mechanism.	This iteration used semi-rigid othoses in a two-part glove to make it suited for all hand sizes, which functioned worse than the rigid orthoses. An attempt was made to reduce the size of the sensor mechanism using flex sensors, which are common among competing products. Instead of using finger modules made from fabric, this iteration used rigid orthoses based on the so-called stack splints. The rigid finger modules were the easiest to equip out of all solutions, but take away the sense of touch and interferes with the stretch fabric.	To make the 'open palm glove' easier to equip, it was split up into more and more components, to the point where the equipment process became overcomplicated. In an attempt to improve upon the design, the open palm glove was replaced with a standard Prescot wrist bace. The shifting of the flex sensors during flexion / extension was solved through a mechanism insipred by the *Raphael Smart Glove* by *Neofect*. Hard rings were integrated into each finger module, which led to a solution that should wrap around a spastic finger without much trouble.

Figure 4.4 - Evaluation of the iterations

For the first scenario, a sensor glove solution with a training schedule that focuses on the extensor muscles can work just as well as a passive assist glove. The second scenario is in line with the original vision of this project, and will allow the separation of functionalities to become even more relevant by allowing the product to also assist in ADL. However, a high-accuracy sensor system will no longer be as important.

Therefore, the default Adjuvo Motion sensor glove will be used to treat onset spasticity (scenario 1), while the result of this project will become a secondary product for patients that already suffer from chronic spasticity, or for whom the sensor glove therapy does not work (scenario 2). With this *"no patient left behind"* approach, Adjuvo Motion can help most spastic stroke patients, with the exception of those suffering from severe spasticity.

Looking back at the competing products; every one of them has a full integration of sensors into the wearable parts, though the electronics have been made almost watertight to make them hand washable (ex. Manus Machina). The separation of these functionality can make the product much easier to clean, as the wearable parts can be tossed into the washing machine.

Since a lower accuracy is required for chronic patients with spasticity (Scenario 2 in figure 4.5), the Adjuvo Motion sensor mechanism is replaced with flex sensors, which make the design of the sensor module much simpler. Thumb abduction / adduction is still measured with a rotary potentiometer. This decision means that the chosen design cannot measure accurate finger angles, but can still distinguish between the different functional grasps analyzed in chapter 2.2.2. This decision is still in line with the vision established at the end of the Analysis stage; *"A smart brace to support spasticity management in post-stroke rehabilitation"*.

The result of this decision is the design shown in figure 4.6, which will be embodied within the next chapter. Changes to this design will still need top be made in order to optimize its functionality and manufacturing process.

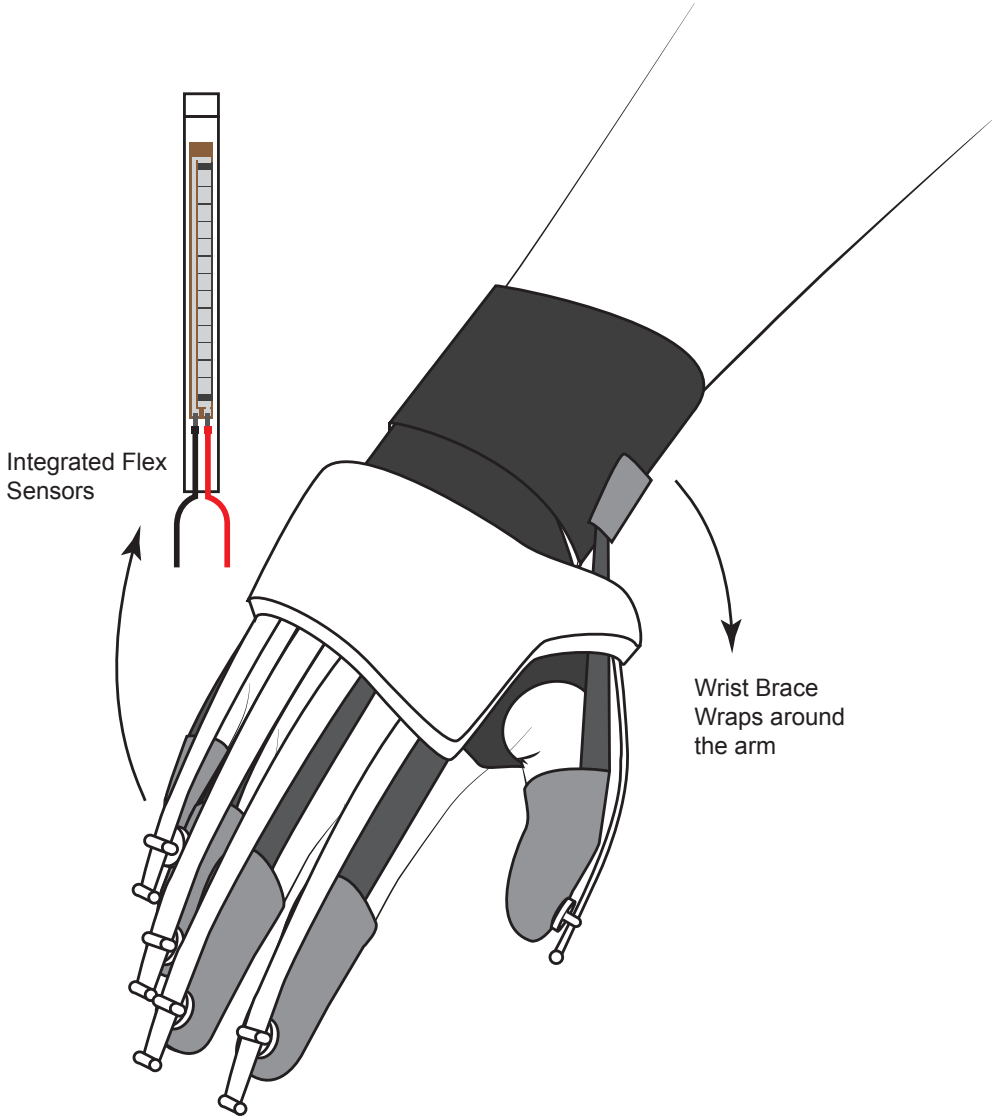
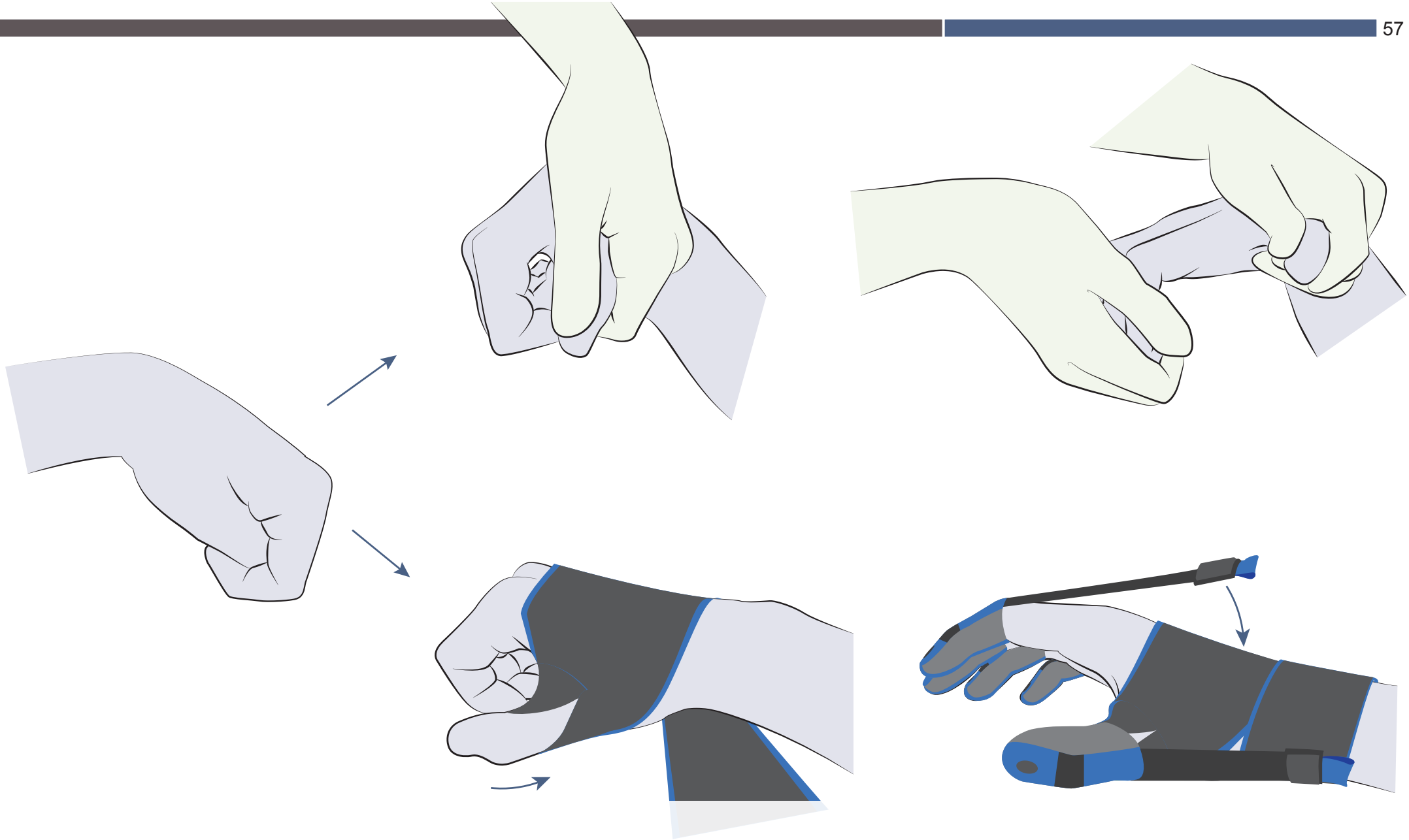


Figure 4.6 - Last iteration of the prototyping stage



5. Adjuvo Auxilius

The Adjuvo Auxilius is an assistive glove that is designed to help spastic stroke survivors, who are rehabilitating from home, in their Activities of Daily Living (ADL) and physiotherapy exercises.

With spasticity, the parts of the brain that have been damaged during a stroke are sending conflicting messages to the muscles, causing them to contract. Because flexor muscles are stronger than the extensors, the contracting muscles pull the affected joints into one position, such as a closed fist of flexed elbow. When spasticity in the lower arm occurs, the hand is formed into a tight fist that inhibits the grasping motions of a stroke survivor. In certain cases this can lead to a neglect or non-use of the affected arm, which will make it difficult to recover from spasticity. This affliction is sometimes paired with a weakness in the arm, which makes it even more difficult to overcome the spastic forces.

Since the grasping motion of the hand is such an important motion in everyday life, the focus of the design was to compensate for spasticity of the finger flexors and the thumb adductor. To compensate for these muscles, the Adjuvo Auxilius adds an additional set of extensor / abductor muscles to the fingers in the form of a stretch material. This material does not actively add kinetic energy to the body, instead storing it when the finger flexes and releasing it when the muscles are relaxed. This compensation of the flexor muscles creates a new, functional ‘open’ position, from which it is possible to perform ADL and stretching exercises. Figure 5.1 visualizes this working principle using the chosen design.

The Auxilius comes with a removable sensor module, which is used to facilitate functional- and stretching exercises at home through the Adjuvo Platform. These exercises serve to create a temporary increase and assessment of the user’s Active Range of Motion. The assessment, which is done through five flex sensors, a rotary potentiometer and an Inertial Measurement Unit, is sent back to the user’s physiotherapist, who can monitor the rehabilitation program and adjust it as needed.

To get the design visualized in figure 5.1, the results of the synthesis stage and the iterations made during the prototyping stage were combined, and a number of design decisions were reviewed This chapter covers the most important decisions regarding the chosen design on a sub-assembly level, starting with the connections between components and the sub-assemblies thereafter.

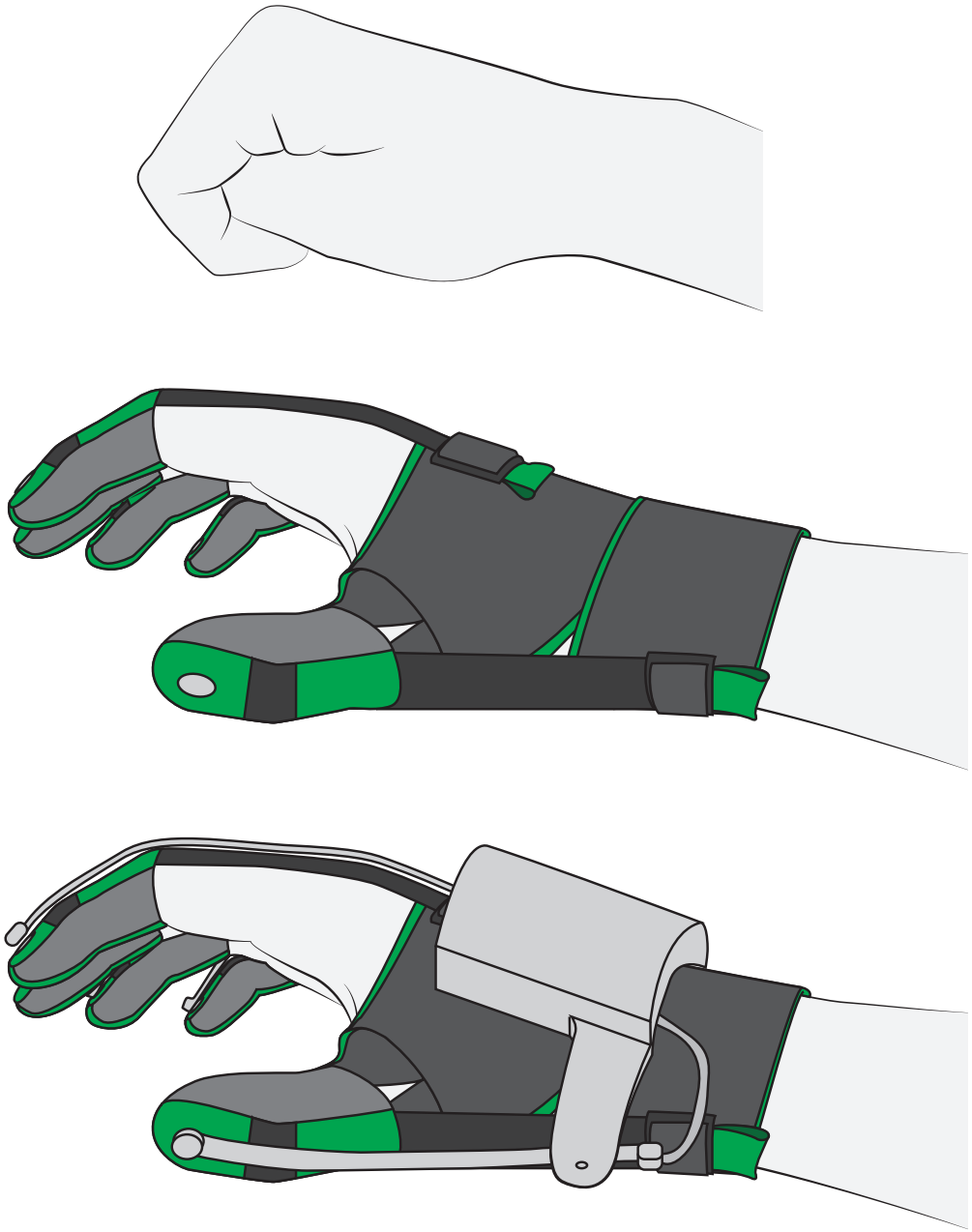


Figure 5.1 - The Adjuvo Auxilius.

