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Long-term user perceptions of an implanted neuroprosthesis for exercise, standing, and transfers after spinal cord injury

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Abstract—This study was completed to understand the usage patterns, system performance, degree of satisfaction, complications, and health benefits as perceived by recipients of a surgically implanted neuroprosthesis for exercise, standing, and transfers in individuals with low-cervical or thoracic spinal cord injury (SCI). A standardized telephone survey was administered to 11 recipients of the Case Western Reserve University/Veterans Affairs (CWRU/VA) implanted standing neuroprosthesis with more than 12 months of experience with the functional electrical stimulation (FES) system. Nine implant recipients were using the neuroprosthesis regularly for standing and/or exercising at the time of the survey. All 11 implant recipients noted improved health and a reduced incidence of pressure sores, leg spasms, and urinary tract infections (UTIs). No incidents of deep-vein thrombosis, infection, cellulitis, or electrical burns because of the neuroprosthesis were noted. System recipients uniformly felt that the neuroprosthesis resulted in better overall health and general well-being. Subjects were moderately to very satisfied with the performance of the neuroprosthesis and unanimously expressed a willingness to repeat the surgery and rehabilitation to obtain the same clinical outcome. All implant recipients reported the system to be safe, reliable, and easy to use. The implanted standing neuroprosthesis appears to be a clinically acceptable and effective means of providing the ability to exercise, stand, and transfer to selected individuals with paraplegia or low tetraplegia.

Key words: FES, FNS, functional electrical system, functional neuromuscular stimulation, neuroprosthesis, spinal cord injury, standing.

INTRODUCTION

Individuals with spinal cord injuries (SCIs) need new options for negotiating architectural barriers; completing essential daily bed, shower, or toilet transfers; and gaining access to high cabinets, cupboards, or shelves that are difficult or impossible to reach from a wheelchair. In spite of advances in social, environmental, and wheelchair design, almost one-third of all individuals with paraplegia still need assistance with activities of daily living, community mobility, or essential transfers [1]. Neuroprostheses using functional electrical stimulation (FES) are rehabilitative tools with the potential to increase independence and address

Abbreviations: American Spinal Injury Association = ASIA, CWRU/VA = Case Western Reserve University/Veterans Affairs, ECU = external control unit, FDA = Food and Drug Administration, FES = functional electrical stimulation, SCI = spinal cord injury, UTI = urinary tract infection.

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the mobility impairments of persons with SCI by providing a means to exercise, stand, and maneuver in a wide variety of environments through the coordinated activation of the paralyzed lower-limb musculature.

FES can facilitate standing and stepping in environments inaccessible to a wheelchair. In addition, FES-assisted transfers can eliminate the heavy lifting and lowering required by caregivers, which becomes particularly important as individuals with SCIs and their family members or spouses age. With increases in longevity because of the advent of antibiotics, the aging sedentary SCI population also faces other life-threatening health problems, such as cardiovascular disease. Regular use of FES can improve cardiovascular fitness and resting arterial blood flow into the lower limbs [2,3], positively impact bone density and joint status without adverse effects on the insensate joints [4–6], and increase resistance to pressure sores by improving tissue oxygen levels, increasing muscle bulk, and altering seated pressure distribution [7]. Significant decreases in spasticity, total cholesterol, and low-density lipids as a result of exercise and ambulation with FES have also been reported [8]. Furthermore, long-term use of lower-limb FES can statistically increase physical self-concept and decrease indicators of depression significantly [9]. Therefore, lower-limb neuroprostheses may be valuable and powerful options in the long-term management of persons with SCIs to keep users psychologically as well as physically fit [10,11].

This investigation examines the personal impact of a new surgically implanted neuroprosthesis for exercising, standing, and transfers after low-cervical or thoracic SCI. It is to help us understand the issues related to system use, health benefits and medical complications, and satisfaction with the technology as perceived by system recipients themselves. The paper summarizes the subjective impressions of recipients of the Case Western Reserve University/Veterans Affairs (CWRU/VA) implanted standing neuroprosthesis as determined by a structured telephone survey of participants enrolled in the preliminary clinical trial of the implanted FES system [12,13]. While relying entirely on subjective self-report by a small group of highly motivated individuals may yield an overly optimistic impression of the neuroprosthesis, this study was undertaken to initiate the process of acquiring and interpreting the perceptions of neuroprosthesis users themselves regarding its value, benefits, and drawbacks.

