

## Preliminary performance of a surgically implanted neuroprosthesis for standing and transfers—Where do we stand?

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**Abstract**—This paper describes the preliminary performance of a surgically implanted neuroprosthesis for standing and transfers after spinal cord injury (SCI) in an initial group of 12 volunteers with longstanding paralysis. The CWRU/VA standing neuroprosthesis consists of an 8-channel implanted receiver-stimulator, epimysial and surgically implanted intramuscular electrodes, and a programmable wearable external controller. After reconditioning exercise and rehabilitation with the system, most individuals with paraplegia or low tetraplegia were able to stand, transfer, and release one hand from a support device to manipulate objects in the environment or to perform swing-to ambulation in a walker. The effort and assistance required for transfers were reduced for users with mid-level tetraplegia, although the maneuvers were not independent. Neuroprosthesis users with tetraplegia and paraplegia alike benefited from the improvements in their general health derived from exercise, including reduced risk of decubiti and self-reported modulation of spasticity. Stimulated responses are

stable and sufficiently strong for function, and implanted components are reliable with a 90% probability of epimysial electrode survival at 4 years post-implant. The techniques employed are repeatable and teachable, and suitable for multicenter clinical trial.

**Key words:** *exercise, FES, FNS, neuroprostheses, standing, transfers.*

### INTRODUCTION

This paper explores the development and initial application of a surgically implanted neuroprosthesis for exercise, standing, and assisted transfers after paralysis resulting from spinal cord injury (SCI). The CWRU/VA standing neuroprosthesis consists of an 8-channel implanted receiver-stimulator, a wearable external controller, and associated software and clinical rehabilitation protocols. This system does not require any surgical changes to existing anatomy, and requires intact and electrically excitable lower motor neurons. From its preliminary performance in the first 12 recipients of the system, the neuroprosthesis appears to be both safe and efficacious with good potential for widespread clinical application and consumer acceptance of the device.

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There are two potential populations of consumers who may benefit from this technology. First, individuals with mid- to low-cervical-level injuries will be able to use the standing system to exercise. Regular exercise involving active contractions of the otherwise paralyzed lower-limb muscles via electrical stimulation may result in improvements in general health, including maintenance of joint range of motion, increased circulation, reduced risk of decubiti, and perhaps better modulation of spasticity. Because of the upper-limb impairment associated with tetraplegia, this population will also be completely dependent on personal assistants for all transfers into and out of their wheelchairs. Stimulating the knee, hip, and trunk extensors can facilitate transfers by eliminating the heavy lifting and lowering required by the caregiver. Although the neuroprosthesis may not enable these individuals to stand independently, it can make standing transfers significantly easier. This is especially important as people with SCI get older and their primary caregivers (i.e., aging parents or spouses) are no longer able to lift them during transfers.

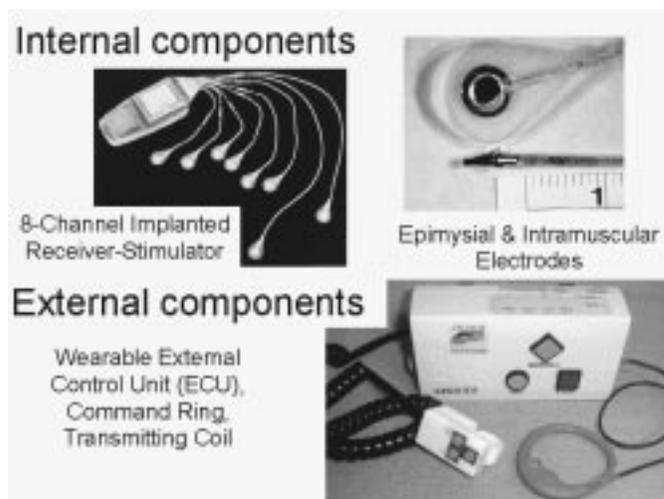
Second, individuals with thoracic spinal injuries will derive the same benefits from exercise and standing, but the neuroprosthesis will provide them with options for independent mobility, especially in transfers between surfaces of uneven heights, which are difficult or impossible for them by conventional sliding or lifting techniques. Furthermore, because of their good upper-limb strength, individuals with paraplegia may be allowed by the system to exert greater control over their environments by standing to reach objects or maneuvering into places that are inaccessible to the wheelchair.

Although finding a “cure” for SCI may be the Holy Grail of some research, many benefits exist that can be realized immediately by restoring the ability to exercise, stand, and transfer individuals with either thoracic or low-cervical SCIs with neuroprostheses employing functional electrical stimulation (FES).

