A tailor-made hand orthosis for patients with ALS to support eating and drinking independently.

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Colophon

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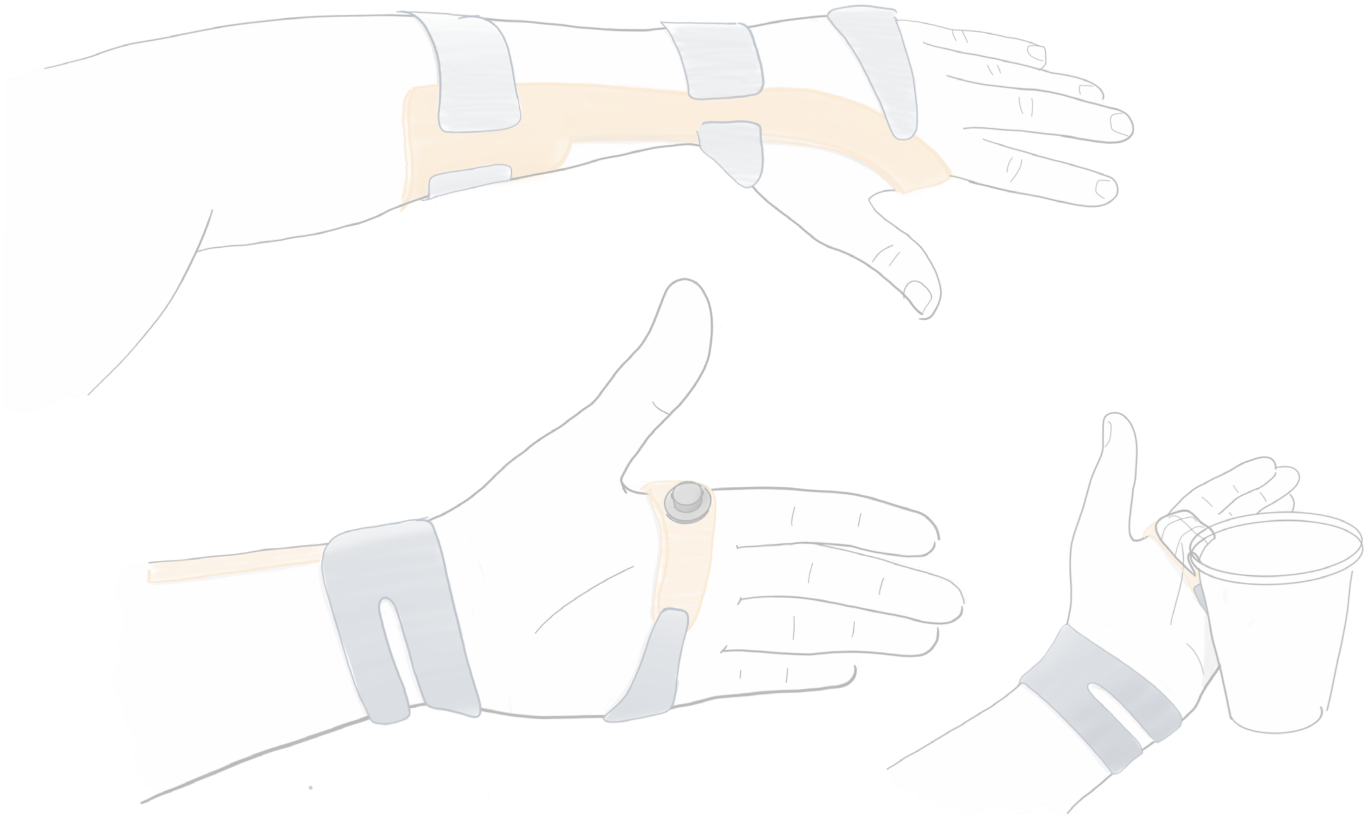
A helping hand during dining.



Preface

This thesis is the final project done to complete the master Integrated Product Design at the Faculty of Industrial Design Engineering at the Delft University of Technology. This project is all about supporting the patient and improving the quality of life, which perfectly matches my incentive. For the past six months, I have put my thoughts to solving the challenge on how to provide more independence for ones suffering from ALS. Working on this thesis has been an exceptional experience for me to learn much about myself and others. ALS is quite a charged subject, a fatal disease, which was definitely tough to process sometimes. But seeing a patient enjoying the use of the tailor-made hand orthosis is my best moment throughout the project. This project would not have been such a success without the help of the following people:

I would like to thank my chair Jos Oberdorf, my mentor Anna Ruiter for giving me structured feedback during the process. They keep pushing me to ask myself critical questions and reflect on my design process.

I would like to thank Paulien Klap, my company mentor for supervising me throughout the project. Her enthusiasm and passion for medical design are very contagious! Discussing and evaluating ideas with her results in many new and valuable insights, it felt like a friend giving thoughtful advice. Besides Paulien, I want to thank all the engineers of Yumen Bionics for advising me when needed, and for the enjoyable office days we had together.

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This project became very personal for me because of the openness of the patients who were eager to share their stories with me. Furthermore, they remained actively involved throughout the project, and I could reach out to them for quick questions. I am passionate about their positive energy and enthusiasm. This motivated me to develop an assistive aid which would be beneficial to them. Thanks, Conny, Chris, Jeanet and Johan.

Also, a big thanks to my roommates and friends, for advising me, my personal spelling check and most important distraction from time to time. Thanks to Jaïr, Jilles, Joost, Marise, Max, Midas, Vera, Willem, and the rest of my friends for an amazing study experience in Delft.

Last but not least, I want to thank my family for being there when I needed it most. They have always shown much interest in my projects at industrial design and beyond. Being most of the time in Delft, I learned how much I appreciate them and certainly cannot live without them.

Enjoy reading!

D.J. Dingemanse

Executive summary

Introduction

This project is about designing a tailor-made hand orthosis for hand support of patients with Amyotrophic Lateral Sclerosis (ALS) -Limb onset to increase independence during desired activities. According to the National Institute of Neurological Disorders and Stroke (2014), ALS, is a progressive neurodegenerative disease which attacks motor neurons in the brain and spinal cord. This results in the wasting away of muscles, by which they are weakened. Patients gradually lose the ability to move, speak, swallow, and, eventually, to breathe unaided within an average of two to four years after the onset of the symptoms (Andersen, P. M., Abrahams, S., Borasio, G. D., de Carvalho, M., Chio, A., Van Damme, P., Weber, M. (2012).

Discover

According to the ALS Association (n.d.), ALS limb onset starts with distal muscle weakness (further away from the heart) and gradually move in the proximal direction (closer to the heart). This means that in most cases, finger strength is lost before weakness in the wrist appears, which is followed by loss of power in the arm. This study starts by evaluating if an arm balancing exoskeleton contributes to performing activities of daily living (ALDs) for ALS patients. However, not being able to control hand movement causes patients not being able to perform essential ALDs. An arm exoskeleton which lacks hand support will not contribute.

Prominent problem

Patients become highly dependent on the care of informal caregivers and assistive aids, which is emotionally and mentally burdensome for both. When patients can perform small tasks like ADLs themselves with assistive aids, it will contribute to the level of independence and unburden the informal caregivers. This study aims to investigate the most prominent problems occurring in the daily life of patients by interviewing four patients. It is found that patients primary prefer to complete dining activities independently because of alleviating their informal caregivers and avoiding home care during these valued times.

Develop

Based on this insight, exploration research is done to find the best way on how to support ALS patients during dining activities. The activity is detailly analysed by dividing dining into smaller actions, which presents the underlying problems. This shows that grasping objects is the first problem which limits patients. A second study compares the applicability of three types of hand support which solve grasp failure: active (dynamic) support, hybrid support, and static support are researched. These supports are discussed with patients and medical experts. The type of support which is operated by patients in the simplest way regarding basic movements and straightforward controlling is chosen to continue for further development. ALS patients can longer operate this type of support, and use this assistive aid immediately without long learning time.

Deliver

A tailor-made static hand orthosis is developed, which provides independence to ALS patients during dining activities. By automatically connecting and releasing to frequently used tableware, no strength of their fingers is required. The orthosis contributes to the level of comfort and addresses the individual differences for patients because it is tailor-made. The orthosis connects to frequently used objects by using a designed connector with magnetic capabilities and a mechanical lock.

Evaluate

This first iteration is evaluated by an ALS patient having mild paralysis in hand. The orthosis is tested while consuming breakfast consisting of fluid and food intake. The orthosis connects well with frequently used objects and operates straightforwardly and simply, which results in performing the dining activities with more independence and ease. Secondly, the results of the study are evaluated with an occupational therapist who agrees that this assistive aid could increase the level of independence for ALS patients. This first iteration can form a base for further development. Still, many iteration steps combined with user tests should follow. The first step would consist of improving the usability of the current connection to cups and other utensils like a fork and a knife.

Reading guide

This report describes the master thesis about designing a tailor-made hand orthosis design for ALS patients to eat and drink independently. The report is divided into five parts, each consisting of several chapters explain essential steps in the process. The colours represent the design phase.

All conclusions made throughout the projects are summarised and presented on the Key takeaways pages. These colouring pages complete the parts and will introduce the reader to the next one. For a quick overview of the process, just read the key takeaways.

Glossary and abbreviations

ADLs	Activities of Daily Living
MND	Motor Neuron Disease
ALS	Amyotrophic Lateral Sclerosis
PLS	Primary lateral sclerosis
PMA	Progressive muscular atrophy

Assistive aid	Designed or intended to assist a disabled person in performing an activity, task, or function especially in an independent manner.
Doffing	Doff is short for do (take) off
Donning	Don is short for do (put) on
Exoskeleton	A wearable mechanic system meant to effectively support upper limb movement for the patient.
Extremity	A limb or appendage of the body.
Physiotherapist	A person qualified to treat disease, injury, or deformity by physical methods such as massage, heat treatment, and exercise.
Occupational therapist	A person to treat injury, ill, or disabled patients through the therapeutic use of everyday activities
Orthosis	A brace, splint, or other artificial external device serving to support the limbs or spine or to prevent or assist relative movement.
Rehabilitation therapist	A person who aims to enhance and restore functional ability and quality of life to those with physical impairments or disabilities affecting the brain, spinal cord, nerves, bones, joints, ligaments, muscles, and tendons.

Dorsal	Dorsal is the back of the hand.
Extension	Extension refers to a movement that increases the angle between two body parts.
Flexion	Flexion refers to a movement that decreases the angle between two body parts.
Pronation	When your hand palm and forearm are facing down, they are pronated.
Supination	When your hand palm and forearm are facing up, they are supinated.
Volar	Volar is the front of the hand.

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Figure 1: Amsterdam city swim, 2019

Project Introduction

This chapter serves as an introduction to the master thesis. It describes the project objectives, research questions and approach.

In this part

1.1 Introduction

This chapter will introduce the reader to Amyotrophic Lateral Sclerosis (ALS), known as a progressive fatal disease, which causes the body to paralyse and eventually die because of respiratory failure. The nature of the disease makes it challenging for patients to live life as they used to. Patients become very dependent on their loved ones and assistive aids. Due to constantly changing needs, it is hard to provide the best care at the right time.

What is ALS?

Amyotrophic Lateral Sclerosis (ALS) is a progressive neurodegenerative disease that causes the death of neurons controlling voluntary muscles (National Institute of Neurological Disorders and Stroke, 2014). The motor neurons reach from the brain to the spinal cord and further to the muscles throughout the body. The progressive degeneration of the motor neurons in ALS eventually leads motor neurons to die. The brain loses the ability to initiate and control muscle movement. This results in wasting away of muscles, by which patients are weakened, and gradually lose muscle control causing not being able to move, speak, swallow, and, eventually to breathe unaided. The most common cause of death is respiratory failure, which occurs within an average of 2–4 years after the onset of the symptoms (Andersen et al., 2012). There are exceptional cases in which ALS patients live much longer than expected like Stephen Hawking did, Figure 2. The illness did not stop him from doing impressive cosmic discoveries, as the illness does not affect the brain functionality or the extraocular muscles (the muscles responsible for eye movement).

Independence

Getting diagnosed with ALS is tough to process. Not only does the patient need to accept that the body will start failing him or her, but one should also learn to live with limits. Since this disease is characterised by difficulties in performing the activities of daily living (ADLs), patients require constant care, which places a burden not only on the patients themselves but also on their family members and friends (Aoun et al., 2013). Patients live an uncertain existence because every morning, when they awaken, they experience more limitations. When the functionality of a body part is lost, it will never return, **'Lost is lost', patient**.

Social isolation

Impaired mobility causes patients to stop driving, travel with public transport, biking or walking, causing ALS patients to become lonely and bound to their residence.

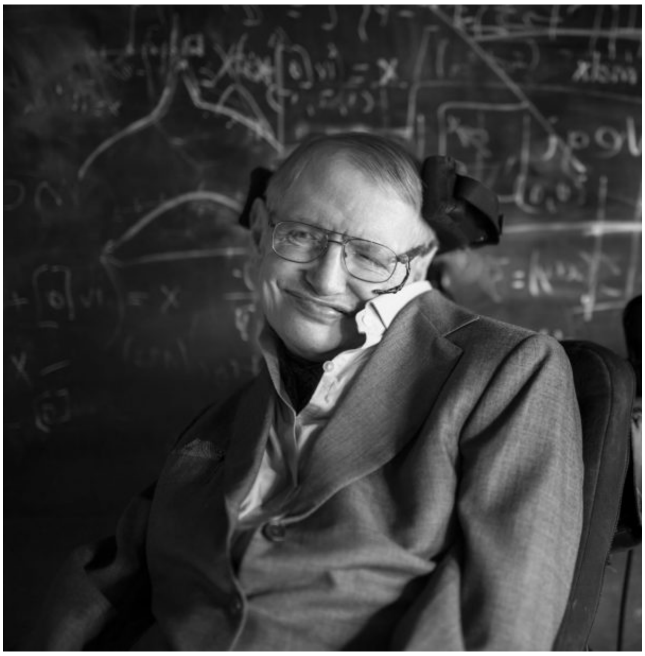


Figure 2: Portratit of Stephen Hawking (Stephen Hawking's Life and Work: A Non-Technical Lecture, 2019)

Occurrence of ALS

ALS usually strikes people between the ages of 40 and 70. In ten per cent of the cases, it is passed on genetically. It occurs slightly more often to males since two-third of all the cases is male. ALS is a very rare disease, on average 1500 persons in the Netherlands suffer from ALS at the moment. This amount of 1500 patients is quite constant because every year 500 persons are diagnosed with ALS and unfortunately 500 patients die as well.

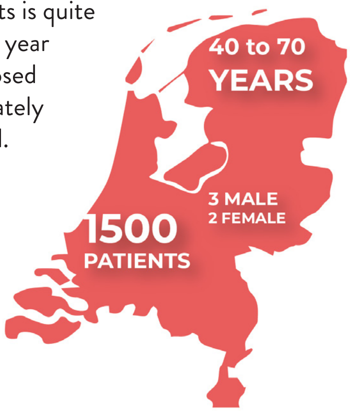


Figure 3: Details about the number of patients in the Netherlands.

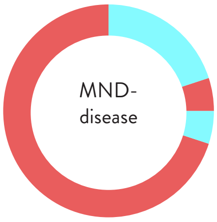
Motor Neurone Disease

ALS is the most known and most common Motor Neurone Disease (MND), other variants of MND-diseases are Progressive Muscular Atrophy (PMA), Primary Lateral Sclerosis (PLS) and Progressive Bulbar Palsy (PBP). All cause impaired functionality in the extremities progressively. The difference between these types lies in the origin of the nerves, causing different outcomes of muscle weakness and progressive variations.

When ALS begins in the muscles of speech and swallowing it is designated as PBP. Starting in these region results in the shortest life expectancy.

PMA is characterised initially by lower motor neurone signs resulting in more generalised muscle wasting and weakness, absent reflexes, loss of weight and muscle twitching.

PLS is characterised by slowly progressive weakness and wasting of muscles with only lower motor neurone involvement and other features (Motor Neurone Disease Association of NSW, n.d.)



Appearance	**Medium survival time from start of symptoms**
PBP (20%)	6 months to 3 years
PMA (5%)	Fast variant 2 to 4 years Slow variant > 10 years
PLS (5%)	8 to 10 years
ALS (70%)	2 to 5 years

Table 1 - Details about the medium survival time from the start of symptoms for MND-diseases.

Is there a solution?

At this moment, there is not a drug which can cure ALS. However, scientists have made significant progress in learning more about this disease. Currently, three drugs (Riluzole, Radicava, and Tiglutik) are approved by the FDA to treat ALS and extend the life with just a few months. The relatively small number of patients means that research budgets from the pharmaceutical industry and the government are small. The vast majority of scientific ALS research in the Netherlands is funded by donations to the ALS Netherlands Foundation, such as Tour du ALS or the Amsterdam City Swim.

Many charity events are organised to raise awareness and funds for finding the cure. In 2014 the Ice bucket challenge went viral to raise awareness for ALS and funding for research (Trejos, 2017), Figure 4 (Slgckgc, 2014).

Figure 4: Ice Bucket Challenge (Slgckgc, 2014).

1.2 Design brief

This master thesis is done to complete the master Integrated Product Design at the faculty Industrial Design Engineering at the Delft University of Technology. The first research challenge is set up together with the Yumen Bionics and is presented below. During the project, this challenge is evaluated and rephrased to fit the needs of ALS patients better.

Problem definition

The main problem of this disease is that the muscles of ALS patients weaken progressively. This has a huge effect on the life of these patients, both mentally and physically. Mentally it is hard to accept that one has to live his or her life with more and more limitations. Physically the body will deteriorate, and less daily tasks can be executed independently, such as self-feeding, dressing and personal hygiene. In this master thesis project, I will focus on returning some level of independence. More specifically, **how can a passive arm exoskeleton be supportive for ALS patients while performing daily tasks independently?** The analysis phase of this project will determine which tasks or actions are crucial or most desired to be completed by ALS patients themselves.

Project scope

The precise scope of the research will follow from the analysis phase and desired tasks by ALS patients. However, the project focuses on support for those with impaired upper limp functionality due to loss of motor neurons. Patients who have ALS with limb onset are the prior target group, while people who develop similar symptoms could also benefit from this assistive aid.

Research question

What are the needs of patients diagnosed with Amyotrophic Lateral Sclerosis (ALS) during different phases of the progression of ALS? Which desired tasks would benefit from a supportive passive arm exoskeleton in what way? What iteration can be done to the arm exoskeleton off Yumen Bionics to fit this purpose better?

Sub research questions are formulated to support answering the main research question.

1. Which phases during the progression of ALS can be distinguished and which physical limits occur?
2. In which phase could ALS patients benefit from technical support during daily tasks?
3. What are the needs and (daily) tasks of ALS patients?
4. In which way can a passive arm exoskeleton be supportive for ALS patients?

Vision

I expect to create an overview which visualises the needs of ALS patients whereby a passive arm exoskeleton could be beneficial to perform daily tasks with more ease. I visualise **a personal add-on device**, which **supports fine motor skills during desired activities**, and can connect physically to the current exoskeleton of Yumen Bionics, see Figure 5. A functional prototype will be built and used to validate the usage. In general, this add-on device should be designed in such a way that it fits the majority of ALS patients and could be provided quickly to the patients to fulfil the current and future needs of an ALS patient in time.

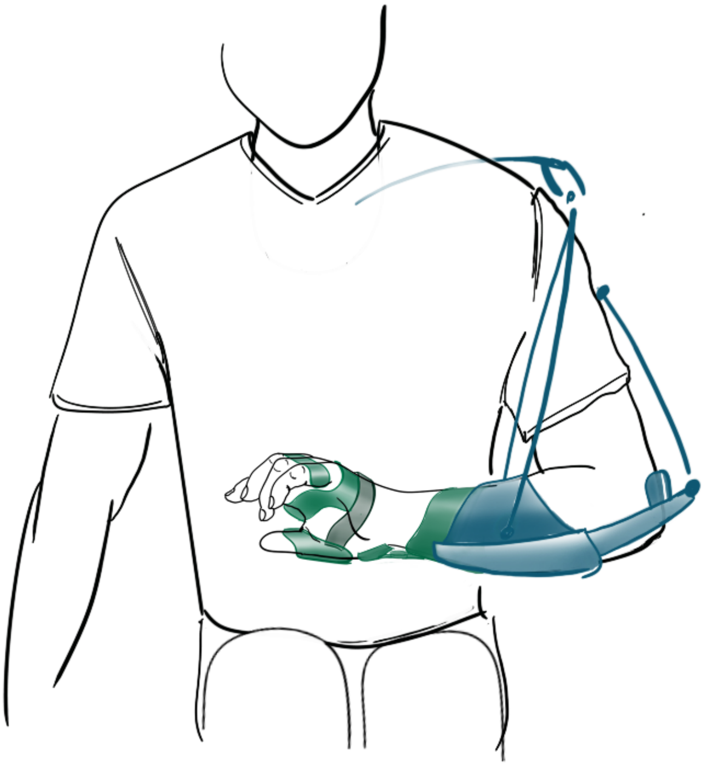


Figure 5: Visualisation of desired vision

Company

This master thesis project is done at Yumen Bionics b.v. This is a social enterprise company, co-founded by the Duchenne Parent Project foundation. This foundation wants to stimulate development of assistive aid for children with Duchenne, which is a muscle disease as well. Yumen Bionics is working independently on the development of a passive arm exoskeleton for children diagnosed with Duchenne (see Figure 6, Duchenne Parent Project, n.d.). The device supports children by lifting the arms, which causes the child's arms to feel weightless. In this way, they can redo things and perform daily tasks with more ease and independence. Since this device showed impressive results for children with Duchenne, the ALS foundation became interested as well. A test with one ALS patient followed, in which potential use is found. This master thesis project will focus on this potential use by further looking into the details of this exoskeleton and by matching its functionality to the needs and wishes of ALS patients.

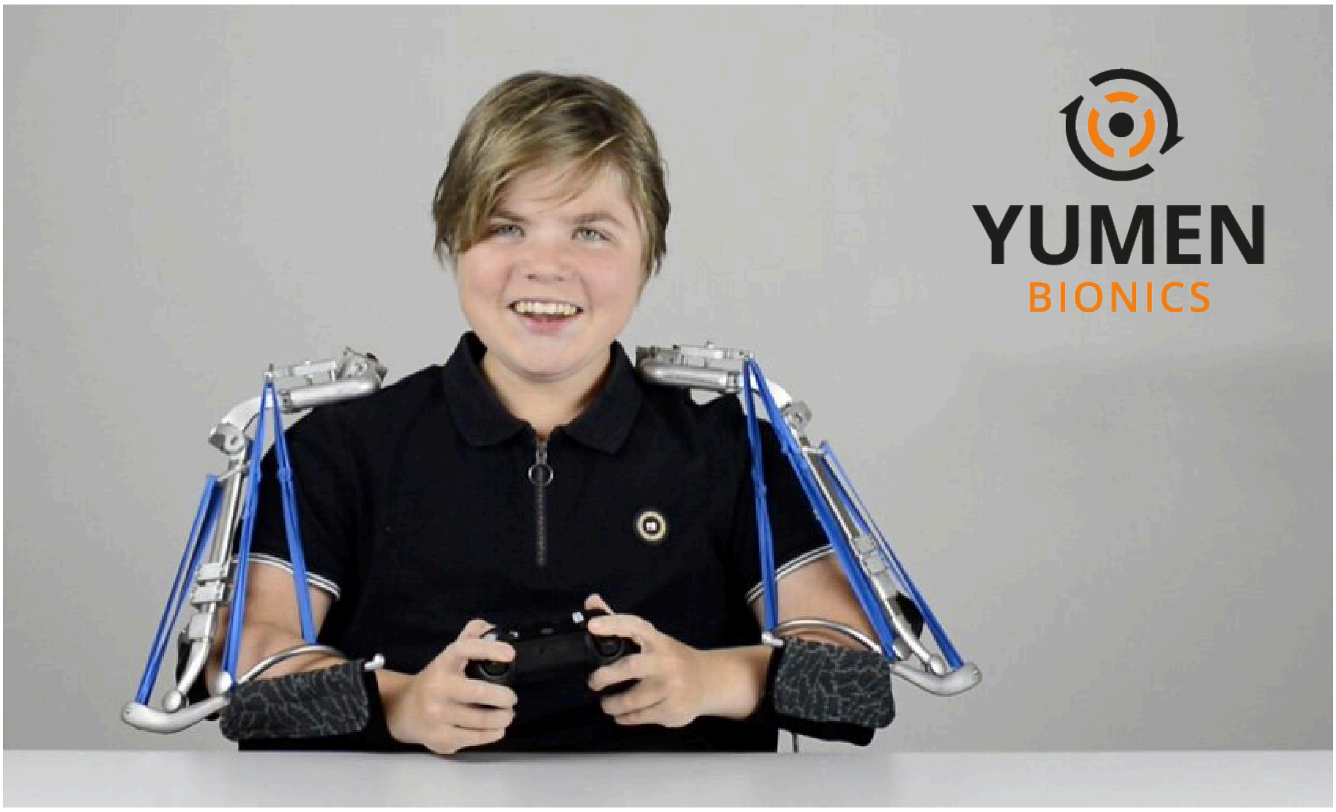


Figure 6: Exoskeleton for children with Duchenne.

1.3 Approach

The approach for this project is inspired by the double diamond model, consisting of an analysis part and a design part, see Figure 7. Within this model four phases can be distinguished: discover, define, develop, and deliver. These phases are structured in the report into five parts. An overview of this process and parts are visualised in Figure 8. To achieve a valued personal solution, a user-centred design approach has been used to discover the most important needs and wishes of the stakeholders.

Analysis

During the discover-phase, literature research and interviews about the context of ALS are performed to understand the initial challenge. Specific needs and desires of patients are found during different stages through interviews with four patients. Experiences with conventional aids are evaluated in the interviews, to provide insight into the usage of the desired aid. The outcomes of these interviews determine which additional information is needed to continue this process.

During the define-phase, the outcomes of the discover-phase are clustered and prioritised. The core challenge of this graduation project is evaluated, and it is questioned if the right problem is being solved. This leads to phrasing the vision accordingly, which forms the basis for further concept development. Medical experts are included in this process to provide feedback to make informed choices regarding the phrased vision.

Design

In the develop-phase, several ideas are generated, and two concepts regarding a support direction are discussed with patients via drawings combined with a video calling session in which the working principle of the concepts is explained. Both concepts are evaluated, and the best valued concept is further developed into a product. Based on the chosen concept a design goal is formulated.

In the deliver-phase, several sprints are held in which design, build, test and review followed each other in order to achieve the design goal by means of a functional prototype. This prototype is tested with one of the ALS patients to validate the design. The results of the test will form the basis of a list of recommendations discussed in the final chapter.