METHODS

The CWRU/VA implanted standing neuroprosthesis is depicted schematically in **Figure 1**. Internal components of the system are identical to a single 8-channel implanted receiver stimulator (IRS-8), in-line connectors, and epimysial and surgically implanted intramuscular electrodes [14–17] and consist of the implanted components of the Food and Drug Administration (FDA) approved neuroprosthesis for hand grasp after mid-level tetraplegia that has been installed in over 250 individuals worldwide [18,19]. For standing, the system targets the hip (gluteus maximus and either semimembranosus or posterior portion of adductor magnus), knee (vastus lateralis), and trunk (lumbar erector spinae) extensor muscles to raise and support the body against collapse. Custom external components of the system for lower-limb applications include a rechargeable wearable external control unit (ECU), with command ring and transmitting coil, and a clinical programming station and charger [20,21]. The ECU provides both power and command signals to the implant, weighs slightly less than 1 lb, and can operate for at least 4 hours on a single charge. ECUs are constructed with an automatic data-logging capability to record the date and length of time and mode in which the system is activated. A clinical interface based on a laptop personal computer (PC) allows clinicians to quickly adjust stimulation parameters and download usage information from the external controller.

Subject Selection and Participation

The inclusion criteria for application of CWRU/VA standing neuroprosthesis are—

1. C6-T12 SCI (American Spinal Injury Association [ASIA] A, B, or C).
2. Intact motor neurons.
3. Skeletal maturity (>18 years).
4. Neurological and emotional stability (>12 months postinjury).
5. Normal ROM (range of motion), 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 compromise.
10. Adequate social support and ability to complete follow-up evaluations and travel.

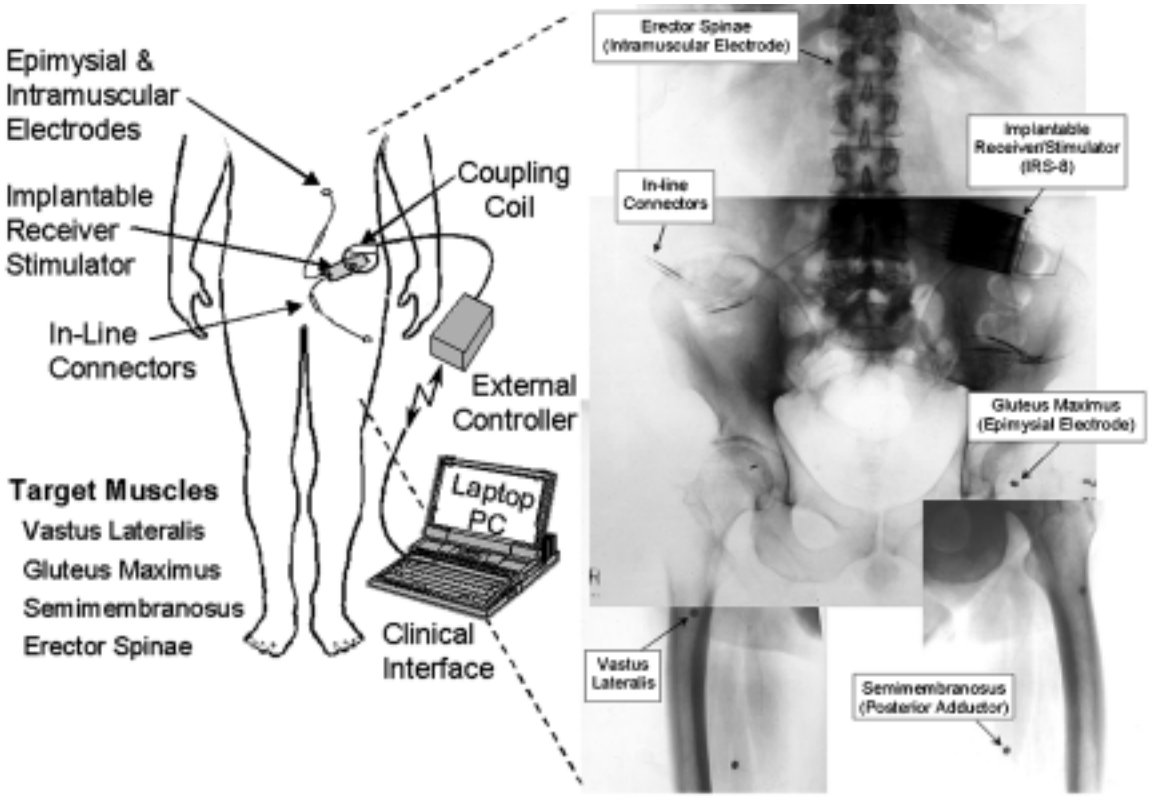

Figure 1.
Schematic representation of CWRU/VA implanted standing system (left) and X ray of final installation (right).

Each volunteer provided informed consent as required by the Institutional Review Boards of both the Louis Stokes Cleveland Department of Veterans Affairs Medical Center and the MetroHealth Medical Center. Subjects in the study then underwent a formal participation timeline beginning with a period of preparatory surface stimulation exercises before implantation (**Figure 2**). A standardized procedure for system implantation developed through a series of cadaver dissection and intraoperative tests was applied to all study volunteers. Epimysial electrodes consisting of platinum disks covered with reinforced elastomer skirts were sutured to the nerve entry points of the lower-limb target muscles, and intramuscular electrodes were inserted at the T12, L1 roots to activate the lumbar erector spinae muscles. Implantation surgery can be accomplished in a single 8-hour procedure based on standard orthopaedic approaches with a minimum of blood loss [13].

