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Outcomes of the NuroSleeve and Occupational Therapy on Upper Limb Function of an Individual with Chronic Hemiparesis Following a Stroke: A Case Report

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Outcomes of the NuroSleeve and Occupational Therapy on Upper Limb Function of an Individual with Chronic Hemiparesis Following a Stroke: A Case Report

Abstract

Background: Upper limb neuromuscular impairments can adversely impact function. This case report investigates the process and outcomes of occupational therapy (OT) for training in the use of the NuroSleeve, a novel research-grade exoskeletal powered orthosis, with a participant with chronic right hemiparesis following a stroke.

Method: The participant engaged in 24 OT sessions using the NuroSleeve over 10 weeks. Therapeutic interventions included neuromuscular reeducation, device management, and engagement in occupation-based activities with training to use the NuroSleeve. The Canadian Occupational Performance Measure (COPM), ABILHAND, Patient Reported Outcomes Measurement Information System Upper Extremity Short Form 7a (PROMIS UE SF), Action Research Arm Test (ARAT), and Manual Muscle Testing (MMT) were administered before and after the 24 sessions.

Results: With the NuroSleeve, there were clinically important increases in COPM performance and satisfaction for 6/8 and 7/8 goals, respectively; ABILHAND showed a clinically important increase of 4.959 logits; and there was an 11-point increase on the ARAT, indicating a clinically important difference. T-score on the PROMIS UE SF was 33.7 (*SD* = 2) compared to 23 (*SD* = 2.8) without the device. MMT remain unchanged.

Conclusion: The data suggest that the NuroSleeve was the primary source of increased function and that incorporating OT with the NuroSleeve has benefits.

Keywords

artificial limbs, exoskeletons, rehabilitation, robotics

Cover Page Footnote

The study is part of a larger repeated measures single-group cohort study (https://clinicaltrials.gov/ct2/show/NCT04798378) and was funded by the Farber Institute at Thomas Jefferson University and the Fitzgerald Translational Neuroscience Fund. The authors thank Alessandro Napoli, Mikael Avery, Phyo Thuta Aung, Namrata Grampurohit, Erica Jones, and Joe Kardine for their contributions to this study. This project was completed in partial fulfillment for the Doctoral Degree in Occupational Therapy at Thomas Jefferson University, Philadelphia, Pennsylvania (JPA, 2nd author). MDS (3rd author) is a co-founder of Nuromo, LLC, a startup company formed to commercialize the NuroSleeve; he is also a co-inventor on a patent application on the NuroSleeve filed by Thomas Jefferson University.

Credentials Display

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Neurological conditions, such as stroke, cerebral palsy, and spinal cord injury, can lead to chronic impairments of the upper limb (UL). These impairments can include paresis, spasticity, and sensory loss, among others, which may adversely affect function and limit engagement in activities of daily living (Raghavan, 2015; Stewart & Cramer, 2013). Activity-based therapy, task-specific training, neuromuscular rehabilitation, static and dynamic bracing, and robotic exoskeletons are treatment methods used to address neuromuscular UL impairments (Bell et al., 2021; Chen et al., 2022; Peters et al., 2017; Rong et al., 2017; Thielman et al., 2004; Veltman et al., 2015). Although many of these methods are used in rehabilitation, studies show varying degrees of benefit (Bell et al., 2021; Chen et al., 2022; Coscia et al., 2019; Grampurohit et al., 2021; Hatem et al., 2016; Mateo et al., 2020; Mehrholz et al., 2020; Rozevink et al., 2021). Particular challenges are encountered when using robotic-assisted technology, including time, weight, ease of use and control, versatility, and comfort (Agarwal & Deshpande, 2019).

This case report details one individual who participated in a larger repeated measures single-group cohort study (https://clinicaltrials.gov/ct2/show/NCT04798378) on the NuroSleeve (a novel, custom-designed powered orthosis), with a focus on the occupational therapy (OT) process.

