

Final Report Symbionics

Perspectief programme





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Perspectief programme

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Putting patients on centre stage

Enable end-users to take centre stage, and develop assistive devices that adapt to the individual patient. That was the central premise of the Perspectief programme Symbionics: Co-adaptive devices, that ran from 2014 to 2019.

The Symbionics programme was the successor of an earlier project called Flextension, funded by the NWO domain Applied and Engineering Sciences, says programme manager Bart Koopman from the University of Twente. 'Flextension was one of the largest projects ever funded within the Open Technology Programme scheme. It was aimed at developing an arm orthosis for patients suffering from Duchenne Muscular Dystrophy. Until several years ago, these patients had a life expectancy of about twenty years. Due to recent medical interventions this has increased to about thirty-five years today, and it will keep increasing further. We need to develop suitable supporting devices to improve the quality of life, and help them stay independent as long as possible.'

Toward adaptive systems

The Flextension project led to a protype of a lightweight arm support that uses spring mechanisms to compensate for the weight of the arm. 'With the Symbionics programme we went one step further, and also looked into the possibilities of developing systems to support the trunk and the head of patients with similar types of muscular weakness,' Koopmans says. The aim was to work on so-called co-adaptive support systems, where not only the patients need to adjust to their support, but the support itself also adjust to the patients' abilities and needs. 'Ideally, this would be a continuous process,' Koopmans comments. 'Progressive diseases like Duchenne Muscular Dystrophy require devices that gradually increase the amount of support over time. But also during the day, the amount of support needed may vary. For example in case of fatigue, the support should be able to take over more of the burden. An important challenge is to determine when that moment has come, and not to overdo it, since it is key that patients keep using their



muscles as much as possible in order to train them.' The programme brought together experts from rehabilitation medicine, human movement science, modelling and control, and mechanical engineering. The focus of the programme was on arm and hand motion, trunk and head balance and form adaptation aimed at ulcer prevention and clubfoot treatment. In this programme, the needs of the individual patient were leading, not the latest technologies that can be applied. 'It is important to see the patients as the end-users and involve them early on in the design process. They often have surprising views on what a useful aid should do for them. As a researcher, it is impossible to imagine what is important for a patient. So, just ask them,' states Koopman.

Tight connection to patients

Involving the patients in the research was no problem at all, since one of the co-founders and co-funders was the Duchenne Parent Project. Director Elizabeth Vroom: 'When we started our organisation about twenty years ago, we begun by investing in medicine development. But when we interviewed our sons about

what these treatments should do, they said that they first and foremost wanted to be able to use their arms and hands. Then we wondered if that wouldn't be possible with technology. We saw a field of opportunities in the medical aids sector, and decided to engage in the development of new technological solutions by co-funding the Flextension project. That project has been very important in gaining momentum for this type of research.'

From an international point of view, a public-private cooperation on this topic and at this scale is rather unique, she says. 'As chair of the World Duchenne Organisation, a have a good overview of what is happening all over the world. And what we have here in the Netherlands is a golden team, which produces excellent academic results, and promising prototypes.'

'Not only the patients need to adjust to their support, but the support itself also adjust to the patients' abilities and needs.' Bart Koopman

Work on reimbursement systems

A big challenge remains to find investors who are willing to turn these prototypes into actual products, she says. That is one of the reasons why we decided to found Yumen Bionics. Their aim is to bring the Flextension arm orthosis to the market, in one way or the other. The fact of the matter is that we are talking about a rather small market, with about 600 patients in the Netherlands, and some 250.000 people worldwide. And not every country has the same way of reimbursing the costs of medical aids. Here in the Netherlands, it is easier to get reimbursement for a medical aid than for a medicine. In fact, the first medicine that has recently become available against Duchenne is reimbursed just about anywhere but here. But for other countries, it is hard to get financial compensation when you are in need of some sort of support system. So if we want any orthosis we develop to become a commercial success, we need to work on the international reimbursement systems as well.'

Both Koopman and Vroom are proud of what Symbionics has resulted in. Koopman: 'Look at what we achieved in just a couple of years: an arm support that is ready to enter market soon. A promising concept for a head support.

A first idea for a trunk support. Adaptive orthopaedic shoes for diabetics. And an alternative treatment for clubfeet.' Vroom: 'This program has indeed been very successful in terms of community building, expanding basic knowledge about human movement, and developing prototypes. There are several projects I am very enthusiastic about, such as the hand orthosis developed by Claudia Haarman and the support systems for the head and the trunk. The Symbionics programme was an impressive bouquet of projects, with a significant added value for the field.'

More to come

And fortunately, this programme wasn't the end of it, Koopman concludes. 'In fact, we have taken it up a notch: in the Wearable Robotics programme, even more partners are involved in the development of soft, lightweight, comfortable, intuitive to control, and affordable Exo-Aids. And in the European Horizon2020 project eNHANCE, we tried to detect the user's intention, based on eye-tracking measurements and personalised behavioural models. Ultimately, the dream is that we are able to help wheelchair-bound people get up from their wheelchair and go to the bathroom all by themselves.'

'The Symbionics programme was an impressive bouquet of projects, with a significant added value for the field' Elizabeth Vroom

Symbionics:

Co-Adaptive Assistive Devices

Budge

4.8 million euros, of which 1.4 million euros were contributed by participating companies and knowledge institutions

Size

six projects, with 9 PhD students and 3 PDEng students

Duration

2014 - 2019

Partners

Delft University of Technology: Precision & Microsystem Engineering, Biomechanical Engineering

Maastricht University Medical Centre:

Human Movement Sciences

Radboud university medical centre: Rehabilitation University Medical Centre Groningen: Biomedical Product Design, Rehabilitation Medicine, Human

Movement Sciences

University of Twente: Biomechanical Engineering,

Biomedical Signals & Systems

VU University: Physics and Medical Technology, Movement Sciences, Orthopaedics

Ilsers

Knowledge institutes:

Adelante, Pontes Medical, Roessingh R&D.