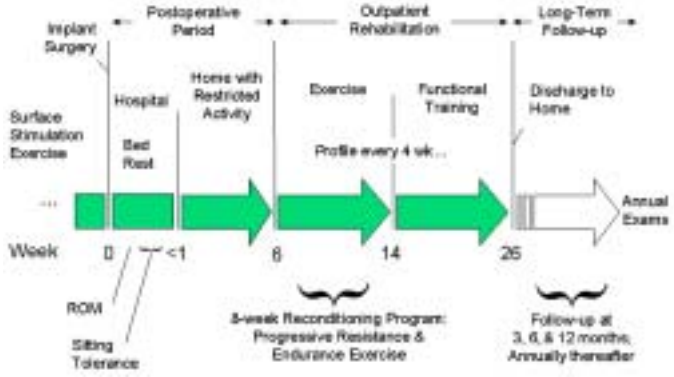

Figure 2.
Participation timeline. Surgery is followed by discharge to home with instructions to limit activity. An 8-week exercise program begins 6 weeks postimplant, followed by rehabilitation and functional training and long-term home-use follow-up.

Postoperatively, each subject was advised bed rest before being discharged home with restricted activity to facilitate the healing process. Rehabilitation was started about 6 to 8 weeks postoperatively. 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, the stimulated responses of the implanted

electrodes were determined every 2 to 4 weeks. After completing training and rehabilitation, subjects were qualified for home use and entered a 12-month follow-up period in which they incorporated exercise and/or standing with the neuroprosthesis into their personal lives (**Figure 3**). Physical follow-up examinations were performed at 3, 6, and 12 months postdischarge [13].

From 1996 to 2002, 13 individuals with SCI (10 with paraplegia and 3 with tetraplegia) were implanted with the CWRU/VA standing neuroprosthesis and were trained to perform stand-to-reach tasks, counter work, transfers, and short distance mobility maneuvers with stimulation in both laboratory and home settings.

For this study, all 13 implant recipients were surveyed by telephone to determine their satisfaction and subjective impressions of the effectiveness and personal impact of the standing neuroprosthesis. Data from two of the participants were excluded from all analyses of the survey results. One individual (subject 12) was explanted several months after the surgery because of a late onset infection and never completed the rehabilitation program with the neuroprosthesis. Data from a second participant (subject 13) were excluded, since he had only approximately 4 months of experience with the system. This paper therefore summarizes the data from 11 implant recipients with at least 12 months experience with the neuroprosthesis postsurgery. Because several neuroprosthesis users had completed the 12-month physical follow-up protocol before the completion and standardization of the formal survey instrument, total experience with the system varied from individual to individual.

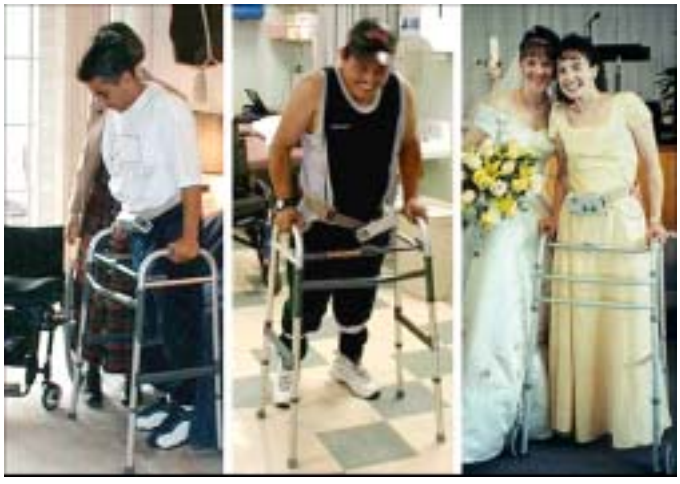

Figure 3.
Recipients of CWRU/VA implanted standing neuroprosthesis using system for transfers, swing-to mobility, and social participation.

Survey Structure and Administration

An independent physician unknown to respondents interviewed all participants over the phone using a standardized questionnaire after explaining the purpose of the survey. Interviewing was conducted over the phone because of the technical nature of some of the questions and the need for clarification via direct contact and dialogue. The interviews lasted on average about 20 to 25 min. The questionnaire was divided into sections related to system use, medical and health benefits, system performance, and user satisfaction. Respondents had the option of selecting more than one answer in several multiple-choice questions and were allowed to give their unprompted opinions in other open-ended questions. These responses were tabulated, and common themes were extracted after all surveys were completed. Some of the items in the questionnaire were divided into three forced-choice answers and then again on a finer scale within each of those categories. This resulted in a 7-point scale from –3 to +3 according to methodology employed in the Usability Rating Scale [22,23]. Median values and other nonparametric statistics were computed for the ordinal data derived from the resulting responses. Descriptive statistics for the clinical characteristics of the study participants (means and standard deviations) were also computed. A summary of items included in the questionnaire is given in **Table 1**.

