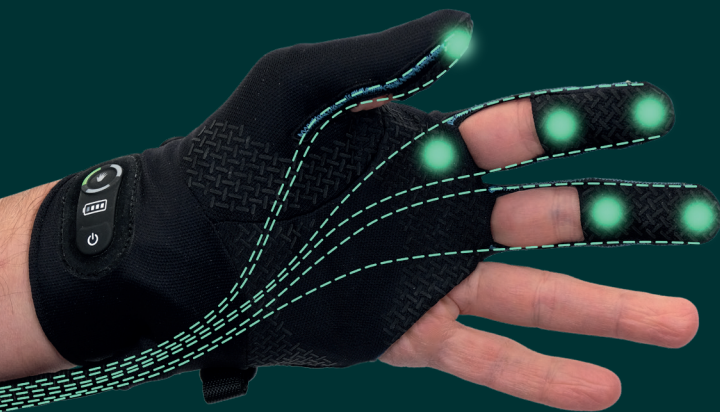


Carbonhand®

Empowering Veterans with Impaired Hand Function



- A 3-finger glove, with state-of-the-art technology using embedded pressure sensors to enhance grip
- Choose how to wear it — Support for your middle and ring fingers or your index and middle fingers.
- Artificial tendons control the force of each finger to improve grip response and strength
- A Bluetooth connected App allows for programming of customized user profiles to fit all user needs and situations
- All day battery life to enhance everyday ADLs



Scan to learn more
about Carbonhand

Indications for Use:

Reduced grip strength and/or impaired hand function due to (but not limited to):

- Spinal Cord Injury
- Amyotrophic Lateral Sclerosis (ALS)
- Multiple Sclerosis (MS)
- Stroke
- Traumatic Brain Injury
- Peripheral nerve injury
- Plexus brachialis injury
- Hand Osteoarthritis
- Rheumatoid arthritis
- Orthopedic injuries



1. Glove - Soft, lightweight, and flexible glove with pressure sensors, artificial tendons, and control pad

2. Power unit - Includes battery, power actuators, control system and glove connector

3. Cord - Contains electrical and bowden cables to transfer sensor signals and forces between the glove and power unit

4. Arm straps - Keeps the cord close to the user in order to avoid entanglement

Smart Flexible Use

The user can choose how to wear the glove, either to support the middle and ring fingers or the index and middle fingers. This allows people with different impairments to benefit from the glove and enables them to wear the glove in a way that supports specific daily activities.



Adapts to the needs

Three profiles are available from the Control Pad on the glove. The profiles can be tailored for different tasks, such as needing more support for gardening and less for household activities.

Proven to enhance quality of life

- More than 360 people have taken part in studies with Carbonhand
- Users experience a sustained and strong grip
- The handling of everyday objects is perceived as being improved
- Carbonhand enhances the user's ability to perform activities in daily living

Scan to see one
Veteran's experience:
What would Carbonhand®
do for your daily living?
"It would change my life".





Accessing Carbonhand via FSS

Bioservo's Carbonhand is available on the Federal Supply Schedule (FSS) through Affirmative Solutions LLC (SDVOSB), a subsidiary of Apiary Medical.

How to Access/Order via FSS

Orders can be submitted by the purchasing agent via phone, fax, email, or GSA Advantage:

FSS Contract Information:

- FSS Contract Number #36F79722D0022
- SIN# A-70
- CAGE Code 54J23
- UEI DNV7E1GBTDW7
- Key Word Search = "Carbonhand Patient Kit"

Carbonhand Patient Kit Part numbers:

| | |
|---------|--|
| 140.RXS | Carbonhand Patient Kit with Right Extra Small Glove |
| 140.RS | Carbonhand Patient Kit with Right Small Glove |
| 140.RM | Carbonhand Patient Kit with Right Medium Glove |
| 140.RL | Carbonhand Patient Kit with Right Large Glove |
| 140.RXL | Carbonhand Patient Kit with Right Extra Large Glove |
| 140.LXS | Carbonhand Patient Kit with Left Extra Small Glove |
| 140.LS | Carbonhand Patient Kit with Left Small Glove |
| 140.LM | Carbonhand Patient Kit with Left Medium Glove |
| 140.LL | Carbonhand Patient Kit with Left Large Glove |
| 140.LXL | Carbonhand Patient Kit with Left Extra Large Glove |