Companies: Baat Medical, Dr. Comfort, Festo, Focal Meditech, Hankamp Rehab, Hocoma, Intespring, Maastricht Instruments, Moog, Orthin/Achilleonzorg, TMSi XSens, VTEC Laser & Sensors.

Other organisations:

Duchenne Parent Project
Dwarslaesie Organisatie Nederland
Foundation to Eradicate Duchenne
FSHD Foundation
Parent Project Muscular Dystrophy
Spierziekten Nederland

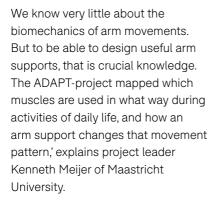


Proiect 13523

Adaptation to arm supports

Dr. K. Meijer (Maastricht UMC+), H. Essers, MSc. (Maastricht UMC+)

Many of the currently available arm orthoses are more or less developed according to a 'one-size-fits-all' philosophy. At Maastricht University and the University Medical Center Groningen Kenneth Meijer, Hans Essers, and Alessio Murgia worked on personalized muscular models to identify the best support solution for each individual patient.



PhD student Hans Essers conducted several experiments with healthy persons and patients suffering from muscular weakness, both in the lab and in their personal environments. The research consisted of two major parts, he explains. 'For one, we studied the acute effects of using an arm support for daily life tasks. For this part of the research, we asked people who had never used an arm support before to come to our lab. There we used accelerometers, optical measurements and electromyography (EMG) to

quantify changes in movement patterns.

Worthwhile to support shoulder or back

These experiments were done both with healthy subjects and with people suffering from muscular disorders, varying from Duchenne muscular dystrophy and Spinal Muscular Atrophy to Facioscapulohumeral muscular dystrophy (FSHD). From the acute experiments, the researchers concluded that FSHD patients display significantly different control programs. 'The open question is whether or not that can be trained, says Meijer. 'By using a support system, in principle you are able to change the muscle program and influence the muscle tensions. For the FSHD patients for example, we saw that by supporting the shoulder muscles, it is possible to increase their maximum reaching distance. So there is definitely an added value of supplying the right





support there. Furthermore, we saw that in this same FSHD patient group, the lower back muscles that control the shoulder are less active than in healthy persons. These muscles are needed to lift your arm higher than ninety degrees. This finding raises questions on how to support that movement best. Perhaps we should rethink using arm supports for that type of movement, and focus on supporting the shoulder and lower back instead.'

In the second part of the study, the researchers wanted to gain insight into

how active patients are at home, and for what kinds of activities they would typically decide to make use of their arm support. For this research, patients with muscular weakness who were already making use of an arm support were found through patients' organisations, such as the Association Spierziekten Nederland. The participants were asked to wear a set of four sensors on their lower and upper arm, wheelchair, and the support for a week, and keep a diary of their activities during that period of time.

Gain independence

'What struck us most, was that some patients try to use the support as little as possible, say Essers and Meijer. 'Even if it would save them energy to use the support, they would still choose to undertake an activity unsupported and rest afterwards. The main reason for them for using the support is to be independent of caregivers, and not need to ask someone else for example to scratch their nose or straighten their glasses every time. This could be valuable information for doctors and insurance companies in deciding when to promote a support system, since sooner might be better. Relieving the load off the shoulders of relatives could be an important reason to prescribe an arm support for a patient.'

Finding the right support

The initial aim of this part of the research was to investigate the possibility to deduce which activity a subject is undertaking from the sensor data alone. But that turned out to be one step to far. Essers: 'From the data of the sensor on the wheelchair and support we could deduce whether a patient was mobile, was resting at one place, or if the support device aided their motions or not. And from the combined data of the wrist and upper arm if he was lifting his entire arm or merely moving the wrist. But other than that, without any further context it is very hard to deduce what someone

is doing.' That doesn't mean that using mobile sensors to observe these patient groups at home is useless, Meijer says. 'We think this mobile sensor network, provided to us by Maastricht Instruments, is very promising for companies like Focal Meditech to speed up the matching process between patient and arm support. At the moment, patients get one type of arm support for a period of several months, to determine whether or not it helps them in the right way. If you can quantify which muscles need to be supported in what way during daily activities in their own home environment, it should become much easier to fit each individual patient with the best available solution.'

Essers is currently undertaking steps to put this way of measuring muscle activity and movement patterns into a smart watch application. And Alessio Murgia is working on a proposal for a follow up research project.

Researchers

Chris Baten, MSc. Arjen Bergsma, PhD Hans Essers, MSc. Prof. Bart Koopman Kenneth Meijer, PhD Alessio Murgia, PhD Prof. Peter Veltink

Users

Adelante
Focal Meditech
FSHD Foundation
Maastricht Instruments
Parent Project Muscular Dystrophy
Roessingh Research and Development
Xsens

'Symbionics was great cooperation between patient organisations, clinicians, scientists from different disciplines and companies. And it worked out well, since you see the same group of people cooperating again in follow up projects and programmes.' Kenneth Meijer

Exploring new application areas

Freek Boesten, Business Development Manager at Maastricht Instruments

'Our company develops wearable sensors that measure a persons' physical activity and posture with unprecedented accuracy. Their specifications make them perfectly suited for scientific research and medical purposes. Currently, our sensors are mostly used on people who move very little, to register for example if someone is sitting, standing or walking. We were interested to participate in this specific research project since it wanted to investigate the movement patterns of upper extremities. For us, this was a good opportunity to explore this new application area. Besides supplying the sensors and adjusting the software in such a way that the data could be used for the purpose the researchers had in mind, our role in this project was also to help shape the focus of the research in order to end

relevant for a broad target group.

