Gloreha (Hand Rehabilitation Glove): summary of clinical results

August 2013

Although Gloreha (Hand Rehabilitation Glove) is a new device, its effectiveness has already been verified thanks to some clinical trials which involved:

- **post-stroke patients in the sub-acute phase** (up to a maximum of 30 days after the event; MAS≤3)[1,2];
- **post-stroke patients in the chronic phase** (at least 3 months after the event; MAS≥1+; MAS≤3) treated with botulinum toxin[3,4,2];
- **post-stroke patients with left neglect or general attention deficit** (cerebral stroke of the right hemisphere; MAS<3)[5,2];

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[1] Vanoglio F., Luisa A., Garofali F., Mora C.; *Evaluation of the effectiveness of Gloreha (Hand Rehabilitation Glove) on hemiplegic patients. Pilot study*; presented at XIII Congress of Italian Society of Neurorehabilitation, 18-20 April 2013, Bari (Italy).

[2] Parrinello I., Faletti S., Santus G.; *Use of a continuous passive motion device for hand rehabilitation: clinical trial on neurological patients*; submitted to 41° National Congress of Italian Society of Medicine and Physical Rehabilitation, 14-16 October 2013, Rome (Italy).

[3] Stagno D., Baricich A., Invernizzi M., Grana E., Cisari C.; *Use of a robotic device in the rehabilitation treatment after botulinum toxin (type A) injection on spastic upper limb after stroke. Pilot study*; presented at XIII Congress of Italian Society of Neurorehabilitation, 18-20 April 2013, Bari (Italy).

[4] Molteni F., Mulè C., Caimmi M., Taveggia G., Missud S., Bianchi P.; *Use of continuous passive motion device for the hand on post-stroke patients: pilot study*. Presented at 39° National Congress of Italian Society of Medicine and Physical Rehabilitation, 16-19 October 2011, Reggio Calabria (Italy).

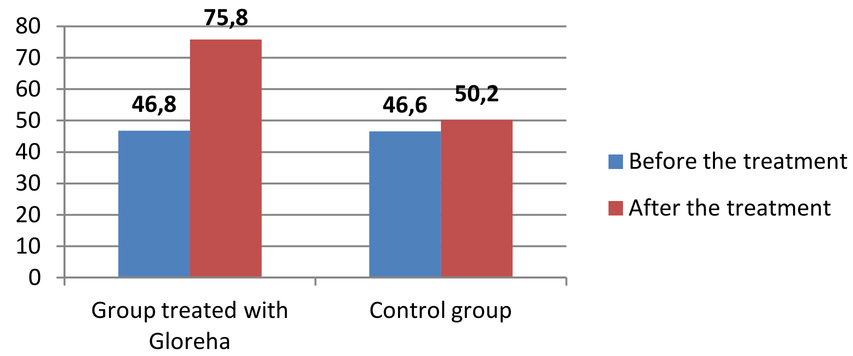
[5] Varalta V., Smania N., Geroin C., Fonte C., Gandolfi M., Picelli A., Munari D., Ianes P., Montemezzi G., La Marchina E.; *Effects of passive rehabilitation of the upper limb with robotic device Gloreha on visual-spatial and attentive exploration capacities of patients with stroke issues*; presented at Congress “Riabilitazione: una scienza in cammino”, 18-20 March 2013, La Villa (Bolzano - Italy) and XIII Congress of Italian Society of Neurorehabilitation, 18-20 April 2013, Bari (Italy).

- **other neurological patients**: patients affected by multi-neurite, traumatic brain injury, meningioma of the spinal cord[2].