## METHODS

### System Components

The internal and external components of the CWRU/VA standing neuroprosthesis are depicted in **Figure 1**. The internal components consist of an 8-channel implanted receiver-stimulator (IRS-8), in-lead connectors, and epimysial and intramuscular electrodes (1–4). The external components consist of a rechargeable



**Figure 1.** Internal and external components of the CWRU/VA standing neuroprosthesis.

wearable external control unit, command ring, transmitting coil, charger, and clinical programming station (5,6). The external control unit provides both power and command signals to the implant, weighs slightly less than 1 pound, and can operate for at least 4 hours on a single charge. A clinical interface based on a laptop PC allows clinicians to quickly adjust stimulation parameters and download usage information from the external controller.

### Target Muscle Selection

With a limited number of stimulus channels available, target muscle selection was a critical issue in the development of the standing neuroprosthesis. A systematic approach was adopted to determine the optimal muscle set for stimulation. First, biomechanical analyses were conducted on able-bodied subjects and in computer simulations to establish the moment-generating capacities of the knee, hip, and trunk extension muscles individually and in combination (7). Next, experiments with users of multi-channel percutaneous systems were organized to determine an acceptable set of target muscles (8,9). Finally, cadaver dissections and interoperative tests with the use of electrical stimulation during other surgical procedures were performed to confirm the muscles selected and plan operative approaches to their motor points (10,11).

The target muscles were carefully chosen based on their ability to keep the knee, hip, and trunk extended against gravity. The muscles were selected primarily to provide postural support rather than balance. Secondarily, they needed to provide power during the sit-to-stand and

stand-to-sit transitions. It was assumed that balance and assistance in ascent and decent could be provided by the upper limbs with the use of a support device, or by an assistant.

The responses of the target muscles needed to be strong, isolated, consistent, and repeatable. In addition, if the neuroprosthesis is to gain widespread clinical acceptance, the muscles need to be accessible through a repeatable surgical approach that is teachable and relatively straightforward, based on standard surgical approaches. With these considerations in mind, one channel was assigned to the vastus lateralis for knee extension, which the theoretical and experimental analyses indicated would be strong enough to support the body without actively flexing the hip (through activation of rectus femoris or other muscles innervated by the femoral nerve). Two hip extensors—the gluteus maximus and the semimembranosus (or alternatively, the posterior portion of adductor magnus)—were selected to build redundancy into the system. It was determined that activation of the lumbar erector spinae to stiffen the trunk would be crucial to unloading the arms and maintaining an erect posture.

### Development of Surgical Approach

Development of the implant procedure involved a series of eight cadaver dissections to determine locations of incisions and surgical approaches that would yield efficient and repeatable exposure of the nerve entry points. A conscious decision was made to preserve all existing anatomy and to avoid any other surgical reconstruction in the study subjects. It was deemed important not to move or cut any tendons, because many of the potential system users expressed a strong desire to avoid any irreversible procedures in case other therapies become available in the future.

A three-phase surgical approach was established. In Phase I, the subject is in the supine position and five incisions are made: two for the vastus lateralis electrodes, one on the anterior abdomen for an intraoperative anode, and two small incisions for the in-line connectors on the lower abdomen. Phase II involves the subject in the prone position with implantation of the erector spinae muscles, the semimembranosus muscles, and the gluteus maximus muscles, and those posterior electrode leads are routed subcutaneously to temporary incisions on each flank. In the third and final phase, the subject is repositioned again to a supine position and the leads are passed from the flank incisions anteriorly to the abdominal connector sites and connected to the IRS-8, which is sutured in place of the intraoperative anode. The surgical procedure for sys-

tem installation is described in detail elsewhere (10).

Although the procedure requires a total of 13 incisions and takes approximately 8 hours to complete, it typically has been accomplished with minimal blood loss on the order of 100 cc or less. There have been no serious long-term complications to date, although there have been two instances of infection that were resolved with appropriate treatment. One case involved an acute superficial infection of a skin incision over an electrode site within 2 weeks of implantation that was treated successfully with oral antibiotics. The other involved a deep infection localized around the IRS-8 that developed 8 weeks postimplantation and required IV antibiotics and removal of the device. The electrodes and leads distal to the in-line connectors were preserved, and the subject is scheduled to receive a replacement implant to resume exercise and standing with the neuroprosthesis.