Our participation in this project has brought us a number of things. In the first place, it led to a proof-of-concept of measurements of upper extremities movement. We are now conducting discussions to assess whether the outcome measures used in the initial experiments, such as the amount and scope of movement, would be the same for all possible application areas, such as quantifying recovery after stroke, or measuring movement limitations as a result of an injury. Furthermore, through the Symbionics programme as a whole, we got to meet other companies that are active in our field. These contacts are very useful, also for the future.

Project **13524**

Research aid as promising product

Prof. dr. ir. H. van der Kooij (Univerity of Twente) en dr. N.W.M. Beckers (Univerity of Twente)

Scientific research is inherently unpredictable. That is nicely illustrated by the PhD work of Niek Beckers within Symbionics project 1.2. He set out to investigate why individual motor learning is improved when two people coupled through a haptic device perform a collaborative motor task, only to find out that isn't the case at all. Luckily, the device he developed to perform his research with turned out to be very promising for further development.

Project leader Herman van der Kooij from the University of Twente - who took over this Symbionics project from Arno Stienen when PhD student Niek Beckers had already been working on it for about two years matter-of-factly recalls what happened: 'The starting point for the theoretical part of the research was a study published by a collaboration between Japanese and English research groups. They claimed that if two people learn the same motor task together while they are physically coupled, then both of them will learn the task faster. We imagined that based on this idea, we could perhaps couple a patient recovering from some sort of movement impairment to a haptic robot or through a haptic device to another patient, and speed up the patient's motor recovery process.'

The researchers varied somewhat on the experiments done by their English colleagues, but saw no effect on learning, neither positive nor negative. And when they tried to reproduce the initial study, they failed to get the same results. 'That meant that the basic assumption underlying the original research plan had vanished in thin air. Although this was a serious bummer for Niek, it was an important result. By falsifying the initial claim, we prevented the introduction of new types of haptic rehabilitation systems that wouldn't have any added value.'

Unintended side effect

The research had a very nice unintended side effect though, Van der Kooij says. 'The device Niek developed to test the initial hypothesis works very well, and can also be used for other applications.'



Beckers' so called BROS (the Bi-partner RObotic Setup) consists of two identical planar parallel robotic manipulanda. Users hold the robot by a small handle that is mounted onto two carbon-fiber reinforced arms. A series of joints allows for movement in the horizontal plane. Through a haptic feedback system, a force exerted by person 1 on system 1 is felt by person 2 who is controlling system 2, pushing his hand in the same direction. Van der Kooij: 'The design is very robust. We have used it intensively and it did not fail. And it is very accurate in measuring and transferring the forces in real time.'

Together with a Master student, Beckers has developed a few simple games for the system. Van der Kooij and Beckers are now actively seeking new application areas for the device. One could for example use these coupled systems to assess upper extremity impairment by asking a patient to perform a certain task with one hand and follow that movement with the other. Or it could be used to quantify whether or not a treatment is useful, by measuring how fast a patient - who is recovering from brain damage - relearns to coordinate bimanual actions,' says Beckers. 'Because the system is

modular, you can add and couple as many individual haptic robots as you want. Perhaps this would also be nice for some sort of group therapy. Although my research showed that haptic collaboration does not necessarily speed up the learning process, but to make training more fun, leading to enhanced therapy compliance.' Hankamp Rehab, the company that helped in building the system, has expressed interest, and Beckers and Van der Kooij are currently discussing options for further development. PhD student Niek

Beckers has worked on his research in close cooperation with the two PhD students from Symbionics project 1.3., Ronald Bos from Delft University of Technology and Kostas Nizamis from University of Twente. Furthermore, as part of this project, PDEng candidate Teun Stortelder has been working at one of the involved companies, Hocoma, on the development of a distal upper extremity training robot that helps people who are recovering from a stroke to use their fingers again.

The Haptic robot in the lab. Photo: Rikkert Harink



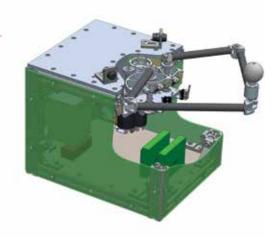
Researchers

Niek Beckers, MSc. Ronald Bos, MSc. Herman van der Kooij, PhD Dick Plettenburg, PhD Arno Stienen, PhD Teun Stortelder, PDEng

3D render is made by Koen Heuver (Hankamp Rehab)

Hsers

Festo Hankamp Rehab Hocoma Moog



Search for applications

Freek Tönis, CEO of Hankamp Rehab and Hankamp Gears

'Our company develops products for the rehabilitation market. In order for our products to be certified to CE standards, regulations require that we are involved in fundamental research. When Arno Stienen from the University of Twente asked me to participate in this project, I said yes without hesitation. We helped Niek with the design and production of his bi-partner robot. At the moment, we

are looking into the possibilities of using this device in a rehabilitation setting. The nice thing about his solution is that it isn't nearly as expensive as other systems with comparable functionality that are currently on the market. What we need now, is solid research into the added value of such a system for rehabilitation practice.'