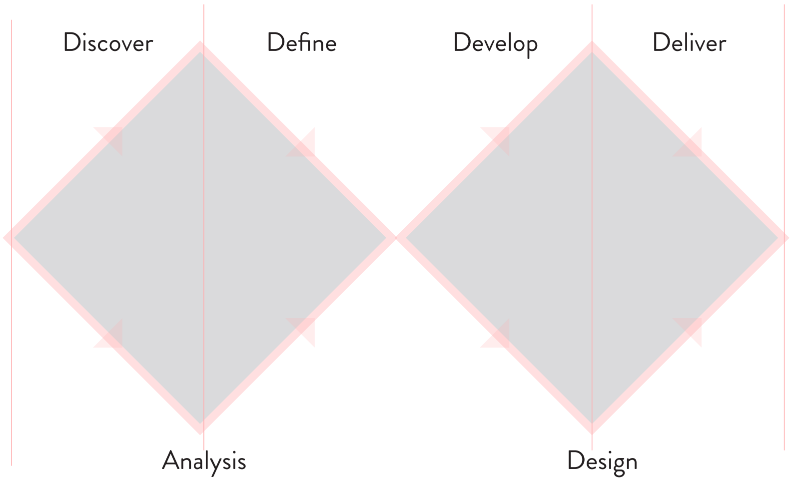


Figure 7: Double diamond model.

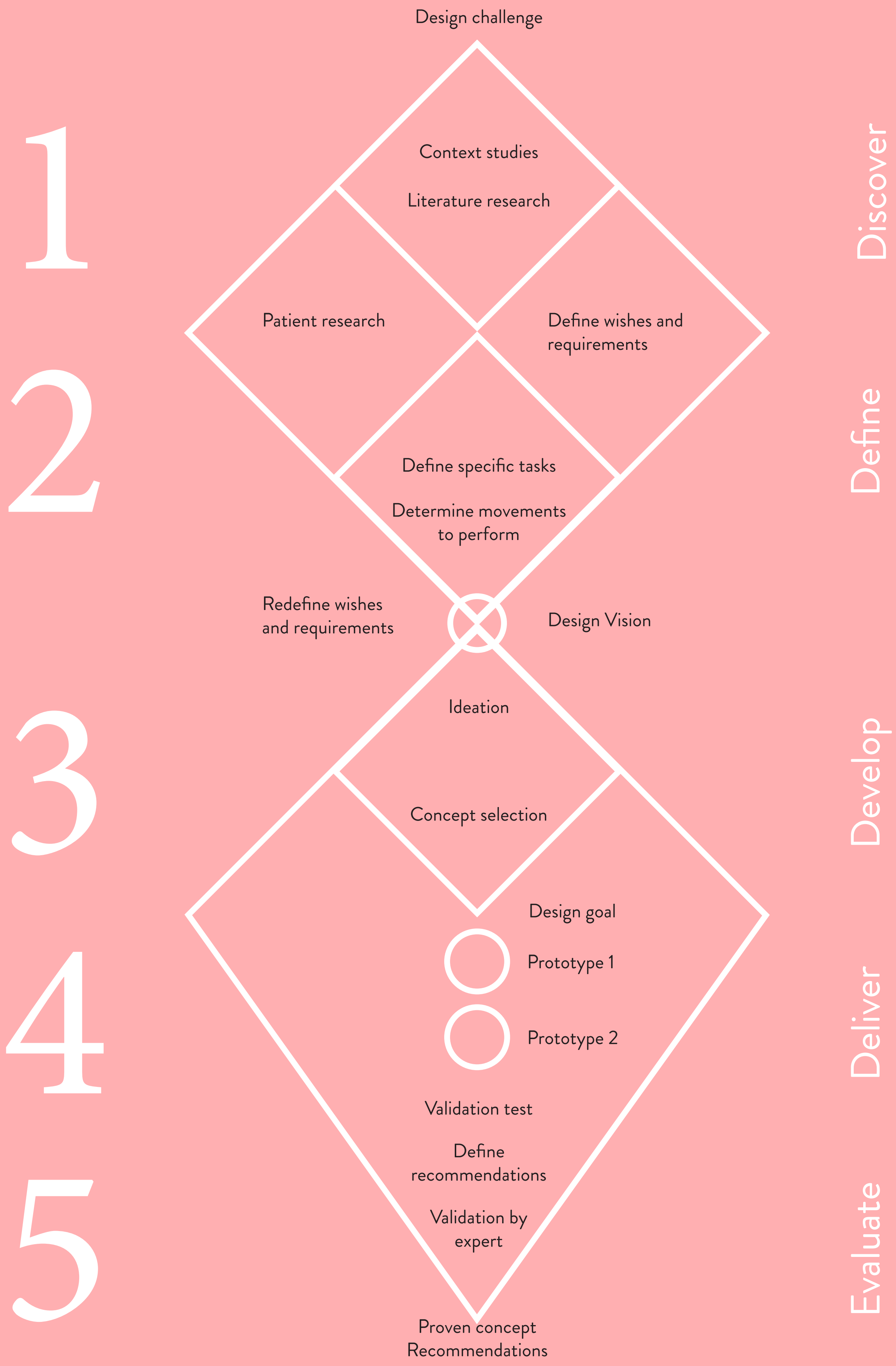


Figure 8: Approach model

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Figure 9: ALS patient at home.

Discover

This part gives a broader understanding of a life living with ALS. Important characteristics of the disease are discussed, resulting in design requirements. The patient's needs and desired activities are discovered by interviews. As of last, an introduction to the world of ALS is given by discussing the role of stakeholders and explaining how products are currently provided to patients.

In this part

2 Design for ALS

Several disease characteristics of ALS make it challenging to design for. The most important characteristic will be explained in this chapter and the consequences for a design of the exoskeleton will be discussed.

2.1 Disease characteristics

Individual differences

Because the disease is heterogeneous, it affects the patients differently, there is no clear path in progression. This makes it challenging to create one solution that fits all or even most patients. Once ALS starts, it almost always progresses, eventually taking away the ability to walk, dress, speak, swallow, and breathe, and shortening the life span. How fast and in what order this occurs is very different from person to person. While the average survival time is more or less three years, about twenty per cent of people with ALS live five years, ten per cent will survive ten years, and five per cent will live twenty years or longer (ALS Association, n.d.-a).
Because patients want to know what to expect after getting the diagnosis ALS, scientists from the medical university of Utrecht made a model which can predict the prognosis for individual cases (H.-J. Westeneng et al., 2018). The results of this study show that patients can be divided into five groups whereby the composite survival outcome (time between the onset of symptoms and non-invasive ventilation for more than 23 h per day, tracheostomy, or death) is predicted. The model could make a prognosis based on 16 characteristics of the patients, including factors like age at onset and progression rate (points per month). However, it could not answer in detail which phases occur in what order, or how gradually, and differently, the phases will follow each other.

Phases of ALS

On average, ALS patients lose about 0.9 Functional Rating Scale points per month. A healthy functional body will score 48 points, while severe disability is noted by 0. Function loss goes extremely fast, and the supportive device should adapt to the patient's ability at that moment. This score is based on a survey which can measure the progression and is most commonly used in clinical trials by doctors to track disease progression of ALS. However, the different phases someone is categorised in do not specify what type of care is needed. The current Rehabilitation Protocol by ALS Centrum Nederland, (Oudenberg, J. et al., 2012) and care for patients with ALS and PSMA describe four phases as follows. Rehabilitations strategies are based on the ALS Health State phase a patient is currently in (G.M. Kiebert et al. 2001).

Phase 1) Mild - a patient is independent.

Recently diagnosed; a mild deficit in one region (i.e. speech, arm, or leg); and functionally independent in speech, upper extremity, activities of daily living and ambulation.

Phase 2) Moderate - a patient is independent because of assistive aid and care.

A mild deficit in all three regions, or moderate to a severe deficit in one region, while the other two regions are normal or mouldy affected.

Phase 3) Severe - a patient is dependent.

Needs assistance in two or three regions; speech is dysarthric and/or patient needs assistance to walk and/or needs assistance with upper extremity activities of daily living.

Phase 4) Terminal phase.

Non-functional use of at least two regions and moderate or non-functional use of a third region.

These phases are very generic and do not go into detail about when a particular assistive aid should be used. It cannot be said when a patient deficit in the upper extremity region and can make use of supportive arm aids because the symptoms per patient are again so different.

Symptoms

Gradual onset, generally painless, progressive muscle weakness is the most common initial symptom in ALS. Muscle weakness starts distal (further away from the heart) and gradually move in the proximal direction (closer to the heart), see Figure 10 (Osteomyoamare, 2010). This means that in most cases, strength in the finger muscles is lost before weakness in the wrist appears and later, strength in the lower and upper arm will be lost as well. In one of the cases described by Tenake et al. (2013), a patient lost his ability to use his right hand in a period of 5 months. Whereby, gradually muscle weakness showed, weakness starting in the thumb and later affected the wrist. Other early symptoms vary but can include tripping, dropping things, abnormal fatigue of the arms or legs, slurred speech, muscle cramps and twitches, and spasms. Some infrequently used muscles may become permanently shortened, causing contractures in which joints (e.g., fingers) are no longer able to straighten fully (ALS Association, n.d.-c).

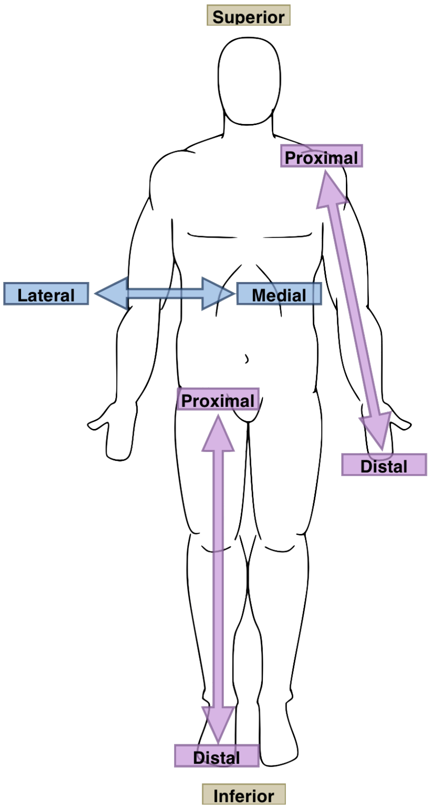


Figure 10: Anatomical directions

Senses

Since ALS attacks only motor neurons, the sense of sight, touch, hearing, taste, and smell are not affected. It is pleasant that these senses still work; the patient can still receive much tactile feedback (information that people can interpret with their sense of touch). Because of this, the patient can better evaluate assistive aid. For many people, muscles of the eyes, digestion and bladder are generally not affected.

Coordination

Deteriorating coordination is also a side effect which makes it more difficult to perform tasks. This effect occurs because the brain is not aware of the new situation of the muscles and is lacking behind (J. Bakers, personal communication, 2020). Because of this, the brain cannot tell the muscle how much to contract or relax. The deterioration of the muscles is only faster than the brain can process, which results in a disbalance of muscle input and output.

Fatigue

Fatigue often occurs for patients with ALS (M. Sanjak, et al., 2001); however, ALS patients mention it is hard to understand how the energy levels work (ALS Association, n.d.-b). One moment a patient can feel tired, but when in bed, the patient is not able to sleep. In general, patients are more likely to tire during a repetitive motion than a motion that requires much strength.

Assistive aids

As the patients become more and more impaired, the usage of several assistive aids is desired. In the beginning, assistance is desired for simple tasks such as bigger handles for cutlery, or a walking stick. Eventually, significant changes must be made to the house like a lift and a toilet with flushing/hairdryer installation because from one week to the next a patient can no longer walk and needs an electric wheelchair to move around the house.

Conclusions

- Because of the individual differences, a care professional should always check the personal situation of a patient to advice an assistive aid.
- Lost strength distal to proximal: The device should first support into this direction as well, meaning first support of fingers and thumb followed by the wrist.
- Fast progression: The solution should be quickly provided to the patients and secondly be able to adapt to the current and upcoming needs of the patient.
- Fine motor skill and precise coordination decrease first: therefore, small movements should be replaced by larger movements.
- Although ALS can differ a lot per person, it is preferable to keep the solution suitable for most ALS patients.

2.2 Exoskeleton

This exoskeleton is developed for children suffering from Duchenne, a muscle disease with different symptoms compared to ALS. In this chapter, the functionality of this exoskeleton is explained, and the applicability for ALS patients will be discussed.

The exoskeleton supports disabled children in lifting their arms. This system is based on a spring mechanism which balances the arms of the child in several directions. This balance system results in a minimal effect of gravity on the arms, which causes the arms to feel weightless. By wearing this device, the children can lift their arms much higher and more often with less effort. In this way, they can perform daily tasks with more ease, and some independence is regained.

Duchenne and ALS

Duchenne Muscular Dystrophy (DMD) is a genetic disorder characterised by progressive muscle degeneration and weakness due to the alterations of a protein called dystrophin that helps to keep muscle cells intact. Both ALS and DMD are progressive and weaken the muscles. However, Duchenne starts at a younger age compared to ALS and primarily affects boys starting at the age of 2 or 3. Duchenne weakens the muscles, but in a different order compared to ALS. The proximal muscles (those close to the core of the body) first weaken, especially in the lower limbs. Later the distal limb muscles (those close to the extremities) will weaken as well. This is a significant difference which is one of the reasons why hand function is not included in the current exoskeleton (Emery et al., 2015).

Figure 11: Exoskeleton Yumen Bionics schematic front view (Yumen Bionics, n.d.-a)

How does it work?

To balance the patient's arms of the user successfully, a lightweight construction (exoskeleton) is combined with a spring mechanism that is connected to the arms of the patient (see Figure 11). The exoskeleton structure is mounted to the (wheel)chair, whereby the chair carries the total weight of the device. The forearms are placed in sleeves which are lifted by the forces of the elastic bands. The bands carry most of the weight of the arms in any direction and are connected to a higher point above the shoulder joint. The right amount of lift must be generated so that the arms are in balance. If too much lift is generated, the patient will continuously have his hands lifted. The stiffness of the elastic band and the point of the attachment determine the amount of lift. The stiffness of the spring can be increased any time, which can be desired if the patient becomes weaker and more lift is needed. When fitting the exoskeleton for the first time, a list of checks and settings should be followed to create an optimised and personal fit for the patient.

Mobile system

The balance system is mostly connected to the wheelchair. Because it is a mobile system, the system can be attached to multiple locations like a couch or dining chair. The children are not capable of relocating the device themselves and need to be assisted by their parents or informal caregiver, which results in less independence. For ALS patients, it will be impossible to relocate the exoskeleton themselves as well.

Figure 12: Exoskeleton Yumen Bionics schematic back view (Yumen Bionics, n.d.-b)

Upper limb support

This exoskeleton supports upper limb movement, which could be beneficial for ALS patients as well. In a user test with one of the patients, the patient showed an increased range of motion, see Figure 13. The arms could be lifted higher, e.g. hand closer to the mouth, which is desired when a patient wants to eat or drink. Secondly, the patient is able to perform the movement more often because performing the movement took less effort. These advantages are evident for the use of the exoskeleton by an ALS patient.
The duration of usage will be limited because muscle strength weakens progressively. When a patient becomes largely paralysed, support of an elastic band is not enough to lift the arms.

Lack of hand support

Since the exoskeleton is designed for Duchenne patients, no hand supporting function is integrated yet. An ALS patient will first lose hand strength before losing arm strength.
An ALS patient, with muscle weakness in the hands, can not suddenly do all kinds of tasks again because they wear the exoskeleton and the arms are supported. If the hands of a patient are not working correctly, it prevents them from performing simple tasks.

Can this device be extended?

According to P. Klap (personal communication, 2020), patients can use the exoskeleton and wear an assistive hand aid at the same time. Wearing an additional assistive aid increases the total weight of the arm, causing a small imbalance. This situation is similar to a situation whereby the patients desire more lift because of weakened muscles. By this imbalance, a new balance point should be found, resulting in changing the elastic band, or the attachment on the exoskeleton. Secondly, the shape of the assistive aid must not hinder the usage of the exoskeleton and the other way around. Since the arms will lay in a sleeve, the shape of the assistive aid must not collide with the attachment of the exoskeleton.

Conclusions

- Arm function can be supported by an exoskeleton but hand function should be support first.
- The question arises, should a redesign and an iteration of the exoskeleton be done or should we take a step backwards and find out if there are more prominent problems that need to be solved?
- Since the exoskeleton can easily be extended, the option arises to combine the use of the exoskeleton of Yumen Bionics with an assistive aid.

Test results

The pictures below show the increased range of motion by using the exoskeleton by an ALS patient.

Without exoskeleton With exoskeleton

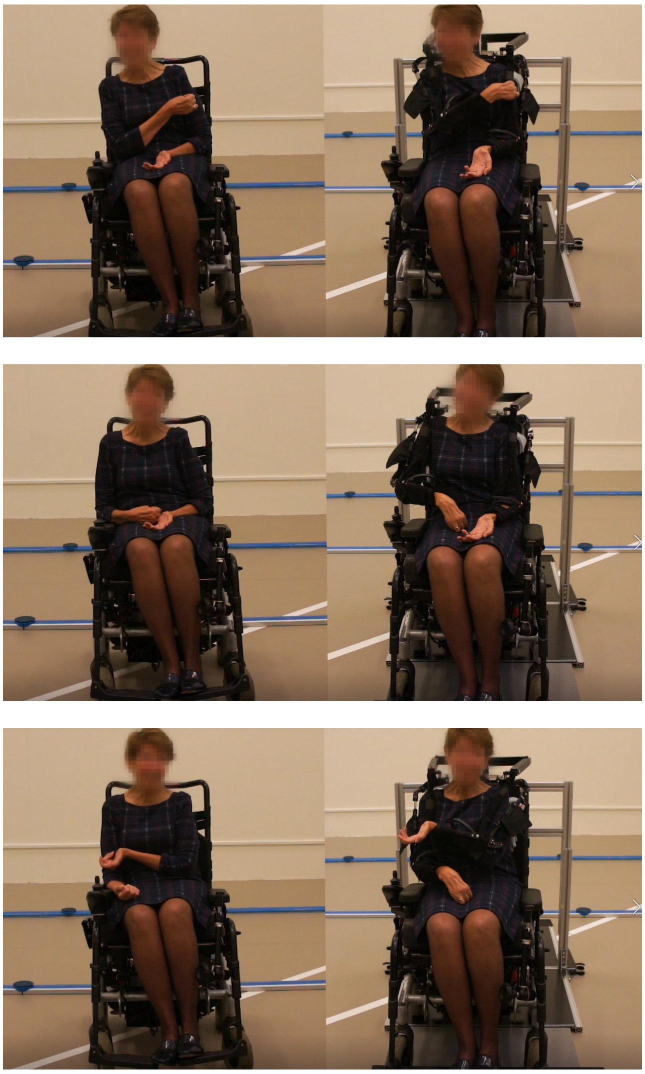


Figure 13: Test result of ALS patient using an exoskeleton (Yumen Bionics, n.d.)

3 Patient research

This chapter will give insights into the most prominent problems experienced by ALS patients. These problems are found by discussing the importance of daily tasks, trough in-depth interviews with four participants. A pre-survey is used to sketch a personal profile of the patients and decide whom to interview.

3.1 Pre-survey

Lewis & Rushanan (2007) describes that maintaining the independence of the patient to execute activities of daily living (ADLs) is the most important goal for medics. This term is used in healthcare to refer to people's daily self-care activities (Noelker, 2013). However, Nair & Wade (2003), describe that life goals for ALS patients are more related to the relationship with spouse, friends or the ability to manage personal hygiene and less to perform ADLs. The following essential questions were not answered by these studies: **'What drives patients to continue life and do not give up?'** and **'What keeps patients busy during the day, and what problems occur throughout the day'**. Four interviews are conducted with patients in different stages of the disease, to find answers to these questions. Since the disease is heterogeneous and progressive, it is necessary to interview patients in different stages of the disease to get a clear overview of the clinical picture of ALS.

Method

An online survey is conducted to generate a patient profile and examine the needs of the patients. The needs are found by asking the patients about two to three positive or negative moments they had from the moment after diagnosis. Furthermore, patients explain why the two mentioned activities are meaningful to them to perform independently. Secondly, an overview of the disease progression is made by filling in ten actions done in daily life. These actions are selected from the activities mentioned by the amyotrophic lateral sclerosis assessment questionnaire (Jenkinson, 2001), found in Appendix A.3. It is asked to state the time when this activity became challenging or impossible to perform relative to the moment of diagnosis. The patients were contacted via a social media channel in an active group of fellow sufferers.

Results

The survey is answered by ten ALS patients, from which eight are male, and two are female, the age ranges from 30 to 69 with a median of 59 and the average age of 55. Nine out of ten participants had a partner, seven out of ten had children, and four participants did continue their work after the moment of diagnosis. The most meaningful moments mentioned by the patients are celebrating life (enjoying the little moments), going on a holiday or spending time with their partner. Most patients mentioned that being introduced to a new assistive aid is a crucial moment for them. The moment people become wheelchair-dependent is experienced as most drastic. From the answers of the patients, a timeline could be drawn, which shows how ALS affects the patients' lives differently. The resulting timeline of two patients can be found in Figure 14. The other timelines can be found in Appendix A. The most desired activities include eating independently, being able to walk again, and using arm or hand function again to work with a laptop.

Conclusions

The progression of the disease is very different per person; there is no strict path to follow, as was stated by Westeneng (2018) and confirmed by the timelines of the patients. Most complaints at limb onset start with the failure of the hands or feet. Patients mention examples like walking with a drop foot or lousy handwriting, as first symptoms. The amount of time between the failure of functionalities is again case-dependent. According to Kiebert et al., (2001), there are phases to distinguish, but the time, duration or boundaries of those phases are not as consistent in daily life, which is also seen if the results of the questionnaire (Appendix A.2).

The important life moments for patients described in the survey are related to the relationship with a spouse, social time with friends, their holidays, or acceptance of impaired function. These vital life moments match life goals, as is stated by Nair & Wade (2003). Patient who are able to preform ADLs independently score these as more important than patients who lost the ability to perform ADLs.

Eventually, the most meaningful activities mentioned by the patients are:

- Eating and drinking (independently)
- Walking
- Typing
- Performing work on the laptop
- Daily tasks which require hand and arm function

The design direction will focus on supporting hand and arm function, during these activities. These activities will be analysed in detail, to find what the difficulties while performing these actions are and why ALS patients still want to perform these actions independently. This will be done in the second part of the research.

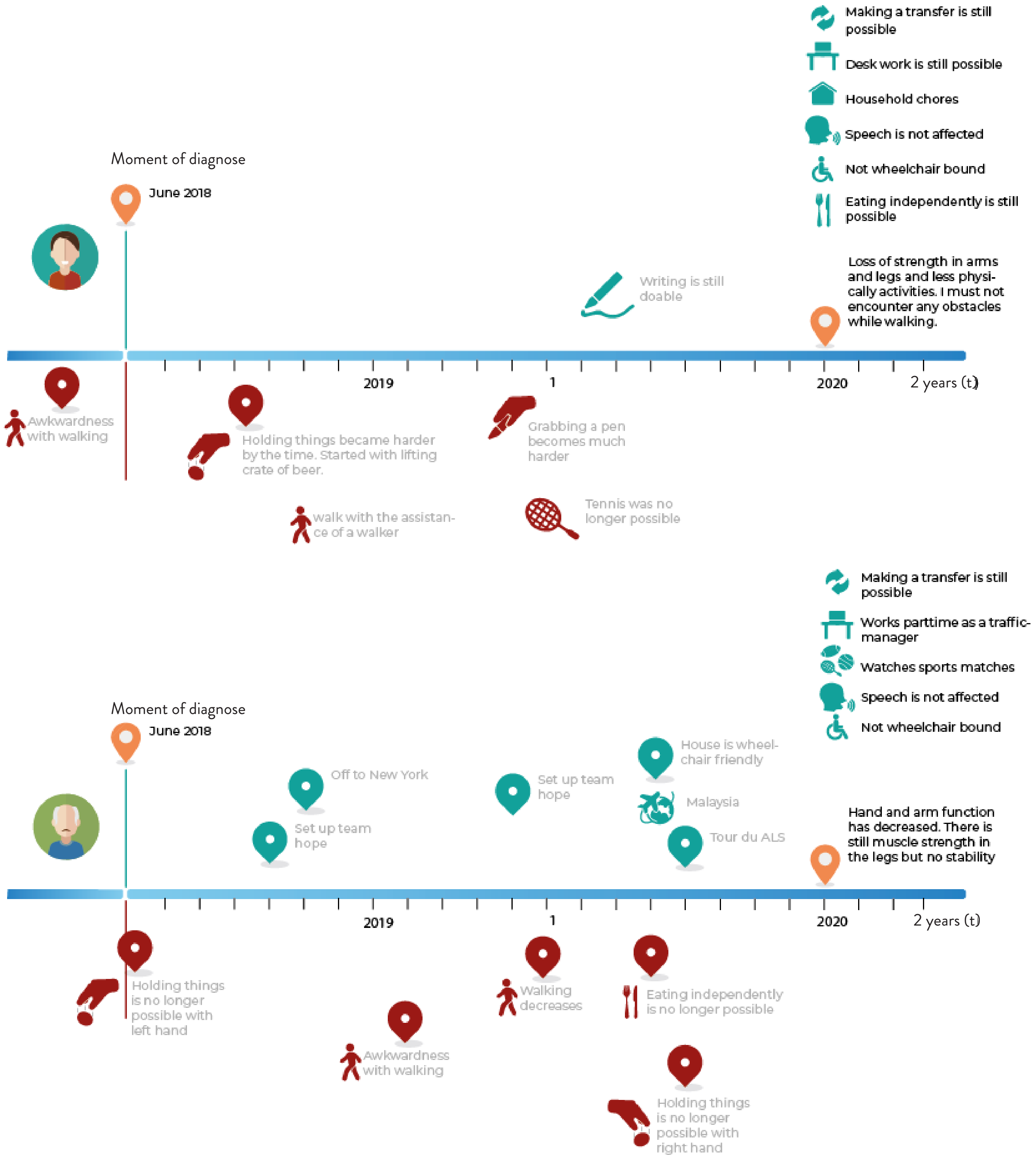


Figure 14: Test result of ALS patient using an exoskeleton.

3.2 Patient interviews

A more in-depth interview with patients is conducted to find answers to the questions, what drives patients as an individual to do specific tasks? Why do certain activities contribute to the quality of life?

'I want to continue life as normal as possible!'