### Subject Selection and Participation

When one identifies candidates for the clinical trial, one of the fundamental prerequisites is intact lower motor neurons so that the target muscles will be electrically excitable. A normal range of motion is also important for the subject to be able to get into a good standing position. There should not be any heterotopic ossification that significantly limits hip motion. In addition, candidates need to be in overall good health and have no history of spontaneous fractures for bone density reasons. The inclusion criteria for the study are summarized in **Table 1**.

Twelve subjects were enrolled in the preliminary trial. Eleven were male and most exhibited complete sen-

**Table 1.**

Inclusion criteria for application of the CWRU/VA standing neuroprosthesis

- |     |   |
|-----|---|
| 1.  | C6-T12 SCI (ASIA A, B or C)   |
|     | i. ASIA B: ability to tolerate stimulation  |
|     | ii. ASIA C: trace or nonfunctional contractions   |
| 2.  | Intact lower motor neurons  |
| 3.  | Skeletal maturity (>18 years)   |
| 4.  | Neurological and emotional stability (>12 months postinjury)  |
| 5.  | Normal ROM, joint integrity, and acetabular coverage  |
| 6.  | No history of spontaneous fractures   |
| 7.  | No orthopedic or medical conditions contraindicating electrical stimulation or surgery (pacemakers, diabetes, colostomy, pregnancy, etc.) |
| 8.  | Good skin integrity and controlled spasticity   |
| 9.  | No seizure disorders or immunological compromises   |
| 10. | Adequate social support and ability to complete follow-up evaluations and travel  |

sory and motor deficits. There was a range of heights and weights, the average being 5'8" and 175 lb. The time since injury at implant varied from 1 to 17 years with an average of 6.2 years. The mean age at implant was 35 years. Clinical characteristics of the study participants are summarized in **Table 2**.

Each volunteer in the study underwent a formal participation timeline beginning with a period of preparatory surface stimulation exercises prior to implantation. After the surgery, each subject was put on bed rest before being discharged home with restricted activity. About 6 to 8 weeks postoperatively, rehabilitation was initiated. Reconditioning exercise consisted of 8 weeks of progressive resistance strength training and endurance exercise and at least 8 weeks of functional training focusing on balance and transfers. During rehabilitation of subjects, the stimulated responses of the implanted electrodes were determined every 2 to 4 weeks. Finally, follow-up evaluations were performed at 3, 6, and 12 months postdischarge. The idealized participation timeline is illustrated in **Figure 2**.

Implant integrity was assessed with the examination of the stimulation thresholds and serial radiographs of the implanted components. Data related to the stimulated strength of the knee and hip extensor muscles were collected during rehabilitation after the 8-week exercise program. Physiological effects were further quantified by examining pre- and postexercise pressure distributions on the seating surface and transcutaneous tissue oxygen, and the effects of stimulation and weight bearing on the insensate joints were determined by initial and terminal

plane films of the hips, knees, and ankles. Standing performance was quantified in terms of body weight distribution between the upper and lower limbs while standing, and a subjective rating scale of preference and perceived effort and assistance required to complete standing transfers with and without the neuroprosthesis.

## RESULTS

### Physiological Effects

The test subjects are in various stages of rehabilitation and long-term follow-up data are still being collected. However, preliminary results demonstrate encouraging peak strengths of the stimulated responses across all subjects, as illustrated in **Figure 3**. On average, the vastus lateralis muscles in the eight subjects completing the exercise portion of the rehabilitation protocol generated more than the 35 Newton-meters (N•m) that are required for standing for a person of average stature (12–16). The standard deviation for peak isometric strength of the vastus lateralis is small, indicating good reproducibility from subject to subject. The responses elicited from electrodes in the individual hip extensors are weaker and more variable. But the decision to build redundancy into the posterior muscles appears to be validated. When stimulated independently, the gluteus maximus and the hamstrings average about 20 N•m each, but when stimulated simultaneously, the output approaches 40 N•m on each leg, which is sufficient for standing.

