



Carbonhand® The clinical evidence

Close to 200 patients have been involved in several studies, using Carbonhand either as an assistive aid, as a tool for rehabilitation or being part of a control group receiving standard of care. The overall results after 4-12 weeks of Carbonhand use are significant improvements in most outcome measures, i.e. grip strength, hand function and user experienced quality of life.

The included study participants may suffer hand impairment due to stroke, MS, peripheral nerve damage, brachial plexus injury, traumatic injuries, spinal cord injuries or weakness due to age.



Carbonhand®

Clinical Evidence Summary

STUDIES FOCUSING ON:

- Assistive device
- · Rehabiltation use
- Activities of Daily Living
- · Usability of device

INCLUDED PATIENTS:

- 189 patients in total
- · Assistive group / Therapeutic group / Control group
- Traumatic hand injuries
- Neurological hand dysfunction
- · Weak hands due to aging

MAIN OBJECTIVES:

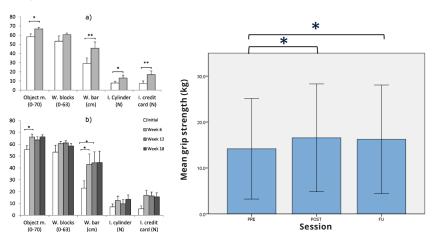
Mean grip strength, pinch strengths, hand function and quality of life. Assistive and therapeutic effects after 4-12 weeks of Carbonhand use.

It has given me a great deal; it got my hand going again.... as I couldn't use it before

/ MS Patient

Statistically significant evidence of using Carbonhand®:

- Increased grip strength
- · Increased pinch strength
- Improved hand function



SOURCES:

https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0220544 https://link.springer.com/chapter/10.1007%2F978-3-030-01845-0_77 https://www.medicaljournals.se/jrm/content/abstract/10.2340/16501977-2650 https://link.springer.com/chapter/10.1007/978-3-030-70316-5_3



PATIENTS:

- In total 91 patients
- · Assistive group / Therapeutic group / Control group
- · Weak hands due to aging

OBIECTIVE:

Mean grip strength, pinch strengths and hand function, assistive and therapeutic effects after four weeks of Carbonhand use

Carbonhand® Clinical evidence [1/4]

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

The first clinical study using Carbonhand as an assistive device during home rehabilitation was made as a randomized controlled trial by Radder et al. in the Netherlands in 2017-2018. 91 older adults with perceived decline in hand function where randomly assigned for a four week intervention in three groups (assistive group, therapeutic group and a control group). 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.

Participants of the assistive and therapeutic group reported high scores on the System Usability Score, The therapeutic group showed improvements in unsupported handgrip strength and pinch strength after 4 weeks of Carbonhand use (p≤0.039).

Statistically significant evidence of using Carbonhand®:

After four weeks of Carbonhand use:

- Increased grip strength with 3 kg (25%)
- Increased pinch strength with 0,4 kg (14%)
- · Improved hand function
- · Appropriate as either an assistive and / or a rehabilitation device

RESEARCH ARTICLE

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

Bob Radder 1.2*, Gerdienke B. Prange-Lasonder 1.2, Anke I. R. Kottink 1.3, Johnny Holmberg 4, Kristin Sletta 4, Manon van Dijk 5, Thomas Meyer 6, Alejandro Melendez-Calderon 7.8, Jaap H. Buurke 1.3.7, Johan S. Rietman 1.2.7

1 Roessingh Research and Development, Enschede, the Netherlands, 2 Department of Biomechanical Engineering, University of Twente, Enschede, the Netherlands, 3 Department of Biosystems and Signals, University of Twente, Enschede, the Netherlands, 4 Eskilstuna Kommun Vård- och omsorgsförvaltningen, ${\sf Eskil Stuna, Sweden, 5~National~Foundation~for~the~Elderly, Bunnik, the~Netherlands, 6~terzStiftung,}\\$ Berlingen, Switzerland, 7 Department of Physical Medicine and Rehabilitation, Northwestern University, Chicago, IL, United States of America, 8 Cereneo Advanced Rehabilitation Institute, Vitznau, Switzerland

* b.radder@rrd.nl



PATIFNTS:

15 patients with C2-C8 chronic Spinal Cord Injury, Stoke Mandeville, UK

OBJECTIVE:

12 week of home training during activities in daily living

Carbonhand® Clinical evidence [2/4]

Home-based rehabilitation using a soft robotic hand glove device leads to improvement in hand function in people with chronic spinal cord injury

During 2019 Osuagwu et al. studied the use of Carbonhand as an assistive device for home-based rehabilitation, for a group of 15 patients with chronic spinal cord injury, during an intervention period of 12 weeks.