5.1 Connections

The product consists of four sub-assemblies: The *Wrist Wrap (A)*, *Finger Modules (B)*, *Sensor Base (C)*, and *Sensor Links (D)*. Since the connections between components shape their individual design, these will be covered first. They are numbered according to the components they unite, and are visualized in figure 5.2. More in depth calculations regarding these components can be found in chapter 6.5 - Durability.

AB - Finger Module to Wrist Wrap

This connection transfers the spasticity forces of 5N to 8N onto the wrist wrap orthosis. The connection should be adjustable to the spasticity force by changing the (pre)tension in the stretch material. Looping the material around hooks on the wrist wrap would create the most durable connection. However, due to the variations in hand sizes between users, the hooks cannot be guaranteed to end up neatly aligned with each finger. A similar problem exists with pop buttons, snap-fits or sliding systems. A Velcro connection, on the other hand, does not rely on additional components sown into the wrist wrap, which relies on Velcro to begin with, and is more cost effective to boot. Durability analysis, covered in chapter 6.5, shows that a Velcro connection is tough enough to withstand the spastic forces for a number of years.

Velcro connections have two sides; one male (hooks, hard) and one female (loops, soft). When a Velcro connection breaks, it is usually the soft female side that breaks first. For this connection, it is beneficial to put the male side on the finger module, which leaves the wrist wrap soft and comfortable while ensuring that the more complex finger modules last longer.

AC - Sensor Base to Wrist Wrap

This connection ensures that the sensor base is kept on the dorsal side of the hand. It should not fall off during exercise, yet should be easy to remove from the wrist wrap. The electronics, assumed to weigh 0.150kg, should not fall off when they are upside down (Fz = ±1.5N), or flung off when the patient pronates/supinates at reasonable speed of 60 degrees per second (Wimpenny, 2016). For the latter situation, the electronics are modelled as a point mass circling the palm at a constant radius of 40mm, which results into a centrifugal force of (F=m*r*ω^2=) 0.006N, which places the maximum force on this connection at ±1.5N.

Again, this connection could be created using pop-buttons, snap-fits or sliding systems, which again provide a robust connection but cannot be guaranteed to line up with the fingers. Another option would be to incorporate metal plates into the wrist wrap, which would allow for a more flexible magnetic connection to be made. However, this would add a number of components to the product for relatively little gain, as the sensor module could utilize the same Velcro connection between the wrist wrap and finger modules instead.

BC - Sensor base to Finger Module

Because the finger modules take up space on the wrist wrap, they take away some of the Velcro surface for the sensor base, weakening the connection. Therefore, the finger modules will have a double-sided Velcro connection, with the male side on the bottom and a female side on top. The choice for Velcro is implied by the previously established connection between the wrist wrap and sensor base. It is desirable to make this connection slightly weaker than the connection between the finger modules and wrist wrap, to prevent the user from removing the finger modules with the sensor module.

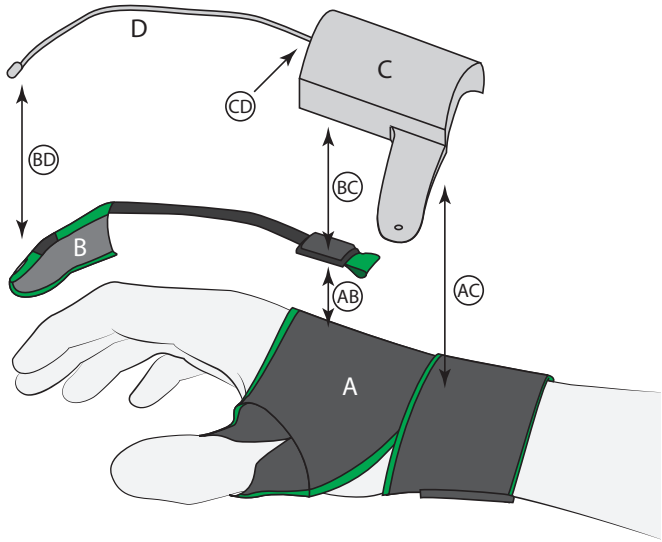


Figure 5.2 - Connections in the Auxilius.

CD - Sensor base to Sensor Link

As the finger flexes, the distance from the MCP joint to Distal Phalanx increases due to the joint movement. In order to compensate for this difference, one end of the flex sensor must be a sliding connection. Figure 5.3 shows two ways of accomplishing this, as well as their advantages and disadvantages.

One of the options is to place a magnetic slider on the fingertip, like the *Raphael Smart Glove* by *Neofect*, while the other integrates the 'slider' into the housing of the sensor base. The first option was used in the later prototypes, but has two major drawbacks: The user must align the (relatively small) sliders, and it adds another five components to the design. Furthermore, there is a chance that this mechanism might infringe on a patent of Neofect (WO2016117758). Placing the 'sliding mechanism' within the sensor base instead of outside it will make the sensor module more complex, but will actually make the product simpler to use and also make it look simpler to the user while removing the need for additional components.

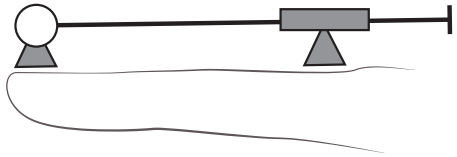
	
Proximal side fixed **Extends beyond the finger**	**Distal side fixed** **Extends into the sensor housing**
+ Fixed, consistent connection between sensor(s) and PCB. + Sensor base can be more compact. Proven to work	+ Sliding mechanism is hidden within the base. + The sensor links do not extend beyond the fingers + No additional component(s) needed.
- The sensor link protrudes beyond the fingers when they are extended, but should retract as - the user flexes. - Requires additional component(s) - Sliding system patented by *Neofect*?	- Connection to PBC must be made with a flexible ribbon cable. - Sensor base must be longer in order to accommodate the travel.

Figure 5.3 - Sliding mechanisms for the flex sensors.

BD - Sensor Link to Finger Module

The final connection is the one that connects the flex sensors to the tips of the individual fingers. The connection must be sufficiently strong to move the sensor links, but weak enough so that all five connections can be removed in a single movement. As previously mentioned in the prototyping chapter; the connection on the finger module should be as small as possible to minimize its impact on ADL.

In the initial *Separate* Concept, magnets were used to create a consistent, self-aligning connection, which was necessary to have a reliable RoM measurement between therapy sessions. Magnets having a holding force of 0.9Kg or ±9N were found to have sufficient force to stay attached to the finger modules while still being easy to remove. However, while a magnetic connection can provide the forces necessary with little to no wear, the need for a consistent connection became less important due to the switch to flex sensors.

Most alternatives, such as snap fits or pop-buttons, were less suited for this connection because they require a bigger 'receiving' mechanism on the end of the finger modules, which get in the way during ADL. Again, this connection could be made with Velcro, but the shear forces acting on it are relatively low. Furthermore, the automatic alignment combined with the relatively low forces needed and minimal mechanism size makes the magnetic connections suited for the chosen design as well.

5.2 Components

With the connections known, the components of the Auxilius can now be determined on a sub-assembly level.

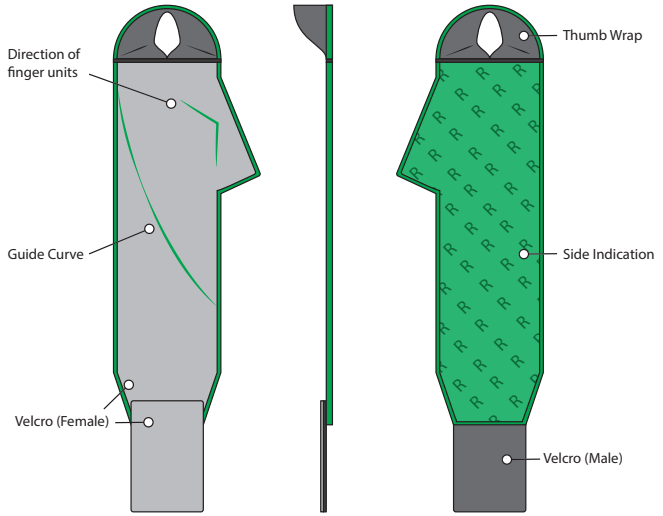
A - Wrist Wrap

The main function of this component is to create a comfortable, stable base for the finger units and sensor module. Because the brace can also be used during ADL, it is desired to stabilize the wrist as well. The design of this component is based on the designs of two existing wrist braces, shown in Figure 5.4, from *Prescot* and *Aptonia*. This shape was chosen because it assists the user in opening their spastic hand: As discovered in chapter 2.2.2, a physiotherapist will first attempt to open the spastic thumb, since it contains the strongest intrinsic hand muscles. Through the way these braces wrap around the thumb, they can be used to pull the thumb (slightly) into abduction, as proximal to the body as possible, as part of the equipment process. Furthermore, this type of brace fits most if not all hand sizes, and can be made from one material. A few adjustments had to be made to make the brace suitable for the chosen context:

Figure 5.4 - Wrist braces by Prescot (Left) and Aptonia (Right)

1. For some hand sizes, the back of the male Velcro fastener would cover the female Velcro below the thumb, removing the Velcro connection for its finger unit. Therefore, another female Velcro connection was added to the back of the fastener, which also increases the potential surface of female Velcro.
2. The wrist brace was separated into a left- and right version, in order to add appropriate use-cues on how to wrap the brace around the wrist. Splitting the brace into two versions is feasible in this context, as most stroke survivors will have only one affected side, and because this component is not expensive to manufacture.
3. Using a subtle curve indicated on the brace, and attempt was made to show the user how to wrap the product around the hand.
4. A slight bulk of material was added to one side of the brace to ensure the dorsal side of the hand is fully covered: This way, the flexible material (B1) of the finger modules can be made shorter, and a stronger connection between the sensor base and wrist wrap is ensured.

The final design of the Wrist Wrap, which incorporates all of these improvements, can be seen in figure 5.5. The dimensions of the wrist wrap have been chosen based on experiments with the two existing wrist braces.



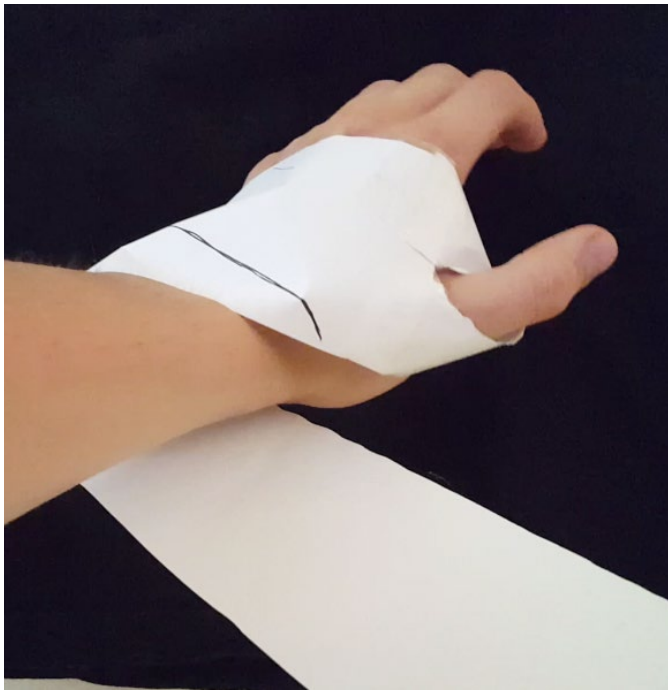


Figure 5.5 - Final shape of the Wrist Wrap.

B - Finger Module

The finger modules are the critical components in this product, as they are subject to the greatest forces and repetitions, and tackle the most difficult problem: Equipping a glove-like structure to a spastic finger in the safest way possible. To improve their design, two decisions made early on regarding the finger modules were reviewed:

Separation for the glove

In the initial concept, the finger modules were left separate from the base glove to reduce the complexity of said glove. The decision to keep these units separate adds five additional steps to the equipment process (attaching the modules to the base glove). However, this separation also offers a number of advantages:

- The critical components, subject to the highest forces and repetitions, can be easily substituted when they break.
- The finger modules become easier to put on, since they are not stuck to the glove itself: The user does not need to pull the stretch material until the 'entrance' of the glove structure is in front of the fingertip.
- The passive assist force is not applied until the user fixes the module onto the base glove. The user can increase the level of passive assist by slowly pulling back the flexible material. It can also prevent hyperextension of the distal phalanx, which could occur if the user lets go before the glove structure is fully equipped, while the flexible material is already connected.
- As a bonus, it opens op the possibility to create customized finger modules for each patient, on an individual finger level.

To summarize; while the separation adds five additional steps to the equipment process, it makes five other steps much easier and much safer. Therefore, the finger units should remain separate from the base glove.

Integration of sensors

Another consideration is to lower the complexity of the product by integrating the sensors into the finger units themselves. This could either be done through flex sensors or by using a conductive material for the passive assist. Figure 5.6 shows the advantages and disadvantages of both, as well as a visualization of what the finger units would look like. The conclusion form the figure is that, while an integrated solution for the finger units makes the product *look* less complex, it actually increases the complexity of the components and the complexity of equipping the finger modules.

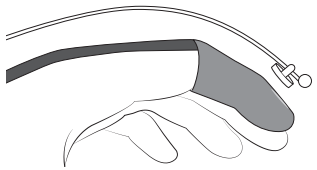
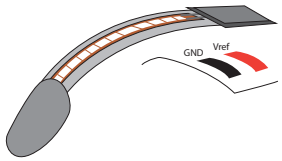
Separate Electronics	Integrate Electronics
	
+ No electronics to be washed – The modules can be thrown directly into the washing machine. + There is already a consistent, secure connection between sensor link and PCB. + The passive assist connection can be made anywhere on the wrist wrap. + Complete separation allows different electronics to be placed on top. + It is easier to replace damaged (electrical) components.	+ Five fewer steps are needed to equip the brace, since a connection between sensor links and finger modules already exists. + The electronics are hidden away within the finger modules. + There is not risk of the sensors diconnecting during use.
- Five additional steps are required to secure the sensors to finger modules. - A consistent, secure connection must be created between sensor & finger unit. - A more complex looking sensor mechanism.	- Electronics are at risk in washing machine: Finger units must be hand washed instead OR the sensors must be removable. - There must be a conductive connection (+ and -) between the sensor base and finger units, that should not be reversed! - The connection between finger units and sensors will become more complex due to the importance of the placement of input voltage and ground.

Figure 5.6 - Integration methods

Another option is to completely integrate all electronics into the glove, similar to the Manus Machina, which will forgo the need for a conductive connection; one of the factors limit integration. However, like the Manus Machina, this will make the product hand washable only, and will remove any benefit from the separation of electronics (Easy to wash, the possibility of using other sensors).

Therefore, even though (full) integration is possible, it would remove benefits in hygiene and make the glove more difficult to equip while gaining little else than a more simple aesthetic. The sensors will not be integrated into the finger units nor the glove base.

Chosen Design

The chosen design for the finger units is shown in figure 5.7.

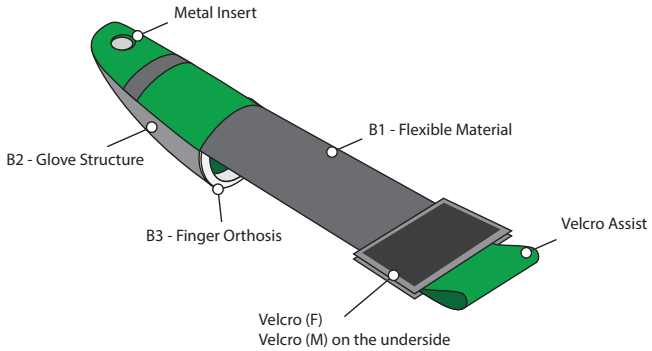


Figure 5.7 - Chosen design for the Finger Units

C - Sensor Base

The sensor base houses the logic circuit which communicates sensor data back to the Adjuvo Platform. It must house a PBC, a Micro-controller with wireless capabilities, five 10kΩ resistors, a rechargeable battery pack and a sliding mechanism for the sensor links, which connect to the PCB through ribbon cables. It is the most expensive sub-assembly, and should therefore be the most durable.

