THE WEARABLE HAND ROBOT

*SUPPORTING IMPAIRED HAND FUNCTION
IN ACTIVITIES OF DAILY LIVING AND REHABILITATION*

Bob Radder

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Part of the work in this thesis was performed within the ironHand and HandinMind projects, partly funded by the Active and Assisted Living (AAL) programme (AAL-2013-6-134), via ZonMw (the Netherlands), Vinnova (Sweden) and SERI (Switzerland) and EUROSTARS (Project E!8227) via the State Secretariat for Education Research and Innovation (Switzerland) and Vinnova (Sweden).

The publication of this thesis was generously supported by:

Cover design: Femke Hugens

Printed by: Ipskamp printing - The Netherlands

ISBN: 978-90-365-4658-4

DOI: 10.3990/1.9789036546584

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PROEFSCHRIFT

ter verkrijging van
de graad van doctor aan de Universiteit Twente,
op gezag van de rector magnificus,
prof. dr. T.T.M. Palstra,
volgens besluit van het College voor Promoties
in het openbaar te verdedigen op
woensdag 21 november 2018 om 16.45 uur

door

Bob Radder
geboren op 6 april 1989
te Alphen a/d Rijn

DIT PROEFSCHRIFT IS GOEDGEKEURD DOOR:

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CHAPTER 1

General introduction

GENERAL INTRODUCTION

Our hands are very important in our daily life. They are used for non-verbal communication and sensory feedback, but are also important to perform both fine (e.g., picking up paperclips) and gross (e.g., lifting heavy boxes) motor tasks. Reduced muscle strength, motor coordination, dexterity or sensibility of the hand can affect the quality of performance in daily activities and work-related functioning, subsequently affecting independence in daily life and quality of life of a person.

HAND FUNCTION AND AGEING

Hand function often declines with ageing, as a result of physiological and anatomical changes. One of the most common changes in the aging hand is the loss of skeletal muscle mass, also known as sarcopenia (1, 2). This loss of muscle mass is a major contributor to decreased strength of the aging hand (3), subsequently leading to functional impairment (4), disability (4) and loss of independence in daily life (5). Literature shows prevalence rates for sarcopenia of 5-13% for older adults above 60 years of age and 11-50% for older adults above 80 years of age (6). An estimation of these prevalence rates shows that, worldwide, today >50 million people are affected by sarcopenia and this amount could rise to >200 million in the next 40 years (2).

The aging hand is also prone to chronic musculoskeletal conditions, such as osteoarthritis (7, 8) and rheumatoid arthritis (9). Worldwide, osteoarthritis is the most common age-related chronic joint disorder which breaks down the cartilage in the joints (10). In the US only, this affects 30.8 million adults (11). The Framingham study showed age-standardized prevalence rates of radiographic hand osteoarthritis of 44.2% for women and 37.7% for men, respectively (12). The prevalence rates for symptomatic hand osteoarthritis are a bit lower, because both radiographic evidence and symptoms of osteoarthritis should be present. Therefore, age-standardized prevalence rates for symptomatic hand osteoarthritis are 14.4% and 6.9% in women and men in a population of young adults of the Framingham study (12), and increased with age to 26.2% in women and 13.4% in men above 70 years of age (7). People with hand osteoarthritis often experience reduced maximal handgrip or pinch strength (7, 13), pain of the hand/fingers (8) and a reduced range of motion of the hand/fingers (14), resulting in difficulties with performing daily activities (e.g., writing, handling small and heavy objects) that require a good grip (7). Rheumatoid arthritis is the most common inflammatory disease of the joints, with prevalence

rates of approximately 1% of the adult population in developed countries (15, 16). In 2005 it was estimated that rheumatoid arthritis affected 1.3 million adults in the US (15). Rheumatoid arthritis typically affects the wrist, thumb and fingers and could result in morning stiffness for more than 1 hour (17), fatigue (18), decreased range of motion (19) and decreased muscle strength (20). These factors contribute to functional limitations, work disability and reduced quality of life (21).

There are also acute diseases, such as a stroke, which are very common among older adults and can reduce arm and hand motor function (22, 23). According to the World Health Organization (24), 15 million people suffer a stroke worldwide each year. A stroke patient often experiences a variety of sensory, motor, cognitive and psychological deficits, of which motor deficits (i.e., decreased strength, muscle endurance or control of (in)voluntary movement) are most common and widely recognized (25, 26). Eighty percent of all stroke patients suffer from a hemiparesis leading to impaired hand and arm motor function (25). This often results in difficulties in performing daily activities for the majority of stroke patients (27). The study of Kwakkel et al. (28) showed that even 6 months post-stroke only 11.6% regain full recovery in dexterity of the impaired upper limb.

HAND REHABILITATION

A further decline of muscle strength is related to reduced physical activity, which again can result in a further decline of muscle strength. Not only for the musculoskeletal system it is important to stay physically active, but also for neuromuscular responsiveness (29), endocrine function (30) and brain function (31). Research showed that physically active older adults are able to recruit additional brain resources to improve motor impairments (32). Therefore, reduced function of the aging hand can possibly be delayed by performing exercises on a regular basis. These exercises can be prescribed following different approaches, depending on the intensity (load or resistance, number of repetitions and series), duration, frequency and type of training (weight-lifting or walking etc.). To prevent or counter sarcopenia, older adults should follow intensive resistance exercises (2, 33, 34). Preferably, exercises should be performed at 70-80% of maximal strength and at least 2-3 times per week. Literature shows an improvement in strength (>50% of hand strength) after six weeks of training (33). To regain also finger dexterity in older adults, skilled finger movement exercises should be performed. These exercises can improve the ability to control a steady pinch force, finger-pinch posture and speed of finger movements in older adults after 2 training sessions of 10 minutes per day (6 days/week) for 8 weeks (35). An exercise program for frail older adults that involves multiple components (strength, flexibility, endurance etc.) is likely to be

more effective for the prevention of functional disability in older adults than a training program that focuses on one-single component (36).

Performing exercises is also recommended for older adults with hand osteoarthritis or rheumatoid arthritis by The European League Against Rheumatism (EULAR) to improve hand function (37). The study of Rogers et al. 2007 (38) showed that older adults with hand osteoarthritis can improve dynamic and static handgrip strength and reduce pain after strength training. Muscle function and fitness of patients with rheumatoid arthritis can also improve after 30-60 minutes strength exercises or aerobic exercises (3x/week) (39). However, patients with osteoarthritis and rheumatoid arthritis are advised to perform in particular low-impact activities, such as swimming, walking, cycling, to decrease the chance on joint inflammation (40).

Exercise training is also highly recommended for stroke patients to regain motor function. There are several therapeutic interventions that have shown to be effective for improving upper limb motor function of stroke patients (41). For example, strength training for the upper limb has shown positive effects on handgrip strength of stroke patients (42). Also constraint induced movement therapy has shown positive effects on upper limb motor function of stroke patients (25, 43). The mechanisms underlying motor recovery are being unravelled by studies that investigated the principles of motor relearning and the process of cortical reorganization in stroke patients. This provides a neural basis for key aspects that have the potential to improve optimal stimulation of upper limb motor function in stroke patients (44, 45). These key aspects include high intensity practice, task-specific and functional exercises with active contribution of the patient (45, 46).

For all populations with arm/hand function problems, as described above, it is important to perform training exercises with high-intensity preferably on a daily basis to improve arm/hand function. Unfortunately, providing such intensive exercises for older adults (with age-related diseases) in a conventional training setting requires predominantly one-to-one attention for each person, which makes it labour-intensive and expensive. Moreover, the population of older adults (with age-related diseases) will rise the coming decades, resulting in increased need for physical assistance and more pressure on the healthcare system (47). However, it is very important that older adults are physically active and perform exercises, because low physical activity and low amounts of exercise seem to be the most powerful predictors of disability in daily life (48).

REHABILITATION ROBOTICS

Technological innovations, of which robotic devices are well known examples (49), are a promising opportunity for arm and hand training. These robotic devices have

been used to support the upper limb in stroke patients to train intensively and in a functional way based on the key aspects of motor (re)learning. Robotic devices can be used for upper limb training of people with both severe and mild upper limb limitations (50). Furthermore, these robotic devices can provide adequate objective and reliable feedback of patients' impairment, performance and progress during therapy. To our knowledge, robotic devices haven't been applied as a training tool for people with osteoarthritis/rheumatoid arthritis or sarcopenia yet, despite the common ground in type of training that all these disorders display, as explained in the previous section.

Initially, most robotic-assisted devices were developed to train the proximal upper limb (i.e., shoulder and elbow) of patients with neurological diseases, in particular stroke patients. These devices showed improved motor function of the proximal upper limb but only limited improvements in functional performance of stroke patients (51-53). Recently, several devices are being designed and developed for the distal upper limb (wrist and fingers) (54, 55). Research showed that robot-assisted therapy of the distal upper limb can improve motor impairments of the entire arm and can improve functional ability of the upper limb (54), which is in contrast to robotic-assisted training of the proximal arm. On the other hand, it is not clear if improved functional ability of the upper limb results in increased use of the affected upper limb in daily activities at home (54).

ASSISTIVE DEVICES

Patients are often left with residual limitations, despite undergoing rehabilitation, affecting their independence in daily activities on the long term. Persons with reduced upper limb function often face a continuous decline in upper limb function that is hard or impossible to counter, although being physically active and performing physical exercises can help maintain their available function. Therefore, those persons often need assistance of upper extremity devices, defined as assistive devices (56), or assistance of (in)formal carers in their daily life activities. With assistive devices, in contrast to (in)formal carers, people can stay or become independent in their performance of daily activities. Assistive devices for the upper limb (e.g., jar opener (see Figure 1.1)) are able to reduce difficulties in performing daily upper extremity tasks with more than 95% (57). Another potential advantage of using assistive devices for the upper limb in daily life performance is their preventive impact on further development of motor problems by stimulating continued functional use of the upper limb.

Devices for supporting arm/hand function are available in many shapes and sizes, ranging from simple assistive devices (such as a jar opener) to fully robotic assistive

systems (such as Assistive Robotic Manipulator) for people with very severe limitations (58) (see Figure 1.1 & 1.2).

Figure 1.1. A jar opener.

Figure 1.2. The Assistive Robotic Manipulator (58).

Simple assistive devices can be very effective for supporting a specific task, but can only be used for this specific task. Robotic assistive systems allow more functionality but often consist of complex, heavy, bulky and expensive pieces of equipment. Both assistive systems (completely) substitute a particular (or a wide range of) function(s) of the user, whereas achieving or maintaining a high level of activity is essential for improved or at least maintain functional performance.

COMBINATION OF AN ASSISTIVE DEVICE AND REHABILITATION ROBOT

Robotic assistive devices have the potential to support self-management. The majority of the current robotic devices are often developed for rehabilitation purposes. They consist mostly of exoskeleton-type designs that are often heavy and non-flexible, which makes it difficult to align with the biological joints of the arm/hand (49, 55). This makes these exoskeleton devices not well suited for long-term and comfortable support of impaired hand function during the performance of a wide range of daily activities, nor are they well suited to be carried around and used ambulatory in a home setting. Recent innovations make it possible to design robotic assistive devices with soft and flexible materials (soft-robotic devices), which opens new opportunities for how wearable assistive devices could be used. A lightweight and flexible wearable robotic device could be used to directly support arm/hand function during a wide range of functional daily activities, while using the arms and hands frequently for prolonged periods during functional daily activities at home. This may turn functional daily activities into intensive and

functional training at home. By combining the assistive function of such a soft-robotic device with, for example, a personalized computer gaming environment, patients can carry out specific exercises for the arm and/or hand on their own at home. This could make physical therapy even more intensive, functional and meaningful, independent from the availability of trained professionals.

The ironHand and HandinMind systems are examples of such novel wearable soft-robotic systems that have been developed in the ironHand and HandinMind projects, by the technical project partners Bioservo Technologies AB and Hocoma AG. Both systems were developed following an iterative design and development process with a user-centred approach. This process started with the identification of user requirements and was followed by multiple iterative cycles for design and testing. The identification of user requirements and clinical evaluation was done by Roessingh Research and Development, together with end-user organizations Nationaal Ouderfonds, terzStiftung and Eskilstuna Kommun Vård- och omsorgsförvaltningen.

Both systems are developed to provide grip support during a wide range of daily activities. The ironHand system consists of a 3-finger wearable soft-robotic glove (Figure 1.3), tailored to older adults with a variety of physical age-related hand function limitations (e.g., older adults with sarcopenia, rheumatoid arthritis, osteoarthritis). The HandinMind system consists of a 5-finger wearable soft-robotic glove (Figure 1.4), dedicated towards application in stroke.

Figure 1.3. ironHand system

Figure 1.4. HandinMind system

In both cases, the wearable soft-robotic system can be connected to a computer with custom software to train specific aspects of hand function in a motivating game-like environment with multiple levels of difficulty. Three different games (see Figure 1.5) were designed to train hand/finger strength, simultaneous finger coordination and

sequential finger coordination. By adding the game environment, an assistive device is transformed into a dedicated training device.

Figure 1.5. Training environment.

THESIS AIM

The aim of the current thesis is to define user requirements, to investigate feasibility and to evaluate the direct (assistive) and clinical (therapeutic) effects of a wearable soft-robotic system that is developed to support impaired hand function of older adults and stroke patients in a wide range of daily activities and in exercise training at home.

THESIS OBJECTIVES

As part of the general aim, this thesis addresses the following research questions:

- 1) What are the main user requirements for a wearable soft-robotic device that is able to support impaired hand function of older adults and stroke patients in daily activities and in exercise training?
- 2) How is feasibility rated of such a wearable soft-robotic glove that should be able to combine assistance of impaired hand function and training exercises by older adults and stroke patients?
- 3) What is the influence of such a wearable soft-robotic glove on functional performance of the impaired hand of older adults and stroke patients?
- 4) What is the effect of prolonged use of such a wearable soft-robotic glove on hand function of older adults and stroke patients?

THESIS OUTLINE

The ironHand and HandinMind systems were developed following an iterative design and development process involving user input throughout the process from many end-users (e.g., older adults, (stroke) patients, carers, healthcare professionals). User input was given during the multiple iterative cycles for design and evaluation. It started with a focus group study (**chapter 2**) to provide input for the design and development of the first prototypes of both wearable soft-robotic systems. This study describes the user requirements for developing a wearable soft-robotic system that should be able to support and train impaired hand function of older adults and stroke patients at home. Next, a series of user trials are described to investigate feasibility and to evaluate direct and clinical effects of subsequent versions of these systems. There was room for design adaptations according to the findings, after each stage of user testing.

First of all, a feasibility study was performed wherein older adults participated to get more insight in the user acceptance and usability of the first prototype of the ironHand system (**chapter 3**). In addition, a feasibility study dedicated to specific application in stroke was performed using the HandinMind system (**chapter 4**). The direct effect of the soft-robotic ironHand glove on grip strength and functional performance of older adults is described in **chapter 5**. In **chapter 6**, the results of a clinical study are presented in which the effect of prolonged use of the ironHand system during daily activities at home was investigated, along with a comparison of applying such a robotic device as a training tool at home against a control group. The effect of prolonged assistive and therapeutic use of the HandinMind system in a small clinical pilot study is described in **chapter 7**. In the end, **chapter 8** includes a general discussion of this thesis.

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CHAPTER 2

User-centred input for a wearable soft-robotic glove supporting hand function in daily life

Radder B, Kottink AIR, van der Vaart N, Oosting D, Buurke JH, Nijenhuis SM, Prange GB and Rietman JS

Proceedings of the 14th IEEE International Conference on Rehabilitation Robotics (ICORR), Nanyang Technological University, Singapore, 2015 Aug 11-14; p. 502-507

ABSTRACT

Many stroke patients and elderly have a reduced hand function, resulting in difficulties with independently performing activities of daily living (ADL). Assistive technology is a promising alternative to support the upper limb in performing ADL. To avoid device abandonment, end-users should be involved early in the design and development phase to identify user requirements for assistive technology. The present study applies a user-centred approach to identify user requirements for wearable soft-robotic gloves targeted at physical support of hand function during ADL for elderly and stroke patients. Elderly, stroke patients and healthcare professionals, participating in focus groups, specified requirements regarding: 1) activities that need support of assistive technology, 2) design of wearable robotic devices for hand support, and 3) application of assistive technology as training tool at home. Assistive technology for the support of the hand is considered valuable by users for assisting ADL, but only if the device is wearable, compact, lightweight, easy to use, quickly initialized, washable and only supports the particular function(s) that an individual need(s) assistance with, without taking over existing function(s) from the user.

INTRODUCTION

The elderly population is expected to increase in the coming decades due to ageing of the society resulting in an increase of the amount of age-related disorders (e.g., stroke) (1, 2). This aging population frequently has a reduced upper limb motor function and experiences a loss of hand grip. As a consequence, they have difficulties with independently performing activities of daily living (ADL) (3-5). This trend causes an increase in the demands for domestic and healthcare services to support elderly and patients with ADL independence (6).

Technical innovations provide the opportunity to support the upper limb in performing ADL and to compensate for loss of functionality in motor function (1). The demand for such assistive technology will increase with increasing age and with lower levels of function or independence (7, 8). Assistive devices can range from simple assistive tools (e.g., a knife with an adapted handle) to robotic systems that substitute activities performed by people themselves in the case of very severe limitations (e.g., a joy stick operated arm attached to a wheelchair (e.g., JACO)) (9, 10). However, many of these assistive devices do not suit the needs of end-users or their environment, which results in device abandonment (1, 7). In many cases, reasons for device abandonment have to do with the design of the device (2, 11). Simple assistive tools are easy to control, but not very functional in the performance of (a wide range of) ADL while most robotic systems allow more functionality but are very expensive, difficult to control, not portable and too bulky to use unobtrusively in daily life (9, 10, 12). To address these issues, it is important to develop an easy to use, inexpensive and compact wearable robotic system that could support people with hand function problems during ADL. Such wearable soft-robotic devices are being developed within the ironHand and HandinMind projects for elderly with age-related reductions in hand strength and stroke patients with hand function limitations, respectively. These systems are specifically intended to provide functional support of the hand during a wide range of ADL.

The uptake of such (robotic) assistive devices depends on factors that enhance acceptance of assistive technology such as affordability, safety, security/privacy, efficiency, reliability and simplicity (6, 13, 14). To better suit the needs of users and increase chances for uptake of such devices in daily life, it is important to apply user-centred design methods (15, 16). These end-users (e.g., healthcare professionals, patients, elderly, carers) should be involved early in the design and development phase of robotic assistive devices, to identify and describe the problems they

encounter in daily life, and highlight barriers and opportunities of robotic assistive devices. Focus groups involving primary and secondary end-users are a valuable methodology to identify user requirements and attitudes towards assistive technology (2, 11, 17). The end-user input during focus groups provides knowledge about priorities of the end-users, such as which activities are most difficult, which functional limitations should be supported and what are the advantages of using assistive technology.

To understand the problems in daily life of end-users with a decline in hand function, the goal of this study is to identify user requirements as input for the development of a wearable soft-robotic assistive device for the support of hand function of elderly and stroke patients in a wide range of ADL.

METHODS

PARTICIPANTS

Five focus groups were organized at Roessingh Research and Development (RRD) in Enschede, the Netherlands and at National Foundation for the Elderly (NFE) in Bunnik, the Netherlands. The focus groups consisted of primary end-users (elderly and stroke patients) and secondary end-users (healthcare professionals for stroke patients (HCPs) and healthcare professionals for elderly (HCPe)), to explore user perspectives towards the use of assistive technology. A total of 28 participants were included, of which 13 elderly (>60 years), 4 stroke patients and 11 healthcare professionals (i.e., physical therapists, occupational therapists, and geriatric therapists). They were recruited via the network of RRD and NFE. Prior to the start of the study, all participants signed an informed consent indicating voluntary participation and agreement with audio-recording of the meeting. No approval of the Medical Ethical Committee was needed for this study, since the study did not fall under the Dutch Medical Research Involving Human Subjects Act.

PROCEDURE

The five focus groups were held in two rounds and each focus group consisted of one particular group of participants. The first round consisted of 3 focus groups (7 HCPs, 4 stroke patients and 7 elderly), the second round consisted of 2 focus groups (6 elderly and 4 HCPe). Selection of questions raised during the focus groups were based on the Users Task Environment (UTE) approach (18, 19), which systematically addresses user characteristics, the task of the supporting device (how, when and where to support) and the environment or context in which the device might be used.

Both rounds of focus groups addressed each UTE category, which progressed to more specific information about the technology in the second round, based on the results of the first round. Examples of questions from both rounds are listed in Table 2.1.

Table 2.1. Questions discussed in two focus groups rounds.

UTE category	First round of focus groups
User	Which tasks or activities in work or daily life are people struggling with?
	Which activities can people perform on their own and if not, what help do they need?
Task	Which activities would people like to perform independently (with help of wearable robotic devices)?
	Which part of the upper limb (hand and/or arm) needs support?
	How frequently will people want to use a wearable robotic device in daily life?
	Where and in what kind of conditions would people use a wearable robotic device?
Environment	Do people want to use a wearable robotic device for assistance only and/or for therapeutic goals (training function)?
	Do people want to receive feedback about their performance (and what type)?
UTE category	Second round of focus groups
User	Which specific gestures are people struggling with and should be supported by a wearable robotic device for the upper limb?
Task	Which sensors should be used to control user's movement?
	Which sensor positions should be provided for the needed support?
	How do people want to operate a wearable robotic device?
	What should the design of a wearable robotic device look like?
Environment	How should a robotic device operate in combination with water?
	What should the training environment look like?

Each focus group started with a short introduction followed by a demonstration of an existing wearable robotic device for basic grasp support only, the SEM-glove (20). All participants tried the SEM-glove to provide a common context. Next, questions were put up for discussion during an interactive presentation about assistive technology for the upper limb. The participants were asked to give input about these questions via a range of methods, such as filling in tables, making rankings, voting for preferred options, etc. The input of each participant was combined with plenary discussions between all participants. In this way, all participants were encouraged to share and discuss their thoughts, ideas, opinions, experiences and expectations. These discussions were mediated by the researchers from NFE and/or RRD. At the end of each focus group, participants were asked to complete a few questions about

age, gender, education and technical affinity. Each focus group had the same structure and lasted approximately 90 minutes.

ANALYSIS

The qualitative data was elaborated by means of the researchers' notes and audio-recordings. The descriptive data of each focus group was coded such that the data could be compared between focus groups. The coded data was discussed between the researchers to look for alternative interpretations, and summarized. From this, common themes or topics were identified to describe the main user perspectives towards use of assistive technology. All topics that the group agreed on or were preferred by a majority of participants in each focus group are represented as the main user perspectives and their corresponding requirements.

RESULTS

The characteristics of participants are presented in Table 2.2. Most of the primary end-users were women (88%), lived alone and had no affinity with technology. In contrast, many secondary end-users did have affinity with technology.

Three topics about assistive technology were identified that describe the attitude of primary and secondary end-users towards wearable robotic assistive devices for the support of hand function in ADL: 1) activities that need support of assistive technology, 2) design of wearable robotic devices for hand support, and 3) application of assistive technology as training tool at home.

Concerning the relevance of these topics, participants regarded the design of the wearable robotic device to be critical for actual use of the device. Whether (or how much) people want to use a wearable robotic device depends firstly on ease of donning/doffing of the device, comfort of wearing (no sweating) and the weight of the device (lightweight). Secondly, the experienced benefit in support of hand function from using the device is appreciated as a reason for expected use of the device.

ACTIVITIES THAT NEED SUPPORT OF ASSISTIVE TECHNOLOGY

The primary end-users could clearly define the support they needed during ADL in terms of the specific activities, functions and gestures that should be supported. They especially need support during ADL involving household chores, personal hygiene and care, eating and drinking and hobbies or outdoor activities. The problems that occur most frequently are difficulties with tasks like wringing out

Table 2.2. Demographic characteristics of participants.

	First round of focus groups			Second round of focus groups	
	Elderly	Stroke patients	HCPs	Elderly	HCPe
Age (years)	72.6 (62-81) ^a	57.3 (50-70) ^a	36.5 (27-48) ^{a,b}	74.2 (62-81) ^a	40.5 (31-51) ^a
Gender (male/female)	0/7	1/3	0/7	1/5	4/0
Time since stroke onset (years)	Not applicable	2-5	Not applicable	Not applicable	Not applicable
Living situation	5 alone 2 with partner	Unknown	Unknown	3 alone 3 with partner	1 alone 3 with partner
Professional status	Not applicable	Not applicable	7 occupational therapist in stroke department	Not applicable	3 physiotherapist 1 geriatric physiotherapist
Affinity for technology	4 yes 2 sometimes 1 no	Unknown	3 yes ^b 3 sometimes	1 yes 5 no	4 yes

^aMean age of focus group (range of age), ^b Missing data of one person

kitchen rags, holding objects, closing and opening buttons or zippers and opening jars, bottles, cans and packages. The problems during these activities are mostly caused by a lack of strength and problems with hand opening (flexibility of the fingers). Some stroke patients mentioned that they also have problems with wrist movements during these activities. HCPs mentioned that the position of the wrist is crucial in these patients and should be supported by the system. On the other hand, elderly mentioned that they don't need support of the wrist. In line with this, almost all participants in the different focus groups mentioned that a wearable robotic device for hand support should be a modular system that can support gripping force and/or hand opening and/or wrist movements, depending on the abilities and limitations of an individual.