Method

Participant

The Thomas Jefferson University Institutional Review Board approved this study. The participant provided informed consent to participate in this trial. He was a 38-year-old White male, 1.5 years post-hemorrhagic stroke at the basal ganglia presenting with chronic right-sided spastic hemiparesis, who was right-hand dominant pre-stroke. Following his stroke, he participated in 8 weeks of inpatient rehabilitation with physical therapy, OT, and speech-language pathology, followed by 3 weeks of 3x/week day-program rehabilitation services, and then several months of outpatient therapies by the same disciplines. He received regular botulinum toxin injections to his right upper and lower limbs every 90 days to reduce spasticity. At the start of this study, he had negligible (0–1/5) strength throughout his right UL on manual muscle testing (MMT). In addition, he was unable to use his right UL functionally, as any attempt to volitionally move his arm resulted in a flexor synergy. As a consequence, he reported becoming accustomed to completing self-care, leisure, and work activities with his pre-stroke non-dominant left UL or with assistance from others.

NuroSleeve

The NuroSleeve's specifications and components have been previously described (Khantan et al., 2023). In this case study, two prototypes of the NuroSleeve were developed. Their main components included the orthosis, main control unit, clinical software for configuration (managed by the study team), and rechargeable battery (Khantan et al., 2023). The first device was a prefabricated, semi-customizable, stainless-steel wrist-driven flexor hinge orthosis (Jaeco Orthopedics, Hot Springs, Arizona), to which a customized motor and microcontroller were added. The second device was a custom-made 3D-printed, powered orthosis developed by the study team and further adapted throughout the intervention period based on feedback from the occupational therapist and participant. Using specialized software, an inertial measurement unit (IMU), placed on the participant's left foot and activated by ankle dorsiflexion, was programmed to trigger the opening and closing of the hand for both orthoses versions. As shown in Figures 1 and 2, the 3D-printed orthosis involved the participant's forearm, wrist, fingers, and thumb, allowing for a gross grasp and modified lateral grasp.

Figure 1
NuroSleeve – Gross Grasp

Note. 3-D printed NuroSleeve performing a gross grasp to carry a basket to simulate shopping and laundry tasks.

Figure 2
NuroSleeve – Modified Lateral Grasp

Note. 3-D printed NuroSleeve performing modified lateral grasp to assist with stabilizing a bowl for feeding and cooking tasks.

OT

Twenty-four 45 to 60-min OT sessions were provided over 10-weeks (average three per week, range per week = 1–3), with two rescheduled sessions. Three theoretical perspectives guided OT with a focus on introducing and employing adaptations that aided function (rehabilitative frame of reference; Gillen, 2014), implementing neuromuscular rehabilitation strategies that targeted UL impairments (neurodevelopmental treatment model; e.g., strength, range of motion [ROM]; Barthel, 2010), and ensuring interventions were client-centered and occupation-based (occupational adaptation model; Kitchens, 2020). Therapeutic activities fell into six broad categories (see Table 1), with the majority of the sessions and time spent on gross motor UL training (e.g., donning jacket) and fine motor UL training (e.g., opening containers).

In general, OT sessions followed this sequence: preparatory activities, device management and education, occupation-based interventions with the NuroSleeve, device and skin management, discussion and planning. Preparatory activities included ROM and weight-bearing activities in standing with support at the proximal and distal right UL (Lee et al., 2013; Pollock et al., 2014). These activities targeted motor control of the impaired right UL, such as reducing spasticity, before engaging in occupation-based interventions. Device management included identifying and addressing various issues related to fit, function, and safety when using the NuroSleeve. Device education was crucial for training the participant and his care partner on proper donning and doffing and facilitated safe and independent use outside of

therapy, which occurred after Session 6. The primary focus of therapy sessions was on the training and use of the NuroSleeve to participate in occupation-based interventions (e.g., meal preparation, childcare tasks).