Method interview

Four participants are selected for an interview; these patients are selected on the stage of progression, ability to speech, impaired arm function, experience with assistive aids and their answers to the questions related to important moments and daily actions in their life.
Two participants are selected which have ALS for more than 13 years and have quite some experience with assistive aids, one of them participated in the user test with the Exoskeleton of Yumen Bionics. Both patients lost almost their entire arm function and need daily support from a caregiver.
The other two participants were diagnosed with ALS in June 2018, their arm and hand function decreased, but they can still do most of the ADLs independently by the time of the interview (January 2020).
The interview consists of three parts which focus on the disease progression, important actions and usage of assistive aids. Discussing their activities and hobbies gave insights into why patients want to continue doing tasks independently.

Life goals

Patients want to keep doing certain activities because they have an individual tendency towards reaching life goals, as described by Ford & Nichols (1987). These goals differ between people and may change over time, but having them is a profound source of happiness and motivation. Most important life goals for patients are: belong to a group, or experience pleasure in the things they do, just as healthy people like to do. Their disability does not stop them from doing activities and reaching these life goals. The activities discussed below are matched to a life goal.

Social belonging

A patient is living in a world which becomes smaller and smaller, causing them to be bound to their residence because travelling by public transport, car, bike or walking becomes too tricky when the disease progresses. Most patients have the urge to 'escape' from their residence and go outside from time to time. They do not want to sit at home the entire day, simply because they are bored and have too much mental energy. This is one of the reasons why ALS patients are so well involved in patient associations and research projects to find a cure.

'Stop driving was for me an infringement on my independence and freedom and is seen as a huge negative milestone'.

Patients mention that continuing their social activities is vital to them because it increases their quality of life. The following social activities are seen as very meaningful to them: spend time with their loved ones, going out with friends to watch football, join a creative workshop and have monthly meetings with colleagues from the patient association.

The ALS community is seen as a powerful and loyal community for fellow sufferers, many stories are shared, and patients learn a lot from each other. Because there is no cure yet, many patients are actively committed to raising funds for ALS research projects. Three patients of the interview participated once or more in the Tour du ALS Mont Ventoux competition, see Figure 15 (Tour du ALS,2019).

Love

Love is the tendency to be affectionate to someone and the urge to be close to and spend time with the person. Patients find spending time with their loved ones crucial. The implementation of these activities strongly depends on the ability of the patient. Activities vary from taking long walks, going out for dinner, and listening to music together. The relationship with their partner changes as well because of the

Figure 15: Tour du ALS (Tour du ALS, 2019).

disease. The relation shifts from a love relationship to a care taking relationship. Where one is no longer equal to the other because one becomes highly dependent on the other.

Feeling useful

For many patients, feeling useful is an essential value to maintain. Although their body lets them down, they want to be useful for their spouse, family and friends. One of the patients takes care of all financial matters of the household. This process is indeed much slower for one with ALS than for one with a healthy body, which can lead to frustrations and sometimes anger. However, patients like to continue these tasks, and it contributes to the feeling of being useful in the home situation. Every patient wants to be helpful in daily life in his or her way.

'I want to do something in return for the close ones taking care of me'.

Individuality

Individuality represents our desire to have an identity as an individual. For patients, this means they would like to continue life as it used to be, doing the activities which have their interests. Examples mentioned are: stay updated from the latest news and Formula 1, have friends over for social activities because the patient is a people person. Being able to continue their hobbies to a certain level is meaningful to them as well.

'Despite being largely paralysed, I am doing quite ok; I can still proceed with my voluntary jobs, which I love.'

Self-determination

Becoming dependent is the main issue for patients; this lowers self-esteem and decreases the feeling of self-determination, which represents the desire to be free and make our own choices.

Uncertainty

The patients are well informed about the consequences of the disease, during the diagnosis and after. However, many of the participants are uncertain about their future because the progression of ALS is unpredictable, and it affects persons in different ways. Patients experienced being unable to do a specific activity from one day to another.

'This causes me to wake up in the morning, not knowing what to expect this day.'

The patients find it very discouraging not to know what to expect. Therefore it is crucial to make preparations and have the right equipment ready and be prepared for the following phase to support the confidence of the patient. For most patients, the fear of losing speech is the worst. One mentions her voice is her true self, as she talks a much, she can not afford to lose this identity. She already wants to start recording her voice in advance.

Goal setting decreases

However, the goals of ALS patients will change over time. The progressive disabilities tend to downgrade the significance attached to goals related to partner, work and leisure. They also reduce the number of goals graded as extremely important (Nair & Wade, 2003). For example, this change is not seen in people with static disability. Goals tend to become less important from the moment it becomes too much hassle to perform themselves. The activity dressing is lost quite early because of the complex and many movements.

Crucial activities

Life goals explain why patients want to continue doing certain activities. It tells us what drives these people to continue to work or take care of household chores. Although not everyone appreciated the same activities equally, there is a general confirmation on the importance of performing the following tasks independently.

- Having the ability to eat and drink independently.
- Doing some computer work for leisure or work.
- Taking care of personal hygiene.
- Performing hobbies (e.g. playing cards, painting, listening to music).
- Having the ability to communicate (verbal and nonverbal).

Some of these tasks involve activities of daily living, which is seen as most important by medical professionals. Rehabilitation focusses primarily on performing ADLs independently. However, the patients mention these five activities as most important for them besides the ADLs. These five activities gave the most meaning to life for patients from the interviews. The foreseen solution will focus on support during these activities. In the next subchapter, the overarching themes will be determined and evaluated.

3.3 Desired activities

Four overarching themes are found which fit the relevant activities for the patients. Each theme is explained below, and its importance is discussed. The importance of activity differs from patient to patient, some are lost with grief and others pass unnoticed. The importance of actions is determined by patients in the interview and the survey.

Dining

Related to: **Feeding**, **Social interaction**, and **Enjoying.**
WHY: Self-feeding is a must in daily life to survive. However, for many people and thereby patients, eating is more than just a must, it goes along with joy, entertainment, and social interaction. Six out of ten patients mentioned that eating independently is their most desired task in the first place. In the household from one interviewee, dinner is mostly a social activity shared with family or friends. Patients desire to keep doing activities in the way they used to do. Independence is especially desired during dining activities because patients do not want to burden their informal caregiver during these favourite moments as they should enjoy their meal as well. Secondly, accepting help from others like home care during this moment is often refused because this is experienced as a violation of privacy and secure home environment. An eating robot could support this activity, but in practice, the eating robot has many limitations, according to the patients. The importance of self-feeding becomes extra clear if one of the interviewees mentioned that for some patients, he knew eating no longer by one's self is a reason to stop living.

Communication and work

Related to: **Social interaction**, **express individuality**, and **self-determination.**
WHY: Communication is essential for an individual to express themself and is highly valued in daily life. In many cases, communication is preferred to be done via speech, if applicable, or via typing applications or eye-tracking devices. Communication is involved in all activities; for example, being able to have a conversation at home, at work or with a medical specialist. If speech is not applicable anymore, a patient can communicate via replacement mediums. The tablet, smart-phone or a computer are often used to prevent isolation and maintain social contacts and express individuality. Being able to communicate contributes to a higher level of self-determination. Patients mention that lack of speed in many communication devices for ALS patients is the reason to stop using the device because it is so frustrating. Therefore, patients prefer to use a computer mouse or a keyboard which is, in their opinion, faster but takes more effort to operate.

Personal hygiene

Related to: **Positive self-evaluation** and **express individuality.**
WHY: Personal hygiene relates to being representative and has positive self-evaluation. For some patients, it is desired to look well-cared. The level of importance of this theme differs per patients and to the specific activity. Male participants find it important to be able to shave, while female participants desired to look well throughout the day. Because of the paralysis, the disease makes personal hygiene more challenging and impossible to do independently, making support desired. Assistance during smaller tasks, such as brushing teeth, is usually done by the informal caregiver. It is the small tasks whereby more independence is desired. A partner of a patient mentioned: 'Brushing the teeth of my husband is something which I never get used to'. More substantial and heavy tasks like washing the patient, are less desired to be done independently or by an informal caregiver. Care professionals perform these tasks usually.

Hobbies and entertainment

Related to: **Individuality**, **belonging**, **joy**, and **happiness.**
WHY: Being able to perform hobbies contributes to the level of the individuality of a patient and can increase the quality of life according to the patients themselves. Having interests in a hobby is intertwined with the personality and is often related to social interaction with a group of friends. Many activities which require mobility have been taken away from the patients, causing patients to value their hobbies which they can still perform as more urgent than before. To continue performing hobbies is desired by the patient despite the paralysis symptoms. Hobbies are very individual and vary a lot; patients mentioned reading, photography, painting, or playing cards.

Conclusions

The visualisation in Figure 16 presents an overview of the four themes. A converting step is made by selecting one of the four themes to become the focus area. A detailed analysis will follow, which will give more insights into the problems of ALS patients during these theme-related activities. After consideration of the values, opportunities and patient's wishes, it is decided to focus on providing support for **dining**. The following factors determined to converge into this direction.

- First, dining is most desired to perform independently by patients because of unburdening their informal caregivers and avoiding home care during these valued times.
- Secondly, dining activities occur in every patient life, multiple times per day which result in a solution for a broader audience. '**Providing support every time someone takes a sip can already mean a lot for me**' as was mentioned by a patient.
- Eating by one's self results in being more independent throughout the day because a patient takes care of their own needs without too much help of others. This causes patients to work or stay at home without requiring assistance from others throughout the day.

Figure 16: Activity themes.

4 Stakeholders

ALS patients deal with many different people who all try to arrange the best care for you. This varies from occupational therapists to municipal employees. This stakeholder analysis presents an overview and explains the relation of the stakeholder to the assistive aid. The stakeholders are divided into three groups depending on the way they influence the usage of the assistive aid.

4.1 Direct usage and support of the assistive aid

The stakeholders in the first group deal with assistive aids directly or provide support for ALS patients. These stakeholders are involved daily and should know how to use the assistive aid and how to assist the patient.

Patient

The patient will be the primary user of the assistive aid. The aid should be developed in cocreation with patients to be sure to fulfil the expectations and wishes. The patient also plays an indispensable role in the promotion of an assistive aid to fellow suffers. Sharing experiences about assistive aid happens much in the close community. A patient always remains the right to have the final say about using a device or not regarding the advice given by the medical specialists and rehabilitation therapy.

Relation to assistive aid: The assistive aid is used by the patients to support daily tasks and improve the quality of life.

Informal caregivers

Many caring tasks will end up with informal caregivers like spouse, family, or friends. These informal caregivers did not choose to take care of patients: it happens to them because there is an emotional connection with the person who needs care (ALS centrum Nederland, 2018-a). As the disease process progresses, this burden will become more intensive physically and emotionally and might overloading the informal caregivers.

Relation to assistive aid: Together with the patient, they decide how to deal with the many medical advices and accept usage of an assistive device. The informal caregivers should know how to use the assistive aid and support the patient if necessary.

Children and friends

Children and friends carry some responsibility in sporadic care for the patient and thereby the assistive aid. Hobbies and social activities are done with friends. The device should be understood by friends or be understood after a brief explanation from the patient. In this way, friends or children can assist when a situation arises.

Relation to assistive aid: Children and friends should know how to use the assistive aid and should help the patient to don and doff the device.

Home care team

The home care team takes over part of the care, which can help to wash the patient and assist with feeding daily. Besides, the home care team can also think along with the patient about the organisation of care and coordination with the ALS treatment team. Because ALS is rare, most home care teams in the Netherlands have little experience providing specific care.

Relation to assistive aid: The home care team should know how to use assistive aid and share usage experience, tips, and trick with the patients.

4.2 Advice for use of assistive aid

The stakeholders involved in this group have professional medical knowledge of the disease and assistive aids. They are responsible for providing proper advice and care to patients.

ALS treatment team

The treatment team is a multidisciplinary team consisting of eight different medical specialists. An ALS treatment team provides guidance on nutrition, exercise, swallowing problems, stuffiness, and providing aids. Their goal is to let patients function independently as longs as possible. There are approximately 40 specialised ALS treatment teams in the Netherlands (ALS Zorgnetwerk, 2018).

Relation to assistive aid: The team selects assistive aids for the rehabilitation treatment and should be convinced about the benefits of usage.

Within the team, the following medical specialists are, in particular, very influential on the usage of an assistive aid. Because they are so influential, their opinion about assistive aids is taken into account when developing a new assistive aids. They have much experience with the patients and are familiar with everyday problems.

The occupational therapist introduces the patient to assistive aids, and together they decide which assistive aid the patient will be using to continue performing ADLs independently. The therapist should be aware of the functional benefits and the points of attention of the assistive aids. Besides, they can help request assistive aids at the municipality. A proactive attitude can contribute to a faster provision of resources.

A physiotherapist examines and treats complaints of the patient, mainly concerning complaints and limitations in daily movements. They also monitor the lung function and provide instructions for breathing and coughing techniques. The physiotherapist must know how assistive aid affects the body movement of the patient and must be convinced that the assistive device does not cause any adverse effects on the body.

As of last, the rehabilitation doctor coordinates the activities of the ALS treatment team, and maps out the medical care including assistive aid that is required.

Online knowledge platforms

'ALS centrum Nederland' is a valued knowledge platform for MND patients and professionals. The centre aims to optimise diagnosis, care, and treatment for patients in the Netherlands, through sharing scientific research and knowledge about these diseases (ALS centrum Nederland, 2019).

Relation to assistive aid: Provide valued information about the assistive aid on the platform for patients and medical professional.

Treatment criteria

'ALS Zorgnetwerk' is a network of caregivers started by ALS centrum Nederland. The ALS Zorgnetwerk monitors, together with patient association 'Spierziekten Nederland', the quality criteria for ALS treatment teams in the Netherlands (ALS Zorgnetwerk, 2018).

Relation to assistive aid: These organisations will test if the assistive aid fulfils the quality criteria of ALS treatment. If so, they should advise including the new assistive aid into the treatment.

4.3 Making aid available or reimburse

The stakeholders included in this group are responsible for providing assistive aids and the possibility of reimbursement.

Municipality
Under the Social Support Act (WMO), the municipality is obliged to make provisions for people who are less self-reliant and less easily involved in society. Unfortunately for the patients, every municipality makes its social support act (WMO) regarding reimbursements (Rijksoverheid, 2015). The municipality typically provides assistive aids like wheelchairs and mobility scooter. To safe budget, it is common to reimburse the cheapest products.

Relation to assistive aid: The municipality decides together with their occupational therapist if the patient will benefit from an assistive device at home.

Uitvoeringsinstituut Werknemersverzekeringen (UWV)
The UWV can request and reimburse assistive aids which supports the patient during work or education. However, the process of receiving the assistive aid can take up to eight weeks, if all the information is correctly provided. This is for most ALS patients too long.

Relation to assistive aid: UWV is responsible for the reimbursement of the assistive aid when it is used for education or work.

Health insurance company
The health insurance company will reimburse assistive aids if the aid is part of medical treatment, or because they are indispensable for performing ADLs because they compensate for the loss of a body function. This reimbursement is included in the primary insurance. A health insurer reimburses medical aids, like a walker, that help during activities which do not contribute to performing ADLs if there is additional insurance.

Relation to assistive aid: The health insurance company will reimburse the assistive aid if this is part of the patient's treatment.

Parties that lend resources
Several parties, like Medipoint and Medicura, are prominent providers of care and welfare products in the Netherlands. As most ALS patients need temporary assistance, assistive aids can be rented. Organisation 'ALS op de weg' focus on providing care for ALS patients specifically. They provide assistive aids which are often not covered by the WMO or UWV, like wheelchair buses, iPads and adapted bicycles (Stichting ALS op de weg n.d.). Because aids are used for a short period, most aids will have multiple product cycles. Conditions like, beneficial to the target group, increase the quality of life, complexity, costs, and more should all be met before 'ALS op de weg' can offer the product on their website.

Relation to assistive aids: This platform would be suitable for providing standard aids which can be used by multiple ALS patients.

Thuis-ALS-Thuis.nl
Thuis-ALS-Thuis.nl is a well-elaborated website developed to introduce patients to assistive aids. On the website, patients can virtually navigate in a household and find information about which assistive aid is useful in which situation, including benefits and explanatory videos.

Relation to assistive aid: This platform is one of the best ways to promote assistive aids and provide information to the patient.

Conclusions
The stakeholders are divided into three groups: stakeholders who play a role during the use of the assistive aid daily, stakeholders who approve and give guidance on the use of an assistive aid, and stakeholders who provide assistive aids. Because many different stakeholders support patients, it is desired that persons without experience can easily understand the device. User tests and cocreation during development with the stakeholders from this group will lead to a better product. Organisations like ALS Centrum Nederland and Spierziekten Nederland determine the quality criteria and have a significant influence on the approval of the use of assistive aids. The treatment team advises these organisations and will support them to determine the quality criteria.
The outcome of research and user tests will define if an aid increases the quality of life and if such aid can be included in the treatment. An assistive aid must become part of if the treatment because the insurance companies will cover it. It will be beneficial if the cost of the assistive aid is kept low. Providing and promoting the assistive device should go via a valued medical specialist, preferable the occupational therapist, or one from the treatment team. The webpage, www.thuis-als-thuis.nl will be an excellent way to introduce aids to a broad audience.

5 Providing care and assistive aids

We learned that several parties are involved in providing assistive aids to patients with ALS. This chapter focusses on this process and addresses the problems or difficulties that arise according to medical professionals and patients. The main problem with providing assistive aids is that they arrive too late.

5.1 Toughs to assistive aids

During the interviews, it is found that patients are eager to accept assistive aids if using them makes life easier. Thereby, the benefits must outweigh the disadvantages of using the device, this seems logical, but there is much more going on than just using an aid. Success factors of assistive aids are related to functionality, the usage of the product, comfort, appearance, and regained independence because of usage.

All the patients mention functionality as the most relevant requirement to use an assistive aid. If the aid makes life easier, patients are more eager to use the device. Making life easier means that it will cost less effort to perform a task, or the informal caregiver is unburdened because the task is taken out of their hands, which is seen during the dining activities.

Ease of understanding and usage of the assistive aid is crucial for patients and their close ones. When an assistive aid becomes too complicated in usage (e.g. when donning takes more time than desired) or precise movement are needed to be able to use the device, patients are less likely to use the aid.

The level of comfort is a critical feature which mostly affects the product in a negative way. The level of comfort is strongly dependent on the duration of usage.

The appearance of the assistive device is secondary to the functionality of the product, although it is seen as a vital wish: ‘I do not want to look more disabled than I already am’.

Devices which are meant for rehabilitation or help them exercise are less accepted since it will not improve their current condition. The patients accepted that life will not become better, and functions will not return somehow. A patient mentioned 'Why should I go to the rehabilitation specialist? He or she is not going to make me better’.

5.2 Consult

Patients are supported by the occupational therapist regarding arranging care and assistive aids quite frequently, which is crucial because of the quick deterioration. Patients have monthly consultation meetings with the occupational therapist via the phone. If the patient does have complaints or would like to meet physically, a meeting will be arranged. This meeting will be at the location of the rehabilitation centre. Once in the three months, patients will go to the rehabilitation centre for a comprehensive check, whereby many tests will be conducted, such as measuring lung function or swallowing function, and more. The patients will consult with several members of the treatment team as well.
The rehabilitation centre offers recreational swimming which is for many ALS patient a pleasant hobby. During these moments, an occupational therapist is often present to chitchat with the patients.

5.3 Bottlenecks

For patients, it is tiring to deal with the many different organisations to arrange care. A critical bottleneck is that the application at the municipalities often takes too long concerning the progressiveness of the disease. As a result, facilities or assistive aids are often no longer appropriate for the patient's phase. Besides, many other problems make the entire process annoying.

In practice, inappropriate facilities are regularly supplied, causing frustration and delays the process of providing proper care. At delivery, it is common that aids are set incorrectly and are poorly explained by suppliers, causing physical complaints, which causes dangerous situations for patients. According to occupational therapist K. Melssen, the advantages of the device must be clear at once, and mistakes should be prevented. Patients do not have time or energy to learn something new as everything is deteriorating.

Because the facilities that are needed for ALS support deviate from the standard package of the municipality, the applications take longer. Therefore patients purchase assistive aids themselves. Involving the occupational therapist in this process saves time for the municipality because they no longer have to collect all the information themselves, as professional medical knowledge is often insufficient at municipalities and suppliers. According to the municipalities, the occupational therapist does not pay enough attention to the financial consequences for the municipality.
However, if the facility is not necessary at the time of the application, it is often not provided by the municipality, which is extremely bad for the timely provision of medical aids to patients. The municipalities do not think along with patients and do not look to the future, which is crucial for ALS.

Conclusions

- An occupational therapist should be closely and actively involved in supporting the patient for the provision of assistive aid He or she can influence the request procedure at the municipality.
- Secondly, it is wise to introduce patients to assistive aids in a clinical environment or at home under the supervision of an occupational therapist, because the first impression and first-time use of a product are crucial for further use and prevention of misunderstanding and accidents.
- Most assistive aids which are affordable are bought by the patient themself to avoid the tedious application procedure.
- Assistive aids will be used temporarily because increased muscle deterioration causes assistive aids to become unusable.

KEY TAKEAWAYS

This key takeaway page gives a summary of the most important conclusions and an explanation of how they translate to wishes and requirements for the foreseen solution. These conclusions are the start of the next part of this report. It is concluded that focused research should be done to find the type of support that is desired by patients and approved by medical professionals for performing dining activities.

PATIENT NEEDS

- The results of the interviews gave much insights about the personal motivation of why ALS patients want to continue certain activities besides ADLs. An overview of the wishes regarding the use and function of the assistive aid can be found in Appendix C.
- Despite the limitations which come along with the disease, patients desire to remain independent. This independence is most desired during dining activities because patients do not want to burden their partner during these activities.

DESIGN FOR ALS

- Because of the rapidly progressive nature of the disease, the usage of assistive devices will be short. That is why assistive aids need to be quickly accessible for and usable by the patients.
- Despite the individual differences in disease outcomes, it is desired to make an assistive aid which fit most or all patients. Meaning the aid will focus on hand support because of paralysed muscles.
- The direction of paralysis is from distal to proximal, causing support to match this direction.
- Making predictions regarding the disease outcomes is difficult, causing patients to make many preparations in advance (like requesting assistive aids).
- It is desired to create a lightweight assistive aid because muscle strength reduces.

EXOSKELETON

- An ALS patient could benefit from a supportive arm exoskeleton of Yumen Bionics to support typing on the i-Pad.
- It is desired to foresee a solution which supports hand function first.
- If more muscle strength is lost, the assistive aid should be wearable simultaneously with the exoskeleton without irritation or hinder.
- When the complete motor function of the upper extremity is lost, the exoskeleton will not be suitable for patients.

PROVIDING CARE

- Most caring tasks are performed by an informal caregiver, which is emotionally and mentally burdensome. If patients can perform small tasks themselves with assistive aids, it will alleviate the informal caregivers.
- Assistive aids can be requested at several organisations which is often a long process. Involving an occupational therapist in the procedure fastens the process.
- Assistive aids will be used temporarily because increased muscle deterioration causes assistive aids to become unusable.
- Stakeholders like: patients, informal caregivers, and ALS treatment team should be involved during the development of assistive aid.

REQUIREMENTS

- The assistive aid should meet the demands to be included in the ALS treatment.
- The assistive aid should include custom made fabrication to address the individual differences of patients.
- The assistive aid should be able to adapt to the changing needs of the patients over time.
- The assistive aid should contribute to the level of independence during dining activities.

WISHES

- Patients can don and doff the assistive aid quickly and with little effort by themselves or with the help of others.
- Patients can wear the assistive aid during the day, without experiencing discomfort.
- The assistive aid should be lightweight.
- The appearance of the assistive aid is minimal and unnoticeable.
- The assistive aid is desired to be cheap because it will be used for a short period.

3

Figure 17: Dining.

Define

This part serves to give an understanding of the problems occurring during dining activities. Ergonomics, human anatomy, and the movements needed for executing dining activities are researched. By doing this converting step a design vision is formulated for solving the right challenge, at the end of this part.

In this part

6 Dining assistance

The outcome of the analysis taught us that support during dining activities is most desired by patients. In this chapter the activity is discussed in detail and the common problems are mentioned.

6.1 Desired support

Dining is seen as all the activities which include food or fluid intake throughout the day. This means that breakfast, lunch, having a cup of coffee, a glass of water, and dinner are all included. These actions consist of challenging movements and are often too much to ask from a patient. To a certain extent, patients can continue to perform tasks independently, but when weakness in the fingers occurs, most of these self-feeding tasks become impossible. Commonly, weakness occurs first in one of the hands, making tasks which require double hand movement impossible. For example, cutting is one of the first things which becomes not do-able.

Activity overview

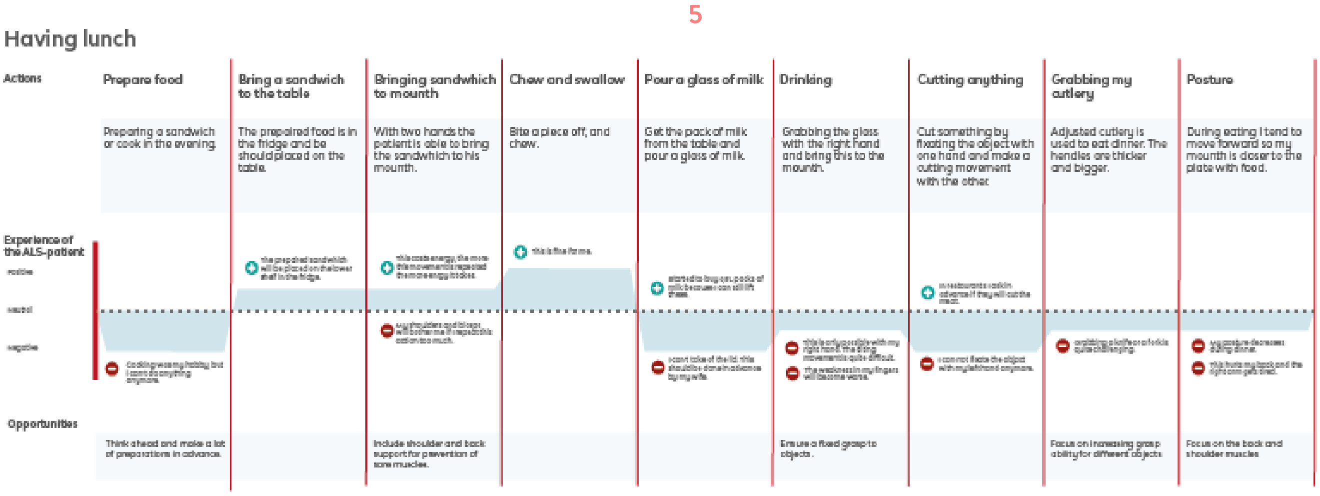
Together with the patients, a detailed overview is made of all the steps required to accomplish an activity they would like to perform independently. This overview clearly showed the steps and expressed the difficulties per step. Within this process, every step is evaluated, resulting in positive, or negative experiences and opportunities. In Table 2, the results of the steps during a lunch activity can be found.