Affirmative Solutions Information

Customer Service Email: info@affirmativesolutions.org

Customer Service Fax: 877-879-7811

Order Questions: 866-994-7986

Hours of Operation: 8 AM – 5 PM EST

Carbonhand is an assistive device in the form of a grip-strengthening glove with pressure sensors in the fingers and palm that detect when the user performs a grip, and then applies force through artificial tendons to ensure a firm grip.

Carbonhand adds force to the grip

Carbonhand is a smart and intuitive grip-strengthening glove that provides power to people with reduced grip strength and/or impaired hand function. It increases independence, and contributes to enhancing the quality of life.

Carbonhand compensates for the loss of grip strength and hand function which makes it possible to perform activities of daily living that people find it difficult to perform or cannot do without the glove.

Some examples of impaired hand functions where Carbonhand can be useful are:

- Central nervous system disorders such as stroke, MS, ALS, or spinal cord injury.
- Orthopedic injuries including fractures in the hand, nerve damage after surgery, or brachial plexus injury.
- Rheumatic diseases or osteoarthritis.



Advanced Technology

- Multiple sensors on each finger and one on the first MCP joint
- Control Pad with three programmable profiles and an activation button, configured via smart app
- An advanced dynamic control system for an intuitive experience
- Artificial tendons in the glove provides a firm grip
- Functions for keeping track of usage and progress



Proven to enhance quality of life

- More than 360 people have taken part in studies with Carbonhand.
- The majority have experienced a sustained and strong grip.
- The handling of everyday objects is perceived as being improved
- Carbonhand enhances the user's ability to perform activities in daily living.

Scan to learn more
about Carbonhand



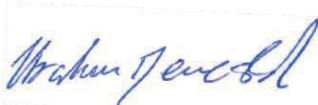
DECLARATION OF CONFORMITY

| | |
|--|--|
| MANUFACTURER | Bioservo AB |
| ADDRESS | Torshamnsgatan 35, 164 40 Kista, Sweden |
| REGISTRATION NUMBER | 3027241828 |
| MANUFACTURER OF THE FOLLOWING PRODUCT: | |
| MODEL NAME | Carbonhand |
| TYPE | C0 |
| INTENDED USE | Grasp assistance |
| DEVICE CLASS | Class I 510(k) Exempt |
| PRODUCT CODE | IQZ |
| DEVICE | Hand, External Limb Component, Powered |
| REGULATORY NUMBER | 890.3420 |
| ONLINE REGISTRATION & LISTING | www.accessdata.fda.gov |

Bioservo hereby assures that the product is in accordance with applicable laws and Food and Drug Administration (FDA or the Agency) regulations.

FDA has not reviewed or agreed with this determination, and FDA registration and listing does not constitute a clearance or approval but does fulfill (for 510(k) Exempt device) the regulatory general control requirement for the firm to inform FDA of what product Bioservo is marketing in the US and where it is manufactured.

| | |
|-------------------------|------------------|
| PLACE AND DATE OF ISSUE | Kista 2024-02-12 |
|-------------------------|------------------|



Ibrahim Derregård QA&RA



Petter Bäckgren CEO



Carbonhand® Request for Quote (Page 1/2)