Proiect 13525

Novel concepts to support hand movement

Dr. ir. D.H. Plettenburg (Delft University of Technology)

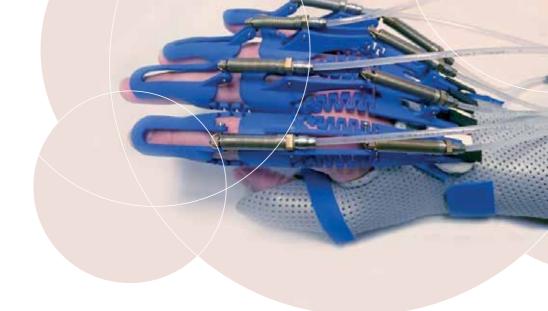
People that suffer from Duchenne Muscular Dystrophy gradually lose muscle strength, progressing from the shoulder toward the hand. In this project, two PhD students and a PDEng worked on novel concepts to support grasping and manipulation of the hand in an intuitive way.

Being able to move your hand at will is very important for a person's autonomy and quality of life. Patients suffering from Duchenne Muscular Dystrophy often express the desire to be able to use their hands for small daily life activities, such as scratching their nose. At Delft University of Technology, University of Twente and Hancamp Rehab, PhD students Ronald Bos and Kostas Nizamis and PDEng candidate Claudia Haarman developed novel concepts to support these types of hand movement. Since people with Duchenne not only suffer from muscular weakness, but also have a sensitive skin, the interaction forces should be gentle. Furthermore, the orthosis needs to be put on finger by finger, since patients suffer from muscle contractions in the fingers, which makes it impossible to put on a glove. None of the existing hand orthoses meets these specific needs.

Investigating hydraulics as alternative solution

At Delft University of Technology, Dick Plettenburg supervised the research of Ronald Bos. 'Ronald started by composing an extensive overview of what kinds of hand orthoses had already been developed. Most of the currently available orthoses are based on electromechanical control. We asked ourselves the question if it would be possible to develop a solution based on hydrau-lics instead. In theory, this could be a lightweight, fast and small alternative.'

The joint research of Bos, Haarman and Nizamis resulted in SymbiHand, an active orthosis controlled by a master hydraulic cylinder that actuates slave cylinders leading to the separate fingers. The hydraulics are controlled by a pump, which is the only electronic component in the system. 'The total mass on the hand



for this first model is 250 grams, but that can be decreased with a better design,' says Plettenburg. This prototype has been tested on a patient, and was able to successfully assist the participant's hand, resulting in lower effort and increased grasping force. 'This shows that hydraulics are indeed an interesting alternative to electromechanics when it comes to designing orthoses.'

Using nerve signals for control

The SymbiHand can help a patient to pinch rather hard, even when all of his muscle power is gone. The trick to that lies in the work Kostas Nizamis did in Twente, says Plettenburg. 'Kostas studied the electromyographic signals in the forearm of Duchenne patients. Even if the muscle power is gone completely, the nerves are still sending signals from the brain to the hand. Kostas found ways

Proof of concept of the active hand support.

Researchers

Ronald Bos, MSc.
Claudia Haarman, PDEng
Kostas Nizamis, MSc.
Dick H. Plettenburg, PhD
Arno H.A. Stienen, PhD

Users

Duchenne Parents Project Hancamp Rehab Festo Pontes Medical TMSI to amplify these signals in such a way that they can be used to control the movement of the fingers through the hand orthosis.'

The fact that there is a working prototype, does by no means indicate that such a hand orthosis will be found on the market anytime soon, warns Plettenburg. 'A lot of further development is needed before we

can start thinking about a marketable product. For example, in this first model, the forces were too high. Since this group of patients has very sensitive hands, that could hurt. And as far as the design goes, the SymbiHand does not look like anything you'd want to wear on a daily basis. There is still a lot of work to be done in improving robustness, the way it looks, and the ease of use.'

Attracting talent

Freek Tönis, CEO of Hankamp Rehab and Hankamp Gears

'Though the SymbiHand prototype definitely demonstrates an interesting new technology, developing it into a user-friendly orthosis will be fairly complex. For the hydraulics to work, you need to put quite some weight on the patients' hand, which is undesirable. For our company, the biggest yield of participating in this specific project is that Claudia Haarman decided to come and work for us. It is hard to find qualified people in our line of work, and in Claudia we found an excellent addition to our team. During her PDEng work at Hancamp Rehab, Haarman developed a novel force transmission mechanism based on tape springs. The actuator force is transmitted to the finger by a system consisting of a tape spring, two slider blocks and an end stop per finger. The tape spring allows for bending in one

direction, and resists bending in the other direction. Where other orthosis often make use of springs to exert a force on flexed fingers, Claudia's design works the other way around: it keeps the fingers extended, and a force is needed to flex them. She is currently pursuing a PhD on this design to further develop it.

The group of patients with Duchenne Muscular Dystrophy forms too small a market to make a product commercially viable. Claudia's design could also be useful for other groups of patients who have problems in flexing and extending their fingers, which makes it an interesting concept for us to invest in.'

To see the SymbiHand in action, view www.youtube.com/watch?v=jpHjlFM0t3Y

Proiect 13526

Taming the trunk

Dr. ir. I.J.M. de Groot (Radboudumc)

Control of trunk posture and head movement are essential to position and visually control your hand and arm for functional use. In this project, that consisted of three sub-projects, researchers from Radboud university medical center, University of Twente and the Vrije Universiteit studied the activities of trunk and arm muscles in healthy persons and in patients, and used this knowledge to develop prototypes of both a head and a trunk support.

