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Original Research

A Pilot Feasibility Trial of an Upper Extremity Assistive System

Emma Hammelef, BSE [a], Saami J. Zakaria, MD [a], Sarah H. Andersen, MA [a], Thomas J. KellyIVMA [a], Namrata Grampurohit, PhD, OTR/L [b], Mikael Avery, MArch, MS, OTR/L [a,c], Alessandro Napoli, PhD [a], Mary Jane Mulcahey, PhD, OTR/L [b], Mijail Demian Serruya, MD, PhD [a]

[a] *Raphael Center for Neurorestoration, Farber Institute for Neuroscience, Thomas Jefferson University, 130 S 9th Street, Suite 2400, Philadelphia, PA 19107*
[b] *Center for Outcomes and Measurement, College of Rehabilitation Sciences, Thomas Jefferson University, 901 Walnut Street, Suite 642, Philadelphia, PA 19107*
[c] *Studio Krea, Collingswood, NJ*

KEYWORDS
Activities of daily living (ADLs);
Hemiplegia;
Neurological rehabilitation;
Occupational therapy;
Rehabilitation;
Stroke

Abstract *Objective:* To develop and clinically evaluate a customizable active upper extremity (UE) assistive system with integrated functional electrical stimulation (FES) that improves function and independence of individuals during activities of daily living (ADLs).
Design: Single-arm, prospective, open-label cohort feasibility trial.
Setting: An academic research institution.
Participants: Subjects were 5 adults with a medical history of stroke resulting in distal UE impairment (N=5). The subjects volunteered from recruitment materials that detailed information about the study.
Interventions: A novel, wearable, lightweight, low-profile, and patient-tailored UE assistive system. It comprises a splint component and FES unit that may each be controlled by electromyography (EMG) signals, inertial measurement units (IMUs), manual control source (joystick), and/or voice control.

List of abbreviations: 3D, three-dimensional; ADL, Activity of daily living; ARAT, Action Research Arm Test; BBT, Box and Block Test; COA, clinical outcome assessment; COPM, Canadian Occupational Performance Measure; EMG, electromyography; FES, functional electrical stimulation; ICC, intraclass correlation coefficient; IMU, inertial measurement unit; MCID, minimally clinically important difference; OT, occupational therapy; PROMIS, Patient Reported Outcomes Measurement Information System; SF, short form; UE, upper extremity.

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Main Outcome Measure(s): Several occupational therapy outcome measures were used, including the Canadian Occupational Performance Measure (COPM), Action Research Arm Test (ARAT), The Box and Blocks Test (BBT), the ABILHAND-Manual Ability Measure, and Patient Reported Outcomes Measurement Information System (PROMIS) UE Short Form.
Results: All participants learned to use our UE assistive system to perform ADLs and were able to use it independently at home. Most participants experienced a clinically meaningful improvement in both performance and satisfaction for the majority of their COPM goals while using the system. All participants experienced improvement in hand grip and release as shown by their baseline and post assessment scores for hand function (BBT, ARAT) and patient-reported outcomes (ABILHAND, PROMIS).
Conclusions: The clinical outcomes suggest that our UE assistive system improves functional performance in patients with UE impairment, allowing them to engage more actively in ADLs. Further innovation including elbow and shoulder components will allow users to have more degrees of freedom during tasks.

Stroke, spinal cord injury, muscular dystrophy, and other neurologic conditions frequently cause debilitating UE motor impairments that last beyond rehabilitation discharge.[1] In adults, there is an enormous burden of cerebrovascular disease; each year, more than 795,000 people in the United States have a stroke.[2] Over 75% of them will have permanent UE impairment at the chronic stage and difficulties performing activities of daily living (ADLs), which diminish quality of life.[3-5] Occupational therapy (OT) and physical therapy are mainstays of rehabilitation for persons with chronic neurologic impairments and incorporate a variety of therapeutic approaches, such as activity-based therapy, neuromuscular and functional electrical stimulation (FES), biofeedback, virtual reality, and robotics. Passive and powered UE assistive systems, including orthoses, are also incorporated into rehabilitation, and studies have shown that therapy while using a UE orthosis leads to improvement in the function of the affected limb while using the device.[6-8]

Although several UE orthoses have been developed, the only commercially available, powered arm orthosis is a myoelectric powered hand-elbow orthosis that implements a myoelectric approach in which up to 4 surface electromyographic (muscle activity) signals control 2 motors that move the brace components, allowing for flexion and extension of the fingers and elbow. This myoelectric strategy is adopted from prosthetics, as myoelectric control has been integrated into prosthetic limb designs for over 70 years.[9,10] Multi-week regimens incorporating the myoelectric powered hand-elbow orthosis as a therapeutic adjunct to rehabilitative therapy have been shown to increase UE function, use, and recovery in individuals with moderate UE deficit due to stroke.[11-13]