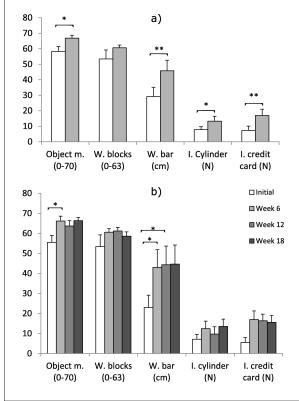
The primary outcome measure was the Toronto Rehabilitation Institute hand function test (TRI-HFT), with secondary outcome measures including pinch dynamometry and the modified Ashworth scale.

The TRI-HFT demonstrated improvement in hand function at Week 6 of the therapy including improvement in object manipulation. A significant improvement in pinch strength, with reduced thumb muscle hypertonia was also detected. Improvements in function were present during the week 12 assessment and also during the follow-up six weeks after the intervention period.

Statistically significant evidence of using Carbonhand®:

After 12 weeks of Carbonhand use:

- Increased grip strength with 40%
- Increased pinch strength with 45%
- · Improved hand function with 15%



SOURCES:

https://link.springer.com/chapter/10.1007/978-3-030-01845-0_77



PATIFNTS.

20 patients with impaired hand function: [1] MS patients [2] Stroke patients

OBJECTIVE:

Experiences after six weeks of Carbonhand use

Carbonhand® Clinical evidence [3/4]

Factors affecting the usability of an assistive soft robotic glove after stroke or multiple sclerosis

For patients living with an impaired hand function after stroke or MS, Palmmcrantz et al from the Division of Rehabilitation Medicine at Danderyd Hospital Stockholm, Sweden, studied the suability among 20 patients (10 stroke and 10 MS patients) using Carbonhand during activities of daily living for a period of six weeks.

Carbonhand enabled participants to produce more power and to hold and sustain the grip (MS and stroke), as well as improving the quality of the grip, which enabled handling and holding household objects (MS and stroke).

Carbonhand was found to be assistive in pursuing leisure activities (MS and stroke) and physical rehabilitation interventions (stroke).

Lasting effects after using Carbonhand were reported (MS, stroke) and manifested as perceived improved mobility and strength (MS, stroke) as well as improved grip (MS, stroke) and coordination (stroke). Lingering paraesthesia in the hand after use was expressed as a positive result (stroke) as well as decreased spasticity after use in addition to improved mobility and coordination in the fingers (MS).



"...the grip has improved and, as I said, it's like mu brain has learned that I have a left hand."

Lasting effects on functioning among participants who found the glove useful in ADL

"It has given me a great deal; it got my hand going again.... as I couldn't use it before" (MS patient)

"The benefit has been that I have been able to use my left hand to lift things up and grasp things." (Stroke patient)

"The positive side is that the glove helps the grip and on the negative side is that I should have had it earlier before my ability disappeared." (MS patient)

https://www.medicaljournals.se/jrm/content/abstract/10.2340/16501977-2650



PATIFNTS:

63 patients with impaired hand function: [1] traumatic hand injuries [2] neurological hand dysfunction [3] weak hands due to aging

OBJECTIVE:

Mean grip strength, pinch strengths and hand function after six weeks of Carbonhand use

Carbonhand® Clinical evidence [4/4]

Six weeks use of a wearable soft-robotic glove during ADL

The aim of this study is to examine the hypothesis, that with a wearable assistive device, performance of functional activities can be enhanced directly, and using of the impaired arm and hand repeatedly during ADL provides intensive and task-specific training at the same time. This might result in improved unsupported arm and hand function after prolonged use.

The participants suffer from perceived hand function problems consisting of 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. Average time from diagnosis to study inclusion is almost ten years.

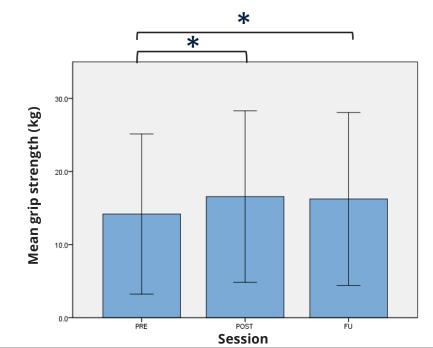
To examine the therapeutic effect of the soft-robotic glove, all tests were performed without using the glove. The primary outcome measure of the study is grip strength (kg), but also hand function (JTHFT) quality of life (EQ5D) and other outcomes are measured.

Statistically significant evidence of using Carbonhand®:

Preliminary data from 49 out of 63 partiipants:

After six weeks of Carbonhand use:

- +2.1 kg improvement in grip strength (+27% vs. Baseline)
- Improved hand function according to JTHFT with 12%
- · Remaining effect after four weeks follow up.



https://link.springer.com/chapter/10.1007/978-3-030-70316-5_3