Table 1

Categories of OT Intervention and Examples of Therapeutic Activities Used in OT Sessions

Guiding Theoretical Perspective	Categories of OT-based Intervention	Example of Therapeutic Activities[a]	Percent of sessions including intervention
RFR; OAM	Seated control activities/balance	Kneeling to use a dustpan; reaching to adjust IMU sensor and tie shoelaces while seated	4%
NDT	Standing control activities/balance	Standing with weight-shifting when using the IMU sensor; dynamic reaching; donning/doffing a backpack	30%
RFR; OAM	Intervention activities while walking	Shopping/laundry tasks of carrying a basket and placing items in it; functional mobility using a backpack	48%
RFR; OAM	Gross motor UL training	Donning/doffing jacket[b]; assembling a plastic frame with bilateral ULs, with right UL as a stabilizer	74%
RFR; OAM	Fine motor UL training	Opening packaging/zipper bags; fastener management; changing diapers; cutting paper; stuffing envelopes	83%
NDT	Strengthening interventions	NMES for strengthening of triceps; weight-bearing through right UL[b] while reaching with left UL as though taking items from a cupboard or shelf.	57%

Note. IMU = inertial measurement unit; NDT = neuro-developmental treatment model; NMES = neuromuscular electrical stimulation; OAM = occupational adaptation model; OT = occupational therapy; RFR = rehabilitative frame of reference; UL = upper limb.

[a] Appreciate the intentional emphasis on occupation-based activities.

[b] The NuroSleeve was not used during these activities.

Baseline and Follow-up Data Collection

A battery of standardized assessments was administered at baseline and follow-up by a trained, licensed occupational therapist not involved in the intervention. With the exception of MMT, which was performed without the NuroSleeve, all follow-up assessments were administered with and without the NuroSleeve.

Canadian Occupational Performance Measure

The Canadian Occupational Performance Measure (COPM; Law, 2014) is a patient-reported outcome assessment that uses a semi-structured interview to identify meaningful goals for the client. Goals were selected based on the level of importance as rated by the participant, using a 10-point scale from 1 (*not important at all*) to 10 (*extremely important*; Law, 2014). For each goal, the participant rated his ability to perform the goal on a scale between 1 (*unable to perform*) and 10 (*performs extremely well*), and satisfaction with performance from 1 (*not satisfied at all*) to 10 (*extremely satisfied*; Law, 2014).

Patient-Reported Outcomes Measurement Information System Upper Extremity Short Form

The Patient-Reported Outcomes Measurement Information System Upper Extremity Short Form (PROMIS UE SF 7a) is comprised of seven questions that asked the participant to rate his ability to perform tasks using a 5-point scale from 1 (*unable to do*) to 5 (*with no difficulty*) (Hung et al., 2017).

ABILHAND

The ABILHAND Manual Ability Measure is a Rasch-based outcome assessment that evaluates the participant's self-reported ability to manually complete 23 everyday bimanual tasks using a 3-point scale: 0 (*impossible*), 1 (*difficult*), and 2 (*easy*) (Penta et al., 2001).

Action Research Arm Test

The Action Research Arm Test (ARAT; Yozbatiran et al., 2008) is a performance-based outcome assessment of UL motor control. The ARAT consists of 19 items the participant performs and is rated on

a 4-point scale ranging from 0 (*no movement possible*) to 3 (*performs with normal movement*). These items are categorized into four subscales: grasp, grip, pinch, and gross movement (Yozbatiran et al., 2008).

MMT

Muscle strength was evaluated using the MMT as described by Kendall and McCreary (1983). Strength was scored on a 5-point scale where 0 = *no muscle activation* and 5 = *normal*, against-gravity strength.