Moreover, all participants only want support of the particular function(s) that need(s) assistance and occur frequently during the day. HCPs mentioned that stroke patients who have moderate to good arm and hand function especially need support of fine motor control activities, while stroke patients who have severely affected hand function need support during basic ADL. For this group, it is important that the affected hand can be used for support during the performance of tasks with the non-affected hand.

The most important gestures specified to require support were similar between healthcare professionals, elderly and stroke patients: palmar grasp, spherical grasp, diagonal volar grasp, lateral grasp and the key pinch (Table 2.3). However, HCPe worried about the fact that every individual has different upper limb impairments and needs another type of support in daily tasks. Preferably, additional grasps needed for both fine and gross motor function as listed in Table 2.3 should be supported by the assistive device as well, to provide assistance during a large variety of functional tasks.

Table 2.3. Grasps requiring support in ADL.

Must be supported	Wished to be supported
Palmar grasp	Hook grasp
Spherical grasp	Pincer grasp
Diagonal volar grasp
Lateral grasp
Key pinch

Elderly, stroke patients and HCPs mentioned that how often (short vs. longer periods of time) people with reduced upper limb function expect to use the device depends on the comfort of the device and the specific activity. Elderly explained they would use the device for a short amount of time (<30 minutes) during daily household chores and/or for a longer amount of time (>1 hour) when performing hobbies or outdoor activities. An elderly participant mentioned: *I will collect all the household chores, do them in a row and then I will doff the device.*

DESIGN OF ASSISTIVE TECHNOLOGY FOR HAND SUPPORT

Most of the participants in the different focus groups agreed that a wearable robotic device needs to be comfortable, lightweight, compact, easy to operate and easy to don and doff. Regarding practical issues, a wearable robotic device for the upper limb should be washable and waterproof, quickly initialized (<1 a 2 minutes) and the battery should last for one full day of using the device (possibly intermittently) without charging. Furthermore, it should support grip force and hand opening (especially for stroke patients) and the glove should specifically support the index finger, in contrast to the existing SEM-glove.

If a device should only support the functions that are problematic, a sensor detecting the user's contribution should be incorporated. There are many options to control the grip force and hand opening, such as pressure sensors, movement sensors, voice recognition, body/trunk operation or muscle tension control. Elderly and HCPE preferred to control the support by the device via pressure sensors and movement sensors, whereas all stroke patients gave preference to a system which recognizes that a movement is (prepared to) be made. HCPE commented further that it would be ideal if pressure sensors are combined with movement sensors. These sensors should be positioned optimally for proper activation of the support when moving and gripping, which should depend on the task (uni- or bimanual) and fine or gross hand motor function. Considering the preferred grasps to support, the sensors should probably be on the fingertips for daily activities with fine motor function and cover a larger part of the finger (distal interphalangeal to metacarpophalangeal joints) for gross motor function.

When asked about how to operate the system and where to access the operation panel, for instance at the glove or at the battery pack, elderly and HCPE preferred operation of the system by an on/off button and a button to adjust the amount of support for grip and hand opening. They preferred to access the operation panel on the glove instead of on the battery pack, because this will be easier to reach for people with upper limb problems.

Many participants mentioned the glove being waterproof as an important preference, regarding use of the glove fully submerged in water (for instance when doing the dishes). At least, it should continue to function when fluids are spilled occasionally. In addition, the glove should be washable for hygienic purposes. The use of a second glove over the glove was proposed as a possible solution, although several healthcare professionals mentioned that elderly or patients may not be able to put a second glove over the glove because of a lack of strength and potentially too much friction between both gloves.

The size of the battery is less relevant than the operation duration without charging, but many participants preferred it to have the size of a smartphone (or smaller). HCPe mentioned that they would appreciate it if the battery could be charged via a cable, but could also be replaced by a spare battery directly when the device is still in use and the battery runs out of power.

APPLICATION OF ASSISTIVE TECHNOLOGY AS TRAINING TOOL

When asked about potential applications other than assisting ADL, most of the participants preferred to use a wearable robotic device not only for assistance during ADL, but for therapeutic goals as well. HCPs could foresee that wearable robotic devices for the upper limb could be used for in- and outpatient treatment. A comment shared among most HCPs was that: *when stroke patients use a wearable robotic device for training purposes at home, it is very important that donning and doffing of the device is very easy*. According to HCPe, the training application should consist of functional exercises instead of basic hand function training. However, elderly would like to train both functional activities and basic hand functions. All participants want to use real objects in training exercises and they expressed no preference for training with or without computer games. In addition, HCPe mentioned that real objects are most suitable to provide functional training, while computer games are important for motivation. If computer games are used for motivation, elderly prefer to play puzzle games and games in a realistic setting. However, concerns were expressed by HCPe that the preference for particular games will depend on the individual. Ideally, there should be a large variety in games and settings. A HCPe mentioned: *a realistic environment may present less of a threshold to start using computer games during training, in case there is low affinity with technology or computers in particular*.

HCPe and HCPs both reported that the gain of the support should be adjustable during training (e.g., 25%, 50% or 75% of maximal strength). Furthermore, feedback about the performance of stroke patients during training is useful for HCPs. They prefer to get feedback by the device about the success of task performance, generated

forces and joint angles. Primary end-users (both elderly and stroke patients) would like to receive feedback as well, preferably about the quality of movement. However, they prefer to get feedback from the healthcare professional and not necessarily from the robotic device or the games. This means that the system should have the ability to send information to the healthcare professional, who can give afterwards feedback to the end-user.

To summarize, the major user requirements are presented in Table 2.4.

Table 2.4. Major user requirements.

	Requirements
1	Only providing support for function(s) that a person can't do him or herself
2	Should be comfortable, compact, lightweight, easy to use and easy to don and doff
3	Active contribution by the user via movement detection and pressure sensing for control of support
4	Assisting and training primarily functional tasks (with additionally basic hand function exercises)
5	ADL domains in need of support are primarily: household chores, personal hygiene/care, eating and drinking and hobbies or outdoor activities
6	Supporting grip and hand opening (and potentially wrist extension)
7	Support particularly palmar, spherical, diagonal volar, lateral grasps and key pinch
8	Allow use in, at least occasional, contact with water or other fluids, both inside and outside of the house
9	Initialising time should be less than 2 minutes
10	The battery should last at least one full day (possibly intermittently) without charging
11	The size of the battery should be the size of a smartphone (or smaller)
12	Access to the operation panel should be on the glove instead of on the battery back
13	The sensors should be placed on the finger tips for fine motor function and cover a larger part along the finger for gross motor function
14	It should be possible to use real objects during training exercises
15	A large variety in games and settings during training
16	The gain of support should be adjustable during training
17	The system should have the ability to send information to the healthcare professional, who can give afterwards feedback to the end-user about their quality of movement

DISCUSSION

The focus group methodology was a useful tool to obtain a wealth of information about user requirements for wearable robotic assistive devices for the upper limb, covering UTE aspects. The additional demonstration of an existing wearable robotic device for upper limb support gave people a better understanding of the opportunities of wearable robotic assistive devices, because most of the participants

had never experienced such devices. This resulted in explicit user input about many aspects of using assistive technology.

First of all, end-users reported that wearable robotic assistive devices should only support the particular function(s) that need(s) assistance, without the device taking over tasks that people can perform themselves. Those highly individual aspects are influenced by personal goals or the specific upper limb impairments of individuals (7). Such a personalised application would also be favourable from a medical point of view, since achieving or maintaining a high level of activity is essential for improved functional performance in ADL, in both elderly and stroke patients (21, 22). Intensive use of the arm and hand, active engagement during movement, and task-specific exercise at a challenging level of difficulty at all times are important aspects to reduce or reverse functional loss in motor function (23). Secondly, end-users agreed that actual use of such devices will depend first and foremost on its ease of use, after which the benefit experienced from using the device is valued. Therefore, there should be a balance between the functional benefit of a device and its burden of use (24), with the burden of use limited as much as possible by the design of the device.

These findings are in line with literature indicating that elderly will use assistive technology when it enables them to perform activities that they identify as meaningful and satisfying (7). Furthermore, specific factors that were mentioned as highly relevant for the design (e.g., not bulky, reliable, easy to use) are in line with 17 design and engineering criteria specified by Batavia et al. based on an evaluation of long-term use of assistive devices (25) and the requirements for soft wearable robotic gloves mentioned in the articles of Polygerinos et al. (26) and In et al. (27). A number of these aspects were further specified by the participants, for instance donning and initializing the device should ideally take less than 2 minutes, the battery should last at least a full day (possibly intermittently), while the battery pack should be no larger than a smartphone. Additionally, the article of Polygerinos et al. (26) specified some more aspects, such as the weight of the glove should be less than 0.5 kg, the waist pack weight should be less than 3 kg and the battery should last at least 2 and 6 hours for continuous and intermittent operation (26). Besides a direct benefit of assistive technology for performance of ADL, the use of assistive devices can reduce personal assistance or care-giving needed from others. A reduction of (in)formal care of four hours per week (28) or 30-42% (9, 10) has been reported. If the uptake of such assistive devices increases through a better user-centred design, this might even result in decreased healthcare costs (e.g., less demand for healthcare professionals or carers) (28).

Elderly and stroke patients are two large populations that frequently encounter upper limb impairments: 60% of the stroke patients experience an upper limb impairment related to their hand and 20-30% of the elderly population (>70 years) experience difficulties in ADL (5, 29). Taking into account the different perspectives of a large group of potential stakeholders, participants in this study were chosen to represent a wide range of primary and secondary end-users, including stroke patients, elderly, and healthcare professionals. This approach was intended to involve perspectives from a broad group of people who might benefit from wearable robotic assistive devices. Nevertheless, it may be that inclusion of additional or other stakeholders could have resulted in deviations from the findings presented here.

After identifying end-user input for the design of assistive technology, the resulting user requirements (see Table 2.4 for a summary of main aspects) are now being taken into account during the development of wearable soft-robotic gloves enabling both assistance and training in daily life. Remarkably, there were many similarities among elderly and stroke patients regarding general requirements like activities in need of support. However, user characteristics (e.g., age, physical condition, motor problems, domestic or occupational situation) and use contexts (e.g., additional support of hand opening and wrist movements in stroke patients) are different between elderly and stroke patients. This still requires specific attention to each target population separately during the design and development of wearable robotic systems. Within both ironHand and HandinMind projects, this approach is intended to enhance user satisfaction and reduce device abandonment in future user evaluations and, ultimately, stimulate practical application of such soft-robotic, ADL-supporting gloves for elderly and stroke patients respectively.

CONCLUSION

For assistive technology to be usable and adopted, the design of assistive technology is critical. It must be based on perceived needs and functional limitations of an individual. All participants considered assistive technology useful to support hand function during ADL, if the device is easy to use, comfortable to wear and only supports the function(s) that need(s) assistance, without taking over users' own functions. The user requirements identified during this process are now being taken into account during the development of wearable soft-robotic gloves that can support grip and hand opening during the most relevant ADL for both elderly and stroke patients.

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CHAPTER 3

A wearable soft-robotic glove enables hand support in ADL and rehabilitation: A feasibility study on the assistive functionality

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Journal of Rehabilitation and Assistive Technologies Engineering 2016; 3: 1-8

ABSTRACT

BACKGROUND: Elderly people frequently experience a decline in hand function, due to ageing or diseases. This leads to decreased independence in activities of daily living (ADL). Assistive technology may enhance independence.

OBJECTIVES: The objective of this paper was to explore user acceptance of an affordable wearable soft-robotic glove (ironHand (iH) system), that supports grip and hand opening in ADL. In addition, functional performance with the iH system was explored.

METHODS: For this study 28 elderly people used the iH system across two sessions. During these sessions, participants performed six functional tasks with and without the iH system. Outcome measures were System Usability Scale (SUS), Intrinsic Motivation Inventory (IMI) and performance time of the functional tasks.

RESULTS: User acceptance scored highly, with a mean SUS score of at least 63.4 (SD=19.0) and a mean IMI score of 5.1 points (SD=0.97 points). Functional task performance improved across repetitions both with and without the glove ($p \leq 0.017$), but all functional tasks were performed faster without the glove ($p \leq 0.032$).

CONCLUSION: Participants perceived the iH system as useful, pleasant and meaningful. The learning curve in functional performance time (improvements across repetitions) is promising, since it suggests there is room for improved performance when a longer acquaintance period is applied.

INTRODUCTION

Hand function often declines with ageing, or due to acute (e.g., stroke) or chronic (e.g., arthritis) diseases (1-3). This results in a decreased ability to grip and manipulate objects (4). In addition, people with reduced hand function can experience decreased functional performance (5-7), decreased independence in activities of daily living (ADL) and decreased quality of life (8-11).

Assistive technology has the potential to improve hand function and independence in daily life. Many different devices are available to assist with or improve hand function (12). However, most current devices are only used in rehabilitation centres or hospitals because such devices are very expensive, not easy to use (therapist supervision is needed in most cases) and too bulky to use during functional tasks (12-14).

Therefore, an easy-to-use and wearable soft-robotic device for the impaired hand of elderly people and patients is being developed in the ongoing ironHand (iH) project. The iH system integrates an assistive system that can support grip strength and hand opening in ADL directly, with a digital training platform to provide specific exercises for the hand at home. The combination of the assistive functionality and therapeutic functionality of the iH system enables hand support during a large variety of functional activities and specific hand training exercises at home.

In order to improve adoption by users, a user-centred process was applied in the development process. As part of this, end-users identified user requirements for the iH concept in an early stage of the project. User-friendly design and ergonomics were identified as major requirements (15). This study provided the first insight in feasibility, in terms of user acceptance (usability and motivation) and impact on functional task performance, of the assistive functionality of the iH system.

METHODS

IRONHAND SYSTEM

The iH system (Figure 3.1) is based on the concept of a soft-robotic glove that can add extra strength to grip for persons with reduced hand function. The glove is portable and can be used to assist the grip during a wide range of ADL (assistive mode of the iH system: iH Assistive System (AS)). In addition, the same glove can be connected to a computer with specialized therapeutic software that allows users

to train specific aspects of function such as strength, finger coordination, finger independence or motor memory in a motivating game-like environment (therapeutic mode of the iH system: iH Therapeutic System (TS)).

Figure 3.1. The ironHand system.

The iH system provides assistive flexion force to the thumb, middle finger and ring finger through a tendon-driven mechanism. The tendon-driven mechanism allows the system to provide active assistance in flexion force. In addition, passive leaf springs (attached to the dorsal side of the glove) are used to support extension of the thumb, middle finger and ring finger. To modulate flexion assistance, the system incorporates pressure sensors (Interlink Electronics) in the finger tips and extension/flexion sensors (Flexpoint) along the fingers. An intention detection logic ensures that the assistive flexion force is only activated in a natural and intuitive way. In addition, the actuators provide support in proportion to the flexion force applied by the user. This ensures that the user maintains an active contribution to

the specific movement. The sensitivity level, maximum supported force in flexion and extension (regulated by the amount of leaf springs) of the iH system are customized for the individual user.

PARTICIPANTS

Four sites, National Foundation for the Elderly (NFE), Bunnik and Roessingh Research and Development (RRD), Enschede in the Netherlands, Eskilstuna Kommun Vård- och omsorgsförvaltningen (ESK), Eskilstuna in Sweden and terzStiftung (TERZ), Berlingen in Switzerland, recruited 30 elderly people (≥ 55 years) who experienced a decline in hand function resulting in difficulties in performing ADL.

Additional inclusion criteria for those participants were: (1) at least 10 degrees of active flexion and extension movement of the fingers; (2) sufficient cognitive status to understand two-step instructions; (3) (corrected to) normal vision; (4) living at home; (5) and signed written informed consent prior to the start of the study.

Exclusion criteria were: (1) severe sensory problems of the hand; (2) severe acute pain of the hand; (3) wounds on their hands that may create problems when wearing the glove; (4) severe contractures limiting passive range of motion; (5) co-morbidities limiting functional use of the arms/hands; (6) insufficient knowledge of the Dutch, Swedish or German language to understand the purpose or methods of the study; (7) and participation in other studies that can affect functional performance of upper limb.

The local Medical Ethical Committees in the Netherlands, Sweden and Switzerland approved the protocol of this feasibility study.

PROCEDURE

Study design

This study was a multicentre cross-sectional study in which the feasibility of the iH AS was tested. Participants performed ADL-like tests in a standardized, simulated ADL environment at NFE, ESK and TERZ supervised by the researchers of NFE, ESK and TERZ, on two separate days (with a minimum of two weekdays between those sessions). Using the iH system for the first time (naive use) was tested on day 1 and a repeated session on day 2 was used to test more experienced use after some repetitions with the iH system. The tests were coordinated and monitored to assure consistent execution across sites by RRD and at each site was supervised by the same researchers.

Experimental protocol

The first evaluation session started with collecting participant characteristics such as age, gender, dominant hand and most-affected hand. At the beginning of both sessions, the amount of support of the iH AS was adjusted to the participants' needs and experienced comfort. Furthermore, researchers provided the participants with additional information to use the iH system properly. The glove was always worn on the most-affected hand.

Next, six standardized and simulated real-life functional tasks were performed with and without the iH AS. These functional tasks consisted of drinking, eating, household cleaning, reading (and writing), dressing and door opening tasks (see Table 3.1 for task descriptions). The execution of these tasks was demonstrated by the researchers before the test started. In addition, the participants received verbal instructions about the execution of the tasks during the test, if needed.

Participants performed each functional task three times with and three times without the iH AS. Sealed envelopes were used to randomize the order of glove use during each session for each individual.

Table 3.1. Explanation functional tasks.

Task	Explanation
Drinking	The participant grasps and opens a bottle of water (0.5L), pours some water in a glass, closes the bottle of water, takes a sip of water and returns the bottle and cup to the starting position.
Eating	The participant takes a knife, cucumber and plate to prepare 3 slices of cucumber. After cutting 3 slices of cucumber, the participants returns the knife, cucumber and plate to the starting position.
Household cleaning	The participant takes a cloth, wrings the cloth for three times and cleans a marked line on the table.
Reading (and writing)	The participant holds a book in the most-affected hand for 30 seconds and if possible, writes the last word on the left page of the book on a paper and returns the book to the starting position.
Dressing	The participant takes jacket off the coat hanger, puts jacket on, closes the zippers/button, opens jacket and returns it to the coat hanger.
Door	The participant takes the key of the door from a seat, puts the key in the door, closes/opens the door and returns the key to the seat next to the door.

ASSESSMENT

User acceptance

After the tasks were done both with and without the glove in both evaluation sessions, participants completed the System Usability Scale (SUS) and the Intrinsic Motivation Inventory (IMI) to assess system usability and participants' motivation during use of the iH system.

The SUS is a 10-item scale giving a global subjective view on system usability. Participants scored each item of the SUS on a 5-point Likert scale ranging from 'strongly disagree' to 'strongly agree'. Scores were translated to a total score between 0 and 100 (16). The system has a good probability of acceptance in daily life of potential users if the system receives a total score above 70. A total score between 50 and 70 is promising, but guarantees no high acceptability in the field, and a total score below 50 indicates a high risk of usability difficulties with the system in the field (17, 18).

The IMI is a questionnaire which measures several dimensions (interest/enjoyment, perceived competence, effort, perceived choice while performing a given activity, felt pressure and tension and value/usefulness) of motivation that patients experience during the performance of a physical activity (19). For the purpose of this study, 'activity' was replaced by 'using the iH system' in each item. To capture the concept of motivation when using a new device in the most solid way, the IMI was evaluated only at the end of evaluation session 2. The 34 items are scored on a 7-point Likert scale ranging from 'not at all true' to 'very true' (19). The level of motivation is higher if the averaged total score on the IMI is closer to 7.

Functional task performance

During the functional tasks, researchers measured the performance time using a stopwatch, observed the execution of the activities (e.g., which hand is used for handling the heavier objects or performing the most difficult movements, speed of movement, fluidity, precision, presence of compensatory movements) and observed the way the participants reacted to the system. This was used to further improve the design of the iH system in next iterations of its development.

From the three repetitions, only the last repetition was used to compare the performance time between the conditions with and without iH AS for each task. In addition, changes over the three repetitions within each evaluation session were assessed to obtain insight in how well participants got acquainted to using the system.

DATA ANALYSIS

IBM SPSS Statistics version 23.0 for Windows was used to analyse the data. The assumption of normality for the SUS scores and the performance duration of the functional tasks was checked by visual inspection of the q-q plot, the box plot, histogram plot and the Shapiro–Wilks test, prior to the statistical analysis. All outcome measures were described by using descriptive statistics.

A Wilcoxon signed rank test or a paired sample t-test was performed, depending on normal distribution of the outcome measures, to compare the SUS scores for the iH AS between both days and the performance times of the third repetition between both conditions with and without iH AS for each task. In addition, repeated measures analysis of variance (ANOVA) or the Friedman test (the non-parametric variant) was used to compare the performance times between multiple repetitions with and without the iH AS. If a significant difference was found for parametric variables, multiple comparisons were performed with a Bonferroni correction. A Wilcoxon signed rank test for multiple comparisons was performed using an adjusted p-value of 0.017, if a significant difference was found for non-parametric variables.

The level of significance was set at $\alpha \leq 0.05$ for all statistical tests.

RESULTS

In total, 28 elderly people (8 in the Netherlands, 10 in Sweden and 10 in Switzerland) completed both sessions of this feasibility study. Table 3.2 shows the characteristics of the individuals at baseline.

Table 3.2. Characteristics of participants at baseline.

	Participants ($n=28$)
Age (years) ^a	72 ± 8 (56–84)
Gender (male/female)	9/19
Living at home (yes/no)	28/0
Affected body side (right/left/both)	14/8/6
Dominant hand (right/left/both)	25/2/1

^aMean ± standard deviation (range)

USER ACCEPTANCE

SUS. Twenty-seven participants completed the SUS for the iH AS after session 1. One participant missed some values resulting in an incomplete SUS. The mean SUS score was 70.1 (SD=14.1).

A subset of the participants (data only available from 17 participants of NFE and ESK) completed the SUS for the iH AS after session 2 as well (see Figure 3.2). The SUS score after session 2 was not different ($p = 0.073$) compared with session 1, with a mean of 63.4 (SD=19.0).

IMI. The scores for each dimension of the IMI were positively rated by all participants ($n=28$), resulting in a mean score on the IMI of 5.1 points (SD=0.97 points) out of 7 points (see Figure 3.3).

Figure 3.2. Individual System Usability Scale scores for the iH AS after evaluation session 1 and 2 (mean scores displayed with dotted lines).

Figure 3.3. Individual Intrinsic Motivation Inventory scores after evaluation session 2 (mean score displayed with dotted line).

FUNCTIONAL TASK PERFORMANCE

During both evaluation sessions, participants had difficulties with performing the dressing task due to the iH system not being slender enough to wear underneath a jacket. Therefore, the dressing task was excluded from statistical analyses. Furthermore, data of the reading task were missing for one participant, data of the door task of session 1 were missing for two participants and data of the door task of session 2 were missing for one participant due to erroneous reporting of the data values and unintentional omission of some values from the scoring sheet.

During session 1, the last repetition of all functional tasks was performed faster without the glove ($p \leq 0.032$) than with the glove. Additional analysis of the NFE and ESK participants showed that the performance time improved over the three repeated attempts either with or without the glove ($p \leq 0.017$), except for the reading and household tasks without the glove (see Figure 3.4).

Data of the functional performance times of the NFE and ESK participants of session 2 showed that all functional tasks were again performed faster without the glove ($p \leq 0.007$) than with the glove. In addition, participants showed improvements in performance time over the three attempts only with the glove during the drinking and eating tasks ($p \leq 0.003$) (see Figure 3.5). Furthermore, Figures 3.4 and 3.5 show that the first attempt of the functional tasks was performed faster in session 2

compared with session 1, supporting the observation of a learning curve between session 1 and 2.

In addition to the data of the functional performance test, participants reported that their performance with the iH AS improved after using the system for a longer time period. They also indicated that they felt the support of the iH AS during the functional tasks. On the other hand, researchers observed that participants experienced some usability issues when using the iH AS. They especially encountered difficulties with grasping the cap of the bottle, opening and closing the bottle, writing, grabbing the plate, grasping the pen and picking up the key.

Figure 3.4. Performance time functional tasks evaluation session 1.