Concluding from these detailed analyses, several challenging movements need to be performed to have lunch: bringing food from plate to mouth, hoover with the hand above food and use fork, move and lift objects from the table, and grasping a cup of coffee in a controlled way. An overview of essential movements and types of grasps can be found on the next page.

The patient mentions, starting to use smaller cans of milk to make it lifting easier because of weight reduction (see step 5 in Table 2). However, the patient is not able to take off the lid of anymore. An informal caregiver should do this in advance. Actions like serving food to the mouth are still executable for the patient because the biceps and triceps muscles (causing flexion and extension of the forearm) are not weakened yet.

Opportunity

The main problem for accomplishing these actions begin with the fact that strength is lost in the fingers and thumb at first. This prevents patients from flexing and extending their fingers, which leads to not being able to grasp and hold utensils, causing patients not being able to self-feed. Stimulating grasp in a way is an interesting opportunity which could help patients to self-feed.

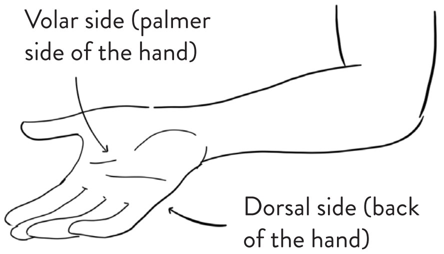


Actions	Prepare food	Bring a sandwich to the table	Bringing sandwhich to mounth	Chew and swallow	Pour a glass of milk	Drinking	Cutting anything	Grabbing my cutlery	Posture
	Preparing a sandwich or cook in the evening.	The prepaired food is in the fridge and be shouldplaced on the table.	With two hands the patient is able to bring the sandwhich to his mounth.	Bite a piece off, and chew.	Get the pack of milk from the table and pour a glass of milk.	Grabbing the glass with the right hand and bring this to the mounth.	Cut something by fixating the object with one hand and make a cutting movement with the other.	Adjusted cutlery is used to eat dinner. The handles are thicker and bigger.	During eating I tend to move forward so my mounth is closer to the plate with food.
Opportunities	Think ahead and make a lot of preparations in advance.		Include shoulder and back support for prevention of sore muscles.			Ensure a fixed grasp to objects.		Focus on increasing grasp ability for different objects.	Focus on the back and shoulder muscles

Table 2 - Overview of experienced difficulties for a lunch.

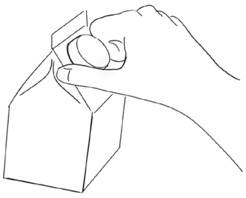
Below, an overview of the movements that are performed during dining is presented. Each movement is enriched with a dining example.

Hand sides



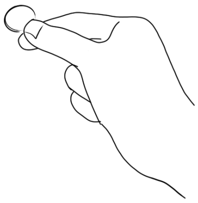
Precision grasps

Lateral pinch



A lateral pinch is used to take the lid of a can of milk.

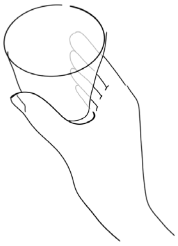
Pinch



A pinch is used to grasp small things.

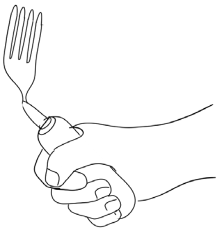
Power grasps

Lumbrical



A lumbrical grasp is used for lifting cups.

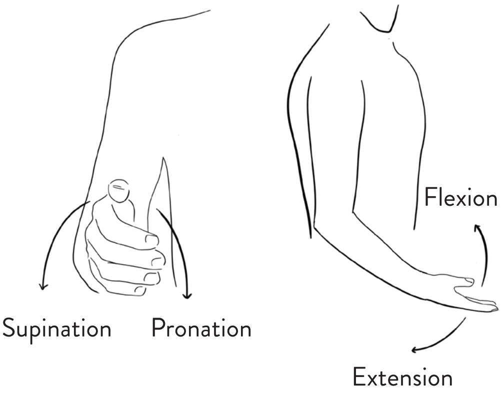
Cylindrical



A cylindrical grasp is used to grasp adjusted cutlery.

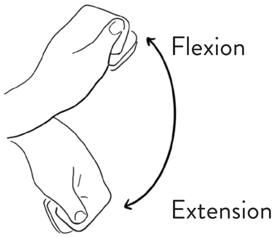
Movements

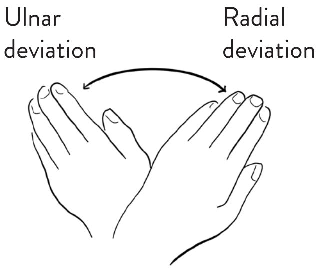
The forearm



Flexion and extension of the forearm are mostly used for serving food to the mouth. Supination and pronation are used for positing the hand in the right position to grasp objects, to stabilise, and tilt cups during fluid intake lift.

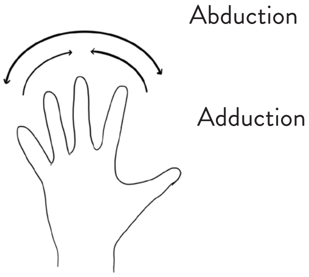
The wrist

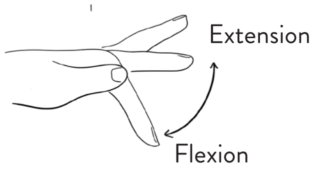




The movement made by the wrist contributes to positioning the hand in the right position for grasping objects, and stabilises the objects in hand. Static wrist strength is crucial for performing ADLs.

The fingers and thumb





The fingers are involved in fine motor tasks; holding thin cutlery, performing precision grasp, and perform power grasps as well.

Figure 18: Overview of essential dining movements.

6.2 Hand anatomy

Below, an overview of the hand is presented with an explanation of which muscles cause which movement. The hand is a complex mechanism composed of many different bones, muscles, and ligaments that allow for a large amount of movement and dexterity. To understand the hand a brief explanation is made, focussing on the skeleton, muscles and briefly the ligaments.

Bones

There are three major types of bones in the hand itself, including: Phalanges (fingers), Metacarpal (hand palm area), and Carpal (wrist) bones consisting of eight bones (see Figure 19, Villarreal, 2007). The metacarpal bones form the middle part of the hand and are connected to the phalanges. The four fingers (digit 2 to 5) have three phalanges: a proximal, an intermediate, and a distal phalanx, resulting in three joints as well. A joint is a bending point between two bones. The thumb (digit 1) has a proximal phalanx and a distal phalanx (Taylor et al., 1955). The bones are not affected with ALS and remain to keep the skeletal function.

Finger movements

The muscles in causing fingers to move can be subdivided into two groups: the intrinsic and the extrinsic muscle groups (Mcguire, n.d.). The precise names can be found in Appendix B. A simplified visualisation of the muscles can be found in Figure 20. The intrinsic group contains the smaller muscles and are located within the hand itself and allow for delicate and precise finger movements. The intrinsic muscle group can be divided into three subgroups: the hypothenar muscle group (movement of the little finger), the thenar muscle group (movement of thumb), and the mid palmer muscle group (movement of digit 2 to 4). The intrinsic muscle group is often the first group of muscle to start deteriorating if the onset of ALS occurs in the upper extremity.

The extrinsic muscle groups are the long flexors and extensors of the fingers. They are called extrinsic because the muscle is located outside the hand region in the forearm. Three anterior forearm muscles accomplish finger flexion (bending). Four posterior forearm muscles control finger extension.

Wrist movements

There is overlap in muscles which extend and flex the wrist and fingers as well. Wrist extension is accomplished by the posterior group muscles, located in the forearm as well. The anterior group muscles accomplish wrist flexion, both muscle groups will deteriorate as second, causing failure of the fingers and wrist.

Arm movements

The biceps brachii, brachialis, and brachioradialis muscles flex the forearm. The triceps brachii and anconeus muscles extend the forearm both located in the upper arm.

Supinate and pronation movement finds it origin in the forearm. The supinator muscle and biceps brachii supinate the forearm. A supinator is a muscle responsible for rotating the forearm such that the palm faces upward. The pronator teres and the pronator quadratus are the primary pronators

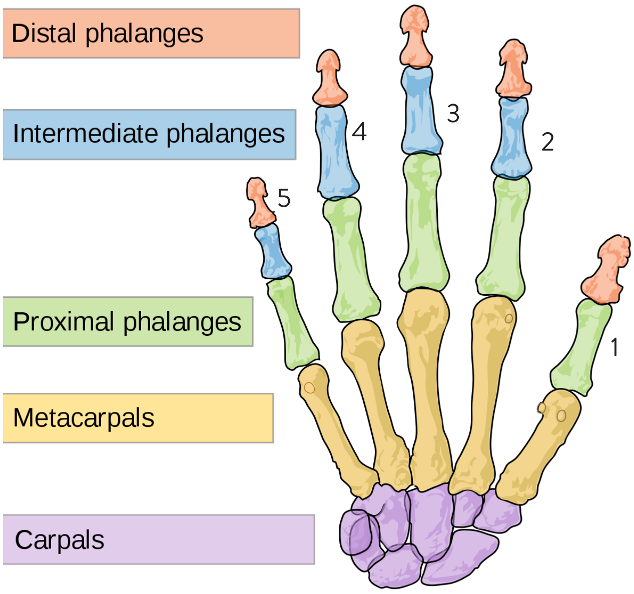


Figure 19: Right hand, Anterior view (Villarreal, 2007).

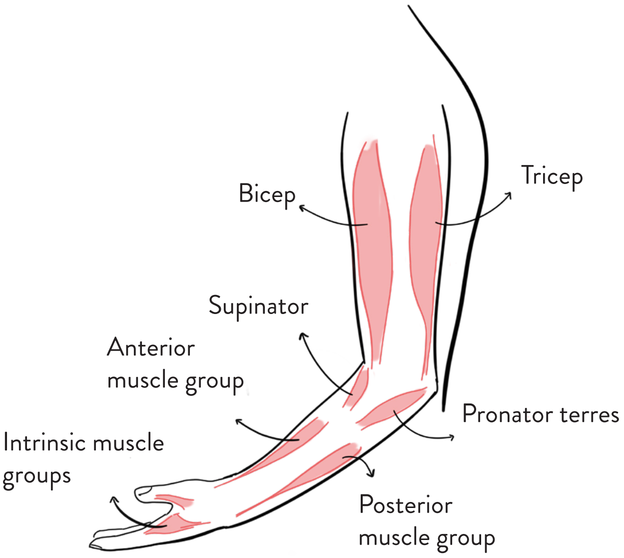


Figure 20: Simplified muscle structure of the human arm.

of the forearm. A pronator is a muscle that rotates the arm so that the palm faces downward. Both muscles are located more proximal than the muscles causing flexion and extension of the fingers. Therefore this movement can be performed longer.

Joints and ligaments

The bones are connected via ligament structures in between. These ligament act as hinges and make sure the fingers move in one specific direction and prevents fingers from overextending. ALS causes fingers and thumbs to dislocate more often, due to the absence of the muscles tissue, which causes damage to the ligaments. Secondly, ALS can cause painful contractures (permanent tightening of tissues such as muscles, ligaments, or skin), which makes it difficult or impossible to move the nearby joints (Majmudar et al., 2014).

6.3 Dining utensils

What kind of grasps are required for performing dining activities?

During dining activities, the patients uses a lot of utensils, like a plate, knife, fork, spoon, napkins, and cups. Size, weight, and shape influence whether an object is easy to grab. All these objects require a type of grasp combined with a movement. The type of grasp is the interface between the person's hand and the object being handled according to A. Hedge (2013). Two types of grasps can be used to fulfil daily tasks, precision grasps, and power grasps. Within these categories there are a few variations of grasps (see overview of grasps in Figure 18). For holding a cup, the cylindrical or lumbrical power grasp is used, which is performed by the extrinsic muscle groups. When holding utensils, a precision grasp is used performed by intrinsic and extrinsic muscle groups. Because precision is lost quickly, performing these grasps will be more difficult than performing power grasps. Therefore, many of the utensils for ALS patients are made with a ticker handle to provide a better hold to the utensil. An example of typical cutlery for ALS patients can be found in Figure 21 (NRS Healthcare, n.d.).

Figure 21: Example of cutlery for ALS patients (NRS Healthcare, n.d.).

Does a thicker handle help ALS patient?

Improving handles helps patients to hold the objects, but it does not help them to lift the cutlery from the table. Patients mention that grasping the cutlery from the table and positioning it in the hand is the hardest thing because this require precise movement. Another phenomenon which could help patients is placing the direction of the handle in such a way that a natural grasp can be performed. In Figure 22, a knife can be seen in which the handle is positioned approximately perpendicular to the blade. This helps patients to hold their wrist in a natural position with more strength.

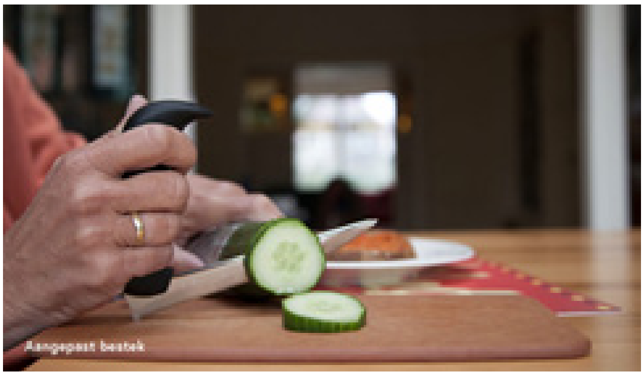


Figure 22: Knife utensils (Thuis-als-thuis.nl, n.d.).

Are there alternatives for ALS patients?

There are several utensils on the market which come with a band or a metal structure which is attached to the hand as can be seen in Figure 23 (Eazy hold, n.d.).

Figure 23: Utility holder by Eazy hold (n.d.).

At first sight, this seems a simple and well-suited product, but it comes with limits. The patient becomes dependent again as he or she is not able to don this band or swap the fork for a spoon due to the limited hand function. Secondly, these tools will not be suitable if weakness in the hand occurs as the wrist is not supported.

Eating robot

An eating robot could assist the patient with food intake. A spoon or fork connected to a mechanical arm serves the food into the mouth. The patient can optimize the desired movement (serving the food for example just a bit higher because a patient is tall), pace, and determine in which order the food is served. By using this device, the patient does not have to move their upper extremities, which makes it suited for patients in a late stage of ALS when many paralysis symptoms are present. In this way, patients can eat independently without anyone having to feed you. This device can be taken to other locations as well. In an early stage, this device is less desired because it takes all the self-determination away, which is related to human goals. However, this aid makes the patient dependent on the informal caregiver as the plate with food needs to be inserted and removed. Other frustrations with this device are that it cannot scoop large pieces and sometimes it scoops wrong.

Other examples of assistive aid during dining mentioned by ALS centrum Nederland (2019) which are provided to ALS patients are plates with ridges and anti-slip mats for single-hand use. Because most patients eat slow, warm water plates can be used to prevent meals from cooling too quickly.

Eating throughout the day

Eating is done a few times per day. To let patients consume a meal, food and utensils should be provided by someone who can, or the 'setting' should be completely prepared in advance. In this way, a patient could still eat independently. However, drinking happens more often throughout the day, causing more assistance as well. The duration and frequency of desired assistance should be considered for further development of an assistive aid.

Figure 24: Eating robot Bestic (Törmänen, 2015).

Location

Eating is mostly done at home, but patients desire to eat at other locations as well. This could be at a friend's place, restaurant, or lunch at work. At home patients will use their utensils, but they are less inclined to bring their special cutlery to locations outside their homes. The main reason for this is that they do not want to be special, or different from their table companions: **'I do rather mess around with the cutlery they have than bringing my own'**. The level of acceptance towards assistive aids shows some adverse effects here. Because if an assistive aid is functional, patients are eager to use it, but why does a patient choose to leave the adjusted cutlery at home, instead of bringing it and eat with more ease? This might indicate that appearance or expression of the individual influence the use of assistance more than expected. Patients desire to take the assistive aid along easily.

Conclusions

- Improving handles of assistive aid improves the use of assistive utensils. However, most hand aids are not sufficient for ALS patients if wrist strength is lost as well.
- It is always desired to be in control when some function in hand is still present.
- The assistive aid should support the patient, but should not take the task off a patient's hands.

6.4 Dining positions

The dining position is analysed as well. A patient describes complaints in his back because he tends to bend over to bring his mouth closer to the plate. This is done because serving food to the mouth will cost less energy because the arms are lifted less high. An arm exoskeleton which helps to lift the arms would alleviate these complaints.

Serve food into the mouth is a movement whereby flexion and extension of all joints and ulnar and radial deviation in the wrist occur, found in the overview in Figure 18). The position of the utensil in the hand influences the motion and the manner of eating. A small study has been performed to experience the benefits of holding a utensil and bringing the utensils to the mouth in three different positions (see Figure 25).

Conclusions

There is not one best way to hold an utensil. This is due to different movements that must be made and the shape of the cutlery. Scooping food might become easy in one position but serving food to the mouth will be more challenging in this position. However, it is most desired to hold the hand in a natural position.

Hand palm pronate grasp

This grasp is a power grasp and is well suited for thicker handles on cutlery. In this position, the hand is already at the maximum pronate position which, makes scooping food too challenging. Serving food into the mouth can be done quite well.

Precision grasp

Using the cutlery in this way is most natural to the patient. From this position, the hand can easily pronate and supinate to scoop up a little bit of food and serve this into the mouth. The precision grasp cannot be performed with thicker handles.

Hand palm supinate grasp

The grasp is a power grip and suited for thicker handles on cutlery. As the maximum supination is already reached, it is very hard to hold the spoon horizontal and serve food into the mouth because the spoon will not reach high enough.

Figure 25: Overview of hand positions.

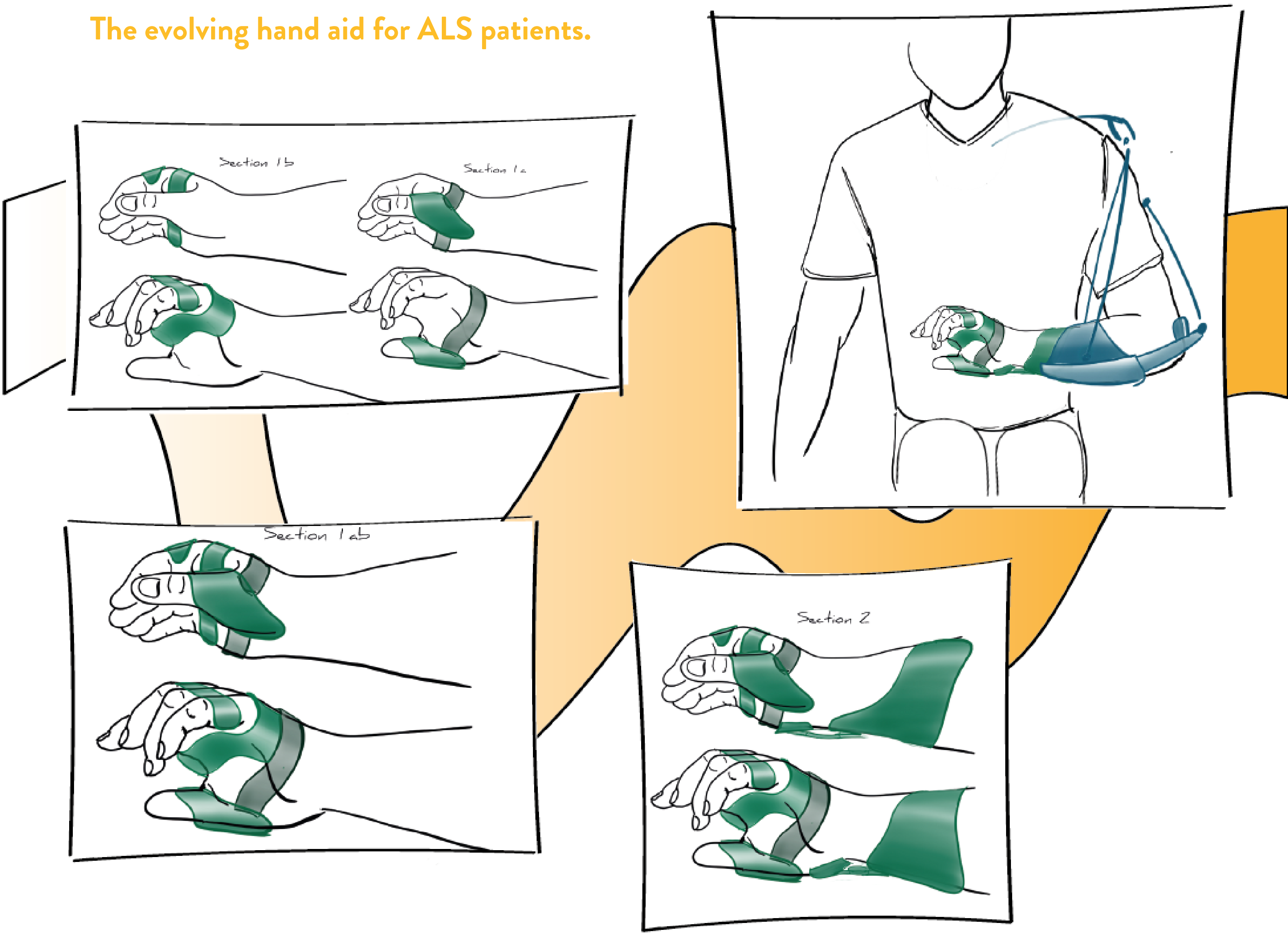
7 Design vision

The previous chapter defined which specific assistance is needed during dining and explained in which order muscles will start to fail and what movements cannot be performed any longer due to this muscle failure. Supporting grasp by means of an assistive aid is a big opportunity to achieve more independence for ALS patients. Therefore the design vision is rephrased to:

The assistive hand aid should give patients more independence during dining activities by assisting them to hold and use objects like, cutlery or cup, as usual.

The muscles weakness starts in the fingers and thumb and will affect more muscles in a proximal direction over time, causing the wrist to follow and lose strength in most cases. The assistive aid should evolve to meet this growing need.

The evolving hand aid for ALS patients.



Key Takeaways

A summary of the conclusions resulted from the part 'define' is given below. A full list of wishes and requirements can be found in Appendix C. The wishes will help to evaluate ideas and concepts in the next part.

MOVEMENTS

- Patients can not grasp objects because of paralysed fingers.
- Precision grasps are the first grasps which cannot be performed anymore.
- Replace precise movements by larger movements.
- The assistive aid must be used or controlled by muscles located more proximally in the arm because this will increase the duration of usage. Muscles like the pronator teres, supinator, bicep, or tricep muscles are suitable for this purpose.

DINING AIDS

- Patients do not want the assistive aid to be noticeable for others when they eat at other locations than at home.
- Patients want to easily bring their utensils to other locations; therefore, they desire the utensils to be small and lightweight.
- When wrist weakness occurs, most dining utensils become inappropriate for usage.

DINING POSITIONS

- Patients desire to eat in the way as they used to do, which results in supporting a natural grasp and positioning the utensils as usual.
- Patients desire to use one assistive aid, instead of switching utensils for different activities. This causes the assistive aid to support during fluid and food intake.
- Since eating is done multiple times a day, the device should either be donned and doffed for the activity or be comfortable enough to be worn all day.

REQUIREMENTS

- The aid should grasp objects from the table like cutlery, varying in size weight and shape.
- The aid should attach safely to frequently used tableware.
- The aid should be operated by the pronation or supination movement or muscles located more proximal.
- The aid should provide static wrist support to prevent wrist extension or flexion.
- The assistive aid should support patients during fluid and food intake.

WISHES

- Patients desire to be assisted by assistive aids in a way that they remain some level of control.
- Patients wish to be supported to eat in a 'normal way'.
- Wearing the orthosis will interfere as little as possible during other activities.
- The aid is beneficial during performance of activities besides dining as well.
- The aid is comfortable enough to prevent donning and doffing frequently.
- Patients have trust in the connection between the assistive aid and the object.
- The assistive aid is operated by simple movements.

4

Figure 26: Donald prototyping.

Develop and deliver

This chapter starts with the ideating on the design vision. For this ideation, two concepts are developed and discussed with medical professionals and patients. Secondly, the steps taken to make a functional prototype are explained as well.

In this part

8 Concept forming

In this chapter, ideas are discussed regarding the type of support. These lead to concepts which are evaluated by patients and medical professionals.

8.1 Type of hand support

As mentioned in the vision, it is desired to support grasp for frequently used objects during dining activities. Hand support can be distinguished in three types: static, dynamic and hybrid. Static orthoses have no movable parts and are most used for prevention of contractures (Andringa, et al., 2013). While dynamic orthoses have moving parts that promote, control, or restore movement. These orthosis can provide external assistance for weak muscles. Hybrid orthoses incorporate features of static and dynamic orthoses in one device. These orthosis cross multiple joints, with the intention to limit movement at some joints and allowing movement at the other joints (Sivan et al., 2019). In this chapter different types of support are explored. The feasibility of the types of support discussed regarding; functionality, usage, and production. By doing this an informed choice can be made about which type of support is most ideal for ALS patients during this activity.

1

Active dynamic orthosis

A dynamic orthosis integrated with a power source could actively provide finger movement. By expressing force on the digits, flexion or extension is realised. Active support of the wrist should be included.

Several mechanisms can be used to perform movements. Cables which pull on one side for extension and the other side for flexion can be used. Other mechanisms can include hydraulic or pneumatic systems which are placed on the dorsal side of the hand.

Smart gloves performing extension and flexion are being developed for stroke survivors on a wide scale, but not yet for ALS patients. The biggest difference between these target groups is the time of usage and rarity in occurrence.

Active support is highly desired because flexion and extension can still be performed if muscles strength is completely lost and no contractures are present. The development of these devices is time-consuming and expensive. Controlling the active orthosis is commonly done via an application or pressure sensors. When muscle control is lost, it would not be possible to control a dynamic orthosis via pressure sensors. The outer structure can limit patients in their movements as well because more resistance occurs during other movements. Secondly, the movement is limited to flex and extension.

Figure 27: Left, Gloreha sinfonia (Gloreha, n.d.) a robotic device for hand rehabilitation. Right, Carbonhand by Bioservo (Cypromed, 2020).

2

Passive support hybrid orthosis.

A passive dynamic orthosis can give support during activities by immobilising digits in a preferred position. It is beneficial if the thumb or fingers are immobilised during grasp because more force can be applied. No counter force needs to be applied, so more effort (or energy) is saved.