Data Analysis

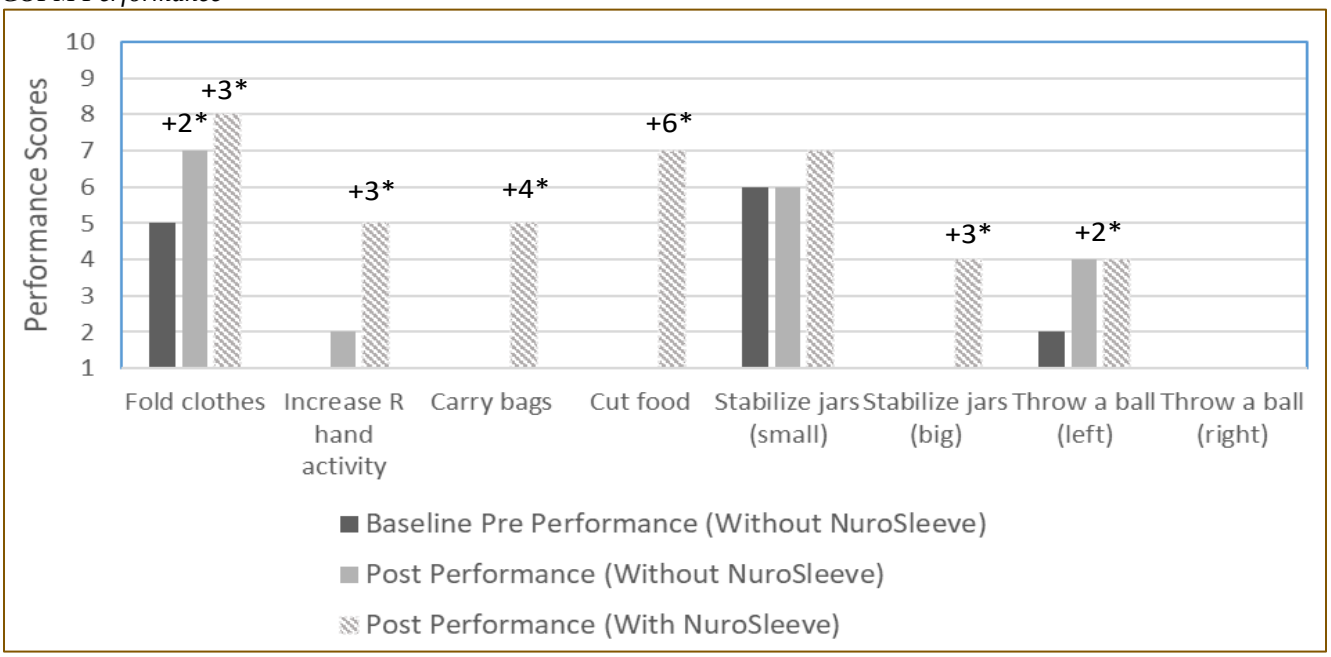
Data were entered into a study-specific database using Excel. Changed scores between baseline and follow-up scores were calculated for MMT, ARAT, and COPM. A change of 5.7 points on the ARAT is considered clinically important for the chronic stroke population (van der Lee et al., 2001). A 2-point change in COPM indicates clinically meaningful change (Law, 2014). PROMIS UE SF raw scores were totaled and converted onto the T-Metric, with a mean of 50 and standard deviation (*SD*) of 10, using an online scoring system (https://www.assessmentcenter.net/ac_scoringservice). Raw ABILHAND scores were converted into logits using an online Rasch-based analysis tool (http://rssandbox.iescagilly.be/abilhand-rasch-analysis-chronic-stroke.html). A change of greater than 0.35 logits on the ABILHAND is clinically important for individuals with subacute to chronic stroke (Wang et al., 2011).

Results

Through the COPM, the participant identified eight goals and rated them of high importance (8–10/10). Baseline performance (see Figure 3) and satisfaction (see Figure 4) scores were low. At follow-up with the NuroSleeve, performance and satisfaction improved in all but one goal. At follow-up without the NuroSleeve, both performance and satisfaction improved in 3/8 goals.