Figure 3.5. Performance time functional tasks evaluation session 2.

DISCUSSION

The present feasibility tests focused on user acceptance. The results showed that the concept of the iH system was well accepted by the majority of the participants, as reflected by the positive SUS and IMI scores. However, all functional tasks were performed significantly faster without the glove, even after repeated use of the glove across two sessions. The results of functional task performance within both sessions showed that performance either with or without the glove improved during three repetitions. Although improvements across three repetitions were less predominant during session 2, performance with the glove of the drinking and eating tasks still improved across repetitions.

This feasibility study, a first stage of user testing, focused on user acceptance including ease of use, usability and motivation, since these are early-stage tests during the ongoing iterative development process of the iH system. As described by the framework of DeChant et al. (20), it is important that the evaluation suits the stage of the development process. Subsequent stages of user testing should focus increasingly on the effect of the iH system after a longer period of use and a larger maturity of the technology.

Participants reported that they appreciated the main components of the iH AS prototype: the support of grip strength and hand opening during ADL. This is

confirmed by the positive SUS and IMI scores. The mean SUS scores of 70.1 and 63.4 for the iH AS indicate good probability for acceptance of the iH AS in the field (17, 18). Although not significant, this slight change might indicate higher expectations in terms of usability when using the system for a second time. Studies that investigated system usability of other types of technology showed similar or higher SUS scores (21-23). The study of Nijenhuis et al. (22) also investigated the actual use of a robotic hand device for training purposes at home by stroke patients. This study showed that stroke patients, who had SUS scores comparable with the participants of this study, were able to independently use such training device at home for on average 15 min/day over 6 weeks.

Participants also scored positive on the IMI with a mean score of 5.1, indicating that participants perceived the iH system as an interesting, pleasant and enjoyable system to improve their hand function in daily life. Comparable IMI scores were found by other studies that investigated motivation of an intervention with rehabilitation technology in a clinical setting (24, 25). Nijenhuis et al. (24) showed that user acceptance of such technology appears to be equal with independent practice with conventional exercises at home. This suggests that the chances for actual use and adoption of the iH system in daily life are promising.

Functional task performance duration without the current prototype was better compared with task performance with the glove, despite the positive reactions of participants on usability and motivation. The slower performance times with the iH AS have probably been affected by several usability issues. This may have hindered participants' ability to experience the full potential of the iH AS. For instance, participants experienced less sensation of the fingertips during the performance of functional tasks with the glove due to the fabric of the glove. In addition, the position of the sensors was not always optimal, and sometimes participants had difficulties in obtaining a good grip on an object due to a reduced friction between the object and the surface of the glove.

Furthermore, the participating elderly performed the functional tasks with the glove worn on the hand they perceived as most affected, which was, in most cases, their dominant hand. This might have caused difficulties with performing fine motoric functional tasks, because these activities are difficult to support with a robotic glove. Therefore, it is important to focus on the gross motor activities. Indeed, many participants mentioned that they liked the assistive function of the iH system during gross motor activities such as lifting and opening a bottle, holding a book, cutting food and turning a key. In other populations, for example stroke patients, the most-affected hand is mainly used to support the healthy hand instead of using the most-affected hand as primary hand to perform functional tasks (26). Therefore, the role

of the gloved, more affected hand in (bi-manual) functional tasks should be taken into account more specifically in subsequent studies with elderly participants. In addition, it is also important to take into account the content of the functional tasks. The selected functional tasks were probably too easy to perform for the current sample of participants. Ultimately, this can result in reduced performance with the iH AS because the glove is sometimes more obstructive than helpful.

In addition, participants have used the iH AS actively only for approximately 20 minutes during the functional task performance test in both sessions to assess feasibility and usability. The learning curves of both sessions with and without the glove show that participants can improve their performance after multiple repetitions. Figures 3.4 and 3.5 show that, in general, the first repetition in session 2 was faster than that in session 1. This indicates that participants learned to perform the task rather quickly with and without the glove. On one hand this implies that the glove is easy to use; on the other hand, that a learning curve in glove use is still present during some of the functional tasks (27). Therefore, in future studies a longer acquaintance period with the iH system should be applied to examine if more progression in performance is possible.

Since soft-robotics to assist upper extremity function is a very young field of research, only one other comparable study was found. The present findings are in line with the study of Polygerinos et al. (28), which showed that a healthy subject completed functional tasks of the Jebsen-Taylor Hand Function Test slower with assistance from a soft-robotic glove as compared with performing those tasks without assistance from a glove. Their conclusion was that such an assistive system might make a difference when participants need to perform multiple functional tasks in a row and are losing handgrip strength during prolonged activity (28).

CONCLUSION

The current feasibility study showed that participants with a perceived decline in hand function were positive about the usability of the assistive functionality of the iH system. However, the participants performed functional tasks faster without the soft-robotic glove than with the glove. The participants especially appreciated support of the iH AS during gross motor activities. The performance time of the functional tasks was improved after multiple attempts with the iH AS. Therefore, a longer time to get used to new assistive technology may be needed to further improve performance with the iH system. Furthermore, design adaptations are needed to improve performance with the iH system, based on the user input

collected during this study. In future studies, a new version of the iH AS will be tested in daily life situations. Additionally, the iH TS will be evaluated as well.

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CHAPTER 4

Feasibility of a wearable soft-robotic glove to support impaired hand function in stroke patients

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Journal of Rehabilitation Medicine 2018; 50: 598-606

ABSTRACT

OBJECTIVE: To investigate the feasibility of a wearable, soft-robotic glove system developed to combine assistive support in daily life with performing therapeutic exercises on a computer at home (the HandinMind system).

DESIGN: Feasibility study.

PATIENTS: Five chronic stroke patients with limitations in activities of daily living due to impaired hand function.

METHODS: Participants performed a usability test and several functional tasks with the HandinMind system across 2 sessions. Feasibility was measured using the System Usability Scale (SUS), Intrinsic Motivation Inventory (IMI) and performance times of the functional tasks.

RESULTS: User acceptance measured by the SUS and IMI was scored high. The median SUS scores of sessions 1 and 2 were 80.0 (interquartile range (IQR) 70.0–88.8) and 77.5 (IQR 75.0–87.5), respectively, and the median IMI score was 6.3 points out of 7 points (IQR 6.2–6.3). Functional task performance was initially slower with the HandinMind glove compared with performance without the glove, but improved up to the level of performance without the glove across no more than 3 repetitions.

CONCLUSION: Chronic stroke patients with impaired hand function were positive about the feasibility of the first prototype of the HandinMind system. However, performance and ease of use of the system should be improved further in future development phases.

INTRODUCTION

Worldwide, stroke, or cerebrovascular accident (CVA), remains a leading cause of permanent disability (1). For optimal restoration of upper limb motor function after stroke, therapy should consist of several key elements: repetitive, high-intensive, task-specific and functional exercises with active contribution from the patient (2-4). Providing such highly intensive therapy in a conventional rehabilitation setting predominantly involves close supervision of a therapist for each patient, which makes it labour-intensive and expensive (5, 6). This will be an even greater problem when the incidence of stroke patients rises further in the coming decades, as is expected due to the ageing population (1). Therefore, the number of new technological innovations that can be used to facilitate exercise programmes fulfilling the key elements of therapy is increasing rapidly, of which robotic devices and therapeutic exercises in the form of games are well-known examples (7-9).

Although more conclusive evidence is needed, robotic devices aimed at training have shown effects on upper limb motor function, but limited improvements in performance of daily activities (5, 10-12). These devices have initially focused predominantly on the proximal upper limb, while the hand also plays an important role in performing daily activities. Therefore, hand training should also be part of the rehabilitation programme to improve functional performance (3). Moreover, the review of Balasubramanian et al. (7) showed that distal robotic training has a generalization effect on motor improvements of the entire arm.

Although robotic training devices can improve motor function and performance to a certain extent, a larger effect is expected when therapy could be applied with a higher frequency and/or duration than is currently possible in many conventional rehabilitation settings (13, 14). This would require (partly) self-administered training by stroke patients, ideally at a person's home when the device is suitable for home deployment (15). More pronounced effects on activity level are expected when functional, task-specific exercises are implemented in robotic therapy, by including functional exercises for the hand (16).

The latest technological innovations concerning soft-robotics allow robotic devices to become wearable and less obtrusive to use in daily life (17-19). This enables an entirely new paradigm for stroke rehabilitation, in which intensive use of the arms and hands in functional exercises become entwined, via assistive support of the impaired hand during daily activities at home. In addition, the assistive support of the impaired hand during daily activities could be combined with performing therapeutic game-like exercises on a computer.

In the HandinMind (HiM) project, such a wearable dual-function system (the soft-robotic HiM glove), is being developed. Since this system is part of an iterative development process, a user-centred approach is used to increase the chances for uptake of such devices in daily life (20, 21). Therefore, the aim of this initial stage of user tests is to obtain a first insight in feasibility of the first prototype of the HiM system. Thus, this study investigated user acceptance (e.g., perceived ease of use, motivation, system usability) and impact of the HiM system during the performance of activities of daily living (ADL).

METHODS

PARTICIPANTS

For this feasibility study, 5 chronic stroke patients with self-perceived hand function impairments resulting in problems executing ADL were recruited through the rehabilitation physician of Roessingh Centre for Rehabilitation (Enschede, the Netherlands). Additional inclusion criteria included age between 18–80 years, >6 months post-stroke, at least 10° of active flexion and extension of the fingers to produce the interaction force that is needed to control the assisted support of the glove, don/doff the glove by themselves (closing the zip of the glove was not necessary for completion of don/doff), living at home, sufficient cognitive status to understand 2-step instructions and (corrected to) normal vision. Exclusion criteria included severe sensory problems, acute pain, spasticity and contractures of the affected hand or co-morbidities that may limited hand function and functional use in ADL, wounds on the affected hand that could lead to problems with wearing the glove, participation in other studies that could affect functional performance of the affected upper limb and having insufficient knowledge of the Dutch language to understand the purpose or methods of the study. The rehabilitation physician, who was familiar with the HiM system, judged whether the potential participant was suitable for participation on the basis of the criteria.

All participants were informed verbally and in writing about the purpose and procedures of the study and signed a written informed consent before inclusion. This study was approved by the Medical Ethics Committee Twente, Enschede, the Netherlands (registration number: NL51270.44.14).

Table 4.1. Explanation of task execution.

Task	Explanation
Drinking	Participant grasps and opens a bottle of water (0.5L), pours some water in a glass, closes the bottle of water, takes a sip of water and returns the bottle and cup to the starting position.
Eating	Participant takes a knife, cucumber and plate to prepare 3 slices of cucumber. After cutting 3 slices of cucumber, the participants returns the knife, cucumber and plate to the starting position.
Household cleaning	Participant takes a cloth, wrings out the cloth 3 times and cleans a marked line on the table.
Reading	Participant holds a book in the affected hand for 30 s and returns the book to the starting position.
Dressing	Participant takes jacket off the coat hanger, puts jacket on, closes the zips/button, takes off jacket and returns it to the coat hanger.
Door opening	Participant takes the key of the door from a desk, puts the key in the door, closes/opens the door and returns the key to the seat next to the door.

DESIGN

In this cross-sectional feasibility study, participants performed various ADL-like tasks (Table 4.1), 3 times with, and once without, the HiM system prototype during 2 sessions on 2 separate days (with a minimum of 4 days between sessions). During the performance of these different tasks, participants were encouraged to think aloud (22). The experiment took place in a controlled laboratory environment at Roessingh Research and Development (RRD), Enschede, the Netherlands. The order of the conditions (with or without HiM system) applied during each session was randomized by a trained clinical researcher using sealed envelopes. Using the HiM system for the first time (naïve use) was tested in evaluation session 1 and exposed use was tested in evaluation session 2. All sessions were supervised by the same clinical researcher (human movement scientist), who had experience with performing these tests.

THE HANDINMIND SYSTEM PROTOTYPE

The first HiM system prototype consists of a wearable soft-robotic glove that was developed to support grip and hand opening of all fingers of stroke patients in a wide range of ADL (HiM assistive system). The same glove can be connected to a computer with specific software to provide a specific training context to train hand function (HiM therapeutic system) (Figure 4.1).

The HiM assistive system consists of 2 parts: (i) the control unit; and (ii) the glove. The control unit houses the actuators, control software and batteries, which allows a use period of multiple hours.

The extra grip strength is regulated by a tendon-driven mechanism that is controlled by sensor input from force sensors (technology from Tekscan Inc., South-Boston, Massachusetts, USA) at the fingertips and extension/flex sensors (Flexpoint, Draper, USA) along the dorsal side of the fingers. This prototype uses an intention detection logic that activates the grip support after the participant initiates contact with an object, detected through the force sensors, and is intended to provide support in a fast, natural and intuitive way. The tendon actuators provide support in proportion to the grip force applied by the participant, with more support supplied when a stronger grip is applied on the object. Grip force is released when the participants release the object and the force sensors detect a reduction of force. In addition, hand opening is supported by passive leaf springs attached to the dorsal side of each finger.

The HiM therapeutic system comprises of: (i) a therapeutic platform (e.g., computer) to which the HiM assistive system is connected; and (ii) therapeutic software including exercises, assessments, patient databases, connectivity features, additional safety mechanisms and a user interface for the patient and therapist (see Figure 4.1).

Figure 4.1. The HandinMind system. *Left:* the HandinMind assistive system. *Right:* the HandinMind therapeutic system.

The HiM therapeutic system supports the following therapy goals:

1. Simultaneous finger coordination: this exercise requires the user to control a robotic submarine equipped with 5 robotic arms that move according to the user's finger angle signals coming from the glove. The user is required to adapt different hand postures in order to collect "coins" or avoid "bombs".
2. Hand strength: this exercise requires the user to control up and down movements of a character on the screen using hand opening and closing movements. The user is required to move and modulate their hand aperture in order to collect points. As the level of difficulty progresses, the glove provides resistance in either closing or opening the hand (according to therapeutic need).
3. Sequential finger coordination: this exercise requires the user to use thumb opposition movements to play a song (similar to a Guitar Hero® game). When the user is not able to play a specific set of notes, the exercise will slow down and help the user identify the correct movement (s)he is supposed to execute.

PROCEDURE

A usability test was performed at the start of session 1 only, to obtain insight into the perceived ease of use of the HiM system prototype upon first, naïve use. The test involved donning/doffing the HiM assistive system, performing a drinking task with the assistive glove and performing a few assignments using the HiM therapeutic system (e.g., start training software, perform calibration, select 3 game exercises, play exercises for 2 min, etc.). Participants received no instructions about how to use the HiM system prototype before or during the usability test. This was done to test the intuitiveness of the glove and training software, in order to gather feedback about how to design the next versions of the HiM system. The researcher closely observed the actions and registered the comments of the participant during the test to identify areas that need improvements.

A functional task performance test was part of both sessions and performed after the usability test in session 1. Prior to this test, participants received instructions about how to use the HiM system prototype properly. Subsequently, the level of hand opening support and the amount of grip support (in terms of sensitivity and maximal gain) was tuned for each individual participant based on the participants' needs and experienced comfort (until support from the glove was experienced). Participants then used the wearable soft-robotic glove during 6 different functional tasks: drinking, eating, household cleaning, reading, dressing and door opening (for

more details about task execution, see Table 4.1). The most-affected hand was used as the primary hand to perform all functional tasks, irrespective of hand dominance. All functional tasks were demonstrated by the researcher before the test started. Furthermore, participants received verbal instructions about how to execute the functional tasks during the test, if needed.

MEASUREMENTS

Fugl-Meyer assessment

Motor function of the arm and hand was measured with the upper extremity part of the Fugl-Meyer assessment (FM). The maximal score on the FM was 66 points (23).

Usability test

The usability test was video-recorded after consent from all participants and the main findings were noted by the researcher. The findings of the full observational analysis have been grouped by the clinical researcher, first to a grouping structure, defined by the overall categories elicited by the patient responses concerning use issues, and sub-divided among specific topics of information, where needed. Subsequently, the common denominators have been extracted across all usability tests by analysing the number of participants that have indicated a particular issue.

Functional task performance test

The performance time of all functional tasks was measured from the start position (lifting hand from table) until completion of the task by using a stopwatch. In addition, the researcher observed and noted striking qualitative aspects of task execution (e.g., remarkable (differences in) speed of movement or fluidity of movement) as a potential sign of issues.

Of the 3 repetitions with the glove, the first 2 were dedicated to getting used to the glove, and only the last repetition was used to compare the performance times between both conditions. Change in performance times over the 3 consecutive repetitions with the glove were used to explore a potential learning effect.

User acceptance

User acceptance of the HiM system in terms of usability and motivation when using the system was measured by the System Usability Scale (SUS) and the Intrinsic Motivation Inventory (IMI), respectively. The English versions of the SUS and IMI were already translated into Dutch, and although the translated versions were not validated, they were also used in other studies, e.g., Nijenhuis et al. (24).

The SUS is a 10-item questionnaire assessing the subjective experiences of usability of a technological system. Each item was scored on a scale ranging from “(1) strongly disagree” to “(5) strongly agree”. The total score of the SUS was translated to a score ranging from 0–100, where higher scores indicate better usability. A score <50 indicates a low probability of acceptance in the field, 50–70 is a promising score, but does not guarantee high acceptance in the field, and a score >70 indicates a high probability of acceptance in the field (25, 26). The SUS was administered in both sessions, after the functional performance tests.

The IMI is a 34-item questionnaire consisting of 6 different domains (interest/enjoyment, perceived competence, effort, perceived choice while performing a given activity, experienced pressure/tension and value/usefulness), assessing an individual’s intrinsic motivation during a physical activity, in this case performing functional tasks with support from the HiM system. Each item was scored on a scale ranging from “(1) not at all true” to “(7) very true” (27-29). A higher score on the IMI indicates a higher motivation during the use of the HiM system. The IMI was administered at the end of session 2 only.

DATA ANALYSIS

Statistical analyses were performed using IBM’s SPSS Statistics software package, version 23.0. Descriptive statistics were used to describe patient characteristics and all outcome measures. In addition, the Friedman test was used to test the differences in performance times between consecutive repetitions of the functional tasks with the glove within both sessions. The overall level of significance was set at $\alpha \leq 0.05$.

RESULTS

The characteristics of the 5 chronic stroke patients at baseline are shown in Table 4.2. No adverse events were observed during any of the tests with the HiM system.

Table 4.2. Characteristics of the participants.

Participant	Gender	Age (years)	Time since stroke (months)	Dominant side before stroke	Affected side	FM- score
1	Female	45	36	Left	Left	NA
2	Male	54	39	Left	Right	49
3	Male	69	20	Right	Left	NA
4	Male	64	21	Right	Right	57
5	Female	64	23	Right	Left	37
Median (range)		64 (45-69)	23 (20-39)			

FM: Fugl-Meyer; NA: not available.

USABILITY TEST

All participants were able to don and doff the first version of the HiM assistive system by themselves. However, closing the zips of the glove was not possible for all participants. Performance of the drinking task with the HiM assistive system was completed successfully without instructions by 3 participants, the other 2 participants needed help due to their impaired hand function. Nevertheless, some aspects of using the HiM assistive system prototype in this functional task were observed to be difficult for most participants (Figure 4.2). This was related predominantly to less sensation, which was experienced and reported by all participants, while performing the task with the glove due to the thickness of the fabric of the glove.

Figure 4.2. Difficulties with the drinking task.

Participants also experienced some usability issues while using the first version of the HiM therapeutic system when no instructions were given, especially regarding selecting and playing the various therapeutic exercises (Figure 4.3).

Figure 4.3. Difficulties with the therapeutic exercises.

FUNCTIONAL PERFORMANCE TEST

Three attempts with the glove (second attempt door opening task of participant 2 during session 1, second attempt reading task of participant 3 during session 1, and third attempt household cleaning task of participant 5 during session 2) were not included in the analysis, because these tasks were not performed according to the given instructions. Furthermore, participant 5 was not able to perform the reading task, because of insufficient arm strength to lift the book. All individual performance times for each task are shown in Figure 4.4.

Figure 4.4. Individual performance times of all tasks. (A) First repetition with glove, (B) second repetition with glove, (C) third repetition with glove, and (D) without glove.

The individual performance times of the participants (Figure 4.4) showed improved performance during the 3 consecutive repetitions with glove (a learning curve in performance), during both sessions. However, the learning curve in sessions 1 seemed larger compared with the learning curve in session 2. There are a few trials in particular in the eating and door opening tasks that interrupt the learning curve in performance for some participants. Additional statistical analysis showed that for the drinking and household cleaning tasks in both sessions ($p \leq 0.039$), and the eating task ($p = 0.019$) and door opening task ($p = 0.005$) in session 1, performance times differed between the 3 consecutive repetitions with the glove. For these tasks, individual participants showed an overall reduction in performance time between the first and third repetitions of 9.4–42.4 s in the drinking task, 5.0–23.5 s in the eating task, 0.3–8.9 s in the household cleaning task, 4.1–15.6 s in the door opening task of session 1. In session 2, they improved performance in the drinking task with 1.4–22.6 s and in the household cleaning task with 0.7–4.7 s.

When we are looking at the performance times of the final repetition with glove and without glove (Figure 4.4), we do not see a clear difference in performance times

between with and without glove for all tasks in favour of performance with glove or without glove, in either session. Overall, median changes showed a small difference between performance with and without glove ranging from -1.1 to 2.5 s, except for the drinking task in session 1 (median difference of 5.8 (IQR 0.6–16.0) s), door opening task in session 1 (median difference of 5.4 (IQR 3.6–18.9) s) and the drinking task in session 2 (median difference of 4.1 (IQR -7.9 to 12.0) s), in favour of performance without glove.

Qualitative observations during the functional performance test highlighted that all participants experienced difficulties with performing fine motoric subtasks (e.g., grasp cap of the bottle from table, grasp cap of bottle during opening/closing the bottle) when wearing the glove. Participants mentioned that they experienced these difficulties with fine motoric tasks due to perceived decreased sensation with the glove. On the other hand, all participants mentioned that they mainly noticed and appreciated the grip support of the glove during gross motor activities, such as holding the bottle, turning the cap of the bottle during opening/closing the bottle, cutting food, wringing the cloth and gripping the key during turning. They also perceived an improved performance with the glove across consecutive repetitions in terms of improved performance time and ease of use. In addition, the dressing task was too difficult to perform for all participants with glove, because the first prototype of the HiM assistive system was too bulky to wear underneath a jacket. Another usability issue observed by 3 participants was an unpleasantly warm and sweaty hand while using the glove.

USER ACCEPTANCE

All 5 participants completed the SUS after both sessions (see Figure 4.5 for individual scores). The lowest SUS score was 65. The median of the SUS of session 1 was 80.0 (IQR 70.0–88.8) and the median of the SUS of session 2 was 77.5 (IQR 75.0–87.5), which was comparable (Figure 4.5).

Each part of the IMI was rated very positively by all participants, with a sub-score of at least 4.8 points per domain (Figure 4.6). The IMI total score varied between 6.1 and 6.3 points, with a median IMI score of 6.3 (IQR 6.2–6.3).

Figure 4.5. Individual System Usability Scale scores.

DISCUSSION

The results of this study showed that the usability of this first HiM system prototype upon first and second use was acceptable and promising, as reflected in SUS scores of 80 and 77.5 (25). In addition, all participants were able to don/doff the glove by themselves, except for closing the zips of the glove. Furthermore, 3 participants were able to complete a functional drinking task with support from the HiM system without any assistance or instructions. Nevertheless, several usability issues were identified, especially concerning difficulties with performing the therapeutic exercises with the HiM system, performing the dressing task due to the bulkiness of the system, opening/closing the bottle with the glove and grasping the cap from the table with the glove without any assistance or instructions. These issues need improvements in future iterations of glove development. Regarding functional performance, performance with the glove was initially slower than without the glove, but performance times with the glove improved across no more than 3 repetitions to levels close to or even up to the level of performance without the glove. This was even more pronounced during session 2. Overall, participants were motivated to use the HiM system and reported improved performance with the glove, although this was not always reflected in the outcomes as quantified via performance times.

Concerning feasibility of the HiM system, participants were positive about its usability and very motivated to use it, as reflected in the high individual SUS and IMI scores. The individual SUS scores of both sessions, ranging from 65 to 95, showed high probability of acceptance of the HiM system for using the device for upper limb rehabilitation and assistance in daily life (25). Other studies (24, 30, 31) that investigated usability of other types of technology for the upper limb, such as (robotic) assistance or training programmes, showed lower scores (<70) on usability indicating promise, but not guaranteeing high acceptance in the field. In addition, the median IMI score of 6.3, with at least a 4.8 on each subscale (Figure 4.6), indicates that participants also regarded the HiM system as an interesting, useful and motivational system to use, aimed at improving their hand function during daily life. The studies from Nijenhuis et al. (32) and Radder et al. (31) showed lower overall IMI scores for stroke patients and elderly people using robotic hand devices for training purposes or assistance in daily life. Interestingly, the studies of Nijenhuis et al. (24, 32) showed that stroke patients were able to use a robotic training device, that received lower SUS and IMI scores, for the upper limb independently at home for at least 105 min a week. This may suggest that stroke patients might be able and motivated to integrate the HiM system into use in daily life. Moreover, the first HiM system prototype will be refined further based on the present usability findings, before it will be applied in a field test. This further enhances the probability of the HiM system to be applicable and usable in daily life.