Select a **Carbonhand Patient Kit** and optional accessory below

| Select | Affirmative Item # | Description |
|--------|--------------------|---|
| | 140.RXS | Carbonhand Patient Kit with Right Extra Small Glove |
| | 140.RS | Carbonhand Patient Kit with Right Small Glove |
| | 140.RM | Carbonhand Patient Kit with Right Medium Glove |
| | 140.RL | Carbonhand Patient Kit with Right Large Glove |
| | 140.RXL | Carbonhand Patient Kit with Right Extra Large Glove |
| | 140.LXS | Carbonhand Patient Kit with Left Extra Small Glove |
| | 140.LS | Carbonhand Patient Kit with Left Small Glove |
| | 140.LM | Carbonhand Patient Kit with Left Medium Glove |
| | 140.LL | Carbonhand Patient Kit with Left Large Glove |
| | 140.LXL | Carbonhand Patient Kit with Left Extra Large Glove |
| | Accessory | |
| | 130 | Carbonhand Button – <i>Free of charge when ordering a Kit</i> |

If this box is ticked, there are Individual Items and/or Additional Notes on the Second Page

VA Contact Information to Appear on Quote

Facility Name: _____
 Department: _____
 Address: _____
 City: _____ State: _____ Zip: _____
 Contact Name: _____
 Phone: _____ Email: _____
 Patient Reference: Initial: ___ Last Name: _____

Shipping information

Send to VA Center Above. If box is not ticked, send to address below:

Name: _____
 Address: _____
 City: _____ State: _____ Zip: _____
 Phone: _____ Email: _____

Sales Agent Contact Information

Name: _____ Phone: _____
 Email: _____

Carbonhand® Request for Quote (Page 2/2)

Fill in the quantity for the **Individual items** you want to order.

| Quantity | Article # | Description |
|----------|------------|--|
| | BIO.111 | Carbonhand® Glove Right size XS |
| | BIO.112 | Carbonhand® Glove Right size S |
| | BIO.113 | Carbonhand® Glove Right size M |
| | BIO.114 | Carbonhand® Glove Right size L |
| | BIO.115 | Carbonhand® Glove Right size XL |
| | BIO.116 | Carbonhand® Glove Left size XS |
| | BIO.117 | Carbonhand® Glove Left size S |
| | BIO.118 | Carbonhand® Glove Left size M |
| | BIO.119 | Carbonhand® Glove Left size L |
| | BIO.120 | Carbonhand® Glove Left size XL |
| | 110 | Carbonhand® Power Unit |
| | 121 | Carbonhand® Carry solution S/M |
| | 132 | Carbonhand® Carry solution L/XL |
| | 122 | Carbonhand® Arm strap S |
| | 124 | Carbonhand® Arm strap L |
| | 125 | Carbonhand® Battery charger |
| | 128 | Carbonhand® Soft case |
| | 129 | Carbonhand® Hard Carry case |
| | 130 | Carbonhand® Button |
| | 2695 | Carbonhand® Belt strap S/M |
| | 2894 | Carbonhand® Belt strap L/XL |
| | 2694 | Carbonhand® Shoulder strap |
| | 2730 | Carbonhand® Power unit sleeve |
| | 3499 | Carbonhand® Power unit sleeve - Double Carry |
| | 066 | Carbonhand® Padded Washing bag |
| | 001MAN.USA | Carbonhand® Instruction Manual |
| | ADJ.KIT | Carbonhand® Glove Adjustment Kit |
| | BIOC.1K | Carbonhand® Clinical Kit |

Additional Notes:

Return to Affirmative Solutions via Email or Fax

Email: info@affirmativesolutions.org

Fax: 877-879-7811

Questions: 866-994-7986

Hours of Operation: 8 AM – 5 PM

Summary of evidence for Carbonhand as an assistive device

Several studies have been performed with Carbonhand, including more than 360 study participants with reduced grip strength and/or impaired hand function due to various reasons and diagnoses.

For example; people with Stroke, Spinal Cord Injury, Multiple Sclerosis, Sarcopenia, and Myopathy benefited from using Carbonhand within these trials.

The results from these trials show:

- Manipulation of several objects encountered in ADL was experienced as improved during the use of Carbonhand
- A sustained and strong grip was perceived as the most beneficial effect while using Carbonhand
- The participants experienced an improved grip strength during the use of Carbonhand
- The usability of Carbonhand was rated as high
- Carbonhand is safe to use.