Figure 3

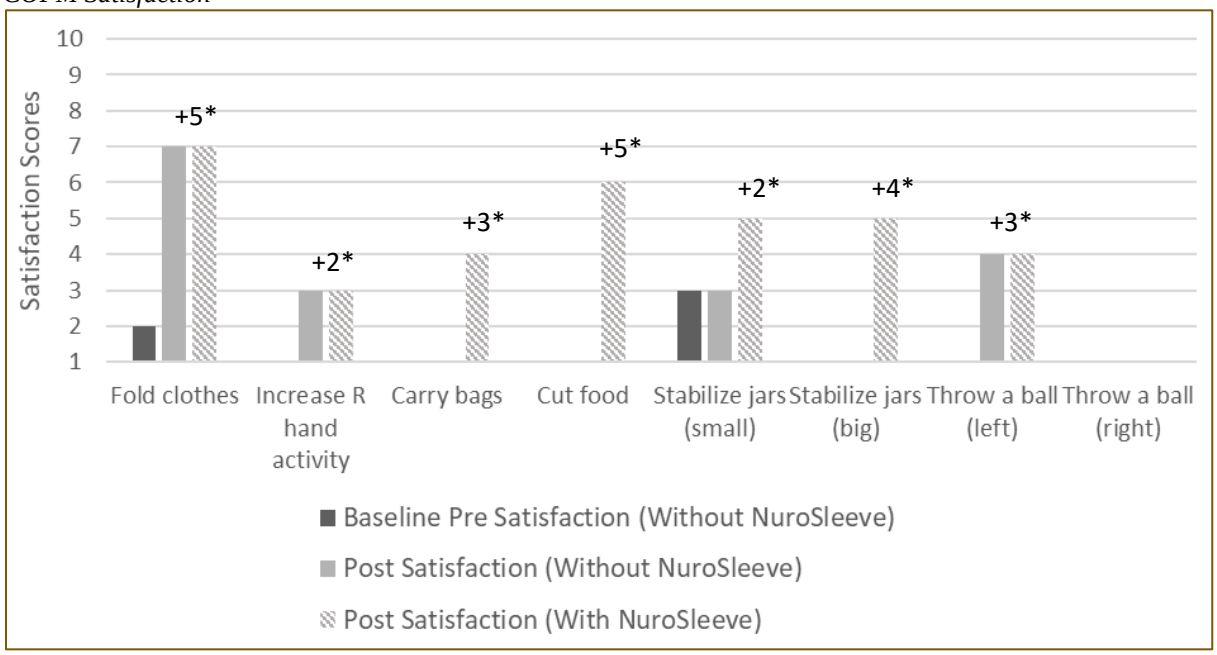
COPM Performance



Note. Performance scores at baseline and follow-up with and without the NuroSleeve. Results showing an (*) indicate a clinically meaningful change, along with the number of points improved from baseline performance scores.
COPM = Canadian Occupational Performance Measure; R = right.

Figure 4

COPM Satisfaction



Note. Satisfaction scores at baseline and follow-up with and without the NuroSleeve. Results showing an (*) indicate a clinically meaningful change, along with the number of points improved from baseline satisfaction scores.
COPM = Canadian Occupational Performance Measure; R = right.

Table 2 provides baseline and follow-up results for the ARAT, ABILHAND, and PROMIS UE SF. At baseline and follow-up without NuroSleeve, only three of the 19 ARAT items were completed or partially completed, yielding a total score of 4. There was a clinically important difference in the ARAT at follow-up with the NuroSleeve, with improvement observed in six items (yielding a total score of 15); the greatest improvement was in the subscale of grasp. Follow-up scores on the ABILHAND and PROMIS UE SF were higher with the NuroSleeve. Clinically meaningful changes were observed on the ABILHAND with and without NuroSleeve. There was no change in muscle strength.

Table 2

ARAT, ABILHAND, and PROMIS UE SF Results

			Follow-Up		Change in Score	
		Baseline	**Without NuroSleeve**	**With NuroSleeve**	**Without**	**With**
	ABILHAND Logit (SE)	-1.335 (0.390)	0.301 (0.409)	3.624 (0.906)	1.636*	4.959*
	PROMIS UE SF 7a T-Metric (*SD*)	39.1 (2.4)	23 (2.8)	33.7 (2)	-17.1	-7.5
ARAT Subscales	ARAT Total	4	4	15	0	+11*
	Grasp (0–18)	0	0	8	0	+8
	Grip (0–12)	0	0	2	0	+2
	Pinch (0–18)	0	0	1	0	+1
	General Movement (0–9)	4	4	4	0	0

Note. ABILHAND and PROMIS UE SF scores are shown in converted logit and T-metric scores, respectively. ARAT results include both total and subscale scores, with subscale score ranges provided in parentheses.
ARAT = Action Research Arm Test; PROMIS UE SF 7A = Patient Reported Outcomes Measurement Information System Upper Extremity Short Form 7A; SE = standard error; *SD* = standard deviation; (*) = clinically important.

Discussion

This report demonstrates that OT, including training in using the NuroSleeve, resulted in improved functional abilities for an individual with chronic and severe unilateral UL impairments following a stroke. After 24 OT sessions, despite no change in volitional motor activity or muscle strength, functional use of the impaired UL improved with and without the NuroSleeve.