RESULTS

Of the 11 subjects interviewed with at least 12 months of experience with the neuroprosthesis, 10 were male and most exhibited complete sensory and motor deficits. Heights varied from 64 in. to 74 in., with an average height of 69 in. ± 3 in. The weights ranged from 125 lb to 250 lb, with an average of 175 lb ± 42 lb. The time since injury at implant varied from 13 months to 202 months, with an average of 76 months (6.3 ± 5.8 years). The mean age at implant was 35 ± 8 years. Experience with the neuroprosthesis ranged from 13 to 67 months postimplant, with an average of 33 ± 17 months (2.7 ± 1.4 years) at the time of the survey. Clinical characteristics of the study participants are summarized in **Table 2**.

Table 1.
Summary of survey questions asked of implant recipients.

Survey Topic	Survey Question
System Use	What do you most like to use your electrical stimulation for?
	What do you use it for most often?
	How often do you use the system for exercise? For standing?
	How long can you stand?
	Why do you exercise/stand with FES?
	Does it help with daily activities?
	Did you ever use braces?
	Is the system easy to use? Do you need an assistant?
	What is the most important function you would like the system to provide?
	What do you think is the most important factor for getting useful function from the system?
	How would you improve the system to make it more functional?
	Do you think FES is safe?
Medical/ Health Benefits	Has your overall health changed (improved) because of using FES (further graded into 7-point scale from "much better" to "much worse")?
	Has the frequency and severity of spasms changed because of using FES (further graded into 7-point scale from "much better" to "much worse")?
	Has the frequency of UTI changed because of using FES (further graded into 7-point scale from "much better" to "much worse")?
	Has the number of pressure sores you experienced changed because of using FES (further graded into 7-point scale from "much better" to "much worse")?
	Do you think it helps in preventing pressure sores?
	Did you have any deep-vein thrombosis before or since using FES?
	Did you have any infection/cellulitis since using the system?
	Did you have any burns while using the system (because of the system)?
	Did you have any falls/fractures while using FES?
	Do you think FES has functional/health benefits?
	Do you have any pain or discomfort associated with the FES when the system is off/on?
Satisfaction	Do you think the research staff gave the realistic picture of what the system can do for you?
	Are you satisfied with the system (further graded into 7-point scale from "very satisfied" to "very dissatisfied")?
	Has the system lived up to your expectations?
	Would you do it again/recommend the experience to others?
	Do you think the FES system is reliable (further graded into 7-point scale from "very reliable" to "very unreliable")?
	What is the least reliable part of the system?
	Selecting the patterns is easy or difficult (further graded into 7-point scale from "very easy" to "very difficult")?
	Operating the command switch is easy or difficult (further graded into 7-point scale from "very easy" to "very difficult")?
	Trying to determine what is going to happen next is easy or difficult (further graded into 7-point scale from "very easy" to "very difficult")?
	Is the external control unit in the way of transfers?
	If you were to change one thing about the external control unit, what would it be?

UTI = urinary tract infection
FES = functional electrical stimulation

Table 2.
Clinical characteristics of neuroprosthesis recipients.

Subject	Sex	Height (in.)	Weight (lb)	Injury Level	ASIA Class	Implant Date	Months Postinjury
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
11	M	69	138	T4	A	2/9/01	200

ASIA Class = American Spinal Injury Association (Classification)

General

Among the 11 participants interviewed with more than 1 year of experience with the neuroprosthesis, 9 were still using the FES system regularly for standing and/or exercising at the time of the survey. One participant (subject 4) was instructed not to stimulate because of medical advice following a rotator cuff tear and a fractured tibia caused by a fall unrelated to the FES system that necessitated withdrawal from the research program. He is likely to resume stimulation once his medical team clears him for its use. Another participant (subject 1) had stopped standing and exercising temporarily because of the lack of opportunity while moving his household and was planning to resume soon. Overall impressions of neuroprosthesis users are summarized in **Table 3**.

Table 3.
Overall impression of neuroprosthesis.

