Introduction

As evidence of the effectiveness of functional electrical stimulation (FES) for different applications continues to emerge for the population with spinal cord injury (SCI), there will be increased demand for a single FES device that can efficiently provide multiple functions. Multi-functional FES devices may decrease the amount of implanted material, reduce surgical time and the number of surgical procedures and allow for easy co-ordination between stimulated functions. The Praxis FES System (Neopraxis Pty Ltd, Lane Cove, NSW, Australia) was developed due to the desire to provide a safe, multifunctional FES system that could be used by people with paraplegia outside of the laboratory environment. Research with an earlier generation of the device demonstrated improved upright mobility and bladder management [1].

The aim of the current study at Shriners Hospitals for Children, Philadelphia is to determine the ability of the Praxis FES System to provide standing and stepping function and improved bladder and bowel management for individuals with motor complete thoracic level spinal cord injuries. This paper focuses on the bladder/bowel component of the system.

Methods

Two adolescent males with paraplegia, aged 18 and 21, have undergone surgical implantation of the Praxis FES System. The bladder/bowel component consists of a stimulator implanted in the lower chest and connected to four electrodes placed near sacral nerve roots (S2, S3, S4) and the conus medullaris. The available stimulation parameters are 0.2-8.3mA amplitude, 25-600µsec pulse duration, and 2-500Hz pulse frequency per channel. Stimulation patterns are delivered to the implanted stimulator using a hand held pocket personal computer that communicates with the internal stimulator via a transmit coil placed on the skin.

Urodynamic studies were conducted post-surgically to assess the acute effects of stimulation on bladder and bowel response. Two aspects of bladder management were investigated: the ability of stimulation 1) to modulate spontaneous bladder contractions and 2) to induce bladder contractions and relax the external urethral sphincter. For bowel management, we studied the ability of stimulation to improve bowel motility by causing smooth muscle contractions in the distal colon.

Bladder management testing - Neuromodulation

In the modulation tests, the bladder was filled at a rate of 30ml per minute. Instrumented catheters in the bladder and rectum measured vesicle and abdominal pressures, respectively. Stimulation was initiated at the onset of spontaneous bladder contractions and reductions in bladder pressure were noted. Stimulation location and stimulation parameters were varied to optimize response.

The results of the acute modulation tests provided the basis for a multi-week study to assess the effect of chronic stimulation on bladder continence. Four conditions were considered:
1) On medication – This was the typical, pre-implant bladder regimen: using anti-cholinergic medication (Ditropan), 5 mg tid, no electrical stimulation, data collected for 7 days;
2) Off medication – Assess bladder management without the use of either medication or stimulation, evaluation initiated four days after medication discontinued, data collected for 7 days;
3) On “continuous” neuromodulation – Stimulate whenever possible, approximately 18 hours per day, data collected for 5 days;
4) On “overnight” neuromodulation – Stimulate only overnight, approximately 7 hours per day, data collected for 9 days.

The patient catheterized on an “as needed” basis and recorded the time of day and the volume voided. Efficacy for each of the four conditions was based on maximizing the average time between successive catheterizations and minimizing the frequency of incontinence and dysreflexive responses.

**Bladder management testing - Voiding**
These studies assessed the ability of electrical stimulation to address two key components of voiding – inducing contractions of the bladder and reducing resistance pressure in the urethral sphincter. In tests to stimulate bladder contractions, approximately 250ml of normal saline were infused into the bladder prior to the onset of stimulation. Instrumented catheters variously measured vesicle, external urethral sphincter, rectal, and anal sphincter pressures. Detrusor pressure was calculated as the difference between vesicle and abdominal pressures. Efficacy was based on an ability to maximize detrusor pressure as stimulation parameters were varied.

Low frequency electrical stimulation capable of generating smooth muscle contractions in the bladder also causes contractions of the striated muscle in the external urethral sphincter – a phenomenon known as detrusor/sphincter dyssynergia. The increased resistance offered by the contracted sphincter prevents voiding. Shaker et al. has shown that superimposing a high frequency stimulation pattern can reduce sphincter response [2]. In tests here, we apply three periods of stimulation - low frequency stimulation only, a combination of low and high frequency stimulation, and low frequency stimulation only. The effect on sphincter pressure is measured.

**Bowel management testing**
Acute studies with Subject 2 were first conducted to assess the effect of stimulation on colon and anal sphincter response. Two tandem, balloon catheters placed in the rectum and in the anal sphincter measured local pressures. Stimulation parameters that maximized bowel contractions and minimized anal sphincter resistance in acute tests became part of a multi-week protocol to assess the impact of two stimulation strategies on bowel management. Efficacy of the stimulation protocols was based on a diary kept by the patient wherein he described the quantity of stool passed during each daily session, the time spent, and a numerical “satisfaction” rating.

**Results**

**Bladder management – Neuromodulation**
Multiple neuromodulation studies with Subject 1 demonstrated the ability of stimulation to acutely suppress spontaneous bladder contractions and thereby reduce vesicle pressure. During these studies, stimulation with parameters 2.5mA amplitude, 350µsec pulse width, and 14-50Hz frequency was applied bilaterally to S3. These parameters corresponded to stimulation levels just below that required for motor response in the lower extremities. When initiated following the onset of spontaneous bladder contractions, stimulation caused vesicle pressure to immediately drop to baseline levels.

