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Preliminary Evaluation of a Neural Prosthesis for Standing after Spinal Cord Injury with Four Contact Nerve-Cuff Electrodes for Quadriceps Stimulation

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Abstract—**This study describes the preliminary performance of an implanted neuroprosthesis for standing and transfers after spinal cord injury. The system is a 16-channel version of the 8-channel Case Western Reserve University/Veteran Affairs (CWRU/VA) standing/transfer neural prosthesis. It includes bilateral four channel femoral nerve cuff electrodes for stimulation of the vastii to provide knee extension. To date, the prosthesis has been implanted in one subject who was previously a user of the original 8-channel CWRU/VA system. In the first four months after implantation of the new neuroprosthesis, this subject has been able to stand for approximately 2.5 minutes with up to 86% of total body weight supported by the lower extremities. These values far exceed the stand time (approximately 1 minute) and body weight distributions (55% on the legs) for the same subject when using the 8-channel system four months after implantation. The nerve cuff electrodes have been stable over the four months since implantation, with little change in stimulation threshold and saturation values, which suggests that there have been no biological effects on the electrodes. These results suggest that the second generation 16-channel neuroprosthesis with nerve-cuff electrodes will provide stronger knee extension moments over a longer duration before fatigue during standing and transfers.**

I. Introduction

There are nearly 200,000 people in the United States with spinal cord injury (SCI), and of those more than half need assistance with activities of daily living [1]-[4]. Paralysis as a result of SCI causes impaired mobility and secondary health complications such as pressure sores, muscle atrophy, and urinary tract infections that can require frequent, costly medical care and hospitalization.

Functional neuromuscular stimulation (FNS) is an intervention which has been shown to restore motor function and mobility after SCI and reduce secondary health complications by electrically stimulating intact motoneurons below the level of injury [5],[6]. In patients with lower level SCI that maintain upper extremity function, FNS has been employed to return standing and transfer function using an 8-channel Case Western Reserve University/Veteran Affairs (CWRU/VA) implanted stimulator with muscle-based (epimysial and intramuscular) electrodes [7]-[9].

To date, the CWRU/VA standing/transfer system has been implanted in 15 subjects with varying degrees of success [10]. In shorter and lighter subjects, maximum stand times have been recorded up to two hours, while, in subjects in excess of 1.7 m tall or 80 kg body weight, maximum stand times have been lower than five minutes. Furthermore, when smaller subjects stand between parallel bars, they are able to distribute up to 95% body weight (%BW) on their legs, while heavier subjects can distribute only 50 to 90 %BW on their legs. Maximum stand time and %BW on the legs are most often limited by insufficient hip or knee extension moment as a result of fatigued or weak hamstring or quadriceps muscles. One reason for the relatively short stand time before quadriceps fatigue in larger individuals is that the epimysial electrodes used in the CWRU/VA system only recruit muscle fibers of the vastus lateralis innervated by nerves near the implanted electrode, so the recruited muscle fiber population is smaller than the total fiber population in the muscle [7]. To combat this problem, in the next generation standing system, a 16-channel stimulator and four contact nerve-cuff electrodes around bilateral femoral nerves are intended to more completely recruit the quadriceps muscles to increase knee extension moment and maximum stand time before fatigue.

In this paper, initial maximum stand time and %BW distribution results are presented for a subject originally implanted in 1999 with an 8-channel CWRU/VA standing/transfer system who had a recent revision to a 16-channel system with bilateral femoral nerve-cuffs. The stability and muscle recruitment properties of the nerve-cuff electrodes are also evaluated.

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II. Methods

A. Implanted Stimulator and Nerve-Cuff Electrodes

The 16-channel implantable stimulator-telemeter (IST-16) was used in this study (Fig. 1a) along with two self-sizing four contact spiral nerve-cuff electrodes (Fig. 1b,c). The IST-16 was connected with epimysial and intramuscular electrodes to the standard muscle set previously used in the CWRU/VA 8-channel implantable receiver-stimulator (IRS-8) standing/transfer system which provides two channels of stimulation to bilateral erector spinae for back extension, two channels to bilateral semimembranosus for hip extension, and two channels to bilateral gluteus maximus for hip extension and abduction [7],[8]. In the new system, two more channels were used to stimulate the long head of bilateral posterior adductors for additional hip extension, and the remaining eight channels were connected to the bilateral four contact femoral nerve-cuff electrodes to provide knee extension (Fig. 2). The nerve-cuff electrodes replaced epimysial electrodes on bilateral vastus lateralis which provided knee extension in the CWRU/VA IRS-8 system. As best as it was possible to determine intraoperatively, the cuffs were placed on the femoral nerves such that they were distal to branches for rectus femoris and sartorius, both of which provide unwanted hip flexion, but proximal to the branches for vastus lateralis, medialis, and intermedius which provide knee extension without hip flexion.

