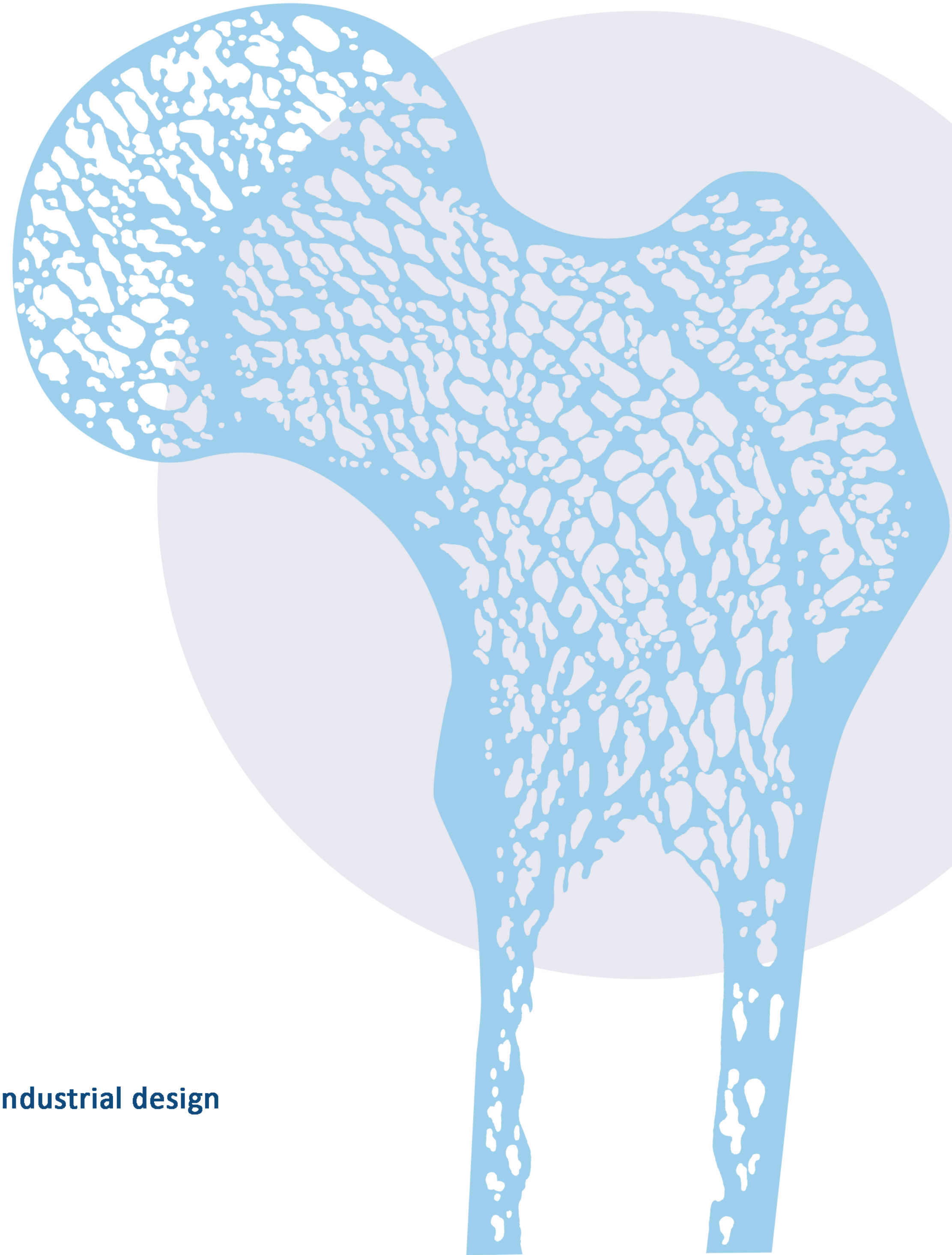
BAAT MEDICAL

Design of a wrist orthosis for chronic stroke patients



Bachelor assignment Industrial design
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Design of a wrist orthosis for chronic stroke patients

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December 30th 2014

Pages: 63

Appendices: A-L, 26 pages, in seperate report

This report is written within the context of the bachelor assignment for Industrial Design

Preface

This bachelor assignment is the result of three months work at BAAT Medical on a wrist orthosis for chronic stroke patients. This report is written within the context of the bachelor assignment Industrial design. It was a great experience to work at BAAT Medical and to learn about the difference between doing projects at the university and development in the business world, which is way more targeted to the quick development of a feasible product than during educational projects.

I would like to thank many persons who have supported and helped me during my bachelor assignment. Ryelle de Wit, for giving me new inspiration on moments I got stuck in the design process, for giving me insight in orthotics and for giving me feedback during the assignment and on my report. Also Edsko Hekman, who gave me feedback on my assignment every friday. Thanks to Ryelle en Edsko for improving my English writing on my first individually written English report. The employees from BAAT Medical, especially Harry Christenhusz, who told me many things about orthotics and the design process as it is done in the business world. One chronic stroke patient who I have asked for feedback during the concept detailing. Sharon Nijenhuis, PhD at the Roessingh Research Development center, for giving me insight in the SCRIPT Project and allowing me to see and speak with three chronic stroke patients. Milou Nijland, a physiotherapist at the Roessingh rehabilitation center, for giving me insight in the life of patients at the rehabilitation center and for allowing me to speak with and see eight stroke patients who are recovering in the rehabilitation center.

Enschede, December 2014

Emma van den Berg

Summary

Motive
Each year, around 2 million people in Europe suffer from a CVA (cerebrovascular accident) or also called a stroke (Kirchhofs et al., 2009). A dramatic increase is expected over the next few years, due to current demographic developments as population growth and the aging of so-called baby boomers. A stroke is the most frequent cause of long-term disabilities. BAAT Medical has been commissioned to design a wrist orthosis, for patients who suffer from wrist problems after a stroke. This orthosis serves as a functional aid during the recovery process. Main focus is the reintegration of patients in their social and professional environment.

The goal of this bachelor assignment is to design of a wrist orthosis for stroke patients.

Recommendations are
- Immobilize the wrist and thumb to prevent a clinched fist, which is a permanent shortening of muscles caused by (semi-)paralysis or spasm.

Motivation
Based on analyses done to overall effects of stroke and specific effects on the wrist, treatment of stroke and a market investigation, options are given what the functionality of an orthosis for stroke patients can be.

Attention is paid to making the orthosis fit to different patients and adjusting the shape, so it is appropriate for the shape of an arm. Also, the closing system for the straps and immobilizing the thumb is taken in account. Reducing pressure points and making sure it is clear how the orthosis should be put on is detailed in the end of this phase.

An end proposal is done with presentation drawings, based on the improvements of different mockups and iterations of these models during the detail phase. The orthosis should be further elaborated and designed by BAAT or by the client if they want to bring it on the market. Recommendations for further design are done.

Consequences
- It is a unique mechanism, which can lead to a strong market position for orthosis made for stroke patients. The confidential report also gives other unique ideas for wrist orthoses.
- Further investigation has to be done to optimize the orthosis for production.
- A calculation of expenses has to be done.

Samenvatting (Dutch summary)

Aanleiding

Ieder jaar krijgen rond de twee miljoen mensen in Europa een CVA (Cerobrovasculair accident), ook wel een beroerte genoemd (Kirchhofs et al., 2009). Er wordt verwacht dat dit aantal enorm zal groeien de aankomende jaren, door demografische ontwikkelen zoals populatiegroei en het verouderen van de zogenaamde baby-boomers. Een beroerte is de meest voorkomende oorzaak van lichamelijke problemen op lange termijn. BAAT Medical heeft de opdracht gekregen om een polsorthese te ontwikkelen voor patiënten die een beroerte hebben gehad. Deze orthese dient als een functioneel hulpmiddel gedurende het herstelproces. De belangrijkste focus hierbij is de reïntegratie van patiënten in hun socials en professionele omgeving.

Het doel van deze bacheloropdracht is om een polsorthese te ontwikkelen voor patiënten die een beroerte hebben gehad.

Aanbevelingen zijn

- Immobiliseer de pols en duim om een vastgegroeide pols te voorkomen, wat inhoud dat de spieren permanent verkort zijn door (deels) verlamming of spasmen.

Motivatie

Gebaseerd op analyses naar de algemene gevolgen van een beroerte en de specifieke gevolgen voor de pols, behandeling van een beroerte en een marktonderzoek, zijn er verschillende mogelijkheden gegeven voor de functies die de orthese kan hebben.

Er is aandacht besteed aan het passend maken van de orthese voor verschillende patiënten en aan het passend maken voor individuele patiënten, door de vorm van de orthese aan te passen aan de vorm van de arm. Ook het sluitsysteem voor de bandjes en het immobiliseren van de duim is meegenomen in het onderzoek. Het verminderen van punten die druk op de arm kunnen veroorzaken en onderzoeken of het duidelijk is hoe de orthese aangedaan moet worden is gedetailleerd.

Er is een eindvoorstel gedaan aan de hand van presentatietekening, gebaseerd op verschillende verbetering van testmodellen en iteraties van deze modellen gedurende de detailering van het concept. De orthese zal verder ontwikkeld en ontworpen moeten worden door BAAT of door de klant als ze het op de markt willen brengen. Er zijn aanbevelingen gedaan voor de toekomst.

Consequenties

- Er moet verder onderzoek gedaan worden om de orthese te optimaliseren voor productie.
- Er zal nog een kostenberekening gedaan moeten worden.

Table of contents

Glossary

Contralateral: The opposite side to where a specific structure or condition occurs. For example: When a stroke occurs at the right hemisphere, a patient experiences muscle weakness at the left side of his body.

CPO: Certified Prosthetist/Orthotist. He is the physician who takes care of the evaluation, fabrication, and custom fitting of artificial limbs and orthopedic braces.

DIP, PIP and MCP JOINTS: Different joints of the hand (see figure 1)

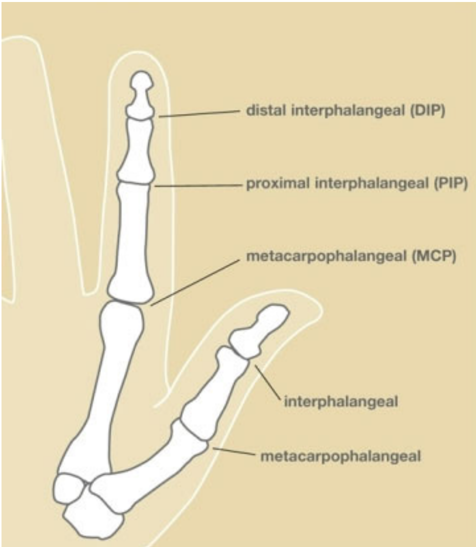


Figure 1. Different joints of the hand with names

Height and width of the wrist: Figure 2 shows what is ment with the hight and width of the wrist or arm

Figure 2. Height and width as mentioned in the report

Hemisphere: Side of the brain

Patient: Person who suffered a stroke

Positioning an orthosis: Placing the orthosis on the right place on the arm

Splint: Splint to immobilize the wrist

1. Introduction

1.1 Goal
Each year, around 2 million people in Europe suffer from a CVA (cerebrovascular accident) or also called a stroke (Kirchhofs et al., 2009). A dramatic increase is expected over the next few years, due to current demographic developments as population growth and the aging of so-called baby boomers. A stroke is the most frequent cause of long-term disabilities.