A structure around the hand will provide guided movement in flexion and extension of the fingers. The thumb can be moved in adduction, abduction, and opposite directions. Both digits will be immobilised and released by the patient into the ideal position to perform a task.

Immobilising joints is seen in static resting wrist-hand orthosis, which may increase the patient’s ability to hold objects and improve overall function (Delisa, 1979). Volar wrist support in 30–35° of extension, also referred to as wrist hand orthosis, improves grip strengt and/or efficiency according to other research (Ivy et al., 2014; Rocha et al., 2005). More info on this phenomenon can be found in Appendix D.

Immobilising joints is proven to be functional (Tanaka et al (2013), but operating the device is mostly done with the other hand. This can be difficult for ALS patients, if the other hand is not functional anymore. The duration of time decreases if usage requires complex movements.

Figure 28: Ambroise Triple-mode arm orthosis (Ambroise, n.d.).

3

Free orthosis static orthosis

The free orthosis offers the patient a secure connection to frequently used objects. This interface is easily been made between the several objects without required assistance of digits. In this way, the fingers remain to keep the range of motion.

A structure around the hand should carry the object and be able to release and hold the object. The interface of the connection between the object and hand can be established by magnets, snap-fit connections or Velcro.

This type of support refers to some utensils seen for dining activities. However, ALS patients are not able to change utensils themselves, therefore they are limited in the use of utensils

A quick fix hold and release to various objects can be an opportunity as a replacement for grasp. Strength and reliability of the connection will be key factors for safe use. The connection will be limited to products and active hand movement is not supported which is less desired.

Figure 29: Pencil holder for children with disabilities (K. Melssen, 2020).

Expert review

An interview with Jaap Bakers is conducted, a physiotherapist specialised in neurological diseases. He is one of the members in the ALS treatment team of UMC Utrecht. He is consulted to give more insights into the situation and evaluate the type of support for an ALS patient. J. Bakers favours active support because he is afraid patients can use a passive orthosis too short because of reduced muscle strength. Secondly, he shared essential lessons regarding the type of support for an ALS patient. These lessons are formed into drivers for selecting the type of support. The interview can be found in Appendix E.

- The type of support should consist of **supporting simple movements**. Support someone as good as possible in low complex movements. Instead of supporting someone in highly complex movements. It the movement becomes too complicated, or a patient has to learn to deal with this for a long time, the type of support will not succeed.
- The type of support or movement should be **familiar to patients or can be learned quickly**. One should not be challenged too much to learn complex actions because the deterioration of the muscles goes faster than learning new movements.
- **Passive support** of digits is, in most cases not enough, because weakness occurs so quickly. If strength in de fingers is lost the thumb will quickly follow or vice versa.
- Immobilisation of the fingers by wearing a splint all day can result in **more contractures**, causing a decreased range of motion of the fingers, which can hinder during side activities such as dressing.
- Stabilising the thumb has an advantage for grasping.
- Stimulating the muscle via EMG does not work for ALS patients because of the deteriorated motor neuron cells. Much more power is needed, causing uncontrolled flexion and extension, which is undesirable.

Conclusion

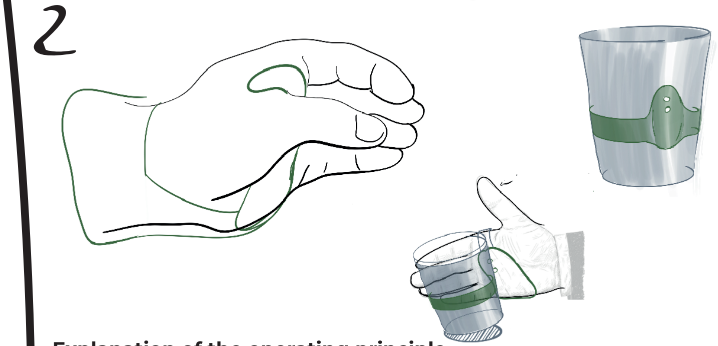
J. Bakers presented a clear preference for the active orthosis, which could be an exciting opportunity to develop further. This type of support will be immensely complex to build within the timeframe of the thesis. Therefore, it is decided to leave this direction out of the process. The other two types of support can be built and tested within the timeframe of this thesis, which is one of the goals of this thesis.

User-centred design

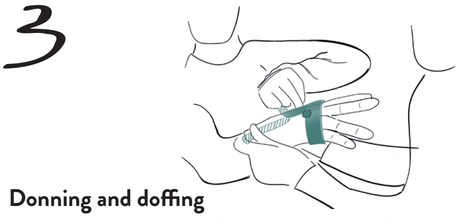
Having a user-centred design approach involves patients in co-creation. The two types of support direction are visualised in a user scenario and presented to the patients from the interview, via a video call connection. The templates of the user scenario can be found on the next page. The scenario is divided into seven steps, visualised in frames. Each frame addresses a wish from patients or a beneficial feature of the assistive aid. Frame one represents the desire of eating independently and is the start of the scenario. The desired result is displaced in frame seven. For both concepts, this will be similar for start and end. The results of the discussion with the patients are formulated into Strengths, Weaknesses, Opportunities and Threats. These results can be found in the orange and green boxes below the scenario.

8.2 Concept validation free orthosis

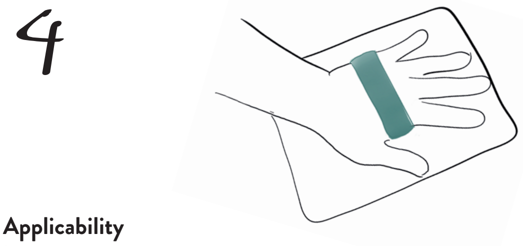
Motivation
'I would like to support and contribute to my family life, but my illness often limits me. For me, dinner is an intimate moment of the day that I share with family and friends. I like to contribute in my way to make it a great moment for everyone.'



Explanation of the operating principle
'This free orthosis supports me during desired actions by automatically grasping objects by, e.g. a magnetic connection. This way, I can grasp various objects with relatively little finger strength. Because the disease is progressive, the wrist must be supported as well to prevent wrist drop.'
The success of this concept will depend on how easy it is to connect to and release objects.



Donning and doffing
'In the morning, my informal caregiver of home care helps me to dress and don the orthosis. I enjoy wearing the orthosis because it is functional. The orthosis is small and offers enough freedom to wear all day. Besides, it does not interfere with other activities.'



Applicability
'The orthosis makes it easier to grasp my tablet or phone, the tablet cover clicks into the orthosis I wear. Online I search for a recipe to find a dish that meets my wishes and way of eating. At the same time, I invite some friends as well.'

S

Strengths

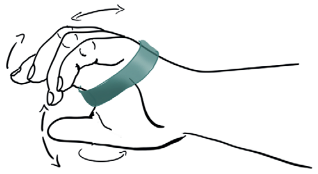
- A magnet will be trusted by patients to act as a connection.
- Making extra preparations to connect magnets to objects in advance is acceptable for patients since many preparations are made.
- This solution fulfils the wish of having a small and minimal appearance.
- The minimal band shaped orthosis contributes to keeping the range of motion and less irritation can occur because little skin contact is present.
- If this aid only helps patients lift a glass or (cup), it would already be worth it because this happens twelve times a day.

W

Weaknesses

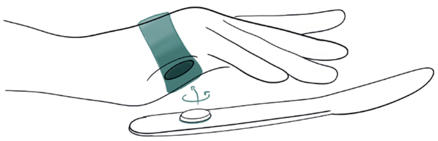
- The aid will become useless when the fingers of the patient are cramped in a position which hinders the connection.
- The aid does not support moving the fingers or opening the hand.
- It does not make the object lighter.
- Connecting to specific objects feels a bit limited, according to the patients.

5



Range of motion
‘By keeping my fingers free in the orthosis, they are very mobile and fewer contractures can occur.’

6



Automatic connection
‘By using magnets or another system, it is easy for me to connect and use my utensils. I prefer to use my own products if a small adjustment could be made. The connector block on my knife connects to the orthosis and results in a firm and secure grip, causing me to accomplish tasks with less effort.’

7

Independence
‘By using this orthosis I can now eat by myself and I do not have to burden my caregiver or friends during this intimate moment.’

Opportunities

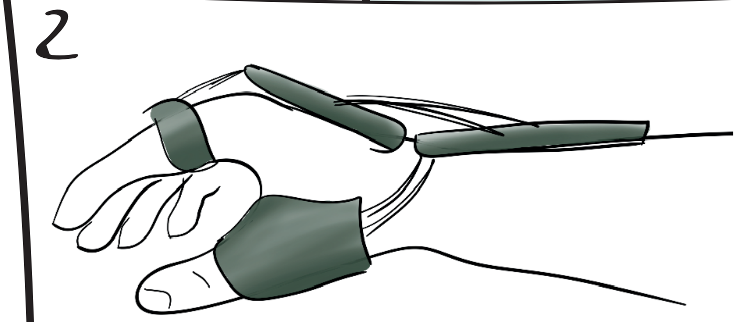
- Little finger strength can still assist to grasp and lift objects.
- The orthosis can be extended to include wrist support as well.
- This system can be used for multiple products in the household, like a toothbrush or remote.
- Medical support pieces can be integrated when these objects integrate a connector piece as well.

Threats

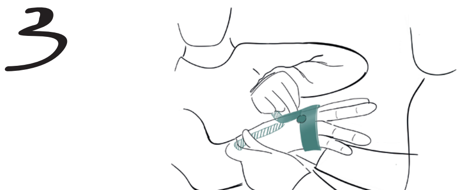
- If the function of the assistive aid is not that beneficial, the patient will not bring it to other places.
- The connection of the magnets could be too weak or irregular, causing objects to fall.
- Objects can still move too much in hand.
- It will not be easy enough to release objects because of the strong magnet.
- The required movement to connect and release the object might become too challenging for the patient after short usage.
- Attaching connectors to personal cutlery would be good but is not necessarily valued by the patients.

8.3 Concept validation passive orthosis

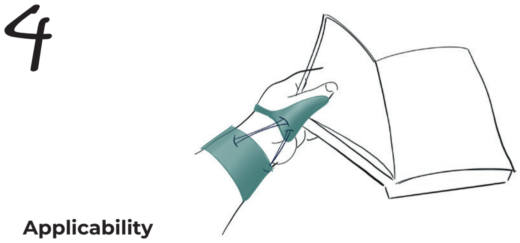
Motivation
'I would like to support and contribute to my family life, but my illness often limits me. For me, dinner is an intimate moment of the day that I share with family and friends. I like to contribute in my way to make it a great moment for everyone.'



Explanation of the operating principle
'This passive orthosis supports me during specific actions by locking joints so that they cannot bend. By Locking the thumb joint, more force can be performed with the other fingers. Because the disease is progressive, the wrist must be supported as well to prevent wrist drop.' The success of this concept depends on the ability to adjust the position of the joints.



Donning and doffing
'In the morning, my informal caregiver of home care helps me to dress and don the orthosis. I enjoy wearing the orthosis because it is functional. The orthosis offers freedom and is comfortable enough to wear all day. Besides, it does not interfere with other activities.'



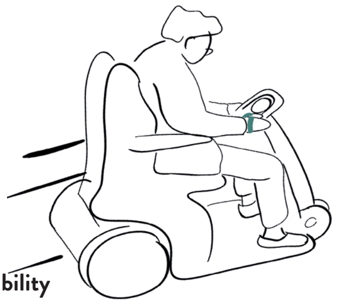
Applicability
'I would like to get some inspiration in a cookbook with delicious dishes that I got from my sister. Through my orthosis, I can use this book again, which is of great value to me.'

S

Strengths
- Fixating the thumb will add to their grasp performance, which is desired during dining activities.
- Changing the position of joints will be desired for dining activities and side activities.
- This orthosis lends itself to integrate wrist stability, which will result in longer operation time of this orthosis.
- This orthosis will not hinder pronation and supination movements.
- Patients can still press a button until a late phase of the disease.

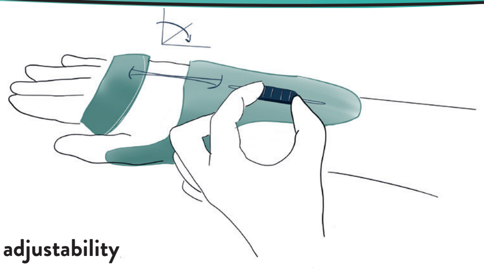
W

Weaknesses
- If one hand becomes too weak to adjust the joints, the device becomes useless.
- The fast progression of the muscles can cause too much weakness resulting in too little strength to operate this orthosis.
- If this aid is donned and doffed multiple times a day, patients will be less likely to use it.



Flexibility
'During the day, I will do the grocery shopping with my mlity scooter, which I received from the municipally. The orthosis wear must not hinder me during this activity or other side activities.'

Independence
'By using this orthosis I can now eat by myself and I do not have to burden my caregiver or friends during this intimate moment.'



Position adjustability
'Just before eating, I adjust the position of my orthosis so that I can easily hold and grasp the cutlery. I do this by sliding a slider on my wrist backwards, which extends my wrist.'

O

Opportunities

- Usually, the patient eats with someone, and this person can assist him or her in adjusting the hand position.
- Lifting pants could benefit from an immobilised thumb.
- A comfortable aid results in less donning and doffing.
- Using the mouth can be an opportunity to adjust the position of the passive orthosis.

T

Threats

- It might be too difficult to understand which hand positions are applicable for which activities.
- Moving a slider to change the wrist angle will soon become too difficult for patients to operate. Making this orthosis probably a temporary solution.
- Depending on the activity, muscles can weaken a lot during the day. It might happen that a patient has become too weak to operate the orthosis in the evening.
- Patient think they might be hindered during side activities because the orthosis looks big.

8.4 Design goal

Results

The patients contributed to the process of evaluating the discussed strengths, weaknesses, opportunities and threats of both concepts. However, the patients could not say if they prefer one of the two concepts because it is hard to imagine when the solution would work if only a drawing and thoughts are shared. Patients would like to try out the assistive aid before having a final opinion.

Experts opinion

Kelly Melssen is consulted for a second opinion on the design. She is an experienced occupational therapist and care-professional in rehabilitation and health care. At the foundation ALS Netherlands, she is responsible for patient contact. She meets many patients and is well aware of the problems that occur in the daily life of a patient. The concepts are discussed in the same set-up as with the patients (the answers can be found in Appendix E).

K. Melssen argued that she does not prefer the passive orthosis over the free orthosis because of the following reasons:

- The movement of the passive orthosis is actually **too complex** for one with ALS. “I foresee some difficulties for patients to understand which joints they must be immobilising during which task.”
- Adjusting the angle of the wrist **seems challenging**, and the result might be unnecessary because patients can function well with a static wrist position.
- K. Melssen is **not completely convinced** that adjustable joints are truly functional to the patient.
- The time of usage will be **too short** because weakness in the fingers will follow quickly after weakness in the thumb occurs or vice versa.

K. Melssen prefers the free orthosis most because of the following reasons:

- The **simplicity** in this orthosis is favoured, and this orthosis would assist during activities such as holding a cup or use cutlery.
- **Simplicity in aid often results in better use of user experience.**
- Locking the wrist in the neutral position is often sufficient to perform most tasks. It may not be the most optimal position for all tasks, but on average, this is fine. Meaning the wrist can be positioned in neutral, and much is still possible. **“I foresee many different applications with this design, not only for ALS patients but for others who have paralysed hand function as well.”**

Conclusion

Based on the outcomes of the consultation of both experts, and considerations of the wishes, it is decided to develop the Free Orthosis into a functional prototype. The following main drivers led me to choose the free orthosis direction.

1. The movement supporting eating and drinking is simple and familiar to patients.
2. This assistive aid supports grasp to objects and provides static wrist support resulting in being suitable for most ALS patients.
3. Based on the design, donning and doffing is considered to be relatively easy and quick in practice.
4. The orthosis is comfortable to wear because fewer pressure spots and skin contact are present.
5. The concept is perceived as more minimalistic than currently available orthoses.
6. This concept maintains some level of self-determination for patients.

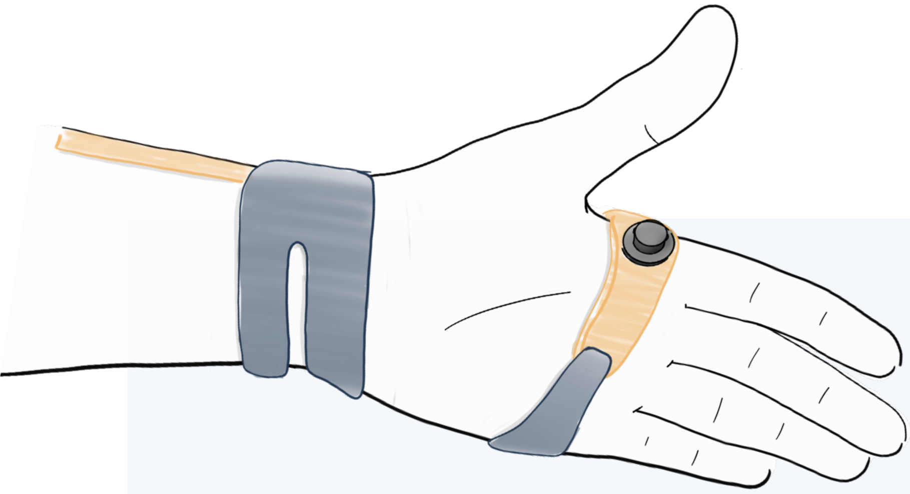
Design challenge

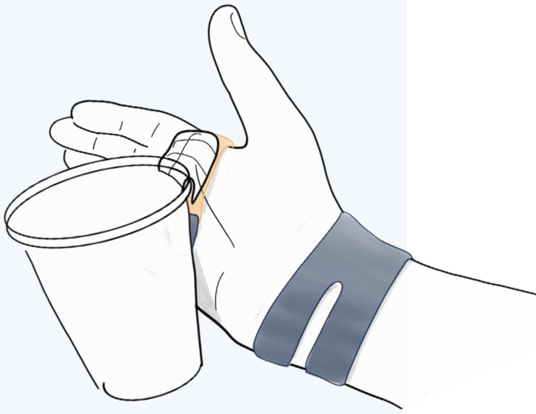
This chosen concept let to the following design challenge, including the most crucial aspects of the main drivers.

Create a comfortable hand orthosis which holds on to objects without using the strength of the fingers and thumb.

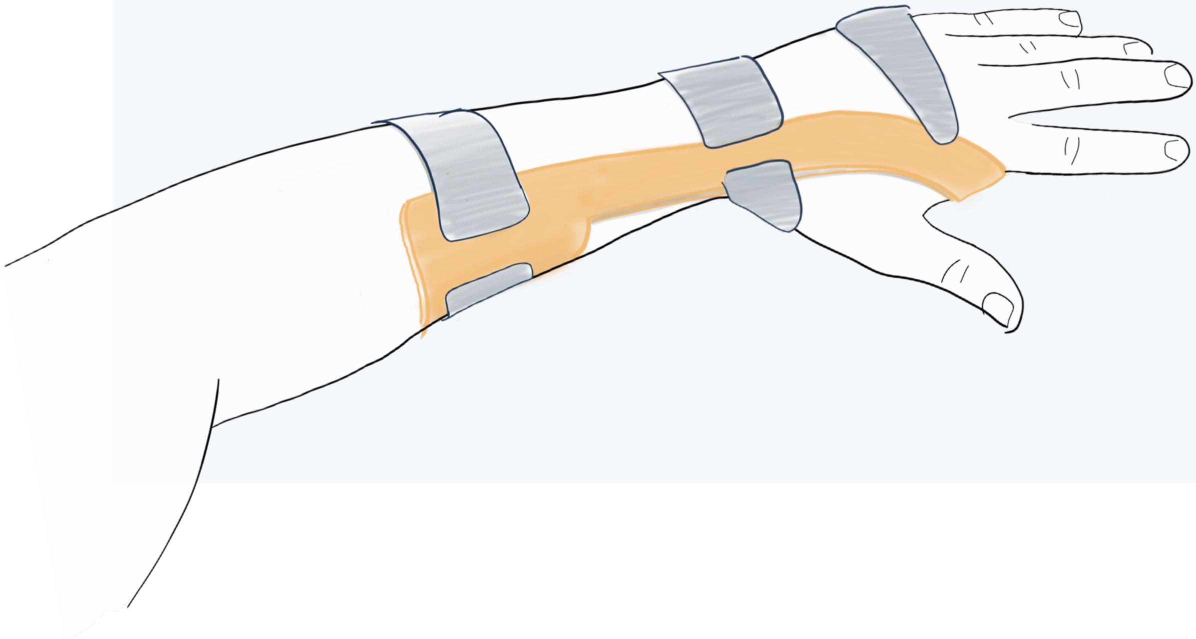
A few risks that can prevent patients from using the orthosis need to be considered in advance. This will help in mitigating these risks during the development phase.

- The most significant risk is that the fingers of the patients will be cramped and hinder during the use of the assistive aid.
- The orthosis is not comfortable enough, causing it to be doffed by the patients to often.
- The movements patients have to make to operate the orthosis are too challenging.





Create a comfortable hand orthosis which holds on to objects without using the strength of the fingers and thumb.



9 Prototype

This chapter explains how a validated concept is made from the chosen support direction. The design choices are made based on wishes of patients, lessons of experts and academic research. Several prototypes are made according to a basic design cycle which consists of; design followed by build, test and learn. An overview of this process can be seen in Figure 30.

Design goal

Create a comfortable hand orthosis which holds on to objects without using the strength of the fingers and thumb.

This challenge is dived into three parts which are solved individually and are later integrated into one product solution which solves the design challenge. The three sub design challenges are:

1. Design a comfortable hand aid which divides the applied forces evenly to the hand.
2. Design an interface which safely holds on to objects and releases them when desired.
3. Integrate sub design challenges one and two into one design.

The following aspects are most crucial to included to consider during the development of the prototype. These are based on the wishes of the patients and the requirements of the assistive aid. More details can be found in the analysis performed in chapter two to six.

Aspects to include in the design of the orthosis.

- Prevent pressure spots, by dividing applied forces to the right areas.
- Create a safe and trustworthy connection to the object.
- Make it easy for one with ALS to grasp and release the object.
- Include customization to fit a large part of the target group.
- Make the product minimalistic and less noticeable.

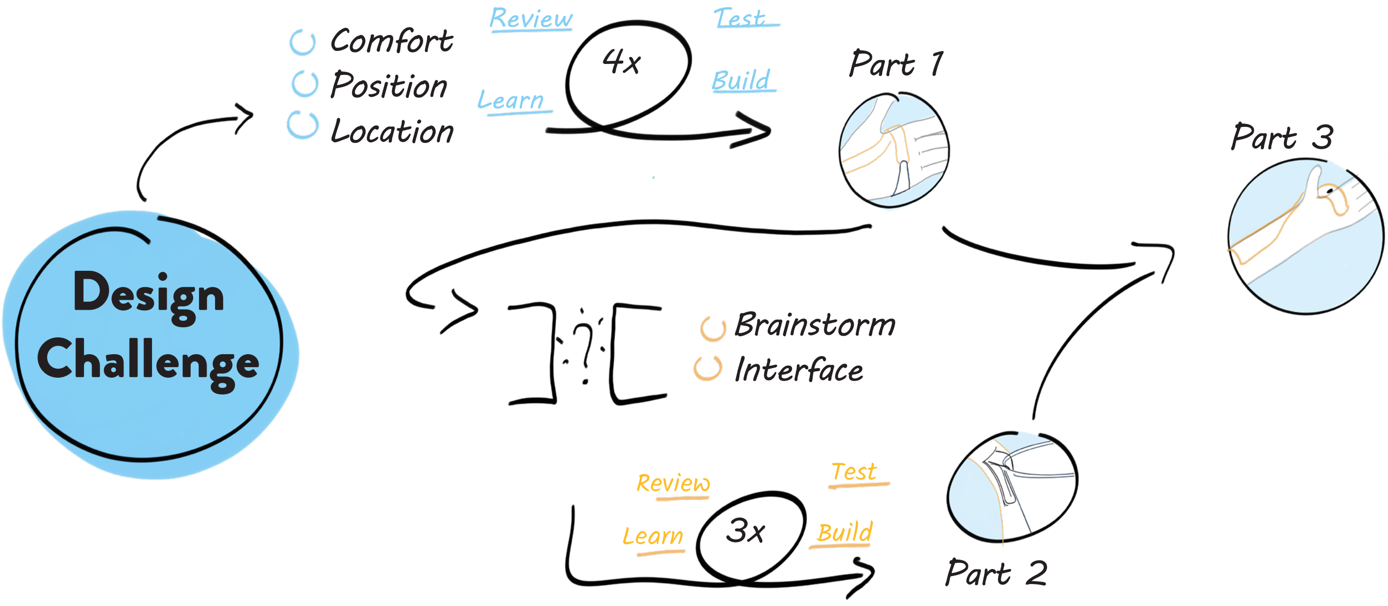


Figure 30: Overview of prototype process

9.1 Comfort in splint design

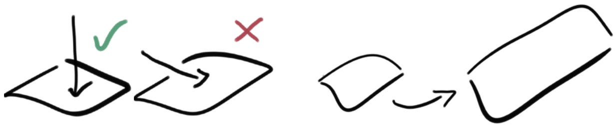
According to P. Vink (2004), comfort in hand aids results from many factors. In order of importance: reliable, functional, a good fit in hand, easy in use, the force exerted from the tool, which is applicable to orthosis design as well. Secondly, Stern et al. (1997) confirm that satisfaction with an orthosis appears to be based on the comfort and ease of its use, not only on the therapeutic effect. To make a comfortable hand orthosis; the guidelines for fabrication of orthosis and hand splinting are followed, described in the book from J. Wilton (2015). Most relevant guidelines are discussed and illustrated below.

Shape

Follow the contours of the skin surface as much as possible. This results in more comfort and a better distribution of the load. Avoid sudden substantial changes in pressure. Roll the edges of the orthosis for a gradual change in pressure. Ensure that the straps follow the contours of the limb or digit. As of last, avoid holes in the orthosis.

Surface area

Increase the surface over which the force is applied, in this way the load is better divided, and pressure spots are prevented, resulting in more comfort. On the other hand, try to reduce the contact with the skin as much as possible to prevent irritation, sweat and heat production.
Every time it is a trade-off on how much load can be divided and how much skin can be left free. Secondly, much valuable tactile feedback (information that people can interpret with their sense of touch) is received by the patient when the volar side of the hand is kept as free as possible. In this way, patients can feel the temperature of the coffee and a patient will be less hindered during other activities. Also, tactile feedback is essential for patients to know how the cup is positioned to the hand. So, patients know where to go with the hand.



