Performance of a Surgically Implanted Neuroprosthesis for Standing and Transfers

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Abstract

The purpose of this study was to determine the clinical performance of a surgically implanted neuroprosthesis for exercise, standing and transfers in individuals with low cervical or thoracic spinal cord injury (SCI). Seven adults with long term SCI received the system, consisting of a CWRU/VA implanted receiver-stimulator (IRS-8), 8 epimysial or intramuscular electrodes and a wearable external controller. Stimulated knee extension strength exceeded 30 Nm with sufficient endurance to maintain 50% maximal output after 40 minutes of cyclic contractions. Standing duration varied from subject to subject (2 to 20 minutes) depending on posture and body size, and upper extremity support forces to maintain balance were typically less than 15% of body weight. Subjects were able to perform pivot transfers with the system, and several could release one hand from a walker to retrieve and manipulate objects. Implanted components were reliable, electrode thresholds and stimulated responses were stable and no radiographic abnormalities or adverse reactions were observed. These preliminary results indicate that a surgically implanted neuroprosthesis for standing and transfers can be safe and effective in reducing the impairment associated with SCI. Multicenter clinical trials are underway.

1. Introduction

Standing and stepping with functional neuromuscular stimulation (FNS) has been achieved with relatively simple systems of surface stimulation in both laboratory and clinical settings [1,2,3]. Lower extremity neuroprostheses employing intramuscular electrodes with percutaneous leads have also been successful in providing functions such as standing, stepping, and stair climbing to individuals with paraplegia [4]. More recently, initial tests of several totally implanted neuroprostheses for standing or stepping with selected subjects have been reported, including systems based on a modified cochlear implant[5], or an implant to activate the lumbosacral spinal roots [6].

Implanted systems for standing have been undergoing successful clinical testing since 1992 in our laboratory [7,8]. Components of a neuroprosthesis for standing currently undergoing clinical evaluation are illustrated schematically in **Figure 1**. The implanted standing system consists of an eight-channel receiver-stimulator [9], and epimysial [10] and surgically-implanted intramuscular [11] electrodes which are surgically installed in the knee, hip and trunk extensor muscles. The implanted components are controlled and powered by a wearable external controller which is programmed via a clinical interface suitable for use by non-technical personnel. This paper reports on the clinical results of a Phase I trial of this implanted neuroprosthesis.

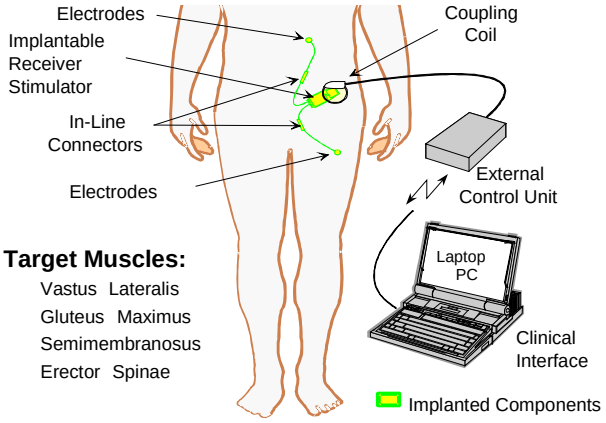

Figure 1: Schematic representation of the CWRU/VA implanted standing neuroprosthesis.

2. Methods

Subjects were recruited for the study from the patient databases of Northeast Ohio Regional Spinal Cord Injury Center at MetroHealth Medical Center and the Louis Stokes Cleveland Department of Veterans Affairs Medical Center, Cleveland Ohio. Inclusion criteria required a) neurologically stable lesions at least 12 months post-injury, b) skeletal maturity (age > 18 years), c) absence of chronic skin, orthopaedic or neurological conditions, d) near normal range of motion, e) lack of seizure disorders

or other contraindications to stimulation or implant surgery, and f) ability to comply with follow-up procedures. Baseline ASIA Sensory and Motor Evaluations were performed at enrollment. Once informed consent was obtained, a pre-operative period of preparatory exercise with surface stimulation was required to assess tolerance and recondition the atrophied lower extremity muscles. Baseline radiographs of the hips, knees and ankles were taken to determine pre-stimulation joint status, and standardized instruments to assess general diability (the Sickness Impact Profile) and perceived health status (Medical Outcome Survey-36) were applied.