Here are the main conclusions of the clinical trials on Gloreha:

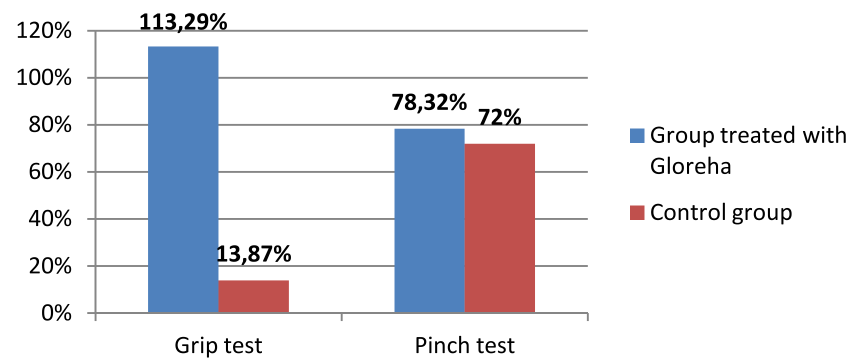
- Gloreha can **improve functional independence** of post-stroke patients in the sub-acute phase.

Vanoglio et al., 2013. The group treated with Gloreha showed a marked average increase evaluated by FIM (Functional Independence Measure) Scale, against a substantial stability in the control group. The treatment consisted of 30 sessions; the duration of each session was 40 minutes. The patients included in the control group were treated by therapists for the same time as the group treated with Gloreha.



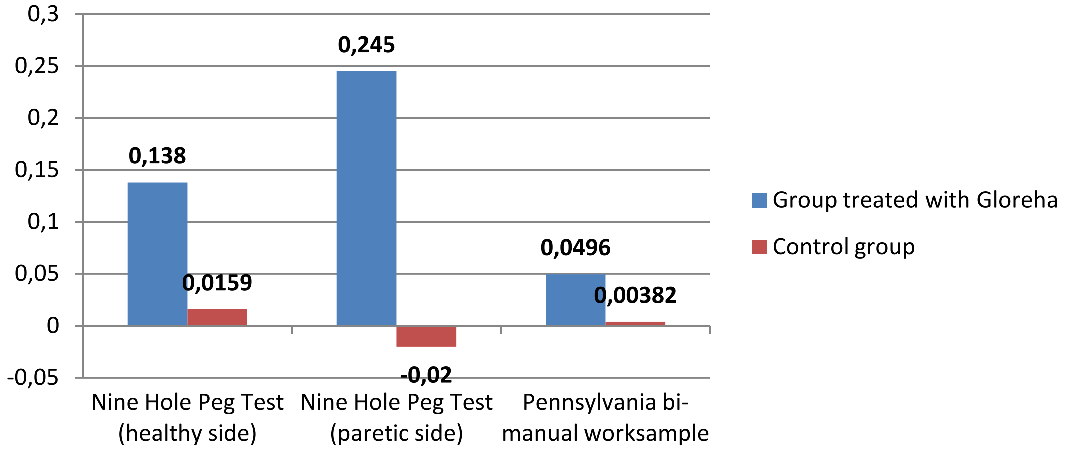
- Gloreha can **increase grip and pinch strength** on the paretic side of neurological patients in the sub-acute phase.

Vanoglio et al., 2013. The group treated with Gloreha developed a higher increment of the strength at the Grip and the Pinch test in comparison with the control group. The treatment consisted of 30 sessions; the duration of each session was 40 minutes. The patients included in the control group were treated by therapists for the same time as the group treated with Gloreha.

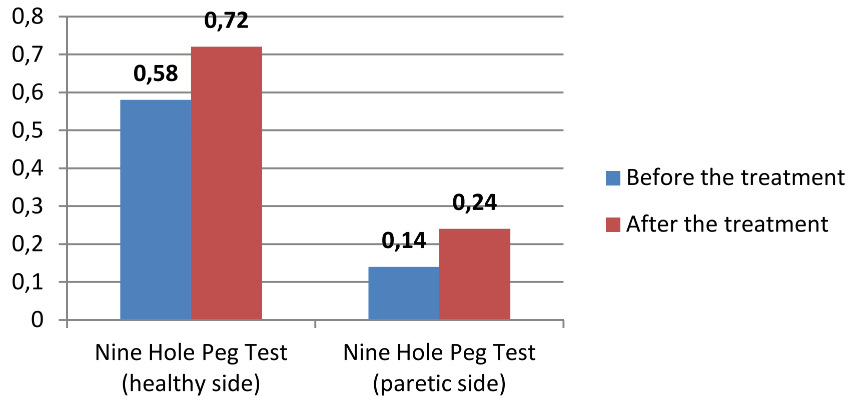


- Gloreha can **improve unimanual and bimanual coordination and dexterity** of neurological patients, especially in the sub-acute phase.