Reference list:

1. Radder B, Prange-Lasonder G, Kottink A, Melendez-Calderon A, Buurke J, Rietman J. Feasibility of a wearable soft-robotic glove to support impaired hand function in stroke patients. *J Rehabil Med* 2018; 50: 598–606.
2. Radder B, Prange-Lasonder G, Kottink A, Holmberg J, Sletta K, Van Dijk M, Meyer T et al. (2018): The effect of a wearable soft-robotic glove on motor function and functional performance of older adults, *Assistive Technology*, DOI: 10.1080/10400435.2018.1453888
3. Osuagwu B.A. et al. (2019) Clinical Trial of the Soft Extra Muscle Glove to Assess Orthotic and Long-Term Functional Gain Following Chronic Incomplete Tetraplegia: Preliminary Functional Results. In: Masia L., Micera S., Akay M., Pons J. (eds) *Converging Clinical and Engineering Research on Neurorehabilitation III*. ICNR 2018. Pp 385-389. doi.org/10.1007/978-3-030-01845-0_77
4. Nilsson M, Fryxell W. A, Wadell C, von Holst H, Borg J. A Helping Hand – On Innovations for Rehabilitation and Assistive Technology. Grip strengthening glove to improve hand function in patients with neuromuscular disorders. Doctoral Thesis. Stockholm: Royal Institute of Technology; 2013. ISBN 978-91-7501-703-7
5. Hermansson L, Gunnarsson M, Lutterman M. Effect of a grip-strengthening glove on persons with reduced hand function. (2014).
6. Palmcrantz S, Plantin J, Borg J. Factors affecting the usability of an assistive soft robotic glove after stroke or multiple sclerosis. Karolinska Institutet, Department of Clinical Sciences, Danderyd Hospital, Division of Rehabilitation Medicine, Stockholm, Sweden. *Journal of Rehabilitation Medicine* (2020). <https://doi.org/10.2340/16501977-2650>
7. Hashida R, Matsuse H, Totsugi M, Omoto M, Shinozaki N, Tanaka J, Nago T. (2016). Study on the Effects of Motor-Assisted Gloves (SEM™ Glove) on Functional Disorders of the hand. *The Kurume Medical Journal* (2018). DOI:10.2739/kurumemedj.MS652007
8. Radder B, Prange-Lasonder GB, Kottink AIR, Holmberg J, Sletta K, Van Dijk M, et al. The effect of a wearable soft-robotic glove on motor function and functional performance of older adults. *Assist Technol.* 2020;32(1):9–15

Improved physical function using a power enhancing glove in persons with IBM

Objective: To investigate if a power enhancing glove is feasible to use in persons with IBM.

Method: Data were collected during The Myositis Association's (TMA) patient conference in 2023. The study included 40 individuals with IBM self-reported hand weakness.

The participants rated their ability to perform self-selected tasks that were difficult for them to perform with and without Carbonhand. Participants selected three activities experienced as difficult and important. They performed the selected activities rating their perceived limitation on a 5-point scale (0 = "unable to do", 4= "without any difficulty") first without the glove and then upon using the glove (see table 1).

The outcome measures were IBM-Patient Reported Outcome, Upper Extremity Function Scale (IBM-PRO), IBM-Functional Rating Scale (IBM-FRS), Health related quality of life measured by EQ5D VAS and Grip strength measured with Dynamometer.

Results: The three most selected activities were lifting free weights, open previously opened jars, lift a heavy bag from the floor, holding a frying pan and picking a coin from a table. In the open-ended questions, participants documented that the glove would be beneficial for use in everyday tasks, lifting objects, grocery shopping, stabilizing the hand and would increase independence.