Applied load

It is best to apply load on thicker skin because these spots tolerate applied forces and deformation better than thin skin. Avoid skin close to bones as this is extra sensitive to discomfort leading to pain.
Perpendicular forces are better to tolerate than forces applied tangentially across the surface of the skin with a rotational effect on the tissue. High loads are commonly transmitted through the skin on the volar surface of the hand, and often tissues respond by forming a callous.

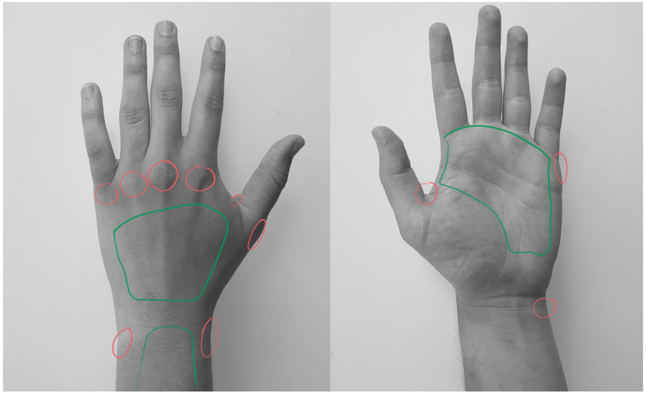


Figure 31: Hand spots to avoid (red), hand spots to use (green)

Duration of usages

Low stress to the skin of short duration is a normal part of living. However, prolonged low stress to the skin results in a displacement of the fluids in the tissue. It may eventually change the capillary flow and ultimately result in Ischaemia J. Wilton (2015). Repeated pressure has a cumulative effect that may cause a progressive inflammatory change, resulting in tissue damage. When the skin remains red after 15 minutes, the orthosis is too harmful.

9.2 Orthosis shape design

The position of the interface between the hand and the objects is determined by advantageous spots on the hand, as explained in chapter 9.1 (see Figure 31). This is combined with the preferred way to hold objects as discussed in chapter 6.4 'Dining positions'. As can be seen in Figure 32, the object is in contact with a point just under the metacarpophalangeal joint of the index finger most often. This place is well suited for an anchor point to attach cups, and cutlery because patients are familiar with this position. Besides it is advantageous to attach to objects above their tipping point so that they will not tip easily.

Prototypes

Several brainstorms for shape determination are conducted to understand how comfort is achieved. Polycaprolactone (protoplastic) is used which has physical properties of a very tough, nylon-like plastic that softens to a putty-like consistency at 60 °C, easily achieved by immersing in hot water (McKeen, 2012, p. 312).

All prototypes are tested with the same point load applied in the location of the foreseen interface. The results of these tests can be found in Appendix F. The test consists of performing the desired movement and wear the aid for a duration of ten minutes. It is clear that the thickest shape (see Figure 33, 2) is most comfortable because no rotation force is perceived at the dorsal side of the hand. Secondly, this shape did not pinch into the hand sides (circled in red), like the other two. As of last, the increased thickness contributes to a better distribution of the applied loads.

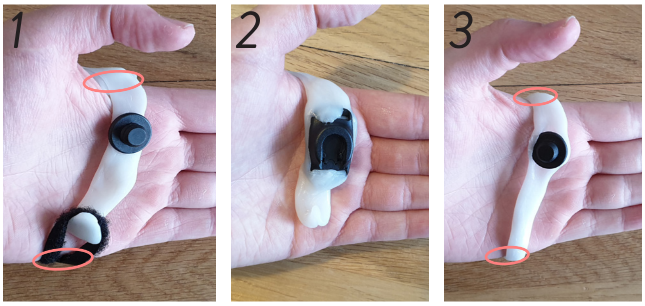


Figure 33: Three designs for the hand palm orthosis.

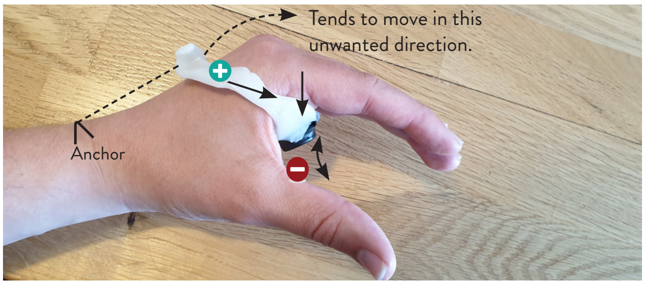


Figure 34: Forces in hand structure.

Figure 32: Hand position for holding a cup.

A second iteration of the thicker design followed, as can be seen in Figure 34. This iteration taught us that when applying a load, the structure tends to move in the wrong direction. Therefore an anchor point near the wrist should be integrated to prevent unwanted mobilisation of the structure. Using a band as anchor point gave too much freedom. Therefore a stiffer and stronger structure is desired, causing less mobility.

The third iteration integrates a stiffer and stronger anchor point made from protoplastic near the wrist. This shape is pleasant in comfort, divides the load evenly, fits well around the hand, and does not hinder movements. Points off risk remain the distance to the web space (circled in red, see Figure 35), the thin shape, causing less stiffness. This shape can serve as a basis for further development.

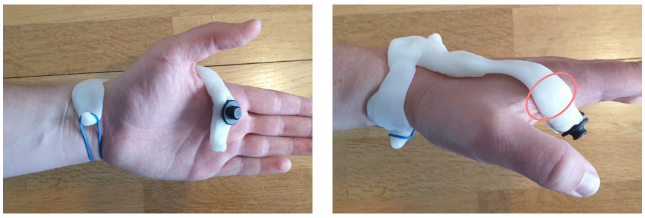


Figure 35: Hand structure with wrist.

Integration of bands

Additional bands are needed to keep the shape close to the hand and limits mobility or loss of contours. In Figure 36, it is seen that the orthosis structure loses contact with the skin, in two positions. The red arrows address the desired band behaviour, which should prevent this from happening. The bands are made from neoprene which is often used in orthoses. Velcro is sewed onto the bands and connects. The bands are formed in such a way they follow the conically contours and rounding of the hand and wrist (see in Figure 37), which results in curved bands. An overview of the bands in the orthosis can be found in the image below, and a detailed overview can be found in Appendix G, Band patterns.

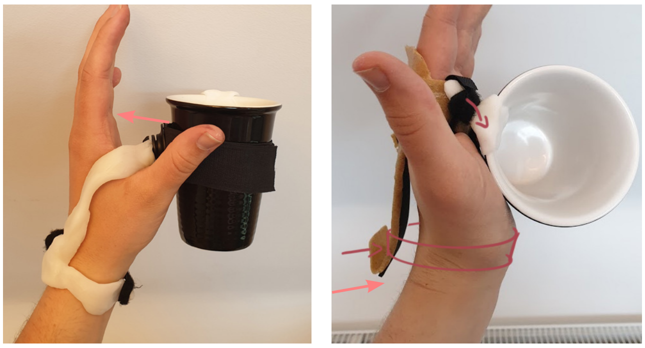


Figure 36: Desired band behaviour.

Figure 37: Desired band positions for the hand and writs.

Figure 38: Overview of the bands used in the extended orthosis.

Shape optimisation

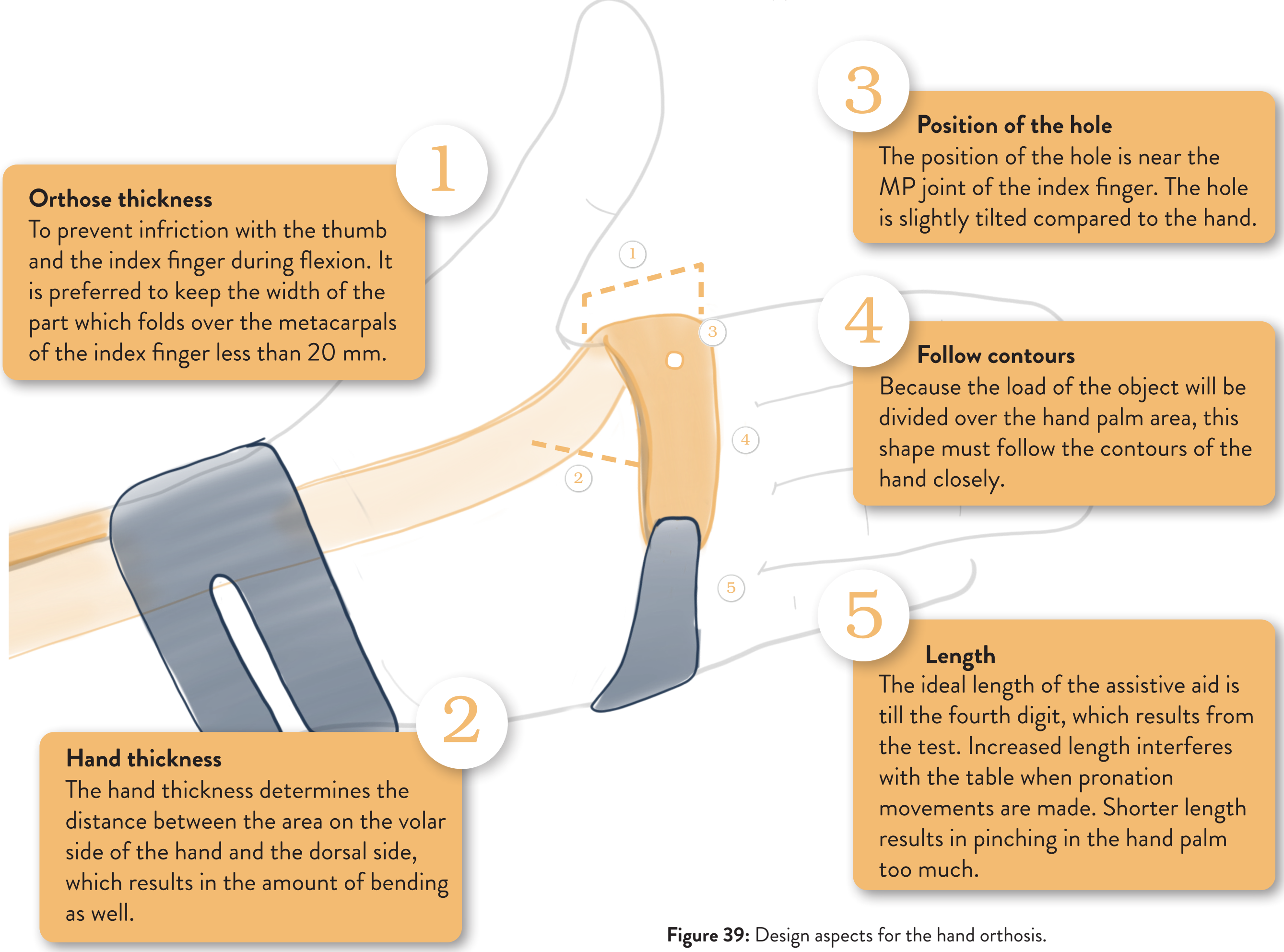
There are four design aspects to optimising a better fit for the user, highlighted in Figure 39. These aspects result in choices for a pattern to fit various hand types. The aspects mainly focus on the hand palm area.

Modular orthosis design

A crucial feature which is not explained by the figure is that two types of orthoses can be made from this pattern. Both patterns will include the four design aspects applicable to the hand palm area, as mentioned above. However, the two types of orthoses will differ in ex- or inclusion of static wrist support. This is a modular response to the increasing paralysis symptoms of the patient, originating from the wishes of the patients.

The pattern which excludes static wrist support results in a **short orthosis**, suitable for patients who have lost strength in the fingers but still have strength in the wrist. Patients desire this short orthosis because they would like to use their wrist when strength is still present. Besides, medical professionals desire this because the movement of joints is always stimulated to prevent contractures (J. Bakers, personal communication, 2020).

The extended pattern, which includes static wrist support, is made into the **extended orthosis**, suitable for patients who lost strength in the fingers and wrist. The use of extended orthosis will quickly follow because of fast progressive muscle loss. The extended orthosis pattern is further designed and is used to develop into a prototype because this will be applicable to most ALS patients. Both pattern designs can be found in Appendix G.



1 **Orthose thickness**
To prevent infriction with the thumb and the index finger during flexion. It is preferred to keep the width of the part which folds over the metacarpals of the index finger less than 20 mm.

3 **Position of the hole**
The position of the hole is near the MP joint of the index finger. The hole is slightly tilted compared to the hand.

4 **Follow contours**
Because the load of the object will be divided over the hand palm area, this shape must follow the contours of the hand closely.

5 **Length**
The ideal length of the assistive aid is till the fourth digit, which results from the test. Increased length interferes with the table when pronation movements are made. Shorter length results in pinching in the hand palm too much.

2 **Hand thickness**
The hand thickness determines the distance between the area on the volar side of the hand and the dorsal side, which results in the amount of bending as well.

Figure 39: Design aspects for the hand orthosis.

Method

It is decided to tailor the orthosis by shaping thermoplastic material instead of scanning and 3D printing a brace or use prefabricated splints. Using thermoplastic material freely has more advantage over the other techniques because it responds better to the needs of the patients.

- The thermoplastic material allows much freedom in adjustments which respond well to the individual differences of the patients.
- Adjustments can be made repeatedly when patients desire changes in position or pressure spots.
- The material is directly tailored to the hand of the patient.
- The orthosis is quickly fabricated, which is desired because patients can experience the use of this tailored orthosis immediately.
- The material is quite cheap, which saves the budget of reimbursement parties, as explained in chapter 4, stakeholders.

Material

Stockx Medical, a company which is specialised in orthoses, is consulted to advise on the material and the thickness. After explaining the purpose, they propose to use ‘Medical Extra Comfort non-sticky thermoplastic 3.3 mm (see figure Figure 41). This material is ideal for immobilise something quickly. Besides, it is suitable for all body parts and ideal for finger, hand, wrist and nose splint. Padding material is not necessary because of the (Extra Comfort) soft foam layer. Prevention of padding is desired because padding always allows more mobility and more heat production. Disadvantages of this material are, thermoplastic material causes sweat production and few colours are available. From this material, a final shape has been made and can be seen in Figure 40.

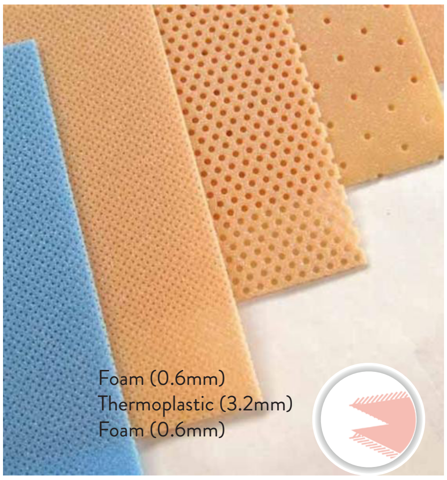


Figure 41: Extra Comfort non-sticky (StockxMedical, n.d.).

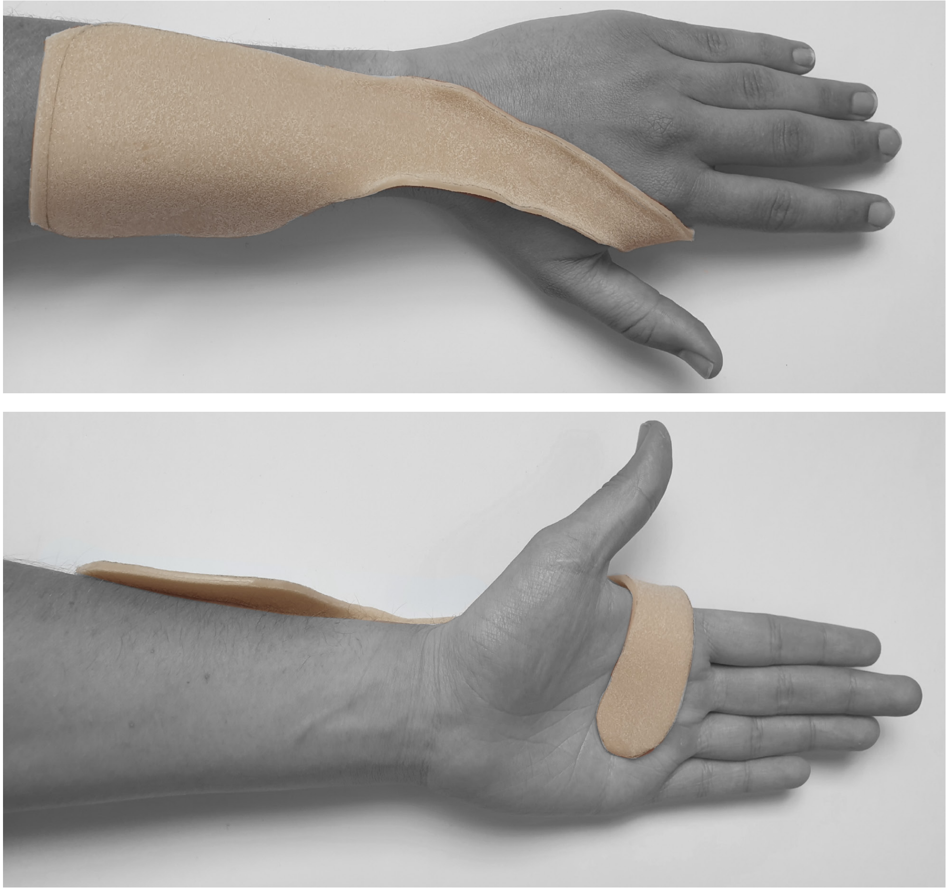


Figure 40: Orthosis pattern which includes wrist support.

9.3 Interface design

This chapter will focus on how to establish an interface from the hand to the frequently used utensils. Figure 42, presents an overview of the established interface. This interface consists of two dynamic connections (blue lines); the connection between the hand and the orthosis, secondly the connection between the magnet and the connector. The static connections (red lines) are between the orthosis and the magnet, and secondly, the connector to the object.

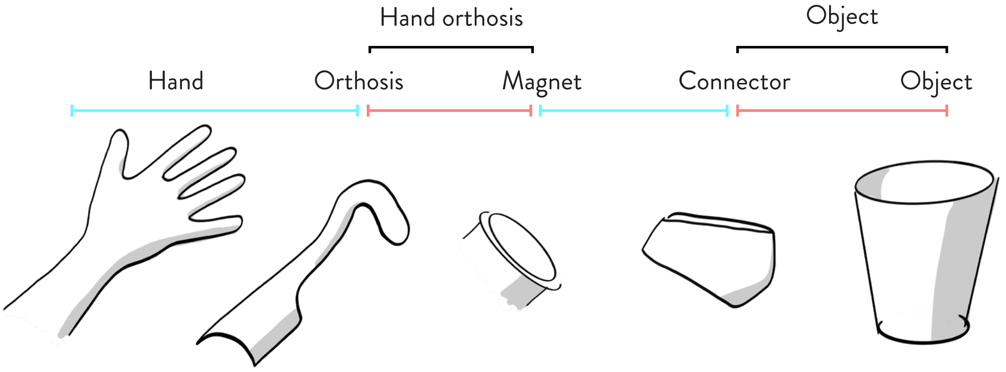


Figure 42: Interface connection.

Desired behaviour

First, because of absent muscle precision ability, it is favourable when the connection between the orthosis and the object is made almost automatically.

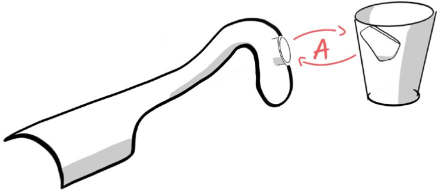


Figure 43: Automatic connection.

Secondly, a patient should be able to release the object with ease. This means the movement cannot be precise or too complicated. A pronation movement or extension of the forearm is executable for ALS patients with paralysed hand function and is, therefore, a suitable choice for releasing

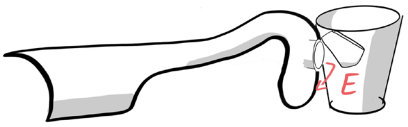


Figure 44: Ease of releasing the object.

As of last, the connection between these two should be trustworthy and secure. Meaning, the connection should hold objects in various positions to prevent unwanted releases and accidents. In Figure 45, three positions of the cup are presented during regular use. In position one the cup is lifted off the table and should be stable in the hand palm, the cup may not cause too much pressure on the hand. The second position, explains that cup must not rotate clockwise or counter-clockwise in hand. Position three explains the cup must not rotate in this direction as well.

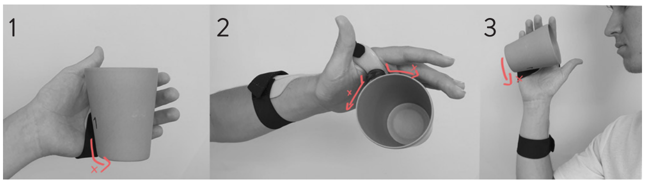


Figure 45: Various positions to hold the object.

Connections

After doing some exploratory research on types of connections, it is concluded that the connection between the object and the assistive aid will be made via a mechanical and a magnetic connection. In Appendix H, the results of the brainstorm and the practical test can be found, which leads to this conclusion. The main reason to choose these connections is that the mechanical connection can hold much strength in various positions. Secondly, the magnetic connection makes connecting much more straightforward and almost automatic. However, releasing this magnetic connection is challenging, and a redesign on the magnet and connector follows, which is explained in the next subchapter 9.4 Dynamic connection.

9.4 Dynamic connection

Fidlock fasteners

Inspiration for magnets performing the desired behaviour is found at Fidlock. This company makes fasteners based on a unique technology, combining the advantages of magnetic fasteners and mechanical connections which results in a new dimension in terms of functionality and safety ('Fidlock - Fidlock', n.d.). Their products are found in helmets, bags and child seats (see Figure 46, Fidlock, n.d.). Sample magnets are ordered from which several prototypes are made to research which adjustments should be made to achieve the desired behaviour for the dynamic connection between the magnet and the connector. The sample magnets and the prototypes steps are explained in Appendix H.

Figure 46: Fidlock fasteners (Fidlock, n.d.-a).

Adjustments

A snap-fit magnet is chosen to be most successful for the desired function, because it is small and connects automatically. A detailed and an exploded view of this magnetic connection with housing can be found in Figure 487 and 48. The male part will be integrated in the orthosis and the female part will be integrated in the connector. After doing the prototype tests, it is concluded that the connection between the magnets is made quickly and almost automatically, which is highly desired. However, sliding the male part out of the female part in the x-direction (see red arrow) is challenging. It results in an uncontrolled movement which is, in most cases too clumsy for usage by one with paralysed hand muscles. A gentle pronation movement around the y-axis (red arrow) is more desired, which results in the following adjustments made in priorly in the clamping ring. The movements are visualised larger in Figure 49. A detailed overview of the connecting and releasing movement can be found in Appendix H, interface movements.

Figure 47: Snap fit male (top) snap fit female (bottom) by Fidlock (n.d.-b).

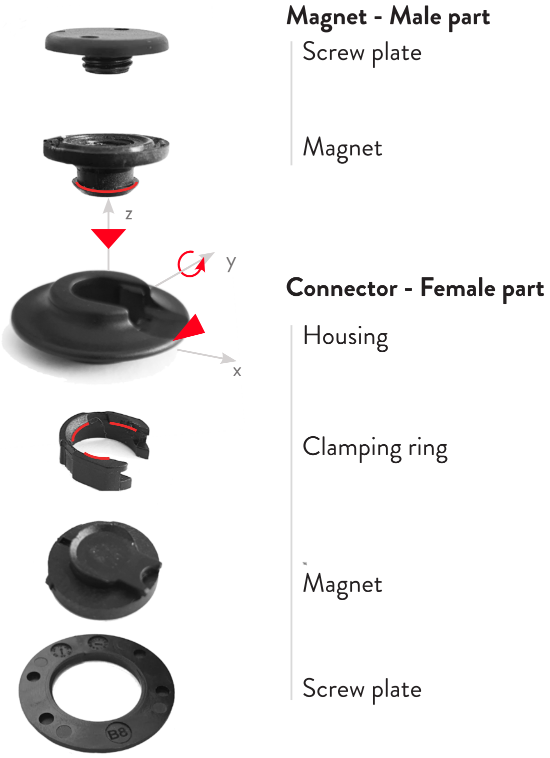


Figure 48: Snap fit, exploded view.

Figure 49: Desired movement.

Clamping ring

The clamping ring is an essential part of the connector. This clamping ring prevents the male part from moving out in the z-direction, as can be seen in Figure 48. The edges of the clamping ring cover a large part of the edge of the male snap pin which acts as the mechanical lock. To allow release via a pronation movement, the edges of the clamping ring must change in position and length. A trial and error method consisting of build, test, review and learn is used to find the optimal location and distances of the new edges. The chronological steps of this research can be found in Appendix H. The redesigned ring can be seen in Figure 50.

Prevention of rotation

Because the snap-fit magnets from Fidlock are cylindrical, rotation around the z-axis is possible. It is not desired that a utensil can move or rotate in hand, as is explained in the desired behaviour in chapter 9.3. Because the utensil should be fixed in this axial direction, a form lock consisting of an axially asymmetrical shape will solve this problem. For the prototype, this rotation problem is solved by folding the thermoplastic material around the male part, causing the shape to become axial asymmetrical, see Figure 51.

Figure 51: Solution to the axial asymmetrical male part.

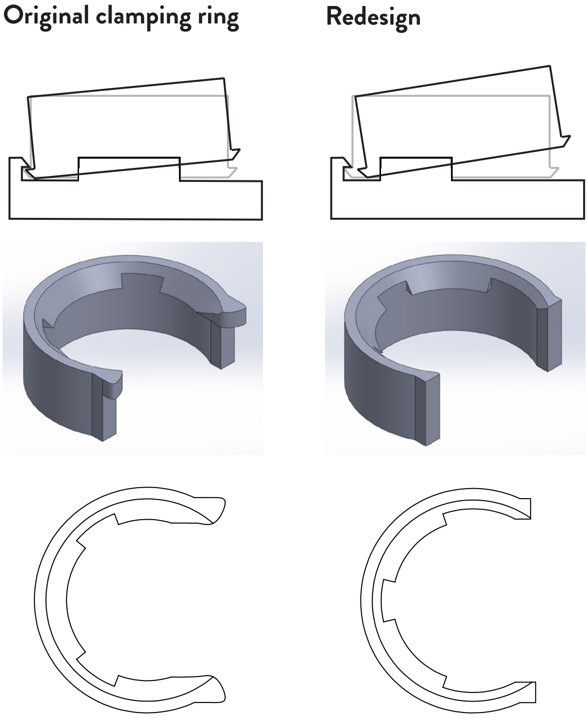


Figure 50: Redesign of the clamping ring.