Vanoglio et al., 2013. The evaluation of unimanual (paretic and healthy limb) and bimanual coordination and dexterity shows averages of delta t1-t0 (t1: after the treatment; t0: before the treatment) in the group treated with Gloreha higher than in the control group. The patients were post-stroke in the sub-acute phase. The treatment consisted of 30 sessions; the duration of each session was 40 minutes. The patients included in the control group were treated by therapists for the same time as the group treated with Gloreha.



Varalta et al., 2013. At the pre-treatment evaluation, after 4 months since hemorrhagic stroke, the patient F.M. had high difficulty in using the left hand to perform exercises that require good capacities of manual dexterity. After the treatment with Gloreha, the patient showed a small improvement in both tests (Purdue PegBoard Test and Nine Hole Peg Test). The treatment was made up of 10 rehabilitation sessions of 25 minutes.

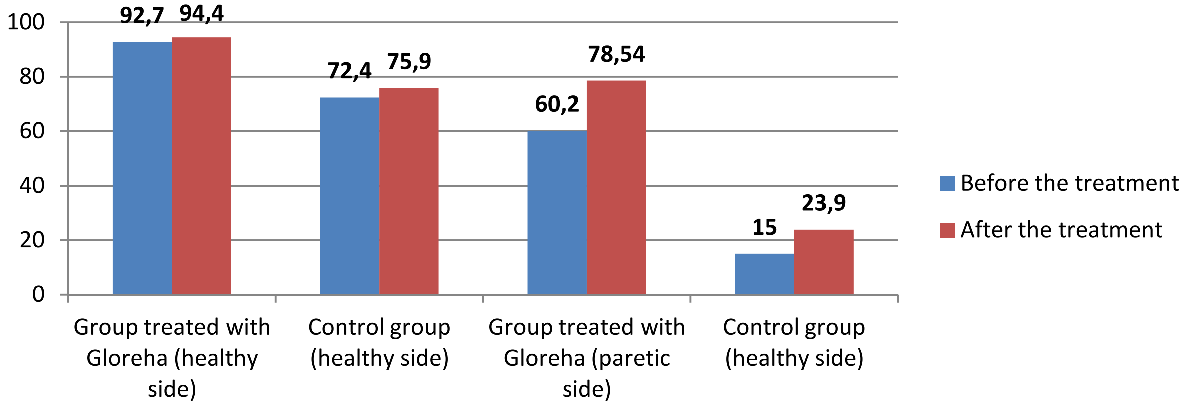


Parrinello et al., 2013. After the treatment with Gloreha, 4 out of 12 neurological patients showed an improvement of manual ability and dexterity, evaluated by Nine Hole Peg Test and Abilhand. The treatment with Gloreha consisted of 10 daily sessions (30 minutes per session); the patients started the treatment at least 3 weeks since the event.

- Gloreha can **increase the motricity (active movement)** of neurological patients.

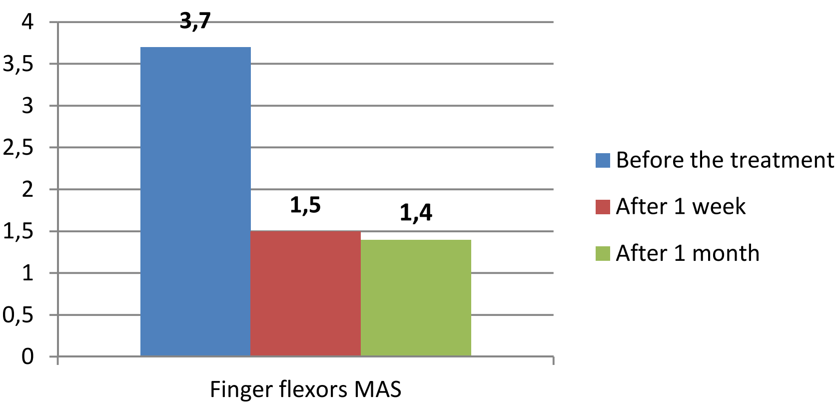
Parrinello et al., 2013. After the treatment with Gloreha, 5 out of 12 neurological patients showed an improvement of hand motricity, evaluated by Motricity Index and Fugl Meyer Assessment. The treatment with Gloreha consisted of 10 daily sessions (30 minutes per session); the patients started the treatment at least 3 weeks since the event.