B. Subject Selection

The IST-16 and bilateral nerve-cuffs were implanted in one male volunteer (age: 53, 7 years post-injury) with motor-complete SCI (T6 level injury). The subject was ideal for the current study because he previously participated in a study with the CWRU/VA IRS-8 standing/transfer system, so a direct comparison of the performance of the two systems could be made for this subject, rather than a comparison across subjects. The subject was also one of the larger participants from the first study (height: 1.73 m, weight: 86.2 kg) who had insufficient knee extension to remain standing for long periods of time; during the systems peak performance the maximum recorded stand time with the IRS-8 for this subject was 4.5 minutes (at approximately two years post-implantation), and %BW on the legs was 95% (3 years post-implantation).

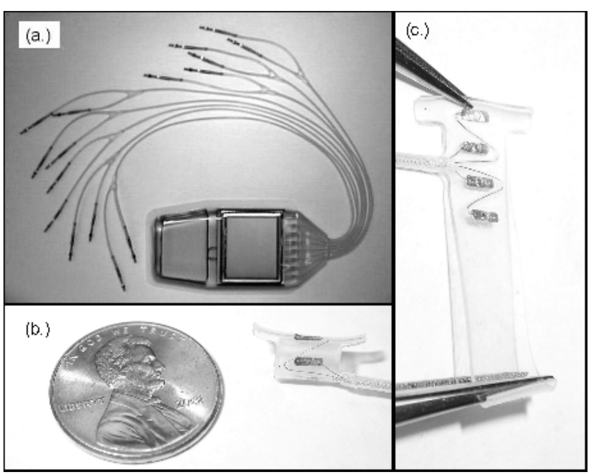

Fig. 1. (a) The IST-16 stimulator which was implanted in a subject with SCI to restore standing function. (b) A self-sizing four contact spiral nerve-cuff electrode used on bilateral femoral nerves in this study to stimulate the quadriceps muscles for knee extension. (c) The unspiraled nerve-cuff. All four contacts and the lead wire are visible.

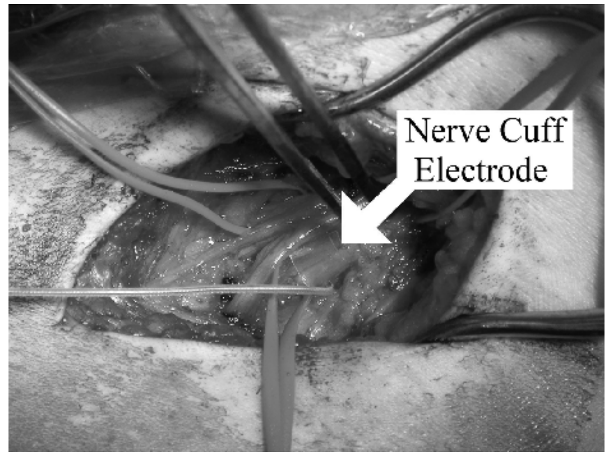

Fig. 2. A spiral nerve-cuff around the femoral nerve. The cuff is placed distal to nerve branches that innervate rectus femoris and sartorius, but proximal to branches that innervate the vastii.

Before the implantation of the IST-16 standing system, this subject's IRS-8 system was not functioning properly for over a year. Because of this long period without the full function of the FNS system, it is likely that much of the benefit the subject originally gained using the IRS-8 system, such as increased muscle mass and reduced muscle fatigability, would have been lost in the interim. Therefore, we believe that it was possible to make a fair side-by-side comparison of the performance of the two systems at specific intervals post-implantation.