The results seen in the acute neuromodulation tests provided the basis for a subsequent study with Subject 1 that compared the effectiveness of chronic neuromodulation with alternative bladder management strategies. Four strategies – on anti-cholinergic medication, no medication, “continuous” stimulation, “overnight” stimulation – were considered. Stimulation parameters for both the neuromodulation protocols were S3 bilaterally, 2.5mA,
350µsec, 14Hz. Figure 1 demonstrates that the catheterization schedule with chronic stimulation is comparable to that seen with the use of anti-cholinergic medication.

![Bladder Management - Voiding Times](image1)

![Bladder Management - Voided Volume](image2)

Figure 1. Results of chronic neuromodulation on bladder management

No episodes of incontinence/dysreflexia occurred while Subject 1 was following his “initial” medication protocol, 5 episodes occurred during the “no meds” period, 1 episode during “continuous” stimulation, and 2 episodes during “night” stimulation.

**Bladder management - Voiding**

None of the stimulation studies with Subject 1 or Subject 2 demonstrated an ability to generate significant increases in detrusor pressure. Therefore, stimulation-induced voiding was not achieved in these initial studies.

Tests that measured urethral sphincter response did demonstrate that high frequency excitation can reduce the increase in sphincter pressure caused by low frequency stimulation. This is shown in Figure 2 where sphincter pressure is plotted versus time and stimulation. The initial rise in sphincter pressure corresponds to low frequency stimulation only (20Hz, 350µsec pulse width, 8mA amplitude for 15 seconds). The effect of two periods of combination stimulation [15 seconds of low frequency stimulation, 15 seconds of simultaneous low and high frequency (500Hz, 350µsec, 8mA) stimulation, and 15 seconds of low frequency stimulation] are then plotted. The reduction in sphincter response during simultaneous application of low/high frequency stimulation demonstrates the effect.
**Bowel Management**

Acute testing demonstrated that low frequency electrical stimulation (20Hz, 350µsec, 8mA) of S3 bilaterally in Subject 2 caused a significant increase in both rectal pressure and anal sphincter pressure. A combination of low frequency and high frequency (500Hz, 350µsec, 8mA) stimulation increased rectal and anal sphincter pressures, but to a level less than that caused by low frequency stimulation alone.

Given these results, two electrical stimulation strategies were defined and implemented into a multi-week test protocol. The first approach (Strategy 1) called for use of only low frequency stimulation applied for 30 seconds, then removed for 30 seconds. This on-off strategy was continued for five to ten minutes to facilitate bowel motility. As required, Subject 1 would then digitally stimulate the anus to evacuate fecal material in the rectum. If necessary, this procedure would then be repeated. A second approach (Strategy 2) followed five to ten minutes of low frequency stimulation with five minutes of low/high frequency combination stimulation. The goal was to reduce anal sphincter resistance and facilitate defecation.

The results of both stimulation strategies are summarized in Table 1. The use of electrical stimulation causes a significant increase in bowel management efficacy and satisfaction.

<table>
<thead>
<tr>
<th></th>
<th>Number of days of evaluation</th>
<th>Number of days failed to defecate</th>
<th>Number of days digital stimulation not required for defecation</th>
<th>Average daily time spent</th>
<th>Satisfaction (1-10)</th>
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<tr>
<td>Pre-implant strategy</td>
<td>7</td>
<td>5</td>
<td>0</td>
<td>52 min</td>
<td>5</td>
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<tr>
<td>Stimulation Strategy 1</td>
<td>17</td>
<td>2</td>
<td>3</td>
<td>32 min</td>
<td>6.6</td>
</tr>
<tr>
<td>Stimulation Strategy 2</td>
<td>29</td>
<td>4</td>
<td>2</td>
<td>23 min</td>
<td>6.7</td>
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</tbody>
</table>

Table 1. Effectiveness of stimulation strategies on bowel management

**Discussion**

This paper focused on the ability of the Praxis FES System to improve bladder and bowel management in adolescent patients with spinal cord injury. Two key components of bladder management were studied – restoring reservoir function through neuromodulation and facilitating voiding through stimulation of bladder contractions and urethral sphincter relaxation. Acute studies in Subject 1 suggest that low frequency stimulation of the S3 root bilaterally inhibits spontaneous bladder contractions and facilitates filling. A multi-week study demonstrated that the catheterization schedule with chronic neuromodulation using the Praxis FES System is comparable to that seen when anti-cholinergic medication is used. Work will continue to define stimulation parameters and periods that further improve the neuromodulation effect.

None of the stimulation studies with Subject 1 or Subject 2 demonstrated an ability to generate significant increases in detrusor pressure. It is likely that this finding is the result of poor initial electrode placement and/or post-surgical electrode movement. An improved electrode design that minimizes movement is currently being evaluated. High frequency stimulation was shown to reduce the increase in urethral sphincter response associated with exciting bladder contractions. These results are consistent with those obtained by Abdel-Gawad et al. in his studies with dogs [3]. In our tests, due to an inability to generate bladder pressures, we could not assess whether the drop in sphincter pressure would allow voiding.
Electrical stimulation provided a significant improvement in bowel management, causing an increased frequency of defecation, a decrease in time required for bowel evacuation, and an increase in subject satisfaction with the bowel strategy. Interestingly, the satisfaction scores correlated not with the time required, but with the quantity of fecal material passed.

References