Vanoglio et al., 2013. The patients treated with Gloreha increased their motricity performance (FIM) both on the paretic side and the healthy one more than the patients included in the control group. The treatment consisted of 30 sessions; the duration of each session was 40 minutes. The control group was composed of patients treated by the therapist for the same time as the group treated with Gloreha.



- Gloreha can **decrease or prevent the hypertonia** of neurological patients.

Stagno et al., 2013. 8 post-stroke patients in the chronic phase showed a decrease in spasticity after 1 week and 1 month since the injection of BoNT-A (botulinum toxin type A) and the start of treatment with Gloreha.



Varalta et al., 2013. The post-stroke patient B.M. in the chronic phase (35 months after the event) showed a lower level of spasticity of the fingers after the treatment with Gloreha (from MAS=2 to MAS=1). The treatment consisted of 10 sessions (25 minutes per session).

Parrinello et al., 2013. 4 neurological patients with spasticity and plegia didn't show any increase in hypertonicity after the treatment with Gloreha. The treatment with Gloreha consisted of 10 daily sessions (30 minutes per session); the patients started the treatment at least 3 weeks since the event.

Vanoglio et al., 2013. The tone of patients treated with Gloreha didn't evolve into spasticity or, in a few cases, just a slight increase of spasticity was recorded. The clinical trial involved post-stroke patients in the sub-acute phase: they were treated 40 minutes for 30 days.

- Gloreha can **reduce the oedema** of neurological patients.

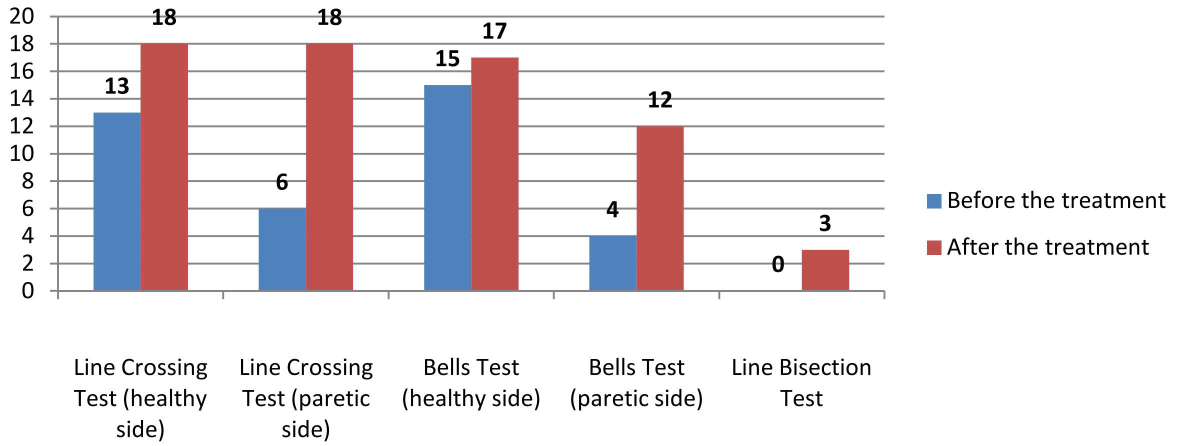
Parrinello et al., 2013. After the treatment with Gloreha two neurological patients showed a reduction of oedema. The treatment with Gloreha consisted of 10 daily sessions (30 minutes per session); the patients started the treatment at least 3 weeks since the event.