Survey Question	Yes	No
Do you use it to stand?	8	3
Do you use it to exercise?	9	2
Does it help with daily activities?	6	5
Do you need a stand-by assistant to use FES for standing/walking?	3	8
Have you ever used braces for standing/walking without FES?	4	7
Do you think it is easy to use?	11	0
Do you think it has functional benefits?	11	0

System Use

System use refers to self-reported usage patterns as perceived by the respondents at the time of administration of the questionnaire. The data from subject 4 were excluded from the usage analysis because his medical condition immediately before the survey precluded stimulation and because he had been instructed not to stand or exercise for reasons unrelated to the performance of the neuroprosthesis. Seven of the remaining ten participants were using the system at least four times a week, and two were using it at least two to three times a week for exercise. Three participants were using it at least four times a week for standing, and four individuals were using it for standing two to three times a week (**Figure 4**). The reasons for not using the

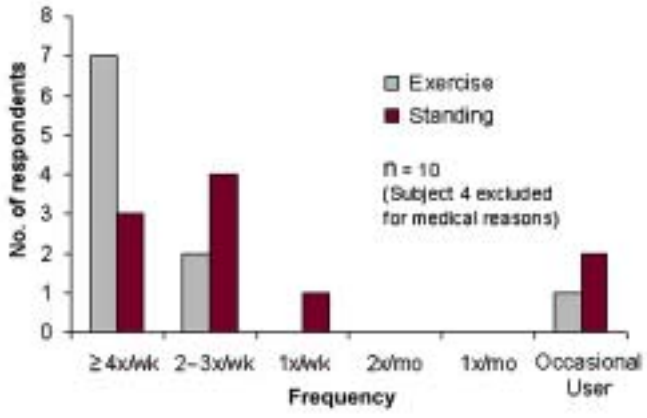

Figure 4.
How often do you use the system? Self-reported frequency of use of neuroprosthesis for both exercising and standing at time of survey.

system for exercising and standing included too busy to use, interfering medical conditions, and lack of opportunity because of personal reasons (moving). One participant (subject 2) was not standing with the system because of the difficulty imposed by his height (6 ft 2 in) and weight (250 lb), although he was still using it to exercise.

Seven participants responded that standing helped them transfer; four felt that standing helped them to be at eye level with others. The other reasons for standing were that it felt good and improved circulation; it allowed moving where the wheelchair would not fit, getting in a pickup truck, stretching out, and exercising; and it improved physical appearance (**Figure 5**). Maximal standing duration varied across users and ranged from under 2 min to more than 40 min. Eight participants felt that exercising would help them to stand and walk, six felt that it reduced leg spasms, seven felt that it made their legs look good, and five felt that exercise with the neuroprosthesis generally made them "feel good." The other reasons for exercising included observations that it made the legs stronger and that it promoted tangible health benefits (**Figure 6**). Six participants felt that exercise was the most important factor for getting useful function from the neuroprosthesis, while five identified "motivation" as the key determinant of clinical outcome. Four of the participants had used braces earlier, and they preferred FES to braces because they considered it easier and safer to use. Eight participants felt that they did not need a stand-by assistant to use FES for standing or swing-to ambulation.

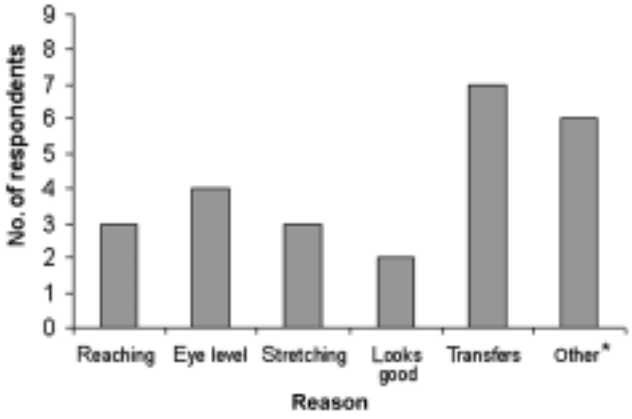

Figure 5.
Why do you stand with the system? Reasons for standing with neuroprosthesis (multiple responses received from 7 of 11 subjects). *Answers included feels good, improves circulation, able to get in pickup truck, able to move where wheelchair will not fit, and tired of sitting.

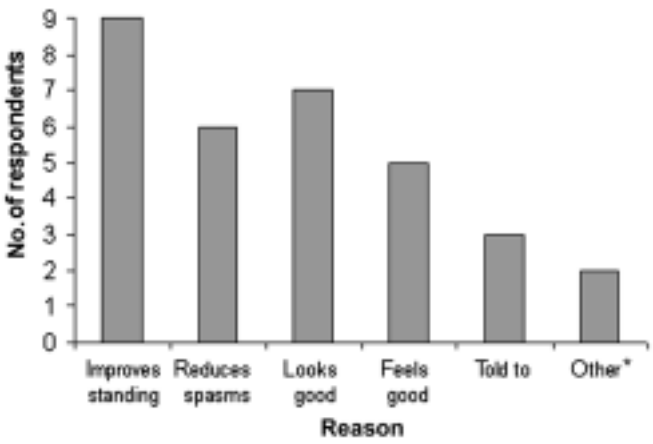

Figure 6.
Why do you exercise with the system? Reasons for exercising with neuroprosthesis and benefits as perceived by survey respondents (multiple responses received from 8 of 11 subjects). *Answers included stronger legs and health reasons.