We intentionally designed our UE assistive system to address concerns raised by a participant in our previous clinical trial where the myoelectric powered hand-elbow orthosis was used to actuate UE movement.[14] Specifically, we designed our system to be customizable in form, function, and controls, lightweight, easy to don and doff, and convenient to integrate into ADLs. The system comprises a modular, hinged, splint component, and FES unit that may each be controlled by electromyography (EMG) signals, inertial measurement units (IMUs), manual control source (joystick), and/or voice control. These features offer several benefits. For one, EMG signals tend to be unreliable and inconsistent; in our experience, individuals with upper motor neuron injury exhibit within-and across-day spontaneous variations in muscle tone and EMG signals. Unlike many "off-the-shelf" UE orthoses, our system is customizable: its splint component is custom-shaped to accommodate the user's anatomy, and the types and locations of its control source(s) are selected by the user and therapist for optimal functionality and ease of use. The functionality of our UE assistive system described in this paper cannot be directly compared with the myoelectric powered hand-elbow orthosis, because it does not currently incorporate an elbow motor. However, our system is lighter in weight (<340 g placed on the user's arm vs >900 g for the myoelectric orthosis forearm piece).

Our study was designed to develop and clinically evaluate our customizable active UE assistive system with integrated FES that improves function and independence of individuals during ADLs. Our goal in developing the system is to meet individual's unique needs and promote the adoption of the technology in clinical settings, at home, and in the community. The National Library of Medicine defines a prosthesis as, "a device designed to replace a missing part of the body or to make a part of the body work better;" we assert that our system is designed to make the upper extremity (UE) work better.[15] The Food and Drug Administration defines a limb orthosis as a device, "worn on the upper or lower extremities to support, to correct, or to prevent deformities or to align body structures for functional improvement," and we assert that this definition does not adequately describe the dynamic and modular nature of our system.[16] Our system may be considered an external, wearable motor neuroprosthetic, analogous to an implanted motor neuroprosthetic.[17]

Our study incorporates an iterative device design process that incorporates feedback from occupational therapists, engineers, physicians, industrial designers, and research participants to improve upon the system design incrementally. The feasibility trial has obtained ethics board approval and is currently active and recruiting. In this report, we discuss the development of our system and clinical findings from the first 5 participants who completed the study.

Table 1 Inclusion and exclusion criteria

Inclusion Criteria	• Four (4) years or older • Weakness in 1 or both arms such that wrist flexion and wrist extension are 3/5 or weaker on the Manual Muscle Testing Scale or willingness to wear a brace that disallows wrist movement. • Etiology of weakness is due to a neurologic disease or injury • Willing to comply with trial instructions • Adult able to provide informed consent prior to enrollment in the study. Child able to provide assent and has a legal parent or guardian able and willing to provide informed consent • Adult fluent in English and child participant has at least 1 parent/guardian fluent in English • Medically stable and living at home in the community. • No joint contracture, spasticity, or other limitations to range of motion in the affected upper limb(s) that would preclude fitting and operation of a wearable, powered orthotic device on the arm • Sufficient sitting balance • No condition (eg, severe arthritis, central pain) that would interfere with movement of the arms, ability to understand verbal commands, and/or participate in the study
Exclusion Criteria	• Visual impairment such that following visually-guided instructions would be challenging even with ordinary corrective lenses • No condition that would pose a risk to the application of electrical current to the body (eg, skin conditions or skin breakdown) • Untreated psychiatric or neurologic disturbances that would affect motivation and trial participation • Excessive pain in 1 or both arms, defined as intolerance to passive movement of the limb by a team member at the screening visit • Excessive spasticity in 1 or both arms that would interfere with device use and fitting. • Advice from any of the individual's health providers that upper extremity powered orthotics or electrical stimulation are contraindicated • Exposed metal (eg, implants, external fixator) on the weak or paralyzed arm • Current alcohol or other substance abuse disorder • Other conditions or circumstances that, in the opinion of the investigators, would preclude safe and/or effective participation, including severe skin conditions, and/or other sequelae that may be contraindicated for using a powered orthotic or electrical stimulation

Methods

The study design is a single-arm, open-label feasibility trial. It was approved by the Thomas Jefferson University Institutional Review Board. Details of the clinical trial protocol are available on clinicaltrials.gov (NCT04798378). Participants aged 4 and older with UE weakness, with wrist flexion or extension less than 3 out of 5 on the Manual Muscle Testing Scale due to a neurologic disease or injury were recruited. Inclusion and Exclusion criteria are listed in table 1, and the demographics of participants are summarized in table 2. Seven participants were enrolled. After consent, standardized clinical outcome assessments (COAs) were administered to establish each participant's baseline functional abilities and to set goals for the trial. Participants underwent three-dimensional (3D) scans of their forearm and hand and received a customized NuroSleeve. They then engaged in 8 weeks of OT sessions and, upon demonstrating their ability to use the NuroSleeve independently, started incorporating it into their ADLs at home. After the 8-week period, the standardized COAs were repeated. This sequence of study activities is shown in figure 1.