BAAT Medical has been commissioned to design a wrist orthosis for patients who suffer from wrist problems after a stroke. This orthosis serves as a functional aid during the recovery process. Main focus is the reintegration of patients in their social and professional environment.

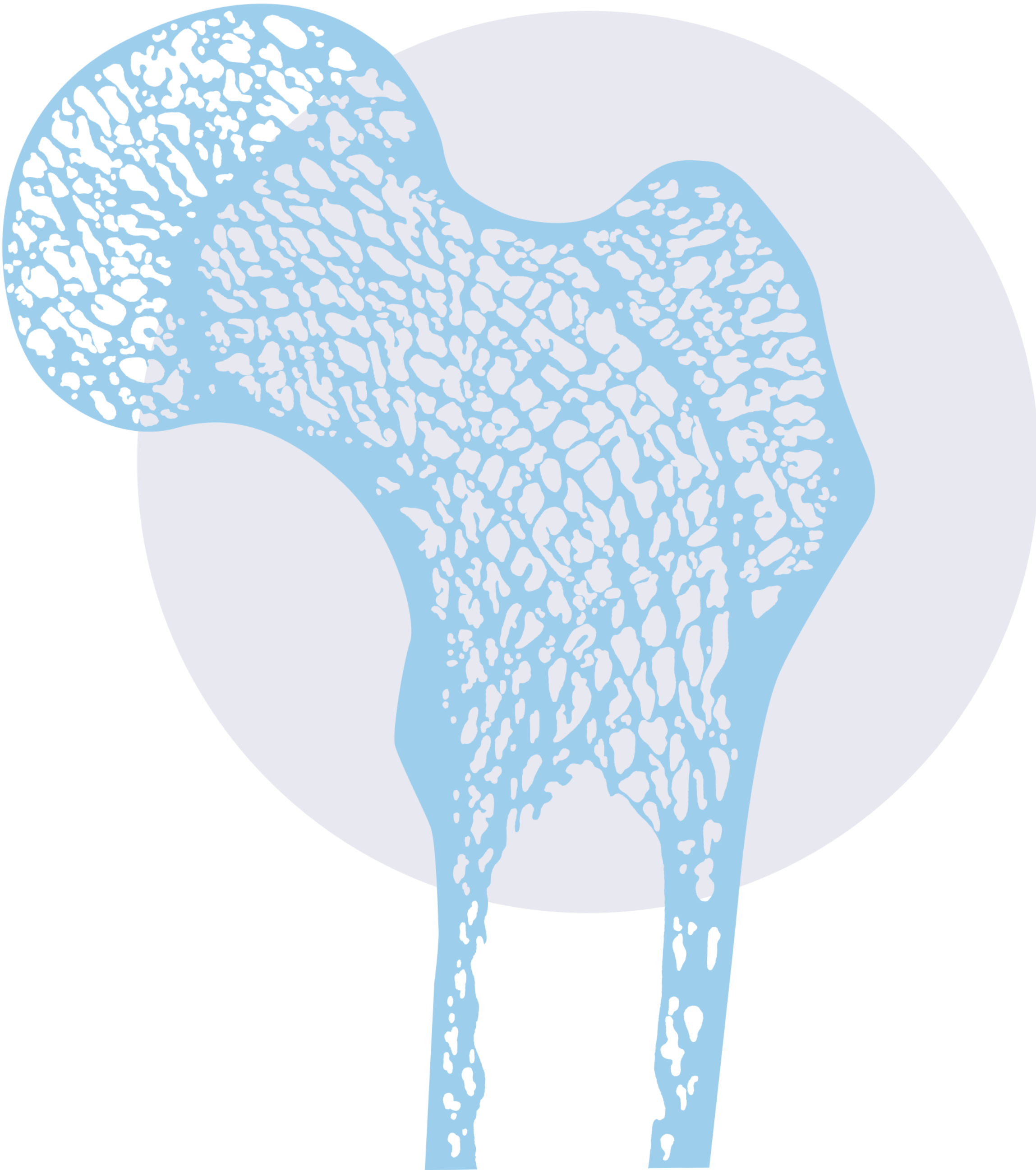
The goal of this bachelor assignment is to design a wrist orthosis for stroke patients. It starts at the very beginning of the design process, with hardly any information known about the requirements. In the end, a concept proposal is done to BAAT Medical by making mockups and based on outcomes of these models, a presentation drawing.

1.2 BAAT Medical
BAAT Medical was founded in 1999 and is specialized in orthopaedic product development. BAAT has grown into a recognized full-service specialist in product development for the orthopaedic market across Europe. They supply a complete service package, from idea generation and engineering towards production and CE marking orthopaedic products under private label. Their customers are critical professionals demanding the highest flexibility, up to date knowledge, service provision and creativity from them. Over the years they developed more than 30 devices.

The mission of BAAT is to empower creative design, development and speed to deliver new medical devices. They focus their energies in the entire product development process from basic user requirements as input of the customer towards CE mark and production. BAAT stands for an innovative orthopaedic specialist in the medical industry with talented engineers, operational excellence, innovation and reliability.

1.3 Structure of Report
Chapter two gives a short description of what happens during a stroke and what the physical and cognitive effects of stroke are. Chapter three shows the general treatment of stroke patients during the different phases they go through, and the specific treatment of the wrist. Chapter four groups the different types of existing orthosis and shows investigation of several ways of donning, doffing and tightening orthoses and other products. In chapter five, the list of the most important requirements for the client are shown, as in chapter six is explained which requirements are taken in account for this bachelor assignment. In chapter seven, several ideas are made with mockups. Based on these ideas, four concepts are created, after which a reasoned choice is made for one concept. This concept is detailed in chapter 8 based on, inter alia, mockups. Chapter 9 gives three presentation drawings, based on the mockups and the detail phase and chapter 10 consists conclusions and recommendations.

Analysis



2. Stroke and effects

2.1 Stroke

A stroke occurs when a blood clot blocks an artery (ischemic stroke) or a blood vessel breaks (hemorrhagic stroke), interrupting blood flow to an area of the brain, see figure 3. When either of these things happens, brain cells begin to die and brain damage occurs. When brain cells die during a stroke, abilities controlled by that area of the brain are lost. Figure 4 shows the anatomy and the functional areas of the brain.

How a stroke patient is affected, depends on where the stroke occurs in the brain, how much the brain is damaged (National Stroke Association, What is stroke?, 2014) and how much time has passed since the stroke.

Among the patients who survive a stroke, a significant amount experiences permanent problems and limitations.

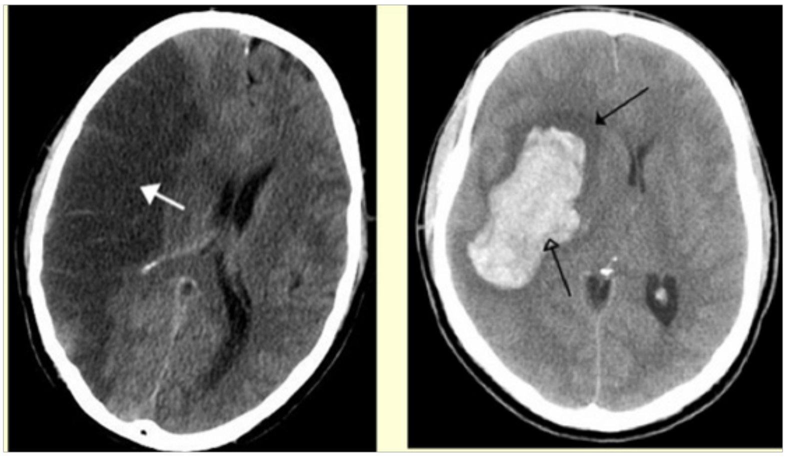


Figure 3: Left: CT scan of an affected brain by an Ischemic stroke (left) and by a hemorrhagic stroke (right)

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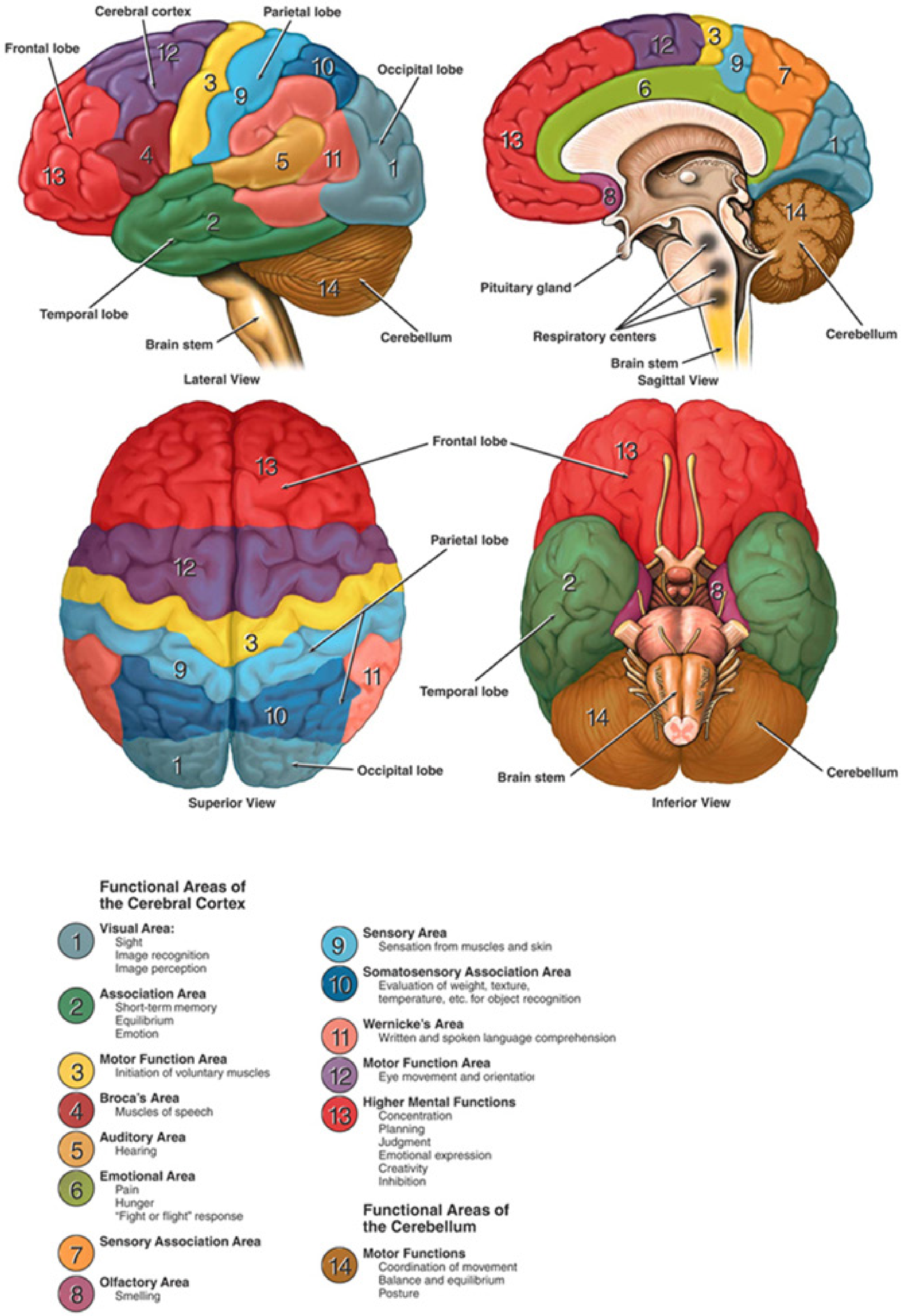


Figure 4 Anatomy and functional areas of the brain (http://www.dana.org/Briefing_Papers/Neuroanatomy-A_Primer/)

2.2 Physical effects of stroke

One side of the brain controls the other side of the body, so all the effects mentioned in this chapter occur on the side of the body contralateral to the stroke.