Medical

All participants felt that their health had improved because of using the system (**Figure 7**). Some of the perceived health benefits as identified by the users of the neuroprosthesis to open-ended questions, such as "Why do you exercise/stand with FES?" (shown in **Table 1** under System Use) included improved circulation and cardiovascular status, reduced risk of pressure sores, decreased risk of osteoporosis, fewer posture problems, prevention of muscle atrophy, stronger muscles, better looking skin, increased bone density, and fewer infections. Responses to the forced-choice questions on perceived changes in medical status (Medical/Health Benefits, **Table 1**) are summarized in **Table 4**. All subjects reported a decreased frequency of

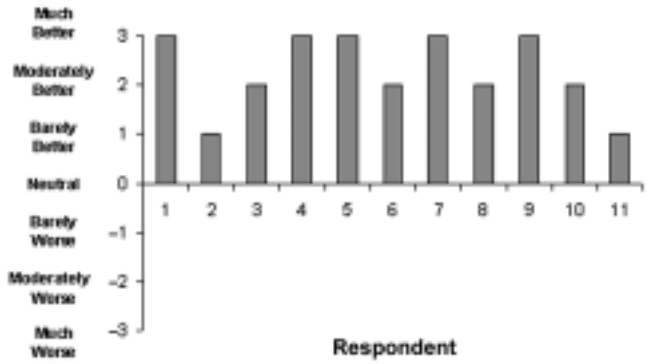

Figure 7.
Has FES changed your overall health? Change in overall health as a result of neuroprosthesis use as perceived by survey respondents.

spasms in the leg muscles by using the system, while three noted that the severity of the spasms had increased because of improved strength in their legs. Six of the respondents who had UTIs before being implanted with the neuroprosthesis reported reduced frequency of UTIs. Five participants felt that the implanted stimulation system helped reduce the number of pressure sores, while six reported no change in the number of skin breakdowns since receiving the implant. Important to note is that the six individuals who reported no change in pressure sore status also reported being pressure sore free before implantation.

Self-reported clinical complications during neuroprosthesis use are summarized in **Table 5**. All six reports of complications occurred independently; that is, no one respondent reported multiple complications. Only two participants had one episode each of pressure sores since using the system. One attributed the incident to the faulty cushion that he was using and reported it as a tissue swelling with no break in the skin. Both respondents felt that the pressure sores were less severe because of neuroprosthesis use. Three study participants reported a total of seven falls while using the system. None of the incidents resulted in injury. One respondent fell one time because of improper operation of the low-battery alarm. Another respondent fell four times because of coil failures, and one respondent fell back into the wheelchair two times when first learning to stand with the system. These latter respondents considered their falls minor enough that they did not report them outside the context of the user survey. Only one participant reported minor discomfort when the system was off, while none of them felt any pain or discomfort associated with it while the system was on. No incidents of deep-vein thrombosis, infection, cellulitis, or electrical burns because of the neuroprosthesis were reported. All the participants felt that the neuroprosthesis offered health and functional benefits.

Satisfaction

All respondents expressed being moderately (+2) to very (+3) satisfied. Respondents unanimously stated that their expectations were met, that they would repeat the surgery and rehabilitation program to obtain the same clinical outcome, and that they would recommend the procedure to others (**Table 6**). All but one reported that the research staff gave them the realistic picture of what the system could do for them. Individual perceptions of satisfaction are summarized in **Figure 8**. In total, 64 percent (7/11) respondents were very satisfied with the system, and 36 percent (3/11) were moderately satisfied. No respondents reported feeling neutral or dissatisfied with the neuroprosthesis. Even the first implant recipients (subjects 1 and 2) who reported minimal use for standing and occasional exercise use were satisfied with their choice to receive the neuroprosthesis and were content with both the performance of the system and the outcomes achieved.

System Performance

All the participants found the system to be safe, reliable, and easy to use. Selecting the patterns and operating the command switch were easy in all cases. All respondents were able to predict easily the next sequence of events while using the system. Most of the complaints regarding the technology involved manipulating the transmitting coil and connectors. Half of the participants noted that the ECU interferes with transfers and wanted it to be smaller in size.

Table 4.
Perceived change in frequency and severity of spasms, urinary tract infections (UTIs), and pressure sores.