**Table 2.**

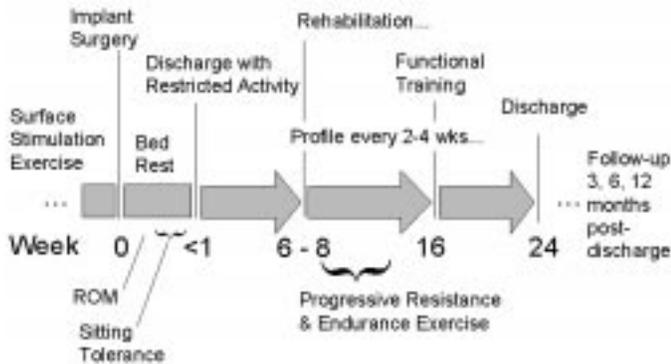
Clinical characteristics of first 12 recipients of the CWRU/VA standing neuroprosthesis

Subject	Sex	Height (in)	Weight (lbs)	Injury level	ASIA* class	Implant date	Months post injury
1	M	72	180	C6	C	9/16/96	83
2	M	74	250	T4	A	7/14/97	46
3	M	65	110	T9	A	7/6/98	27
4	M	69	202	T6	A	3/19/99	93
5	M	64	168	T8	A	8/20/99	33
6	F	66	125	C7	B	11/12/99	20
7	M	68	190	T6	A	12/3/99	15
8	M	69	150	C5	A	6/9/00	106
9	M	69	198	T5	B	8/25/00	202
10	M	73	220	T8	A	12/8/00	13
11a	M	69	138	T4	A	2/9/01	200
12b	M	68	165	T8	A	5/4/01	48

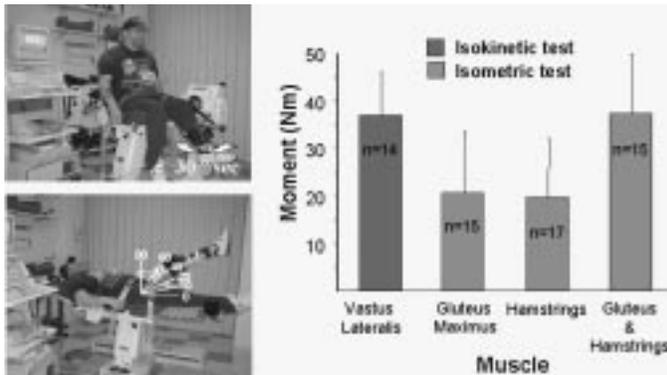
\* - American Spinal Injury Association Classification

a - First subject at the University of Kentucky

b - First subject at Albany Medical College

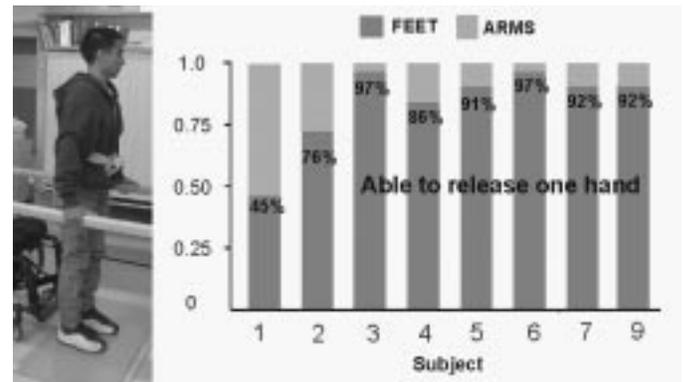


**Figure 2.** Idealized study participation timeline and sequence of events for standing neuroprosthesis recipients.



**Figure 3.** Mean peak strength elicited with the implanted standing neuroprosthesis. Knee extension moment was measured isokinetically at 30° per second to minimize risk of long bone fracture, and hip extension strength was measured isometrically at evenly spaced angles distributed throughout the range of motion.

One figure of merit for standing performance with the neuroprosthesis is the percentage of body weight being placed on the legs. Ideally, this value should approach 100 percent if individuals can stand without placing any weight on their arms for support. Body weight distribution is assessed with the subjects standing on a force platform between parallel bars that are instrumented to measure the forces placed on them by the arms (17,18). As shown in **Figure 4**, most of the study subjects can stand with more than 90 percent of their body weight on their legs because balance is maintained by light touch on the assistive device. Five of seven subjects with paraplegia who completed rehabilitation were able to release one hand to manipulate objects in the environment while standing with the system.



**Figure 4.** Body weight distribution between the upper and lower limbs while standing with the implanted neuroprosthesis.