The sensor base consists of two halves: A bottom half, onto which the electronics are mounted and over which the sensor links slide, and a top half, which serves mostly as a cover for the electronics. Figure 5.8 shows the two halves of the sensor base.

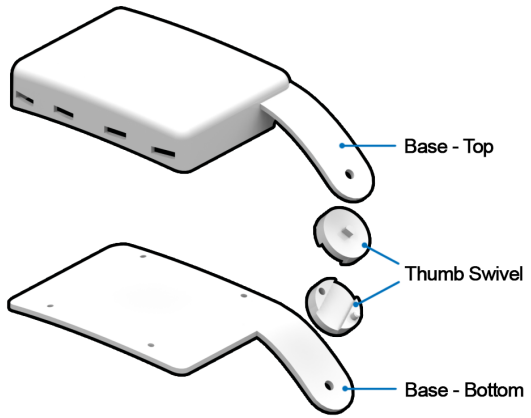


Figure 5.8 - Sensor Base housing

The sensor base will need to be long enough to accommodate the travel of the sensor links, as well as the difference in finger lengths between users. During flexion/extension, the maximum travel of a finger unit was assumed to be on average 30mm. Using DINED Dutch Adults 20-60 as a reference, the difference in finger length between P95 male (largest) and P95 female (smallest) is (83-63=) 23mm. This brings the total amount of travel to 53mm, which must be completed within the sensor base. Taking into account a material thickness of 2.5mm and 5mm of play, the sensor base must then be up to 65mm long. To accommodate for the size difference between fingers, the front of the sensor base is curved, following the pattern of the MCP joints.

The width of the sensor base must cover the hand width of a P50 male+female, 85mm, in order for the sensor links to match up. The variation between the P5 and P95 percentiles is (99-73=) 26mm, which is compensated for by the sensor links: They can deviate to the left and right. The bottom of the sensor base must be appropriately curved to match the general curvature (transversal arch) of the dorsal side of the hand. This maximizes the area of the Velcro that connects it to the wrist wrap.

Lastly, the sensor base must be at least 15mm high to create enough clearance for the sensor links. A height of 20mm will ensure there is more than enough space for the electronics and that the sensor module is high enough for the user to easily grab on to it.

Like the fingers, the thumb flexion/extension is measured using a flex sensor. To measure thumb abduction/adduction, a *Bourns* rotational potentiometer is used. This requires a special mechanism that combines rotation and sliding. Figure 5.9 shows the chosen mechanism that incorporates these components. It was designed to be as small as possible.

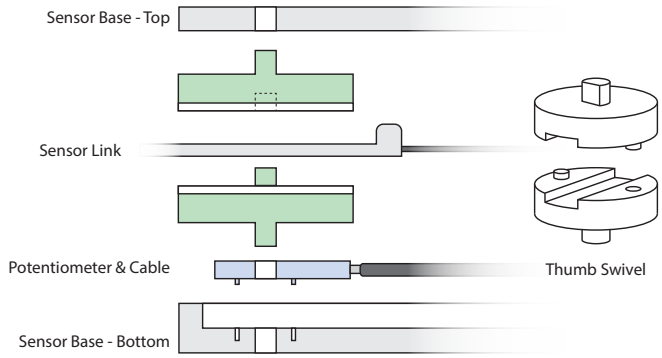


Figure 5.9 - Thumb Sensing mechanism

The mechanism must be positioned roughly over the CMC joint of the thumb, which is why it is placed outside the main housing. Instead, a separate component, the *Swivel*, is sandwiched between the upper and lower halves of the sensor base. The swivel, which is created using the same component twice, is used to guide the sensor link of the thumb while transferring the abduction/adduction movement to the rotational potentiometer. A cable containing an input voltage, ground- and reference voltage runs through the bottom half of the from the potentiometer in the mechanism back into the housing

D - Sensor Links

The sensor links hold the flex sensor and magnet, placed inside a flexible material to keep it together. As covered in the *Connections* section, the sensor link slides in- and out of the sensor base, and thus requires a ‘stopper’: A raised section that prevents the link from being pulled outside the base. Behind this raised section is a ribbon cable that folds back to connects the electronics to the internal PCB. The working principle can be seen in figure 10.

Assuming the sensor base is placed 20mm from the users MCP joints, the sensor links must be (83+30+20=) 143mm long from the raised section. This size is required to allow a male with a P95 finger length to still be able to perform full flexion with the sensor module on. Users with smaller hands, up to a 5th percentile female, can push the links further into the sensor base, which can accommodate for the difference, as determined earlier.

The magnets at the end of the sensor links are Ø6x3mm, and have a holding force of 0.9kg or 9N, which have, though experimentation, proven to provide sufficient strength while still being easy to remove.

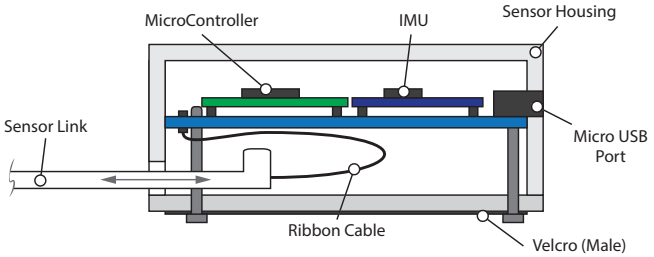


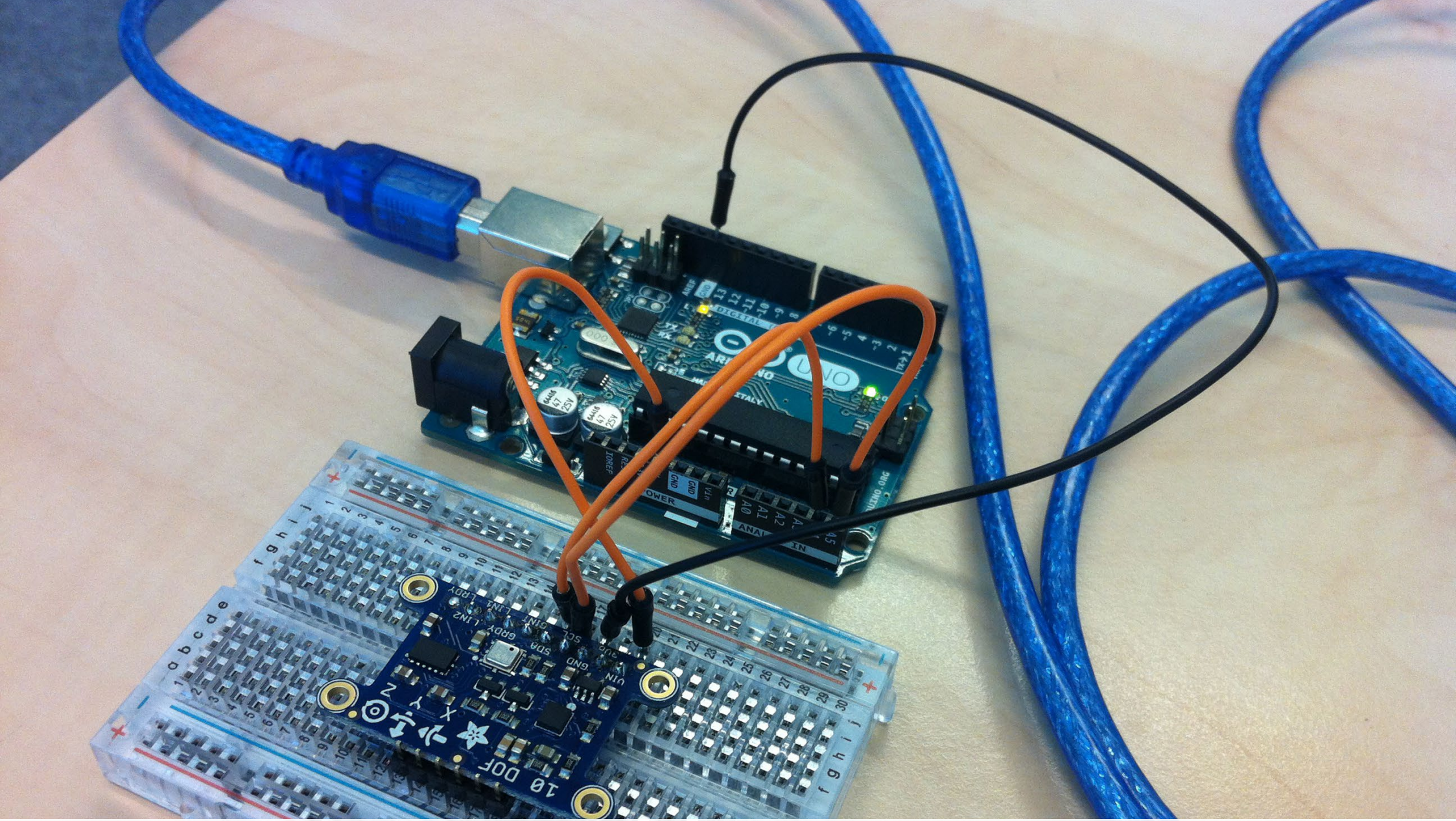
Figure 5.10 - Sensor Link sliding mechanism.

5.3 Auxilius Design

Figure 5.11 shows the Bill of Materials for one product set containing one Wrist Wrap, five finger units and one sensor module.

Part Number	Item	Quantity	Custom Design
A	*Wrist Wrap*	*1*	*Yes*
B	*Finger Module*	-	-
B1	Flexible Material	5	Yes
B2	Glove Structure	5	Yes
B3	Finger Othosis	5	Yes
B4	Metal Insert	5	No
C	*Sensor Module*	-	-
C1	Sensor Module - Bottom	1	Yes
C2	Sensor Module - Top	1	Yes
C3	Thumb Swivel	2	Yes
-	Microcontroller	1	-
-	PCB	1	-
-	Lithium-Ion Battery - 400mAh	1	No
-	Mirco USB connection (Female)	1	No
-	9 DOF Intertia Measurement Unit (IMU)	1	No
-	10kΩ resistor	5	No
D	*Sensor Link*	*5*	*Yes*
-	Flex Sensor - 4.5”	5	No
-	Magnet Ø6x3mm	5	No
-	Ribbon Cable	5	No
-	*Bolts M2.5x25mm*	*4-8*	*No*

Figure 5.11 - List of components.



6. Embodiment Design

6.1 Approach

The Embodiment design stage covers the materialization of the Adjuvo Auxilius on a component level. The aspects addressed in this stage are the Material Selection, Durability and Production Method(s) of each custom component, followed by a more global detailing of the product Aesthetics and Cost Price.

With a Use Case based on the scenario's made in chapter 2.1.5, the forces and load cycles on each component and connection were established. Based on the design established in chapter 5, the material stresses are calculated, which serve as a guide for the material selection. This selection was based on material data gathered from the *Cambridge Engineering Selector*.

Based on the materials selected for the critical components, their Durability can be determined. Finally, the material selection, combined with an estimation of the potential market penetration, forms the basis to choose the right production methods. Finally, a concise aesthetics study is performed to tie all of the materials together, and to find a way to integrate further use-cues into the product.

With the materials and production methods of the components known, a cost estimation can be created for each sub-assembly, which is combined into the production- and purchase price of the full product, which will consist of one Wrist Wrap, five Finger Modules and one Sensor Module. Lastly, this chapter will cover, in abstract, the algorithms used to transform the input from the sensors into useful data for a physiotherapist.

While most aspects covered in the embodiment design are interconnected, they are covered in separate sub-chapters, as shown in figure 6.1.

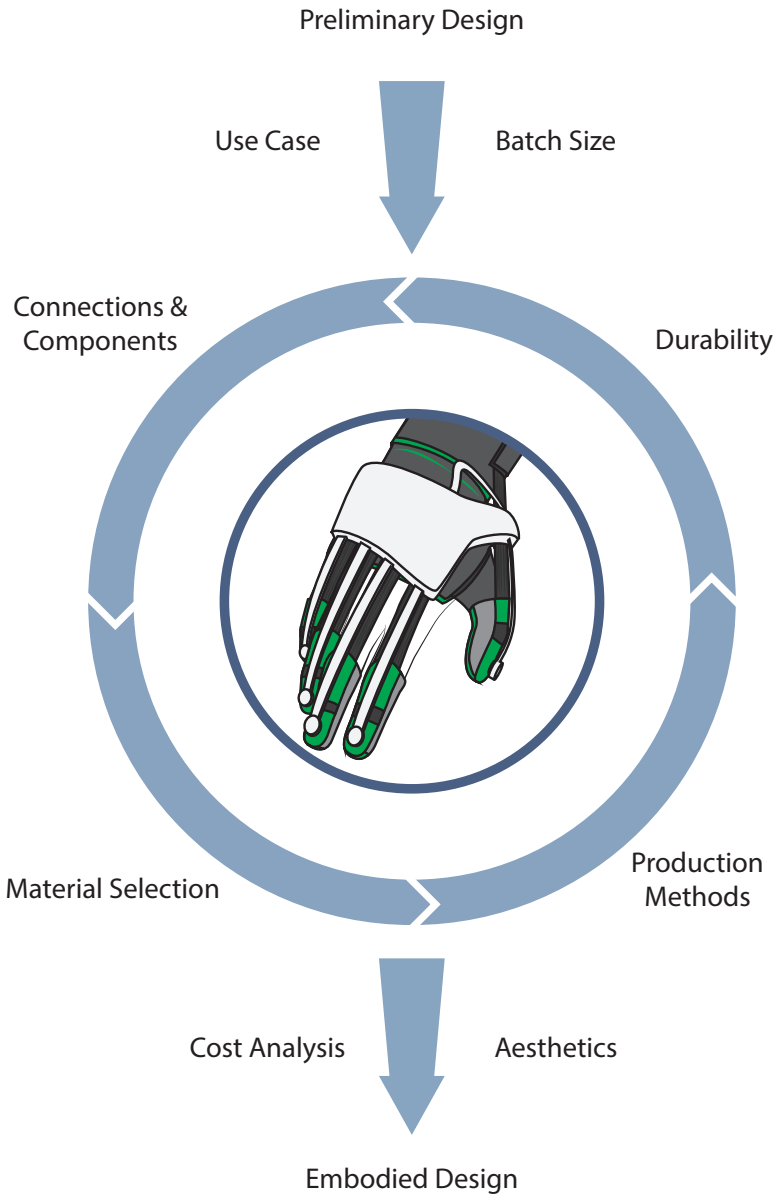


Figure 6.1 - Overview of the embodiment stage

6.2 Scenario

Use Case

The use case, based on the scenario created in the Context Analysis chapter, is used to identify a number of requirements regarding the product's lifespan. It is assumed that the brace is used every day for 4-8 hours during ADL, and 5-7 days a week for 30-90 minutes of therapy. The higher ranges represent intense use, which would only occur of an extremely motivated stroke survivor were to use it. Still, the product should be able to withstand this intense use in order to accommodate for all intensities of rehabilitation therapy.

Before and after therapy, the wrist wrap and each of the finger modules must be equipped and/or adjusted. After that, the sensor module is equipped and removed again. The wrist wrap, senor module and finger units will require only 1 to 2 apply/remove cycles, each to a different area of the wrist wrap. This assumption includes a re-adjustment of the connections. With the user equipping the full brace one per day in the morning, this would result in 365 to 730 apply/remove cycles each year for the aforementioned connections.

During therapy and/or stretching exercises, a 'moderate pace' of opening and closing the hand every 5 seconds is assumed, based on self-timing. If the user trains 5 days a week for 30 minutes, the product will go through (52*5*30*(60/5)=) 93600 repetitions a year for the therapy part only. If the user is highly motivated and uses the product 7 days a week for 90 minutes, the number of repetitions becomes (52*7*90*(60/5)=) 393120 repetitions a year.

