

# Neuroprosthesis for grasp restoration in individuals with high spinal cord injury – lost in translation !?

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## Introduction

In Europe 330.000 people are suffering from a spinal cord injury (SCI), of which 40-50% are tetraplegic. The bilateral loss of the grasp function severely limits the ability to live independently and retain employment. Tetraplegic patients are often young of age due to sports accidents. Therefore, any improvement of a lost or limited hand function is highly desirable not only for the patients' quality of life (QoL) but also for economic reasons.

If surgical options for grasp restoration like tendon transfers are missing due to a low number of strong muscles under voluntary control, Functional Electrical Stimulation (FES) is the only method for compensation of grasping deficits. Although the high impact on the users' QoL of the invasive Freehand grasp neuroprosthesis (NP) was proven, it did not succeed commercially. Only scarce information on QoL is available for non-invasive systems mainly used for research purposes. In the framework of the foundation of a dedicated upper extremity outpatient clinic we aim at the assessment of usability, satisfaction and impact on QoL of a non-invasive grasp NP and to identify barriers for successful translation from research results into clinical routine.

## Methods

In our outpatient clinic individuals with chronic cervical SCI with a missing or weak grasp function, but voluntary shoulder movements and elbow flexion on at least one side, are routinely offered an individually adapted, custom-made grasp NP (Figure 1).

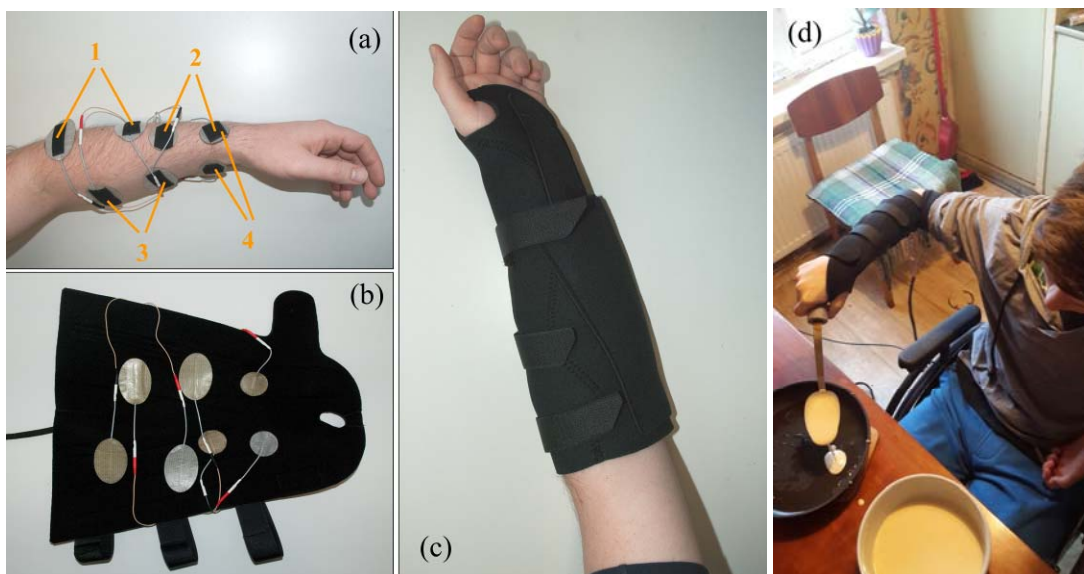


Figure 1 Subfigure a: Electrode positions together with the channel numbers (1 – ext. dig. comm., 2 – ext. poll. long., 3 – flex. dig. sup. und flex. poll. long., 4 – opp. poll. via N. medianus) of the stimulator. Due to space limitations, channel 2 and 4 share a common electrode. Subfigure b: Electrodes fixed with a velcro strap in a personalized forearm sleeve for easy and quick electrode mounting. Subfigure c: Mounted forearm sleeve. The sleeve is manufactured individually for each user. Subfigure d: grasp NP user performing activities of daily living.

For stimulation the Motionstim 8 from Medel (Hamburg, Germany) with a proprietary firmware is used. Pulse currents are set individually, pulse frequency is fixed at 20 Hz for a sufficiently powerful tetanic contraction without causing too

much fatigue. The grasp can be controlled by sensors recording movements of the contralateral shoulder or wrist extension of the stimulated hand.

After 4-12 weeks of FES-muscle training, end users are supplied with the NP. After another 8 and 16 weeks assessments are performed according to the International Classification of Function (ICF, WHO) including the International Standards for Neurological Classification of SCI (ISNCSCI), Medical Research Council Scale (MRC), passive and active range of motion (ROM), Modified Ashworth Scale (MAS), Beck-Depression-Inventar (BDI-II), FES-force, Grasp-and-Release-Test (GRT), Van-Lieshout-Test Short Version (VLT-SV), Quebec User Evaluation of Satisfaction with assistive Technology (QUEST), Assistive Technology Device Predisposition Assessment (ATD-PA, Section D).

## Results

So far 5 potential end user were screened (age 18-52 y; Ø time after injury: 36 m [9-63]; neurological level: 3x C4, 1x C5, 1x C3; 4x SCI due to trauma, 1x surgery complication), with 2 exclusions due to severe denervation and restricted shoulder function. FES-training was performed from 7 to 11 weeks. 3 users are using the NP, 2 of them participated in the 8-week assessment. For ISNCSCI, ROM, FES-force, MAS, BDI-II no changes were detected.

During the 8 weeks improvements were detected in the GRT (successful attempts  $52.3 \pm 37.9$  w/o vs.  $130.0 \pm 42.9$  with NP), as well as the VLT-SV ( $5.3/50 \pm 2.3$  w/o vs.  $19.0/50 \pm 3.06$  with NP). The QUEST shows a good overall satisfaction. Both users rate the applicability (+0.67/+1.00 [Scale from -3 to +3]), self-confidence (+1.00/+0.75) and subjective competence (+1.17/+0.47) positively. The NP was rated positive in regard to its intended purpose (ADT-PA: 45/53 of 60 points).

## Conclusion

For successful use of a grasp NP several prerequisites must be fulfilled e.g., a low degree of denervation, unrestricted ROM and a high motivation of end users, caregivers, industry partners, and health care providers. A “one NP fits all users”-concept does not exist and a high degree of individualization and adaption is necessary to achieve a satisfactory functional outcome. Nevertheless, a substantial functional improvement can be achieved with non-invasive NPs. Studies with more end users are needed to proof the positive impact on QoL. Future technical enhancements will hopefully enlarge the number of potential NP users, thereby ensuring a commercial success.