“When stroke occurs in the brain stem, depending on the severity of the injury, it can affect both sides of the body and may leave someone in a ‘locked-in’ state. When a locked-in state occurs, the patient is generally unable to speak or achieve any movement below the neck.”(American Heart Assocation, 2012)

Most common physical effects of stroke are:
(Stroke Association, 2013) (National Stroke Association, Effects of stroke, 2012)

- **Muscle weakness**
  Weakness at one side of the body is the most common physical effect. Around 80% of stroke survivors experience movement problems because of this. This weakness can vary from a very mild weakness to complete paralysis.
- **Fatigue**
  Many patients find it difficult to keep active for a long time, both physically and emotionally. For instance, patients might struggle to use their cutlery towards the end of a meal. They often become tired more quickly than before the stroke occurred.
- **Pain**
  Patients might feel pain if the stroke has damaged the brain’s ‘pain center’ (the thalamus) or it can be caused indirectly as a result of muscle tightness or physical weakness, for instance.
- **Spasticity or flaccidity**
  This are changes in muscle tone. If the muscle tone has increased, patients may develop very tight, stiff muscles, known as spasticity. When the muscle town is decreased, it is called flaccidity. Spasticity affects up to a third of the stroke survivors and always occurs on the weaker side of the body.
- **Shortening or lengthening of muscles**
  Stiffness and spasm can cause a permanent shortening of the muscles. This can also occur if a patient cannot move their limbs fully and regularly. If this happens, the muscles and soft tissue around joints can change in shape. This can cause some muscles to change length, becoming shorter or longer. Sometimes this length can be permanent and the muscle and joints become fixed in position.

2.3 Cognitive effects of stroke

As mentioned in section 2.1, the effects of a stroke depend on which area of the brain is affected. When a stroke occurs in the right hemisphere, a patient can experience problems with processing visual information and his behavioral style can become quick and inquisitive. When the left hemisphere is affected, the patient can have speech or language problems and his behavioral style can change to cautious and slow.

Most common cognitive effects are: (Commissie CVA Revalidatie, 2001):

- **Loss of orientation**
- **Change in attention**
    - Especially the speed of information processing is low, which leads to a delayed reaction. Around 70% of the patients have problems acting under time pressure.
    - A decreased arousal level, falling asleep regularly and having less attention during a conversation. Or with an increased around level, being restless and irascible.
    - Not being able to suppress insignificant information
    - Quickly distracted
    - Having difficulties to react on more than one task, or to react on different elements in one complex task. Furthermore, many basic skills cannot be executed automatically.
- **Memory loss**
- **Change in vision**
    - Agnosia is a disorder in recognizing stimuli of the sensory systems. It only affects a single modality, such as vision or hearing.
    - Neglect is a disorder where the side of the body or/and the environment contralateral of the stroke of the patient is neglected. It often occurs in the acute phase at around 70% of the patients with a stroke on the right hemisphere and around 50% of the patients who have a stroke in the left hemisphere. An important characteristic of neglect is that the patient is not or partially aware of the reduced attention for the contralateral side, see for an example figure 5.

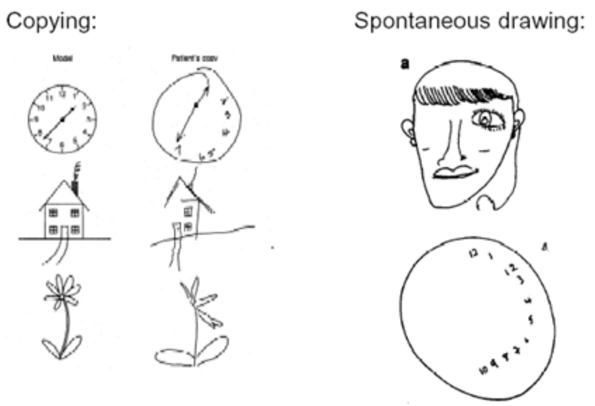


Figure 5 Drawing of a patient with Neglect

- **Change in visual information (right brain affected)**
  Problems with knowing where something is, estimating heights, distance, speed etc.
- **Apraxia**
  The inability to execute learned movements. For instance, a patient brushes his hair with a toothbrush. Apraxia often comes together with other disorders such as neglect.
- **Disorder in executive functions**
  The patient is not able to take care of himself. He cannot execute complex actions without structure from outside, or maintain social relationships, whereas his memory or language is still intact.
- **Change in emotion and behavior**
  Emotional lability, taking less initiative, being bad-tempered, a change in sexuality and changes in personality.
- **Communication disorders (left brain affected)**
  Having trouble with expressing himself or understanding information.

2.4 Effects on wrist

"Of all stroke survivors, more than half experience impairments of the upper limb in the chronic phase, including loss of strength and dexterity, spasticity, muscle contracture, pain, and edema." (Andriga, Port, & Meijer, 2013). Figure 6 shows images of the different wrist problems after a stroke, which can also be a combination of the shown problems.

"Patients with a more severe paresis have a higher risk of developing spasticity and muscle contractures of the wrist and finger flexor muscles. Spasticity is due to damage to the motor cortex, the part of the brain involved in the planning, control, and execution of voluntary movements. Without appropriate spasticity treatment or contracture prevention, patients are at risk of developing a clenched fist, a hand which is deformed into a fist by shortening of flexor muscles of the fingers and soft tissue" (Andriga, Port, & Meijer, 2013)

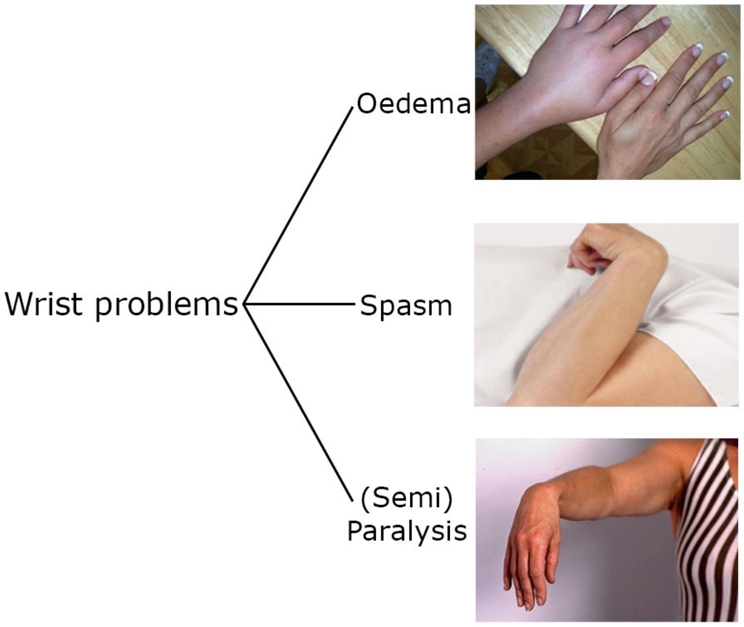


Figure 6 Wrist problems after stroke.

The most common effect patients experience on their wrist is muscle weakness, especially in the acute phase, but there are many differences between patients who experience wrist problems. (S. Nijenhuis, 2014) Effect of Spasticity can vary from light muscle flicker to severe spasm, where the wrist is in flexion and the radial deviation (see for the movements of the wrist appendix A). Some patients have a combination of contractures and weakness, while others have a completely paralyzed limb. This can get better to a greater or lesser extent during the acute phase and by rehabilitation, but this also is not the same for every patient. Due to a shortage of movement, fluid can pool in the tissues of the hand and forearm, causing edema.

3. Treatment

3.1. Introduction

After a stroke, patients go through three partially parallel phases (Commissie CVA Revalidatie, 2001). During these phases, the patient's environment changes regularly and is not the same for every patient, see figure 7.

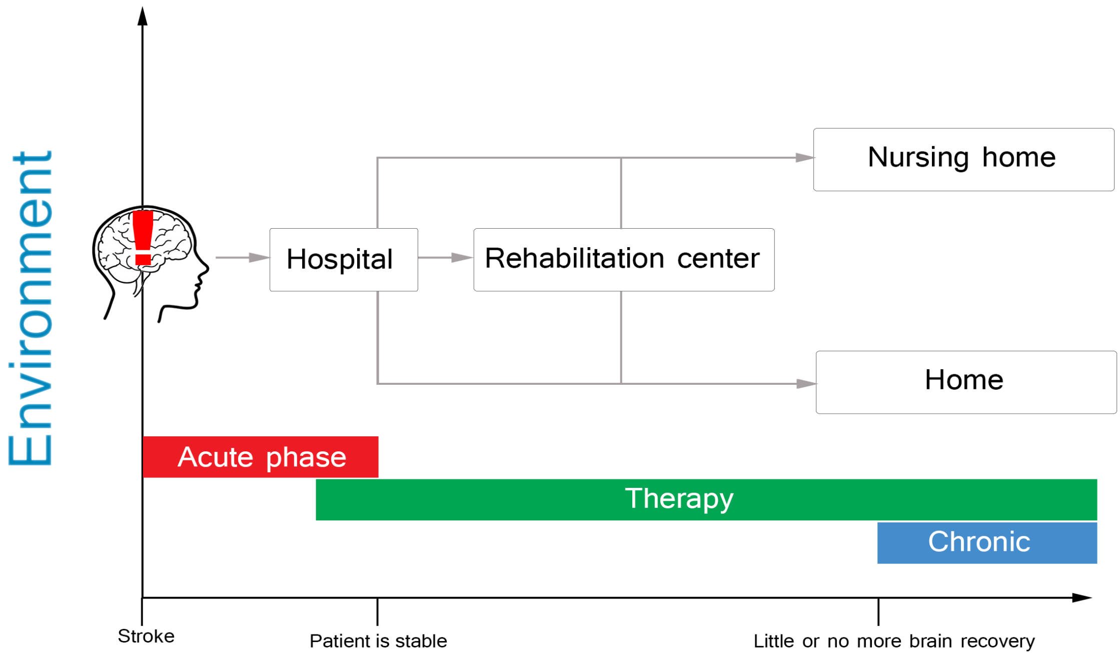


Figure 7 Environment of the patient from the moment a stroke occurs to the chronic phase

The three phases are:

1. Acute phase: starts when the stroke occurs. Diagnostics, prevention of complications, prevention of progressive damage to the brain and the first treatment take center stage in this phase. It ends when the patient is physically stable and the acute intervention has ended.
2. Rehabilitation phase: focus on preventing and reducing the disorders and limitations in activity and participation. If possible, this phase starts parallel with the acute phase.
3. Chronic phase: starts when it is clear what disorders, limitations in activities and participation the CVA patient has to live with. Usually, this becomes clear after six months, because the largest amount of the recovery (naturally as well as by therapy) takes place in this period.

