Clinical Results from Implanted FNS Systems for Mobility after Spinal Cord Injury

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ABSTRACT
The purpose of this report is to describe the clinical outcome from implanting FNS systems for standing and walking mobility in individuals with low cervical or thoracic level spinal cord injuries. Case histories of two implant recipients are reviewed in terms of electrode performance, exercise and functional use of the 8- and 16-channel systems. Both subjects were able to exercise and stand repeatedly with the implanted systems. Stepping was successfully accomplished with the 16-channel system. Although spillover and position dependence have been observed in several instances, the responses of the epimysial electrodes are stable and adequate for functional activities. Assessment of functional use and long-term follow-up of system performance is currently in progress.

I. INTRODUCTION
This paper reports on the preliminary clinical results from the use of the surgically installed CWRU/VA 8-channel receiver-stimulator (IRS-8) for lower extremity mobility in individuals with spinal cord injuries. Previously, lower extremity functions have been demonstrated the laboratory with chronically in-dwelling percutaneous intramuscular (IM) electrodes or multi-channel implants designed for other CNS applications [1]. This study attempts to quantify the initial clinical outcome of systems for standing, stepping and simple household mobility based on readily available, general purpose implantable technology developed specifically for neuromuscular stimulation in the extremities.

II. METHODS
FNS systems based on the IRS-8 and epimysial electrodes [2] were installed surgically in two volunteers. One individual with incomplete tetraplegia was given an 8-channel system for standing and to facilitate standing transfers. Short distance walking was attempted in another volunteer with complete paraplegia via a 16-channel system consisting of two 8-channel implants.

After one week of bedrest post-implantation and three weeks of limited activity to promote electrode encapsulation, subjects began rehabilitation with FNS. Threshold and maximal stimulus values for selective activation of the target muscles were determined, and initial exercise patterns were developed. The intensities and durations of the exercise programs were progressively increased over the next 6 to 8 weeks to recondition the paralyzed musculature.

Coordination patterns were then specified for functional activities. Performance was monitored in terms of system integrity, operation of implanted components, stimulated isometric and isokinetic strength of the epimysial electrodes. Clinical measures of independence, home use and functional ability with the systems are currently under development.

III. RESULTS
Both subjects tolerated the implantation procedure well, recovered from the surgeries without incident, and achieved their functional goals after completing rehabilitation with FNS. All implanted components are functioning within specifications as evidenced by surface potential and coupling power measurements. Stimulus thresholds stabilized after implantation, although several electrodes exhibited position dependence or spillover to adjacent muscles. Results for each case study are summarized below.

Case 1: Subject LH (C7 incomplete) received an 8-channel standing system utilizing IM electrodes in June of 1992 [3]. He demonstrated the ability to stand and perform standing transfers and reported using the system regularly for exercise at home. Although the implanted electronics remained operational, system performance degraded slowly over time as the IM electrodes moved or broke with rotation of the IRS-8 in its subcutaneous pocket. In September of 1996 he underwent a revision of the system in which the non-functional electrodes were replaced with epimysial devices and a new IRS-8 was sutured to the abdominal fascia. He returned as an outpatient to test the stimulated responses of the new system and update the patterns of electrical stimulation for exercise. In April of 1997, Subject LH stood with the newly implanted system for the first time. The new system remains fully operational at 9 months post-implant, and the epimysial electrodes are providing strong contractions adequate for exercise and standing. LH is again utilizing the system for exercise regularly at home.
The isometric hip extension moments produced by the new epimysial electrodes in the gluteus maximus and posterior portion of the adductor magnus are illustrated in Figure 1. These responses exhibit stable, moderate thresholds that appear to be repeatable from day to day and consistent with other reports in the literature [4].

Case 2: Subject AS (T10 complete) had the 16-channel dual-implant system installed in November of 1996. Stimulated responses after 8 weeks of exercise showed evidence of significant strengthening, although dependence on hip position was observed in the quadriceps electrodes. This is illustrated in Figure 2, and is most likely due to changes in the spatial relationship of the epimysial electrodes to the femoral nerve because of their medial location in the femoral triangle. These electrodes recruit sartorius and rectus femoris at increased pulse durations, which has not compromised standing performance. This may be avoided in the future with a more lateral location to selectively recruit the vastus lateralis.

Although individual hip flexors (sartorius and TFL) are relatively weak, the erector spinae electrodes activate iliopsoas at higher levels of stimulation. This recruitment pattern was used to assist with hip flexion in his functional stepping patterns. Training with the system for standing and stepping were initiated in March of 1997. In May of that year, he demonstrated the ability to step distances of over 20 feet without stopping in the parallel bars. AS is exercising at home and continues gait training in preparation for functional use of the system outside of the laboratory.

IV. CONCLUSIONS

In both cases, the implanted systems have been successful in providing a means to exercise and stand at home with FNS. Stepping has been achieved in the laboratory with the 16-channel system. Performance of epimysial electrodes and all implanted electronics appears to be suitable for long-term clinical use. Although further effort is needed to optimize the implantation, exercise and training procedures, these systems seem adequate for immediate use. Current efforts are directed toward quantifying functional utility of the systems in the home environment, and preparation of initial small-scale clinical trials.

V. REFERENCES


VI. ACKNOWLEDGMENTS

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