The NuroSleeve

The NuroSleeve is an active UE assistive system composed of a custom, motorized 3D-printed splint, an external FES unit,[a] a main control unit, a clinical software suite for configuration, and a rechargeable battery. Its current design facilitates opening and closing of the hand via a linear actuator motor. Both the motor and FES component can be controlled by 1 or more sensors. The control options include (1) signals from surface EMG sensors[b] that could be placed at a muscle selected by the research therapist (eg, biceps, triceps, brachioradialis, and wrist extensor muscles); (2) signals from IMU sensors[c] placed at the shoulder, leg, or other location convenient for the user; (3) manual control from a small joystick[d]; and/or (4) voice recognition[e] (V3, ELECHOUSE, Shen Zhen, China). Each study participant worked with the occupational therapists to identify the most suitable control mode for their abilities and preferences. These control options were enabled via the NuroSleeve's main control unit and the clinical software suite, shown in figure 2.

The NuroSleeve incorporates optional FES. The microcontroller is agnostic as to whether a given control signal (eg, IMU positioned on the ipsilateral shoulder) is used to trigger the motor or the electrical stimulator: this decision is made by the therapist and user. The FES electrodes can be placed wherever they are deemed most helpful and may assist in actions that are combined simultaneously with the motorized hand open-close function (eg, stimulating the brachioradialis to add supination to hand grasp) or assist more indirectly (eg, stimulating muscles of the shoulder girdle for proximal stabilization or shoulder elevation). This

Table 2 Participant demographics

Participant ID	NS1	NS3	NS4	7NS6	NS7
Age range at time of trial enrollment	41	53	40	53	52
Biological sex	Man	Man	Man	Woman	Man
Race/ethnicity	Caucasian, Hispanic	Caucasian, Non-Hispanic	Caucasian, Non-Hispanic	Caucasian, Non-Hispanic	African American, Non-Hispanic
Body mass index	31.01 kg/m^2	25.5 kg/m^2	27.31 kg/m^2	27.98 kg/m^2	43.64 kg/m^2
Pre-stroke hand dominance	Left-handed	Right-handed	Right-handed	Right-handed	Right-handed
Stroke history	Large right-sided spontaneous basal ganglia hemorrhage	Ischemic stroke in right middle cerebral artery territory due to dissection and occlusion of the right internal carotid artery	Left basal ganglia hemorrhagic stroke	Right parietal-temporal cortical and subcortical hemorrhagic stroke	Lacunar right basal ganglia stroke
Other medical history	Decompressive hemicraniectomy	Traumatic brain injury superimposed upon stroke: may have affected cognition, processing speed, coordination of motor control	Major depression	None	Decompressive hemicraniectomy
Number of years since stroke at time of enrollment	7	4	3	20	2
Active chemical denervation (with botulinum toxin injections) of paretic arm at time of enrollment and while enrolled	Yes	No	Yes	Yes	No
Employment status at time of enrollment	On disability	On disability	On disability	Full-time employed office worker & cashier, driving	Full-time employed, police dispatcher (had been patrol until stroke made it unsafe to handle firearm)
Exam findings at time of enrollment	Left spastic hemiparesis, left inferior quadrantanopsia, hyperreflexia	Hypomimia, left upper extremity weakness, left leg brace	Right hemiparesis	Left hemiparesis	Left hemiparesis
NuroSleeve Orthosis Version	Jaeco	Jaeco	3D-printed	3D-printed	3D-printed
FES feature used	No	No	Yes	Yes	Yes