As soon as patient shows symptoms of a stroke, he will be hospitalized in a special stroke unit most of the time, or on the intensive care if there is no stroke unit in the hospital. Early diagnostics and treatment take place by a multidisciplinary team. The diagnosis will be determined following a fixed protocol, which consists at least a CT scan (determining if there are areas of abnormality in the brain, a duplex ultrasound (test to see how blood moves through the arteries and veins) and an ECG (recording of the electrical activity of the heart).

The team of physicians at the stroke unit consists of a neurologist, rehabilitation specialists, nurses, a physiotherapist, a speech therapist and an occupational therapist. The physiotherapist and the occupational therapist will exercise with the patient as soon as possible, because most of the recovery takes place in the first twelve weeks after the stroke.

After a patient is stabilized, the treatment will continue at the nursing department of the hospital. Ongoing investigations will be finished, the patient will get treatment to prevent another stroke in the future and the rehabilitation will continue. In consultation with the caretakers, a policy is made for the future. (Orbis medisch centrum)

A patient will remain in the hospital 5 to 21 days. Depending on the severity of the situation, the patient can go home, to a rehabilitation center or to a nursing home (Figure 7).(Nederlandse Hartstichting, 2014). Patients who are moved to a rehab center stay there for about three months. After this, patients will go home most of the time, sometimes still following therapy, depending on their motivation.

3.2. Assessment of stroke severity

There are several ways to determine the amount of movement in the wrist of a patient. In this section, it is investigated where these methods base their measurements and results on. This can be used to find out how an orthosis can measure improvements in the wrist movement of a patient.

3.2.2. Biomechanical motion capture

Recording of movement of people is an objective way to measure movements. Motion capture is applicable for observing the range of motion of the wrist, the type of movements, how smooth and at which speed wrist movements are executed. This also shows compensation of the patient with his trunk for example.

Motion capture is used inside a laboratory, with for example Vicon motion capture, see figure 8. This system makes use of infrared reflective markers attached at certain points on the patient's body. Infrared cameras detect these markers, so the movement can be visualized.

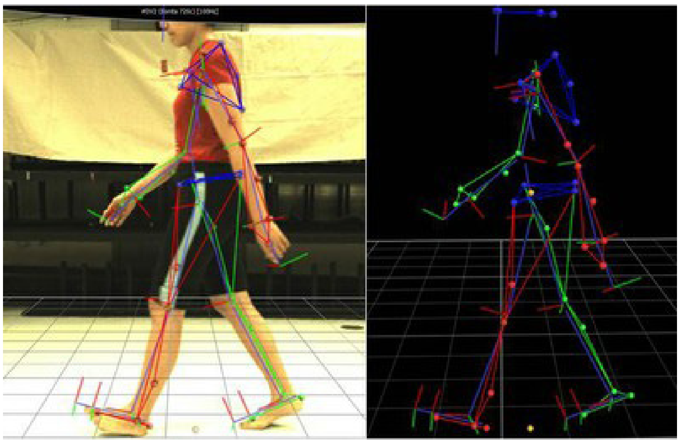


Figure 8 Vicon motion capture (University of Louisville)

3.2.3. Fugl-Meyer assessment (FMA)

This is an overall assessment, evaluating and measuring functioning and recovery of post-stroke hemiplegic patients. It is one of the most widely used quantitative measures of motor impairment. It consists of five sub-scales that relate to various aspects of a patient's upper and lower extremity:

1. Motor
2. Balance
3. Sensation
4. Joint Range of Motion
5. Pain

Each component of the FMA may be evaluated and scored individually or, a total possible summative score for all five sub-scales of 226 may be used to track a patient's degree of recovery.(Rehabilitation institute of Chicago, 2010) The complete assessment will be filled in by the therapist

3.2.4. Action Research Arm Test (ARAT)

An evaluative measure to assess specific changes in limb function among hemiplegic patients. It assesses a client's ability to handle objects differing in size, weight and shape and therefore can be considered to be an arm-specific measure of activity limitation (Figueiredo). It consists of 19 items subscaled in four groups:

1. Grasp
2. Grip
3. Pinch
4. Gross movement

3.3. Wrist treatment

Several interviews have taken place, to investigate what treatment is necessary for stroke patients with wrist problems. Based on these findings, it is determined what the functionality of the orthosis could be. One of this interviews was with Sharon Nijenhuis, who is currently a PhD student at the SCRIPT project. More information of this project can be found in Appendix C.

Figure 9 summarizes which treatments are available for which wrist problems, to make this section more insightful. Edema will not be taken in account for this bachelor assignment. Further explanation can be found in the different subsections.

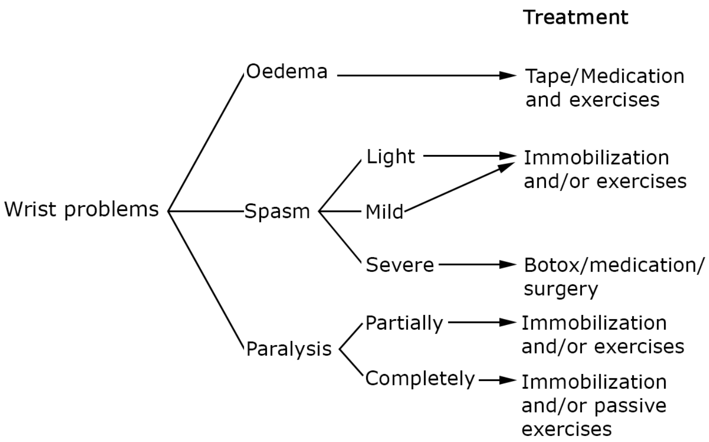


Figure 9 Treatment for wrist problems

3.4. Wrist immobilization

Some stroke patients are unable to fully extend their wrist and/or fingers by themselves, which can lead to a deformed hand (section 2.4). To prevent this, and to prevent lying on their hand during the night and stiff muscles in the morning, some patients have to wear a splint for at least eight hours every night, or during the day.

For patients with a (semi-) paralyzed hand and no spasm, the splint should immobilize the wrist into a functional position of 20-30 degrees of extension, slight ulnar deviation (10°) and the thumb opposed and adducted (Figure 10 and 11) See for more information about these movements appendix A. With the wrist in this position, the fingers naturally form a grasp. To keep the wrist in this position, a three point pressure system has to work on the wrist, see figure 10 (Becguglielmino, 2014)

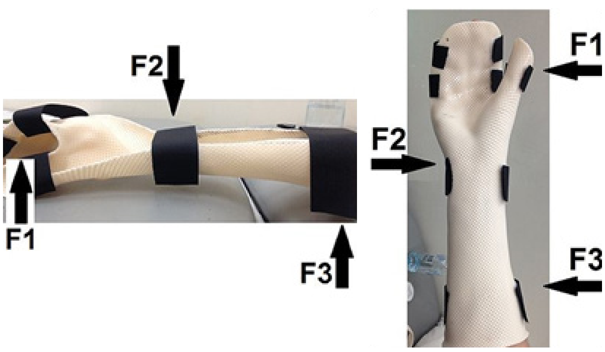


Figure 10 Three point pressure system acting to stabilize the wrist

Figure 11 Thumb opposed and adducted

Patients with light to mild spasticity in their hand, cannot wear a splint that completely immobilizes the fingers during contractions, because this is very painful. There is an orthosis on the market which is applicable for patients with spasticity. More information about this can found in section 4.1. Competition.

Patients with slight movement in their wrist and hand are sometimes able to exercise with their wrist besides wearing a splint. There are also patients without movement in their wrist or hand at all, making them unable to do exercises.

3.4.1 Prescribing wrist immobilization

A physiotherapist, CPO or occupational therapist is the professional who prescribes immobilization. When the professional knows which orthosis is appropriate for the patient, he will order it, assemble it and adjust it to the patient. He will be the one explaining to the patient when, how and how long the orthosis should be worn.

3.5. Wrist exercises

3.5.1. Prescribing exercises

Recovery of the wrist function takes place especially in the first four weeks after a stroke. Learning is a necessary condition for recovery and can be stimulated and shaped by rehabilitation; and this most in the first 6 months after the stroke (Timmermans, Seelen, Willmann, & Kingma, 2009). For patients who are expected to achieve at least some capability with their wrist and hand within 4 weeks after stroke, every opportunity should be encouraged to regain function in the affected upper limb.

For those with a poor motor recovery without return of any capability in those four weeks, therapy should be focused on achieving and maintaining a comfortably mobile arm and hand, and compensation strategies with the non-paretic arm should be considered. (Kwakkel, 2009)

Two third of occupational therapists and physiotherapists prescribe upper limb exercises to persons with stroke if they can elevate their scapula and have grade 1 finger/wrist extension, which means that there is muscle flicker, but no movement. They tend not to prescribe exercises to people with shoulder pain or increased tone. The majority of therapists also prescribe exercises to be completed independently outside of therapy time. (Connell, McMahon, Eng, & Watkins, 2014)

3.5.2. Type of exercise

After a stroke has occurred, many different ways are possible to activate affected muscles again on different levels (Timmermans, Seelen, Willmann, & Kingma, 2009). Training on a functional level aims at body structures and functions, like strength exercises (for an example figure 12). Active training aims at skills, task execution and activity completion, like training daily activities in figure 13 and constrained-induced movement therapy in figure 14, where the non-affected side is restrained, leading to more exercising with the affected side. For both types of therapy, repetition of the exercises is important. This helps to restore the connection between the brain and the affected limb.