During ADL, the hand is assumed to open and close once every minute, because it involves less continuously repeated motions compared to therapy exercises. Using the glove for 4 to 8 hours every day would result in (52*7*4*60=) 87360 to (52*7*8*60=) 174720 repetitions respectively. With the ADL and therapy together, the passive assist and sensor parts of the product will go though 180960 to 567840 repetitions each year, with the majority of these made during therapy sessions.

The forces acting on the finger modules (and their connection to the wrist wrap) will vary per user. The developers of *Gloreha*, an active device that uses a similar force-transfer system, claim that their product can use up to 5N of force to compensate for spasticity levels of MAS 0-2 (and possibly 3) based on '*clinical suggestions*' (Gloreha, n.d.). In a study by Park et al (2016), their active exotendon device used a force of ±40N to overcome spasticity levels of MAS 1-2 in the four fingers with a single actuator. Assuming the loss of cables and the effect of intrinsic hand muscles comes down to 2N, this would put the maximum spastic force at 8N per finger; slightly above the '*reasonable level of strength*' of the *Gloreha*. This same study included simulations using the human hand model in the *GraspIt!* software by Miller and Allen (2004), which revealed that the 'tendon' of the index finger travels up to 57mm during its full Range of Motion. This distance of travel, along with the force range of 5-8N, are used as requirements for the stretch material in the finger units.

Potential Users

Since the batch size of the product will affect the chosen materials and production methods, this is also part of the use case. Using the data gathered in the analysis stage, a batch size estimation can be made:

Each year, 44.000 Dutch people suffer from a stroke. It is assumed that 90% of stroke victims survive the incident. Of these survivors, 81% rehabilitate in their (nursing) home, and 80% suffers from some form of impairment in the upper extremities. From the studies done by Sommerfield et al (2012), it was observed that roughly 60% of stroke survivors suffered from some form of spasticity, with a score on the Modified Ashworth Scale (MAS) of 1 to 4. Welmer et al (2012) and Watkins et al (2002) both found that roughly 25% of spastic stroke survivors suffer from severe spasticity (MAS >=3), which is not the intended target for this product. Assuming a market penetration of 10%, this leaves (44000*0.9*0.8* 0.8*0.6*0.75*0.1.=) 1140 potential users each year. This is a relatively small batch size which makes high-investment production methods, such as injection moulding, less suited.

6.3 Material Selection

A - Wrist Wrap

The material of the Wrist Wrap must be washable, and should allow air and water to pass through for ventilation purposes. The material should be flexible enough to twist around itself. Using the *Cambridge Engineering Selector (CES)*, a list of materials was made using the following material properties:

The forces on the wrist wrap are assumed to range up to 10N, depending on how tight the user wishes to make the fit. Assuming a minimum thickness and a minimum width of 2mm and 50mm respectively, the maximum normal stress is 0.5 MPa. A safety factor of 2x puts this maximum stress at 1MPa.

However, putting the brace on too tight will constrict the lower arm and its blood vessels to the point where it becomes uncomfortable or even impossible to wear. Users should be encouraged not to put the wrist wrap on as tight as possible, but rather to a level that is comfortable. One way to restrict the tightness of the wrist wrap is to use a material with a higher Young's Modulus: If the material stretches too much, it becomes easy to wrap it too tight. This is the case with the wrist brace from *Aptonia*, which elongates up to 140mm at 20N! Assuming an acceptable maximum elongation of 40mm or (L/L0-1=) 11%, based on that of the more comfortable *Prescot* brace, the Young's Modulus of the material should be higher than (E=σ/ε=) 9 MPa. This calculation includes the displacement from the fabric around the thumb, which will be made from the same material.

Figure 6.2 shows the materials that have passed the CES filters. One of the notable materials that passed the test is Polyester: Most "breathable" fabrics used for sporting gear are made with various ratios of Polyester and Elastene, where the ratio of Elastene greatly determines flexibility (Samurai Sports, n.d.). The key to creating the 'breathing' fabric is to have the material absorb the moisture form the skin, which will allow it to evaporate. The Wrist Wrap will therefore be made from a Polyester-Elastine weave, with the Elastene Ratio kept at 15% to prevent over-compression of the wrist. While the Elastene will lower the Young's Modulus and Yield Strength of the overall material, the Polyester will still be sufficiently strong, with a Yield Strength of at least 8MPa.

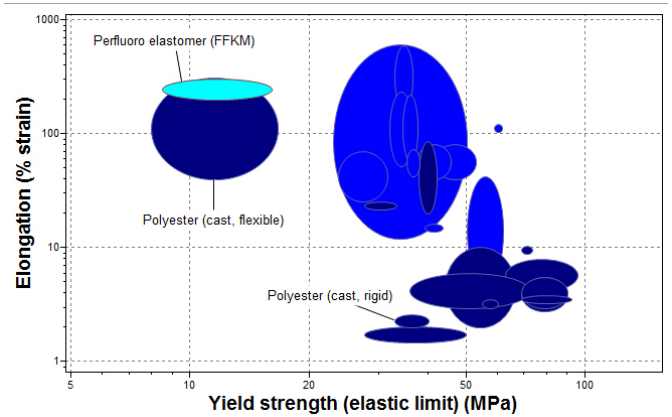


Figure 6.2 - CES Materials for the Wrist Wrap

B - Finger Modules

The finger modules are broken down in to four components; the flexible material (B1), glove structure (B2), finger orthosis (B3), and metal insert (B4), as seen in figure 6.3.

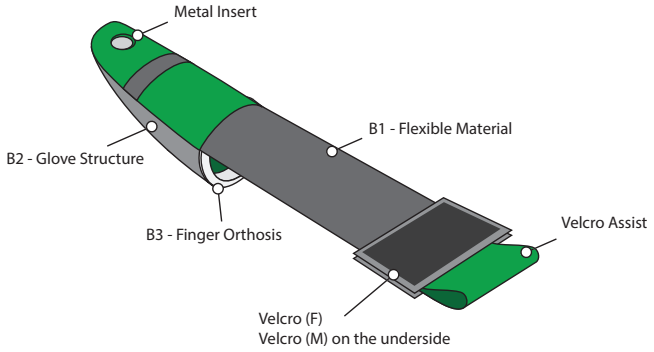


Figure 6.3 - Finger Module overview

B1 Flexible Material

The flexible material is what makes or breaks the finger module. Through experimentation, a width of 10mm was found to be too small (the material slides to one side of the finger) and 25mm to be too big (there is not enough room on the wrist wrap to contain all finger units). A width of 20mm was chosen to free up to 15mm of space for the finger units while still keeping a stable connection.

The Young's modulus of the material must be low enough to that the material can stretch the entire range of motion of the user. The flexible material is assumed to expand from 40mm to 90mm during flexion, resulting into an elongation of (L/L0 -1=) 125%. The Young's Modulus should therefore be at most (E=σ/ε=) 0.4 MPa to allow the material to stretch sufficiently during the normal stresses of use.

With the large amount of elongation required in this component, most metals and thermosetting polymers are unsuited. Instead, solid elastomers and stretch fabric materials are considered. Elastomers, however, feel rough against the skin and do not let through moisture, which will make the finger modules uncomfortable to wear. This leaves the choice for stretch fabrics. Most elastic bands used in clothing are made from a combination of Polyester and Elastene fibers, with a respective ratio of 1:3 or 1:4. For these reasons, the choice was made to use a weave of Polyester/Elastene fiber for this component.

Assuming this component is subjected to 10N of normal force during use, the flexible material will be subjected to 0.25 MPa of normal stress if the material has is treated as a solid, with a thickness of 2mm. However, the material is more likely to consist of fibers in different kind of weaves, as seen in figure 6.4. If the material cross-section is therefore treated as fifteen individual 'fibers' with a diameter of 0.75mm, the total stress comes down to 1.5MPa or 0.1 MPa per fiber.

Figure 6.4 - Flexible Material Elongation

While the bending of the material across the finger also affects the material stresses, this effect is unpredictable due to the high variance in finger movement and lengths. Furthermore, in a real situation the fabric will have a more complex weave than "15 straight fibers". To compensate for these elements, a safety factor of 5 is assumed, which places the maximum stress on 7.5MPa or 0.5 MPa per 'fiber'. Due to the Elastene component in the material of at most 66.7%, this Yield strength is again divided by 1/3, meaning the total yield stress should be at least 0.75MPa.

Using material data from the *Cambridge Engineering Selector*, material properties of Low/Medium density Polyethylene (PE) were retrieved. Low/Medium density PE was used as a reference, since it is the least durable type of this polymer. The Young's Modulus of PE is at least 170MPa, much higher that the one previously calculated. The reason the material is still suited is because this Young's modulus is based on a solid material. The weave of the fabric and the Elastene compound will allow the material to stretch to the lengths shown in figure 6.4.

B2 Glove structure

The Glove structure transfers the forces from the flexible material to the finger. As an additional level of passive assist, a second flexible connection was integrated halfway into the structure, which makes use of the same flexible material component (B1). Figure 6.5 shows how the connection is established.

While the glove structure could be much easier to equip if it covered only the distal phalanx, this increases the risk of placing the DIP joint into hyperextension. On the other hand, the spastic forces should be compensated for as proximal to the body as possible (by having the glove structure cover the whole finger), which will make it difficult to equip to a spastic finger. As a compromise; the glove structure encompasses the distal- and medial phalanx, creating an easy to equip glove with reduced risk of hyperextension.

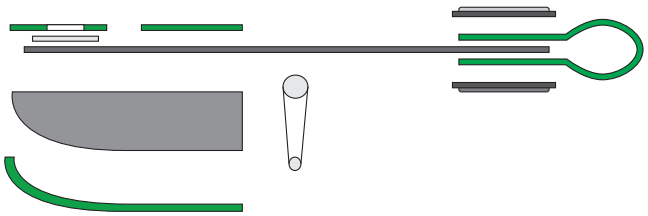


Figure 6.5 - A Cross section of the Finger Unit

For the glove structure, it is required that the material; 1) lets through air and moisture, 2) is as thin as possible, and 3) does not stretch, since this is the function of the flexible material. With a Yield Strength of 100 MPa and a Young's Modulus of 5.5 GPa, Cotton was found to fulfill these requirements best while also being safe to place in the washing machine. Being a natural fabric, cotton is 'breathable', meaning it absorbs moisture quicker, which will reduce the amount of sweat staying the user's hand during exercise. This sweat will then evaporate over time.

Due to the variance between the finger lengths of users, the glove structures should come in different sizes

B3 Finger Orthosis

The finger cirrhosis shape is embedded in the glove structure and provides a handhold for the unaffected hand to slide the finger module over a (closed) spastic hand. It must be small enough to fit between the phalanges while it is closed, yet large enough to provide sufficient handhold for the unaffected hand. Appendix G covers a few alternatives to this shape. In the end, the shape in figure 6.6 was deemed most suitable.

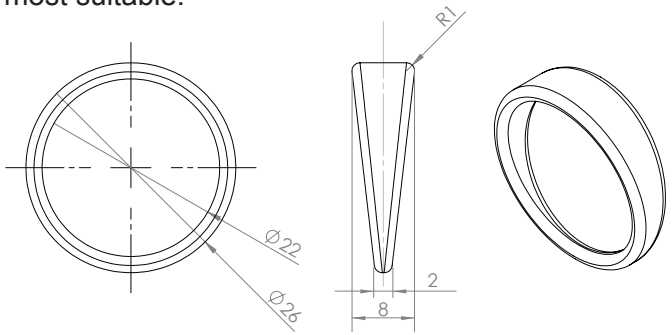


Figure 6.6 - Finger Orthosis

The bottom of the 'ring' is 2mm; small enough to fit between the phalanges without getting in the way. The ring widens to 8mm; big enough to hold with one's unaffected hand. It is sown into the ends of the glove structure, sealing off the edges of the fabric and creating the required support. It is important that the ring is positioned proximal to the PIP joint to avoid it conflicting with the joint during flexion.

A rigid finger orthosis would provide sufficient handhold for the user. However, they can become very uncomfortable for users with large fingers or can get in the way of those with small fingers. Therefore, the finger orthosis should be a semi-rigid elastomer which can accommodate for bigger fingers and will be soft enough not to cause discomfort during movement.

The finger orthosis will not be subject to high forces, since it is not a load-bearing component: As part of its function, it will only be subject to forces when equipping the brace. The orthosis should not break when it gets caught between two phalanges or catches on a joint. The forces needed to move the orthosis are assumed to be the same as the spastic forces on the finger; 5-8N. With a minimum cross section of a 2mm diameter circle, the maximum stress on the material will be 1.27MPa during use.

Silicone Rubber will provide the finger orthosis with sufficient strength to resist this force, while having a low toxicity and, most importantly, being resistant to moisture. As with the glove structure (B2), this component should come in different sizes. The orthosis will scale with the glove structure to create Small, Medium and Large versions.

B4 Metal Insert

The metal insert provides the magnets a place to attach to, which means it must be made from a ferrous metal. It is a simple disk shape with a diameter of 10mm, no more than 2mm thick. These measurements ensure that the metal will fit within the fingertip portion of the glove structure (B2).

Because the finger modules should be washable, the metal should be water-resistant. Therefore, Stainless steel was chosen as the material for this component. Since the shape of this component is very basic, and can bought off the shelf or laser-cut.

C - Sensor Base

The sensor base is subjected to two types of forces during use: One is applied when the module is removed, while the other occurs when the sensor links reach their maximum extension and pull the sensor base forward. The latter situation happens when the sensor links are too short for the user or when the sensor module is pulled off while the sensor links are still connected. Figure 6.7 illustrates these situations.

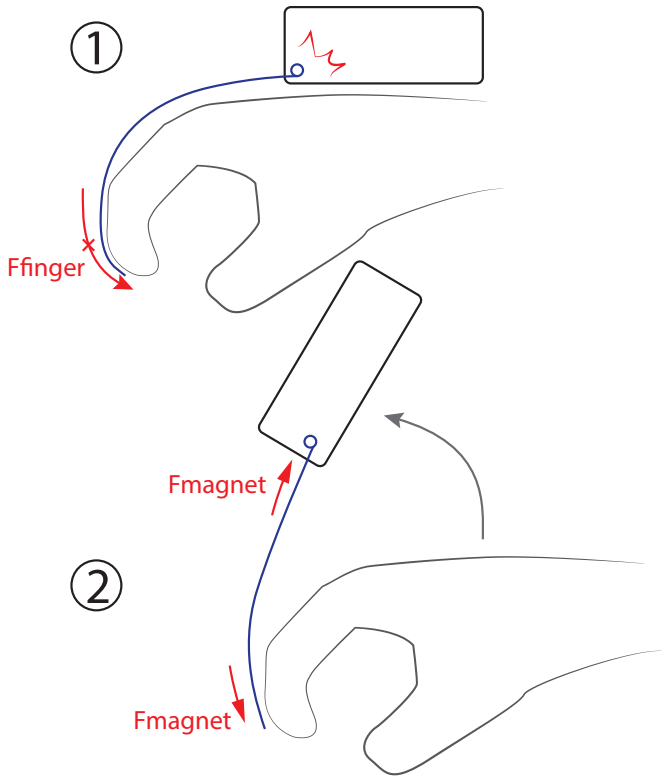


Figure 6.7 - Forces on the Base through Links.

Because the connection between the finger module and sensor link is magnetic, the links will break loose when the finger force exceeds the holding strength of the magnets; 9N. This force assumes the sensor link is moved directly upwards. In reality, the magnets have a significantly smaller holding strength in a shear direction, which is the case both situations in figure 6.7. Nevertheless, the maximum force on the top half of the sensor base will be 12.7MPa, assuming four sensor link forces of 9N each are transferred to the utmost edge of the top half of the sensor bottom, which is treated as a 'wall' of 20mm high, 85mm wide and 2mm thick. This calculation neglects the effect of the other walls in the component.