### Functional Outcomes

For subjects with paraplegia, stand to reach, counter work, transfers, and mobility skills without a wheelchair were emphasized during rehabilitation. Individuals with paraplegia are able to accomplish independent transfers from the wheelchair to higher surfaces prohibitive to conventional methods. Transfers for users with mid-tetraplegia were not independent but were greatly facilitated by the neuroprosthesis. The system performed the heavy lifting and lowering phases of a standing pivot transfer, and the assistant need only help with the relatively easy job of repositioning and balance. Several volunteers with paraplegia or low tetraplegia were also able to accomplish a swing-to gait with the neuroprostheses. These abilities have clinical utility postdischarge for the subjects in the areas of occupation, recreation, participation, and socialization as illustrated in **Figure 5**.

### Usability Assessment

Another important measure of success is the subjective impressions of users of the neuroprosthesis and their assistants. A usability and preference scale was developed to assess user perceptions of effort and assistance during transfers with the neuroprosthesis. Details of this rating scale and its development methodology have been described previously (19,20). The users and their assistants rated the transfers as difficult, moderate, or easy and then again on a finer scale within each of those categories. This resulted in a seven-point scale from very difficult (−3) to very easy (3). The users and their assistants were also asked to identify which transfer method they prefer—FES or non-FES. FES and conventional transfers are performed under two conditions: to and from a



**Figure 5.** Examples of functional uses of the CWRU/VA implanted standing system: (a) functional ability through examples of (from left to right) reach, counter work, transfers, and mobility, and (b) clinical utility through examples of (from left to right) occupation, recreation, participation, and socialization.

surface at the same height as the wheelchair (level transfers) and at a height that is at the limit of what can be achieved without FES (high transfers).

Overall, the results indicate that level transfers with and without FES are equivalent in difficulty, yet subjects prefer conventional transfers. However, high transfers with FES are deemed easier than conventional transfers. All users refused to attempt non-FES transfers from low to high surfaces and preferred using the neuroprosthesis for this purpose. Perhaps most importantly, all subjects indicate that they would go through the surgery and rehabilitation again to achieve the same results.

Other clinical observations regarding the outcome of the implanted standing system are summarized in **Table 3**.

### Technical Performance

In regard to the technical performance of the system, most (72 out of 76) of the epimysial electrodes maintained low, stable stimulus thresholds. This indicates no

**Table 3.**

Summary of clinical outcomes observed following application of the CWRU/VA standing neuroprosthesis

- No radiographic abnormalities at joints poststimulation
- Standing times range from 3 to >40 minutes
- Risk of pressure sores decreased
  - Increased tissue transcutaneous O<sub>2</sub>
  - Decreased peak pressures under ischial tuberosities
  - Hypertrophy of muscle
- Reported improvements in spasticity
- Subjective feelings of improved health

biological reactions and mechanical integrity. Four mechanical failures evidenced by high stimulus thresholds have been noted. These failures are typically due to separation of the platinum stimulating disk from its flexible silicone backing because of a stiff adhesive used for strain relief in the manufacturing process. All failures have been in electrodes in the posterior muscles, suggesting that there might also be an interaction with shear forces that develop during sitting or sliding transfers. Because of the redundancy incorporated into the hip extensor muscles, loss of a single posterior electrode seldom seriously compromised standing performance. Notwithstanding, the epimysial electrodes exhibit approximately a 95-percent success rate and damaged components were successfully replaced. Statistical analysis of the preliminary data from 70 electrodes with more than 3 months follow-up indicates a 90-percent probability of epimysial electrode survival at 4 years postimplant. Also noteworthy is that there have been no implant or connector malfunctions and only one failure because of movement of an intramuscular electrode in the erector spinae.

These preliminary clinical and technical results were sufficiently encouraging to justify determining the safety and efficacy of the neuroprosthesis in a multicenter clinical trial, which has already begun. Collaborating centers include Albany Medical College, the Baltimore VA, the University of Kentucky, Washington University, and the Houston VA. To date, a training workshop for all the collaborating centers has been conducted and screening clinics in Albany and Kentucky have been completed. Surgeon training for the Albany and Washington University centers has been initiated and all therapist training has been completed. Two subjects have been implanted so far at collaborating sites in Kentucky and Albany (Subjects 11 and 12 in **Table 3**) and follow-up is ongoing. Research objectives of the multicenter trial are

to distribute this device to other medical centers and to increase the number of subjects studied in order to analyze the impact of the neuroprosthesis statistically.