Figure 12 Strength exercise

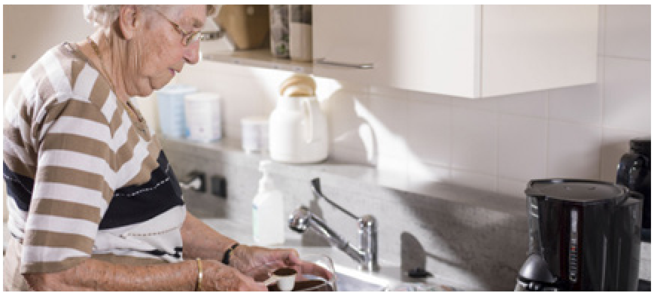


Figure 13 Training daily activities

Figure 14 Constraint-induced movement therapy

When there is no or hardly any movement in the hand of a patient, it can help to electrically stimulate the nerves that make the muscles contract. It may help to regain control over the limb, see figure 15. Another therapy can be mirror box therapy, see figure 16. When a stroke patient puts his weakened hand in the mirror box, and moves his strong hand, the mirror box gives the illusion movement is occurring in the hand affected by the stroke. The mirror tricks the brain and the weak hand into working better.

Figure 15 Electric stimulation

Figure 16 Mirror Box therapy.

Exercises to regain movement in the arm are being practiced in sequence from proximal to distal. So first reaching of the arm will be practiced and will recover. Second, movement of the elbow and wrist and at the end, movement in the fingers.
For the wrist, mainly flexion and extension is useful for patients in daily activities. Grasping an object, lifting it and putting it back down again is most often done with the arm, which can be practiced with many different tools, see for an example section 4.1.2. The exercises most frequently prescribed by therapists are aimed at enlarging the range of motion and at stretching the arm muscles, because the wrist and fingers are often flexed after a stroke. (S. Nijenhuis, 2014)(Connell et al.,2014). The specific exercises mostly depend on the goals of the patient. If he likes to work in the garden for example, he will perform different exercises than someone who likes to play on the computer.

3.5.3. Moment of exercise

For every phase, the moment and the time a patient is exercising their affected side, depends on a large number of factors like the severity of the condition, what part of the brain is affected, cognitive effects, goals of the patient etc.

1. <u>Acute phase</u>

It is important patients start exercising their affected side as soon as possible, preferably the same day the stroke occurred or the day after, so that recovery can occur as quickly as possible.
During the acute phase, the patient is still in the hospital. There are many investigations a patient must undergo, which can make it hard for the therapists to find time for exercising with the patient.

2. <u>Rehabilitation</u>

When a patient goes to a rehabilitation center, it is important the patient exercises the major part of his day. This gives the greatest chance of full recovery. They have an extremely busy schedule, for an example see appendix B. This also emphasizes the huge differences between patients.

3. <u>Chronic phase</u>

In the chronic phase, most of the recovery and rehabilitation is done. Still, it is important the patient keeps moving their paralyzed limbs, to prevent muscle stiffness. Depending on the motivation of the patient, he sometimes will keep on following therapy, but much less intensive. In many cases, the therapy will not be reimbursed by the health insurance.

It is recommended that a patient practices his wrist movement around half an hour a day (Kwakkel, 2009).

4. Market investigation

4.1. Competition

As described in section 3.4 and 3.5, patients with wrist problems have to immobilize and/or exercise their wrist and hand. For the competition, a distinction has been made between stabilization and exercising the wrist, because there is a big difference between these two treatments and their goals.

4.1.1. Immobilizing

Immobilizing wrist and/or fingers

When a patient experiences (partial) paralysis and/or light spasm in their wrist and fingers, it can be necessary to immobilize only the wrist, see for example figure 17a, or both the hand and the wrist. An example of this is the Manu-Hit Digitus (Sporlastic Orthopaedics) (figure 17), which stabilizes the wrist, metacarpus and finger joints.

Figure 17a. Wrist splint (Spica)

Figure 17b. Manu-Hit Digitus

Immobilizing wrist and extending fingers after contracture

For patients with light to mild spasm, an orthosis which immobilizes the wrist joint and brings back the fingers into a straight position after a contracture can be used. The Saebostretch (Saebo) (figure 18) for example allows fingers to flex when a muscle tone occurs, and brings the fingers back in position when they relax. It has three interchangeable hand pieces, each with a different grade of stiffness.

Figure 18 Saeobostretch

4.1.2. Exercising

Exercising with tools

A patient can practice grasping, lifting and putting objects down, alone or with the help of a therapist. This can also be seen as competition, because an orthosis is not necessary to execute these actions. However, the patient must have some wrist or finger movement to practice with this. An example of these tools can be seen in figure 19.

Figuur 19 Tools used in in the Roessingh Rehabilitation center in Enschede

Exercising without tools (with or without therapist)

Another possibility is to exercise the wrist without tools, see figure 20. This takes less muscle power and energy of the patient than practicing with tools. Yet it can be more difficult, because when a patient can really hold objects, it’s easier to explain and understand how the movements of the exercise should be done.

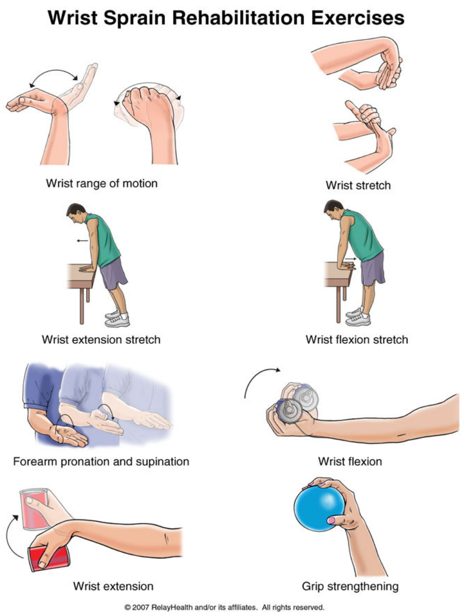


Figure 20 Moving the wrist without tools

Exercising with orthosis

There are several orthoses on the market, supporting the hand during exercises. An example is the Saeboflex (Saebo) (figure 21), which positions the wrist and fingers into extension in preparation for functional activities. The patient can grasp an object by voluntarily flexing his or her fingers. The extension spring system assists in re-opening the hand to release an object. A low-tech solution, like a simple ball to squeeze in a sort of glove (figure 22) can also be used for exercising. For both a high-tech or low-tech system, the patient must be able to slightly move their wrist and hand.

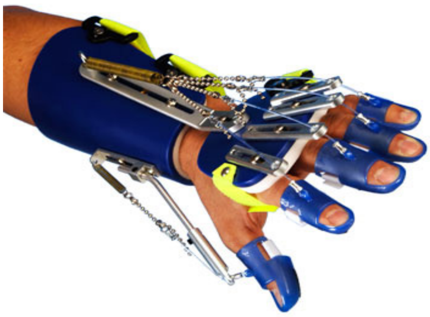


Figure 21 Saeboflex

Figure 22 Exercising with ball

Electrostimulation

As mentioned in section 3.5, electrostimulation can be used to stimulate the nerves that make ones muscles contract. An example of this is the system of Baromedical (figure 23), which is a customized stimulation program to gradually extend the wrist and open the hand when a person has a clenched fist. Electrostimulation can be used for patients who have no or slight wrist and/or hand movement.

Figure 23 Electrostimulation with BaroMedical

4.2. Donning, doffing and tightening

A stroke patient should be able to put on the orthosis with one hand. Therefore, some different techniques for donning, doffing and tightening are presented in this section. This gives an idea of what is on the market and can give inspiration for the design phase.

Many wrist and/or hand orthoses make use of the thumb to put on and position the orthosis, which can be seen in figure 24 to 28.

4.2.1. Laces and Velcro

A combination of laces and Velcro can be an easy system for tightening, see figure 24. A patient can pull tight the laces with one hand and attach the Velcro to the orthosis. Putting on and off these orthoses can be done like a kind of sock.

Figure 24 Poroflex Lace Wrist Brace (Health and Care) and laces from Corflex Orthopedic Rehabilitation Products

4.2.2. Boa Technology

The Boa closure system is used in shoes, medical braces and other equipment, see figure 25. It can be put on like a sock and is very easy to tighten with one hand. A problem can be that it is a patented system, making it expensive for the client to apply it on the new orthosis.

Figure 25 Boa closure system in an orthosis

4.2.3. Air

Inflating the orthosis after putting it on, is another way to tighten the orthosis. An example of this is the Cry Pneumatic Wrist support, see figure 26. This system helps diminish swelling/edema, but it could also be used for tightening.

Figure 26 Cry Pneumatic Wrist Support (Corflex Orthopedic Rehabilitation products)

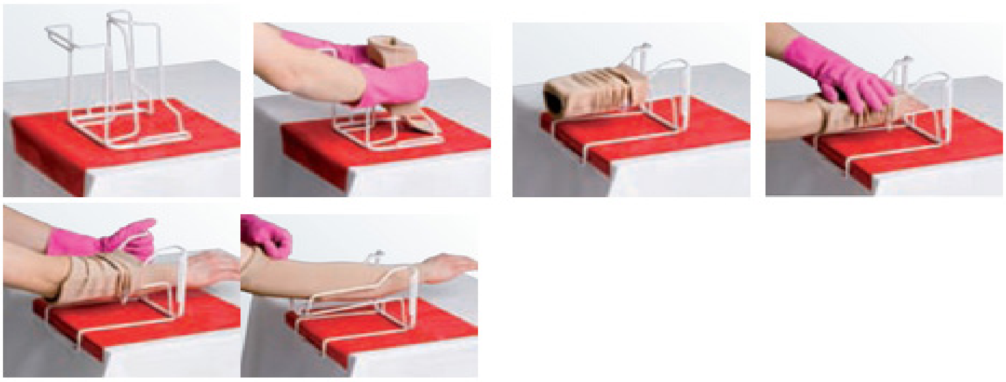
4.2.4. Wrapping

Doffing and/or tightening an orthosis can be done by wrapping for example Velcro around the hand, see figure 27.

Figuur 27 Wrapping Velcro around wrist

4.2.5. Additional aids

Aids can be used to make donning easier for patients with one affected hand. The Medi Arm Valet (figure 28) can be used to lift the affected arm of the table, making donning easier.



Figuur 28 Medi Arm Valet (Cozmedix)

5. Demands from client

5.1. Introduction

The requirements of the client imposed on the wrist orthosis are analyzed. The most important ones for the client are featured in this section, the complete list can be found in Appendix D. The requirements in this section as well as in the appendix are literally the same as the client has given them to BAAT Medical.

The client itself does not have a clear picture of how the product should function or look. Based on analyses made in the previous sections and a meeting with the client, some arguments can be given to change or improve some initial requirements from the client and even to add some requirements.

This section is divided in three types of demands. First, the requirements of the client according to the application of the orthosis are listed and examined. Second, the same is done for the appearance. And third, it is done for the functionality. In section 5.5, an overview of what the functionality of the orthosis could be is created. This will be used as input to set the bachelor assignment framework in chapter 6.