In a single operative procedure, epimysial electrodes were implanted bilaterally into the vastus lateralis, semimembranosus (or alternatively, the posterior portion of adductor magnus) and gluteus maximus muscles, and intramuscular electrodes were inserted at L1/L2 to activate the motor roots innervating the lumbar erector spinae. After a period of bedrest and restricted activity to promote healing, an 8-week program of progressive resistance and endurance exercise with the implanted system was initiated. Recruitment properties (stimulus thresholds and values at which spillover or reflex activation occurred) were monitored throughout.

Upon completion of strength and endurance training, patterns of stimulation were constructed for the sit-to-stand and stand-to-sit transitions and a 2 to 3 month period of rehabilitation was initiated. System users progressed from standing in parallel bars to independent standing in a walker, to standing pivot transfers to surfaces higher or lower than their wheelchairs, to swing-through gait. Balance training included stand-to-retrieve tasks and releasing a hand to manipulate the controls of the external control unit.

Subjects were discharged to home for unsupervised use of the system, and returned for follow-up evaluations at 3, 6 and 12 months post-discharge.

System reliability was assessed through repeated measurement of recruitment properties, surface potentials and radiographs of the implanted material. Strength and endurance of the stimulated contractions were measured with a Biodex Pro System 3 dynamometer. Strength was assessed isometrically throughout the range of motion for the hip extensors, and isokinetically for the knee extensors. Endurance of the knee extensors was indicated by the ratio of peak moment after 40 minutes of cyclic isokinetic contractions (1 sec. ON, 3 sec OFF) to initial values. The effects of exercise and standing on tissue viability and the risk for pressure sore development were assessed via transcutaneous oxygen (T_cPO_2) measurements and seated pressure distributions before and after the exercise phase. A formal questionnaire was also administered to determine the effects of the system on the perceived incidence of pressure sores, urinary tract infections, and frequency/severity of spasms.

Functional performance was measured in terms of elapsed standing duration and the percentage of body weight placed on the legs. Standardized assessments of effort and assistance required for standing transfers (the Functional Performance Measure), as well as user and assistant preference for conventional or FNS-assisted transfers (the Usability Scale) were also applied. System use was recorded by the external control unit and downloaded for analysis at each follow-up interval.

3. Results

Since 1996, a total of 7 subjects with long term SCI (avg. 3.8 years) received the implanted neuroprosthesis. Characteristics of the study cohort are summarized in **Table 1**. Subjects ranged in age from 27 to 47 years (avg. 34) at time of implant. Five subjects presented with thoracic injuries (T4 to T9) resulting in complete motor and sensory deficits (ASIA Classification A), and two subjects had incomplete low cervical lesions with some preserved sensation (ASIA B) or minor motor sparing insufficient for functional movement (ASIAC). Surgical installation in all cases was completed without incident and resulted in minimal blood loss with no subsequent clinical complications. Subjects 1-3 have completed long-term follow-up. Subjects 4-7 are still in various stages of rehabilitation and are scheduled for long term follow-up.

Subject	Sex	Height (cm)	Weight (kg)	Injury Level	ASIA Class*	Months Post Injury
1	M	183	82	C6	C	83
2	M	188	114	T4	A	46
3	M	165	50	T9	A	27
4	M	175	92	T6	A	93
5	M	162	76	T8	A	33
6	F	168	57	C7	B	20
7	M	173	86	T6	A	15

* - American Spinal Injury Association Classification

Table 1: Characteristics of neuroprosthesis recipients.

System reliability: All implanted stimulators, leads and in-lead connectors are fully operational in all subjects and follow-up intervals. Stimulus thresholds were stable in 43 out of 46 implanted epimysial electrodes, representing 93.5% reliability. A total of three epimysial electrodes in two subjects early in the series (Subjects 2 & 3) showed elevated thresholds 6 to 18 months post-implant and other behaviors consistent with discontinuities between the stimulating disk and lead. All such devices were implanted in the posterior muscles (gluteus maximus or posterior adductor), suggesting that body weight and shear during sitting or sliding transfers may have

contributed to the failures. Similar instances have not occurred in later subjects, indicating that improved surgical techniques or manufacturing practices may have increased reliability. Failed electrodes were successfully replaced and continue to be operational. Intramuscular electrodes in the erector spinae have been 100% reliable.