C. Evaluation of Nerve-Cuff Stability

At periodic intervals after implantation (6 and 14 weeks), stimulation parameters were tailored to the subject in order to promote the most complete recruitment of desired muscle fibers while avoiding stimulation spillover to antagonist muscles and overstimulation of agonist muscles which might cause decreased contraction time before fatigue. For each contact in the nerve-cuff, stimulation parameters including current amplitude and pulse width were varied during stimulation at a frequency of 20 Hz while a physical therapist performed a manual muscle test. With the subject laying supine, threshold and saturation pulse widths were determined for each of three current amplitudes (0.8, 1.4, and 2.1 mA). Threshold was defined as the minimum pulse width which generated a visible muscle contraction and saturation was defined as the minimum pulse width that generated a maximum muscle contraction but did not result in spillover to undesired muscles. Spillover to rectus femoris and sartorius was determined by palpation of their tendons at the hip. Threshold and saturation values were compared over time.

D. Maximum Stand Time and %BW Distribution

After 14 weeks of a daily rehabilitative exercise regime, the subject's muscle strength was sufficient for standing. For the sit-to-stand transition, all electrode contacts were ramped up to saturation and then maintained at the saturation current amplitude and pulse width for the duration of the stand. Stand times were measured with a stopwatch from the beginning of the sit-to-stand transition to the beginning of the stand-to-sit transition. %BW distribution was measured with the subject standing on two force plates (AMTI, Watertown, MA) with his hands on a set of instrumented parallel bars (JR3, Woodland, CA).

III. Results

A. Nerve-Cuff Stability and Stimulation Parameters

For all four contacts on both left and right nerve-cuffs, threshold and saturation data at 6 and 14 weeks post-implantation are shown in Fig. 3. It is important to note that all four contacts were not used in the standing system because it was found that contact 2 on the left side and contacts 3 and 4 on the right side recruited rectus femoris or sartorius and could cause hip flexion during standing. These contacts were therefore also not included in the daily rehabilitative exercise regime.

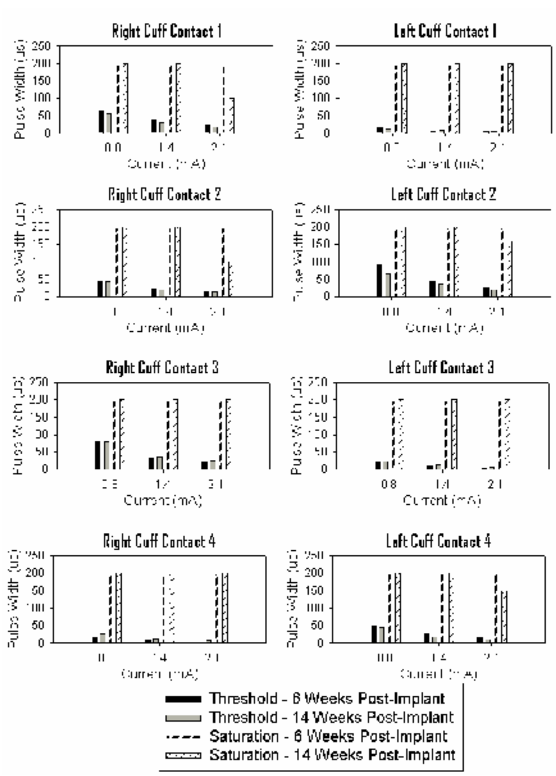

Fig. 3. Threshold and saturation pulse width values for various current amplitudes on all four contacts of both left and right nerve-cuff electrodes.

TABLE I
STIMULATION PARAMETERS USED DURING STANDING

Contact #	Current Amplitude (mA)	Pulse Width (µs)
Left 1	2.1	200
Left 3	2.1	200
Left 4	1.4	200
Right 1	2.1	100
Right 2	2.1	100

Note that left contact 2 and right contacts 3 and 4 were not used during standing because they recruit rectus femoris and/or sartorius.

Based on the week 14 saturation values, the stimulation parameters in Table 1 were used during standing. Stimulation during standing was applied at 16 Hz on all contacts.

B. Maximum Stand Time and %BW Distribution

Displayed in Fig. 4 are maximum stand time and %BW distribution on the legs at four months post-implantation. Also shown are the same data for this subject at four months post-implantation with the IRS-8 system and epimysial electrodes. At four months post-implantation with the IRS-8 system and epimysial electrodes, maximum stand time was approximately 1 minute and %BW on the legs was 55%. With the IST-16 system and nerve-cuff electrodes, maximum stand time at four months post-implantation was approximately 2.5 minutes and %BW supported by the legs was 86%.