5.2. Application

Client requirements:

1. Must be a modular system, the patient or professional only has to pay for what he needs
2. Should allow use during the acute phase after a stroke, the rehabilitation phase and the chronic phase
3. Must be able to support the wrist at night time
4. Shall inhibit contractures and spasticity

5.2. Appearance

Client requirements:

5. No medical appearance, more `lifestyle look´, bracelet like
6. Must be suitable for 80 percent of the target group
7. Able to wear under common clothes

There is no clear definition of “lifestyle”. The question is whether the client knows what appearance fits the lifestyle of the target group. For this assignment, there will be paid nog attention to the appearance.

5.3. Functionality

Client requirements:

8. Must have an angle-adjustable wrist
9. Should allow daily activities
10. Should be wearable for 24 hours

It is not necessary that the orthosis should actually be wearable for 24 hours. As said in section 3.4, a wrist splint should be worn for at least eight hours and exercising will not take longer than around one hour in sequence.

5.4. Complete orthosis and bachelor assignment

Possible (combination of) options for an orthosis are given in figure 29. This figure gives examples of existing solutions for the different functions.

For this bachelor assignment, the main focus will be the design of an orthosis which immobilizes the wrist.

This figure is removed for confidential reasons.

Figure 29 Possible (combination of) options

6. Assignment framework

This bachelor assignment will contain **the design of an orthosis that immobilizes the wrist**. The appearance of the orthosis will not be taken into account for this bachelor assignment.

For this purpose, different ways of immobilizing the wrist will be designed.

The location of the wrist splint will have an influence on the donning and doffing of the orthosis. Different places of the splint and donning and doffing will be done by sketching, but more by making mockups. At least three concepts will be created. Donning and doffing of these concepts will be tested on myself, the engineers of BAAT and finally on one chronic stroke patient. The goal of this bachelor assignment is to **make a presentation drawing at the end of the tests, and give recommendations for further design.**

6.1. User requirements and functionality

The requirements for this assignment are divided in three sections: the general requirements (6.1.1), functionality of the orthosis (6.1.2) and the appearance (6.1.3.),

6.1.1. Overall

1. Usable for stroke patients who suffer from a (semi-)paralyzed wrist
2. Usable for patients who suffer from light to mild spasm in their hand after stroke
3. Usable in the chronic phase after stroke (Wish: also for acute and rehabilitation phase)
4. Usable outside of therapy time
5. Prevent deformed hand
6. Patient should able to put on orthosis without additional tools
7. Usable for a patient who has normal strength on the good side of his body to put on the orthosis
8. Usable for a patient who is cognitive able to live individually on his own
9. Should not cause painful pressure at the arm or hand of the patient
10. Wish: Make use of at least two different types of feedback (for example numbers and colors)

6.1.2. Functionality

11. Should prevent the patient from developing a clenched fist
12. Physician should be able to bend the part that immobilizes the wrist in different angles, making it fit for each patient
13. Should keep the wrist in 20-30° extension and 10° ulnar deviation
14. A physician should be able to bend the splint to make it appropriate for a patient, so the wrist of the orthosis should be angle-adjustable.
15. Suitable to wear at night
16. Suitable to wear for 8 hours
17. Should not cause pain or skin damage
18. Wish: Can be used bilaterally (for both sides)
19. Wish: Can be worn underneath clothes

6.1.3. Appearance

The exact appearance will not be investigated for this assignment.

7. Ideas and concepts

For the design phase, ideas are created for various aspects of the orthosis. First, sketches and models for donning, wearing and doffing the orthosis are made. Second, the same is done for immobilizing the wrist, sometimes together with donning and doffing. Four concepts including donning, doffing, wearing and immobilizing will then be chosen. The thumb of the orthosis will be taken into account during detailing of the chosen concept.

After making a choice for a concept, it will be further detailed.

7.1 Donning, wearing and doffing

Some additional market investigation is done to find more ways of donning, doffing and tightening the orthosis, see appendix E.

A brainstorm session with the project team of BAAT Medical is done to generate ideas for, among other things, donning and doffing the orthosis and immobilizing the wrist. The results from this session can be found in Appendix F.

7.1.1. Model and conclusions

Some idea sketches are made, based on the analysis made and the brainstorm session. Because it is difficult to conclude from a sketch whether donning and doffing is easy, quick models have been made and sometimes improved. For each model, a clear target is defined and conclusions for further improvement are made. A short overview of the models is shown in figure 30. All pictures and findings of the models can be found in Appendix G.

Figure 30 From left to right: Model 1, Model 1.2,, Model 2, Model 3.1, Model 3.2, Model 4

Overall conclusions are:

1. Positioning the orthosis with help of a hole or a place for the thumb, gives a good impression of how the orthosis should be worn.
2. It is hard to see the difference between a left- or right hand orthosis, more time could be spend on this in the detailing of the final concept. On the other hand, a patient or a physician orders an orthosis for only the affected hand, and the patient for who this orthosis is designed should be aware of which hand that is.
3. Closing the orthosis is easy if the orthosis stays partly on top of the arm, see figure 32 a and b.
4. Hard parts are helpful for positioning an orthosis, as can be seen in figure 32. It also gives an idea of what the in- and outside of the orthosis is.

Figure 32 a, b Using a hard part for easy positioning and closing of the straps

5. Having high pressure spots on the hand has to prevented, especially around the thumb, the wrist and on top of the hand, which are sensitive places.

7.2 Immobilizing wrist

One of the functions of the orthosis is to immobilize the wrist. This can done with the three point pressure (3PP) system mentioned in section 3.4 (figure 33)

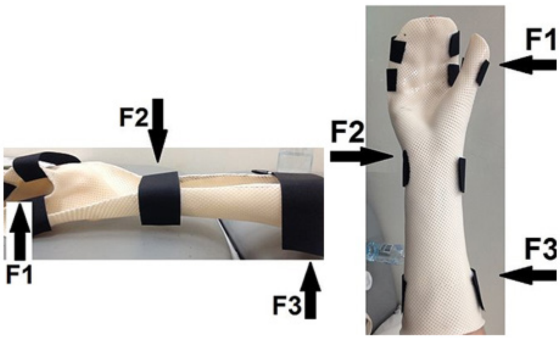


Figure 33 3PP system for immobilizing wrist

Different models for splinting the wrist are made in the same way as for donning and doffing. An overview of all the models is shown in figure 34. More pictures, details and findings of these models can be found in appendix H.

Figure 34 a,b,c,d,e. From left to right: a Splint Model 5, Model 5, Model 6, Model 7, Model 8

Overall conclusions and recommendations are:

1. A splint on the dorsal or ulnair side of the arm can also be used for positioning of the orthosis, for example see figure 34b.
2. Using a splint at the side of arm can only be done if it fits exactly around the wrist.
3. A higher part for immobilizing is stronger than a long and wide splint (for example: Figure 34d is stronger than figure 34a). This can be done by adding height, ribs, or a stand-up edge.
4. When a splint is positioned at the anterior side of the arm and is bent in 20-30˚ extension, it gives a good indication of where to put the palm of the hand.
5. The edges of the splint should not cause any pressure points on the skin.

7.3 Concepts

Four concepts are created from the models and the sketches. The material, geometry and properties of this part, the exact place of this, the working and the specific closure method will be detailed after a choice for a concept.

7.3.1. Concept #1.

This concept is removed for convidential reasons.

7.3.2. Concept #2: Hard part

Concept #2 is based on model 7, see figure 34 and appendix H. Immobilizing the wrist and positioning of orthosis will be done with the same part of the orthosis. It is possible to make small openings in this hard part and still keep the same functionality, covering less skin of the arm and hand of the patient. In this concept three straps are used instead of crosswise straps, making closing easier (conclusions from appendix H).

This concept is easy to use during positioning and immobilizing, using little material. The disadvantage of this concept is that it is hard to make it fit for different people, because immobilizing only happens when the hard part of the orthosis fits exactly around the wrist.

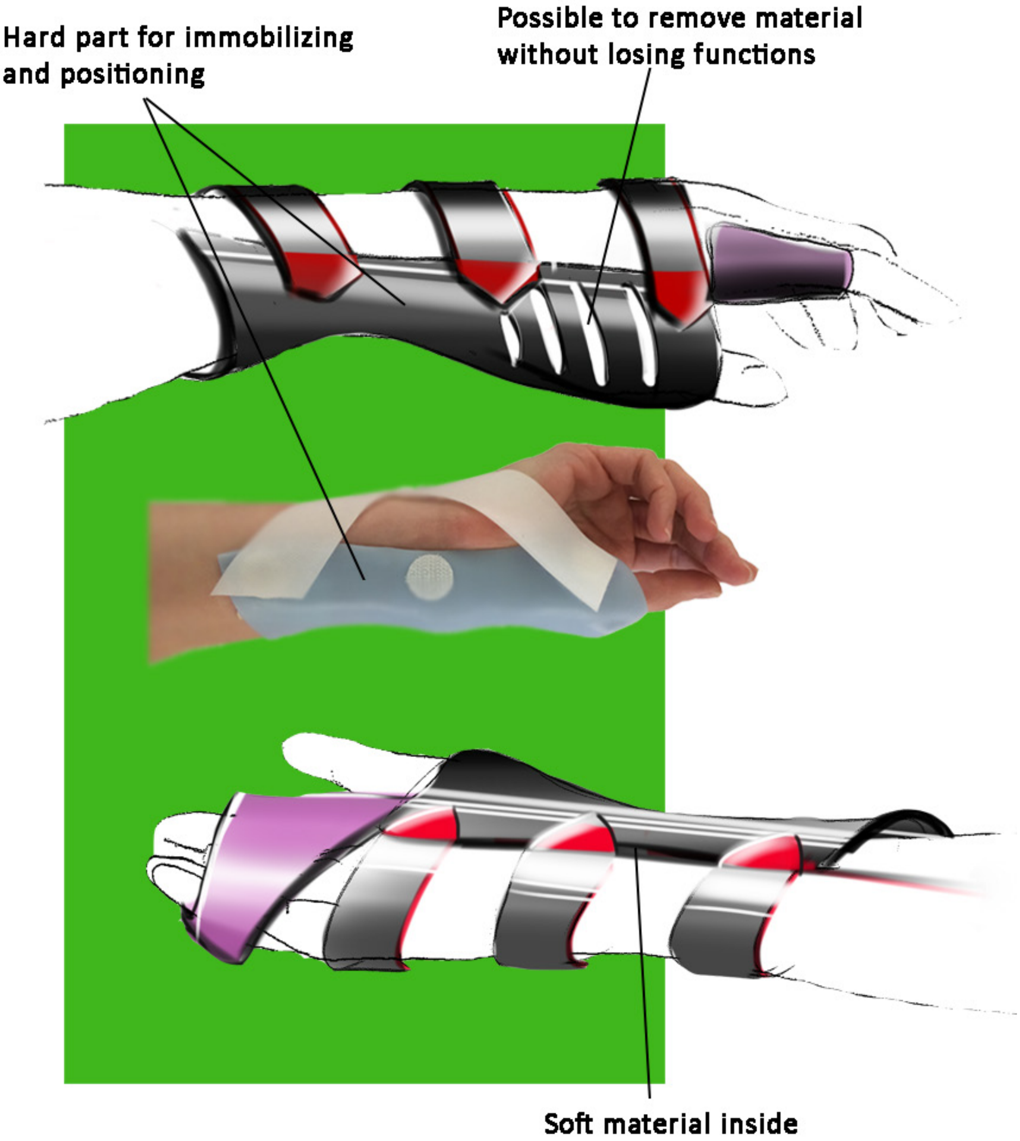


Figure 38 Concept #2. Hard part

7.3.3. Concept #3.

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Figure 40. Intersection concept 3.