The usability test of this feasibility study revealed some examples of experienced usability issues upon first use that need improvements for independent use of the HiM system at home. Our findings are in line with Demain et al. (33), who have suggested that barriers to assistive technology use are related to the simplicity of the design of assistive technology, such as difficulties with donning/doffing and initializing the device. Similar findings were observed when elderly subjects with age-related decline in hand function were asked about use of assistive technology to assist with ADL (34). When these issues are addressed in a proper way, potential users of assistive technology did consider assistive devices as a home-based solution for intensive and functional upper limb rehabilitation, as well as for support during ADL. However, a prerequisite for using such a system is that it complies with user requirements (e.g., easy to operate, compact, simple to apply, portable etc.) for assistive technology (33-35). In addition, the system would be adopted only if the user perceives that the device enhances their functional performance and/or independence (35).

Regarding performance enhancement, there was no difference in functional task performance duration found between with and without glove performance in the

majority of tasks. In our previous study (31), we observed that older adults with reduced hand function performed faster without the glove compared to with the glove during the same functional tasks as performed by stroke patients in the current study. The difference in influence of the glove on performance duration between both populations may be related to the severity of hand function problems. It is likely that participants with larger limitations in hand function can experience a larger gain when using the glove than participants with substantially less hand function limitations. This could be the case for people with limited hand function only, because the glove could not support insufficient arm strength (for example, holding a book). Stroke patients often experience a restricted range of motion, loss of sensory function or strength and increased muscle tone in their affected arm/hand causing severe motor loss and function (36), whereas elderly (possibly with rheumatoid arthritis or osteoarthritis) can experience decreased ability to perform daily activities due to reduced grip strength, sensory changes or pain (37). This results in that the glove would be less suitable for stroke patients with these severe impairments.

Concerning the amount of glove use, the HiM system was only used actively for approximately 20 min in both sessions to assess the feasibility of the HiM system. During these 20 min, participants showed large improvements in performance duration (median changes up to 38.8%) with the glove across only 3 consecutive repetitions, indicating a steep learning curve in both sessions. These learning curves showed that participants learned rather quickly how to make use of the glove after only 3 consecutive repetitions (see Figure 4.4) (38). It is important to consider that more progression in performance with the glove is possible, because participants probably have not yet reached a learning curve plateau. Therefore, performance with the glove might become even faster compared with performance without the glove after a longer learning period with the glove.

LIMITATIONS

Several limitations may have affected the interpretation of the results of this feasibility study. Firstly, the statistical analysis needs to be interpreted with extreme care, since these analyses involved a small sample of stroke patients ($n=5$). Therefore, descriptive interpretations of the individual results of the stroke patients are also shown in this feasibility study. Secondly, stroke patients performed the functional tasks in this study with their most-affected hand, which could have been their dominant or non-dominant hand. This might have caused difficulties in performing functional tasks with and without the glove, because the most-affected hand of stroke patients is often used to support the non-affected hand instead of using it as

primary hand to perform functional tasks (39). Therefore, subsequent studies should take the role of the gloved hand into account. Thirdly, participants performed the functional tasks with and without the activated glove only. The fact that participants did not perform functional tasks with an inactivated glove makes it difficult to establish the influence on task performance of wearing a glove itself, for instance via loss of sensation, in particular during the performance of fine motoric activities (e.g., grasping the cap from the table). Fourthly, it is difficult to perform fine motoric tasks with the glove and to support fine motoric tasks with a soft-robotic glove. Therefore, usability of the current glove needs to be improved for fine motoric tasks, which should not be ignored during next design iterations. On the other hand, participants liked the extra support during gross motor activities. Therefore, gross motor activities should not be ignored in subsequent studies. Finally, no detailed evaluation of movement execution and quality of task performance were performed in extension of the single aspect of timed performance. Therefore, additional research is needed to investigate the effect of the HiM system in ADL in more detail, in terms of functional task performance, movement execution and handgrip/pinch strength, as well as the effect of the HiM system after prolonged use.

CONCLUSION

This feasibility study showed that chronic stroke patients with limitations in ADL due to impaired hand function were positive about the usability of the first HiM system prototype and were motivated to use it. The system is aimed at intensive and functional upper limb rehabilitation as well as assistance during ADL. Nevertheless, design adaptations are needed to improve ease of use, usability and system performance. Functional performance duration with the glove improved across 3 repetitions up to the level of their performance time without the glove.

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CHAPTER 5

The effect of a wearable soft-robotic glove on motor function and functional performance of older adults

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Assistive Technology, 2018, 30, 1-7

ABSTRACT

Reduced grip strength, resulting in difficulties in performing daily activities, is a common problem in the population of older adults. Newly developed soft-robotic devices have the potential to support older adults with reduced grip in daily activities. The objective of this study was to evaluate the direct, assistive effect of grip support from the wearable, soft-robotic ironHand glove.

In total, 65 older adults with self-reported decline of hand function resulting from various disorders participated in this cross-sectional study. They performed various hand function tests with and without the glove during a single session. At the end, usability was scored.

Participants were able to produce more pinch strength with the glove compared to without glove ($p \leq 0.001$) and usability was rated very positively. However, this was not reflected in improved functional performance with the glove, as measured with timed tasks ($p < 0.001$). Furthermore, no correlation was found between baseline handgrip strength and changes in performance (between without and with glove) of all assessments ($\rho \leq 0.137$, $p \geq 0.288$).

Further design adaptations are desired and more research is needed to investigate if performance with the glove can improve, when taking quality of task performance into account, or when applying a longer acquaintance period with the glove.

INTRODUCTION

Decline of hand function in older adults as a result of age-related loss of muscle mass (i.e., sarcopenia) (1) and/or age-related diseases such as stroke, rheumatoid arthritis or osteoarthritis (2, 3), is a common problem worldwide. The decline in hand function, in particular grip strength, often results in increased difficulties in performing activities of daily living (ADL), such as carrying heavy objects, doing housework, (un) dressing, preparing food, and eating (4-6).

Two common approaches to address functional limitations in daily life are personal assistance (i.e., help from others, such as a spouse or a caregiver) and assistance using assistive devices (i.e., jar opener or cane) (7, 8). Personal assistance or assistive devices are used by 74%–92% of the older adults above 55 years that experience functional limitations in daily life. Many of those older adults ($\approx 70\%$) experience less difficulties while performing upper-extremity tasks with assistance compared to without assistance; moreover, in 32%–36% of the older adults, the difficulties in upper-extremity tasks are resolved. The severely disabled older adults often need both personal assistance and assistance from assistive devices (9). However, most of those severely disabled older adults prefer to use assistive devices only, because the use of assistive devices increases self-control and functional independence (7).

Currently, assistive upper-limb devices are available in many shapes and sizes, ranging from simple assistive devices (e.g., jar opener) to technological innovations (e.g., robotic devices) that can compensate for the loss of functionality in motor function. Although simple assistive devices can be very effective, they can only be used for a specific task and targeted in particular people with mild hand function limitations. Fully assistive robotic devices allow for improved functionality, but often consist of heavy and bulky equipment, and they are expensive and often not portable (or wheelchair mounted) (10). Such devices, for instance joystick-controlled robot arms, can have a major benefit on personal independence (11), but they are targeted specifically at people with very severe physical limitations.

Recently, a few research groups have started development and evaluation of robotic devices that have been designed with flexible and soft materials (e.g., cable-driven, fluidic soft actuators, soft pneumatic actuators) to provide assistance in either therapeutic exercises or daily activities for the proximal and/or the distal upper limb (12-15). This results in lighter and portable, or even wearable (fully ambulant) devices, which are easier to put on/off. These features make such devices highly suitable for use during ADL. The assistive soft-robotic ironHand system is a comparable soft-robotic system, in this case supporting grip (controlled by pressure

sensors). It has a particularly very lean design resulting in comfortable use during functional activities and is fully wearable, with a battery life of several hours. This makes the ironHand system suitable for application in the home environment. It enhances the existing hand function, without completely taking over from the user, targeting a wide range of people with mild-to-moderate hand function limitations, not necessarily related to a specific disorder. In contrast to the ironHand system, most assistive (soft)-robotic devices (as described above) are developed specifically for people with neurological diseases and/or are not yet mature enough for large-scale clinical testing.

During the design and development process of new assistive devices, such as the ironHand system, it is important to apply a user-centered approach with an iterative design (16). The advantage of using such approach is that potential concerns for the use of assistive devices, for example, physical comfort, simplicity, and ease of use of such robotic devices (17) could be addressed in the design and development phase, which could increase acceptability and uptake of such devices. Therefore, potential end-users were involved early in the design and development process of the ironHand system to identify user requirements for such soft-robotic system (18). This was followed by initial user tests that showed positive results related to feasibility and user acceptance of a previous version of the ironHand system (19).

To our knowledge, the direct effect of such assistive soft-robotic device has not been investigated yet in a large population with hand function limitations. Therefore, the objective of this study was to measure the direct, assistive influence of a next version of the ironHand system on pinch strength and functional performance (as measured with the box and blocks test (BBT) and Jebsen–Taylor hand function test (JTHFT)) in a large population of older adults with hand function limitations, along with perceived usability. It was expected that older adults would perform better on those tasks with assistance from the glove, and that this assistive effect would be larger in older adults with more pronounced weakness.

METHODS

SUBJECTS

Subjects were recruited across four participating sites: Roessingh Research and Development (RRD), Enschede and National Foundation for the Elderly (NFE), Bunnik in the Netherlands; Eskilstuna Kommun Vård-och omsorgsförvaltningen (ESK), Eskilstuna in Sweden; and terzStiftung (TERZ), Berlingen in Switzerland.

Subjects over the age of 55, who experienced difficulties in performing ADL due to hand function limitations, were eligible to participate in this study. No specific criteria regarding disease or diagnosis were applied in this study. Subjects had to meet the following inclusion criteria: (1) self-reported difficulties in performing ADL, related to hand function decline; (2) most-affected hand is the dominant hand; (3) at least 10 degrees of active flexion and extension movement of the fingers to produce the interaction force that is needed to control the assisted support of the glove; (4) sufficient cognitive status to understand two-step instructions; (5) (corrected to) normal vision; and (6) living at home.

A subject was excluded if he/she had (1) severe sensory problems of the hand; (2) severe acute pain of the hand; (3) wounds on their hands that may create problems when wearing the glove; (4) severe contractures limiting passive range of motion; (5) insufficient knowledge of the Dutch, Swedish, or German language to understand the purpose or methods of the study; and (6) participation in other studies or rehabilitation that can affect functional performance of the upper limb.

This study was approved by the local ethical committees in each of the three countries and all subjects gave their written informed consent prior to inclusion into this study.

DESIGN

A cross-sectional study design was used in this multicenter study, wherein each subject performed various standardized hand function tests. Each subject completed the tests during roughly 1.5 h on one day. All tests were performed with and without the glove in a controlled environment across the four sites to assess the orthotic effect of the glove. At each site, all tests were supervised by one clinical researcher. Before the study started, all involved researchers were instructed and trained by researchers from RRD, as the coordinators of the study, to assure consistent execution of the hand function tests across sites.

IRONHAND SYSTEM

The wearable soft-robotic glove, the ironHand, provides assistance of grip to the thumb, middle finger, and ring finger. The ironHand consists of two parts: (A) the control unit (about 600 g) that contains the battery, control software, and actuators to generate the support and (B) the grip supporting glove (about 85 g) (Figure 5.1). A cord connects the control unit with the glove and holds the artificial tendons as well as electrical cables for sensors. The ironHand can be worn as a regular glove (illustrated in Figure 5.1), with the control unit attached to the belt or trousers at the

waist. The index finger and little finger are not covered by the glove to retain tactile input.

The amount of force added to the grip is controlled by pressure sensors of thickness 0.5 mm (Interlink Electronics) in the fingertips of the thumb, middle finger, and ring finger. Actuators in the control unit apply force to the grip via a tendon mechanism, such that the force becomes larger when the user applies higher force to the object and vice versa. The gain of this control mechanism (i.e., sensitivity) and maximal amount of force added by the glove can be tuned for each individual. The maximal added force is limited to 20 N. The user needs to apply about 1 N on the sensor for the glove to detect it. Response time is in the range 0.5–2 s depending on grip.

Figure 5.1. The ironHand system. A: Control unit. B: Glove.

EXPERIMENTAL PROTOCOL

Sealed envelopes were used to randomize the order of glove condition applied for each subject. For either condition, the same order of tests was applied. Prior to performance of comparative hand function tests, maximal handgrip strength was measured (without glove) to describe the degree of functional limitations of the present sample (6, 20). Next, pinch strength and functional task performance were measured with and without glove. During assessment of pinch strength, each subject received the same amount of maximal support of the glove (20 N), with the same control settings. During assessment of functional task performance, the amount of support of the glove was set to a level that was experienced as most comfortable by each participant and adjusted to the needs of the participant. At the end, participants completed the system usability scale (SUS), which measures the subjective experience of usability of the ironHand system during the test (21).

ASSESSMENTS

Maximal handgrip strength test

Maximal handgrip strength of the most affected hand was measured with the Jamar hydraulic hand dynamometer (Patterson Medical Ltd., Warrenville, IL, USA) with the handle position set at 4 for all attempts for all subjects. The positioning of each participant was standardized as described by the American Society of Hand Therapists (22). The participant had to squeeze the handgrip of the dynamometer maximally for 5 s. Handgrip strength was expressed in kilograms (kg). The subject had three attempts and between all the attempts there was at least 60 s rest. The best of the three attempts counted.

Maximal pinch strength test

Maximal pinch strength was measured with the Baseline® Lite™ Hydraulic Pinch Gauge dynamometer (Fabrication Enterprises, White Plains, NY, USA), following the same positioning procedure as described for the maximal handgrip strength test. The pinch strength was measured between the thumb and index finger and thumb and middle finger. The participant was instructed to grasp the pinch dynamometer with the distal segment and ventral side of the thumb and finger. The other fingers were not allowed to give any support. The subject had three attempts for each combination and between all the attempts there was at least 60 s rest. The highest value of these three attempts was used for further analysis.

Jebsen-Taylor hand function test

The JTHFT is a valid and reliable test to assess the functional performance (23, 24). It consists of seven different unilateral hand skill tasks related to ADL: (1) writing 1 sentence of 24 letters, (2) turning over 7.6- × 12.7-cm cards, (3) picking up small, common objects (i.e., paper clips, coins, and bottle caps) and move these to a box, (4) simulated feeding (i.e., teaspoon with beans), (5) stacking checkers (test of eye-hand coordination), (6) picking up large empty cans, and (7) moving weighted (450 g) cans (23, 24). The subject performed each task with the most-affected hand while sitting comfortably close to the table. The duration of each task from start (lifting hand from table) to completion of the task was recorded in seconds with a stopwatch (maximal duration is 120 s per task) and summated as the total score.

Box and blocks test

The BBT is a valid and reliable measurement to evaluate unilateral gross manual dexterity (25). The subject had to grasp and transport as many blocks as possible

within 1 min from one compartment to the other, one by one, over a partition. The number of blocks counted after 1 min serves as the outcome measure (25, 26).

System usability scale

Subjective experiences of system usability was measured with the SUS. The 10 questions of the SUS were scored on a 5-point Likert scale ranging from 1 (strongly disagree) till 5 (strongly agree). The total score of the SUS ranges from 0–100 and was calculated as described in (21). A higher score indicates better usability of the system. A system that scores below 50 on the SUS can be almost certain of usability difficulties in the field, an SUS score between 50–70 indicates OK usability, an SUS score above 70 indicates a good probability of acceptance, and an SUS score above 85.5 indicates excellent usability (27, 28).

STATISTICS

The software package IBM SPSS statistics version 23.0 for Windows was used to analyze the data. All outcome measures were first checked for normal distribution by visual inspection of histogram plots, which was verified with the Shapiro–Wilk test. Participant characteristics and outcome measures were described with descriptive statistics using mean $\pm$ standard error of the mean (SEM).

The differences between both conditions (with and without glove) were examined with a paired sample t test for all outcome measures. Additionally, correlation analyses were performed for handgrip strength and changes in performance (between without and with glove) of all individual assessments using the Pearson's correlation coefficient. The overall significance level was set at $\alpha < 0.05$.

RESULTS

Sixty-five older adults (Table 5.1) between 56 and 89 years old with different diseases and diagnoses, ranging from rheumatoid arthritis/osteoarthritis (41 persons) to natural age-related loss of strength (5 persons), stroke (4 persons), carpal tunnel syndrome (4 persons), and other diseases (11 persons), participated in this study. Handgrip strength data indicate that the participants of this study ranged from “weak” to “normal,” based on cutoff points related to increased risk for mobility limitations (29, 30).

Table 5.1. Demographic characteristics ($n=65$).

Gender (male/female)	14/51
Age (years) ^a	72.1 ± 0.9 (56-89)
Handgrip strength (kg) ^{a,c}	15.9 ± 1.2 (2.0-40.8)
Most-affected body side (right/left/both) ^b	49/9/7
Dominant side (right/left/both)	52/8/5

^aMean ± SEM (range); ^bThe glove was worn on the dominant hand if both sides were most affected; ^cOne missing value

Pinch strength data were available of 63 participants and 64 participants completed the BBT. In addition, 10 participants had some difficulties to complete all subtasks of the JTHFT, resulting in 55 complete JTHFT datasets.

Pinch strength between the thumb and index finger (+0.4kg (+11.0%), $p = 0.001$) and the thumb and middle finger (+0.5kg (+13.6%), $p < 0.001$) was larger with glove compared to without the glove (see Figures 5.2 and 5.3). On the other hand, performance with glove compared to without glove was worse during the BBT (-5 blocks (-11.0%), $p < 0.001$) and JTHFT (+17.2 s (+22.0%), $p < 0.001$) (see Figures 5.4 and 5.5). All subtasks of the JTHFT were also performed slower with glove compared to without glove ($p \leq 0.026$).

Correlation analyses showed no correlation between baseline handgrip strength and changes in performance (between without and with glove) of all outcome measures ($q \leq 0.137$, $p \geq 0.288$).

The mean SUS score of 61 completed questionnaires was 72.2 (SEM=2.2), indicating a good probability of acceptance of the ironHand system in daily life. Individual scores on the SUS showed that 7 participants (11.5%) scored below 50, 18 participants (29.5%) scored between 50 and 70, 20 participants (32.8%) scored between 71 and 85.5, and 16 participants (26.2%) scored above 90.

Figure 5.2. Mean ($\pm$ SEM) pinch strength between thumb and index finger.

Figure 5.3. Mean ($\pm$ SEM) pinch strength between thumb and middle finger.

Figure 5.4. Transported amount of blocks (mean $\pm$ SEM) on the BBT.

Figure 5.5. Total mean ($\pm$ SEM) performance time on the JTHFT.

DISCUSSION

The present study showed that older adults with hand function limitations due to heterogeneous causes can produce more pinch strength with the soft-robotic ironHand glove compared to without the glove. On the other hand, performance of the JTHFT and the BBT was worse with the ironHand glove compared to performance without glove. No correlation was found between handgrip strength and changes in performance without versus with glove. Although performance in functional tasks with the ironHand glove was worse, usability was rated very positively.

The ironHand system is part of an ongoing iterative development in which a user-centered design is applied to enhance the chances for uptake of such a novel system in daily life (16). Therefore, the results of earlier user tests (19) were used to improve the design of the current ironHand system. Usability, as measured with the SUS, of the current ironHand system is scored high, which indicates good probability of acceptance in daily life (28), and is similar compared to other types of innovative technological applications for patients (31, 32). In addition, usability of the current ironHand system improved compared to usability of the previous version of the ironHand (19). This suggests that some of the earlier identified use issues have been addressed with adequate design changes. However, users think that there is still room for improvement, of which the most pronounced suggestions were improved tactile information with the glove and water resistance of the glove. These suggestions for improvement of the ironHand system should be taken into account during the next development phase(s).

Recently, the research group of Polygerinos has investigated the direct effect of a comparable application of a different assistive soft-robotic glove (15). They showed that a healthy subject performed four subtasks of the JTHFT slower with an assistive pneumatic glove controlled by muscle activity compared to normative JTHFT data of healthy subjects. This finding of the study of Polygerinos et al. (15) is in line with the results of this study, in which overall performance time of the JTHFT was 22% slower with the ironHand glove compared to performance without glove. Participants in the current study mentioned that they felt hindered to some extent by the ironHand glove (e.g., decreased tactile information with glove), in particular when handling small objects. They experienced most support of the assistive ironHand glove during lifting (heavy) cans. Therefore, these developments are promising in particular for the support of grip strength during gross motor activities for a prolonged time for persons with reductions in handgrip strength.

In another study of Polygerinos et al. (33), a patient with muscular dystrophy used their assistive pneumatic glove controlled by muscle activity during execution of the BBT. Their findings showed that this patient with muscular dystrophy improved his/her performance on the BBT with 40%. This is not in line with the results of this study, in which a heterogeneous population with hand function limitations showed a reduction of 11.0% in performance with the ironHand glove compared to without glove. This difference in performance between both studies could be related to the severity of hand function limitations of the subject(s). The subject of the study of Polygerinos et al. (33) had a baseline BBT score of 10, whereas the mean baseline score on the BBT of the present study was 49. The ironHand glove, controlled by pressure sensors instead of muscle activity, requires an interaction force to be generated between the hand and the object to add some extra force to the grip. In contrast to a muscle-controlled glove, this requires active performance of a grasp, exerting at least some force on an object, which is too difficult for people with severe hand function limitations. Therefore, the ironHand can only be used by people with less severe hand function limitation, which might make it more difficult to find an improvement on the BBT. Correlation analyses of the group of participants in the ironHand study with “weak” to “normal” hand function showed no relation between base- line handgrip strength and changes in functional performance with versus without glove. Even though baseline handgrip strength is a strong predictor for functional performance and quality of life (6, 34), this study did not find a difference in the glove’s orthotic effect between people or sub- groups with varying levels of limitations.

Another factor that is believed to play a role in the lack of improvement found on the current timed performance tasks, based on the perception voiced by participants during testing, is that the response time of 0.5–2 s between grasp initiation and actual grasp support might influence users’ performance by pausing their movement until they perceive the added support. This could have an effect on the time that is needed for grasping, holding, and releasing an object. Therefore, subsequent research should investigate in more detail the specific influence of the use of the ironHand glove on (sub-) movement times during functional tasks.

In addition to the use of pressure sensors to control the extra force applied by the ironHand glove, several other human–robot interfaces might be considered to control the assistive force applied by a soft-robotic glove, such as mechanical solutions (switches), auditory sensors that record voice commands, and sensors that detect biological signals (EEG, EMG) (15, 35). Although it is not clear at this point which type of sensor modality would be most suitable for controlling an assistive glove, some indication for control of therapeutic training of the upper extremity was

derived in the review of Basteris et al. (35). Control strategies requiring active movement initiation may be most beneficial for improvements in upper-limb motor function (35) after poststroke robot therapy, which would match the control strategies as used in the assistive ironHand glove and assistive glove as described in the study of Polygerinos et al. (33).

In addition to the use of the ironHand glove as an assistive device in daily activities, the ironHand glove might also be regarded as a training device by providing a tool to actually turn everyday activities into extensive and highly functional training. Several reviews have shown positive effects of robotic devices used for rehabilitation purposes in a clinical setting (36, 37). However, so far, no studies have investigated the effect of using wearable assistive robotic devices for self-administered practice at home, while this has the potential to decrease practical limitations such as therapist availability for robotic training in a clinical setting. This will be even more important in the coming decades when pressure on healthcare systems will increase due to the growing population of older adults and the associated higher prevalence of age-related diseases. Besides a potential benefit regarding practical limitations (e.g., therapist availability, travelling time, logistic issues), participants could increase time in practice independent of therapists' availability. The study of Kwakkel (38) showed that at least 16 h of training is needed to improve functional performance. This could be achieved easier when robotic assistive devices are available and effective for self-administered practice at home. This aspect will be addressed in future research with the ironHand system.