Based on this maximum stress, the *Cambridge Engineering Selector* was used again to filter through possible polymers to use. Three main polymers types were shown to be strong enough: ABS, PET and PP. Of these materials, ABS is the only one that has an 'excellent' rating for Polymer Thermoforming and Injection Moulding: Using ABS, the sensor housings can be either thermo-formed or 3D printed which are the most feasible methods for the shape and relatively low batch size of this product.

Thumb Connector

Since the forces on this component are assumed to be equal to or lower than those on the sensor housing, the ABS was deemed as a suitable material for this component as well. This ensures a consistency between materials within the sensor base.

D - Sensor Link

Neglecting the effects of the electrical components on the material strength, the sensor link can be modelled as a hollow beam with an outer diameter of 10x2.5mm and an inner diameter of 7x1mm. The maximum force on the links will be 9N, as the magnetic connection will disconnect at forces higher than its holding strength. This places the maximum normal stress on the sensor links at 0.5MPa.

The sensor links are produced by insert-molding the flex sensor, magnet and part of the ribbon cable into an elastomer. The choice for elastomers was implied, since the sensor links would need to bend with the fingers, which requires a large elongation at small forces. The material for the sensor links is Silicone Rubber, which was chosen due to its excellent flexibility, mold-ability and resistance to water and household cleaning agents.

6.4 Production Methods

Parallel to selecting the materials, the production methods for the passive assist were determined. Since the potential market penetration of the Auxilius is ‘only’ 1140, an emphasis was made on using production methods that were cost-effective in low batch sizes.

A - Wrist Wrap

The main material used is a Polyester-Elastine mix with a female Velcro connection on the ‘top’ side and a double-sided Polyester Velcro connection sown onto the end of the wrap. Due to its flat nature, it can be cut out of a single sheet of material, as shown in figure 6.8 and its edges can be finished by sowing a different color material around them. The thumb compensation is made from a separate loop of PE-Elastine, creating the same shape as the *Aptonia* brace which creates a greater surface area around the thumb, reducing the pressure on its Proximal Phalanx. The ‘bottom’ of the Wrist Wrap is made a different color, which can be used to denote its side (Left or Right). The version for the opposite hand can be created by mirroring the shape of the main wrap. Due to the way it is worn, the wrist wrap is a ‘one size fits all’ solution.

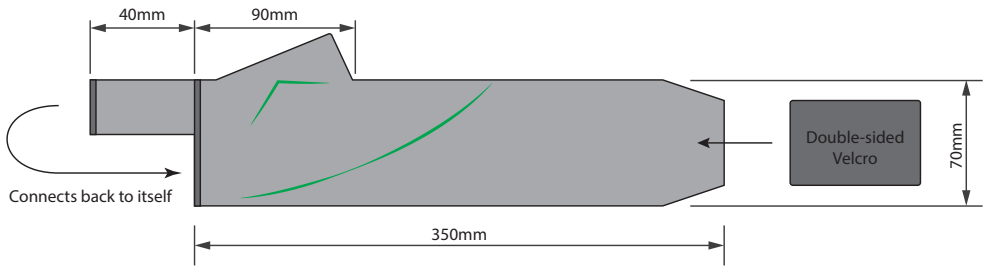


Figure 6.8 - Pattern for the Wrist Wrap

B - Finger Module

The glove structure will be manually cut from sheets of cotton, while the stretch material will come in strips that can be cut to the right size. Due to the fabric nature of the Wrist brace, it will have to be sown together using Nylon yarn. Figure 6.9 shows the steps needed to create one finger module. This process takes considerable time, which can be sped up by using a sewing machine.

The finger orthosis will be made by casting the silicone with hardener in a metal or plastic mold, much like the sensor links. Due to the simplicity of its shape, the orthosis can be molded in a single step, and can be performed by hand. The mold can be extended to create multiple finger orthoses simultaneously.

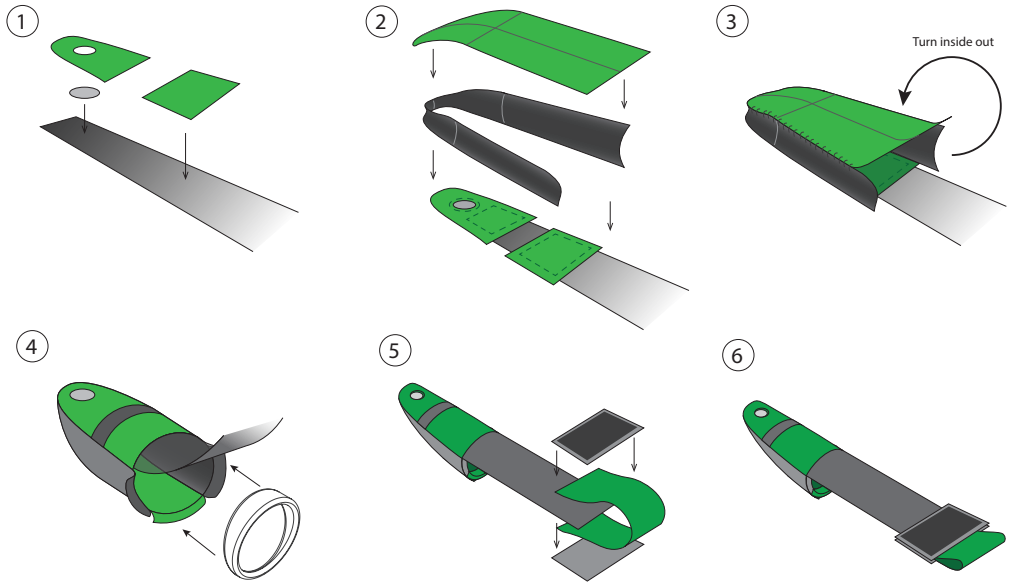


Figure 6.9 - Production of a single finger unit.

C - Sensor Base

Due to the excellent moulding properties of ABS, it seems that injection moulding would be a suitable way to create the desired shapes. However, this process would require a significant investment in up to three high-pressure molds which would make the overall product much more expensive due to its small batch size. Thermoforming is a suitable alternative to achieve the desired shape, but this method requires a number of post-production steps, such as cutting off burrs and drilling holes.

Instead, both halves of the sensor base and the thumb swivel will be 3D-printed. This method fits with the chosen material, ABS, which is commonly used in most commercially available 3D printers. With a purchase price of around €2000 (Coolblue, n.d.), the total cost of a single 3D printer translates to an additional manufacturing cost of roughly €2 on the entire product, based on a batch size of 1000 Auxilius. 3D printing will require little to no post-processing, and the same printer can be used to create components of other Adjuvo Motion products as well.

D - Sensor Link

Figure 6.10 shows the three components within the sensor link, as well as the mold used to create them. The moulding process consists of three steps: First, Mold A, the top of the sensor link, is filled with silicone rubber, and any excess material is removed. Next, the flex sensor, soldered to the ribbon cable, and the magnet are placed into the soft material. The last step is to fill Mold B with silicone and placing this on top of Mold A using the four alignment holes. Since silicone binds well with itself, the two halves become one during the curing process. After the rubber has cured, the sensor links can be removed. The molds themselves can be made from plastic or metal, and do not require advanced machinery to produce.

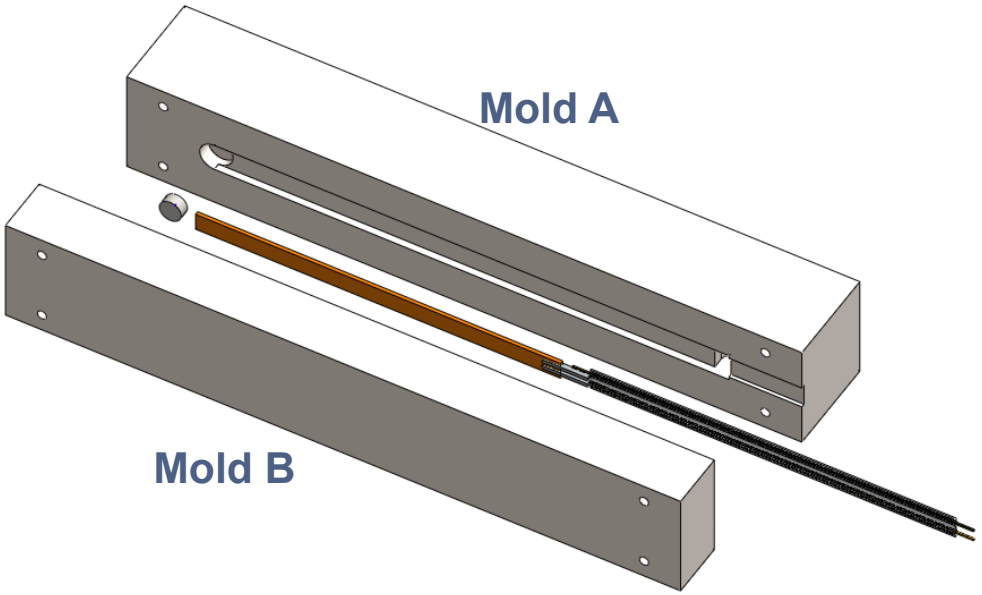


Figure 6.10 - Sensor Link Production

6.5 Durability

The durability of the Adjuvo Auxilius is determined by that of its connections, critical components and electronics. The lifespan of the battery is also brought under the electronics durability, since it affects the lifespan of the product. The calculations in this chapter are based on the use case set in chapter 6.2, which indicates the forces and repetitions per year on each of the components.

Connections

The Velcro connections between the components are critical to determine the lifespan of the Wrist Wrap, Finger Modules and Sensor Base. These connections, which were chosen in chapter 5, are partly based on these calculations. The magnetic connection between the sensor links and finger modules definitely outlast the Velcro connections, and is therefore not considered for this analysis.

There are two main types of Velcro: Polyester and Nylon, which have a cycle life of 1000 to 5000 respectively before dropping below 50% of their strength. The strength of a Velcro connection relies on its surface area, with even one square centimeter having a 'dynamic shear strength' of 12 to 15N / cm^2 and a 'dynamic tensile strength' of 7.6N / cm^2 (source-3M sheet), which is sufficiently high for the forces in this application. Using Linear interpolation, the number of apply / remove cycles before the shear- or tensile force drops below a certain threshold can be calculated. By dividing the maximum allowable number of cycles by the amount of cycles per year, the lifespan of the connection can be determined.

Velcro connections have two sides; one male (hooks, hard) and one female (loops, soft). When a Velcro connection breaks, it is usually the soft female side that breaks first.

AB - Finger Module to Wrist Wrap

This connection transfers the spasticity forces of 5N to 8N onto the wrist wrap orthosis, and is applied between 365 to 730 times a year. Using linear interpolation, this connection would last for at least 0.9 years using Polyester Velcro or 6.4 years using Nylon Velcro, until shear forces drop below 8N. If a shear force of only 5N is required, the connection will last 1.8 to well over 9 years. This calculation assumes a Velcro surface area of one cubic centimeter as a 'worst case scenario. For this connection, it is beneficial to put the male side on the finger module, which leaves the wrist wrap soft and comfortable while ensuring that the more complex finger modules last longer.

AC and BC - Sensor Base to Wrist Wrap and Finger Module

This connection ensures that the sensor base is kept on the dorsal side of the hand, and must handle forces of up to 1.5N. Assuming this connection is applied / removed 730 times a year, one square centimeter of Polyester- and Nylon Velcro will last 2.2 and 11 years respectively before their tensile strength drops below the required 1.5N. The Velcro will need to be applied to the bottom of the sensor module using an adhesive backside, of which little material properties are available. Therefore, the adhesive is assumed to last least as long as the Velcro itself.

Finger Modules

The flexible material is the critical component in the finger units. It is made of a Polyethylene-Elastic combination, and is subjected to forces of up to 0.75MPa. Low/Medium density PE was used as a reference, since it is the least durable type of this polymer.

With a Yield Strength of 9MPa and an estimated Fatigue strength of 5.3MPa at 10^7 cycles, the stretch material is guaranteed to last for at least as many repetitions, which equates to 17.6 years based on 567840 repetitions per year. Even by assuming the material will last only half as long, the stretch material will still last for 8.8 years.

Electronics

Flex Sensors

Flex sensors generate reliable data until they have been bent over 1 million times, though this lifetime can be shortened if they are bent the other way (SpectraSymbol, n.d.). If the flex sensors are subject to this 'correct' bending only during therapy sessions, they will last for at 2.5 years, based on a maximum of 393120 repetitions per year. If the lower range of 93600 repetitions per year is reached, the sensors will last over 10 years instead.

Rotary Potentiometer

The rotary potentiometer last up to 1000000 cycles (Bourns.com, n.d.), which equates to 10.6 years of normal use (93600 repetitions per year), or 2.5 years of intense use (393120 repetitions per year). Incidentally, the *Bourns* potentiometers will last the same amount of cycles as the flex sensors in the finger links, which means that the electronics will break at roughly the same time.

Battery

A rechargeable Lithium-Ion battery is used to power the microcontroller. This keeps the sensor part free of cables which might otherwise limit the user during training, especially during pronation/supination movements. Is also allows the user to move around during training. The sensor holder should have a female micro-usb connection on the outside to allow the battery to be recharged. This also provides an alternative communication method for the microcontroller, should the battery fail or should wireless communication cease to function.

Using a small LI battery of 400mAh, the sensor module will last up to 112 hours before it must be charged via the USB cable, assuming that the electrical components use up to 2.5 mA even when not used, and assuming a safety factor of 0.7 on battery life to compensate for other factors that might influence the performance. As with any wireless device, the performance of the battery will diminish over time. At some point, it will need to be replaced, which is why the battery will have a plug-in connection to the PCB.

Conclusion

Due to the modularity of the product, the individual components can be easily replaced. Therefore, a better understanding of the life-cycle is made by splitting the overall lifetime up between the three sub-assemblies:

The wrist wrap is the least durable component, due to it being the female side of nearly every Velcro connection. However, it is also the easiest product to produce. Therefore, this component makes use of the less durable Polyester Velcro, which will need to be replaced after 1.9 years, when the female Velcro connection becomes too weak to hold the male connectors.

The finger modules will last for at least 2.2 years before their Polyester Velcro connection to the Wrist Wrap fails. The choice for the least durable connection was made to ensure that the modules are replaced roughly every two years, since they will be subject to the most wear during normal use.

The electronics in the wrist wrap can last anywhere between 2.5 to over 10 years, depending on how often the user performs therapy exercises each day. By placing male Nylon Velcro with an expected lifespan of 11 years on the bottom of the sensor base, the connection can be guaranteed to last at least as long as the maximum lifespan of the electronics.

A 'package' that a user would receive or purchase should contain 1 wrist wraps, 5 finger modules and one sensor module, which will last the user for the next two years until the wrist wrap and finger modules must be replaced. At the same time, the sensor module can be examined for electronic deterioration. Since the sensors are only used during therapy, there exists an opportunity to have the Adjuvo Platform keep track of the number or repetitions that each sensor module has made, based on the results of the exercises.

6.6 Aesthetics

With all components identified, a quick study in aesthetics was performed to allow the new product to fit into its intended context of use. Based partly on input from physiotherapists, the design should look "*Modern*", "*Hygienic*", "*Simple*" ans "*Sportive*", and should not appear to be "*Medical*", although this association will always be present due to the context of use. The mood-board in figure 6.11 was created in an attempt to capture these characteristics.

The mood-board contains two gloves that match the envisioned characteristic. Much of the '*Sportive*' characteristics in these gloves comes from the mesh fabric used, which allows for ventilation during exercise. A *'Portal Gun'* from the game *Portal* is also present, as it shares the same aesthetics and includes the use of cables and light.