7.3.4. Concept #4: Three parts

This concept is based on model 8, see figure 34 and appendix H and makes use of three hard parts, with a rigid connection between them, to immobilize the hand during flexion and extension. To prevent radial and ulnar and radial deviation, two straps are added.

The three hard parts are harder put on and off than the other concepts, but closing the straps is easy to do and not much material is necessary.

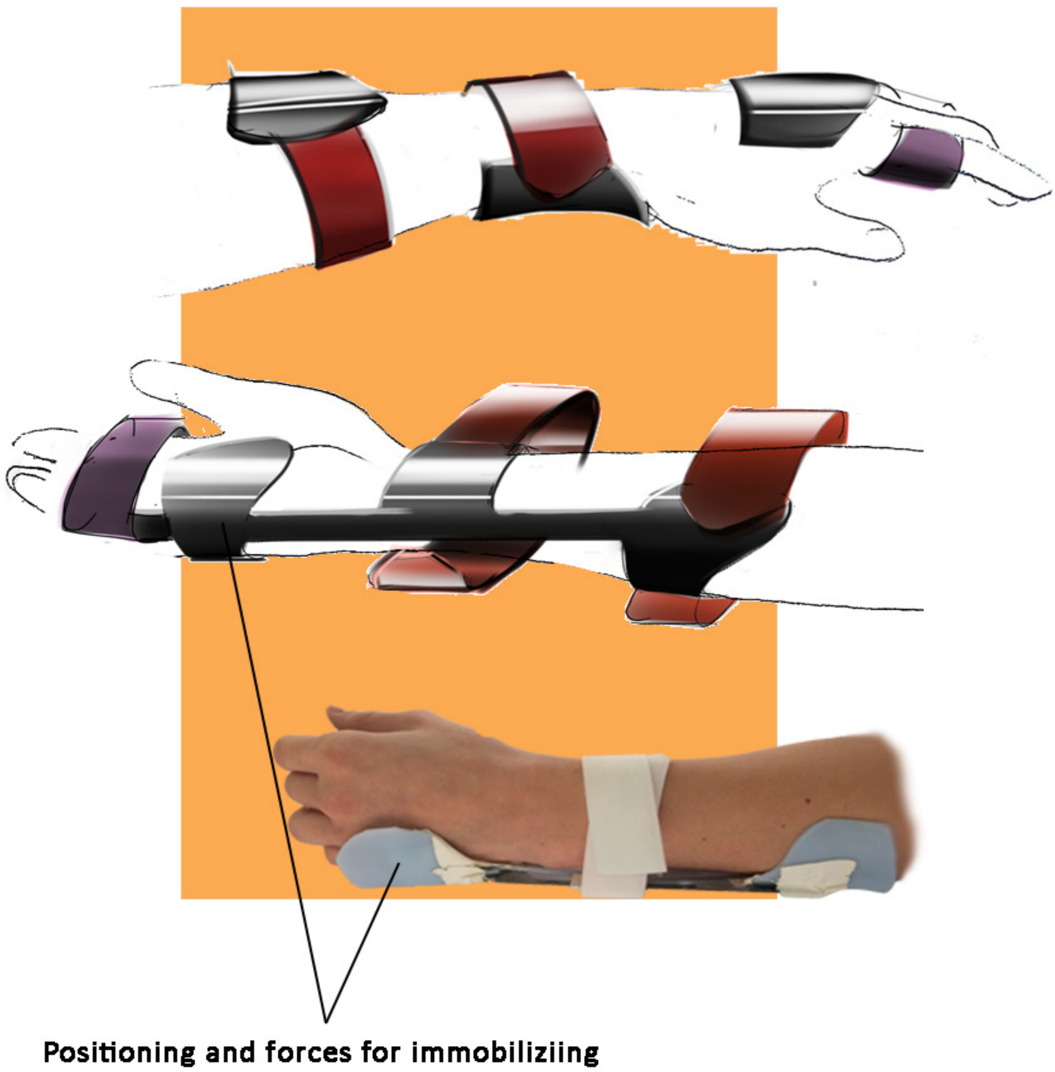

Figure 41 Concept #4. Three parts

7.4. Comparing concepts

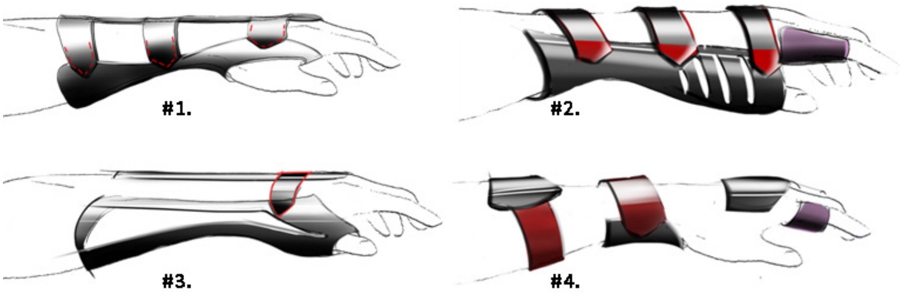

Figure 42. Concept 1 to 4

All four concepts, see figure 42, are compared to the user requirements and the functionality for this assignment, see appendix I. It can be concluded that concept #4 meets the requirements the least, but it still meets all the requirements to some extent. Also, the difference compared to the other concepts is small. Therefore, the advantages and disadvantages of each concept are also mapped in section 7.3. They are compared to each other concerning donning and doffing and the viability of the concept. Also, the amount of material necessary and the unique selling points of the concept are taken in account. An overview of the advantages and the disadvantages are mapped in table 1, where the different aspects are scored from 1 (very bad) to 5 (very good)

Table 1. Comparing concepts to different aspects

Concept	Donning	Doffing	Viability	As little material as possible	Originality	Fit for different persons	**Total**
#1.	5	5	2	1	5	5	**26**
#2.	5	5	3	3	3	1	**24**
#3.	5	3	4	4	5	3	**29**
#4.	3	3	4	5	-1	3	**21**

7.5. Concept choice

Concept #4 will not be chosen, because it scored the lowest on the requirements and functionality for this assignment (appendix I) and is inferior to the other concepts in section 7.4. Concept #2 and #3 are both difficult to fit to different persons, but this is easier to accomplish with concept #3. For this reasons, concept 3 is chosen. An important aspect which is also taken in account for this choice is the originality of this concept, which can be a unique selling point for the client.

8. Concept detailing

8.1 Introduction

There are different aspects of the concept which have to be detailed. For this bachelor assignment, attention will be paid to different subjects, see for an overview figure 43:

1. Fitting the orthosis to different patients and individual patients.
2. Donning, doffing and tightening the orthosis.
3. Immobilizing the wrist.
4. Adding feedback to the orthosis, so a patient knows how put on the orthosis.
5. Reduce pressure points.

Figure 43. Subfunctions of the orthosis

8.2 Fitting

8.2.1. Different patients

The sides of the orthosis can have a lower stiffness than the bottom of the orthosis (see figure 40), making it fit for different persons. However, the stiffness should still be high enough to maintain a preformed shape for easy donning. There are several ways to accomplish this, based on the formula for stiffness: $k = \frac{3EI}{l^3}$

1. Choose a material with a higher Young's Modulus for the bottom of the orthosis and another material with a lower Young's Modulus for the sides
2. Give the bottom a higher wall thickness than the sides
3. Change the geometry, so the cross-sectional area of the sides is lower and the bottom has a large cross-sectional area

Choosing option one takes time for the production process, because the two materials have to be connected to each other. However, adding extra material to the bottom which can be bent is necessary, because a physician should be able to bend the orthosis a little to make the wrist angle-adjustable, see the requirements in section 6.1.2. Option two is not possible, because the orthosis will probably be injection molded, which is difficult for a part with a varying wall thickness, so option three is chosen. To try this, openings are made in a small part of plastic, see figure 44, after which the part is bent in a preformed shape, see figure 45. This does make the material more flexible on the sides to fit for different persons.

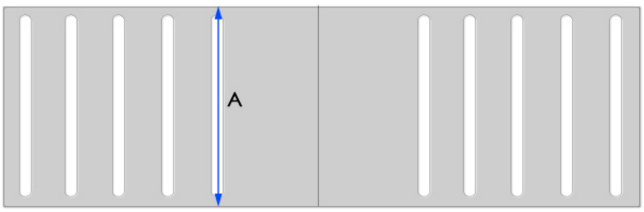

Figure 44. Openings in material, unfolded

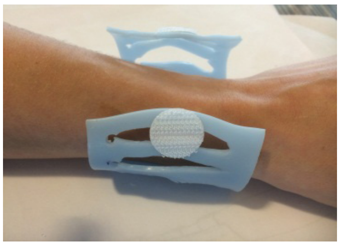

Figure 45. Model 9: Openings in plastic, preformed

Given the fact that the arm has different circumferences over its length, the openings are implemented in a larger model, see figure 46. In this same model less material is used than model 1.2, as mentioned in the concept drawing (figure 39).

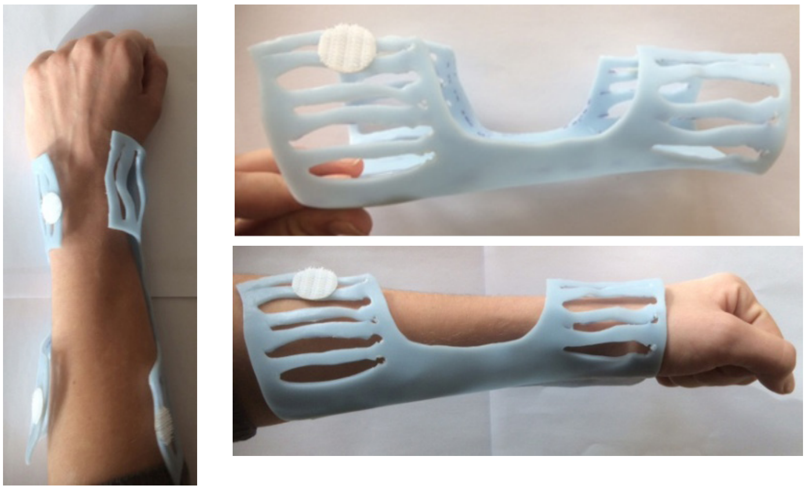

Figure 46. Model 10: Openings in the orthosis and using less material

8.2.2. Fit to patient

The openings of the model are flexible, but before it can be tested on different persons, the unfolded shape of the model should be more applicable for the form of the upperarm. The shape of this is improved by making a form study out of paper, see appendix J. or all the models. The final shape of these models is shown in figure 47.