Several limitations of this study may have affected the interpretation of the present study results. First, this study focused on timed performance tasks and not on quality of movement. Improvement in performance with the ironHand glove might have been measured if participants' experiences with the ironHand glove (such as pain and performance of grasping) were also measured. Second, the hand dynamometer turned out unsuitable to assess handgrip strength with the glove as direct assistive effect, due to the force sensors at the glove's fingertips misaligning with the dynamometer. Therefore, only pinch strength could be used to assess the direct effect on hand strength in the current study. In the near future, a custom-designed force sensor (e.g., a cylinder) should be considered to also evaluate the glove's effect on hand grip strength. Fourth, participants of this study had no severe hand function limitation, because an active performance of grasping is needed to use the ironHand glove. Third, participants had no experience with the ironHand glove. They used the ironHand glove only once during this cross-sectional study. Further research is needed to investigate if performance with the ironHand glove improved after prolonged use.

CONCLUSION

This study is one of the first studies investigating the direct effect of a wearable soft-robotic glove for the support of grip in daily life performance in a large sample of older adults with hand function limitations. The findings of the present study showed that older adults with hand function limitation are able to produce more pinch strength with the ironHand glove but performed worse on timed performance tests like the BBT and JTHFT. Despite the decreased performance on the BBT and JTHFT, usability of the ironHand glove was rated very positively. Design adaptations are advised, and subsequent research is needed to investigate if functional performance with the glove improves, for instance using qualitative measures of task performance or after a longer use period.

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CHAPTER 6

Home rehabilitation supported by a wearable soft-robotic device for improving hand function in older adults: a randomized controlled trial

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Submitted to: Plos One (July 2018)

ABSTRACT

New developments, based on the concept of wearable soft-robotic devices, make it possible to support impaired hand function during the performance of daily activities and intensive task-specific training. The wearable soft-robotic ironHand glove is such a system that supports grip strength during the performance of daily activities and hand training exercises at home.

This randomized controlled clinical study explored the effect of prolonged use of the assistive ironHand glove during daily activities at home, in comparison to its use as a training tool at home, on functional performance of the hand.

In total, 91 older adults with self-perceived decline of hand function participated in this study. They were randomly assigned to a 4-weeks intervention of either assistive or therapeutic ironHand use, or control group (received no additional exercise or treatment). All participants performed a maximal pinch grip test, Box and Blocks test (BBT), Jebsen-Taylor Hand Function Test (JTHFT) at baseline and after 4-weeks of intervention. Only participants of the assistive and therapeutic group completed the System Usability Scale (SUS) after the intervention period.

Participants of the assistive and therapeutic group reported high scores on the SUS (mean=73, SEM=2). The therapeutic group showed improvements in unsupported handgrip strength (mean $\Delta = 3$) and pinch strength (mean $\Delta = 0.5$) after 4 weeks of ironHand use ($p \leq 0.039$). Scores on the BBT and JTHFT improved not only after 4 weeks of ironHand use (assistive and therapeutic), but also in the control group. Only handgrip strength improved more in the therapeutic group compared to the assistive and control group. No significant correlations were found between changes in performance and assistive or therapeutic ironHand use ($p \geq 0.062$).

This study showed that support of the wearable soft-robotic ironHand system either as assistive device or as training tool may be a promising way to counter functional hand function decline associated with ageing.

INTRODUCTION

Hand function predominantly determines the quality of performance in activities of daily living (ADL) and work-related functioning. Older adults with age-related loss of muscle mass (i.e., sarcopenia) (1) and/or age-related diseases (e.g., stroke, arthritis) (2, 3) suffer from loss of hand function. As a consequence, they experience functional limitations, which affects independence in performing ADL (3-5).

An effective intervention for improving hand function of (stroke) patients should consist of several key aspects of motor learning, such as high-intensity and task-specificity in repetitive and functional exercises that are actively initiated by the patient him/herself (6, 7). In a traditional rehabilitation setting, those kinds of interventions are performed with one-on-one attention from the healthcare professional for each patient. This might become problematic in the near future when the population of older adults with age-related diseases (e.g., stroke, rheumatoid arthritis) with hand function decline will rise, resulting in an increased need for healthcare professionals and a rise of healthcare costs (8). Therefore, new alternatives to provide intensive therapy for all patients are needed in the future.

New technological developments, such as robot-assisted hand training, have the potential to provide such intensive, repetitive and task-specific therapy. Several reviews (9-11) already showed positive results on motor function after robot-assisted training of the upper extremity. However, limiting factors of robot-assisted therapy are the need for supervision of a healthcare professional, the high costs of the devices and the limited availability of wearable devices for training at home (12). Furthermore, it is often not efficient in transferring the trained movements into daily situations (6). Therefore, the next generation robotic training approaches should pay substantial attention towards home-based rehabilitation and the functional nature of the exercise involved.

A new way of providing functional, intensive and task-specific hand training would involve using new technological innovations that enable support of the affected hand directly during the performance of ADL, based on the concept of a wearable robotic glove (13-18). In this way, the affected hand can be used repeatedly and for prolonged periods of time during functional daily activities. These robotic gloves can use different human-robot interfaces to provide assistance for the affected hand, such as an EMG-controlled glove, a tendon driven glove, a glove controlled by force sensors etc. (13, 14, 16, 18, 19). All these robotic gloves use soft and flexible materials to make such devices more lightweight and easy to use, accommodating wearable

applications. This concept of a wearable soft-robotic glove allows persons with reduced hand function to use their hand(s) during a large variety of functional activities and may even turn performing daily activities into extensive training, independent from the availability of healthcare professionals. This is thought to improve hand function and patient's independence in performing ADL.

Therefore, an easy to use and wearable soft-robotic glove (ironHand system), supporting grip strength and hand training exercises at home, was developed within the ironHand project (20). Previous studies have examined feasibility (20) and the orthotic effect of the ironHand system (21). In a first randomized controlled clinical study, the effect of prolonged use of such an assisting glove during ADL at home on functional performance of the hand was explored, in comparison to its use as a training tool at home.

METHODS

PARTICIPANTS

Four sites (1) Roessingh Research and Development (RRD), Enschede, (2) National Foundation for the Elderly (NFE), Bunnik in the Netherlands, (3) Eskilstuna Kommun Vård- och omsorgsförvaltningen (ESK), Eskilstuna in Sweden and (4) terzStiftung (TERZ), Berlingen in Switzerland were involved in the recruitment of the participants. Inclusion criteria for participation into this study were: older adults over the age of 55; self-reported difficulties in performing daily activities, related to hand function decline; at least 10 degrees of active flexion and extension movement of the fingers; able to don/doff the glove by themselves; discharged from specific arm/hand therapy; sufficient cognitive status to understand two-step instructions; (corrected to) normal vision; and living at home. Potential participants were excluded if they had: severe sensory problems, acute pain or wounds on their hands that may create problems when wearing the glove; severe contractures limiting passive range of motion; insufficient knowledge of the Dutch, Swedish or German language to understand the purpose or methods of the study; and participation in other studies that can affect functional performance of upper limb.

An informed consent form was signed by both the participating individuals and the researchers before the study started. The study was approved by the local Medical Ethical Committees in the Netherlands (registration number: NL56746.044.16), Switzerland (registration number: KEKTGOV2015/16) and Sweden (registration numbers: 2016/923-31/2 and 2017/466-32).

DESIGN

In this multicentre, longitudinal, randomized controlled trial, participants were randomly assigned (using a block randomization list) into three different groups (assistive, therapeutic or control group). The assistive group used the ironHand system independently during the performance of ADL at home or at work. The therapeutic group performed hand exercises with the ironHand system independently at home and the control group did not receive the ironHand system nor followed any arm/hand therapy. The duration of the treatment was 4 weeks for all groups.

During evaluation sessions within one week before the start of the study and within one week post training, the participants performed various hand function tests to assess the therapeutic effect of the different modes of the ironHand system. All tests were performed in a controlled environment across the four sites: RRD, NFE, ESK and TERZ.

The researchers involved in the study received instructions about how to handle, operate and explain use of the ironHand system to participants by personnel from the technical project partners (Bioservo Technologies AB, Hocoma AG) prior to the start of the study. Also, they were instructed on how to execute the hand function tests by researchers from RRD (coordinator of the study), following a standard procedure.

INTERVENTION

The ironHand assistive group

Participants assigned to the ironHand assistive group received the wearable soft-robotic glove for independent use during daily activities at home or work for 4 weeks. It was recommended to use the assistive ironHand glove at least 180 min/week during the most common ADL, such as dressing/undressing, eating/drinking, functional transfers and personal hygiene. Nevertheless, they were free to choose for which activities, when and for how long they used the glove. The participants were asked to register the amount of use and activities in which they used the ironHand system in a diary.

The ironHand therapeutic group

Participants assigned to the ironHand therapeutic group used the soft-robotic glove in combination with a laptop with the therapeutic ironHand software as a training tool independently at home for 4 weeks. These participants were recommended to perform the hand exercises (games) with the ironHand system for (a minimum of)

180 minutes a week. These exercises were controlled by active arm and hand movements, recorded from flex and force sensors in the glove. Therefore, a calibration procedure presented as a game was performed, to assess participants' current active range of motion of the hand and fingers at the end of the baseline session. After the calibration game, the therapist made a therapy plan (in which the exercises and starting levels were defined) based on the limitations and treatment goals of the participants. The therapist could choose three different games designed to train hand strength, simultaneous finger coordination and sequential finger coordination (see Figure 6.1) and three difficulty levels (easy, medium and high). During the exercises, participants received feedback about points collected during the game and corresponding scores. The participants were asked to register the amount of use and games that were played in a diary.

The control group

Participants assigned to the control group did not follow a specific intervention during the intervention period. They continued their normal activity pattern of their most-affected hand.

Participants of the assistive and therapeutic group received an ironHand system for their most-affected hand. Before the participants took the ironHand system home, researchers gave instructions about all aspects of the ironHand system, demonstrated it to and practiced with the participant, until the researchers were confident that the participant knew how to use the system at home properly. Additionally, participants received a manual with most important information about the system and a phone number that they could call in case of problems. Furthermore, participants of all three groups were contacted weekly during these 4 weeks of intervention to make sure the participant was doing well and to investigate the progress of the participant. If the games or difficulty level was too easy or too difficult for the participants of the therapeutic group, it was possible to change the order of games and difficulty levels via remote access during their weekly contact.

DEVICE

The ironHand system was developed to support older adults and patients with self-reported hand function limitations during the performance of daily activities (the assistive functionality) or hand training exercises (therapeutic functionality). The assistive functionality of the ironHand system (see Figure 6.1, left panel) provides extra strength to the grip of the thumb, middle finger and ring finger of persons with reduced hand function. The grip support is applied by artificial tendons in the

wearable soft-robotic glove (placed along the length of the fingers), actuated via motors in the control unit of the system. The extra grip strength is modulated by pressure sensors (Interlink Electronics) in the finger tips. An intention detection logic ensures that the extra strength to the grip is activated in a natural and intuitive way and only after an active contribution by the user. Furthermore, the actuators of the system provide extra force to the grip in proportion to the grip force applied by the user.

The therapeutic functionality of the ironHand system (see Figure 6.1, right panel) provides a motivating game-like environment to train specific aspects of hand function, such as hand/finger strength, finger coordination or finger independence. The system consists of a therapeutic platform referring to a computing system (e.g., PC or laptop) to which a soft-robotic glove can be connected. The flex sensors along the dorsal side of the 5-finger glove control the hand training exercises played on the PC or laptop. The hand training exercises, assessments, connectivity to other devices, patient database, additional safety mechanisms and user interface are embedded in the therapeutic software.

Figure 6.1. The ironHand system.

EVALUATION

For both evaluation sessions, the same order of tests was applied, as follows. First, maximal handgrip strength and pinch strength of the most-affected hand were measured with a dynamometer. Next, hand function performance of the most-affected hand was measured with the Jebsen-Taylor Hand Function Test (JTHFT) and the Box and Blocks Test (BBT). The System Usability Scale (SUS), that measures subjective experience of usability of the ironHand system, was completed at the end of the post-evaluation session, only by the participants of the assistive and therapeutic intervention groups.

ASSESSMENTS

Maximal handgrip strength

Maximal handgrip strength was measured with the Jamar hydraulic hand dynamometer, Patterson Medical Ltd., Warrenville, IL, USA, with the handle position set at 4 for all attempts for all subjects. The positioning of each participant was standardized as described by the American Society of Hand Therapists (22). The participant had to squeeze the handgrip of the dynamometer maximally for 5 seconds. Handgrip strength was expressed in kilogram-force (kgf). Each participant had three attempts, with at least 60 seconds of rest between subsequent attempts. The best of three consistent attempts was used for analysis.

Maximal pinch strength

Maximal pinch strength was measured with the Baseline®Lite™ Hydraulic Pinch Gauge dynamometer (Fabrication Enterprises, White Plains, New York, USA), following the same positioning procedure as described for the maximal handgrip strength test. The pinch strength was measured between the thumb and index finger and thumb and middle finger. The participant was instructed to grasp the pinch dynamometer with the distal segment and ventral side of the thumb and finger. The other fingers were not allowed to give any support. The subject had 3 attempts for each combination and between all the attempts was at least 60 seconds rest. The highest value of the three consistent attempts was used for further analysis.

Jebsen-Taylor Hand Function Test (JTHFT)

The JTHFT assesses functional performance and consists of 7 different unilateral hand skill tasks related to ADL: (1) writing 1 sentence of 24 letters (2) turning over 7.6- x 12.7-cm cards (3) picking up small, common objects (i.e., paper clips, coins and bottle caps) and move these to a box (4) simulated feeding (i.e., teaspoon with beans)

(5) stacking checkers (test of eye-hand coordination) (6) picking up large empty cans (7) moving weighted (450 g) cans (23, 24). The subject performed each task with the most-affected hand while sitting comfortably close to the table. The duration of each task from start (lifting hand from table) to completion of the task was recorded in seconds with a stopwatch (maximal duration is 120 seconds per task) and summated as the total score.

Box and Blocks Test (BBT)

The BBT evaluates unilateral gross manual dexterity. The subject had to grasp and transport as many blocks as possible within one minute from one compartment to the other, one by one, over a partition. The number of blocks counted after one minute serves as the outcome measure (25, 26).

System Usability Scale (SUS)

Subjective experiences of system usability were measured with the SUS. The 10 questions of the SUS were scored on a 5-point Likert scale ranging from 1-strongly disagree till 5-strongly agree. The total score of the SUS ranges from 0-100 and is calculated as described in (27). A higher score indicates better usability of the system. A system that scores below 50 on the SUS can be almost certain of usability difficulties in the field and is not acceptable, a SUS score between 50-70 indicates marginal acceptability, a SUS score above 70 indicates a good probability of acceptance, a SUS score above 85 indicates excellent usability and a SUS score above 90 indicates best imaginable (28, 29).

Only participants of the assistive and therapeutic group completed the SUS, because the control group did not have sufficient experience with the ironHand system to validly answer questions about its usability.

Use time

Use time was recorded using a diary in both assistive and therapeutic intervention groups.

STATISTICAL ANALYSIS

Statistical analyses were performed with the software package IBM SPSS statistics version 23.0 for Windows. First, histogram plots of all outcome measures were checked for normal distribution by visual inspection. Descriptive statistics, using mean $\pm$ standard error of the mean (SEM) or the median (interquartile range), were used to describe the participants' characteristics, outcome measures and use time. To investigate differences between the three intervention groups at baseline, an One-

Way ANOVA was performed for ratio/interval data and a Chi-squared test or the Fisher exact test for nominal/ordinal data.

To investigate the training effect of ironHand system use, a mixed-model analysis was performed for each outcome measure (handgrip strength, pinch strength, BBT, JTHFT), with time of measurement as within-subject factor and group as between-subject factor. For the JTHFT, first a log-transformation was performed before the mixed-model analysis was performed, to normalize the data, which was successful for all groups on the following subtasks of the JTHFT: 'card turning', 'checkers', 'large, heavy objects', and total performance time JTHFT. For the JTHFT subtasks of the groups that didn't follow a normal distribution, even after a log-transformation, ('writing' therapeutic group, 'small, common objects' assistive group, 'simulated feeding' assistive and control group, 'large, light objects' assistive group, 'total performance time JTHFT – without subtask writing' assistive and control group), a Wilcoxon signed rank test was performed to compare pre-post evaluation. Thereafter, the individual differences between pre-post evaluation for these JTHFT subtasks were calculated for each group, which did follow a normal distribution. Subsequently, a one-way ANOVA was performed for these subtasks to investigate the difference between groups for training effect of ironHand system use. The difference in amount of ironHand use between the assistive and therapeutic group was analysed with the Mann-Whitney U test. Additionally, correlation analyses were performed for ironHand use time with differences between pre-post evaluations of all clinical assessments using the Spearman's correlation coefficient. The overall significance level was set at $\alpha \leq 0.05$.

RESULTS

A total of 91 participants (Table 6.1) were included in the study, of which 14 participants dropped out (for various reasons varying from personal problems, health issues and technical issues). Of the 91 included participants, 74 (81%) were older adults with self-perceived hand function limitations due to various age-related problems (of which the most prominent were rheumatoid arthritis and osteoarthritis), and 17 (19%) were stroke patients with hand function limitations. Of those 91 participants, 30 were allocated to the assistive group (5 dropped out), 28 to the therapeutic group (6 dropped out) and 33 to the control group (3 dropped out) (see Figure 6.2). When using baseline handgrip strength as indicator for self-reported mobility difficulties (<37 kg (men) and <21 kg (women) (30)), the current participants comprised largely people classified with weak grip (95%).

Table 6.1. Descriptive characteristics of participants ($n=91$)^a.

Characteristic	Total (n=91)	Assistive group (n=30)	Therapeutic group (n=28)	Control group (n=33)
Age (years) ^b	73 (± 1)	74 (± 2)	71 (± 2)	73 (± 1)
Gender (M/F) ^b	28 (31%) / 63 (69%)	10 (33%) / 20 (67%)	5 (18%) / 23 (82%)	13 (39%) / 20 (61%)
Dominant hand (R/L) ^b	83 (91%) / 8 (9%)	27 (90%) / 3 (10%)	24 (86%) / 4 (14%)	32 (97%) / 1 (3%)
Most-affected hand (R/L/both) ^b	59 (65%) / 18 (20%) / 14 (15%)	20 (67%) / 6 (20%) / 4 (13%)	15 (54%) / 7 (25%) / 6 (21%)	24 (73%) / 5 (15%) / 4 (12%)
Baseline handgrip strength (kgf) ^b	15.3 (± 0.8)	16.3 (± 1.4)	12.4 (± 1.5)	16.9 (± 1.3)

^aMean ($\pm$ SEM) or Count (%); ^bno significant difference between groups ($p \geq 0.053$)

Figure 6.2. Enrolment participants.

THERAPEUTIC EFFECT OF THE IRONHAND SYSTEM

Overall, visual inspection of Figures 6.3-6.6 showed that participants of the assistive, therapeutic and control group improved performance on almost all outcome measures after 4 weeks, which is most pronounced in the therapeutic group.

Handgrip strength and pinch strength (of thumb with index finger) only increased significantly ($p \leq 0.039$) in the therapeutic group by respectively 3.1 kgf (24.9%) and 0.4 kgf (14.4%) from pre- to post-evaluation (see Figures 6.3-6.5). The number of blocks transferred during the BBT only increased significantly in the assistive (3.7

blocks, 8.5%, $p = 0.007$) and control group (2.6 blocks, 5.9%, $p = 0.025$) from pre- to post-evaluation, indicating better performance (see Figure 6.6).

Figure 6.3. Mean ($\pm$ SEM) handgrip strength.

Figure 6.4. Mean ($\pm$ SEM) pinch strength between thumb and index finger.

Figure 6.5. Mean ($\pm$ SEM) pinch strength between thumb and middle finger.

Figure 6.6. Transferred amount of blocks (mean $\pm$ SEM) on the BBT.

Table 6.2. Subtasks scores for all intervention groups on the JTHFT^a.

Subtask	Assistive group		Therapeutic group		Control group	
	Pre	Post	Pre	Post	Pre	Post
Writing ^b	23.1 ± 1.1	22.2 ± 1.1	18.9 (14.5-38.0)	15.7 (12.3-32.8)	21.3 ± 1.1	18.7 ± 1.1*
Card turning	11.3 ± 1.1	8.8 ± 1.1*	12.2 ± 1.1	9.3 ± 1.1*	10.3 ± 1.1	8.4 ± 1.1*
Small, common objects	10.5 (8.4-21.0)	9.6 (7.3-12.5)*	13.2 ± 1.1	11.4 ± 1.1*	12.1 ± 1.1	10.8 ± 1.1*
Simulated feeding	11.9 (8.8-16.5)	10.0 (8.5-14.5)*	12.7 ± 1.1	11.7 ± 1.1	10.2 (7.7-15.0) ^b	10.2 (7.8-14.1)
Checkers	10.1 ± 1.2	9.7 ± 1.2	10.0 ± 1.1	8.3 ± 1.1*	8.0 ± 1.1	7.6 ± 1.1
Large, light objects	6.6 (5.2-8.7)	5.4 (3.9-7.1)*	7.2 ± 1.1	6.4 ± 1.1	6.9 ± 1.1	6.2 ± 1.1*
Large, heavy objects	7.9 ± 1.1	6.1 ± 1.1*	7.7 ± 1.1	6.2 ± 1.1*	7.6 ± 1.1	6.6 ± 1.1*
Total performance time ^b	80.7 ± 1.1	70.0 ± 1.1*	82.9 ± 1.1	71.8 ± 1.1*	73.6 ± 1.1	66.3 ± 1.1*
Total performance time - without subtask writing	55.8 (45.0-94.2)	46.2 (35.3-62.2)*	64.6 ± 1.1	54.6 ± 1.1*	52.0 (39.4-71.8)	47.5 (37.2-67.5)*

^aNormally distributed data is represented as mean ± SEM and data not following the normal distribution is represented as median (interquartile range); ^bMissing data of 5 participants in the assistive group, 6 in the therapeutic group and 7 in the control group because they were not able to perform the writing task; *significant difference from pre-evaluation.

Results (mean $\pm$ SEM) of the different subtasks of the JTHFT are presented in Table 6.2. Lower performance time on any subtask indicates better performance. The assistive group improved performance ($p \leq 0.015$) in 5 subtasks of the JTHFT ('card turning', 'small, common objects', 'simulated feeding', 'large, light objects', 'large, heavy objects'), the therapeutic group improved performance ($p \leq 0.029$) in 4 subtasks of the JTHFT ('card turning', 'small, common objects', 'checkers' and 'large, heavy objects') and the control group improved performance ($p \leq 0.017$) in 5 subtasks of the JTHFT ('writing', 'card turning', 'small, common objects', 'large, light objects' and 'large, heavy objects') after 4 weeks intervention.

In most outcome measures (handgrip and pinch strength, BBT and JTHFT), the improvement over time did not differ significantly between groups ($p \geq 0.221$). For handgrip strength an interaction effect for group and time ($p = 0.009$) was present (Figure 6.3), with improvements from pre- to post evaluations in the therapeutic group ($p < 0.001$), but no change in the assistive group ($p = 0.135$) and control group ($p = 0.561$). When represented as relative change with respect to baseline values, the therapeutic group became 25% stronger after 4 weeks of ironHand system use, in contrast to an improvement in the assistive group of 12% and a decrease of 2% in the control group.

USE TIME

Use time was available from subjectively reported diaries from 21 participants (excluding drop-outs). Total use time of these participants was on average 879 (± 194) minutes, or 15 (± 3) hours. When calculated as average use time per day, this reflects 31 (± 7) minutes each day for 4 weeks. The mean training duration, averaged per week over 4 weeks, was 220 (± 49) minutes. When distinguishing between intervention groups (Figure 6.7), we can observe that the assistive group ($n=9$) used the system on average about twice as long as the therapeutic group ($n=12$) (average daily use 45 ± 12 min vs. 21 ± 7 min). This observed group difference was significant ($p = 0.033$). However, it should be noted that the variation between individuals is large, ranging from 18 to 3375 minutes per 4 weeks.

Figure 6.7. Daily use (min/day), separately for assistive group (AG) and therapeutic group (TG).

Correlation analyses showed for some outcomes a relation between use time and change scores per group, for the assistive and therapeutic groups. Most pronounced correlations, approaching significance, were observed for the assistive group with pinch strength between thumb and middle finger ($r = 0.67$, $p = 0.071$) and the therapeutic group with pinch strength between thumb and index finger ($r = 0.55$, $p = 0.062$).

EXPERIENCES OF END-USERS

SUS data were available from participants allocated to the assistive or therapeutic groups (total 58 included, of which 47 completed the post-evaluation and 11 dropped out).

Mean SUS score across both groups was $73 (\pm 2)$, varying on individual level between 48 and 100. When divided per group, mean SUS for the assistive group ($n=25$) was $77 (\pm 3)$ and for the therapeutic group ($n=22$) $69 (\pm 3)$. According to adjective ratings scales corresponding with the SUS score (29), the ironHand system used as assistive device is perceived as having good usability and used as training tool to have OK usability (Figure 6.8).

Figure 6.8. Frequency distribution of SUS score, categorised by adjective ratings [30], separately for assistive group (AG) and therapeutic group (TG).