Perceived Change with FES	Number of Subjects Responding (n = 11)			
	Frequency of Spasms	Severity of Spasms	UTIs	Pressure Sores
Much Better	2	2	3	4
Moderately Better	4	5	3	1
Barely Better	4	1	—	—
Same (no change)	1	—	5	6*
Barely Worse	—	1	—	—
Moderately Worse	—	—	—	—
Much Worse	—	2	—	—

*No incidents of pressure sores prior to FES.

Table 5.
Clinical complications during neuroprosthesis use as reported by survey respondents.

Reported Clinical Complications	Number of Subjects (n = 11)	
	YES	NO
Pressure Sores	2*	9
Deep Vein Thrombosis	—	11
Infection/Cellulitis	—	11
Burns from FES	—	11
Fractures from FES	—	11
Falls While Using the FES	3	8
Pain/Discomfort While System is ON	0	11
Pain/Discomfort While System is OFF	1	10

*Both report pressure sores improved with FES.

Table 6.
Satisfaction with neuroprosthesis as perceived by survey respondents.

Perceptions of Satisfaction	Number of Subjects (n = 11)	
	YES	NO
Expectations were met.	11	0
Would repeat process for same results.	11	0
Would recommend FES to others.	11	0

One participant suggested that it would be better if the ECU were wireless, with a range of 2 to 3 feet, eliminating the transmitting coil and cable for the remote finger switch.

DISCUSSION

The objectives of the study were first to understand the usage profile, system performance, complications, patient satisfaction, and health benefits as perceived by the recipients of the CWRU/VA implanted standing neuroprosthesis. Second, the study was intended to elicit practical suggestions from system users to improve the operation and function of the neuroprosthesis. In persons with low-cervical or thoracic SCIs, use of the implanted neuroprosthesis has already been shown to provide the stimulated muscle strength required to be able to stand, transfer, as well as exercise [12]. This investigation was to begin to acquire and interpret the personal perceptions and subjective opinions of neuroprosthesis users regarding their experiences with the system.

At the time of the survey, the neuroprosthesis was used regularly both therapeutically and functionally by the respondents, who tended to employ it to exercise slightly more frequently than to stand. The participants were aware of the negative effects of paralysis and perceived that FES may improve their cardiovascular and general health by exercising the paralyzed muscles, although this must be inferred from interpretation of the responses to the open-ended survey questions and needs to be further quantified. In addition, they were all able to identify important functionally related reasons for standing in their own words and without forced-choice options.

Overall, recipients were unanimously satisfied with the system, as evidenced by the lack of neutral or negative ratings of satisfaction (**Figure 8**). This response was consistent across all subjects, regardless of clinical outcome. Furthermore, the implanted neuroprosthesis also appears to be convenient and reliable, overcoming shortcomings of previously reported percutaneous systems that required continual attention from their users to clean and dress electrode exit sites [24].

The survey was constructed and conducted in a manner to minimize several common sources of error that may have biased in the results. Highly motivated, energetic, and active individuals, such as those selected to be the first recipients of the implanted neuroprosthesis, may tend to overestimate the number of times they use an assistive

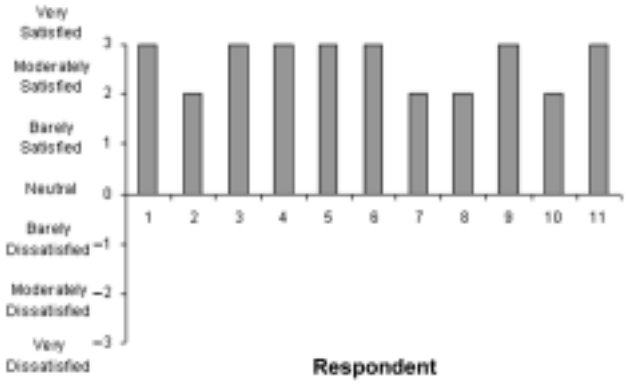

Figure 8.
Are you satisfied with the FES system? Level of satisfaction with implanted neuroprosthesis.

technology and underestimate the problems encountered [25]. Relying entirely on subjective self-report therefore may have given an overly positive picture of the neuroprosthesis. We tried to minimize the possible effects of selection bias by reporting the results from recipients who have been using the system for more than 12 months. This process was to ensure that the initial novelty had worn off and that the participants could answer honestly and truthfully from their experience rather than from their optimistic expectations. Moreover, survey respondents tend to be more honest when they understand that their opinions are valued and contribute to identifying important changes to system designs, as in this case.

Even so, the results of this study need to be interpreted carefully. Since the survey instrument was administered at various times postsurgery, the total experience with the neuroprosthesis varied from user to user. Although the uniformity of responses suggests otherwise, varying experience with the system might have influenced the results. Certainly, a better prospective experimental design would be to conduct the survey at the same point in time with each volunteer, thus eliminating any possible temporal effects. Doing so was impossible for the current retrospective study, since the survey instrument was not finalized until many neuroprosthesis recipients had already accrued more than 1 year of experience with the system. The survey has since been added to the set of standardized physical evaluations administered at the 12-month postdischarge follow-up interval, so data collected from future neuroprosthesis users will be synchronized in time.