Strength and endurance: After completing the program of reconditioning exercise, total motor scores with stimulation were 15 to 21% greater than without FNS, as illustrated in **Table 2**. Subjects who completed the exercise protocols were able to stand for sufficient lengths of time to complete various activities ranging from standing transfers to working at a counter or retrieving objects from shelves. The amount of practice and training, body size, hip and trunk extensor strength, and quadriceps endurance appear to be important influences on standing duration. Measures of strength and endurance are summarized in **Figure 2**. Mean isokinetic knee extension moments produced by epimysial electrodes in the vastus lateralis exceeded 35 Nm, and mean isometric hip extension moments generated by the gluteus maximus and hamstrings approached 20 Nm each and appear to be additive when stimulated simultaneously. Mean strengths of these muscle groups are adequate for standing function. The vastus lateralis exhibited good fatigue resistance after exercise with the neuroprosthesis. High endurance (fatigue ratios > 0.75) generally coincide with better performance in terms of standing duration.

Subject	ASIA Motor Score w/o FNS	With FNS	% Increase	Standing Duration (min)
1	45	52	15.6	unavailable
2	50	59	18.0	< 3*
3	50	59	18.0	> 20
4	50	60	20.0	≈ 5**
5	51	61	19.6	> 15
6	43	52	20.9	> 10
7	50	58	16.0	≈ 1**

* Limited by weight/size, hip extension strength, VL endurance
** Max times unavailable; subjects still in rehabilitation phase

Table 2: ASIA Motor Scores and elapsed standing times

Clinical benefits: Tissue oxygen levels in the ischial region under both unloaded (side-lying) and loaded (seated) conditions improved significantly with stimulation. After completing the conditioning regime, neuroprosthesis users demonstrated a mean increase in T_cPO_2 of approximately 15%. The effects of alternating left/right gluteal stimulation with subjects seated in their wheelchairs resulted in cyclic variations in mean ischial region interface pressures. Regular use of the neuroprosthesis can lead to increased blood flow in loaded tissues and variations in seated pressures to minimize the risk of local tissue breakdown. Neuroprosthesis users also reported a decrease in the frequency of spasms, although severity of spasms tended to increase. No degenerative changes to the insensate ankle, knee, hip or vertebral joints have been noted on x-ray after use of the neuroprosthesis.

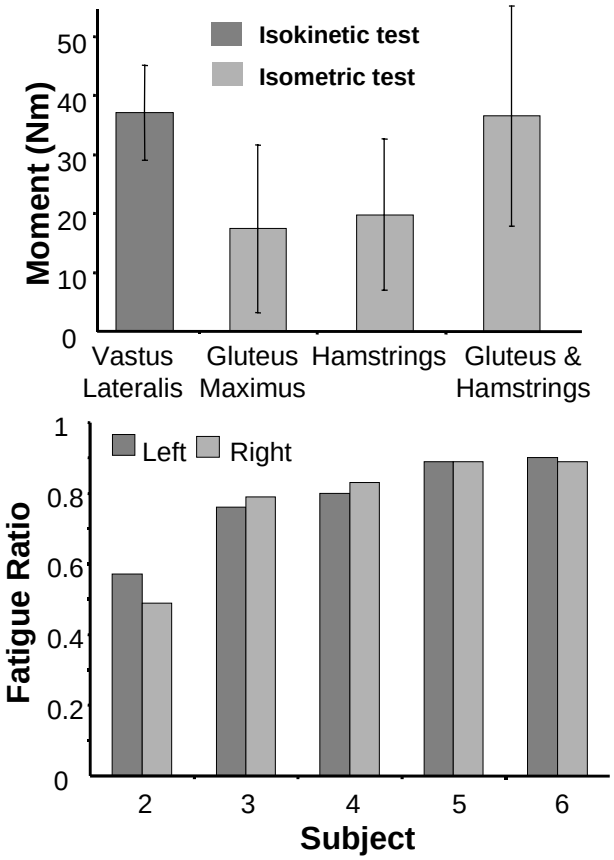

Figure 2: Summary of knee and hip strength and endurance. Top: Mean extension moments generated with electrical stimulation; Bottom: Individual fatigue ratios (peak final to initial knee extension moment during 40 minutes cyclic contractions)

