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Six weeks Use of a Wearable Soft-robotic Glove During ADL: Preliminary Results of Ongoing Clinical Study



Anke I. R. Kottink, Corien D. M. Nikamp, Jaap H. Buurke, Foskea Bos, Corry K. van der Sluis, Marieke van den Broek, Bram Onneweer, Janneke M. Stolwijk-Swüste, Sander M. Brink, Johan S. Rietman, and Gerdienke B. Prange-Lasonder

Abstract In this ongoing study, an assistive wearable soft-robotic glove, named Carbonhand, is tested at home for 6 weeks by subjects with decreased handgrip strength to receive a first insight in the therapeutic effect of using this assistive grip-supporting glove during ADLs. Preliminary results of the first 13 participants showed that participants appreciated use of the glove to assist them with daily life activities. Even more, grip strength without glove improved and functional performance showed increases as well. These preliminary findings hold promise for observing a clinical effect of using the soft-robotic glove as assistance in ADLs upon completion of data collection.

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1 Introduction

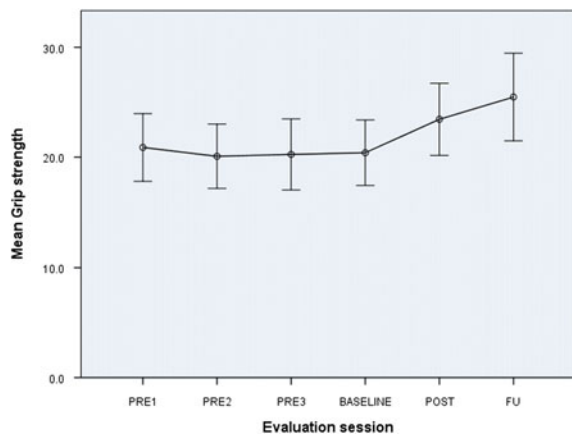
Hand function is very important to perform activities of daily living (ADLs). One of the most common problems concerning hand function is a decrease in hand strength, which occurs across a wide range of disorders. Specifically, people with reduced hand function often have difficulties with holding and manipulating objects, subsequently leading to difficulties with independently performing ADLs [1]. These limitations can have a negative effect on their participation in society or on quality of life [2]. Wearable robotics seem a promising approach to enable direct support of motor function for prolonged periods in the home environment of patients. With a wearable assistive device, performance of functional activities are supported directly, while it is hypothesized that using the affected arm and hand repeatedly during ADLs provides intensive and task-specific training at the same time. This might result in improved unsupported arm and hand function after prolonged use. In the present study, the aim was to investigate if six weeks home-use of an assistive soft-robotic glove during ADLs resulted in a therapeutic (i.e. clinical) effect on hand strength and hand function.

2 Methods

2.1 Study Design

This ongoing study consists of a multicenter uncontrolled intervention study and takes place in seven centers in the Netherlands. All participants will be assessed five times, consisting of three pre-evaluations, a post- and follow-up evaluation.

Fig. 1 Carbonhand system



2.2 Participants

The aim is to include 63 chronic patients with decreased handgrip strength. Subjects with a wide variety of disorders are included, such as traumatic brain injury, spinal cord injury, orthopaedic problems or a stroke, but all in a chronic and stable phase of disease. Main inclusion criteria are: at least 10° active extension of wrist/fingers and 10° active flexion of fingers. Main exclusion criteria are: severe acute pain of the most-affected hand, severe contractures limiting passive range of motion, severe spasticity of the hand and receiving arm-/hand function therapy during the course of the study. The study is approved by the Medical Ethical Committee of Twente and the Dutch Health Inspectorate. All participants signed an informed consent prior to study start.

2.3 Intervention

The soft-robotic glove was manually adjusted to each individual participant. All participants used the soft-robotic glove during ADLs at home for six weeks. Participants were free to choose for which activities, when and for how long they used the system. However, it was recommended to use the glove at least 180 min a week during the most common ADLs, such eating/drinking, functional transfers and personal hygiene.