All activities were perceived easier to perform with the glove ($p \leq 0.039$) with ratings on perceived limitation reflecting "with little difficulty" (3) to "without difficulty" (4).

| Chosen activity | Without the glove | With the glove |
|--|-------------------|----------------|
| Lift a heavy bag from the floor n=15 | 2 (2-2) | 4 (4-4) |
| Open previously open jars, n=16 | 1 (1-2) | 4 (3-4) |
| Lifting free weights, n=16 | 2 (1-2) | 4 (3.25-4) |
| Lifting and holding a frying pan, n=11 | 1 (1-2) | 3 (3-4) |
| Picking a coin from a table, n=8 | 2 (1.3-3) | 3.5 (2.3-4.0) |

Conclusion: Based on preliminary analysis the glove appears to increase hand function and might improve physical function in persons with IBM who experience impaired hand function. However, persons with severe limitation in combination with reduced function in the arm might not benefit of the glove in daily activities. A prospective intervention study is planned to further investigate the usefulness of the glove.

Malin Regardt, Helene Alexanderson, Stephanie Hunn, Lindsay N Alfano, Roland Mischke, Ingrid de Groot, Anneli Dihkan, Therésia Danielsson, Annika Rydgård, Humza A Chaudhry, Lesley-Ann Saketkoo. A poster was presented at The 5th Global Conference on Myositis (GCOM), Pittsburgh 13-16th of March 2024 by Malin Regardt OT, PhD. at Karolinska Institutet. Results to be published.

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

Objective: To evaluate the direct, assistive effect of grip support from the wearable, soft-robotic glove.

Method: 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.

Result: 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 ($\rho \leq 0.137$, $p \geq 0.288$) since the sensors sewn into the glove did not cover the areas needed to activate the glove when measuring hand grip strength with a hand dynamometer (Jamar).

Further design adaptations have been made with Carbonhand and these areas of the glove are now covered with sensors, improving the usability and functional performance further.

Conclusion: 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.

Radder B, Prange-Lasonder G, Kottink A, Holmberg J, Sletta K, Van Dijk M, Meyer T et al. (2018): The effect of a wearable soft-robotic glove on motor function and functional performance of older adults, Assistive Technology, DOI: 10.1080/10400435.2018.1453888

Clinical Trial of the Soft Extra Muscle Glove to Assess Orthotic and Long-Term Functional Gain Following Chronic Incomplete Tetraplegia: Preliminary Functional Results

Objective: The aim of this study was to evaluate if the glove has an orthotic and/or long-term rehabilitative effect on hand grasp function in individuals with chronic incomplete tetraplegia.

Method: The design of the study is interventional with outcome measures recorded before, during and after using the predecessor of Carbonhand, SEM Glove. The 15 study participants had a Spinal Cord Injury (SCI) - incomplete chronic tetraplegia (C2-C8), age from 18-65 years old. They were advised to use the glove at their own homes during 12 weeks for at least 4 hours a day. They returned for reassessment after Week 6 and Week 12 and were followed up after Week 18. Grip strength and hand function were measured at each assessment session with and without wearing the SEM glove. General hand function was assessed using Toronto Rehabilitation Institute hand function test (TRI-HFT).

Result: Grip strength increased from Initial, 9.9 ± 2.9 Kg (mean \pm std error); Week 6, 14.0 ± 3.0 Kg and Week 12, 14.0 ± 3.2 Kg. A main effect of testing session was found for grip strength, $F(3,21) = 7.97$, $p = 0.005$. The TRI-HFT (instrumented) results suggest that participants experienced a significant improvement in hand function up to Week 12.

Conclusion: Measurements of grip strength did not show a statistically significant change at Week 6 assessment, but TRI-HFT test which measures manipulation of several objects encountered in ADL, revealed a significant improvement in function at Week 6 and Week 12.