Assistive devices are mostly designed to support one specific function, such as an arm orthosis that enables someone who is suffering from muscular weakness to lift his arm and grasp a cup of tea from the table. Unfortunately, when the tea is not within immediate reach, that same patient probably won't be able to bend over and reach out to pull it closer, since his muscles are too weak to pull his trunk back up against the force of gravity. This project was aimed at solving the problem of how to develop a trunk and head support that assist for example patients suffering from Duchenne Muscular Dystrophy in daily activities, without restricting their movements. At Radboudumc. PhD student Laura Peeters investigated the relation between pelvis, trunk and head movement in interaction with upper

extremity movement, both in healthy children and in children with muscular weakness as a result of Duchenne Muscular Dystrophy (DMD) or Spinal muscular atrophy (SMA). For example, she asked eighteen boys with DMD and twenty-five healthy controls to perform several tasks when sitting unsupported, like reaching forward and sideward, drinking and displacing a dinner plate. 'Since she needed people who are able to sit without support for ten minutes on end, and the muscle strength of DMD patients deteriorates rather quickly, this meant that her subjects were fairly young, explains project leader and rehabilitation physician Imelda de Groot. 'We are very grateful that these patients and their parents were willing to take days off from school and work to come to our hospital and cooperate in this research.'

Overcompensation leads to fatigue

Laura recorded the movements of the arms, head, pelvis, and sub-sections of the trunk with an optical motion capture system and measured the muscular activity with the aid of electromyography (EMG). Boys with DMD turned out to use their trunk more intensively to compensate for reduced arm function. 'Say for example they wanted to lift their right arm. Then they would typically lean to the left to help their upper arm overcome gravity.' Furthermore, the measurements showed that the patient group used an increased percentage of their maximum muscle capacity to perform tasks. 'This means that even for relatively simple tasks, patients need to perform at the best of their muscular ability. That is exhausting. So if we can develop a supportive system that lifts some of the burden, they might save some energy for other activities, concludes De Groot

At VU University, PhD student Nauzef Mahmood developed a prototype of a trunk support that should help patients in getting back up after bending forward. 'We have developed this prototype together with Laevo,' says project leader and movement scientist Idsart Kingma. 'That company is selling an exoskeleton that supports the back during heavy lifting, based on a specialized gas

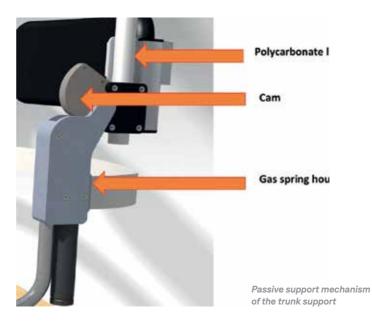
spring. Nauzef based the trunk orthosis on the same idea.' His prototype has five interface areas with the body: a front pad placed on the sternum, two adjustable side pads to provide stability, one back pad to support the lower back and a cushion to sit on. To compensate for gravity, a rotating joint containing the gas spring enables the top of the device to bend backward and forward with respect to the cushion.

Lowering muscle activity

Together with Laura Peeters in Nijmegen, Nauzef studied how the trunk support affected the amount of muscle activity needed to flex the trunk to predefined inclination angles and extend it back to an upright position. In ten healthy people, the muscle activation levels of the thoracic muscle and the lumbar back muscles dropped by twenty percent. Then we proceeded to measurements in a few patients. Unfortunately, we had to conclude that for this study. their characteristics were too different to obtain any generalizable results,' says Kingma.

This first prototype of a trunk support was a passive one. The ultimate aim though is to develop a support system that responds to the intentions of its user. At the University of Twente, Stergios Verros looked into different options to control such an active trunk support. Project leader





and biomechanical engineer Bart Koopman: 'The main question he tried to answer was how to control and operate such a support in an intuitive way. The problem with people who have been stuck in a wheelchair for a longer time, is that they tend to gain fat tissue. This decreases the power of the EMG signal, making it harder to base the control on measurements of the muscle activity. Stergios has looked for alternative ways of control.'

Finding the right controls

First, the PhD student made a setup to measure muscular power, where subjects needed to press their trunk against a bar. From these measurements, Stergios could deduce both what range of muscle power needs to be controlled, and what control intervals would be useful. He also looked into different control interfaces, and how suitable they would be for these types of support systems, says Koopman.

Verros compared a joystick, force on the sternum, force on the feet and EMG. All of these interfaces turned out to be feasible solutions, each with their own advantages and disadvantages. For example, force on the sternum is a fast way of controlling a device, but it also turned out the most fatiguing option. A control system based on applying a force on a base plate with your

feet turned out to be slower, but easier to implement.

Supporting the head

Besides on the the trunk support, at the Vrije Universiteit Nauzef Mahmood also worked on a head support, says Kingma. 'That system is based on the same idea: bending over is not that hard, since gravity will help you. You need the most support in holding the head in a bend forward position, and in lifting your head to an upright position.' The interviews the three PhD students held during the project with the patients provided crucial information for this design, says Kingma. 'Patients found fixation of their heads in one position very oppressive. They wanted to be able to turn their head, for example to look sideways when crossing a street in their wheelchair That was the main challenge here: finding a solution that compensates for gravity and at the same time enables rotation of the neck and head'

De Groot adds: 'Current head supports fixate the neck in a position where the patient is constantly facing the ceiling. We need better designs to enable them to look other people in the eyes, or to look around. Nauzef's first prototype is a very promising solution for that problem.' User committee member Focal Meditech is interested in the concept.