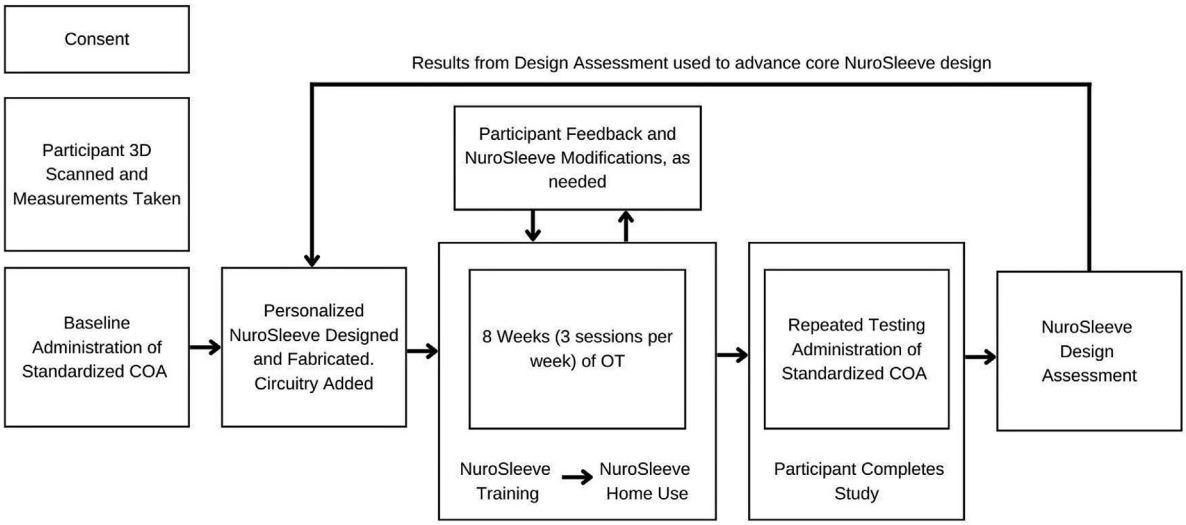

Fig 1 Sequence of study activities in the NuroSleeve clinical trial.

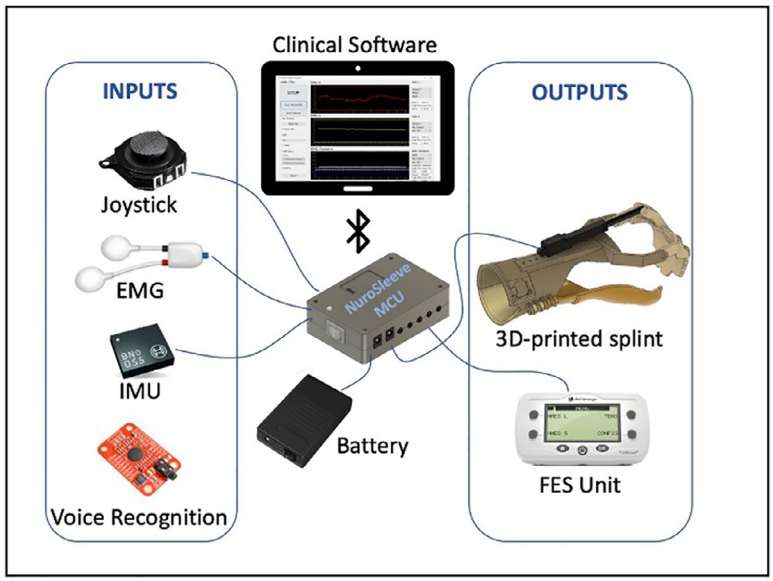

Fig 2 The NuroSleeve consists of the main control unit (center) which accepts different input control signals (left) to control 1 or more end effectors (right). Implementations are customized for each patient by the occupational therapist using the clinical configuration software.

functionality may be compared to the commercially available Bioness H200, a forearm orthosis that incorporates FES to the hand muscles. While the H200 may be used independently, it is marketed as a rehabilitation modality rather than as an assistive device.[18]

Occupational therapy

Study participants engaged in individualized 45-minute OT sessions 3 times per week over an 8-week period. OT sessions were tailored to participants based on their baseline evaluation and goals (as defined in the Canadian Occupational Performance Measure (COPM), subsequently described). While improving performance in the selected COPM activities was the primary goal of the intervention, the study incorporated principles of motor learning and motor control and task-specific activity-based therapy[19–21] into each session, with and without the use of the NuroSleeve. The study therapists trained each participant on how to use the NuroSleeve to achieve their COPM goals. Once comfortable with the device and deemed ready to do so, the participant used the NuroSleeve unsupervised at home. The Spinal Cord Injury Physical Therapy and Occupational Therapy Basic Data Set was used to record intervention details.[22]

Clinical outcomes

The following outcome measures were implemented for all participants pre- and post- the 8-week period of therapy to assess the use of their affected UE. Participants completed assessments with and without the NuroSleeve worn and were given rest breaks of at least 30 minutes between the

with- and without-device trials. The assessor was the same for pre- and post-assessments of each participant.

Canadian Occupational Performance Measure (COPM)

The COPM is an outcome measure designed to assess patient outcomes in areas of self-care, productivity, and leisure. The participant identifies activities that they would like to be able to do or perform better in, then rates their ability to perform each activity, and their satisfaction with their ability to perform it. It is rated on a scale of 1 (not able to do it at all/not satisfied at all) to 10 (able to do it extremely well/extremely satisfied).[23] The test-retest reliability (intraclass correlation coefficient, or ICC) of COPM in adults with impairment in 1 or more ADLs is 0.67 for performance and the minimally clinically important difference (MCID) is 2 for performance.[24-26]

Action Research Arm Test (ARAT)

The ARAT is an observational test used to assess UE function. It consists of 19 task items grouped into categories of grasp, grip, pinch, and gross arm movements. Performance on each item is rated on a 4-point scale ranging from 0 (no movement possible) to 3 (movement performed normally).[27,28] The maximum score is 57.[29] The ARAT has an ICC of 0.97 in stroke and an MCID of 5.7 for chronic stroke.[30,31]