Vanoglio et al., 2013. All the patients, treated with Gloreha or by a therapist, decreased the level of oedema. The treatment consisted of 30 sessions; the duration of each session was 40 minutes.

Molteni at al., 2011. After the treatment with the prototype of Gloreha 5 out of 7 post-stroke patients with oedema showed a reduction of their symptoms.

- Gloreha can **improve the capacities of visual-spatial exploration** in post-stroke patients with neglect.

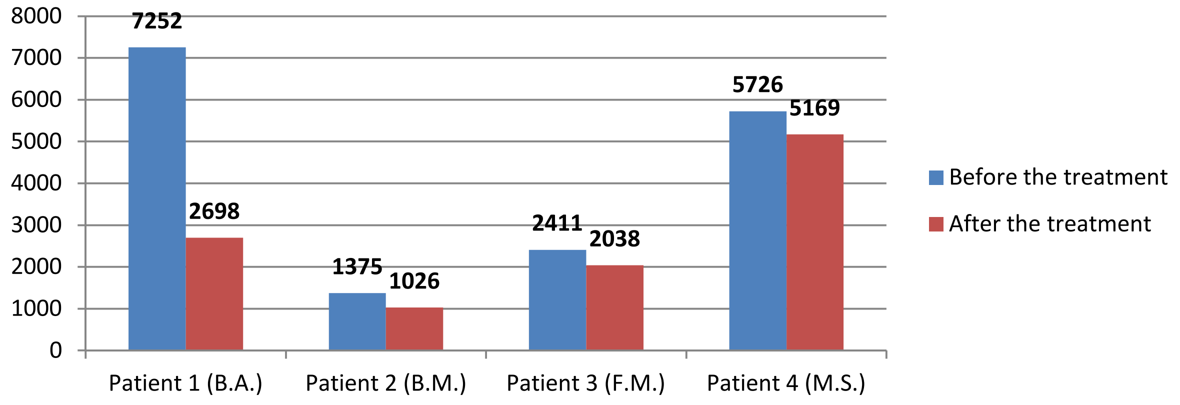
Varalta et al., 2013. After the treatment with Gloreha, the patient F.M. showed an improvement in the Line Crossing Test, Bells Test, Line Bisection Test.



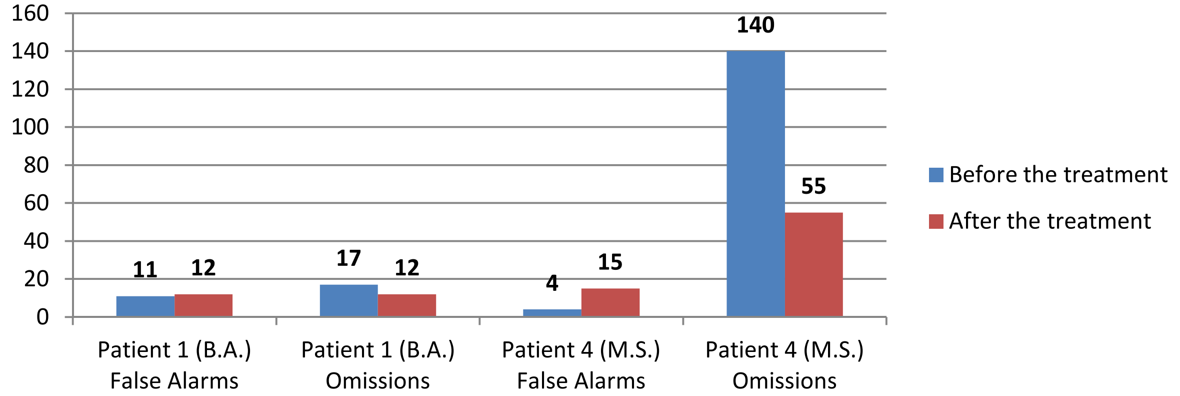
Parrinello et al., 2013. After the treatment with Gloreha, the patients with neglect showed a partial improvement in their capacity of visual-spatial exploration. The treatment with Gloreha consisted of 10 daily sessions (30 minutes per session); the patients started the treatment at least 3 weeks since the event.