They have been working on actuated head supports themselves, with PDEng Anoek Geers. Geers studied the current use of headrests, formulated the bases for the new generation head support and built a prototype. Currently, she is working on the next phase of the design at Focal Meditech, and pursuing a PhD at the same time

We are going to apply for a patent for Mahmoods' head support, says Kingma. 'And Focal Meditech is interested in further developing it. As far as the trunk support goes, the researchers involved are applying for an NWO Demonstrator grant to work on that some more.'

Going the extra mile to enter the market

Micha Paalman, CTO Yumen Bionics

'The predecessor of Symbionics, the Flextension program, resulted in a prototype of an arm support. After the project ended, Yumen Bionics was founded to further develop this support and bring it to market. During the time the Flextension program ran, we learned that to improve arm movement, you also need to work on the head and the trunk. This specific Symbionics project was aimed at understanding the support of the hand function as a whole, instead of focusing on supporting the arm alone. The researchers investigated the whole chain of the arm function, reaching from the hand function all the way to the trunk movement and the head function. The nice thing about project 2.1 is that it covered the entire chain: from measuring movement during daily life activities to actually developing first protypes of both

a head and a trunk support. Though it is nice that we now have a deeper understanding of arm, head and trunk movements, I do think that if the project would have focused more on the mechanical side of the design, we would have ended up with something that would be closer to market than it is now. Companies typically tend to be only interested when an idea is as close as possible to their own line of products. This could hamper the adoption of the knowledge in the market. As far as this specific Symbionics project is concerned, we strongly promote that Focal Meditech will take up the head support and develop it further. Of course, as Yumen Bionics, we will help them in any way we can to get a support system with so many urgently needed functionalities on the

All an all, within this project, the first steps have been made toward a trunk and a head support that ultimately should be integrated with the existing Flextension arm support. Koopman: 'As the life expectancy of Duchenne patients increases, we need more support systems that can help improve their quality of life. This project has resulted in several promising concepts. The next step is to go from passive systems to systems that are able to adapt to the needs and possibilities of the user. That is something we will work towards in the Wearable Robotics program.'

Support for spinal segments

De Groot: 'This project has been instrumental in gaining more knowledge about trunk movement. All of the currently available support systems are based on the premise that you need to support something that resembles a tree trunk. But a spine is very flexible. In order to mimic natural behaviour, a support system should allow for independent movement of the different spinal segments.' Kingma adds: 'That is also true for head movements. Mechanics tend to think of a neck as a simple joint. But when you look closer, you see that to bend your head, other vertebrae are needed than to rotate it. That makes it rather challenging to develop a single system that supports all possible head movements,

from two dimensional bending and rotating to three dimensional tilting.

De Groot concludes: 'Of course we first and foremost need to find a cure for devastating diseases like Duchenne muscular dystrophy. But as long as these neuromuscular disorders are incurable, smart aids like arm, trunk and head supports can make life a lot easier for these patients.'

Researchers

Arjen Bergsma, MSc.
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Imelda de Groot, MD, PhD
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Hsers

Baat Medical

Duchenne Parent Project
Focal Meditech
Foundation to Eradicate Duchenne
FSHD stichting
Hankamp Rehab
Intespring
Parent Project Muscular Dystrophy
Roessingh rehabilitation Centre
Spierziekten Nederland

'Within the Symbionics programme, technicians and clinicians truly interacted. Everyone was very involved, contributed from their own expertise, and was prepared to listen to other points of view. That was very stimulating.' Imelda de Groot

Better knowledge leads to better support systems

Paul Groenland, General Manager and founder Focal Meditech B.V.

'We are glad that we participated in the Symbionics programme, since it has increased both our knowledge and our network. There are not that many funding possibilities for research into solutions for everyday problems. We are a compant that develops technical aids to enable people struggling with functional impairments to regain some of their independence. For us, these types of collaborations with academia are crucial to fill in voids in our knowledge and help base our products on consolidated knowledge about the human body and needs of patients.

It is my firm believe that technology should understand and adapt to humans instead of the other way around. Take the Geers has been working on during this Symbionics-project. Current head supports tend to fixate the head in a certain position. Anoek has been working on ideas to develop a head rest that supports the head without limiting its movements. Since two years turned out to be too short to come to a mature prototype, we decided to ask Anoek to come and work for us. Currently, in a cooperation with Roessingh Research and Development and University of Twente, she is investigating the movement of the human head into more detail in order to decide exactly what movements a technical aid should be able to make, and in what way exactly we should support the head and neck.'

Project **13527**

Objectification as a starting point for improvement

Prof. dr. ir. G.J. Verkerke (University of Twente) en dr. P.G.M. Maathuis (University Medical Center Groningen)

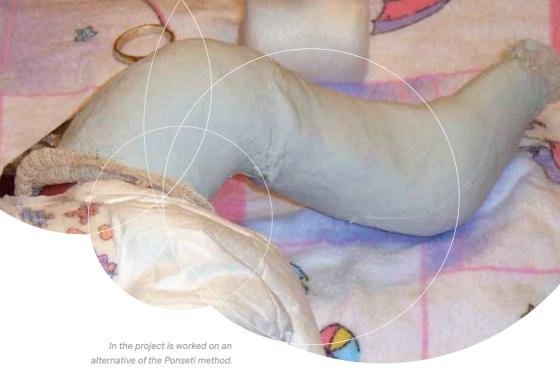
Clubfoot is the most common congenital disease affecting the lower leg of new-borns. The Golden Standard to treat this disease is the so-called Ponseti method, which includes position corrections followed by plaster casts. Though this method is very effective, nobody really knows why. In this Symbionics project, clinicians and technicians did a first attempt to quantify the method, and developed a prototype brace as an alternative for the plaster casts.