## DISCUSSION

Although most physiological data from the latter volunteers appear to be consistent, there did appear to be a learning curve associated with candidate selection and implantation technique. Consequently, the results seemed to improve after the first few surgeries. This is particularly evident from the body weight distributions presented in **Figure 4**. Subjects early in the series exhibited hip range of motion limitations (Subject 1) or a relatively large body size (Subject 2). In addition to these less than ideal physical characteristics, the surgical approaches for localizing the motor points of the target muscles were still new, which probably contributed to the large percentage of body weight placed on the arms during standing and their inability to release a hand from the walker. The rapid improvement in body weight distribution, standing posture, and performance in subsequent volunteers may be attributable to the experience accumulated in both identifying appropriate implant candidates and operative technique for optimal stimulated responses of the target muscles.

Some of the limitations that were observed have to do with partial activation of the available muscles. For example, targeting the vastus lateralis excludes the knee extension that could be produced by the other vasti muscles. In addition, only a fraction of all the motor units of the vastus lateralis is being activated. When the vastus lateralis is stimulated in isolation, the track and pull on the patella must be considered and patellar dislocation is a conceivable potential risk. It will be interesting to see if lateral displacement of the patella becomes an issue in long-term follow-up. To date, no lateral patella deviation is evident, or any other FES-induced damage to the insensate joints.

There is a great deal of intersubject variability and a wide range of standing times with the system, from 3 minutes to more than 40 minutes, and this seems to be related as much to body size and standing posture as to properties of the stimulated responses. Ideally, it would be desirable to see prolonged standing durations that are more consistent from individual to individual. More complete activation of the hip and knee extensors through better electrode placement, alternative electrode designs,

additional stimulus channels, or improvement of the strength and endurance of the stimulated responses through alternative exercise programs might achieve this. Even so, the relatively short standing times on the order of several minutes exhibited by some subjects in this study have been sufficient to complete standing transfers and stand-to-reach activities and therefore may still have valuable functional implications.

There are many opportunities for improvement with this neuroprosthesis. In particular, standing performance can certainly be improved, especially for large or heavy individuals, who need help to transfer the most. This can be achieved by exploring ways to recruit more muscles with new implants with more stimulating channels (such as a 16-channel implant currently under development that would allow for 8 channels per limb). An alternative avenue is to more fully recruit the muscles already implanted with other electrode designs, such as a cuff electrode. If more of the quadriceps could be selectively recruited without stimulation of the sartorius or rectus femoris muscles, this could create some useful knee extension without active hip flexion that would be counterproductive to upright standing.

For this possibility to be investigated, a series of quantitative cadaver dissections has been initiated to get design parameters for stimulating nerve-cuff electrodes. Branch-free lengths and nerve circumferences are being examined, and fascicles are being traced from entry point to nerve trunk. We hope to identify possible locations of monopolar-stimulating cuff electrodes to more fully activate the vastus lateralis or some other combination of the uniaxial vasti while avoiding the rectus femoris. In addition, determining the fascicular structure of the femoral nerve may allow us to design multicontact stimulating cuffs and a new generation of implantable stimulators capable of selectively activating the muscles that extend the knee and void those that flex the hip. In our clinical experience, strong hip and lumbar-trunk extensions are critical to upright standing posture and a primary determinant of the body weight placed on the arms for support during standing with the neuroprosthesis (7,21,22). Efforts to maximize knee extension should not be at the expense of hip and trunk extension. Increased attention needs to be focused on improving stimulated hip and trunk extensions, which have traditionally been considered secondary to strong knee extension in FES standing. Finally, one of the criticisms of this system is that users have to carry a walker with them everywhere they go. Although the necessity of a walker is required for

balance, the system does not tie a user to a single specialized support device that must be transported with them in order for the system to operate, as in some other attempts at standing neuroprostheses (23,24). The system was designed to allow recipients to use any grounded object, such as a counter or other solid object in the environment for light touch, to maintain balance.

## CONCLUSIONS

Preliminary data collected to date indicate that the CWRU/VA standing neuroprosthesis is safe and effective for providing a means to exercise, stand, and transfer to qualifying individuals with low-cervical or high-thoracic spinal cord injuries. With proper candidate selection, surgical implementation, and rehabilitation, the neuroprosthesis can be successful in providing upright posture and preventing collapse to facilitate transfers or provide options for enhanced mobility such as swing-to ambulation or reaching tasks while standing. The techniques employed are repeatable and teachable, and the stimulated responses are stable and sufficient for function. The standing neuroprosthesis enables consumers to perform a variety of tasks that would otherwise be impossible or prohibitively difficult. These initial findings are encouraging, and the preliminary clinical and technical outcomes need to be further quantified with long-term follow-up in larger-scale multicenter trials.

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