Box and Block Test (BBT)

The BBT is a test of manual dexterity. The participant transports as many (2.5 cm^2) blocks as they can over a 15.2 cm tall partition in 1 minute. The score is the number of blocks transported.[32] The measure has an excellent ICC of 0.96 in UE paresis and an MCID of 5.[33]

ABILHAND-Manual Ability Measure

The ABILHAND is an inventory of 23 activities for which the participant characterizes as either impossible, difficult, easy to complete, (or "not applicable" if they have not completed the activity within the past 3 months). It is scored using the Rasch model, which converts the raw ordinal score into a linear measure, where a higher score indicates less difficulty completing the tasks.[34] The score is expressed in logits, a linear unit that expresses odds of success, with a range from -10 to 10. It has an ICC of 0.85 and an MCID of 0.26 to 0.35 logits in stroke.[35,36]

Patient Reported Outcomes Measurement Information System (PROMIS) UE Short Form

PROMIS, sponsored by the National Institutes of Health, is a system of validated, reliable measures that assess participant-reported outcomes. The PROMIS UE short form (SF) is in the physical function instrument in which the participant rates their ability to complete tasks on a 1-5 scale, where 1 is unable to do and 5 is without any difficulty. A maximum score is 35.[37] The raw score is converted to a T score to standardize the score, with a mean of 50 and a standard deviation of 10. The measure has demonstrated validity across varied clinical populations for comparing symptoms and quality of life indicators.[38] It has an MCID of 2.1.[39]

Results

The NuroSleeve was successfully developed through an iterative process (fig 1) that incorporated feedback from both participants and occupational therapists. The initial design incorporated a commercially available stainless-steel orthosis, the "Flex-Hinge Wrist Hand Orthosis"[f] as its splint component. The splint was manually fabricated by a technician at Jaeco to match the dimensions of the participant's impaired forearm and hand, using measurements and calculations made in a downloadable Orthometry Form.[40] A linear actuator[g] was fixed to the splint to drive opening and closing of the hand by moving the second and third fingers, shown in figure 3.

Feedback from study participants and clinicians led to an improvement in the splint component that permitted movement of all 4 fingers and provided a more precise fit to the user's forearm and hand. The next — and current — design of the NuroSleeve uses 3D printing to create a splint that accommodates the user's anatomy. The process involves taking a 3D scan of the participant's impaired hand (including the forearm, thumb, and 4 fingers), from which a computer-aided design model is created and printed using carbon fiber-reinforced nylon. The resulting splint has 4 sections: forearm, cuff, thumb, and fingers, as shown in figure 4. A linear actuator motor is attached to the forearm section and permits movement of all fingers against a stable thumb. The 3D customized NuroSleeve splint component weighs between 175 g and 310 g, depending on the size of the user's hand.

Study participants and clinicians found that using a mechanical switch or an IMU was more practical to use than

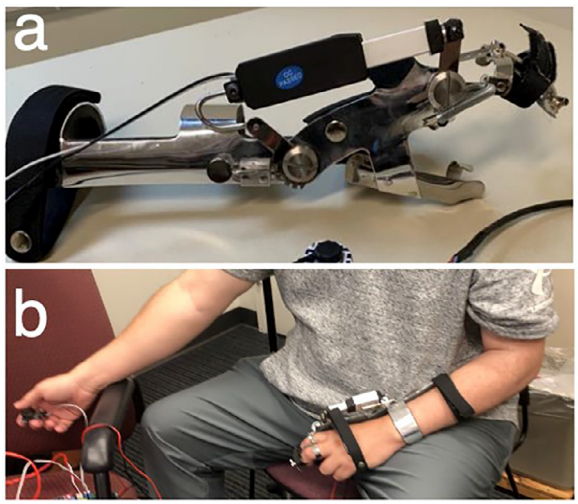

Fig 3 (a) The NuroSleeve design that incorporated the Jaeco Flex Hinge Wrist Hand Orthosis, (b) Participant NS3 with the NuroSleeve donned, opening the affected hand by using a push button in the non-affected hand.