A clubfoot is a congenital complex foot deformity, which occurs in one out of every 1000 children. Currently, such a foot is treated within a week after birth with the Ponseti method. A doctor will manipulate the foot into a slightly corrected position and fixate it with a plaster cast reaching from toe to diaper for one week. This is repeated 5 to 8 times until the foot is fully corrected. After this casting period the child has to wear a brace during the night for about four years to prevent relapse.

The effectivity of the treatment is by no means a topic of discussion, says orthopaedic surgeon Patrick Maathuis from the University Medical Center Groningen. 'We know it works rather well, but interestingly enough, we don't really know how it works. For example: we apply the casts for one week at a time, but there is no empirical proof that this is indeed the optimal period. As physicians, we tend to do things the way we are used to, without questioning the reasoning behind it. That's what makes collaborating with technicians so interesting for me. From their background, they ask different types of questions, which is very refreshing.'

Inspiration from scoliosis solution

The idea for this specific research project grew gradually, say both Maathuis and project leader Bart Verkerke, who is professor in BioMedical Product Development at both the University Medical Center



Groningen and the University of Twente: 'Previously, we have been working on an adaptable corrective device for scoliosis, a medical condition in which a person's spine is curved sideways. Instead of forcing the patient's spine in a predefined mould, our solution was to constantly apply a force, and by doing so, correct the spine's position in a gradual way. We wanted to explore the possibility to use this same idea of applying a constant force to develop a new kind of clubfoot treatment.'

Maathuis: 'The first thing the technicians asked me as a doctor was: "What force do you use to manipulate the foot?" Since they weren't satisfied with my answer

'There has been ample contact between the PhD's of all six projects to exchange ideas. In terms of technology, the differences between the various projects weren't that big.' Bart Verkerke

"as much as needed, based on the response of the child", PhD student Bob Giesberts first developed a method to measure the forces doctors exert on the foot in different stages. The nice thing is that with this project, for the first time we researched the basis of this commonly used treatment, to find out how it works and what improvement possibilities there are.'

Measuring force and temperature

Giesberts developed an instrumented clubfoot model with force sensors and asked 17 different practitioners to treat it with the Ponseti method. The variability between the different practitioners turned out to be very high. Furthermore, he developed a small sensitive and robust force sensor to determine how fast the tissue in the clubfoot adapts to the new position after each manipulation, by measuring the force the foot exerts on the cast. From measurements during the treatments of ten clubfeet it became clear that the foot tissues adapt to the new position within several hours, leading to the hypothesis that the required correction time may well be much shorter than the generally accepted period of one week.

'An interesting bycatch was the finding that the plaster casts induce rather severe temperature changes in the foot,' says Maathuis. 'Since the calibration of the force sensor required a temperature sensor to be plastered in as well, we got the opportunity to measure how the exothermic reaction between the plaster and the water and the subsequent endothermic evaporation of the water influenced the temperature of the foot.' Giesberts found that during the drying of the cast, the temperature could drop down to

26 degrees Celsius. This potentially discomforting temperature lasted for 12 hours after the cast had been placed.

Promising prototype

Finally, within the scope of the project, a variety of concepts for a dynamic clubfoot brace have been developed, Verkerke says. 'Both Baat Medical and Orthin played important parts in this development. Baat Medical provided us with some useful insights into design protocols that are needed to ascertain CE certification. and they performed some initial market research to get an idea of what kinds of companies would be interested in producing such a brace. They also developed a prototype for us. Orthin helped us develop and produce another prototype.' The most promising design turned out to be a spiral-shaped brace that uses a spring to apply the proper correction moments on the foot.

Verkerke: 'Together with Orthin we are now looking for ways to expand on this first prototype. We are writing a proposal for the Medical Ethical Committee to use the brace instead of the plaster casts in ten actual patients. To pay for this research, we will apply for an NWO Demonstrator grant.' Maathuis: 'This research has made the first small but important steps towards a possible alternative for the Golden Standard Ponseti

method. It will take some time to convince clinicians to move away from the treatment they are used of giving. But if we are able to prove in a small clinical trial that the brace works evenly well and has less disadvantages, that will be a major step toward a treatment that enables parents to cuddle with and bath their child without having to work around a large plaster cast.'

Researchers

Bob Giesberts, MSc Edsko Hekman, MSc Patrick Maathuis, PhD Prof. Bart Verkerke

Hsers

Achilleonzorg
Baat Medical

Motivated to help young children

Marion Wieringa, Managing Director Achilleonzorg, of which Orthin is a part

We have been cooperating with orthopaedists of the University Medical Center Groningen for over thirty years. Our prosthetists actually work in the hospital. As soon as a child is done with the plaster casts, they come in, take all the measures needed, and produce the handmade, tailormade braces that are needed for that specific patient. Of course we are a commercial company, and we need to make a living for our fortysomething employees, but for us, our main motivation lies in improving these little patients' quality of life. That is why we didn't hesitate for a moment when we were asked to participate in this project. The fact that a treatment like the Ponseti method is well-established and works well, should never be a reason to stop looking for better alternatives.