Another source of bias may be that participants in an intense program of research or therapy may develop personal relationships with the staff involved. This could tempt respondents to avoid providing negative answers that would disappoint the people providing the technology and rehabilitation necessary for implementing the neuroprosthesis. Hence, a physician unknown to the implant recipients who was not directly involved in their care conducted the survey to avoid personal relationships from influencing the responses. In this way, we attempted to minimize the possible effects of interaction bias in the results.

A great deal of intersubject variability was found in the maximal elapsed standing times reported with the system. This seemed to be related to the injury level, body size, standing posture, and properties of the stimulated responses. Nevertheless, implant recipients were consistently satisfied with their outcomes and could perform self-selected activities of personal importance, such as standing pivot transfers and standing to reach inaccessible objects, within the limits of their standing abilities. Ideally, seeing more consistent and prolonged standing durations among all implant recipients would be desirable. More complete activation of the hip and knee extensors through better electrode placement, alternate electrode designs (such as stimulating nerve cuff electrodes), additional stimulus channels, or improvement of the strength and endurance of the stimulated responses through alternative exercise programs might achieve this [16].

Usage does not seem to be related to demographic variables such as age, injury level, or time postinjury at implant. Although the two occasional users are also the first two volunteers to receive the implanted neuroprosthesis, their usage patterns appear to be related more to external factors (opportunity), individual physical characteristics (height, weight, hip range of motion limitations), and lack of experience of the research team with a new surgical procedure in the early stages of the program. Improved selection criteria with increased attention to body size and joint ranges of motion, and maturation of the surgical and rehabilitation implementation protocols improved the clinical performance in later subjects who tended to report using the system more frequently than the initial recipients of the neuroprosthesis. Nonetheless, all subjects, including the first two occasional users, reported feeling satisfied with the system and were content with its performance.

Of the seven reports of falls while using the system, several were related to the operation of the system external hardware. One respondent fell because of improper operation of the low-battery alarm, and another fell because of problems with the transmitting coil and cable. None of these incidents resulted in any injury, and all except the low-battery alarm were unreported until the survey was conducted. In response to this information and user feedback, the ECU software was modified to ensure proper charging, battery status display, and user safety. All units were recalled from all participants to implement the upgrade. Additionally, the transmitting coil and connector have been reexamined and detailed operating instructions have been updated to minimize any risk associated with those components. No further incidences of these modes of failure have occurred after the aforementioned modifications.

These results represent a “snapshot” of user perceptions at a single moment in time at least 12 months postimplant for a small group of system recipients. Further

study is required to investigate how the opinions of neuroprosthesis users might change over time with increasing age and experience with the system, and increased confidence in the results can be obtained by expanding the sample size.

CONCLUSIONS

The study indicates that the CWRU/VA standing neuroprosthesis is a safe and effective way for individuals with low-cervical and high-thoracic SCIs to exercise, stand, and transfer. Among the 11 participants interviewed with 12 months or more experience with the neuroprosthesis, 9 were still using it regularly for standing and/or exercising at the time of the survey. Seven participants were using it at least four times a week and two were using it at least two to three times a week for exercise. Seven participants were using it for standing at least two to three times a week. The participants felt that standing helped them to transfer, be at eye level with others, improve circulation, and move into wheelchair inaccessible spaces. The maximal elapsed standing times varied among individuals but were clinically acceptable, functionally relevant, and sufficient to accomplish personal goals.

"Motivation" and "exercise" were identified by the participants as the most important factors for gaining maximum benefit from the system. All the respondents felt that the neuroprosthesis had both therapeutic and functional impact and noted improvement in overall health since using the neuroprosthesis. Perceived health benefits included improved circulation, reduced risk of osteoporosis, increased bone density, less postural problems, stronger muscles, and prevention of muscle atrophy. All respondents reported a decreased frequency of spasms in the leg muscles, although this may be accompanied by an increase in spasm strength. Decreased frequency of UTIs and decreased incidence of pressure sores because of system use were also reported. No incidents of deep-vein thrombosis, infection, cellulitis, or electrical burns because of the neuroprosthesis were reported. All respondents expressed satisfaction with the neuroprosthesis. They uniformly reported that their expectations were met and would repeat the surgery and the rehabilitation program to obtain similar clinical outcomes. All the participants found the system to be safe, reliable, and easy to use.

While user satisfaction is high, many improvements in the system remain to be implemented, including accessing and controlling additional muscles for standing balance and stability and reducing intersubject variability in standing performance. The valuable input from the consumers of this assistive technology will help to improve the design and shortcomings in the existing components and configuration of the system and allow the neuroprosthesis to be applied to a broader segment of the SCI population.

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