Standing performance: The distribution of body weight supported by the upper and lower extremities while standing with the neuroprosthesis is illustrated in **Figure 3**. Most subjects were able to stand with little upper extremity effort while stimulated contractions of the knee, hip and trunk extensors prevented collapse. In 4 out of 6 cases, balance was maintained through light touch on a support surface typically less than 10% of body weight). All but the earliest subjects were able to release one hand intermittently from a walker or other assistive device, and all but one were able to perform standing transfers with the neuroprosthesis. Users and their assistants reported a preference for FNS-assisted transfers over conventional methods when moving to and from high surfaces. Transfers to heights impossible to perform by conventional lifting transfers required moderate effort or assistance with the neuroprosthesis.

Long-term satisfaction and usage: To date only three subjects have completed the one-year long-term follow-up schedule. Usage logs and formal questionnaires

will be analyzed to determine quantitatively the clinical performance of the system once additional subjects have completed the evaluation protocol. Initial qualitative data indicate that users are satisfied with the system and derive an improved sense of well being and perception of general health from it. Implant recipients appear to value the ability to exercise with the neuroprosthesis and utilize it regularly at home to stand or perform other exercises. No instances of decubitus ulcers or urinary tract infections have been reported during follow-up intervals.

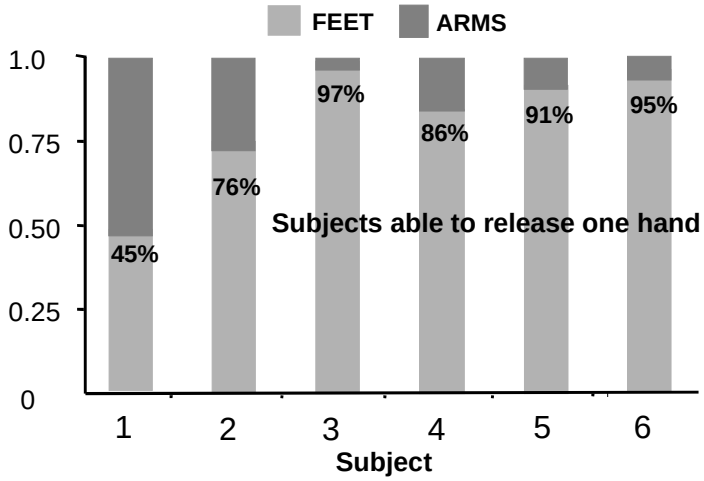

Figure 3: Distribution of mean vertical support forces during quiet standing with the neuroprosthesis. Data are unavailable for Subject 7 who is still in the rehabilitation phase of the protocol.

3. Conclusions

These data indicate that the implanted components of the neuroprosthesis are reliable and suitable for long-term clinical use. Performance of epimysial electrodes in terms of stimulated strength and endurance is reproducible and sufficient for function in the muscles selected for implantation. Exercise with the neuroprosthesis results in demonstrable improvements in strength and endurance over non-FNS baselines, and health benefits in terms of tissue viability, seated pressure distribution and frequency/severity of spasms appear to accrue from system use. Standing can be repeatedly achieved with 85% or more of body weight supported by the lower extremities, and a majority of system users are able to release one hand to manipulate the system controls or other objects.

This preliminary clinical trial of an implanted lower extremity neuroprostheses for standing clearly indicates that continuous open-loop stimulation of the trunk, hip and knee extensors can allow people with paraplegia or low tetraplegia to exercise, perform standing transfers and overcome physical obstacles. In addition, users of the implanted standing neuroprosthesis can exert a greater control over their environment through the ability provided by the system to reach and manipulate objects that are otherwise inaccessible from the wheelchair.

The implanted neuroprosthesis is reliable, results are repeatable, and surgical techniques as well as post-operative rehabilitation methods are teachable and therefore suitable for further evaluation in multicenter trials. The system appears to be well accepted and positively impacts overall health while providing options for transfers or other maneuvers that would otherwise be difficult or impossible without significant personal assistance or extensive bracing.

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