Osuagwu B.A. et al. (2019) Clinical Trial of the Soft Extra Muscle Glove to Assess Orthotic and Long-Term Functional Gain Following Chronic Incomplete Tetraplegia: Preliminary Functional Results. In: Masia L., Micera S., Akay M., Pons J. (eds) *Converging Clinical and Engineering Research on Neurorehabilitation III*. ICNR 2018. Pp 385-389. doi.org/10.1007/978-3-030-01845-0_77

Helping Hand – On Innovations for Rehabilitation and Assistive Technology. Grip strengthening glove to improve hand function in patients with neuromuscular disorders

Objective: The aim of the trial is to evaluate how a grip-enhancing glove can improve hand functions in patients with neuromuscular disorders.

Method: A mixed method design was applied for this feasibility trial. Method A total number of 9 study participants was included. The Grippit test for determining the grip strength, the Nine Hole Peg test for determining the fine motor skills and the Sollerman test for determining general hand functions and activity.

Result: The study showed that patients may benefit from the grip-reinforcing glove, but that it varies depending on diagnosis and the patient's disease status in general. A number of patients experienced improvements reported as 7-8 on a scale (0-10), while others did not experience any major improvement at all. Both from the participants and the observer's point of view, the utility of the glove was most obviously illustrated by the performance of the power grip in lifting heavy objects, by the pinch grip in the Nine Hole Peg test and in writing.

The performance in these tasks seemed clearly related to the participants overall evaluation of the glove. Even severely reduced grip strength was compatible with a beneficial effect of the glove in lifting objects.

The two participants with most impaired grip strength reported the best effect.

Conclusion: The study's results demonstrate potential in the use of the glove, with regard to hand function, activity level and user experience. In the study no adverse events or negative side effects that would restrict further trials with the SEM™ Glove (predecessor of Carbonhand) were observed.

Nilsson M, Fryxell W. A, Wadell C, von Holst H, Borg J. A Helping Hand – On Innovations for Rehabilitation and Assistive Technology. Grip strengthening glove to improve hand function in patients with neuromuscular disorders. Doctoral Thesis. Stockholm: Royal Institute of Technology; 2013. ISBN 978-91-7501-703-7

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

Objective: The first aim of this study is to assess the effect of the SEM glove on hand motor function in patients with prior stroke or MS with regard to both users and clinical perspectives. A second aim is to explore individual factors that may impact on the utility of the glove.

Method: A mixed methods design comparing everyday activities before the introduction of the SEM glove with everyday activities after the SEM has been introduced and been available for daily use. Participants with Stroke (n=10) or Multiple Sclerosis (MS) (n=10) were clinically assessed, instructed to use the glove in activities of daily living (ADL) for 6 weeks and to share their experience of using the glove in weekly telephone interviews and one semi-structured interview. Primary outcome: Goal achievement according to the Canadian Occupational Performance Measure (COPM).

Result: The soft robotic glove was used by the participants in a great variety of activities of daily living (ADL). A sustained and strong grip was perceived as the most beneficial effects while using the glove.

Conclusion: The study highlights important aspects to be considered in the development of new soft hand robotics for sustained use in ADL after a CNS lesion.

Palmcrantz S, Plantin J, Borg J. Factors affecting the usability of an assistive soft robotic glove after stroke or multiple sclerosis. Karolinska Institutet, Department of Clinical Sciences, Danderyd Hospital, Division of Rehabilitation Medicine, Stockholm, Sweden. Journal of Rehabilitation Medicine (2020). <https://doi.org/10.2340/16501977-2650>

Effect of a grip-strengthening glove on persons with reduced hand function

Objective: The primary objective is to evaluate if the glove will have an impact on activities in daily life and participation. The secondary objective is to evaluate quality of life with and without usage of the glove.

Method: The trial is a randomized controlled trial (RCT) with cross-over design. Method A total number of 16 participants with a reduced grip-strength due to MS or myopathy has been included. The primary outcome measure is Disability of the arm, shoulder and hand (DASH). The impact on activity and participation will be measured by Individually Prioritized Problem Assessment (IPPA). Quality of life will be measured by SF-36.