DISCUSSION

This study shows first of all that older adults that used the ironHand system as assistive device or as a training tool were capable to use the ironHand system by themselves at home. Both groups used the ironHand system for a substantial amount of time, with the assistive group using the ironHand system twice as long as the therapeutic group. Usability of both systems was perceived acceptable. When comparing pre- and post-evaluations for all groups separately, participants of the therapeutic group showed improved unsupported handgrip strength and pinch strength after 4 weeks of ironHand system use, while the improvement in functional performance in the assistive and therapeutic groups did not differ from that in the control group. Only handgrip strength improvements from pre- to post-evaluations did differ between groups, participants of the therapeutic group improved more compared to the assistive and control group. No significant correlation was found between the total duration of ironHand use and changes in performance, for the assistive and therapeutic groups.

To our knowledge, this is one of the first user trials that applied and tested a fully wearable robotic system to support hand function at home for unsupervised use

during an extended period of multiple weeks. Moreover, this was done in a large group of older adults with hand function limitations. It also involved two scenarios that provide a unique approach, where the ironHand system was used as assistive device or as a training tool. The findings emerging from this extensive user trial indicate first of all that the ironHand system was very well accepted by the users. The majority of SUS ratings fell in the higher categories: 'good', 'excellent' and even 'best imaginable', for both assistive and therapeutic systems. The findings regarding user experiences showed an improved usability across the subsequent iterations within the ironHand project, as indicated by a gradual increase of SUS scores of both the assistive system and the therapeutic system across its previous development stages (20, 21, 31). The present level of usability indicates high probability for acceptance in the field (28).

The usability of the ironHand system regarding SUS scores is similar to that reported for other assistive or rehabilitation technology. A passive orthosis to support wrist and hand movements of stroke patients during game-like exercises at home received an average SUS score of 69 in its first iteration (32) and 73 in its second iteration (33). The usability ratings of the ironHand system are comparable to these findings, with an average SUS score of 73. In terms of use time, the ironHand system scored considerably better (220 vs. 105 and 118 minutes a week) than the passive orthosis reported by Nijenhuis et al. (32, 33). In addition, the study of Wittmann et al. 2016 (34) showed promising results on feasibility of high dose unsupervised arm therapy at home for stroke patients using an inertial measurement unit-based virtual reality system.

The findings from this study showed that unsupported handgrip strength improved in the therapeutic group and functional task performance improved after 4-week use of a soft-robotic glove at home, either as assistive device or as training tool. However, improvement of functional performance in the technology-assisted groups was not different from the improvement observed in the control group. Remarkably, the control group received no exercise programme and still improved their performance. It is possible that participants improved their performance due to a learning effect on the clinical tests. Such a learning effect might be even more pronounced in those participants that used their non-dominant hand. In addition, a role of response bias (in particular, demand characteristics (35)) cannot be excluded either. It is possible that participants allocated to the control group became more aware of their affected arm in daily life due to their participation to the study in itself, and used their affected arm/hand more than they would have done prior to the study, even though they were instructed to continue their normal activity pattern. Unfortunately, we did not measure their normal arm activity in daily life, so we could not control for

this. These issues make it difficult to explain the observed improvement in the control group in the current study, which complicates interpretation of the current findings.

Nevertheless, hand strength did improve more after therapeutic use of the ironHand system than in the assistive or control group. In terms of application as a rehabilitation tool in the therapeutic group, improvements in handgrip strength, pinch strength and functional use of the arm/hand have been reported after robotic hand rehabilitation, applying mostly stationary and/or portable systems as training device in clinical settings after stroke (36-38). The study of Vanogli et al. 2017 (38) showed that improvements after robotic rehabilitation were significantly higher to those after control intervention consisting of a dedicated program of regular exercises. The studies of Nijenhuis et al. (32, 33) examined the effect of a portable, though not wearable, hand training system after stroke, applied at home with offline supervision, and also reported improved hand function. In this case, the system was stationary yet portable, and not suitable for assistance of daily life activities. In comparison to a control group receiving regular home exercises, no difference was found (39), indicating that technology-assisted training results in similar improvements in hand function as regular exercise programmes. Several wearable systems for hand rehabilitation have been developed recently (see (12) for an overview), but no other clinical studies focusing on hand function changes using fully wearable systems intended for home use could be identified at this point, especially in comparison to use of the wearable system as daily support and/or a control group.

Regarding training interventions for reduction of age-related decline in hand function, intensive resistance training has been reported as one of the most efficient interventions to counter or prevent sarcopenia, with improvements of up to >50% in strength after six weeks of training at a rhythm of 2-3 sessions per week (40). After ironHand therapeutic use, which partially involved resistance training exercises, substantial improvements in handgrip strength were observed, indicating that such application of a soft-robotic glove combined with dedicated (strength) exercises may be a way to provide motivating strength training to address sarcopenia.

Remarkably, a similar effect, although to a smaller degree, was present in older adults using the assistive system to support performance of functional activities during daily life. Moreover, there was no decline in strength and functional performance after using the assistive system. This suggests that using the hands intensively during submaximal yet highly functional activities has a training effect in itself, and could be beneficial in dealing with sarcopenia as well, although the comparable findings in the control group complicate this inference. A review

indicating that a multi-component physical exercise programs (involving endurance, flexibility, strength, etc.) showed less functional decline in frail elderly than single-component programs focussing on strength only (41), may indicate support for this. This may also be relevant specifically in case of hand osteoarthritis, where exercise has shown to have a beneficial influence on hand function, pain and finger stiffness (42). Similarly, functional practice is known as one of the essential elements for motor relearning after stroke (6), suggesting that application of a soft wearable robotic glove may be a dedicated solution to enable highly functional treatment. It is also possible that the support from the assistive glove enabled people to use their arms and hands in more strenuous and/or higher dose activities than would otherwise be possible in their daily life. Considering that low physical activity and low amounts of exercise seem to be the most powerful predictors of ADL disability (43), technological support as proposed with this ironHand system facilitating people to increase their activity level during their daily lives, can be very promising to counter or prevent functional decline associated with ageing.

Recently, development of wearable soft-robotic gloves aimed at supporting people with disabilities in daily life have attained considerable attention (13-18, 44), and the field is growing (45). To our knowledge, none of these research groups have yet investigated the effect of such assistive robotic devices in daily life among a large sample of people with hand function limitations. One research group has published a study into the direct influence of their soft-robotic glove, pneumatically actuated and controlled by muscle activity (46). So far, they showed a reduced performance on JTHFT in one healthy subject compared to normative JTHFT data of healthy subjects (13) and increased performance on the BBT with the assistive glove in one patient with muscular dystrophy (47). The results of the JTHFT are in line with those from the ironHand project (as reported in (21)), but the findings on the BBT are not in line with those from the ironHand project (as reported in (21)). Other wearable systems for hand rehabilitation have been developed as well (14, 44, 46), but these have neither been evaluated during a longitudinal study.

These recent technological developments in the field of wearable robotics are directed towards more unobtrusive support of the arm in a real life setting, which is intended to further facilitate highly functional and intensive training, even enabling more self-administered scenarios (37). This presents a dual application of soft-robotics: as assistive device in daily life, which is believed to have a direct benefit on functional independence (13, 14) and/or as training tool to improve unsupported functioning. The findings of the orthotic effect of the ironHand assistive system (21, 48) and the training effect of the ironHand therapeutic system (as described in this study) support that both of these approaches can indeed benefit people with hand

function limitations. Even more, based on the current findings a third scenario appeared, where users of the assistive system improve unsupported hand function over time. This may be related to a large variety of functional activities being supported in daily life throughout the day, which likely turns everyday activities into highly functional and intensive practice. This underlines the major potential that a soft-robotic wearable glove system can have for increasing functional independence of a very large group of users with varying causes of hand function limitations.

Even though the current study is one of its kind and has generated a large amount of highly valuable information regarding the user acceptance and potential impact on daily lives of the ironHand system, some aspects of the study have given rise to several lessons and recommendations. First, timed performance of functional tasks may not necessarily capture the full potential of the training effect provided by the ironHand system. The JTHFT was specifically selected based on its validity for application in the elder population, and we anticipated that a timed outcome measure would be more sensitive to change in a relatively high functioning population (participants were living at home independently and were able to perform most ADL tasks, despite perceiving limitations in this respect). Adding an outcome measure that can capture more detailed information about movement or task execution in future research should be considered to better understand how a wearable glove system influences hand function. Second, the population involved in the current trial was rather heterogeneous, as intended to examine the potential of the ironHand system across a broad user population. A more in-depth analysis investigating potential differences between subgroups according to disorder or level of physical limitations could shed more light on the therapeutic potential of the ironHand system, and might distinguish which users would benefit most from assistive or therapeutic application of the ironHand system. Third, not only participants in the assistive and therapeutic group showed improvements in performance but also the participants in the control group showed improvements in performance on some outcome measures, for example on the BBT. This indicates that there is also a learning effect for performing the clinical tests.

CONCLUSION

The current randomized controlled trial is one of the first of its kind in investigating the impact of using a wearable soft-robotic device for hand support during multiple weeks at home. Findings of this user trial showed that participants were capable to

use both modalities (assistive and therapeutic) of the ironHand system by themselves for a substantial amount of time at home. After 4 weeks of ironHand use in the therapeutic group, participants showed improvements in unsupported handgrip strength and pinch strength. Functional performance improved not only after 4 weeks of ironHand use (assistive and therapeutic), but also in the control group who received no additional exercise or treatment. Only handgrip strength improved more in the therapeutic group compared to the assistive and control group. These results suggest that, even though the findings from the control group complicate interpretation of the results on functional performance from the technology-supported groups, technological support from wearable robotics as provided through the ironHand system may be promising to counter functional decline associated with ageing in general, or specific age-related disorders (varying from rheumatoid arthritis and osteoarthritis to stroke).

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CHAPTER 7

Applying a soft-robotic glove as assistive device and training tool with games to support hand function after stroke: preliminary results on feasibility and potential clinical impact

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Proceedings of the 15th IEEE International Conference on Rehabilitation Robotics (ICORR), London, United Kingdom, 2017 July 17-20; p. 1401-1406

ABSTRACT

Recent technological developments regarding wearable soft-robotic devices extend beyond the current application of rehabilitation robotics and enable unobtrusive support of the arms and hands during daily activities. In this light, the HandinMind (HiM) system was developed, comprising a soft-robotic, grip supporting glove with an added computer gaming environment. The present study aims to gain first insight into the feasibility of clinical application of the HiM system and its potential impact. In order to do so, both the direct influence of the HiM system on hand function as assistive device and its therapeutic potential, of either assistive or therapeutic use, were explored. A pilot randomized clinical trial was combined with a cross-sectional measurement (comparing performance with and without glove) at baseline in 5 chronic stroke patients, to investigate both the direct assistive and potential therapeutic effects of the HiM system. Extended use of the soft-robotic glove as assistive device at home or with dedicated gaming exercises in a clinical setting was applicable and feasible. A positive assistive effect of the soft-robotic glove was proposed for pinch strength and functional task performance 'lifting full cans' in most of the five participants. A potential therapeutic impact was suggested with predominantly improved hand strength in both participants with assistive use, and faster functional task performance in both participants with therapeutic application.

INTRODUCTION

Neurorehabilitation research has shown that training programs for patients after stroke should ideally consist of high intensity, task-specific and functional exercises with active contribution of the patient, to have the best chance for improving arm/hand function (1, 2). Conventional rehabilitation involves predominantly one-to-one attention of a therapist for each patient, which is a challenge when aiming to provide high intensity training and involves high costs (3, 4). This is impeded further by an increased ageing of the population, associated with a higher prevalence of stroke patients and less healthcare professionals available to provide such intensive training.

Robot-assisted arm/hand training is increasingly applied as a means to provide such highly intensive therapy and shows positive effects on motor function of the trained joints (5-7). Although these robotic devices can provide training that fulfils at least some of the essential aspects of motor learning, such as high-intensity and task-specificity, they often don't (optimally) address the desired functional nature of the exercise (1). This is thought to contribute to the lack of a substantial impact of robotic training on activity level. Besides, the contemporary application of robotic training has focused mainly on the clinical setting, with associated practical limitations in therapist availability and training intensity. If robotic devices could be used for self-administered practice, i.e., (more) independent from the therapists' availability, training intensity could be increased. Therefore, the next generation robotic training approaches should pay attention to self-administered application and address its functional nature by involving hand function (8).

Several systems have been developed for providing robot-assisted hand function training (9), which has been reported to result in hand function improvements (10, 11). Recent technological developments in the field of wearable robotics are directed towards more unobtrusive support of the arm in a real life setting (12-14), which might further facilitate highly functional and intensive training, potentially in more self-administered scenarios (8). This presents another application of soft-robotics beyond training tool: as assistive device in daily life, which is expected to have a direct benefit on functional independence (14, 15). Moreover, since a large variety of functional activities can be supported in daily life throughout the day, everyday activities might serve as highly functional and intensive practice, independent from the availability of healthcare professionals. Therefore, it is even conceivable that use of wearable assistive devices may have a training effect in itself, improving unsupported hand function after prolonged use in daily life.

To allow prolonged use of such an assistive device in everyday activities at home for stroke patients, an easy-to-use system was developed within the HandinMind (HiM) project. This system is based on the technology of an existing soft-robotic glove for workers (SEMGlove, Bioservo Technologies, Kista, Sweden), re-designed and adapted for stroke application. The assistive glove is extended with a dedicated therapeutic functionality (by Hocoma AG, Volketswill, Switzerland). The HiM project applied a user-centred design, by involving stroke patients and related users early on in design and testing phases in an iterative fashion, to enhance the chance for adoption of the technology in the end (16).

After repeated usability testing and refinement of previous prototypes, the next step was to assess the performance of the HiM system in practice, which can be a clinical or home setting. This paper aims to gain first insight into the feasibility of clinical application of the HiM system and its potential impact. In order to do so, both the direct (orthotic) influence of the HiM system as assistive device and its therapeutic potential, regarding both assistive and therapeutic functionalities, for improvement of hand function were explored. The direct influence was investigated by comparing hand function tasks with and without assistance from the HiM glove during a single evaluation. The therapeutic potential is explored via a pilot longitudinal study with the HiM system being used for 5 weeks, either as assistive device at home or as training tool in a clinical setting.

METHODS

PARTICIPANTS

Five chronic stroke patients with hand function limitations were recruited via Roessingh Center for Rehabilitation (Enschede, the Netherlands). All participants had to have had a unilateral stroke more than 6 months ago, be discharged from specific arm/hand therapy and live at home. In addition, they had to be free from severe spasticity, contractures, co-morbidities and wounds on their hands. Besides, they had to be able to don the HiM glove themselves. All participants provided written informed consent prior to inclusion. The study protocol was approved by the local medical ethics committee.

STUDY DESIGN

A longitudinal, randomized pilot trial was applied to gain first insight into potential therapeutic effects of either assistive or training use of the HiM system. Its direct influence (comparing performance with and without glove) was explored during

additional cross-sectional evaluation added to the baseline session. After baseline evaluation, participants were allocated to either Assistive Support (AS) or Training support (AS) group. The AS group used the HiM assistive system during daily activities at home and the TS group used the HiM therapeutic system as a training tool in a clinical setting at the rehabilitation centre. Both groups used the system for 6 weeks. Additionally, during the last week TS combined the use of the HiM therapeutic system as a training tool in a clinical setting with its use as assistance during daily activities at home, to explore potential feasibility and (dis)advantages of combining both approaches into one unique scenario. The present preliminary analysis focused on investigation of the single applications as a starting point, so the combination AS-TS is beyond the scope of this paper.

HANDINMIND SYSTEM

The HiM system contains assistive functionality (Figure 7.1, left panel) and therapeutic functionality (Figure 7.1, right panel). A control unit contains a battery, one motor for each finger and a microcontroller that controls the HiM assistive system functionality. A glove applies the forces, generated by the motors, by artificial tendons sewn into the glove along the length of the fingers. Force from force sensors (FlexiForce, Tekscan Inc., South Boston (MA), USA) at the fingertips is scaled and used as a reference for an inner loop that controls the tension of the artificial tendons measured close to the glove by setting the voltage of the motor. It is a positive feedback loop that, when scaled properly, makes the added grip force proportional to the user-generated grip force (i.e., when the user decreases grip force, the glove decreases grip force). The input from flex sensors (Bend Sensor, Flexpoint Sensor Systems Inc., South Draper (UT), USA) along the dorsal side of the fingers controls therapeutic software, mapping finger movements to virtual (game) movements. The therapeutic platform includes a laptop to which the HiM assistive system can be connected. The therapeutic functionality of the HiM system is embedded in therapeutic software that includes assessments and patient's results, exercises, additional safety mechanisms, connectivity to other devices. The HiM system is a fully wearable and ambulant assistive technology, when used as assistive device (see Figure 7.1, left panel). The connection to the therapeutic software allows the user to train with motivating game-like exercises (see Figure 7.1, right panel) and visualize his/her progress through automated reports.

Figure 7.1. Overview of the HiM system, featuring assistive functionality (left panel) and additional therapeutic functionality (right panel).

INTERVENTIONS

The AS group received the HiM assistive system for use during daily activities at home for 6 weeks. It was recommended to use the assistive wearable soft-robotic glove for at least 180 minutes a week during the most common ADL such as dressing/undressing, eating/drinking, functional transfers. Nevertheless, participants were free to choose with which the activities, when and for how long they used the HiM assistive system. Participants were asked to register the activities and duration in which the system was used.

The TS group used the HiM therapeutic system as a training tool in a clinical setting for 6 weeks, 180 minutes a week. The participants received three sessions of 60 minutes of game exercise training a week. The sessions were supervised by an

occupational therapist (OT), who had been trained in operating and applying the HiM therapeutic system prior to the start of the study and who was not involved in the evaluation measurements.

Games on a computer screen (see video for illustration: <https://youtu.be/cUyu9R3gWuA>) were controlled by active arm and hand movements, recorded via bending sensors integrated in the glove textile (and the optional inertial sensors). The game exercises were adapted to each person's ability during a quick calibration exercise prior to each training session, which defined the participants' current active range of motion of the hand and fingers (and possibly arm). The choice of exercises and definition of the starting levels was done by the therapist, taking into account each participant's limitations and treatment goals. Three games were designed to target simultaneous finger coordination, hand strength and sequential finger coordination (see Figure 7.1, right panel, for a short description of games). The participants received feedback within the exercise about points collected during the game and corresponding scores. The HiM therapeutic system automatically recorded training time.

EVALUATION

All participants performed evaluations one week before the start of the study (baseline, T0), after 5 weeks of either HiM assistive system or HiM therapeutic system use (T1) and within one week post-training (T2). In this paper, only T0 and T1 are included in analyses. All tests were performed with and without the wearable soft-robotic glove at T0 to explore its direct effect, except for hand grip strength and questionnaires. Additionally, upper extremity Fugl-Meyer assessment (FM) was done (without glove) at T0 to map motor status (17).

Maximal pinch strength between index finger and thumb was assessed at T0 and T1 with a pinch gauge (Baseline Lite Hydraulic Pinch Gauge, Fabrication Enterprises, White Plains (NY), USA). Participants were seated comfortably with the elbow close to their body and 90 degrees flexed. They were asked to grasp the pinch gauge between the ventral side of the distal segment of the thumb and index finger, squeeze maximally and maintain for 5 s. The other fingers were not allowed to give any support. Three attempts were performed, spaced by at least 60 seconds. The highest value was used for analysis (18).

Maximal handgrip strength was measured at T0 and T1 with a dynamometer (Jamar hydraulic hand dynamometer, Patterson Medical Ltd., Sutton-in-Ashfield, UK), following the same procedure as described for pinch strength, but now holding the hand dynamometer in their affected hand (19, 20).

The Jebsen-Taylor Hand Function Test (JTHFT) was applied at T0 and T1 to evaluate functional hand ability (21-23). The test consists of 7 different unilateral hand skill tasks related to ADL: (1) writing a letter of 24 sentences; (2) turning over 7.6x12.7 cm cards; (3) picking up small, common objects (e.g., paper clips, coins and bottle caps) and move these to a box; (4) stacking checkers; (5) simulated feeding (e.g. teaspoon with beans); (6) picking up large empty cans; (7) moving weighted (450 g) cans. Duration of task completion was recorded in seconds (maximal duration is 120 seconds per task) and summated as the total score. The subtest 'writing letter' was omitted from the analysis due to variation in hand dominance between participants. To investigate feasibility, user acceptance was evaluated via the System Usability Scale (SUS) and by recording the use time of the HiM system in both groups. The SUS was completed at the end of the use period (T1). It is a simple, valid and reliable assessment for systems' usability. It uses a 5- point Likert scale for 10 questions about system usability. The answers can range from '1-strongly disagree' till '5-strongly agree'. The total score of the questions are multiplied by 2.5, so that the maximum score is 100 (24, 25). Use time was recorded using a diary in the AS group, where participants reported their daily use time of the system at home. For TS participants this was derived from the training session logs of the OT supervising the session.

DATA ANALYSIS

The data of the outcome measurers were analysed using IBM SPSS Statistics version 19.0. A non-parametric test was applied to explore the direct effect among the five participants, comparing pinch strength and JTHFT with and without the HiM glove at T0 via a Wilcoxon signed ranks test ($\alpha \leq 0.05$). Due to the small sample size of the pilot clinical trial, only descriptive statistics (counts and relative changes with respect to T0) were applied to gain a first insight into the therapeutic effect in either group.

RESULTS

Of the five stroke patients, 4 were mildly and 1 was moderately affected (Table 7.1). Three participants were allocated to AS and two to TS. Post-training data from one participant (05, AS group) was not yet available at the time of reporting and therefore only included in the direct effect comparison at T0.

Table 7.1. Participant characteristics.

Gender (male/female) ^a	3/2
Age (years) ^b	64 (58-76)
Dominant side (right/left) ^a	4/1
Affected body side (right/left) ^a	2/3
Stroke severity ^a	4 mild/1 moderate
FM at T0 (points) ^b	55 (48-57)
JTHFT total at T0 (seconds) ^b	67.76 (57.58-364.54)

^a Frequencies; ^b Median (min-max ranges)

DIRECT EFFECT

Pinch strength (Figure 7.2) was larger with compared to without glove (by 11% to 27%) in three out of four participants (missing pinch data at T0 of one participant). JTHFT total scores were higher (slower performance) in four out of five participants (by 14% to 33%) with glove. Pronounced differences were observed for subtest 'picking up small objects', performed slower in all participants (by 6% to 40%) with glove than without. On the other hand, subtest 'lifting full cans' showed faster performance (by 2% to 24%) with glove support in three of five participants (Figure 7.3). The difference on JTHFT subtest 'picking up small objects' was significantly different ($p \leq 0.043$), other comparisons with and without glove weren't significant in this small sample. It was noted that, among the five participants, the one showing the most consistent benefit of glove support was the most affected stroke patient (FM at T0 of 48 points).

THERAPEUTIC EFFECT

Most participants showed a tendency for increasing performance (without glove) on pinch and/or grip strength, after 5 weeks of glove use, especially the two participants in the AS group with improvements ranging between +15% in grip strength (Figure 7.4) and +43% in pinch strength per participant, with respect to T0. TS group participants showed individual changes from -3% (grip) to +11% (pinch). Several JTHFT (subtest) scores improved (Table 7.2), especially in the two participants in the TS group: 'simulated feeding', 'stacking checkers' and 'lifting full cans', with reductions in performance times ranging from -8% to -39% individually. JTHFT 'turning cards' improved in all four participants across both groups. JTHFT total scores improved in both TS participants and declined in both AS participants.

Figure 7.2. Individual (lines) and median (bars) values of pinch strength with and without glove.

Figure 7.3. Individual (lines) and median (bars) values of JTHFT subtest 'lifting full cans' performance time with and without HiM glove.

Figure 7.4. Individual changes in grip strength without glove from T0 to T1, separated for AS and TS.

Table 7.2. Individual change scores^a of JTHFT (%).

JTHFT (sub)tests	AS		TS	
	P02	P03	P01	P04
Turning cards	-10%	-4%	-2%	-35%
Picking up small objects	-35%	+16%	+34%	-9%
Simulated feeding	+65%	+28%	-8%	-21%
Stacking checkers	+21%	-2%	-39%	-19%
Lifting empty cans	-9%	+25%	+14%	-17%
Lifting full cans	-16%	+39%	-16%	-10%
JTHFT total	+7%	+15%	-4%	-20%

^aChange scores with respect to T0, calculated as $(T1 - T0) / T0 \times 100$

USER ACCEPTANCE

Usability of the HiM system for assistive support was rated as good to excellent with SUS scores of 65 and 100 at T1 (participant 03 and 02, respectively). The HiM therapeutic system was rated as having OK usability (moderate) by participant 01 (SUS score of 37.5) and excellent by participant 04 (SUS score of 90). Use time varied largely between participants. In AS, one participant (02) reported use of the system for about 30 minutes a day (~200 minutes per week), whereas the other (03) used the system only about once a week, because she felt it was too cumbersome to put on by

herself relative to its corresponding gains. TS participants followed the scheduled appointments, resulting in a general use time of 180 minutes per week.