This figure is not shown for confidential reasons

Figuur 47 Final shape of the form study

The arm of a person does not have the exact same circumferences during the night, because of less or more blood flow, change in environmental temperature and so on. The orthosis should therefore have some elasticity, to prevent wrist strangulation. This can be done by making the sides of the orthosis act more springy as in figure 48. The disadvantage of making the sides this way, is that it is less strong than the openings in figure 45, because the cross-sectional area is very small, see also figure 49.

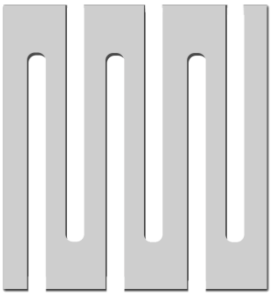

Figure 48 Sides acting like a spring

Figure 49. Difference between springy sides and openings

The final orthosis will probably have sides which are a combination between the openings and the springy sides. The material which is used to make mockups for this assignment is not appropriate for cutting small openings, making it hard to draw a good conclusion about this. See the recommendations in sectio 10 to optimize this.

8.2.3. Sizes

It is necessary to know how many different sizes should be made for production and what the sizes of the (different) orthosis should be. For this reason, the sizes indicated in figure 50 are measured for 11 adults. This are not enough persons to give a well-considered conclusion, but it gives an indication. The width of the thumb is known in Dined, so this is not measured.

The minimum and maximum dimensions for a, b, d and e and the dimensions of the different sizes can be found in appendix K. Based on these calculations, two sizes should be produced.

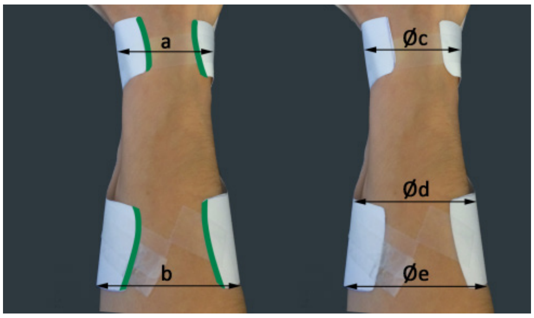

Figure 50. Dimensions that are measured

8.3. Splint

It is a requirement of the client to make the angle of the wrist adjustable, so an aluminum strip will be added to the bottom of the orthosis to make that possible. This will also add extra stiffness to the bottom. The strip has to be attached to the plastic very tight, so the plastic can bend along with the strip, see figure 51.

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Figuur 51. Attachment of aluminum strip to the plastic in a mockup

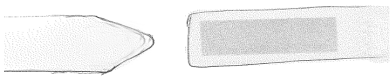
8.4. Donning

8.4.2. Closing system of straps

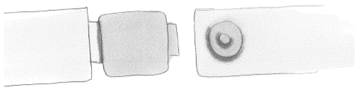
In order to make it easier to make a decision for a closing system (closing, tightening and opening), all closing systems appropriate for the straps are categorized in four ways:

1. Predefined steps

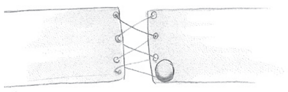
2. Continious steps (For example velcro)



3. Different mechanisms for closing and tightening (for example magnetic closure and pull tight with velcro)



4. Laces for closing and tightening and a system to "lock" the laces (For example BOA)



Implement method 4 is difficult to accomplish, because laces prevent a patient from laying down his affected hand in the orthosis.

The advantage of method one is that it is possible to injection mold it directly to the orthosis. For example see the hook in figure 56. A huge disadvantage of this system is that it is not easy to detach it with one hand.

Figuur 56 Plastic closing system

Method two is easy to achieve with Velcro, which is familiar for most people and relatively cheap. A disadvantage is that it is not very original or innovating, it sticks to other types of fabric like clothes and can get wrapped up when the straps are too long. The third method provides many opportunities for unique solutions, such as Fidlock systems(Fidlock). Fidlock uses connections with a magnetic closing system and can be detached mechanically. These are easy to use for patients with one hand, but using these connections is expensive and the closures are quite large. Also, an extra mechanism has to be implemented for tightening the orthosis, which will cost extra money.

The final choice for the closing system will probably be based on the price, except when it can be demonstrated that a more original closing system really adds a unique selling point to the product. For this assignment, the choice is made to use a Velcro closure, which is probably the most familiar for people with the age of the target group (mostly patients are older than fifty). This gives also the opportunity to use elastic straps, making the orthosis fit during the night.

8.4.3. Test closing system with chronic stroke patient

One chronic stroke patient has been asked how she thought about using Velcro for closing the orthosis. She has had an ischemic stroke in her left hemisphere in 2011, which resulted in no movement at all at the right side of her body in the acute phase. She recovered at a rehab center and lives at home now, is able to walk and can move her arm, except for subtle maneuvering of her fingers. The strength in her arm is not as good as before the stroke.

8.4.3 - 8.5.4.

This sections are removed for confidential reasons

8.5.5. Thumb
The thumb of a person will be immobilized in an opposed and adducted position (section 3.4), which is a natural position of the thumb during a tenodesis grasp.

The thumb of the orthosis will be made out of the same plastic as the part for the wrist and arm. To make the part for the thumb strong enough, an stand-up edge will be added to take care for strengthening, see figure 68. If this is not strong enough, extra ribs have to be added to the plastic.

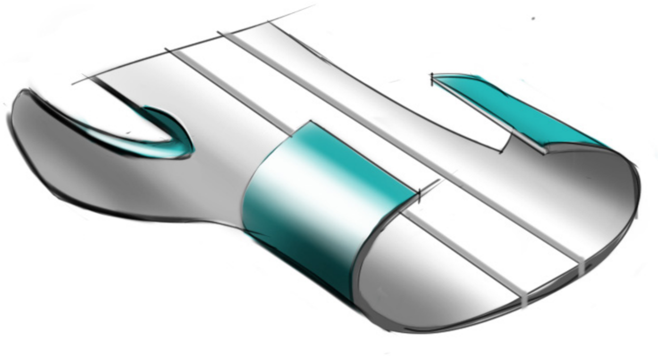


Figure 67. Thumb part with stand-up edge (straps are not included in this drawing)

8.6. Adding feedback for patients positioning/tightening
Patients need to know how to position, close and tighten the orthosis. The first time they get an orthosis, a professional like a physiotherapist will explain to the patient how to do this. The problem is that a patient can suffer from memory loss (section 2.3), so it is possible they have forgotten the explanation when they need to use the orthosis at home. This means it has to be clear how the orthosis should be worn from the product itself, so the patient has to be able to see how to put his hand into the orthosis. It should be taken into account that some patients suffer from problems with spatial reasoning or language.

Patients can see by the shape of the orthosis how it can be worn. There is a special part where the thumb can be put in, after which the fingers and arm are automatically on the right place. The same persons who are measured for the sizes for the arm, are asked to put in the arm in the mockup without explanation.

Patients who suffer from severe problems with spatial reasoning and therefore do not understand how to position this orthosis themselves or how to use Velcro, are probably not able to live on their own. The orthosis is made for chronic patients, so it is not appropriate for patients which cognitive problems.

8.7 Reduce pressure points
The orthosis should not cause any skin damage or pain due to sharp edges of the orthosis, so all edges and corners which can be painful must be rounded with padding around or inside it. Also, the inside of the orthosis will have padding, because only plastic on the skin will cause sweating and pressure points.

Furthermore, the transition from stiff parts to less stiff parts should not be very high; this would cause painful pressure to the patients. This can be solved by making the sides of the orthosis partly act like a spring, see section 8.2, causing less stiffness than the bottom of the orthosis.

9. End Proposal

Figure 68. End proposal: Plastic model, black padding and location of the straps

10. Conclusions and recommendations

10.1. Conclusions

The goal of this bachelor assignment was **to design of a wrist orthosis for stroke patients** and make a concept proposal by presentation drawings.

Based on analyses done to effects of stroke, different treatments and a market investigation, options are given what the functionality of the orthosis could be. On one hand, an orthosis should immobilize the wrist and/or fingers in an extended position for eight hours during the night, to prevent permanent shortening of muscles. On the other hand, it is important patients exercise with their affected hand to regain as many movement as possible after a stroke. This can be done by integrating the possibility to exercise with an orthosis.

For this assignment, the choice is made to immobilize the wrist and thumb. Thus the goal for this assignment is accomplished. The mechanism should be further elaborated and designed by BAAT or by the client if they want to bring it on the market.

10.2. Recommendations

10.2.1. Appearance

The appearance of the orthosis should be worked out more than is done now. This can be done by showing different mood boards or collages to stroke patients, and ask them for their preference. The colors, mood and patterns can be implemented into the orthosis.

10.2.2. Sides

For the next mockups, another material should be used than is done for this assignment, for example a plastic which can be milled. By doing so, smaller and more openings for the sides can be made which will be more precise, leading to a better conclusion about the type of openings.

10.2.3. Sizes

To draw a well argued conclusion about the different sizes and the dimensions for production, anthropometric measurements of more adults should be taken into account, especially persons with extremely small and large arms and hands. When this is done, the two different sizes have to be made with mockups which should be tried on to those persons.

10.2.5. Closing system

Only one chronic stroke patient has been asked if she understood the chosen closing system. This needs to be tested with more patients, after implementing the elastic straps as mentioned in section 8.4.2.

Testing of the closing system can be done with a mechanical test, which opens and closes the straps 730 times (opening and closing every night, for two years), based on two years guarantee of the client.

10.2.8. Thumb

The part for the thumb should be more optimized, which is not done in the last mockup. This can be done by making paper models for only the spring plate and the thumb, cut out that shape in the blue plastic and mold it until the right shape is found.

10.2.9. Reduce pressure points

The orthosis should not cause sweating or pain during wearing. This can be done by making small holes in the plastic, without losing its function, and choose a right type of padding. Mockups have to be made to feel if the orthosis does not cause pain, pressure and sweating during eight hours of wearing. These mockups should also have rounded edges as mentioned in section 8.7.

10.2.10. Production and expenses

Further investigation has to be done to optimize the orthosis for production. The shape should be optimized for injection molding. Simulation programs such as Solidworks Moldflow can be used to simulate the injection molding process, which improves the part quality.

Also, a calculation of expenses has to be done to investigate if the product can compete against other existing products. It does not matter if it is slight more expensive than other products, if the hinging mechanism is a unique selling point and leads to more selling of the orthosis.

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