Result: No significant differences were observed between the groups. However, significant differences were found during the test period; when using the SEM™ Glove, mean scores on the IPPA (-8.1; $p=0.008$) and QuickDASH (-14.2; $p=0.021$) improved. There was no statistically significant difference on the SF36.

Conclusion: The positive effect on activity in daily life and participation during usage of the glove indicate that people with reduced hand function may be able to live independently to a higher extent, with the glove as an assistive device.

Hermansson L, Gunnarsson M, Lutterman M. Effect of a grip-strengthening glove on persons with reduced hand function. (2014).

Study on the Effects of Motor-Assisted Gloves (SEM™ Glove) on Functional Disorders of the hand

Objective: The purpose of this study was to evaluate the effectiveness of the device on the grip and pinch strength of patients with functional disorders of the fingers.

Method: A non-randomized controlled study. All participants included had an intervention period of two hours. A total number of 30 study participants with impairment of the upper extremity were enrolled. The assistance of the device for the grip and pinch strength of each subject were assessed by the difference between the measured values with and without the Glove. The instrument Action Research Arm Test (ARAT) was used as well as functional movements in ADL.

Result: The study participants, after using the glove, improved their grip strength in 61 of 80 (67.8%) of the ADL activities. The participants experienced an improved of grip strength with the glove. Since the grip strength was measured with Smedley's dynamometer, no increased effect was seen with the glove. Smedley's dynamometer does not activate the glove sensors. Pinch strength (thumb - middle finger) significantly increased (worn-not worn difference (N): mean = -4.1, CI95 (1.6, 6.6). Analysis of factors related to improvement in hand function when wearing the Glove extracted manual muscle tests (MMTs) of the upper extremity 4 or higher.

Conclusion: The participants provided valuable suggestions for improvements to the glove. For example, the palm plate was mentioned as a disturbance moment in grip. The new, improved version of the glove Carbonhand has a new technology that makes it possible to remove the plate. No adverse events were found during the trial.

Hashida R, Matsuse H, Totsugi M, Omoto M, Shinozaki N, Tanaka J, Nago T. (2016). Study on the Effects of Motor-Assisted Gloves (SEM™ Glove) on Functional Disorders of the hand. The Kurume Medical Journal (2018). DOI:10.2739/kurumemedj.MS652007

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

Objective: The primary objective is to evaluate the effect of prolonged use of the glove, on hand and grip function.

Method: This pilot randomized controlled clinical study explored the effect of prolonged use of the assistive 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-week intervention of either assistive therapeutic 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.

Result: 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 Δ = 3) and pinch strength (mean Δ = 0.5) after 4 weeks of glove use ($p \leq 0.039$). Scores on the BBT and JTHFT improved not only after 4 weeks of glove 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.

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

Radder B, Prange-Lasonder GB, Kottink AIR, Holmberg J, Sletta K, Van Dijk M, et al. The effect of a wearable soft-robotic glove on motor function and functional performance of older adults. *Assist Technol.* 2020;32(1):9–15

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

Objective: To perform a feasibility study with the first prototype of Carbonhand developed within the EU-project HandinMind combined assistive support in daily life with performing therapeutic exercises on a computer at home.

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

Result: High scores on usability for this first prototype of the HandinMind system. The participants initially performed functional tasks slower with the HandinMind glove compared with without the glove, but performance improved up to the level of performance without the glove across no more than 3 repetitions.

The study participants learned how to use of the system quickly. User acceptance measured by the System Usability Scale (SUS) and Intrinsic Motivation Inventory (IMI) was scored high.

The study participants also presented suggestions for improvements of the glove.

Conclusion: With further improvements, this system may enable intensive functional hand training for stroke patients without the need for supervision by a therapist.

Radder B, Prange-Lasonder G, Kottink A, Melendez-Calderon A, Buurke J, Rietman J. Feasibility of a wearable soft-robotic glove to support impaired hand function in stroke patients. *J Rehabil Med* 2018; 50: 598–606.