DISCUSSION

The preliminary findings of the present study showed first of all that application of the soft-robotic glove as assistive device at home during multiple weeks was feasible and perceived as acceptable. Use of this glove with added computer exercises in a clinical setting was practically applicable, but usability was moderate. These ratings of the HiM system's usability generally indicate a good chance for acceptance in the field (25). Especially the assistive system received good to excellent usability ratings, meaning it is very promising for adoption by users in their daily life. Nevertheless, some aspects remained cumbersome for stroke patients, of which the most pronounced is donning difficulties for people with more than mild-moderate hand function impairments. This is an essential point of attention when developing an assistive glove for application in stroke, specifically for more severely affected patients, for whom hand support may be even more valuable.

In the present study, a direct assistive effect of the soft-robotic glove seemed present in most of the five participants for pinch strength and JTHFT 'lifting full cans'. On the other hand, performance of JTHFT 'picking up small objects' was worse with the glove compared to performance without glove. This is along similar lines as the findings from a group developing a glove with combined assistive and therapeutic functionality, comparable to the HiM concept but controlled by muscle activity. Although they reported that a healthy subject performed several JTHFT tasks with glove support slower than normative data of healthy individuals without support (15), they did show increased performance on the Box and Blocks Test with the assistive glove in one patient with muscular dystrophy (26). The present findings on the JTHFT further suggest that handling small objects is hindered to some extent by the glove. This implies that the assistive glove would be more useful to support gross motor activities.

With regard to the therapeutic effect, the current data suggest that (unsupported) functional task performance may improve after 5 weeks use of the HiM system, especially as training tool. Hand strength also seems to improve during 5week use of the system, especially as assistive device. The improvements in hand function after using the HiM system as a training tool are generally in line with robotic hand training studies that have applied mostly stationary and/or portable systems in clinical settings (8, 10, 11). Several wearable systems for hand rehabilitation have

been developed (12-14), but these haven't been evaluated during a longitudinal study into hand function changes so far.

This is one of the first studies exploring the practical application of a fully wearable, ambulant system to support hand function post-stroke during an extended period in a pilot longitudinal design. The present findings suggest a potential benefit of a soft-robotic glove, possibly extending beyond its proposed therapeutic effect as training intervention in a clinical setting, or its suggested direct assistive effect. Moreover, improved unsupported hand strength was observed after 5-week use of the HiM system as an assistive device with no specific training exercises involved. This might be a first indication of the possibility of such wearable devices to support daily activities of people with hand function limitations and to provide a tool to actually turn everyday activities into highly intensive, functional training. The present findings need to be interpreted with considerable care, since it involves a pilot study with a very small sample of chronic stroke patients. This limits analysis to a case-by-case approach and prevents comparison of the potential of assistive and therapeutic functionalities. In addition, the donning difficulty especially for participants with moderate/severe hand function limitations may have contributed to a ceiling effect on some of the outcomes. Besides, a hand dynamometer turned out unsuitable to assess grip strength with the glove as direct assistive effect, due to the force sensors at the glove's fingertips misaligning with the dynamometer. Therefore, only pinch strength could be used to assess the direct effect on hand strength in the current study. A custom-designed force sensor (e.g., a cylinder) should be considered in future research (15). Likewise, timed performance of functional tasks may not necessarily capture the full potential of the support provided by the glove. We are therefore currently elaborating analyses towards more detailed performance information.

CONCLUSION

This is one of the first studies exploring the application of a fully wearable system to support hand function post-stroke and its clinical potential after extended use. Although careful interpretation is warranted due to its small sample, the current findings propose that the HiM system as assistive device can directly improve strength and gross functional task performance. Moreover, 5 weeks of assistive and therapeutic application may have improved unsupported hand strength and task performance. Nevertheless, several use issues should be improved, such as ease of donning for stroke patients with more severe hand function limitations.

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CHAPTER 8

General discussion

GENERAL DISCUSSION

The main aim of the current thesis was to identify user requirements, investigate feasibility and evaluate the direct (assistive) and clinical (therapeutic) effects of the wearable soft-robotic ironHand and HandinMind systems. Both systems were developed to support impaired hand function in a wide range of daily activities and to perform exercises at home in older adults and stroke patients. These two systems were developed by the technical project partners Bioservo Technologies AB and Hocoma AG, whereas Roessingh Research and Development (together with end-user organizations as Nationaal Ouderfonds, terzStiftung and Eskilstuna Kommun Vård- och omsorgsförvaltningen) focused on the identification of user requirements and (clinical) evaluation of these systems.

Both systems were developed following an iterative design and development process in which a user-centred approach was applied. This was done to suit the needs of the potential users and increases the chances for uptake of the devices. Therefore, potential end-users were involved early in the design and development phase to identify user requirements for a soft-robotic device (**chapter 2**).

The ironHand system was developed for older adults with various age-related hand problems, whereas the HandinMind system was tailored specifically to stroke patients. Two separate systems were developed, because both populations have different hand function limitations. Specifically, stroke patients experience a restricted range of motion, loss of strength, increased muscle tone and loss of sensory function in the affected arm/hand (1), whereas older adults (possibly with rheumatoid arthritis or osteoarthritis) experience mainly reduced grip strength, sensory changes or pain (2). Both systems were developed to support grip, but the HandinMind system was also developed to support hand opening. Furthermore, the HandinMind glove supports five fingers versus 3 fingers in the ironHand glove, because stroke patients often experience severe loss of function of all fingers.

After its first design based on the identified user requirements (**chapter 2**), consecutive versions of the ironHand and HandinMind gloves have been tested with end-users in subsequent stages of user testing to evaluate feasibility (**chapters 3 & 4**), direct (**chapters 5 & 7**) and clinical (**chapters 6 & 7**) effects of a wearable soft-robotic system.

USER REQUIREMENTS

The aim of **chapter 2** was to determine the main user requirements for a wearable soft-robotic device that is able to support impaired hand function in older adults and stroke patients during activities of daily living and to perform exercises. A focus group study that involves potential end-users is a valuable methodology to gather this information (3-5). Therefore, early in the design and development process, user requirements and attitudes towards assistive upper limb devices were gathered in a focus group study (described in **chapter 2**). A large group of potential end-users (i.e., older adults, stroke patients, healthcare professionals) were involved in this study. It showed that the design of an assistive upper limb device is critical and is influenced by specific personal goals and impairments. Most important aspects that were considered by the potential end-users were that the device should be wearable, compact, lightweight, easy to use, quickly initialized, washable and only supporting the particular function(s) that an individual needs assistance with, without taking over existing function(s) from the user. The potential end-users also agreed on the fact that actual use of such devices will depend first and foremost on its ease of use, after which the benefit experienced from using the device is valued.

The identified requirements (**chapter 2**) were in line with general design requirements for an assistive device (e.g., compact, lightweight, reliable, comfortable, easy to use and set up) specified by existing literature (3, 4, 6-8). Additionally, more specific information was needed for the design of an assistive system for the hand. The focus group study gave us more insight into main user requirements related to the activities and grasps that need support from the assistive system. Support was desired for activities of daily living as household chores, personal care, eating and drinking, which involved in particular palmar, spherical, diagonal volar, lateral grasps and the key pinch. Three other aspects that were further specified included the time needed for setting up the device (i.e., donning and initializing the device), which should ideally take less than 2 minutes, the battery life, which should last at least 1 day (possibly intermittently) and the size of the battery, which should be comparable to the size of a smartphone. The findings of our focus group study were in line with literature (8). Polygerinos et al. (8) also specified some other design requirements, which were obtained from literature and discussions with therapists, specifically for wearable soft-robotic gloves. These included the weight of the glove which should be less than 0.5 kg, the waist pack weight which should be less than 3 kg and the battery which should last at least 2 and 6 hours for continuous and intermittent operation, respectively.

There were many similarities between the older adults and the stroke patients regarding the main design requirements (as specified above) for developing a wearable soft-robotic glove. However, differences were also noted, such as stroke patients having other user characteristics (e.g., motor problems, physical conditions) and desire additional support of hand opening and wrist movements on top of grip support.

This shows that it is very important to apply a user-centred approach during the design and development process of such a new system to identify the need of the potential end-user, because the design of the device is often mentioned as critical for the uptake or implementation of the device (3). Besides this, effectiveness of the device, to which extent the function of the device improves the user's functioning in daily life, is also very important (4, 6) for device adoption in the end.

FEASIBILITY OF A WEARABLE SOFT-ROBOTIC GLOVE

In the focus group study, potential end-users already agreed on the fact that actual use of such devices will depend first and foremost on its ease of use, after which the benefit experienced from using the device is valued. The feasibility study with the ironHand system in **chapter 3** focused on feasibility (user acceptance, usability etc.) of the first ironHand prototype that should be able to support impaired hand function during the performance of activities of daily living and to perform exercises by older adults. Additionally, a first insight in functional performance was obtained. This study shows that the first ironHand prototype was rated positively on usability and motivation. Initially, functional performance tests showed slower functional performance times with the ironHand glove compared to without ironHand glove. However, functional performance improved within only 3 repetitions up to the level of performance without glove, while using the system for the first time (naïve use). A few days later, participants showed faster functional performance times with glove during more experienced use compared to naïve use. This indicates a steep learning curve when using the ironHand glove.

The first HandinMind prototype was also rated very positively on usability and motivation by stroke patients with mild-to-moderate hand function impairments as described in **chapter 4**. Similarly to the ironHand, the stroke patients also showed improved functional performance after only 3 repetitions during naïve use, on the same functional tasks as in the ironHand feasibility study. However, initial functional performance times with the HandinMind glove were not different from performance times without the HandinMind glove. When comparing the functional performance times of the stroke patients in the HandinMind study (**chapter 4**) and older adults in the ironHand study (**chapter 3**) on the same functional tasks showed

that overall older adults performed the functional tasks faster than the stroke patients.

The gloves that were used in both feasibility studies supported not only grip strength but also hand opening. The extra hand opening functionality was mentioned as design requirement in the focus group study (**chapter 2**) by stroke patients. It was also tested in the population of older adults to investigate if the additional hand opening functionality could be of an added value for them as well. The focus group study apparently gave very accurate results, because the feasibility study confirmed that older adults did not want/need hand opening support.

Both systems were tested following the same research protocol, enabling comparison of both studies. It seems like the first versions of the glove acted less as a hindrance in stroke patients compared to the older adults. A difference in severity of hand function problems, as indicated by slower performance times in stroke, might play a role in this. Also, the most-affected hand was used to perform the functional tasks in both studies. This might play a role, since it could have been the dominant or non-dominant hand. In daily life, stroke patients often use their most-affected hand to support the non-affected hand in daily activities and not as primary hand (9). This is irrespective of hand dominance, while older adults (with sarcopenia, osteoarthritis, rheumatoid arthritis) often use their dominant and most-affected hand as primary hand to perform daily activities. Because the ironHand glove was tested in a larger population compared to the HandinMind glove (28 older adults vs. 5 stroke patients), the results of the HandinMind feasibility study should be interpreted with extreme care.

Studies that investigated usability and motivation of other types of technology or interventions with rehabilitation technology found comparable scores on the System Usability Scale (SUS) (10-12), and Intrinsic Motivation Inventory (9, 12, 13). Only the study of Ambrosini et al. (14), in which a passive arm exoskeleton was evaluated, found substantially higher SUS scores (median = 90) compared to the SUS scores in the feasibility studies with the ironHand (median = 71 or 65) and HandinMind glove (median = 80 or 77.5). Participants in the study of Ambrosini et al. (14) (three spinal cord injury; one multiple sclerosis; two Friedreich's ataxia) had very limited arm function compared to the participants in the feasibility studies with the ironHand and HandinMind system. They were not capable of eating, combing or dressing themselves autonomously before the study started. Nevertheless, they were all able to accomplish daily activities (such as a drinking and reaching task) with the support of the passive arm exoskeleton, which gave the participants a new experience (14), and is likely related to such a high SUS score compared to other studies.

Since the research field of wearable soft-robotic gloves is relatively young, only one study was found in which functional task performance was evaluated with a similar application (15). This study showed that one healthy subject performed 4 subtasks of the Jebsen-Taylor Hand Function Test (JTHFT) slower with support of an EMG-controlled soft-robotic glove compared to normative data of healthy subjects on the JTHFT. This is in line with the results of the functional performance tasks in the feasibility studies with the ironHand and HandinMind systems, even though Polygerinos et al. (15) didn't perform a direct comparison between performance with and without glove in the same subject. A similarity between all these studies is that participants were not familiar with using a soft-robotic glove during daily activities, which might have affected the performance with support of a soft-robotic glove during activities of daily living and might not be representative of how people would perform when they've practiced more with the glove. However, to test intuitiveness and usability of a new system, it is important that people are not familiar with the system at this stage in the development process. Of course, this has consequences for how well comparisons of performance with and without support can be interpreted, and can therefore be only viewed as a first insight in its potential effect.

DIRECT EFFECT OF A WEARABLE SOFT-ROBOTIC GLOVE

After focusing on usability of the soft-robotic glove in the feasibility study, which was valued as very promising, the direct functional benefit of the device was the next step of user testing. In **chapter 5**, a cross-sectional study ($n=65$) showed that older adults with impaired hand function have more pinch strength with the ironHand glove compared to without the glove, but functional performance was faster without the ironHand glove. Similar findings resulted from the clinical pilot study ($n=5$) in which the direct effect of the HandinMind glove was tested in stroke patients (**chapter 7**). However, again these results with the HandinMind glove should be interpreted with extreme care due to the small sample size of 5 stroke patients.

In recent years, the research field of (wearable) soft-robotic devices, aiming to support impaired hand function in people with disabilities in daily life and rehabilitation, has attained considerable attention. The field is still growing with an increasing number of research groups developing soft-robotic solutions (8, 16-22). To our knowledge, so far there are no other studies published that have investigated the direct effect of assistive gloves in a large group of older adults with disabilities. Two recent pilot studies investigated the effect of a similar application of an assistive soft-robotic glove (15, 23). These studies applied a similar set-up as the one described

in **chapter 5**, but involved only one participant in each study (i.e., case-studies). Polygerinos et al. investigated the direct effect of their initial wearable EMG-controlled soft-robotic glove in two persons, one healthy subject and one subject with muscular dystrophy (15, 23). They showed that the healthy individual had slower performance times during 4 subtasks of the JTHFT compared to normative JTHFT data of healthy subjects (15). Improved performance on the Box and Blocks Test (BBT) with the glove was seen in the individual with muscular dystrophy when wearing the glove (23). When comparing their results to those in the present thesis, the JTHFT results of the one healthy person are in line with the results of the ironHand and HandinMind studies. In contrast, the results from the one muscular dystrophy patient on the BBT are standing out from the lack of benefit found in our research.

Comparison between the results of the EMG-controlled glove with ours is hindered by the fact that Polygerinos et al. (15, 23) tested only one participant. Furthermore, in the case of the JTHFT performed by the healthy person, normative data was used for performance without glove, instead of directly comparing performance with and without glove, as was done in the ironHand and HandinMind studies. Nevertheless, it can provide some insight in potentially relevant aspects concerning the potential assistive effect of soft-robotic gloves, in the light of absence of other similar approaches in this new field. The difference in performance on the BBT between the study of Polygerinos et al. (23) and the ironHand study might be explained by the difference in severity of hand function limitations of the subject(s). The mean baseline score on the BBT was 49 in the ironHand study versus 10 of the subject with muscular dystrophy in the study of Polygerinos et al. (23). In general, people with severe hand function limitations have more room for improvement using an assistive device compared to people with less hand function limitations. This is supported by the results of the clinical pilot study with the HandinMind glove in which the most-affected stroke patient showed the most consistent benefit of glove support. Furthermore, the ironHand and HandinMind gloves are in particular used by people that have less severe hand function. Because the ironHand and HandinMind gloves are controlled by pressure sensors, they require an interaction force between the hand and object to add grip support. The assistive glove in the studies of Polygerinos et al. (15, 23) is controlled by EMG, which might be more useful for people with severe hand function limitations. At this point, it isn't clear which type of sensor modality would be most suitable for controlling the support applied by an assistive glove for a particular target population.

In addition to force or EMG control, several other human-robot interfaces could be considered to control the support applied by an assistive glove, such as mechanical

solutions (switches), auditory sensors that record voice commands, and sensors that detect other biological signals (e.g., EEG) (15, 24). A review by Basteris et al. (24) suggests that human-robot interfaces requiring active movement initiation by the patient may be most beneficial for improvements in arm/hand motor function in stroke patients after robot therapy, which would match control strategies such as used for the assistive gloves in the ironHand and HandinMind projects and by Polygerinos et al.. However, further research is needed to find out which control modality would be most suitable for which type of user and considering specific application as an assistive tool. In any case, such a device for older adults should be simple and easy to use, considering the identified user requirements in **chapter 2**.

THERAPEUTIC EFFECT OF A WEARABLE SOFT-ROBOTIC GLOVE

Although the contemporary versions of the soft-robotic system could not support a direct functional benefit in daily life for mild-to-moderate affected older adults and patients as measured using timed performance, it was hypothesized that this could present a new way of intensive functional training for people with hand function limitations, which might improve unsupported hand function. Especially the finding that both systems showed a direct effect on pinch strength indicates the potential for improving unsupported hand function after prolonged use of such device.

The clinical trial in the ironHand project (**chapter 6**) showed first of all that older adults with self-perceived hand function limitations were able to use the system for a substantial amount of time in daily life at home. Moreover, older adults that used the ironHand system as training tool at home were indeed able to improve unsupported handgrip strength, pinch strength and functional performance after an intervention of 4 weeks. Remarkably, functional performance also improved after 4 weeks of assistive ironHand use during daily activities. However, older adults who received no additional exercise or treatment (control group), unexpectedly also improved their functional performance, but not their handgrip strength. Similar results are found in the clinical HandinMind pilot study (**chapter 7**), in which 3 stroke patients showed a tendency for improving performance (without glove) on pinch strength, handgrip strength and functional performance after 5 weeks of HandinMind use, either as assistive or training device. Interpretation of these findings is obscured by the control group in the ironHand clinical study that did improve functional performance over 4 weeks, without specific intervention. It is possible that the specific attention for their hand function in pre and post evaluations raised their awareness for how they used their hands in daily life. However, whether they in fact increased their hand use in daily life wasn't measured during the trial.

Conventional hand training exercises have shown to be beneficial for older adults with sarcopenia, in particular exercises that are performed at 70-80% of maximal strength and at least 2-3 times per week (25). Bautmans et al. (25) showed improvements in hand strength up to more than 50% after 6 weeks training. The clinical ironHand study showed improvements for the assistive and therapeutic group up to an overall improvement of 25% for handgrip strength after 4 weeks. The difference in amount of improvement might be explained by the intensity of exercise training. Participants in both the assistive and therapeutic group probably did not perform exercises at 70-80% of maximal handgrip strength. The main goal for both groups in the ironHand study was focused on improving hand function in general, not specifically handgrip strength. Additionally, the duration of the intervention in the current study was 2/3 of that in Bautmans et al. (25). It is possible that longer use of the ironHand system increases its effect on hand function and/or grip strength.

In addition, the ironHand system could be beneficial in the prevention of strength loss. Both groups in the ironHand study showed no decline in strength or functional performance. This suggests that participants that use technological support as proposed with this ironHand system are able to use their hands intensively during submaximal yet highly functional activities or exercise training, which could be beneficial for the prevention of sarcopenia. It is also possible that support from the assistive ironHand system during daily activities enables persons to use their hands more frequently in their daily life, which could increase their activity level. This is even possible without the need of extra trainings sessions, because people can use the device in daily activities. In this way, the ironHand can be very promising to counter or prevent functional decline associated with ageing, since low physical activity and low amounts of exercise seem to be the most powerful predictors of disability in activities of daily living (26). Additionally, patients train their hand function without the need of extra training sessions. However, to support such a preventive effect, a prospective longitudinal study would be needed.

The improvements in hand function after using a wearable soft-robotic system as a trainings device (rehabilitation tool) are generally in line with robotic hand training studies in stroke that have applied mostly stationary and/or portable systems in clinical settings (27-29). Robotic systems have not been applied to people with rheumatoid arthritis or osteoarthritis so far. Nijenhuis et al. (12, 13) and Chen et al. (30) investigated hand function changes after home-based therapy with a stationary and/or portable system in chronic stroke patients. Both studies showed improvements in hand function immediately after the intervention, but these were lost at 3 months follow-up in the study of Chen et al. (30). This was in contradiction with the study of Nijenhuis et al. (12), in which improved arm function was

sustained two months after training. This discrepancy might be explained by the fact that Nijenhuis et al. (12) had a longer training period (4 vs. 6 weeks) and a shorter follow-up period (2 vs. 3 months) compared to the study of Chen et al. (30). The training intervention in the study of Chen et al. (30) has not resulted in more use of the affected hand in daily life, as improvements in upper limb function returned to baseline 3 months after therapy. To promote spontaneous use of the affected hand, participants could be asked to wear a device with assistive functionality to support daily activities (during and after therapy) like the ironHand or HandinMind glove, which might drive further gains in performance after therapy. It is even possible to use such a wearable soft-robotic device during daily activities early in the rehabilitation process to improve hand function without the need of extra training sessions. Which application (combination) regarding the assistive and therapeutic functionalities would be most beneficial for which target population needs further research.

PERCEPTION VS. MEASURABLE EFFECTS

The results on usability and motivation show the users' perspective (**chapters 3 & 4**), which often doesn't fully match with measurable, objective outcomes, as seen in **chapters 5 - 7**. The iterations of the ironHand and HandinMind systems showed high scores on usability, which further improved during the subsequent iterations, both for assistive and training use (31-33). Despite the positive user experience, functional performance was better without glove compared to with glove. Early in the design and development process (**chapters 3 & 4**), decreased sensation was one of the main aspects that users were concerned about for having a negative effect on functional performance with glove. Despite changes in the design of the glove and its textile, the decreased sensation was still mentioned in subsequent stages of user testing (**chapters 5 - 7**). Therefore, this use issue is believed to have affected functional performance speed with glove. Beside this, it is possible that usability of the different iterations of the ironHand and HandinMind systems has been overrated by the participants, for instance by scoring the potential of the device instead of scoring usability of the current system, despite instructions to consider the system as it is. Nevertheless, usability scores of the soft-robotic systems are comparable to usability scores of other types of technology or interventions with rehabilitation technology (10-12), except for the higher usability scores that were found in the study of Ambrosini et al. (14).

For the ironHand and HandinMind glove, functional performance was measured with timed performance tests. These tests were selected because we expected that a

timed outcome measure would be more sensitive to change in a relatively high functioning population (participants were living at home independently and were able to perform most daily activities, despite perceiving limitations in this respect). In addition, the JTHFT was specifically selected for the ironHand and HandinMind studies based on its validity for application in the population of both older adults and stroke patients. The disadvantage of the JTHFT (**chapters 5 - 7**) or the timed performance tasks as used in the feasibility studies (**chapters 3 & 4**) is that these tests could not capture detailed information about quality of movement. The finding that timed performance tests showed slower performance times with the soft-robotic ironHand and HandinMind glove compared to without glove can have multiple causes. Besides a potential influence of a decreased sensation in the fingertips due to the glove, performance time could be influenced by the response time of the glove that is needed to generate extra force. On the other hand, it might be possible that a soft-robotic glove doesn't influence timed performance so much in the current participants, but predominantly targets other aspects of performance, such as quality of movement or the number of tasks participants can perform independently before fatigued.

Therefore, it is relevant to evaluate the potential of soft-robotic gloves with measurements that can assess quality of movement as well as quantity of movement. Sivan et al. (34) identified that the Fugl-Meyer Scale, Action Research Arm Test and Wolf Motor Function Test are good examples of outcome measures that could be used in robotic studies. In addition, kinematic analyses are an appropriate measurement to analyse quality of movement (34), for example quality of hand movements with a wearable soft-robotic glove. On activity level, the ABILHAND is a good example of a questionnaire that could be used to evaluate if people perceive themselves to be better able to perform more activities with a soft-robotic glove (34). Another possibility to quantify quality of movement during the performance of daily activities is wearable sensor systems. These sensors could be worn on the hand to assess actual performance during specific functional activities (35). These measurements should be used in the future to better understand how a wearable soft-robotic glove influences hand function.

Handgrip strength while wearing a soft-robotic glove was difficult to assess with a standard hand dynamometer, due to misalignment between the force sensors on the glove's fingertips, and the grip on the dynamometer. In the future, a custom-made force sensor (e.g., a cylindrical sensorised object) should be considered, to evaluate handgrip strength with a soft-robotic glove more accurately. For instance, a custom-

made force sensor as used in the study of Polygerinos et al. (15) to evaluate force magnitude and distribution with a soft-robotic glove would be a good example.