IV. Discussion

Based on initial data presented here, the nerve-cuff electrodes and IST-16 implanted stimulator appear to be performing well. The nerve-cuff threshold and saturation pulse width values stayed constant and stable over the first three months after implantation, and for all contacts there was a large difference between threshold and saturation pulse widths. In terms of control of the neural prosthesis, this is highly advantageous, because it means that these electrode contacts have a large dynamic pulse width range over which stimulation can be varied. A large dynamic range is important because it allows for precise tuning of stimulation to produce graded muscle forces and joint moments.

As compared to the IRS-8 system and epimysial electrodes, the IST-16 system and nerve-cuff electrodes are initially performing favorably. Maximum stand times at four months post-implantation with the nerve-cuffs far exceed those recorded at a similar time interval after implantation of epimysial electrodes. Also, during standing with the nerve-cuffs, the subject is able to support far more of his body weight on his legs, which suggests that he is able to maintain a more upright posture on more rigidly locked knees than he could with epimysial electrodes and the IRS-8 system.

While the stand time and %BW values collected four months after implantation of the nerve-cuffs are much improved over the values from four months after implantation with epimysial electrodes, they are still

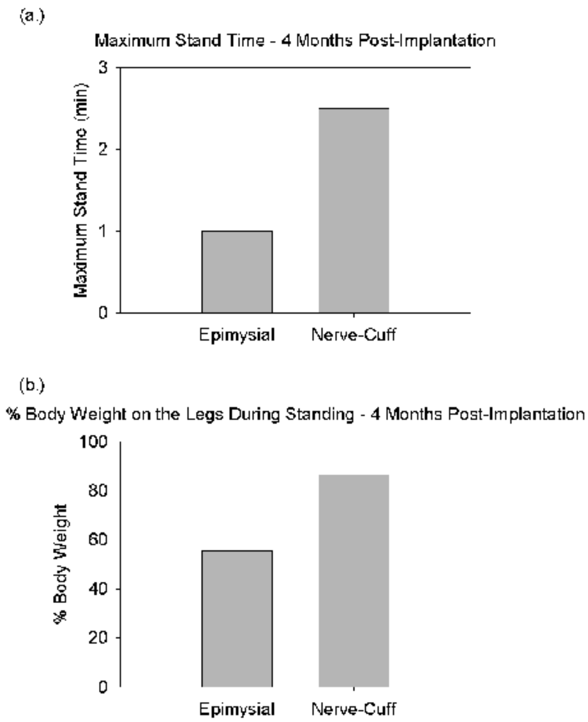

Fig. 4. (a.) Maximum stand time and (b.) %BW on the legs at four months post-implantation. Data are shown for both the IRS-8 standing system with epimysial electrodes on vastus lateralis and the IST-16 standing system with nerve-cuff electrodes on femoral nerves.

significantly less than desired. Currently, during standing, the subject's quadriceps muscles are able to maintain sufficient moments to lock the knees throughout standing, but stand times and body weight distributed over the legs are limited by upper extremity fatigue. The subject's standing posture is often marked by abnormal hip flexion which causes him to support extra weight on his arms to maintain balance. This excess hip flexion is likely a combination of insufficient hip extension moment and a lack of practice with the new system. Over time, hip extension moment will likely improve as a result of training and exercise, and posture will continue to improve as the subject practices with the system, thereby extending maximum stand times and increasing %BW supported on the legs during standing.

V. Conclusion

By stimulating the femoral nerve it should be possible to more completely recruit the knee extension muscle than by stimulating directly stimulating on the muscle bellies of the quadriceps. This more extensive recruitment of the quadriceps allows the subject to support more body weight on the legs for a longer period of time before fatigue. We have shown that, within the first four months after implantation of a 16-channel neural prosthesis and four contact cuff electrodes around the femoral nerves, a subject can support a larger %BW on his legs for a longer stand duration before fatigue than he could previously at four months after implantation with an 8-channel neural prosthesis and epimysial electrodes.

In the future, we intend to continue testing the stability of these electrodes, as well as to continue monitoring stand times and %BW supported by the legs. We expect to see further improvements in both of these metrics as the knee and hip extensors continue to strengthen and gain more fatigue resistance.

Further work with the nerve cuffs will involve selectively stimulating individual fascicles within the femoral nerve to recruit separate muscle populations with each of the four cuff contacts. By separating out individual fiber populations within the muscle, it may be possible to stimulate some fibers to produce knee extension while other fibers rest, so that the effects of fatigue will be further reduced, allowing for even longer stand times.

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