The conclusion of the mood-board is that white and black can be used to distinguish between the wearable parts and electronics. Due to how easy white fabric is to stain, especially during ADL, the wearable parts should be mostly black.

Accents of blue or orange are used to indicate which side (Left or Right) the brace is intended for. The left sided gloves have blue accents, while the right sided gloves have orange accents. This way, it is clear at a glance which of the two the user is equipping. The two versions are shown in figure 6.12. In this figure, two implementations of the two colors are shown; one that uses the blue- or orange as the main color, shown on the outside, and the inside two designs, which use these colors as accents only.

Figure 6.11 - Mood-board for the design

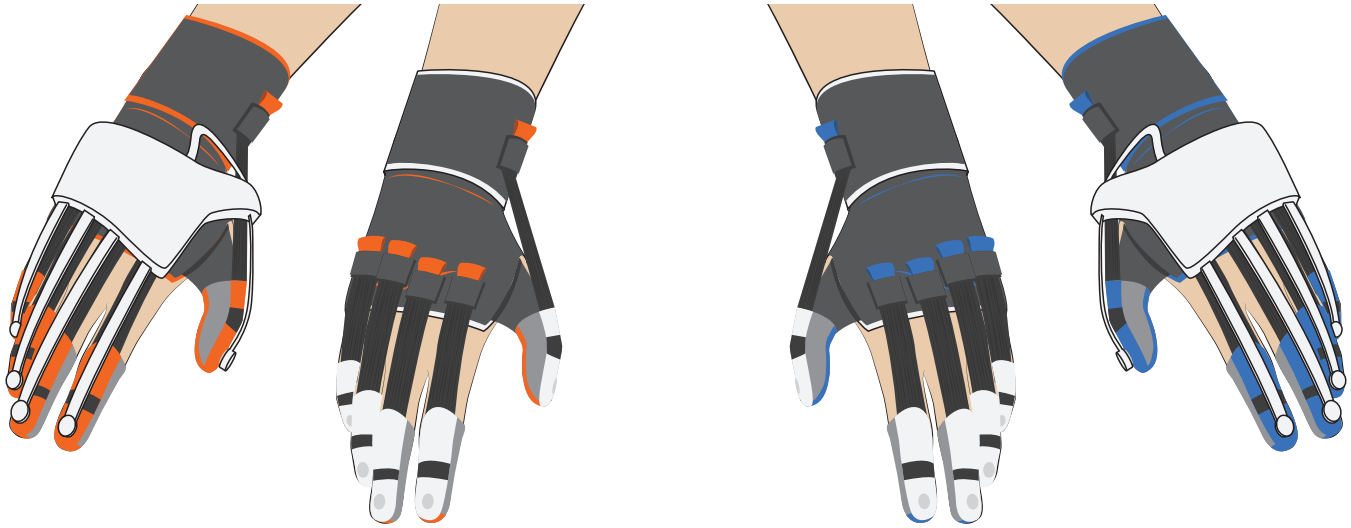


Figure 6.12 - Left- and Right sided gloves.

6.7 Cost Price Estimation

With all components fully embodies, a concise cost analysis was made to determine the pricing of the individual modules, as well as the price of one complete passive assist brace. For this calculation, a batch size of 1000, based on the 1140 potential users, as calculated in Chapter 6.2. Naturally, as the batch size increases the component prices decrease.

For the eight custom components, material costs were calculated by using a price per kilogram estimation from the *Cambridge Engineering Selector (CES)*. The weights were calculated by multiplying the component volume, assessed though the CAD software Solidworks, with the material density taken from the CES. The exception for this is the Wrist Wrap, the price of which is based on the purchase price of the Prescot Wrist Brace, which is €2.75.

Because the custom sensor base components will be made using 3D Printing, their production cost is negligible. The costs of any one-time investments, such as the printer, are indicated separately. Molds for the Finger Orthosis and Sensor Links are estimated to be €500 each. The assembly of each component is estimated to take one hour per sub-assembly, performed by a worker earning an hourly rate of €15,-.The exception to this rule is the Sensor Link, which is easier to create.

The cost prices for each off the shelf components was based on their commercial prices at reputable Online vendors, such as *Sparkfun* and *Adafruit*.

Each of these individual calculations lead to the production prices in Figure 13. Assuming a sales margin of 140%. This means that a full Adjuvo Auxilius package would cost €250 to produce and €350 to sell. The price distribution is nearly even between the finger modules, sensor base and sensor links. Individually, the sensor base is most expensive, but there are five finger modules and sensor links per Auxilius which bring their total cost up to the same level. The most expensive element of the finger modules is their assembly, while the more expensive flex sensors bring up the price of the sensor links.

Audjuvo Auxilia — Batch Size 1000

Part	Component	Material	Production	Material Cost	Production Costs	Subtotal
Wrist Wrap						
A	Wrist Wrap	PE/Nylon	Sewing	€ 2.00	€ 15.00	€ 17.00
					Single Component	*€ 17.00*
					Subtotal	*€ 17.00*
Finger Modules						
B1	Stretch Material 40mm	PE/Nylon	Off-Shelf	€ 0.05	€ -	€ 0.05
B2	Glove Structure	Cotton	Sewing	€ 0.02	€ 15.00	€ 15.02
B3	Finger Orthosis	Silicone Rubber	Moulding	€ 0.01	€ -	€ 0.01
	Metal Insert	Stainless Steel	Off-Shelf	€ 0.80	-	€ 0.80
					Single Component	*€ 15.87*
					Subtotal	*€ 79.36*
Sensor Base						
C1	Sensor Module - Top	ABS	3D-Printing	€ 0.07	€ -	€ 0.07
C2	Sensor Module - Bottom	ABS	3D-Printing	€ 0.04	€ -	€ 0.04
C3	Thumb Swivel	ABS	3D-Printing	€ 0.01	€ -	€ 0.01
-	Microcontroller	-	Off Shelf	€ 12.00		€ 12.00
-	PCB	-	Off Shelf	€ 3.00	€ 15.00	€ 18.00
-	LI-Battery 400mAh, 3.7V	-	Off Shelf	€ 6.95		€ 6.95
-	9DOF IMU	-	Off Shelf	€ 20.00		€ 20.00
-	10x 10kOhm Resistor	-	Off Shelf	€ 2.50		€ 2.50
	1x Rotary Potmeter	-	Off Shelf	€ 1.60		€ 1.60
					Single Component	*€ 61.18*
					Subtotal	*€ 61.18*
Sensor Links						
D	Sensor Link	Silicone Rubber	Moulding	€ 0.03	€ 5.00	€ 5.03
	Flex Sensor 4.5"	-	Off Shelf	€ 12.50	€ -	€ 12.50
	Ribbon Cable 100mm	-	Off Shelf	€ 0.07	€ -	€ 0.07
	Magnet 6x3mm, 0.9kg	-	Off Shelf	€ 0.35	€ -	€ 0.35
					Single Component	*€ 17.95*
					Subtotal	€ 89.75
Production Materials						
-	3D Printer	-	Off Shelf	€ 2.00	-	€ 2.00
-	Finger Orthosis Mould		Custom	€ 0.50	-	€ 0.50
-	Finger Link Mould		Custom	€ 0.50	-	€ 0.50
					Subtotal	€ 3.00

Total Production Price	€ 250.29
Retail Price	€ 350.41

Figure 6.13 - Cost Price Breakdown

6.8 Algorithms

Fingers

The flexion and extension of each finger is measured using flex sensors. The resistance of these sensors increases as they bend. Using a voltage divider with a 10kΩ resistor, shown in figure 6.X, the bending of the sensor can be determined though its reference voltage (*Vref*). This reference voltage is translated into an analog signal between 0 and 1023, representing 0 to 5V respectively.

The analog signal will vary between two integers, *IMax* and *IMin*, representing the flex sensor and finger in their fully extended and fully flexed state respectively, which are relatively similar for each person. Assuming that, during unobstructed movement, the (spastic) fingers move along a fixed path *P*, the position of the finger on this path can be determined with the reference integer *Iref* using the formula for P(t) in figure 6.14. A RoM assessment can be performed with this algorithm by determining the range between *IMax* and *IMin* the user can reach.

Using linear interpolation, *Iref* can be used to roughly determine the finger angles, which can only be used to create a graphical representation of the finger movement, for exercise purposes.

Abduction and Adduction of the thumb are measured using an absolute rotational potentiometer, which works similar to the bending sensor, with a reference signal that varies between 0 and 5V, or 0 and 1023.

Wrist

An Inertial Measurement Unit (IMU) will measure the Pronation / Supination, Dorsal- / Palmar flexion and Radial- / Ulnar deviation of the wrist. To ensure a consistent measurement and to compensate for drift, a 9DoF IMU is required, containing an accelerometer, gyroscope and magnetometer (compass). By aligning the IMU with the dorsal side of the hand, the movement of the wrist relative to the Earth's gravity is determined. Using a single IMU means that the product cannot measure Dorsal- / Palmar flexion and Radial- / Ulnar deviation relative to the lower arm, and can therefore not accurately assess wrist function. However, this is the case for all State of the Art products that measure wrist movement. While adding a second IMU of €20 would extend the functionality to the wrist, it also increases the cost price by at least

Micro Controller

The mircrocontroller will run a simple algorithm that collects the reference voltage of the five flex sensors, the IMU and the potentiometer as analog signals, and sends these over wireless communication along with the device ID to a computer. If a cable is connected, the data should be sent through serial communication instead. Since most modern games can run at up to 60 frames per second, the controller collects the data every 10ms which is more than enough to prevent any visual lag. It is up to the console on the computer to decide when to actually process this data.

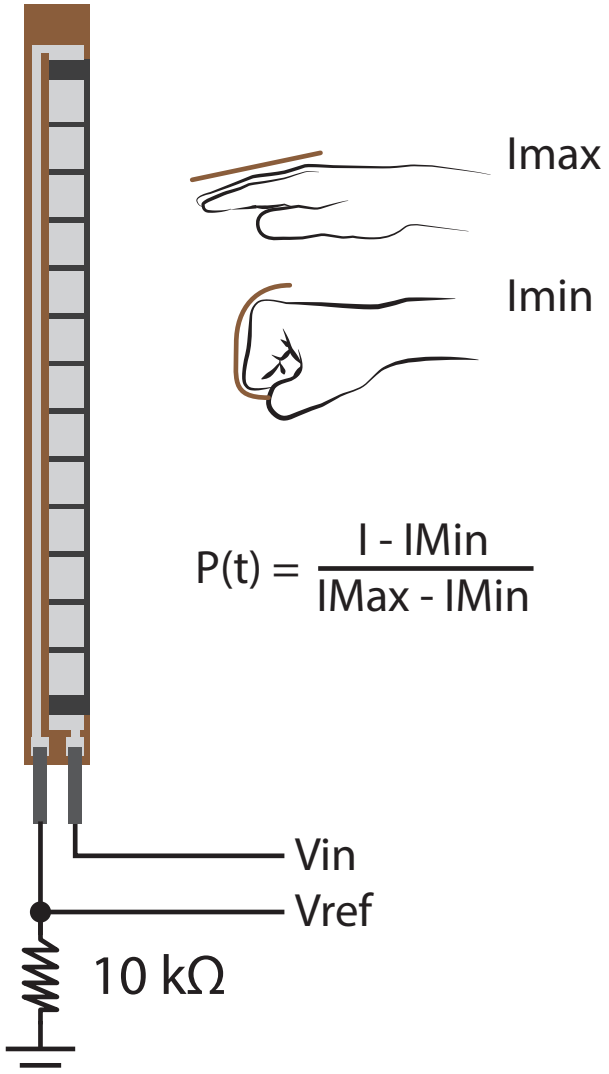


Figure 6.14 - Flex sensors

6.9 Conclusion

The embodiment stage concludes with every detail of the Adjuvo Auxilius known: The product consists of 20 components, 9 of which were not available off-the-shelf, and were embodied in this stage. The resulting design is visualized in figure 5.15, and its Bill of Materials is shown in figure 5.16 below.

The product will cost roughly €250 to build and €350 to purchase, which will last the user for at least 2 years, after which the orthoses should be replaced. The more expensive electronics, however, will last anywhere from 2,5 to 10 years, depending on the intensity of the training it is used for.

The next step is to evaluate the design of the Adjuvo Auxilius, based on the requirements set in the Analysis Stage

Part Number	Item	Quantity	Material	Production Method	Custom Design
A	*Wrist Wrap*	*1*	*Neoprene & Velcro*	*Sown by hand or machine*	*Yes*
B	*Finger Module*	-	-	-	-
B1	Flexible Material	5	Elasticised Band (PE)	Off the shelf component	Yes
B2	Glove Structure	5	Cotton Fabric	Cutting & Sewing	Yes
B3	Finger Othosis	5	Silicone Rubber	Molding	Yes
B4	Metal Insert	5	Stainless Steel	Off the Shelf component	No
C	*Sensor Module*	-	-	-	-
C1	Sensor Module - Bottom	1	ABS	3D Printing	Yes
C2	Sensor Module - Top	1	ABS	3D Printing	Yes
C3	Thumb Swivel	2	ABS	3D Printing	Yes
-	Microcontroller	1	-	Off the shelf component	-
-	PCB	1	-	Off the shelf component	-
-	Lithium-Ion Battery - 400mAh	1	-	Off the shelf component	No
-	Mirco USB connection (Female)	1	-	Off the shelf component	No
-	9 DOF Intertia Measurement Unit (IMU)	1	-	Off the shelf component	No
-	10kΩ resistor	5	-	Off the shelf component	No
D	*Sensor Link*	*5*	*Silicone Rubber*	*Insert Molding*	*Yes*
-	Flex Sensor - 4.5”	5	-	Off the shelf component	No
-	Magnet Ø6x3mm	5	-	Off the shelf component	No
-	Ribbon Cable	5	-	Off the shelf component	No
-	*Bolts M2.5x25mm*	*4-8*	*Stainless Steel*	Off the shelf component	*No*

Figure 5.16 - Bill of Materials

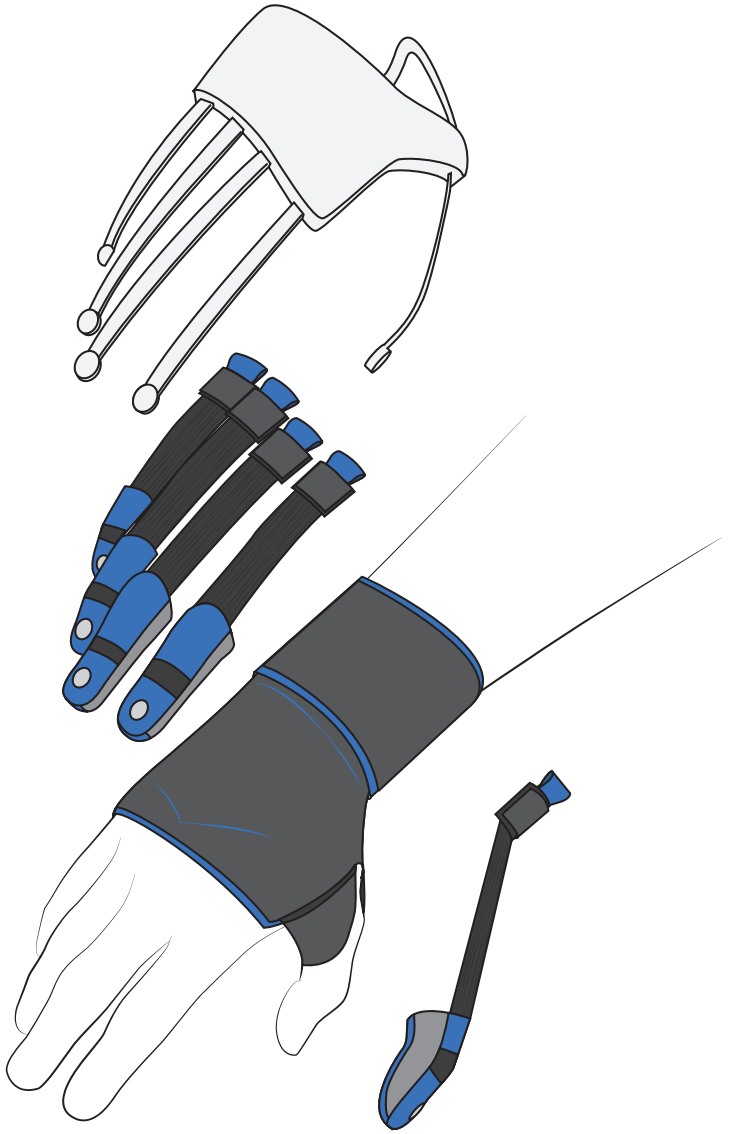


Figure 5.15 - The Adjuvo Auxilius

7. Evaluation

The goal of the evaluation stage is to validate the product in terms of its working principle and its most important requirements. At the end of the Analysis stage, 9 of the most important requirements were identified:

1. The brace can be donned by the user themselves (Evaluated with user test).
2. The product can be put on within 1 to 5 minutes. (Evaluated with user test)
3. The device compensates for up to 5N-8N of force per finger.
4. The level of spasticity compensation is adjustable.
5. The mechanism must NOT put the fingers in hyperextension.(Evaluated with user test)
6. The brace measures finger and thumb flexion, thumb abduction/opposition, and wrist flexions, deviations and pronation/supination.
7. The product can detect a Large Diameter-, Tripod-, (Lateral) Pinch-, Sphere- and Tool Grasps.
8. The device increases the Active Range of Motion (RoM) of the joints in the lower arm of spastic stroke patients through stretching exercises. (Evaluated with user test)
9. The device will have a production price of €200-€300.