On one hand, such objective measurements should be added to make sure all measurable effects can be quantified, whereas now quality of movement received less attention. On the other hand, it is possible that objective outcomes may not be leading in the decision of people to use/not use such as soft-robotic system. The potential end-users described in the identified user requirements (**chapter 2**) that actual use of such devices will depend first and foremost on its ease of use, after which the benefit experienced from using the device is valued. Therefore, it is highly important that users' experience during the design, development and evaluation process shouldn't be neglected.

TARGET POPULATION

The studies in the present thesis have indicated that support from a soft-robotic system in its current form seems beneficial for older adults with osteoarthritis, rheumatoid arthritis or sarcopenia or stroke patients, since they did experience the direct benefit (in terms of more pinch strength and/or handgrip strength) and therapeutic benefit (in terms of more pinch, handgrip strength or better functional performance) of such system (**chapters 5 - 7**).

The cross-sectional study of the ironHand project (**chapter 5**) did not show that older adults (with rheumatoid arthritis/osteoarthritis or sarcopenia) with lower baseline handgrip strength scores have more direct benefit of the glove, or vice versa. The clinical pilot study of the HandinMind project (**chapter 7**) have not examined the relation between baseline handgrip strength and changes in performance for stroke patients, after direct or after prolonged use of a soft-robotic system. Although only 5 participants participated in this study, it seems like stroke patients with moderate impairments (based on the Fugl-Meyer assessment) might experience the most benefit of glove support.

Based on qualitative observations, the 3-finger soft-robotic glove seems most suitable for older adults, whereas the 5-finger soft-robotic glove seems most suitable for stroke patients. Stroke patients prefer to receive grip and hand opening support of all fingers, which was not needed for older adults with self-perceived hand function limitations (**chapters 3 & 4**). Although both populations experienced less sensation with a soft-robotic glove, they were positive about its usability in general. Nevertheless, try-out sessions for both ironHand and HandinMind studies showed that a soft-robotic system would only be usable and valuable if the user is able to don/doff the glove themselves and is able to generate an interaction force between

the hand and object that is needed to add grip support. The glove would be suitable for a wider target population if the design of the device would change such that it would be easier to don/doff the glove for people with severe hand function limitations. Furthermore, use of a combination of pressure sensors with another human-robot interface (e.g., EMG) might make the soft-robotic system more suitable for a wider target population, including people with more severe hand function limitations. This would only be possible if it is not needed to generate an interaction force between the hand and object with such a device to add grip support. The study of Polygerinos et al. (23) already showed that an EMG-controlled soft-robotic system had a positive direct effect on performance of a patient with more severe hand function limitations (BBT score of 10) compared to the participants that participated in the ironHand and HandinMind studies. Nevertheless, more research is needed to investigate if performance also improves in a larger population of people with severe hand function limitations.

FUTURE PERSPECTIVE

A wearable soft-robotic system, such as the ironHand or HandinMind system, could be an ideal system for older adults and patients with hand function limitations to compensate for their limitations in activities of daily living and to perform functional exercises. To increase the chances for uptake, these devices should comply with several key user requirements. For example, it should be easy to use, it should support the diminished hand function of patients (based on assist as needed algorithms, i.e., not take over from them), patients should be able to don/doff the device independently without support from others, and patients should be able to use it unobtrusively in activities of daily living or for training purposes. When such a system is available, this thesis showed that older adults and stroke patients are motivated and able to use a wearable soft-robotic system in daily life. Moreover, they experience a direct effect of a wearable soft-robotic system through improved pinch strength, and they can even improve their hand function after its prolonged use as either assistive device in activities of daily living or training system.

A wearable soft-robotic system has a lot of potential for older adults and patients to stay or become (more) independent in their performance of daily activities. It can support people with hand function limitations while performing activities of daily living directly, and it can even improve unsupported hand function after prolonged use as well. This is an indication that such devices could not only be used to support activities of daily living, but can also be used to provide a tool to actually turn

everyday activities into highly intensive, functional training. Additionally, it could be an ideal device for patients early in the rehabilitation process, because patients could increase the intensity of training enormously by training their hand while performing functional daily activities, even in-clinic. Perhaps this might result in increased willingness or motivation to train and could drive further gains in performance during and after therapy. To further extend the possibilities of these devices in the near future, these devices could be combined with a remote monitoring system (telerehabilitation (12)) for independent training and (indirect) feedback on performance from a healthcare professional at home. A healthcare professional is able to monitor use and progress via an online user-interface and can give feedback on performance. This would give patients the possibility to train independently at home under remote supervision of a healthcare professional.

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APPENDIX

Summary

Samenvatting

Dankwoord

About the author

Progress range

SUMMARY

Our hands are used for different aspects in daily life, such as non-verbal communication, sensory feedback and performing daily activities. Older adults and stroke patients frequently experience a decline in hand function due to loss of grip strength, resulting in difficulties in independently performing activities of daily living.

Technological innovations, based on the concept of wearable soft-robotic devices, make it possible to support impaired hand function during the performance of daily activities and to provide intensive task-specific training at home. The ironHand and HandinMind systems are examples of such novel wearable soft-robotic systems that have been developed in the ironHand and HandinMind projects. Both systems are developed in an iterative design and development process, where the ironHand system is tailored to support grip of older adults with a variety of physical age-related hand function limitations and the HandinMind system is developed to support grip and hand opening of stroke patients. It is possible to connect a personalized computer gaming environment to both systems to perform specific exercises as well.

In this thesis, the aim was to define user requirements, to investigate feasibility and to evaluate the direct (assistive) and clinical (therapeutic) effects of a wearable soft-robotic system that is developed to support impaired hand function of older adults and stroke patients in a wide range of daily activities and in exercise training at home. As part of this aim, the following research questions have been described in **chapter 1**:

- 1) What are the main user requirements for a wearable soft-robotic device that is able to support impaired hand function of older adults and stroke patients in daily activities and in exercise training?
- 2) How is feasibility rated of such a wearable soft-robotic glove that should be able to combine assistance of impaired hand function and training exercises by older adults and stroke patients?
- 3) What is the influence of such a wearable soft-robotic glove on functional performance of the impaired hand of older adults and stroke patients?
- 4) What is the effect of prolonged use of such a wearable soft-robotic glove on hand function of older adults and stroke patients?

The first research question has been investigated in the focus group study as described in **chapter 2**. In this focus group study, several requirements for the first

prototypes of the ironHand and HandinMind systems were specified by potential end-users as older adults, stroke patients and healthcare professionals. This information is very important to enhance the acceptance of such devices in daily life and avoid device abandonment. The participants of the focus groups specified requirements regarding: 1) activities that need support of assistive technology, 2) design of wearable robotic devices for hand support, and 3) application of assistive technology as training tool at home. They concluded that assistive hand devices are a valuable tool to support impaired hand function in activities of daily living, but only if the device is wearable, compact, lightweight, easy to use, quickly initialized, washable and only supports the particular function(s) that an individual need(s) assistance with, without taking over existing function(s) from the user.

These requirements were used as input for the development of the first prototypes of the HandinMind and ironHand systems. During the first stage of user testing, both systems were tested on feasibility as described in **chapters 3 & 4**. In **chapter 3**, older adults performed several functional tasks and rated user-acceptance of the ironHand system. User acceptance, in terms of motivation and usability, of the ironHand system was rated high. The functional tasks were performed faster without glove compared to with glove. However, their performance improved across only 3 repetitions with glove up to the level of performance without glove, while using the system for the first time. When using the system again during the same tasks a few days later, performance with glove was improved even further, which suggests that there is room for improvement if participants use it for a longer period of time. In **chapter 4**, chronic stroke patients performed the same functional tasks as the older adults in **chapter 3** and rated user-acceptance of the HandinMind system. They also improved their functional performance with glove within only 3 consecutive repetitions, but the slower performance with glove with respect to without glove was absent in stroke patients.

After focusing on feasibility, the soft-robotic gloves were tested for the direct functional benefit in **chapters 5 & 7**. In **chapter 5**, older adults with hand function problems as result of various disorders ($n=65$) performed several hand function tests with and without glove during one session. They produced more pinch strength with glove compared to without glove, but functional performance was slower with glove compared to without glove. There was no correlation found between baseline handgrip strength of the older adults and differences in performance without and with glove. Similarly, stroke patients showed the same results for the HandinMind glove in the clinical pilot study ($n=5$) as described in **chapter 7**.

Although both systems could not support a direct benefit for older adults and stroke patients during timed performances tests, pinch strength was enhanced with the

glove. Beyond a direct influence, these systems might enable a new way of intensive functional training when using the glove for a longer period of time during daily activities. Possibly, this has a therapeutic effect regarding unsupported hand function. Therefore, clinical trials with the ironHand and HandinMind systems, in which older adults and stroke patients used the system continuously for several weeks, were performed (**chapters 6 & 7**). Older adults, who used the ironHand system for 4 weeks, were able to use the system for a substantial amount of time at home. During this period, older adults improved unsupported handgrip strength, pinch strength and functional performance when using the ironHand as trainings tool at home. Functional performance also improved if the ironHand was used as assistive device during activities of daily living. However, functional performance also improved in the group of older adults who received no additional exercise or treatment (control group), hindering interpretation of these results. Three stroke patients that participated in the clinical HandinMind pilot study (**chapter 7**) also showed a tendency for improving performance (without glove) on pinch strength, handgrip strength and functional performance after 5 weeks of HandinMind use, either as assistive or training device. This suggests that both the ironHand and HandinMind system, applied as either assistive device or training tool, is a promising way to counter decline in hand function.

The main findings of this thesis are discussed in **chapter 8**, including recommendations for further research. In short, this thesis shows that a wearable soft-robotic system (e.g., ironHand or HandinMind system) has a lot of potential for older adults and patients to provide hand support in activities of daily living and to perform functional exercises at home. The possibility to perform functional exercises intensively at home might increase the willingness and motivation to train, which could drive further gains in performance. However, the following recommendations are given to extend the possibilities of wearable soft-robotic gloves and future research: 1) to develop a system that is easy to use autonomously for a wide target population, including people with severe hand function limitations, 2) to extend the evaluation of soft-robotic gloves with measurements that can assess quality of movement as well as quantity of movement, 3) to combine the system with a remote monitoring system for independent training which could be used for (indirect) feedback on performance from a healthcare professional.

SAMENVATTING

Onze handen worden gebruikt voor verschillende zaken in het dagelijks leven, zoals non-verbale communicatie, sensorische feedback en het uitvoeren van dagelijkse activiteiten. Ouderen en patiënten na een beroerte ervaren vaak een achteruitgang van handfunctie als gevolg van verlies van grijpkracht. Dit resulteert in problemen bij het zelfstandig uitvoeren van activiteiten in het dagelijks leven.

Technologische innovaties, die gebaseerd zijn op het concept van draagbare soft-robotische apparaten, maken het mogelijk om een verminderde handfunctie te ondersteunen tijdens de uitvoering van dagelijkse activiteiten en om thuis een intensieve taakspecifieke training te geven. De ironHand en HandinMind systemen zijn voorbeelden van dergelijke nieuwe draagbare soft-robotische systemen die zijn ontwikkeld in de ironHand en HandinMind projecten. Beide systemen zijn ontwikkeld in een doorlopend proces van ontwerpen- en ontwikkelen, waarbij het ironHand systeem is afgestemd op de ondersteuning van handfunctie van ouderen met een verscheidenheid aan lichamelijke leeftijdsgebonden beperkingen van de handfunctie. Het HandinMind systeem is ontwikkeld om grip en handopening van patiënten na een beroerte te ondersteunen. Het is mogelijk om een gepersonaliseerde computeromgeving op beide systemen aan te sluiten om ook specifieke hand oefeningen uit te voeren door middel van computerspellen.

Het doel van dit proefschrift was om gebruikersvereisten te definiëren, de haalbaarheid te onderzoeken en de directe (ondersteunende) en klinische (therapeutische) effecten te evalueren van een draagbaar soft-robotisch systeem dat is ontwikkeld om verminderde handfunctie van ouderen en patiënten met een beroerte te ondersteunen bij een breed scala aan dagelijkse activiteiten en bij het thuis trainen van de hand. Als onderdeel van dit doel zijn de volgende onderzoeksvragen beschreven in **hoofdstuk 1**:

- 1) Wat zijn de belangrijkste gebruikersvereisten voor een draagbaar soft-robotisch systeem dat in staat is om een verminderde handfunctie van ouderen en patiënten na een beroerte te ondersteunen bij dagelijkse activiteiten en bij het trainen van de hand?
- 2) Hoe wordt de toepasbaarheid beoordeeld van een dergelijke draagbare soft-robotische handschoen die in staat zou moeten zijn om ondersteuning van verminderde handfunctie en trainingsoefeningen te combineren door ouderen en patiënten na een beroerte?

- 3) Wat is de invloed van een dergelijke draagbare soft-robotische handschoen op de functionele prestaties van de aangedane hand van ouderen en patiënten na een beroerte?
- 4) Wat is het effect van langdurig gebruik van een dergelijke draagbare soft-robotische handschoen op de handfunctie van ouderen en patiënten na een beroerte?

De eerste onderzoeksvraag is onderzocht in de focusgroep studie zoals beschreven in **hoofdstuk 2**. In deze focusgroep studie werden verschillende vereisten voor de eerste prototypen van de ironHand en HandinMind systemen door potentiële eindgebruikers, waaronder ouderen, patiënten na een beroerte en professionele zorg medewerkers, gespecificeerd. Deze informatie is erg belangrijk om de acceptatie van deze systemen in het dagelijks leven te vergroten en hiermee te vermijden dat de systemen niet gebruikt worden. De deelnemers aan de focusgroepen stelden eisen op voor zo'n systeem omtrent: 1) activiteiten die ondersteuning van ondersteunende technologie nodig hebben, 2) ontwerp van draagbare robotische systemen voor handondersteuning, en 3) toepassing van ondersteunende technologie als trainingshulpmiddel thuis. Ze concludeerden dat ondersteunde hulpmiddelen voor de hand een waardevol hulpmiddel zijn om verminderde handfunctie te ondersteunen bij activiteiten van het dagelijks leven. De voorwaarden hiervoor zijn dat het systeem draagbaar, compact, licht, gebruiksvriendelijk, snel geïnitieerd, en afwasbaar is. Ook dient het alleen de specifieke functie(s) te ondersteunen waar een persoon hulp bij nodig heeft, zonder de bestaande functie(s) van de gebruiker over te nemen.

Deze vereisten werden gebruikt als input voor de ontwikkeling van de eerste prototypen van de HandinMind en ironHand systemen. Tijdens de eerste fase van de gebruikerstesten werden beide systemen op toepasbaarheid getest, zoals beschreven in **hoofdstukken 3 en 4**. In **hoofdstuk 3** hebben ouderen verschillende functionele taken uitgevoerd en de gebruikersacceptatie van het ironHand systeem beoordeeld. Gebruikersacceptatie, uitgedrukt in motivatie en bruikbaarheid, van het ironHand systeem werd als hoog beoordeeld. Bij het eerste gebruik van de handschoen werden de functionele taken sneller uitgevoerd zonder handschoen ten opzichte van met de handschoen. In slechts 3 herhalingen verbeterden de prestaties met handschoen echter tot het niveau van presteren zonder handschoen. Toen vervolgens het systeem enkele dagen later opnieuw werd gebruikt tijdens dezelfde taken, werden de prestaties met de handschoen nog verder verbeterd. Dit suggereert dat er ruimte is voor verbetering als deelnemers het voor een langere periode gebruiken. In **hoofdstuk 4** hebben chronische patiënten na een beroerte dezelfde functionele taken uitgevoerd als de ouderen in **hoofdstuk 3** en hebben zij de

gebruikersacceptatie van het HandinMind systeem beoordeeld. Zij verbeterden ook hun functionele prestaties met de handschoen binnen slechts 3 opeenvolgende herhalingen, maar patiënten na een beroerte presteerden met handschoen niet langzamer ten opzichte van zonder handschoen.

Nadat de systemen op toepasbaarheid waren getest, werden de soft-robotische handschoenen getest op het directe functionele effect in **hoofdstukken 5 en 7**. In **hoofdstuk 5** hebben ouderen met handfunctieproblemen als gevolg van verschillende aandoeningen ($n=65$) verschillende handfunctietesten uitgevoerd met en zonder handschoenen tijdens één sessie. Zij produceerden meer kracht dat geleverd werd tussen twee vingers met de handschoen in vergelijking tot zonder handschoen. Echter waren de functionele prestaties langzamer met de handschoen in vergelijking tot zonder de handschoen. Verder werd geen correlatie gevonden tussen de baseline handknijpkracht van de ouderen en verschillen in prestaties zonder en met handschoen. Op dezelfde manier vertoonden patiënten na een beroerte dezelfde resultaten voor de HandinMind handschoen in de klinische pilotstudie ($n=5$) zoals beschreven in **hoofdstuk 7**.

Hoewel beide systemen geen direct voordeel tonen voor ouderen en patiënten na een beroerte voor testen waarbij een tijd gemeten wordt, werd de kracht die geleverd kan worden tussen twee vingers wel verbeterd met de handschoen. Naast een direct effect kunnen deze systemen ook ingezet worden tijdens functionele training wanneer de handschoen gedurende langere tijd wordt gebruikt tijdens dagelijkse activiteiten. Mogelijk heeft dit een therapeutisch effect op de niet ondersteunde handfunctie. Daarom werden klinische onderzoeken met de ironHand en HandinMind systemen uitgevoerd, waarbij ouderen en patiënten na een beroerte het systeem gedurende een aantal weken continu gebruikten (**hoofdstukken 6 en 7**). Ouderen, die het ironHand-systeem 4 weken gebruikten, konden het systeem gedurende een aanzienlijke tijd thuis gebruiken. Tijdens deze periode werd de niet ondersteunde handknijpkracht, de kracht die geleverd kan worden tussen twee vingers en functionele prestaties verbeterd bij het gebruik van de ironHand als trainingshulpmiddel thuis. Functionele prestaties verbeterden ook als de ironHand werd gebruikt als hulpmiddel tijdens activiteiten van het dagelijks leven. De functionele prestaties verbeterden echter ook in de groep van ouderen die geen aanvullende oefening of behandeling kregen (controlegroep), waardoor de interpretatie van deze resultaten lastig is. Bij drie patiënten, die deelnamen aan de klinische HandinMind-pilotstudie (**hoofdstuk 7**), werd een tendens om de prestaties (zonder handschoen) te verbeteren op handknijpkracht, de kracht die geleverd kan worden tussen twee vingers en functionele prestaties na 5 weken gebruik van het HandinMind systeem, als ondersteunend hulpmiddel of trainingssysteem zichtbaar.

Dit suggereert dat zowel het ironHand als het HandinMind systeem, dat wordt toegepast als ondersteunend hulpmiddel of trainingssysteem, een veelbelovende manier is om achteruitgang van handfunctie tegen te gaan.

De belangrijkste bevindingen van dit proefschrift worden besproken in **hoofdstuk 8**, inclusief aanbevelingen voor verder onderzoek. Kort samengevat laat dit proefschrift zien dat een draagbaar soft-robotisch systeem (bijvoorbeeld het ironHand of HandinMind systeem) veel mogelijkheden biedt voor ouderen en patiënten om ondersteuning van de hand te bieden bij het uitvoeren van activiteiten in het dagelijks leven en om functionele oefeningen thuis uit te voeren. De mogelijkheid om thuis functionele oefeningen intensief uit te voeren, kan de bereidheid en motivatie om te trainen vergroten, waardoor de prestaties verder kunnen stijgen. De volgende aanbevelingen worden echter gegeven om de mogelijkheden van draagbare soft-robotische handschoenen en toekomstig onderzoek uit te breiden: 1) een systeem ontwikkelen dat eenvoudig autonoom te gebruiken is voor een brede populatie, inclusief mensen met ernstige handfunctiebeperkingen, 2) de evaluatie van soft-robotische handschoenen uit te breiden met metingen die de bewegingskwaliteit en de hoeveelheid bewegingen kunnen beoordelen; 3) het systeem te combineren met een systeem op afstand voor onafhankelijke training en dat gebruikt kan worden voor (indirecte) feedback op de prestaties door een zorgverlener.

DANKWOORD

Het promotieonderzoek en het daarbij behorende proefschrift is af, maar dit was niet tot stand gekomen zonder de hulp en steun van vele collega's, vrienden en familie. Daarom wil ik graag de gelegenheid nemen om alle mensen die hier een bijdrage aan geleverd hebben te bedanken.

Allereerst wil ik bedanken, Gardienke en Anke, met wie ik dagelijks samenwerkte binnen het ironHand en HandinMind project. Wat heb ik in de afgelopen jaren veel van jullie mogen leren! Door jullie ben ik gegroeid in uiteenlopende zaken, van hoe ik het beste een onderzoek kon opzetten en organiseren, tot hoe ik het beste mijn onderzoek kan presenteren tijdens (inter)nationale congressen en het beschrijven van de resultaten in wetenschappelijke artikelen. Daarnaast kon ik altijd bij jullie terecht voor inhoudelijke adviezen, feedback op geschreven artikelen of gewoon een gezellig praatje! Gardienke en Anke, ontzettend bedankt voor de begeleiding en gezelligheid de afgelopen jaren.

Hans en Jaap, ook jullie wil ik hartelijk bedanken voor de begeleiding tijdens mijn promotieonderzoek. Jullie konden mij met jullie inhoudelijke kennis en inzicht altijd weer een zetje in de goede richting geven. Maar daarnaast zal ik ook zeker niet de gezellige momenten die wij samen beleefd hebben vergeten. Bedankt voor de fijne samenwerking!

De wetenschappelijke studies in dit proefschrift waren niet tot stand gekomen zonder de inzet van de vele deelnemers die mee hebben gedaan aan de verschillende onderzoeken van het ironHand en HandinMind project. Hartelijk bedankt! Daarnaast hebben veel Europese collega's die werkten binnen het ironHand en HandinMind project bijgedragen aan de totstandkoming van dit proefschrift. I would like to thank: Martin, Stefan, Johan, Tomas (Bioservo Technologies AB, Kista, Zweden), Alejandro, Serena, Lars, Alexander (Hocoma AG, Volketswil, Zwitserland), Johnny, Kristin, Johan (Eskilstuna Kommun Vård- och omsorgsförvaltningen, Eskilstuna, Zweden), Thomas, Sabine (terzStiftung, Berlingen, Zwitserland) and Nina, Liesbeth, Marije and Manon (het Nationaal Ouderenfonds, Bunnik, Nederland) for the good collaboration and their contributions (e.g., inclusion of the many patients/older adults, data collection etc.) to all the work in the ironHand and HandinMind projects.

Verder wil ik graag al mijn collega's bij RRD bedanken voor de gezellige en goede werksfeer waarin ik heb mogen werken. Er waren altijd wel collega's bij wie je terecht kon voor inhoudelijke adviezen, feedback op je artikelen of gewoon een

gezellig praatje bij de koffiehoeck of lunchwandeling. In het bijzonder wil ik toch 3 collega's, die ik nu zeker ook goede vrienden mag noemen, bedanken voor de afgelopen jaren waarin we vele nieuwtjes, roddels, en frustraties gedeeld hebben. Juliet, Carola en Erik bedankt dat ik bij jullie altijd terecht kon voor een luisterend oor, leuke gesprekken, etentjes en leuke activiteiten buiten werk om! Daarnaast vind ik het leuk Erik, dat jij samen met Niels Waterval mijn paranimf wil zijn.

Tot slot wil ik graag mijn familie en vrienden bedanken voor alle interesse en steun in mijn promotieonderzoek. Maar boven al, mijn vrouw Irene. Het was niet altijd even makkelijk om te wonen in Amsterdam en te werken in Enschede, en uiteindelijk mijn proefschrift af te schrijven naast mijn baan bij DICA. Dat heeft zeker de nodige inspanningen van ons beide gevraagd. Tijdens mijn periode in Enschede was er altijd weer die vroege wekker, die eenzame avonden en nachten, de frustraties over het treinverkeer etc.. Toch kon ik altijd op je rekenen en hebben jouw vele lieve, bemoedigende woorden en vele knuffels er altijd weer voor gezorgd dat ik met goede moed verder kon.

Daarnaast wil ik graag mijn lieve ouders, zusje, broertjes, en schoonfamilie bedanken. Jullie waren altijd geïnteresseerd in mijn werk en wilden maar al te graag weten hoe dat nou precies werkte met "die handschoen". Wat hebben we gelachen toen jullie het allemaal een keer hebben mogen proberen. Maar gelukkig gaat het niet altijd over werk en kan ik ook altijd bij jullie terecht voor de nodige gezelligheid en ontspanning.

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