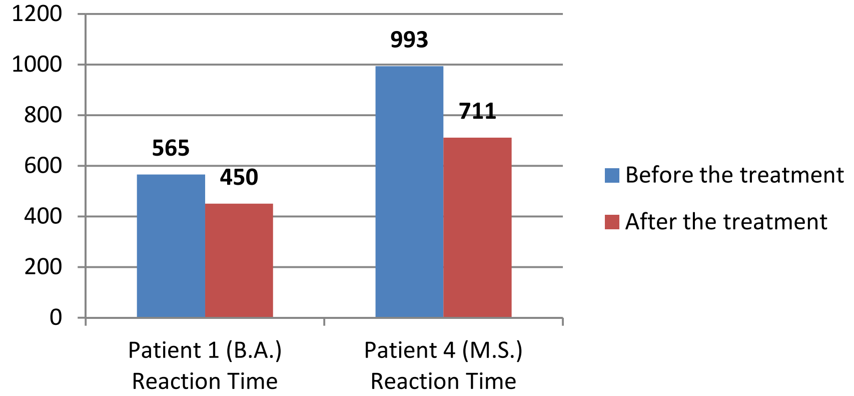
- Gloreha can **increase the speed of noticing visual stimuli in the left hemifield and reduce the reaction time during sustained attention tests** in post-stroke patients with neglect or general attention deficit.

Varalta et al., 2013. All the patients involved in the clinical test showed a decrease of the reaction time in the stimuli test (Saccadic Training).



Two patients out of four showed an improvement in SART (Sustained Attention to Response Task) Test, both in the reaction time and the score. The treatment with Gloreha was composed of 10 sessions (25 minutes per session).

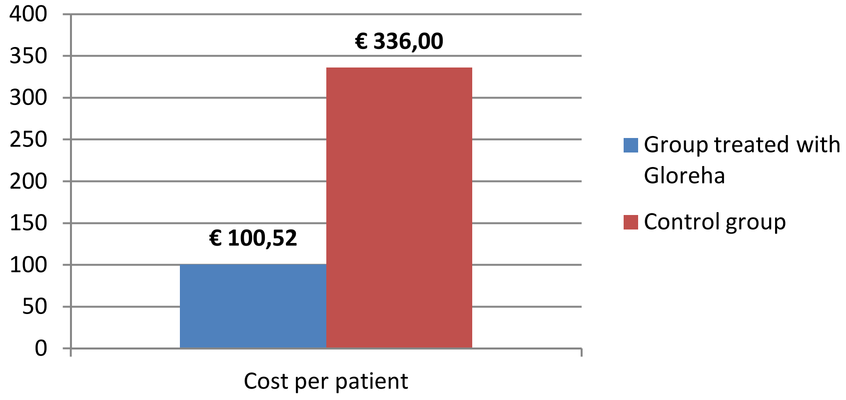




- Gloreha is **well tolerated by patients**: all the tests show a high compliance level.

- Gloreha **can increase the time of treatment, at a limited cost**: Gloreha can bring a significant advantage in economic terms and enable the reallocation of human resources (i.e. therapists).

Vanoglio et al., 2013. The cost of traditional treatment, performed by therapist, was higher than the cost of Gloreha treatment (the time necessary for the therapist to use the device was considered; the cost of the device was not considered). The treatment was composed of 30 rehabilitation sessions (40 minutes per session).



Vanoglio et al., 2013 concludes that **Gloreha treatment is not inferior to the standard treatment**. Actually the group treated with Gloreha showed in general more significant clinical improvements in comparison with the control group, but further trials are needed to have more solid data.

New clinical trials are in progress to substantiate and expand the results mentioned above, using a bigger sample size and also testing Gloreha on patients with:

- multiple sclerosis;
- brain tumour;
- spinal cord injury;
- traumatic brain injury.