The greatest improvements were seen with the NuroSleeve donned. Our findings demonstrated that with the NuroSleeve, the ability to grasp was partially restored, and the ability to perform activities was superior to the ability without the NuroSleeve. Moreover, this case study showed that with the NuroSleeve, there was greater satisfaction with the method/degree to which activities were performed.

It is important to note that outcomes measured by the COPM and ABILHAND were clinically important. With the NuroSleeve donned, performance and satisfaction had clinically meaningful improvements for 6/8 and 7/8 COPM goals, respectively, and the improvement on the ABILHAND exceeded the clinically meaningful threshold by 4.609 logits. Similarly, with the NuroSleeve, there was an 11-point improvement over baseline on the ARAT, nearly double the minimally clinically important difference of 5.7 for individuals with chronic stroke (van der Lee et al., 2001), with the primary gains seen in grasp, as anticipated.

While scores on the PROMIS UE SF at each time-point with and without the NuroSleeve were consistently below average (mean = 50, *SD* = 10), at follow-up with the NuroSleeve, UL physical functioning approached 1.5 *SD*s of average (33.7, *SD* = 2) whereas without the NuroSleeve, UL physical functioning was greater than 2.5 SDs below average (23, *SD* = 2.8). It is interesting to note that PROMIS UE SF baseline scores were higher than follow-up scores. It is plausible that the participant rated his performance at baseline considering the use of his non-impaired UL, whereas, at follow-up, he responded considering his impaired UL. Since some of the PROMIS UE SF items are typically performed bimanually, if used to assess unilateral improvement, explicit instruction to the participant to focus on the UL of interest may be prudent. We did not provide instructions in this case.

The contribution of OT to the successful use of the NuroSleeve is important to highlight. It aligns with research that shows using exoskeletal robotics in OT positively influences function in people with UL impairment after a stroke (Iwamoto et al., 2019). Following stroke, spasticity can make passive ROM difficult, thereby creating challenges when donning orthoses. Such was the case with the individual in this study despite receiving botulinum toxin injections regularly. As a consequence, OT sessions usually began with interventions to reduce tone and increase hand ROM in preparation for using the NuroSleeve. OT also coached the participant to use the NuroSleeve as the "helping hand" to stabilize objects (e.g., a bowl for feeding, paper for cutting) while using his unimpaired UL as the primary hand to perform precise, fine motor movements (e.g., manipulating a fork for feeding, cutting with scissors). In this way, the goal of OT was not necessarily focused on using the NuroSleeve for primary hand function but rather on improving the ability to perform activities with as little difficulty and frustration as possible.

Perhaps the most salient contribution of OT is its approach to authentic client-centered therapy. Research indicates that client-centered goals may help develop intrinsic motivation, leading to greater active participation by the client in therapy sessions (Fu et al., 2020; Rosewilliam et al., 2011). In this case study, OT focused not only on COPM goals but also on goals that emerged throughout the 10 weeks. For example, while not a COPM goal, childcare tasks, such as feeding and changing diapers, were incorporated into therapy with the NuroSleeve.

It is important to note the limitations of this study; namely, it is a report of one participant enrolled in a feasibility study of a developing investigational technology, the NuroSleeve. The results cannot be generalized. Also, the PROMIS UE SF is a patient-reported outcome measure that includes both bimanual and unimanual activities. At baseline, the participant was not instructed to focus on his impaired UL while responding to this measure. However, at follow-up, the same measure was administered with and without the NuroSleeve, which likely directed attention to the impaired limb, making baseline and follow-up comparisons tenuous.

This case report is part of a larger feasibility study on early development of the NuroSleeve, with a focus on the OT process. Although work is underway on the NuroSleeve's capacity for restoring elbow and shoulder functions, these functions were not fully explored with this participant. It is plausible that with additional proximal movement and control, the participant in this study may have realized greater function. Finally, we did not conduct a follow-up assessment with the participant to assess if function gained and use of NuroSleeve were sustained.

This case report described OT for training on the use of the newly developed NuroSleeve. The study demonstrated the feasibility of training a person with a chronic stroke to use the NuroSleeve for improvement in abilities to perform functional activities.

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