According to our nature as instrument makers, we had a very hands-on role in this project. All of the prototypes have been made at our premises. Also, one of our instrument makers has contributed much knowhow about what can and can't be done with certain materials and designs, and how to make sure that a design is robust and easy to use in daily practice. I am very happy with the prototype that eventually resulted from this cooperation, and I sincerely hope that further medical trials will show that a brace can indeed be a good alternative for the current plaster casts. I imagine it would be a major relief for the parents if their children wouldn't have to be covered in those large plaster casts

Project **13528**

Alleviating foot sole pressure

Prof. dr. K. Postema (University Medical Center Groningen)

Patients suffering from Diabetes Mellitus are at risk of developing foot ulcers. These ulcers are hard to treat and can even necessitate amputations of the foot or lower leg. At the University Medical Center Groningen, PhD student Roy Reints developed two adjustable footwear concepts for the prevention of Diabetic foot ulcers.

In the Netherlands alone, 800.000 people are diagnosed with Diabetes Mellitus. Around three percent of these patients will develop a foot ulcer. In fifteen percent of these cases, an amputation of the foot or lower leg is needed. The main goal of this project was to develop two insoles that help in the prevention of diabetic foot ulcers, with the ultimate aim to lower the number of long term hospitalizations and lower leg amputees, and to improve the quality of life.

'Diabetes induces neuropathy.

Since the proprioceptive feedback is decreased, people are not aware of any high pressure spots that can develop under their foot sole,' explains project leader Klaas

Postema. 'Furthermore, as a result of the disease, the skin quality and the amount of subcutaneous support tissue decrease and the blood circulation deteriorates. All in all,

bones are more likely to press down on certain points of the foot sole during standing or walking. This leads to damage faster, and the damage heals slower.'

The main goal of the Symbionics project was to measure both the pressure and the shear stress the foot sole experiences and to alleviate those when they exceed certain thresholds. 'The most challenging part turned out to be measuring the shear stresses,' Postema comments. 'One of the companies that was involved in our user committee, VTEC, has been working on this for quite some time, but unfortunately in the end had to conclude that it wasn't possible.'

Adjustable rocker

That doesn't mean at all that the project failed, he says. 'PhD student Roy Reints has studied different rocker soles to optimize the heel-to-



toe gait and thus alleviate the pressure on the forefoot and first toe." A rocker sole shoe has a thicker-thannormal outer sole with rounded heel to ensure the wearer has a natural foot unroll. Together with the American diabetic footwear producer Dr. Comfort, Reints developed an adjustable rocker profile which allows for easy adjustments to the apex position and apex angle. 'Our design enables moving the line where the sole starts to go up under the forefoot in a flexible and fluent way, tailormade to the patient's pressure profile.' A prototype has been made in the form of a loose exterior sole that can be

attached to a shoe with Velcro. 'Since during the project, Dr. Comfort changed its focus somewhat, we are currently discussing business opportunities with another company that is interested in our concept." A second concept Reints developed, is a self-adjusting insole that automatically changes the supporting surface when pressures exceed a set threshold. That is a truly remarkable piece of work," says Postema. 'When we started the project, we were aiming for an electronic system of pressure sensors and some sort of actuators. But what Roy came up with, is an

ingenious mechanical system, which is much simpler, cheaper and doesn't need any wires or batteries.' The inner sole Reints invented consists of three-dimensional hexagon-shaped elements, that drop down only when pressures are exceeding a certain threshold. 'This system effectively distributes the pressure in a seamless way. And the beauty of it is that when the location of the pressure spots changes over time, the system will adjust itself and offload high pressures at other locations. It is easy to produce, has a very direct way of controlling the pressure and is easy to use. We are currently in the process of filing for a worldwide patent.'

Within the scope of the project, the researchers conducted a small initial study to test the impact of wearing a combination of the rocker profile and the newly developed insole. 'This combination turned out to significantly lower the peak pressures under the foot. In a follow up project, these effects will be studied in further detail'

Researchers

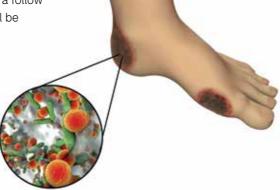
Juha Hijmans, PhD Prof. Klaas Postema Roy Reints, MSc. Prof. Bart Verkerke

Users

Dr. Comfort

VTEC – lasers & sensors

'I really enjoyed the yearly symposia, where I have learned a lot from interacting with people from different backgrounds who were working on so many interesting topics.' Klaas Postema



Fun with bolts and joints

Dr. Roy Lidtke, Assistant Professor of Internal Medicine, Section of Rheumatology, Rush University Medical Center, Staff Physician Physical Medicine and Rehabilitation, St. Luke's Hospital, previously medical advisor for Dr. Comfort

'During the period that I was working as a consultant for Dr. Comfort and DJO global, Klaas Postema asked the company to cooperate on a project about rocker bottom shoes. The timing was spot on: the company was considering a line of rocker bottom shoes, since traditionally they weren't very successful in a commercial sense. We were looking for ways to produce a shoe that could be tailored to the individual, but produced in bulk. Roy visited me here in the US several times for about a week during which we would fabricate different prototypes. That was fun: I could combine my expertise on biomechanics with my experience in shoe fabrication to teach Roy the ropes. We would typically go to a hardware store to buy the bolts and joints

we needed and then turn his ideas into prototypes. Roy's designs are very promising. But the problem with these types of inventions always is how to produce them in a cost effective way and market them, and not in the least, how to find the right company to do so. During the course of the project, Dr. Comfort has been sold and changed its course. And since I left the company two years ago, I doubt they are planning to take this any further. To build a solid business case, the next step would be to organize a clinical trial and test in a longitudinal study to see if these outer and inner soles indeed prevent ulcers or help them heal faster. And if that turns out to be the case, the researchers need to find the right company to take this to market.'

Colophon

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