2.4 Soft-robotic Glove

The Carbonhand system (Fig. 1) is based on the concept of a wearable soft-robotic glove that can provide extra grip strength to the thumb, middle and ring finger. A tendon-driven mechanism in the system is used to provide assistance in flexion of the fingers. The amount of assistance is modulated by pressure sensors in the fingertips and movement sensors along the fingers. The extra grip strength is always activated in a natural and intuitive way and in proportion to the force applied by the user due to an intention-detection mechanism. Glove settings (e.g. maximum force, sensitivity level) can be tuned for each individual.

2.5 Study Procedure

All involved therapists received an extensive training prior to the study in order to adapt the soft-robotic glove and its settings to each individual participant and to standardize the execution of the measurements across centers. Three pre-evaluations

Fig. 2 Change in grip strength (kg) over time



(T0, T1 and T2) were scheduled in three weeks for each participant. After the third assessment, the intervention period started, in which the participant used the soft-robotic glove at home for a period of six weeks. After ending the intervention period, a post-evaluation (T3) took place. Four weeks after the intervention period a follow-up evaluation (T4) was scheduled.

2.6 Outcome Measures

To examine the therapeutic effect of the soft-robotic glove, all tests were performed without using the glove. The primary outcome measure of the study was grip strength of the (most) affected hand, measured with the Jamar dynamometer (Patterson medical, Warrenville, IL, USA). A selection of secondary outcome measures is presented here: Jebson-Taylor Hand Function Test (JTHFT) and user experience, measured by self-reported grading (1–10) of ease of donning, ease of use and support from glove.

2.7 Data Analysis

Data was analysed using IBM SPSS Statistics (v23.0). A baseline value was calculated as the mean of the three pre-evaluation values, to average out day-to-day changes. Data was inspected for normality using normal probability plots and Kolmogorov-Smirnov tests. In order to assess the effect of the intervention over time, and because of the preliminary character of the study, paired-samples t-tests were performed between evaluation sessions. Descriptive analysis were performed

for participant characteristics and user experience ratings. The significance level was set at 0.05.

3 Results

3.1 Participants

Of the 13 participants included so far, nine (69%) were female. Mean age was 53 years (range 36–75 years; SD 12 years). Mean time after injury was 5.8 years (range 9 months–24 years; SD 7.8 years). The most prevalent causes of hand function limitations were trauma (46%) and rheumatoid arthritis (23%), followed by osteoarthritis, juvenile idiopathic arthritis, neuropathy and amyloidosis (each 8%). All but one participant had their right hand affected (most), which was their dominant hand. Data were missing for grip strength (T4) from two and for user experience (T3) from one participant.

3.2 Outcome Measures

Grip strength improved significantly from baseline (mean 20.4 kg; SD 10.8; indicating stable phase pre-intervention, see Fig. 2) to post-intervention (mean 23.4 kg; SD 11.8) with 3 kg (SD 4.7; $p = 0.038$). JTHFT did not change significantly, but showed a trend of improved performance after intervention. Performance was faster by 5.0 s (SD 8.7) from baseline to post intervention ($p = 0.074$) and 6.1 s (SD 10.7) from baseline to follow-up ($p = 0.087$). User experience grades were positive, with a mean grade of 8.3 for ease of donning (SD 1.1) and 7.3 for both ease of use and support from glove (SD 1.5 and 2.0, resp.).

4 Discussion

The goal of the present study was to explore first outcomes of a therapeutic effect of a soft-robotic glove on grip strength in patients with hand function problems, after using the glove for six weeks during ADLs. Findings of the first 13 participants showed that grip strength improved and hand function also tended to increase. The improvement in JTHFT performance from baseline to follow-up reached the level of its minimal clinically important difference (6 s faster execution of total test), indicating that at least a portion of the participants achieved a more functional task performance.

In addition, a high grade for donning the glove was found, which is often considered a bottleneck in use of hand devices. This implies that use of this soft-robotic glove at home is feasible, without users requiring help from a spouse or family member to start using the glove in their daily life.

However, the current statistics should be interpreted with caution, due to the underpowered sample and the lack of correction for multiple testing in this ongoing study.

5 Conclusion

The findings at the current stage of this ongoing study, with 21% of needed participants, hold promise for observing a therapeutic effect of using the soft-robotic glove during ADLs, upon completion of data collection: unsupported hand strength and hand function improve after 6-week assistive glove use.

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