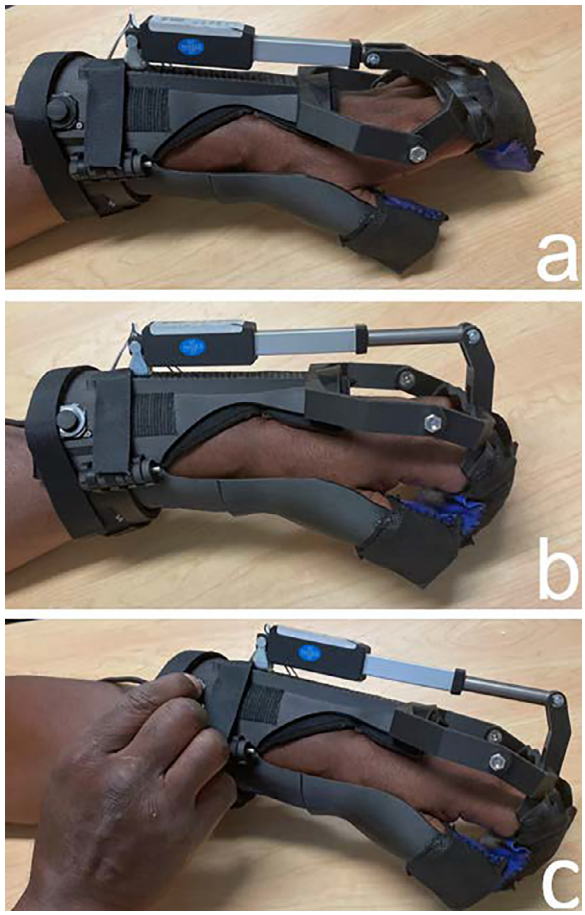

Fig 4 Participant NS7 wearing the 3D printed NuroSleeve design (a) in the hand open position, (b) in the closed position, (c) and triggering finger flexion by using an mounted joystick controller with the unaffected hand.

EMG, because they reduced the amount of time required to calibrate and set up the NuroSleeve's operational parameters. The manual controller and IMUs allowed participants to use the NuroSleeve without needing to connect to a computer to re-adjust any settings. Consequently, the NuroSleeve system setup was quick (less than 2 minutes) and only needed adjustment when the participant and the therapist wanted to change the control strategy.

NuroSleeves were designed, customized, and fabricated for 5 participants. Participants completed 24 OT sessions over 8 weeks and began using the NuroSleeve at home between 2 and 6 (mean =3.4) weeks of OT. As of the time of this manuscript, 2 participants (NS2 and NS5) have not completed therapy sessions because their UE deficits related to limitations of mobility about the elbow and shoulder respectfully, requiring design of new components to support and mobilize those joints.

Figure 5 and supplemental table S1 show the results of the primary outcome measure, COPM. Participants NS1, NS4, and NS7 experienced a clinically meaningful improvement (≥2 points) in both performance and satisfaction for most of their COPM goals while using the NuroSleeve independently at home and in the community. Table 3 provides baseline and post assessment scores for hand function (BBT, ARAT) and patient-reported outcomes (ABILHAND, PROMIS). Some outcome measures were not collected, due to either patient fatigue or research coordinator error; these are marked as NT, indicating "not tested" in the table. All participants who completed BBT and ARAT experienced improved handgrip and release; for some, this improvement was seen when not wearing the NuroSleeve. Participants NS4 and NS7 had decreased PROMIS scores post-assessment; however, participants NS1, NS3, NS4, and NS6 exhibited a clinically meaningful improvement in more than 1 outcome score.

Participant NS4 experienced minor skin discomfort during the fitting sessions and once at home using the NuroSleeve. This was resolved by smoothing a rough patch on the NuroSleeve, applying moleskin, and repositioning the participant's fingers within the device. There was 1 adverse event deemed unrelated to the intervention (breakthrough seizure due to known epilepsy). Participant NS7 exhibited a decrease in gross motor function (eg, lifting the hand to behind the head) over the course of the trial on the ARAT (baseline score 9 declining to 2, with or without the NuroSleeve), even though the ability to perform everyday bimanual activities were improved in the same duration on the COPM.

Discussion

Our preliminary findings demonstrate the feasibility of designing and fabricating the NuroSleeve, which improves upon the limitations of currently available UE orthoses and assistive systems. Incorporating 3D scanning and printing techniques with user-specific post-processing resulted in a NuroSleeve that was lightweight and comfortable for each user. The unique interdisciplinary and iterative design approach enabled real-time feedback from participants and clinicians to drive improvements. These improvements include changing the 3D print components to facilitate easier donning and doffing and adding more options for control. Further improvements to the NuroSleeve, including adding more proximal components (such as an elbow motor), are currently being developed.

At the beginning of the study, all participants exhibited severe levels of UE impairment as quantified on the baseline measures. With therapy intervention, all participants successfully learned how to use NuroSleeve to performance of activities and transitioned from using the NuroSleeve during supervised therapy to independent use at home. Overall, participants experienced a considerable improvement in both self-identified goals and functional outcomes. In COPM, ARAT, and ABILHAND, clinically meaningful improvements were seen in most or all participants. The most improvement was seen in COAs that measure hand function, which suggests the effectiveness of the NuroSleeve while in use.