9.5 Interface position

Connection rules

To connect the orthosis to the object, both magnets must be concentrically aligned, which is visualised by the dotted red line in Figure 52. The male part is statically fixed into the orthosis and can not change in direction. The female part is integrated into the connector and should be positioned in the right position. The housing of the female part is adjusted, so it connects to the specific surface of the object and is concentrically aligned with the male part. Because different angles between the object and the orthosis are present, an explanation of both determined angles for cup and spoon is given below.

In general, it is desired to keep the object close to the hand, causing the housing to be small and to limit the excess housing material of the connector, shaded in pink (see Figure 53). Protoplastic is used to act as replacement housing and is formed in the right shape to position the magnet in the desired place and angle. The protoplastic is permanently attached with adhesion to the cup for the prototype.

Connection to cup

The following iterations steps are taken to determine the desired place and angle between cup and orthosis.

- Firstly, the cup is placed in an optimal position in hand.
- Secondly, the female part is connected to the male part in the orthosis, and the angle is determined.
- This angle is translated into a specific housing, which connects the magnet to the surface of the object seamlessly.

Different cups require different angle plates because the slope or radius of the cup varies.

User test results

The orthosis connects to the cup with ease. The release is done via a pronation movement which executable and reliable. Holding the cup in the desired various positions without water is fine. However, a cup filled with water results in losing the connection too quickly, and in falling of the cup. This is caused by two things, the reduced length of the edges, which functions as a mechanical lock and the axially asymmetrical piece. Therefore it is decided to test during the validation test with a second cup as well with smaller adjustments to the clamping ring. These specific adjustments can be found in Appendix H.

Aligned with magnet but not with surface.

Figure 52: Desired hand position during use of cup.

Aligned with magnet and with surface.

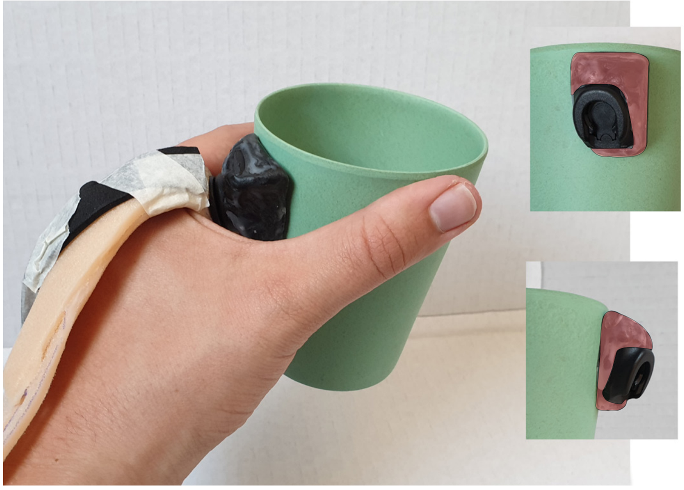


Figure 53: Hand position during use of cup.

Connection to cutlery

A different housing than the cup housing is desired to connect a spoon to the orthosis. In Figure 54, the position and the angle between the spoon and the orthosis can be found. Concluding from a user test, it is desired to make this angle 50°. The test consists of performing a scooping movement and serving food into the mouth. The user can choose the location of the connector on to the utensil. Using a fork and knife will result in a different angle between the utensil and the orthosis.

For the prototype, the attachment of the connector to the utensil is made via a cable tie, this would work as well when this would be developed into a real product.

User test results

The user test showed impressive results because it was straightforward to connect and to release the spoon. The utensil connection is reliable because the spoon did perform undesired behaviour once.

Conclusions

The magnets received from Fidlock must be adjusted to achieve the desired behaviour. All parts must be redesigned in the way as is explained. The production of the pieces can be similar to the current parts since the changes are small but crucial.

- The male part of the magnet should be changed into a shape which is axial asymmetrical.
- Secondly, the edges of the clamping ring should change in position and length.
- The housing of the female magnet should be kept to a minimum.
- The housing of the connector for frequently used utensils must be designed.

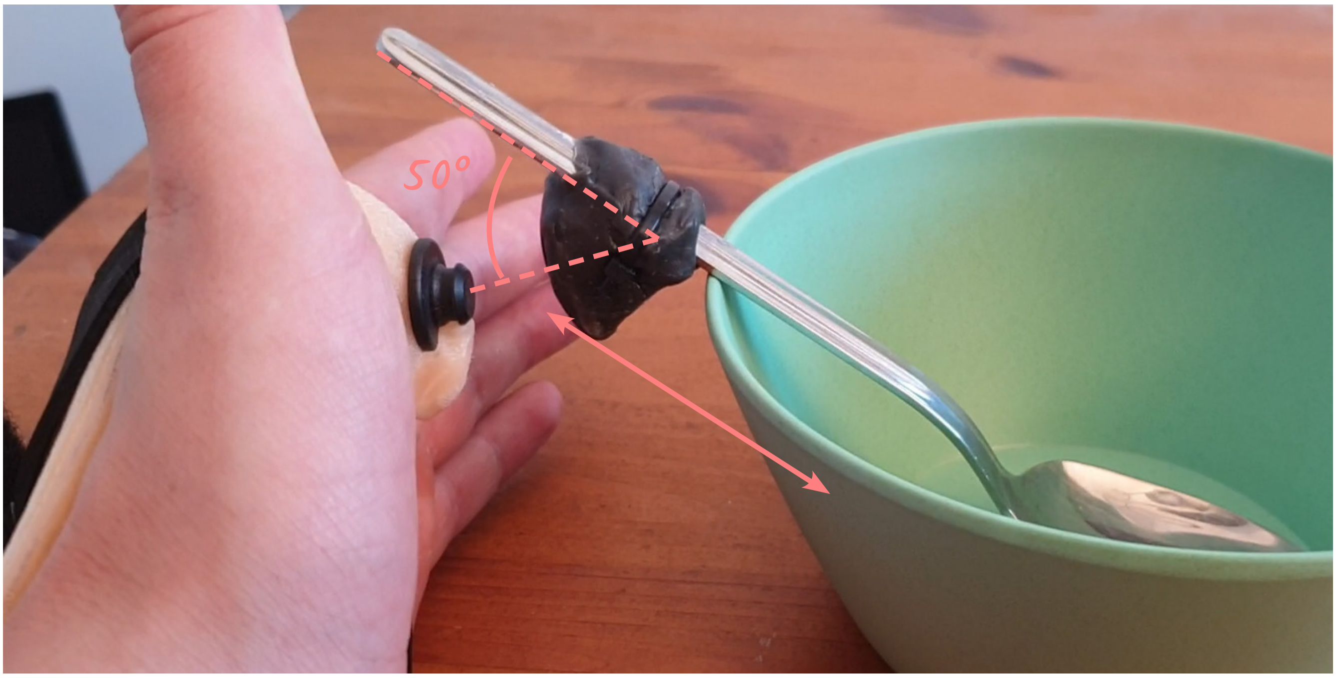


Figure 54: Hand position during use of cutlery.

9.6 Integration and tailoring

This subchapter explains how the components are integrated into the precut of the orthosis. Secondly, it describes the steps to tailor the orthosis to the hand of the patient.

Orthosis precut

The first step explains how the magnet is integrated into the precut shape of the orthosis. This step takes place before the orthosis is at the occupational therapist's place. The orthosis consists of two sheets of thermoplastic material. The pattern of the material and the location of the hole are predefined and cut out of the thermoplastic material in advance. The screw plate of the male magnet is clamped in between the two sheets and protrudes through the hole of sheet 1, see Figure 55. The two sheets stick firmly together when the thin comfort foam is scratched off before immersing the sheets in hot water. The other part of the magnet is screwed on the screw plate, while the material is still warm and flexible, which results in a tight fixation. The orthosis precut is now finished, see Figure 56.

Tailoring

The second step consists of forming the orthosis to the hand of the patient. The precut shape of step one is immersed in hot water again (see Figure 57) until the material is flexible, approximately two minutes. The orthosis is taken out of the hot water and dried, to remove painful hot water. If the orthosis is dry, the shape is folded around the hand of the patient, see Figure 58. During this procedure, the magnet must be at the right location and the right angle. The orthosis should cool to stiffen, which can be accelerated by sprinkling cold water over the orthosis. All edges must be rounded by locally heating the material.

Figure 57: Precut orthosis immersed in hot water for two minutes.

When a medical specialist confirms the shape and the position of the wrist, the neoprene bands are attached. The bands have pads of Velcro sewed on, and are adhered to the orthopaedic thermoplastic material by locally heating both materials with a heat gun or hairdryer. This is a regular procedure for attaching bands to an orthosis (Schwartz, 2020). A Velcro closure is secure enough and connects the bands around the orthosis. The result of the above steps can be seen in figure Figure 59.

Figure 55: Magnet integration.

Figure 56: The orthosis precut. Consisting of sheet one and sheet two.

Figure 58: Precut orthosis folded around the hand.

Figure 59: Band are attached to the precut orthosis.

9.7 Prototype overview

This chapter serves to provide an overview of the prototype. The prototype consist of the following five pieces:

- A **tailor-made hand orthosis**.
- **Cup one**, which connects and releases via an rotation movement.
- **Cup two** which connects in the same way as cup one, but releases by sliding out of the lock.
- A **Spoon** with a similar connector as is used in cup one.
- A **bowl** without any adjustments.
- Remaining tableware (fork and knife) represent a showcase.

The next page contains pictures of the hand orthosis worn by an ALS patient. Foces is put to the position of the objects in hand.

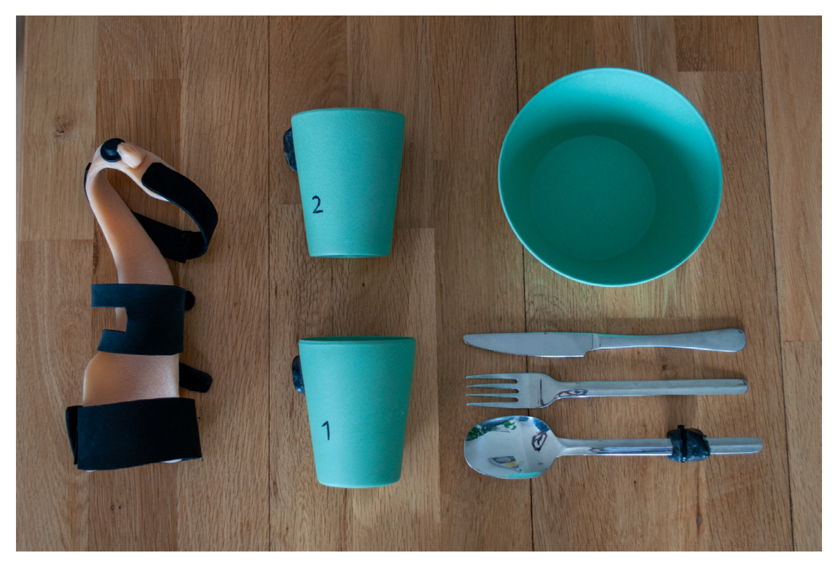


Figure 60: Representation of breakfast, served using the attributes of the tailor-made hand orthosis.


Connected to cup one

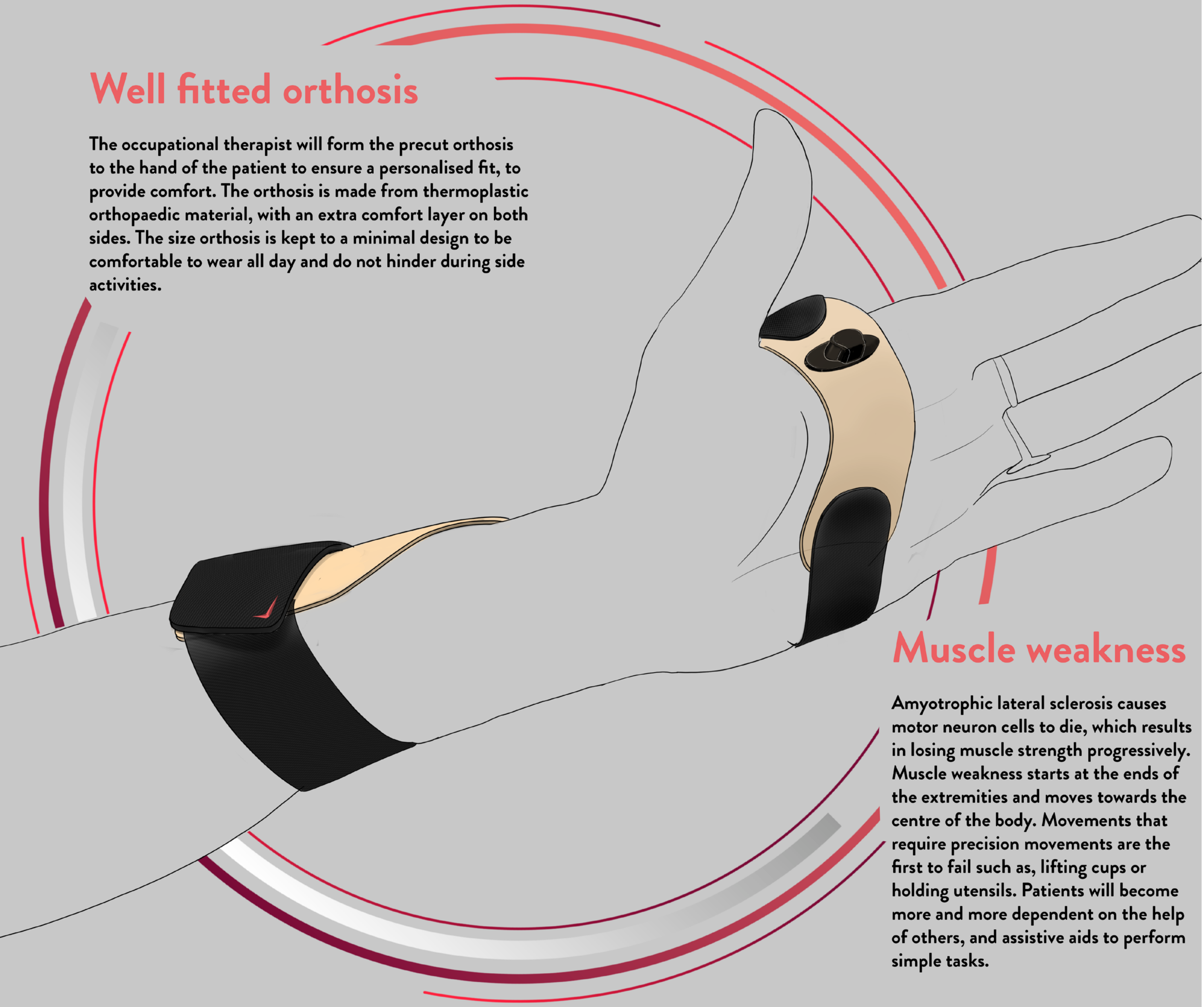
Connected to cup two

Connected to spoon

Figure 61: Prototype overview.

Well fitted orthosis

The occupational therapist will form the precut orthosis to the hand of the patient to ensure a personalised fit, to provide comfort. The orthosis is made from thermoplastic orthopaedic material, with an extra comfort layer on both sides. The size orthosis is kept to a minimal design to be comfortable to wear all day and do not hinder during side activities.

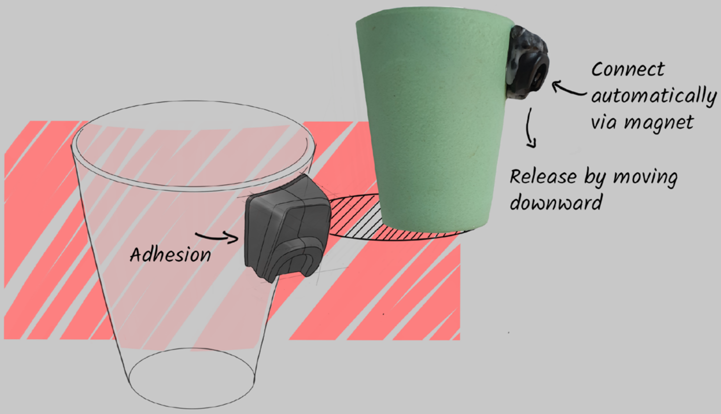


Muscle weakness

Amyotrophic lateral sclerosis causes motor neuron cells to die, which results in losing muscle strength progressively. Muscle weakness starts at the ends of the extremities and moves towards the centre of the body. Movements that require precision movements are the first to fail such as, lifting cups or holding utensils. Patients will become more and more dependent on the help of others, and assistive aids to perform simple tasks.

A magnet connection integrated into tableware

A strong magnet, in combination with a mechanical fit, establishes the connection safely. These blocks are integrated into tableware like cutlery or cups. By using the orthosis, the patient can connect to these objects with low effort and without using the strength of their fingers.



A TAILOR-MADE HAND ORTHOSIS FOR PATIENTS WITH ALS TO SUPPORT EATING AND DRINKING. INDEPENDENTLY.

"Using this hand orthosis contributes to my level of independence and to maintain my privacy because I can perform activities by myself."

10 User scenario hand orthosis

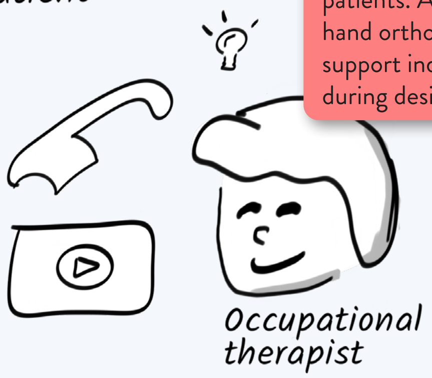
Chapter "5. Providing care" explains that patients often experience difficulties when receiving care or assistive aids. A future user scenario has been designed to prevent these unpleasant situations. This user scenario consists of the following eight essential steps.

1

Request
I have ALS and will soon encounter many difficulties in my daily tasks. I want to stay independent and be prepared in advance, especially during dining activities. I find information online about assistive aids which seems suitable for supporting me. Platforms like 'thuis-als-thuis' or 'ALS Centrum Nederland' provide valuable information.

2

Provide care
As an occupational therapist, I try to provide the right care and assistive aids to encourage independence for ALS patients. A tailor-made hand orthosis could support independence during desired moments.

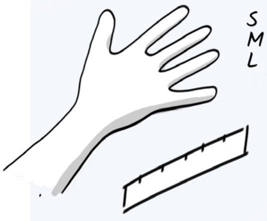


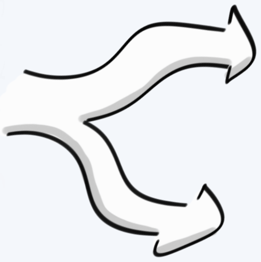
3

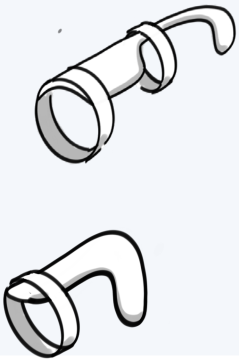
Determine size
The occupational therapist has a try-out version of the assistive aids in the clinic, ready to be tested by the patient, instantly. The therapist and the patient decide together if an additional short (without wrist) orthosis is constructed in addition to the extended (with integrated wrist) orthosis. Some measurements need to be taken in advance to determine which size is best for the patient.

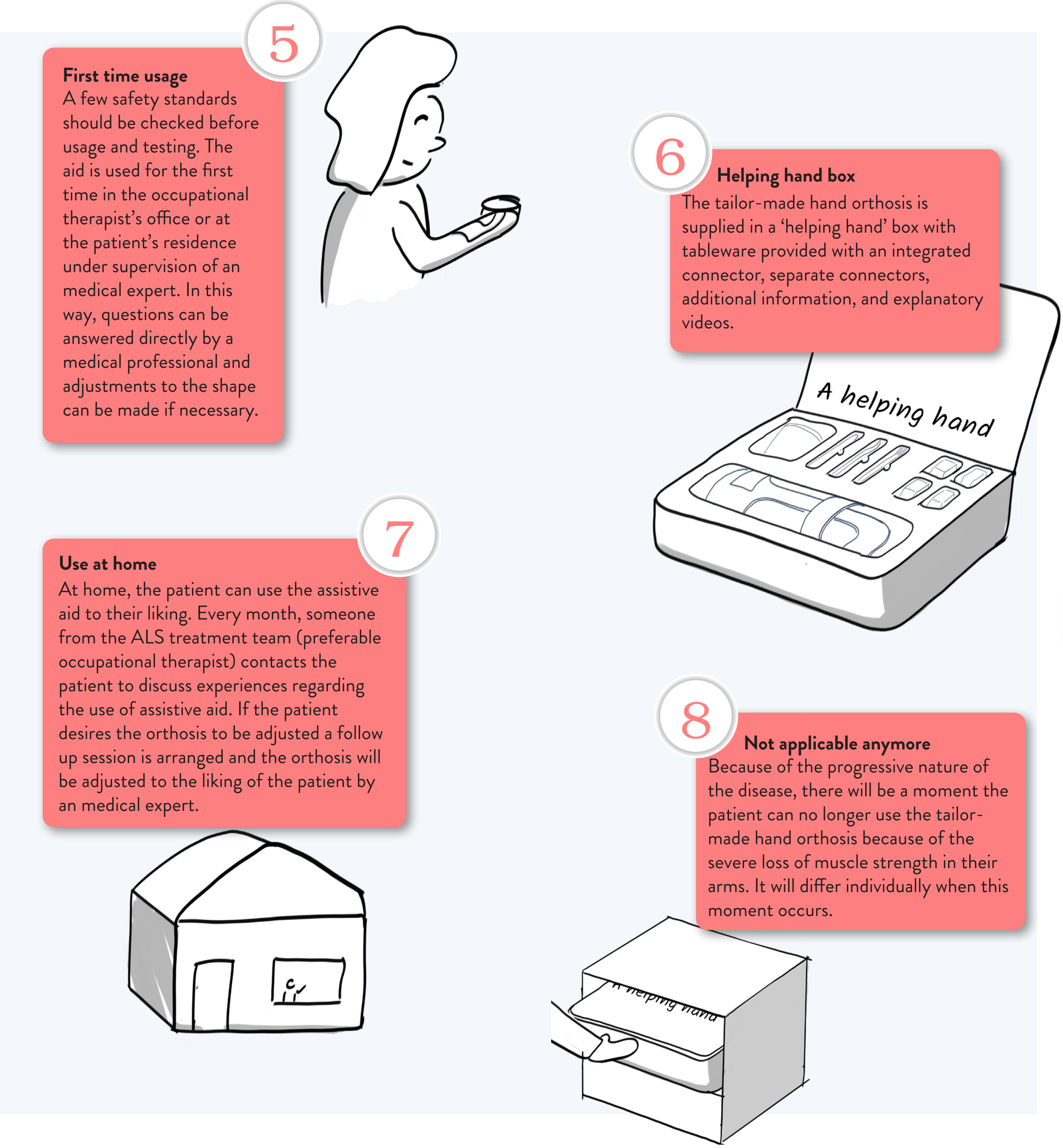
4

Fit on
The precut thermoplastic orthosis is immersed in hot water, dried and placed on the arm of the patient. Let the orthosis cool and stiffen. Attach the bands to the orthosis.









5

First time usage
A few safety standards should be checked before usage and testing. The aid is used for the first time in the occupational therapist's office or at the patient's residence under supervision of an medical expert. In this way, questions can be answered directly by a medical professional and adjustments to the shape can be made if necessary.

6

Helping hand box
The tailor-made hand orthosis is supplied in a 'helping hand' box with tableware provided with an integrated connector, separate connectors, additional information, and explanatory videos.

7

Use at home
At home, the patient can use the assistive aid to their liking. Every month, someone from the ALS treatment team (preferable occupational therapist) contacts the patient to discuss experiences regarding the use of assistive aid. If the patient desires the orthosis to be adjusted a follow up session is arranged and the orthosis will be adjusted to the liking of the patient by an medical expert.

8

Not applicable anymore
Because of the progressive nature of the disease, there will be a moment the patient can no longer use the tailor-made hand orthosis because of the severe loss of muscle strength in their arms. It will differ individually when this moment occurs.

Figure 62: Overview of providing aid.

Key Takeaways

A summary of the choices made in the chapter 'develop and deliver' is given below. The design of the tailor-made hand orthosis is finalised, and a functional prototype is built. This prototype will be used for a user test to validate the design choices in the next part.

REFLECTING ON MAIN DRIVERS

- The usage of the orthosis is straightforward because of the designed interface, in which the connection is made automatically. Releasing objects is done via an uncomplicated movement which ALS patients can execute.
- The design is less minimalistic than expected. A user test will determine if patients will agree with this.
- Since the orthosis supports grasp to objects without requiring finger strength, it will benefit the majority of ALS patients.
- The user test will define if the orthosis is small enough not to hinder during side activities, just as it will be tested whether some level of control is maintained for the patients.
- The shape causes the orthosis to be easily donned and doffed. However, connecting the bands might be more challenging for patients.

COMFORT

The following factors contribute to achieving comfort in the orthosis:

- The orthosis seamlessly follows the shape of the patient's hand because it is tailored around the hand directly.
- The open structure of the orthosis results in a lightweight orthosis and less skin contact, causing less irritation.
- The orthosis becomes extra comfortable because soft foam on the top layers is present, which is pleasant to the skin of the patient.
- The shape divides the load of the objects over the hand palm region. This region tolerates applied load well because of the thicker skin and habitation of pressure at this area.

PROVIDING PROCEDURE

Most essential aspects regarding the procedure of providing the hand orthosis to the patients are:

- The patient can either get the orthosis because it is part of the treatment for ALS or buy the orthosis themselves from a medical point.
- A medical specialist should tailor the (extended) orthosis to the hand dimensions of the patient in order to achieve an optimised fit. During this moment, it is decided if the patient would like to use a short orthosis as well. If so, the orthosis will be made additionally.
- A medical professional should guide a patient during the first time usage of the assistive aid. This session can take place at the revalidation clinic or the residence of the patient.
- The product is delivered in a 'helping hand' box. This box contains the tailored orthosis, a set of cups, cutlery and some extra connectors which can be connected to various objects.
- After the orthosis is provided to the patient, contact should be remained to evaluate the hand orthosis. If the patient desires an adjustment to the orthosis, a tailor session can easily be redone.

PARTS & PRODUCTION

Precuts

The Precut is produced according to the pattern for different hand sizes based on typical orthosis measurements. Adjustments regarding the pattern, to the liking of patients or medical professionals, are allowed to be made on site.

Bands

The bands used for fixating the orthosis to the hand should be standardised, according to the design conditions, which guarantees a good fit. Velcro connections are sewed into the bands and heated to adhere to the orthosis.

Objects

The integration of the connector to the object is not designed yet. For the cause of the prototype, standard objects are used, and the connectors adhere to the cups, and a cable tie attaches the connector to cutlery. These parts should be optimised to be safe for daily usage and frequent cleaning.