While six of these can be tested objectively, requirements 1, 2, 5 and especially number 8 must be tested by the intended user in order to evaluate the design of the *Auxilius*.

7.1 Requirement Testing

The most straightforward requirements to test are those that can be objectively assessed by looking at the results of the embodiment stage.

3. The device compensates for up to 5N-8N of force per finger.

The device compensates for spasticity using a elastic fabric to create an additional set of extensor muscles. It does so for the MCP and DIP joints. The flexible material used by the Adjuvo Auxilius can withstand forces over 10N. As calculated in chapter 6.1, this would result in a material stress of 0.75MPa versus a Yield strength of 9MPa.

4. The level of spasticity compensation is adjustable.

The level of compensation can be adjusted by moving (pre-loading) the flexible material. Due to the Velcro connection between the finger modules and wrist wrap, the level can be adjusted with significant freedom. However, there is no indication of the level of passive assist on the brace itself. A small, colored ribbon on the end of the finger module makes the Velcro connection easier to adjust or remove.

6. The brace measures finger and thumb flexion, thumb abduction/opposition, and wrist flexions, deviations and pronation/supination.

The Auxilius measures each of these movements with one DoF: The finger- and thumb flexions are measured using flex sensors, while thumb abduction/opposition is measured using a rotational potentiometer. An Inertia Measurement Unit is used to measure the wrist movement relative to the ground, which is sufficient for finger stretching exercises, but cannot give any results regarding palmar/dorsal flexion or ulnar/radial deviation relative to the wrist.

7. The product can detect a Large Diameter-, Tripod-, (Lateral) Pinch-, Sphere- and Tool Grasps.

As determined from the grasp taxonomy analysis in chapter 2.2.2, a product should be able to measure each finger flexion, thumb flexion and thumb abduction with at least one DoF. The Adjuvo Auxilius does so using five flex sensors and a rotary potentiometer to achieve this measurement with one DoF each, and passes this requirement.

9. The device will have a production price of €200-€300.

In Chapter 6.4, the estimated production price for the entire passive assist brace is €250, which is inside the range set by this requirement.

7.2 User testing

Goal

The goal of the user test was to evaluate the product on the remaining four requirements. Each requirement was assessed by a different aspect of the test, using the prototype seen in figure 7.1. This prototype contains the sensors for the fingers only. Due to time constraints, the user tests were limited to healthy subjects only.

Figure 7.1 - The prototype created for user tests.

Method

Testing methods for the individual requirements were established first, in order to design a method that would test all four requirements. Afterwards, they were compiled in to one setup.

1. The brace can be donned by the user themselves.

This requirement is tested by having the participant put on the Wrist Wrap, finger modules and sensor module by themselves, after showing them the equipment process. No help is to be provided at first. If the participant fails to put on the product by themselves after 5 minutes, the product fails both this requirement (1) and the next (2) for this user. The participant should be assisted with the equipment steps for the next stages.

2. The product can be put on within 1 to 5 minutes.

The user is instructed to put on the brace by themselves, which is timed in order to assess this requirement. This step is skipped if the first requirement (1) is already failed. Filming the user test will make it much easier to time this step. To take into account a 'learning curve', the equipment process is repeated two to four times per user to determine if it becomes easier after the user becomes familiar with the product.

5. The mechanism must NOT put the fingers in hyperextension.

Due to the glove-structure of the finger modules, it is difficult to see whether or not they place the Interphalangeal joints in hyperextension, even on a video. Instead, this is asked as a question while the participant is equipping the brace. Hyperextension of the MCP joint is easier to detect, and a note will be made whether or not any hyperextension occurs. Should the hyperextension occur and cause pain for the user, the test should be called off.

8. The device increases the Active Range of Motion (RoM) of the joints in the lower arm of spastic stroke patients through stretching exercises.

This requirement is tested by measuring a participants active Range of Motion (RoM) with a Goniometer both before, during and after performing tasks with the passive assist brace. This can only truly be tested on spastic stroke patients, as there will be little to no noticeable difference between measurements on healthy subjects. If there is an increase in active RoM, this requirement is passed.

Based on the results of three pilot-studies, the testing methods for these four requirements were compiled into a three-step evaluation:

First, the participant is asked to equip the brace two to four times, after being shown the equipment process. Next, they are to perform five tasks while wearing the brace, which are based on exercises present in stroke assessments such as the *Chedoke Arm and Hand Activity Inventory*. These exercises are used to simulate a combination of Activities of Daily Living and Therapy sessions, and are marked as a pass / fail. The form used to write down the results of the tests is shown in figure 7.2.

When testing with spastic stroke patients, the third part of the test measures the RoM of the Thumb and Index finger before, during and after wearing the brace. The choice to measure only these two fingers was made to reduce the amount of data-points and thus the time it takes to complete the test. For healthy subjects, the active RoM section will not be administered.

Adjuvo Motion

A smart brace to support spasticity management in post-stroke rehabilitation

Evaluation Form

Date :
Participant :
Prototype :
M/V :
Stroke/Spastic? :

Test 1 – Equipping

Attempt	Time Glove	Time Sensors	Notes / Remarks
#1			
#2			
#3			
#4			

Does the brace put the finger into hyper-extension?

Test 2 – Handling during Activities of Daily Living

Requesting the participant to handle a few objects, with the sensor part equipped:

1. Picking up a ping-pong ball, and place it in an empty cup — pass / fail
2. Picking up a pencil and writing their name — pass / fail
3. Picking up a coin from the table — pass / fail
4. Picking up and drinking from a cup of water. — pass / fail
5. Picking up a cup of water and pouring it into an empty one — pass / fail

Test 3 – Range of Motion

(In case of spasticity) Does the product increase the user's active range of motion?

	Thumb Abd		Thumb MCP		Thumb IP		Index MCP		Index PIP		Index DIP	
	Min	Max	Min	Max	Min	Max	Min	Max	Min	Max	Min	Max
Before tasks												
Prototype Equipped												
After tasks												

Figure 7.2 - Evaluation Form for the user test

Results

In total, the test was conducted on 5 healthy subjects.

All of the subjects were able to put the brace on by themselves after seeing the equipment process. However, 3 of them were confused by the shape of the *Prescot* Wrist Wrap; attempting to wrap it around the palmar side first, which would leave the back of the hand without any Velcro connection.

Equipping the wrist wrap, finger modules and sensor module takes an average of 1:15 minutes, and stays relatively constant as the participants become more familiar with the product. Figure 7.4 shows the equipment times of the Adjuvo Auxilius per user, as well as the average per number of attempts.

After the brace was properly equipped, the participants completed on average 5 out of 5 tasks without much effort, with the exception of task number 3: Picking up a coin from the table. Due to the shifting of the cotton fabric, picking up small objects with the Adjuvo Auxilius remains a challenge.

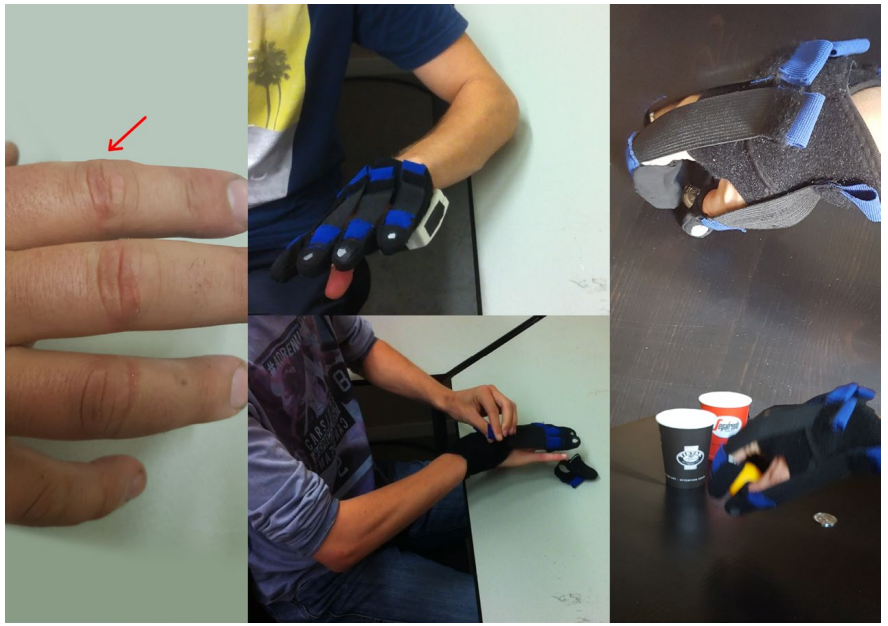


Figure 7.3 - Impressions from the user tests.

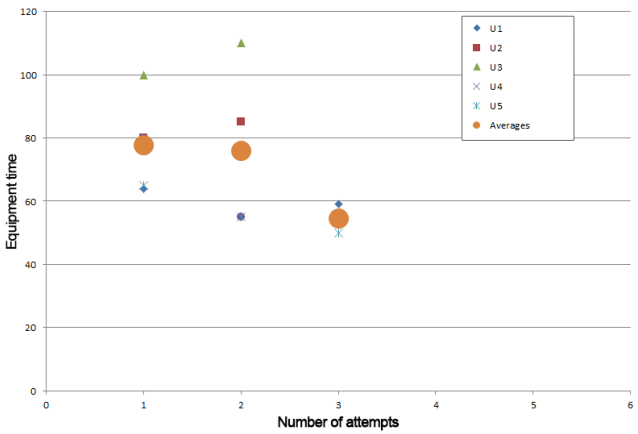


Figure 7.4 - The 'learning curve' of the Auxilius

Discussion

Prototype

Several comfort issues can be attributed to the way the product was prototyped: It used PLA rings for the finger orthoses which were 3D printed. This made the finger modules uncomfortable for several users, especially those with larger fingers. This again stresses the importance of making the finger orthoses from a semi-hard or flexible material. Furthermore, since these units were integrated on the inside of the finger modules, they would create a small 'pocket' in the glove structure just after the orthosis, on which a spastic finger might get stuck. As a result of this discovery, the decision was made to integrate the finger orthoses on the outside of the glove structure instead.

Another issue that was a result of the prototyping method was the fact that the sensor links were too long to fit the smaller fingers like the pinky finger. This problem occurred because the sensor base made rectangular and was not long enough to accommodate the travel needed to equip it to a smaller finger. This issue, combined with the less than ideal sliding mechanism, led to the decision to redesign these sensor links.

The magnetic connections were not as suited for the context as originally anticipated, due to them attaching to each other, and requiring dexterous movements to remove. Therefore, this connection must be improved in a next iteration of the sensor links.

Lastly, a Prescot Wrist Brace was used to simulate the Wrist Wrap, which did not function as desired. It did not cover the entire dorsal side of the hand, which meant the finger units would take up space for the sensor module, which in turn, made for a less stable connection of the electronics.

Requirements

Though one can with certainty say that the Adjuvo Auxilius passes requirements 1,2 and 5 when used by a healthy person, the results of this evaluation cannot be extended to spastic stroke patients. The last requirement, dealing with an increase of Active RoM, could not be evaluated using healthy subjects only.

However, there is one positive to using healthy subjects: Because some stroke survivors suffer from a (temporary) loss of their sense of touch, a healthy subject has a greater chance of noticing small discomforts, which might go unnoticed to a stroke survivor. It is therefore desirable to test the comfort of the Auxilius with both healthy and affected subjects.

Since the working principle of the Adjuvo Auxilius is similar to that of the *Saebo* products, a hypothesis could be made that the Auxilius would work roughly as well as these existing products. However, there is no guarantee until the product is tested with the intended users.

7.3 Design Improvements

Based on the feedback from the user tests, the design of the Adjuvo Auxilius was changed to better fit the intended use. The largest change was made to the sensor base- and links, and a small adjustment to the finger units was required. Furthermore, two extensions on the product are proposed, which extend the functionality of the *Adjuvo Auxilius*.

Sensor Link Mechanism

The sliding mechanism created by the sensor base does not function as well as intended, with the finger links getting stuck and their extension limited by the size of the sensor base. With sliding mechanisms proving to be more trouble than they are worth, an attempt was made to create flexible sensor links. By replacing the material between the flex sensor and magnet with another elastomer that can extend up to 50mm as seen in figure 7.3, the problem of the shifting sensor links can be solved. This solution removes the need for ribbon cables due to a direct connection of the flex sensor to the PCB. It also ensures that the sensor base can be made significantly smaller, since it does not have to accommodate the travel of the sensor links.

Connection to Finger Module

Due to the magnets in the sensor links continuously attaching to each other and due to the larger shear forces in the new sensor mechanism, the decision

was made to change the magnetic connection between the sensor links and finger modules to Velcro. This material is used throughout the rest of the product, and is more than capable of resisting the higher shear forces. It can also easily be incorporated into the existing production process of the finger units. The male side of this Velcro connection will be attached to the sensor links through an adhesive backside, and will last at least at much as the Velcro connection on the sensor base; 2.2 years.

Placement of finger orthosis

The finger orthosis was originally embedded on the inside of the finger units. However, this creates a small 'pocket' into the glove structure where a spastic finger might get stuck. Therefore, the decision was made to embed the finger units on the outside of the finger units instead, as seen in figure 7.5.

Alternate Finger Units

An alternate version of the finger units can be created by switching the flexible material with a rigid one. This way, the fingers and thumb can be fixed in an slight 'open' position where the extensor muscles must be used to open the hand. By relaxing the extensors, the hand returns to being slightly opened. This can be used to create a grasping motion where only the extensor muscles are used. However, this alternate version is mostly suited for patients with low levels of spasticity, who can still compensate for their increased flexor tone by training the extensor muscles. Due to the modular nature of this design, the alternate finger modules can be easily incorporated into the solution.