Study limitations

One potential limitation was that some of the outcome measures did not provide an objective measure of NuroSleeve functionality. In addition, some of the tasks selected by participants in the COPM required more than improved grasp strength or hand function to achieve. For these tasks,

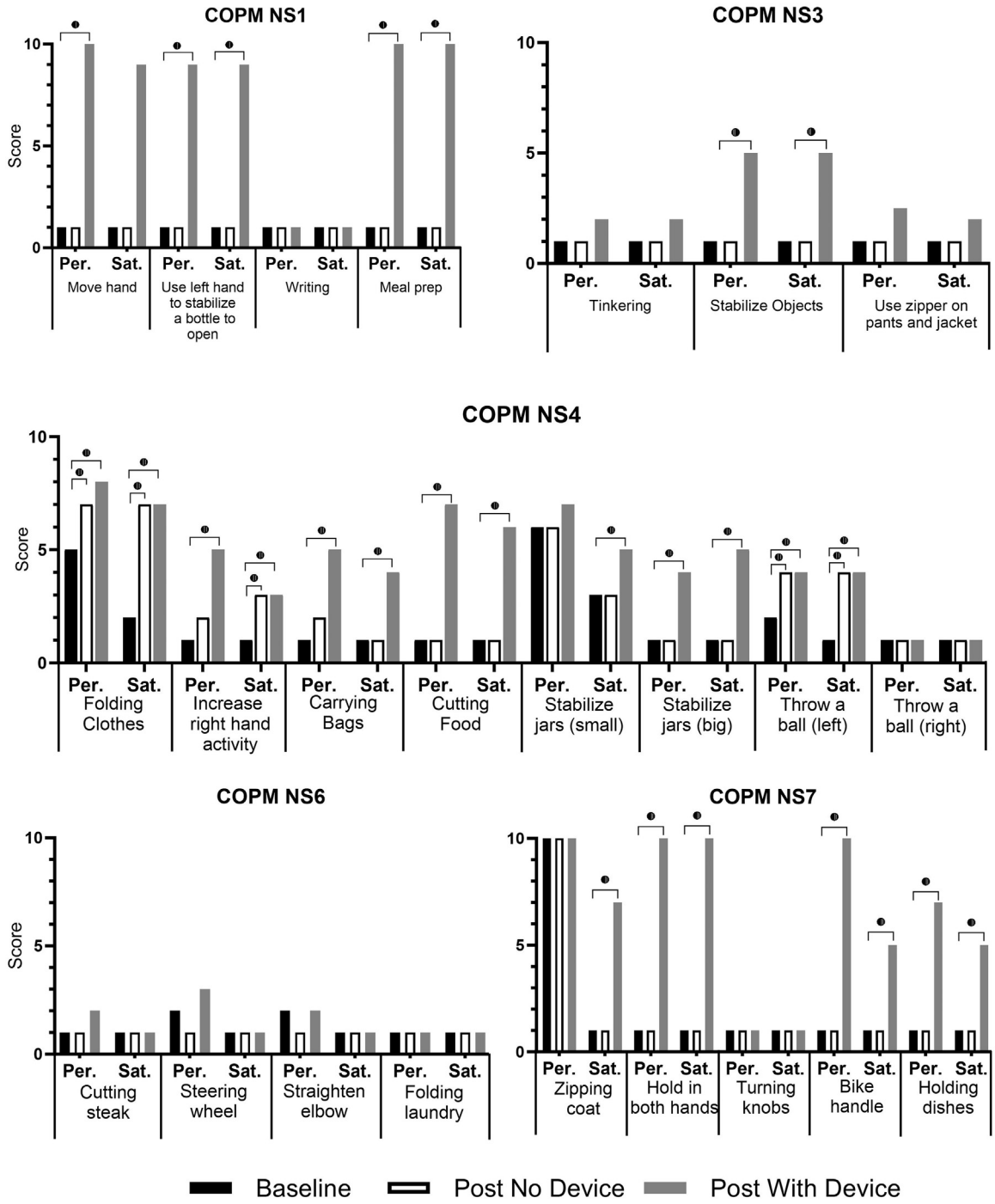

Fig 5 Performance and satisfaction scores on the COPM. The COPM rates performance "Per" (1= not able to do at all, 10= able to do extremely well) and satisfaction "Sat" (1= not satisfied at all, 10= extremely satisfied) of patient identified goals. "Post" scores refer to those achieved at post assessment visit. Values with a circle (•) have clinically meaningful improvement.

such as throwing a ball, folding laundry, straightening the elbow, and turning a knob, it was difficult to differentiate what role or improvement, if any, the NuroSleeve may have made because completion of these tasks relied more on proximal strength than hand strength. Similarly, while the PROMIS UE-SF has been validated for use in people with stroke, its score reflects how easily a task can be completed, regardless of how it is completed: hence it cannot differentiate whether or how the assisting (non-affected) hand might be used for a given task. Many of the tasks evaluated (lifting a heavy object, changing an overhead lightbulb, and passing a turkey or ham to others at a table) required mobility and strength at the elbow and/or shoulder, and required use of the non-affected hand in addition to strength and function of the affected hand.