Magnet and connector

Because both magnets (male and female) need to be adjusted to achieve the desired behaviour, it is advised to design an optimal dynamic connection together with a specialist party like Fidlock, a producer of various magnetic and mechanical fasteners. The most crucial elements of the design are;

- Create an axial asymmetrical male magnet which fit with the female magnet in one way.
- Adjust the housing of the female magnet to align concentrically with the male magnet and fit the surface of the object seamlessly.
- Adjust the edges of the clamping ring to allow release via pronation movement and remain a stable connection to the objects in various positions.

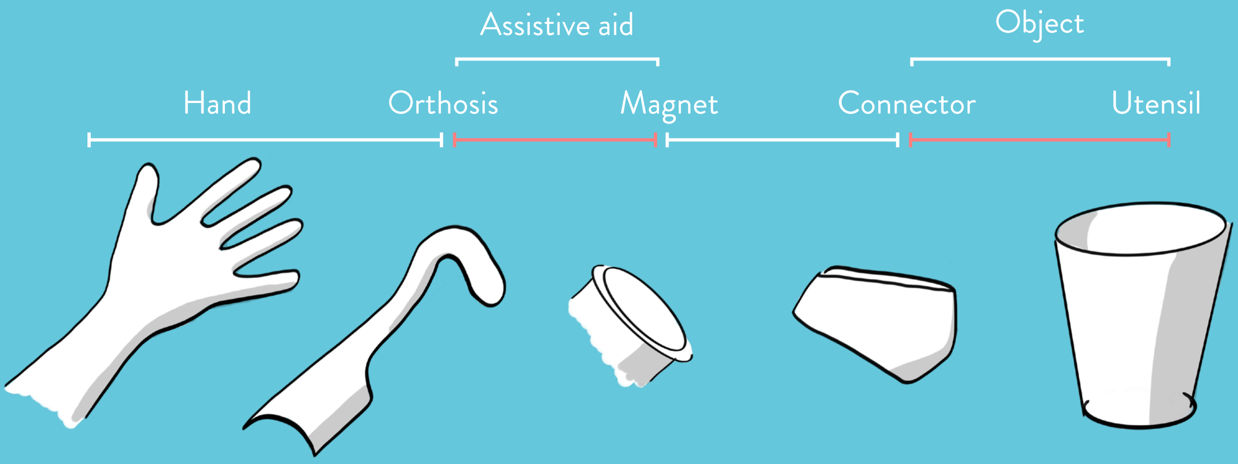


Figure 61: Interface connection.

5

Figure 64: Footage of the user test with ALS patient.

Evaluation

This is the final part of the report, which consists of a validation test, a last consult with the a medical expert, the overall conclusions and the recommendations.

In this part

11 Design validation

A validation test with one of the participants is done to evaluate the design of this assistive aid. The aid is tested on the level of comfort, the ease of use and if independence is experienced. The test consists of a few assignments and an interview. The participant has mild paralysis complains in her non-dominant hand. The test is conducted at a distance to keep the risk of contamination of Covid-19 as low as possible. All test supplies are sent to the participant in advance. Through a video connection and film assistance of an informal caregiver, all activities could be attended and recorded.

Research question

Does this assistive aid give patients with mild to server loss of finger and hand function more independence during dining activities?

Hypothesis

- **This assistive aid increases independence to patients during dining activities because patients can switch utensils themselves.**
- **The assistive aid provides more independence because it is easier or more comfortable for the patient to eat with the orthosis than eating with adjusted cutlery.**

Method

It is decided to tailor the orthosis in advance because it will complicate the procedure a lot if the patient or an informal caregiver with no experience has to do this themselves. However, tailoring the orthosis is a essential aspect for increasing comfort. This issue is addressed by tailoring the orthosis to a hand model with similar hand dimensions (deviation of 3 mm) as the patient.
The patient received the box of all test supplies in advance (Figure 65), and the setup of the test is visualised in Figure 66. The test setup consisted out of three parts, a safety and comfort check and predefined assignments combined with a structured interview. All the assignments are executed by the non-dominant hand wearing the orthosis. The assignment consists of consuming a typical breakfast for the patient. The complete test protocol, including questions, can be found in Appendix I.

Part one consists out of the following safety checks, perform some essential extension, flexion movements, and evaluates the level of comfort perceived while wearing the orthosis. As of last donning and doffing is discussed in this part as well.

The second part consists out of performing side activities involving a laptop, driving an mobility scooter or taking a nap. The goal of this part is to find out if the orthosis is interfering with other activities.

Part three consist out of testing the assistive aid in a typical user scenario; consuming breakfast. The goal is to find out if the orthosis is simple in usage, if connecting to objects is established with low effort, and if objects are released with ease.

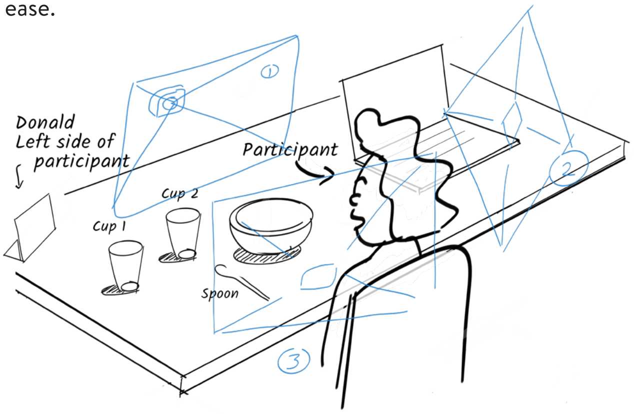


Figure 66: Test setting at patient's residence.

Figure 65: Test supplies.

Results from part one

Donning the orthosis is **simple** and can be done by the patient. The patient places the orthosis on her left arm and fastens first the forearm band than the hand palm band end as last the wrist band. Explaining the usage of the orthosis and the donning procedure to others is straightforward; it is clear at once for the patient and the informal caregiver.
The orthosis **fits quite well** even though it is made at a distance. The shape follows the contours of the hand palm closely, and sharp edges are not present in the orthosis. There was no need to apply extra foam for comfort.
The extension of the wrist could be a bit less, according to the patient. Overall, much freedom was perceived by the patient because the orthosis did not hinder during the basic movements.
Two points of slight **irritation** are perceived because the orthosis applies too much pressure on the head of the ulna bone (circle), and the orthosis presses on the wrist (rectangle), both circled in red in Figure 67.
Two of the three bands have the right length; the band around the hand palm was a bit too long according to the patient. The Velcro connections were excellent for fastening and releasing the orthosis.

Figure 67: Points of attention

Results from part two

The orthosis did **not hinder** during side activities because the participant can continue to work on a laptop, drive her mobility scooter, and pull on a jacket. The participant is quickly accustomed to wearing the orthosis; it fits well and is comfortable. The participant can wear the orthosis throughout the day without experiencing irritations.

"I am wearing the orthosis for one hour already and do not experience irritations or hinder during side activities"

Figure 69: Points of attention

"Because my righthand functions well, I can don the orthosis myself."

Figure 68: Donning the aid.

Figure 70: Participant driving her mobility scooter with the orthosis.

Results of part three

The usage of the assistive aid is clear at once after seeing the instruction video. The participant connects effortlessly to the objects, **'I place my hand beside the cup, and it takes it at once, it just fits well'.** The movement to connect to the objects is described as a scoop movement or fish-hook idea and is well understood. The thumb or fingers do not contribute to grasping the cup or the spoon, as can be seen in Figure 71.

Release cups

Releasing cup one is **done easily** because this can be done via a rotation movement. Releasing cup two from its lock **takes more effort**. This is because the participant should slide out of the lock instead. Sliding out of the cup is currently hindered because the connector is placed too low on the cup. Resulting in too little space between the table and the cup to slide out, see figure Figure 72a. Besides, the thumb is required to accomplish this action, which is unwanted. Increase the height by placing the cup on a platter makes it easier to slide out of the lock with less thumb support, see image Figure 72b. The position of the cup in hand is perceived as pleasant.

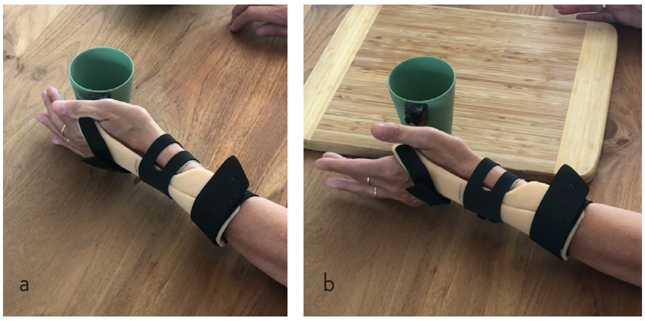


Figure 72: Releasing from cup two on the table and on the platter.

Figure 71: Consuming breakfast without using the strength of their fingers.

Usage of spoon

The participant cannot connect with the spoon when it is on the table because the magnet is pointed downwards. This results in stumbling actions causing frustration. If the spoon is placed in the bowl in advance, there is enough space to place the hand in the right position. Then it is **straightforward and natural to connect** and release the object.

Position

Since the orthosis fixates the wrist statically, all activities are done with a static wrist. This made serving food to the mouth with a spoon different. The participant mentioned **'you have to get used to it, but it is fine. It is easier than holding thicker cutlery.'** The participant did lean forward much to consume food or fluid intake. This is seen more often for patients with weakness in the arms. The patient did not mention this as being bothersome.

Conclusion

The patient concludes that using the assistive aid increases her level of independence. If weakness occurs in her dominant hand, she is sure that this assistive aid will support her. The main reason for using this aid is that she can eat alone with more ease, without the help of her informal caregiver or home care. In this way, she remains to keep her privacy and self-esteem.

The movements for connecting and releasing the objects were clear at once, and dexterity is quickly developed during the validation test by repeating the movements.

The ease of grasping objects is achieved because connecting to objects happens automatically and do not take extra effort. This aid has more support than the thickened cutlery because the grasp is more secure and more reliable. **'The assistive aid makes a firm connection instead of having to focus on the grasp myself. Therefore, I have more trust in this orthosis than in my own hand.'**

After wearing the orthosis for two hours during the test, it is still quite comfortable. After wearing the orthosis for the entire day, it became a bit uncomfortable because the bands were too warm, and perspiration under the orthosis occurred.

Discussion

The test represents a real-life scenario by consuming a usual breakfast. However, for the test, it is desired to do all tasks with the paralysed (non-dominant) hand, which is a bit uncomfortable in the beginning. Nevertheless, the tasks are better performed with an orthosis than without one. As long as her dominant hand functions well, the participant will not need the orthosis for her non-dominant hand. However, the **value of this product is proven**. The patient desires to use the orthosis as soon as her right-hand start to weaken.

The sore point (just behind the wrist) experienced with fitting, can probably be resolved by tailoring the orthosis to the hand of the participant directly. This is something which should be tested when the participant and the researcher can see each other face to face.

The participant perceived the dorsal extension of the wrist as too much. This could depend on the preference of the patient or the mobility of the wrist and muscles. A medical expert should indicate if changes in this position can be adjusted to the liking of the patient.

Figure 73: A happy participant after completing all tests.

11.2 Expert review

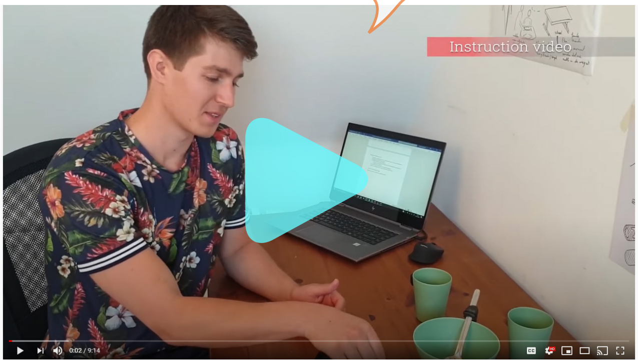
K. Melssen is once again consulted to share her thoughts about the design of the orthosis. She has been involved in the project from the beginning. The results of the user test and the instruction video are combined into one evaluation video sent to her and others. The video can be found via the following link, see Figure 74. The results from the validation with K. Melssen are summarised below.

Improving the quality of life

K. Melssen is very enthusiastic and says, **‘it is beautiful that it works in this simple way’**. It is immediately apparent that this orthosis is beneficial and functional for usage in daily life for ALS patients. Being supported during drinking or eating are essential values which **contribute to the quality of life**. It means the world to patients if this device can replace drinking through a straw, or remain independent longer.

A tailored orthosis improves comfort

Choosing a cock-up splint on the dorsal side of the arm is convenient because much tactile feedback remains. Secondly, the shape is easy to don or doff, straightforward to fabricate and ben around the hand of the patient. **Creating a tailor-made orthosis from a thermoplastic material is highly valued because much more freedom, and thereby, comfort is achieved than wearing standardised orthotics.** By tailoring the orthosis directly to the patient, the occupational therapist can include personal wishes, such as the amount of extension of the wrist. This is very valuable and takes little effort to adjust this. Besides, if muscle weakness decreases of or wishes change over time, adjustments in the shape of the orthosis can be made repeatedly. Nowadays this role is now often fulfilled by orthopaedic instrument makers, specialised in orthoses, in collaboration with occupational therapists.



Click the image to see the video.

Figure 74: Evaluation video.

Iterations

The functionality of the orthosis is proven; however, much iterations should be done before this product is ready for market launch. These iterations focus mainly on the integration of various utensils and the bands, and all recommendations can be found in chapter thirteen.

Risks

The most significant risk is that if pronation and supination of the forearm become impossible. From this moment, the hand orthosis will become less suitable for ALS patients. The other risk is that the hand of the ALS patients is cramped and in the way of the orthosis, disabling the beneficial function.

Conclusion

Overall K. Melssen praises the design and thinks a much broader target group, like children with upper limb reduction defect (when an upper limb of a fetus fails to form ultimately during pregnancy), or anyone with limited hand function, **would benefit from this assistive aid, which makes the development more valued.**

12. Conclusion

This report presents the concept of a **tailor-made hand orthosis, which supports independence for ALS patients during dining moments in an early stage of the disease**. Patients primarily prefer to complete dining activities independently because of alleviating their informal caregivers and avoiding home care during these valued times, which results from patient interviews. Referring to the design vision and the design goal, it is stated that the assistive aid should give patients more independence during dining activities, by assisting them to hold and use objects like cutlery or cups. Secondly, the assistive aid should respond to muscle weakness starting in the fingers and progressing to the wrist. This is formed into a design goal '**Create a comfortable hand orthosis which holds on to frequently used objects without using the strength of the fingers and thumb**'. The following factors determine the appreciation of this concept.

Tailor-made

This hand orthosis is designed for patients with ALS upper limb onset; it addresses improved functionality for patients who lost strength in their fingers and wrist. Besides being beneficial for ALS patients, this orthosis is beneficial to any patient with limited hand function. The orthosis is **comfortable** and **fits perfectly** since it is tailored to the patients directly, closely following the specific hand contours. Secondly, the orthosis is made from a flexible material, which gives the tailor much freedom to follow the wishes of the patient. This results in even more comfort and is highly valued. Furthermore, the modular design of the orthosis meets the wishes of the patient to wear the short orthosis first when wrist strength is still present. As of last, it is essential to remember that the progression can significantly differ per patient. A medical specialist should always consider if this assistive aid will be beneficial to this specific patient.

Straightforward usage

This concept is evaluated by an ALS patient having mild hand paralysis. The patient tests the orthosis in a familiar scenario, namely consuming breakfast, which is part of everyday dining activity. This test shows that the orthosis connects well with frequently used objects and is **straightforward** and **simple to operate**. The patient connects without using the strength of their fingers or wrist, causing the patient to perform dining activities with more ease and independence.

Increase the quality of life

The patient who tests the orthosis mentions her level of independence increases because she can eat alone with more ease, without the help of her informal caregiver or home care. This increases her level of **privacy** and **self-esteem** which adds to **the quality of life**. Occupational therapist K. Melssen agrees that this assistive aid could increase the quality of life for ALS patients after seeing the evaluation video. This is the first step to include this tailor-made hand orthosis in the treatment of ALS patients. To continue this advice should be shared with third parties developing the quality criteria of care for ALS patients.

Duration of usage

Since ALS is progressive, there will be a time the patient can no longer use the assistive aid because of muscle deterioration. The usage duration is **strongly dependent on** the ability to perform **pronation** and **supination** movements. If these movements can no longer be made, the assistive aid becomes too challenging to use. Medical experts agree that it is impossible to predict (in weeks/months) for patients how long they can use the assistive aid.

Appearance

Not much attention is paid to develop the appearance of the orthosis to the liking of the patients yet. Most appearance features result from the fact that this improved the level of comfort and functionality. Besides, patients find functionality more important than the appearance of an assistive aid. However, when this assistive aid is further developed, iterations on **appearance should be included**.

Integration of the exoskeleton

The design briefly mentions that an iteration on the exoskeleton of Yumen Bionics will be developed. Early in the process, it is concluded that an improvement of the exoskeleton would not improve the quality of life for ALS patients if hand support is left out. Understanding the disease characteristics, distal muscle weakness to proximal, led me to design the other way around. **Designing supportive hand function first, followed by moving towards the exoskeleton**. This results in an orthosis which is not an actual extension of the exoskeleton but can be worn simultaneously. A user test with both devices must be conducted to give insights in the simultaneous usability of both devices.

Future steps

The orthosis design is validated with one patient and one medical expert, who are positive about the design. A product like this is new to the market, making it **attractive to use this concept as a basis for further development**. However, before this concept can be turned into a real product, ready for safe usage by ALS patients, many iterations combined with user tests should follow. The first step would consist of improving the current interface (connector) of both cups and design interfaces to include utensils like a fork, knife, and cup with nose clearance (so patients can drink without tilting their head). The second step will include a cost estimation of the production regarding all the pieces and the integration of tableware. All summarised recommendations can be found in the next chapter. Since ALS is such a sporadic disease, only 200 to 400 Dutch patients could potentially make use of this assistive aid, annually. Broadening the target group by including patients having limited hand function, will benefit more patients and increases the number of products significantly.

13. Recommendations

Project

- Having a **user-centred design** approach adds much value to the project and results in a design that meets the wishes of the patients better. I would recommend involving patients and medical experts closely during the development of an assistive aid.
- **Personal adjustments** within the settings or the usage of an assistive aid are required to fit a patient better. Providing this freedom is especially crucial for ALS patients because their symptoms are case-specific. When adjustability is included in the assistive aid, more patients could use the assistive aid, and the duration of usage can be increased.
- I would advise **continuing this project** because it increases the quality of life for ALS patients, which is, in my opinion, priceless. However, an estimation of the development and production cost could have been made if more time was available. This will be especially valuable for third parties to evaluate the feasibility of this project.

Integration of the exoskeleton

- The integration of the orthosis to the exoskeleton consists of a few steps. First, realise that patients will **use the exoskeleton when extension and flexion of the forearm become challenging**. By this time, pronation and supination are probably impaired.
- If the patient can no longer perform these movements, it will be better to **attach the orthosis to the sleeve of the exoskeleton statically**. The sleeve already consists of solid parts to which the orthosis can be attached. The required pronation movements are limited by the sleeve but can be replaced by ad- and abduction movement of the upper arm (shoulder joint). A user test should indicate if the orthosis can be operated when it is worn with the exoskeleton simultaneously.
- When a patient is able to perform a supination and pronation movement, **the orthosis should remain free of the sleeve**. In this way, the patient remains control about pronation supination movements. Fitting both devices should indicate if the orthosis should be shortened to prevent contact with the sleeve. Shortening the orthosis will result in a worse load deviation. However, this seems unlikely but should be concluded case-specifically from a user test with both devices.

Specific recommendations

Usage

- **Cramped fingers** because of contractures will prevent connecting to objects, which is the biggest threat to being able to use the orthosis. One solution to prevent this could not be invented in advance because the situations will differ per patient. However, the free shape of the orthosis is an advantage. By changing the pattern, the orthosis can be extended and folded over the cramped fingers. Future tests should be done by patients with cramped fingers to see if this would work.
- The assistive aid is developed and tested for **left-handed** usage. **Right-handed** usage will require a mirrored pre-cut, and adjustments in the position of the connector. Further research on this interface aspect should be done.
- During the tests, it is not tested if the **short orthosis** is perceived to be as usable or as comfortable as the extended orthosis since this prototype is not made. However, the patient likes the idea of using the short orthosis when strength in the wrist is still present. The first iteration of this orthosis should be made to confirm these findings.

Connector

- The dynamic connection of the male part and the female part can be reduced in size. The prototype used standard samples, while newly designed connectors could result in **smaller connectors**, which are less visible to others.
- For now, it is still undefined how the connector is **attached to the cups or cutlery** in the best way. Durable adhesion stickers (used to mount GoPro's to surfboards) could be a solution. Features like safety, size, appearance, and dishwasher safe should be considered for future research.
- The objects can be placed **closer to the hand palm** because the test shows that the thumb is not included in grasping objects.
- The clamping ring in the connector on cup one is suitable for connecting and releasing, but lifting a filled cup results in **failure** of the connection too often because too much material from the edges is removed.
- The clamping ring in the connector on cup two should be optimised in a way that it is **easier to release** (sliding out of) the object because this current interface remains too challenging for ALS patients to execute. Placing the connector of cup two higher on the cup so that the hand has enough space to slide out of the connector improves releasing.

- The connector on cutlery should be **optimised to fit forks and knives**. The different orientations during use desire to make adjustments in the housing of the magnet.

Bands

- The appreciation of the device improves when patients can don and doff the orthosis themselves. Therefore, it is desired to **optimise the bands** so the patient can grasp the bands with limited finger strength. The ends of the bands should be free of Velcro and should have a loop, which is easier to hold on to with little strength.
- The patients desire to change the colour of the bands to the **colour of their skin** since they want to use an assistive aid which is less noticeable for themselves and others.

Orthosis design

- The orthosis **interferes with the head of the ulna bone**, which results in irritation. Making the orthosis smaller or creating a cut-out can avoid this spot and prevent the irritation.
- An **orthotics** (a medical clinician responsible for the prescription, manufacture and management of orthoses) should do a final evaluation on the shape of the orthosis.
- The orthosis is a bit **too warm** after wearing the orthosis for a day. Perforated materials allow for greater ventilation, and are more lightweight, and therefore more comfortable, but stiffness reduces. Explore with these thermoplastic splinting materials to find an optimum between stiffness, weight, heat reduction, and amount of ventilation.
- A suggestion for **different hand sizing** is made, user test with various ALS patients should indicate how critical different hand sizing is for the level of comfort.
- It may be **challenging** for ALS patients to keep their hand in an **optimum position during** tailoring and cooling the orthosis. A test should follow to determine if this is indeed challenging for ALS patients.

Object improvements

- An overall comprehensive '**helping hand**' box, including all supplies for the tailored hand orthosis, should be developed.
- The light cup used in the prototype does not **seem safe and stable** according to the occupational therapist. Several adjustments to improve the stability of the cup could be made. For example, increasing the surface of the bottom, applying an antislip edge or increasing the weight. All objects which are part of the tableware can be optimised for the development of a new set, specially designed for usage by ALS patients with a tailor-made hand orthosis.

Appearance

- Patients should appreciate the **feel and the look** of the orthosis. When this is accomplished, the patient will w**ear the aid more often** and with more joy, according to patients. Therefore, it would be wise to let patients select the colour. This increases the involvement and the level of self-determination. A start could be to design the orthosis in three colour variations.
- The orthosis could also be **matched to the clothing** of the patient instead of the colour of their skin. In this way, the orthosis can reach being less noticeable as well.

Personal reflection

For the last six months, I have been working on my master thesis with pleasure. This has been the most valuable experiences of my master. During the entire process, I learned a lot about myself as a designer, which I will address in this chapter and take along to my next adventure. By doing this project, I know that improving the lives of others through developing convenient design solutions, is my best motivation.

Process reflection

My process has been stable and smooth, the goals set in the beginning are all met by the final design. The steps I have taken followed each other logically because I used the double diamond design process. Selecting one of the support directions, as described in chapter eight, was the biggest hurdle in the project. It felt like not having enough information and time to elaborate on the steps, design choices extensively. Therefore, I learned to selectively make trade-offs regarding the most relevant information present at that time. Besides, taking the lead to consulting experts and patients contributed to making informed choices and being able to manage the project within the timeframe.

Personal contact

I valued personal contact with the stakeholders most. I prefer to reach out to people when I need answers, rather than searching the internet and find answers myself. Finding solutions by conducting an orientating survey, four patient interviews and iteration sessions, and five expert meetings resulted in unexpected and personal insights. I appreciated the contact with the patients greatly, they taught me so much about their life and how ALS affects their life, which was a pure eye-opening moment. Choosing this strategy contributed to my learning goal of applying a user-centred design approach, which I will include in my future design projects.

Challenges I faced

Designing for ALS was quite challenging and took some perseverance because of the problematic symptoms which come along. This resulted in being insecure about the value of a concept and the following questions arisen: 'Is this type of support valuable if it can only be used for 2 months?', 'What if the solution is too challenging for a patient to operate?'
It helped reduce the uncertainties by accepting that not all patient's problems could be solved. Heard from patients, that lifting a cup with more ease would already be an immense improvement in their daily life, taught me to see this from their perspective.

Create core competencies or design goals for every phase of the project, by filtering most relevant information is one of my learning goals as well. Using applied design methods like determine main drivers, wishes, requirements, and swot analysis helped me to make design choices in a structured way.
I know my writing skills are not the best but during this project, I paid attention to improving my writing skills as well. Throughout the report, I followed a structured approach which led me to first think in advance 'what do I want to explain. Secondly, why is it important to mention, and as of last, how can I present the information clearly?' This made reporting more structured, consistent and better to read.

Working at Yumen Bionics

Working at Yumen was great to experience what it is like to work in a small company in the health care branch. I felt very welcomed and appreciated by all my colleagues. Unfortunately, I had to work from home for half of the project, causing me not to increasing my experience of working within a company in the way I hoped for. Working from home made the collaboration less naturally. However, I kept actively involved by speaking with my supervisor once a week and joining the stand-up meetings from time to time.

Prototyping

A large part of my project consisted of prototyping orthoses. I was completely new to this topic and gained much knowledge by making iterations and getting feedback from medical experts. This contributed to my last learning goal of improving my mechanical prototyping skills.

As of last, I am proud of the design process I went through, and I am pleased with the end result. By using all my design skills and following a user-centred design approach, the problems ALS patients face daily are extensively analysed. This resulted in a solution which fits most of the ALS patients well and is positively evaluated by patients and medical professionals.

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**All other images are self made.*

A tailor-made hand orthosis for patients with ALS to support eating and drinking independently.

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