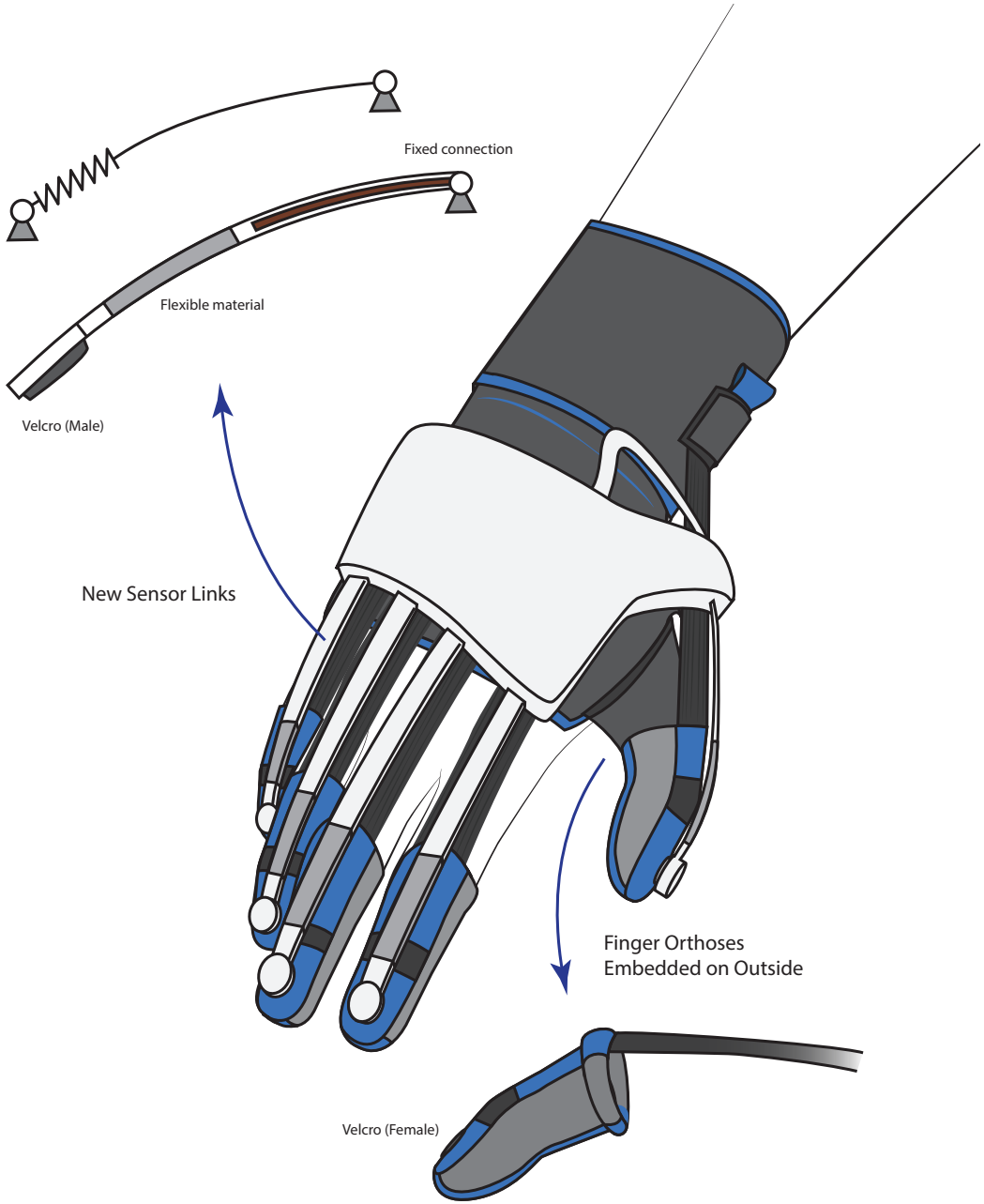
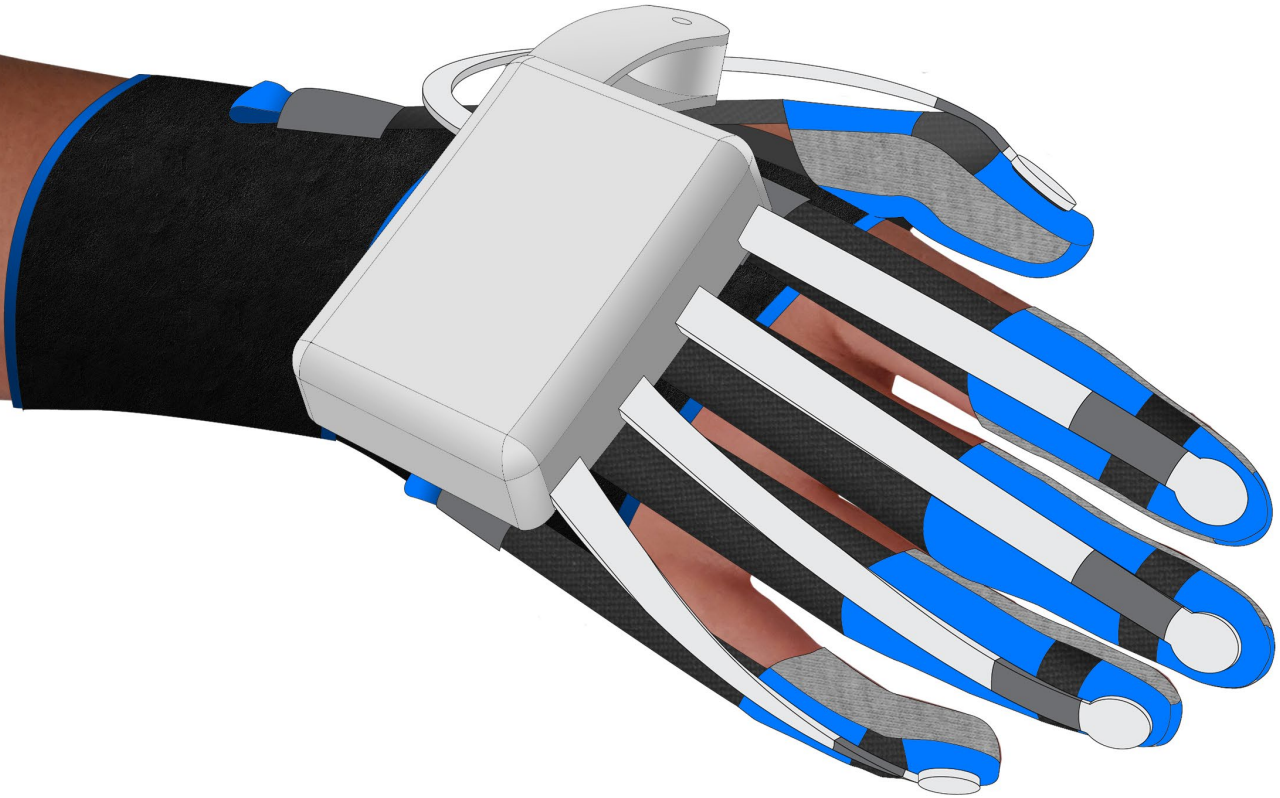
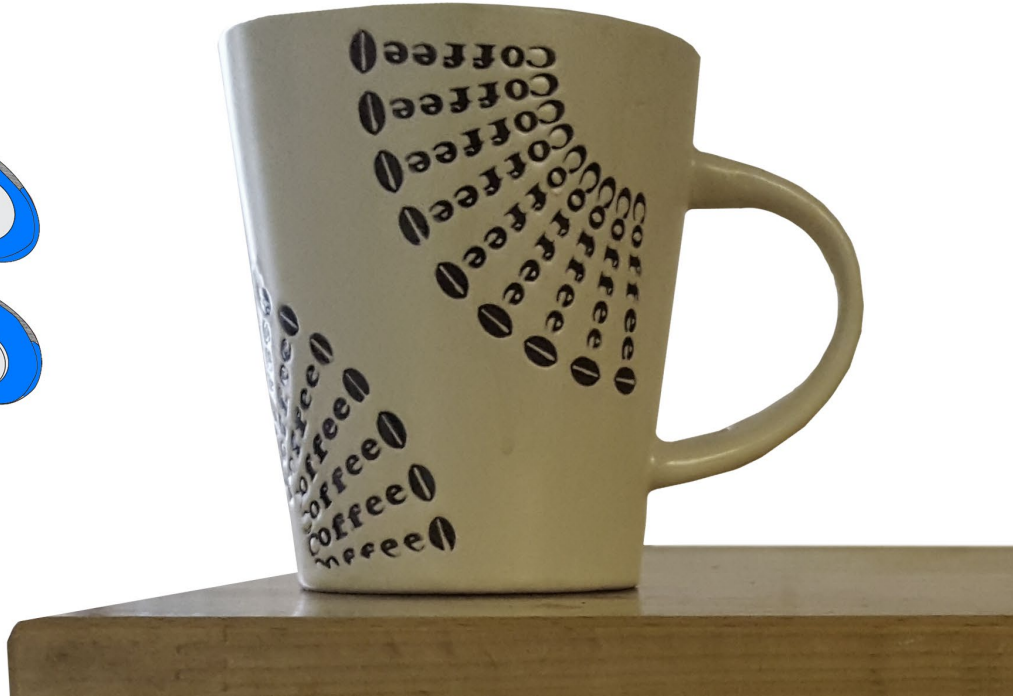


Figure 7.5 - Improvements based on the results of the user tests





8. Conclusion

This report covers the design process towards a smart, assistive brace for stroke survivors suffering from spasticity.

8.1 Process

Through a literature review regarding stroke rehabilitation and existing passive-assist and sensor solutions combined with expert interviews, a design vision was established to create a framework for the design of a smart assistive glove. Throughout this stage, requirements and opportunities were identified and later quantified by literature studies into human factors and relevant technologies. The analysis revealed that, while passive assist- and Range of Motion measurement products have been applied with varying degrees of success to stroke rehabilitation, a combination of these functionalities did not exist yet.

Idea synthesis was performed to find the best suited combination of said functionality. By dividing the framework into three sections, and by breaking these down into smaller sub-problems, a three Morphological Charts were used to create an overview of all solutions, which were combined in various ways to create three feasible concept designs. The performance of these designs were compared to an existing sensor solution and to each other, using seven objective criteria that were weighed with the help of a physiotherapist. The most feasible design created a separation between the soft orthoses with integrated passive assist and the electrical components of the product.

This chosen concept underwent four iterations, which were tested with prototypes, before a consensus on a design was reached. The resulting design was embodied in terms of material selection, production methods, durability costs and sensing algorithms. The resulting design consists of three parts: A wrist brace that serves as a base to connect the second part; the finger modules ‘finger modules’, which compensate for spasticity through a flexible material that serves as an additional set of extensor muscles. The third and final part is a sensor module, which contains all of the electronics and is used during stretching exercises. The product can be used without the sensor as a brace to assist during Activities of Daily Living.

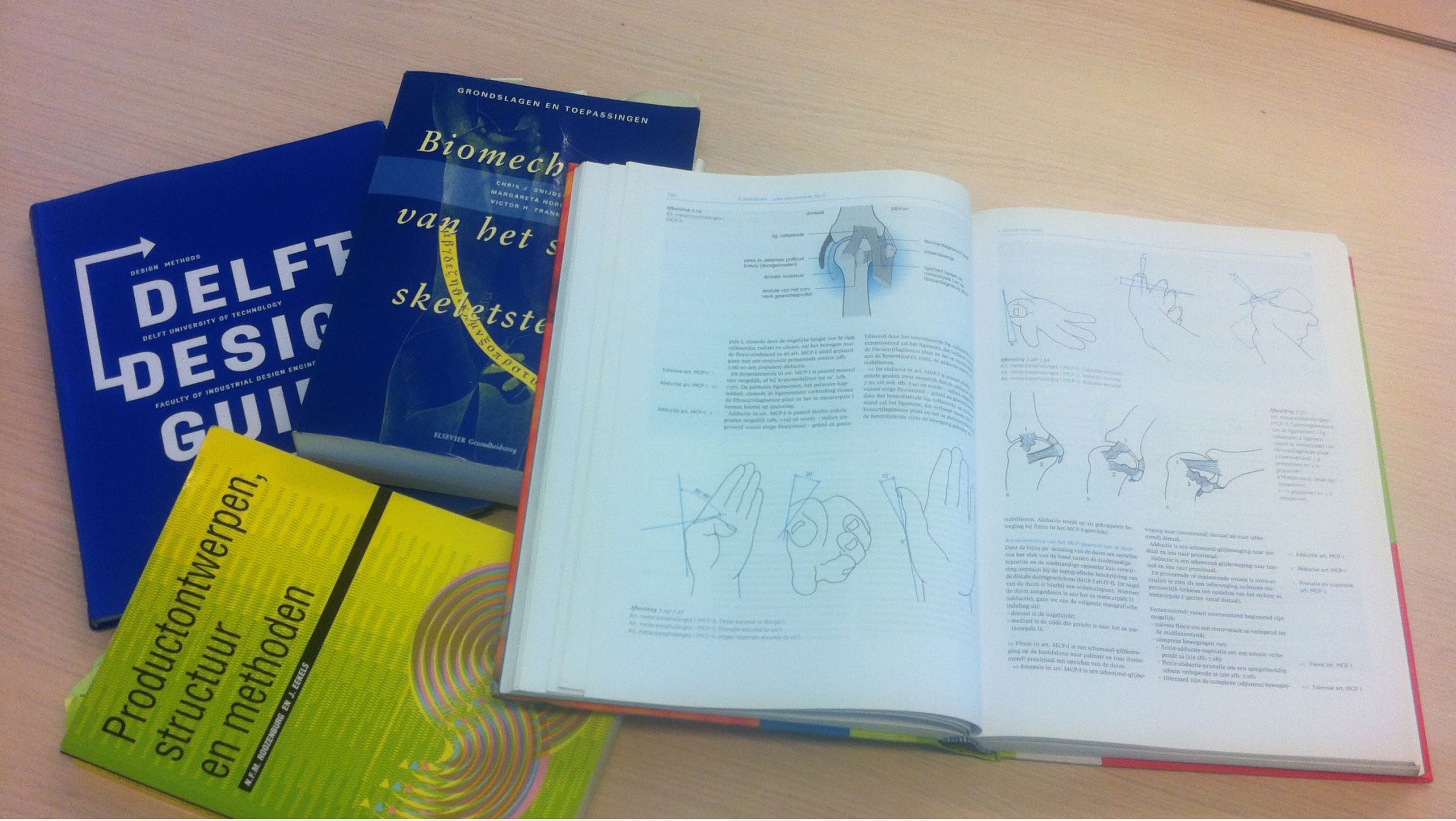
In the evaluation stage, the product was assessed based on its performance regarding the most important requirements set up during the analysis stage. Several of these could be assessed by using the results of the embodiment stage, while others were tested using a proof-of-principle prototype.

8.2 Product

The resulting product, the Adjuvo Auxilius, passes most of its theoretical requirements, being an affordable solution for spasticity forces up to 8N. Using flex sensors, the sensor module can detect the most common grasps in standardized stroke assessments. However, no definite answer can be given regarding its performance with spastic stroke patients as of yet. The user tests revealed a few crucial elements to making the Auxilius more easy to use by both healthy and spastic users, but could not prove the effectiveness of the product in practice. Based on feedback from users, the design was adjusted to the one seen in the figure on the left.

The obvious next step is to test the Adjuvo Auxilius with at least one stroke patient suffering from spasticity, and adjusting its functionality based on the feedback from this session. Further talks with rehabilitation experts are also required to put together an exercise program that will run on the Adjuvo Problem. Furthermore, there are alternate afflictions such as Cerebral Palsy and Multiple Sclerosis where spasticity is present, which could make for promising alternate markets to apply the Auxilius.

When these steps are complete, the Adjuvo Auxilius will make a valuable addition to the Adjuvo Platform for patients suffering from spasticity, and will help bring the rehabilitation center that much closer to home.



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