In addition, the sample size of 5 is not sufficient to perform meaningful statistical tests and we will need more participants to achieve statistical significance.

Table 3 Baseline and post assessment scores

		Baseline	Post Assessment		Change Score	
			Without NuroSleeve	With NuroSleeve	Without	With
NS1	ARAT	1	2	9	+1	**+8**
	BBT	0	0	3	0	+3
	ABILHAND Logit (SE)	-1.044 (0.378)	**-0.24 (0.369)**	**3.837 (0.702)**		
	PROMIS SF V2.0 T-Metric (SD)	28.8 (2.2)	**35.3 (2)**	**36.5 (2)**		
NS3	ARAT	0	0	10	0	**+10**
	BBT	0	0	6	0	**+6**
	ABILHAND Logit (SE)	-2.282 (0.464)	**-1.814 (35)**	**0.135 (0.359)**		
	PROMIS SF V2.0 T-Metric (SD)	22.2 (3)	23 (2.8)	**31.5 (2.6)**		
NS4	ARAT	4	4	15	0	**+11**
	BBT	0	0	1	0	+1
	ABILHAND Logit (SE)	-1.335 (0.39)	**0.301 (0.409)**	**3.624 (0.906)**		
	PROMIS SF V2.0 T-Metric (SD)	39.1 (2.4)	23 (2.8)	33.7 (2)		
NS6	ARAT	0	6	4	**+6**	+4
	BBT	0	NT	1	NT	+1
	ABILHAND Logit (SE)	NT	NT	NT		
	PROMIS SF V2.0 T-Metric (SD)	16.2 (3)	**30.7 (2.2)**	**30.3 (2.1)**		
NS7	ARAT	9	2	2	-7	-7
	BBT	0	0	0	0	0
	ABILHAND Logit (SE)	NT	-1.267 (0.556)	-0.178 (0.572)		
	PROMIS SF V2.0 T-Metric (SD)	51.1 (4.5)	44 (3.5)	44.4 (3.3)		

NOTE. Change scores are shown for the performance-based measures (ARAT and BBT). Bolded values show clinically meaningful improvement.

Future directions

These preliminary findings justify the continuation of this feasibility trial and the design of a future randomized, prospective trial. Because we cannot blind participants or therapists to the study intervention, an adaptive, cross-over trial design may be warranted. Finally, while mass practice without a device has appeal in principle, none of our current participants would have been able to make the time commitment that mass practice requires. Thus, a prospective control arm consisting of a matched number of sessions of OT without NuroSleeve may be the only way to determine whether the intervention (device use + therapy) would have a significant benefit over therapy alone. For future participants, we may select additional outcome measures that will focus specifically on the change in performance of the impaired limb while using the NuroSleeve.

One of our longer-term goals in developing the NuroSleeve is to make active, wearable UE movement restoration systems more accessible to the public. For any active UE movement restoration system to be widely scalable, financial barriers and technical support issues must be addressed. In addition, clinicians must become familiar with this technology, to see it not only as a viable tool that can be incorporated into rehabilitation therapy sessions, but also as a practical, assistive system that can be used at home to enhance independent function in ADLs. Our interdisciplinary approach involves clinicians in the design process, which will hopefully improve buy in and utilization. 3D printing allows for ease of manufacturing and customization, which we anticipate will decrease costs and, in turn, facilitate payer coverage once adequate prospective studies are completed.

Conclusions

We have designed, developed, and assessed the feasibility of independent home use of the NuroSleeve, an active UE movement restoration system customized for the user in form and function. It is lightweight, easy to don and doff, and is easily incorporated into therapy sessions and at home use during ADLs, thus overcoming many limitations of currently available UE orthoses and stimulators. We've also found success in our interdisciplinary and iterative design

approach, which has enabled rapid and meaningful improvements to the NuroSleeve design. The clinical outcomes observed for the 5 participants suggest that the NuroSleeve improves functional performance of patients with UE impairment and enables them to engage in ADLs more actively. We will continue to refine and improve upon the NuroSleeve; work is underway to incorporate elbow and shoulder components to permit the user more degrees of freedom during functional tasks. We have also initiated a product development process so that future iterations of the NuroSleeve may be available to more individuals and potentially become part of clinical care.

Suppliers

a. Chattanooga Continuum; DJO LLC.
b. MyoWare 2.0; Advancer Technologies.
c. BNO055, Bosch Sensortec GmbH.
d. PSP Thumbstick; Adafruit Industries.
e. V3; ELECHOUSE.
f. "Wrist Driven Flexor Hinge"
g. PA-07; Progressive Automations.

Corresponding author

Mijail Demian Serruya, 130 S 9th Street, Suite 2400, Philadelphia, PA 19107. *E-mail address:* Mijail.Serruya@jefferson.edu.

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