Gloreha was developed in accordance with the conclusions of the most recent scientific literature:

- **a rehabilitation treatment after stroke has to be intensive, repetitive, functional, task-oriented, specific, customizable**[6,7];

[6] Kollen BJ, Lindeman E. *Understanding the pattern of functional recovery after stroke: Facts and theories.* Restorative Neurology and Neuroscience 2004;22:281–299

[7] Van Peppen RP, Kwakkel G, Wood-Dauphinee S, Hendriks HJ, Van der Wees PJ, Dekker J. *The impact of physical therapy on functional outcomes after stroke: what's the evidence?* Clin Rehabil 2004;18:833–62.

- biomechatronic devices, robotic systems and computer interfaces can be useful for facilitating functional recovery and reducing motor impairment of upper limb[8,9,10,11];
- a repetitive training program based on flexion and extension of the fingers can improve the function of plegic hand after stroke: it can reduce the oedema, maintain or increase the range of motion and muscle lengths, prevent spasticity[12,13,14,15,16];
- passive stretch can prevent connective tissue accumulation in muscle[17] and help motor learning[18,19,20];
- the exercises with devices works on plastic processes in the central nervous system thanks to neuromotor, visual and audio feedback: **multi-sensory action-observation systems enable patients to re-learn impaired motor functions through the activation of internal action-related representations**[21,22];

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[8] Masiero S, Celia A, Rosati G, Armeni M. *Robotic-assisted rehabilitation of the upper limb after acute stroke*. Arch Phys Med Rehabil 2007;88:142-9.

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[10] Hesse S, Schulte-Tigges G, Konrad M, Bardeleben A, Werner C. *Robot-assisted arm trainer for the passive and active practice of bilateral forearm and wrist movement in hemiparetic subjects*. Arch Phys Med Rehab 2003;84:915-20.

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[14] Giudice M.L. *Effects of Continuos Passive Motion and elevation on hand edema*. The American Journal of Occupational Theraphy, 1990; Oct; 44(10):914-21

[15] Dirette D., Hinojosa J. *Effects of continuos passive motion on the edematous hands of two persons with flaccid hemiplegia*. The American Journal of Occupational Theraphy, 1994; May; 48(5):403-409.

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[17] Williams P E, Catanese T, Lucey E G, Goldspink G: *The importance of stretch and contractile activity in the prevention of connective tissue accunulation in muscle*. J Anat 1988; 158: 109-114.

[18] Seitz et al. *A common frame work for perceptual learning*. Curr. Neurobiol 2007, 17:1-6.

[19] Winter et al. *Hands-on theraphy intervention for upper limb motor dysfunction following stroke*. Cochrane Database Syst Rev 2011 Jun 15; 6:CD006609.

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[21] Lee MM, Cho HY, Song CH. *The mirror therapy program enhances upper-limb motor recovery and motor function in acute stroke patients*. Am J Phys Med Rehabil 2012;91(8):689-96

- motor imagery, passive movement, movement observation, hand exercises in VR (Virtual Reality) can activate sensorimotor areas of the brain[23,24,25,26,27].

Gloreha can be used in accordance with the most advanced rehabilitation treatments: Motor Imagery, Mirror Therapy, Constraint-induced Therapy, Bimanual Training.

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[22] Sale P, Franceschini M. *Action observation and mirror neuron network: a tool for motor stroke rehabilitation*. Eur J Phys Rehabil Med. 2012 Jun;48(2):313-8. Epub 2012 Apr 20.

[23] Szameitat AJ, Shen S, Conforto A, Sterr A. *Cortical activation during executed, imagined, observed, and passive wrist movements in healthy volunteers and stroke patients*. Neuroimage. 2012 Aug 1;62(1):266-80. doi: 10.1016/j.neuroimage.2012.05.009. Epub 2012 May 11

[24] August K, Lewis JA, Chandar G, Merians A, Biswal B, Adamovich S. *FMRI analysis of neural mechanisms underlying rehabilitation in virtual reality: activating secondary motor areas.* Conf Proc IEEE Eng Med Biol Soc. 2006;1:3692-5.

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