An Implantable Neuroprosthesis for Restoring Bladder and Bowel Control to Patients With Spinal Cord Injuries: A Multicenter Trial

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Objective: To evaluate the safety and efficacy of an implanted neuroprosthesis for management of the neurogenic bladder and bowel in individuals with spinal cord injury (SCI).

Design: Prospective study comparing bladder and bowel control before and at 3, 6, and 12 months after implantation of the neuroprosthesis.

Setting: Six US hospitals specializing in treatment of SCI.

Patients: Twenty-three neurologically stable patients with complete suprasacral SCIs.

Intervention: Implantation of an externally controlled neuroprosthesis for stimulating the sacral nerves and posterior sacral rhizotomy.

Main Outcome Measures: Ability to urinate more than 200mL on demand and a resulting postvoid residual volume of less than 50mL.

Results: At 1-year follow-up, 18 of 21 patients could urinate more than 200mL with the neuroprosthesis, and 15 of 21 had postvoid volumes less than 50mL (median, 15mL). Urinary tract infection, catheter use, reflex incontinence, anticholinergic drug use, and autonomic dysreflexia were substantially reduced. At 1-year follow-up, 15 of 17 patients reduced the time spent with bowel management.

Conclusions: Neural stimulation and posterior rhizotomy is a safe and effective method of bladder and bowel management after suprasacral SCI.

Key Words: Bladder, neurogenic; Electric stimulation; Rehabilitation; Rhizotomy; Spinal cord injuries; Urinary incontinence.

LOSS OF BLADDER CONTROL causes some of the most common complications of spinal cord injury (SCI). Impaired bladder emptying can lead to chronic urinary infection and stone formation. Elevated storage pressure in the bladder may be transmitted to the kidneys and can lead to hydronephrosis and renal damage. Incontinence is common, hindering social rehabilitation and increasing the risk of pressure ulcers. Autonomic dysreflexia is also common and can lead to dangerously high blood pressure. These complications may need to be controlled with frequent administration of anticholinergic drugs and antibiotics, which can be costly and have undesirable side effects.

Conventional bladder management for patients without voluntary bladder control includes several techniques, such as intermittent catheterization, indwelling catheterization (urethral, suprapubic), manual expression and the use of reflex bladder contraction, and surgical procedures, such as external sphincterotomy, bladder augmentation, or urinary diversion. Although the death rate from renal failure in patients with SCI has declined in the past 50 years, such individuals still require frequent outpatient and inpatient treatment, costly supplies, and much care and training, with resultant inconvenience for themselves and their families.

Traumatic injury to the spinal cord is also associated with the loss of bowel control. Intractable constipation may lead to episodic fecal impaction, which in turn may require manual disimpaction and the use of enemas and cathartics. The loss of bowel control often means that evacuation requires extensive amounts of time and the assistance of health care providers or attendants. Conventional bowel management and its complications can prevent many patients with SCI from living and participating in a normal social environment.

Stimulating the sacral anterior nerve roots produces contraction of the bladder, as well as the external urethral sphincter and pelvic floor. It has been thought that such stimulation would be ineffective in producing voiding and be potentially dangerous to the upper urinary tracts. Brindley et al,[1] however, by using electrodes implanted intrathecally and connected to a subcutaneous stimulator, showed that intermittent bursts of stimuli interspersed with intervals of no stimulation, could produce poststimulus voiding. The stimuli are summated by the smooth muscle of the detrusor to produce sustained bladder pressure, and though the striated muscle of the external urethral sphincter and pelvic floor contracts during stimulation, it relaxes rapidly in the longer intervals between stimulation, thus, allowing urine to flow. A physician can control voiding pressure by selecting stimulation parameters on an external controller that conveys power and stimulus parameters to the implanted stimulator by radio transmission. Results from many

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centers indicate that the technique is effective in emptying the bladder, and there is little evidence of damage to the upper urinary tracts.[2] In fact, when the implantation is combined, as it usually is, with posterior sacral rhizotomy, the state of the upper tracts can improve greatly.[3-6] For many years, Sauerwein[7] and Madersbacher and Fischer[8] and others have strongly advocated performing posterior rhizotomy in conjunction with implantation of the stimulator. The rhizotomy renders the bladder areflexic, permitting it to store urine at low pressure, which reduces the risk of ureteric reflux and hydronephrosis and greatly reduces reflex incontinence. The rhizotomy also abolishes autonomic dysreflexia originating in the bladder or the lower bowel.

Stimulation of the sacral parasympathetic nerves also increases motility in the lower bowel, reducing constipation, and, with appropriate adjustment of stimulus parameters, can produce defecation in some patients in a manner analogous to poststimulus voiding. Stimulation of the S2 nerves can also produce penile erection in some men. Many centers have reported good results from this combined use of stimulation and rhizotomy; worldwide, the neuroprosthesis has been implanted in more than 1600 patients since 1982.[2,9-11]

Sarrias et al[12] propagated a modification of the technique in which electrodes were placed on the mixed sacral nerves extradurally in the spinal canal, and the posterior sacral rhizotomy was performed intrathecally at the conus medullaris. This placement of the electrodes avoids passing cables through the dura mater, simplifies the division of the posterior roots, and reduces the handling of the anterior roots. This technique has been less widely reported, but it has produced promising results. We report here the results of a prospective, multicenter trial of the safety and efficacy of this technique for restoring bladder and bowel control to individuals with complete suprasacral SCIs.

METHODS

The Neuroprosthetic System

The neuroprosthetic system[a] used in this study has implantable components that are activated by an external controller operated by the user. Electrodes are implanted surgically on the sacral nerves and are connected by subcutaneous wires to a receiver-stimulator implanted under the skin of the abdomen (fig 1). This receiver-stimulator has no batteries and is powered and controlled by radio transmission from the external controller operated by the user and programmed by a clinician. The user selects the program for bladder or bowel control and then switches the device on as needed to deliver the programmed pattern of stimulation to the sacral nerves.

Surgery

The procedure for implanting the internal components has been described previously.[13] Briefly, a laminectomy of S1 to S3 exposes the sacral nerves in the spinal canal. Intraoperative stimulation makes the identification of those nerves that produce detrusor contraction possible. Electrodes are typically placed on the S2 to S4 nerves bilaterally and held in contact with them by a sleeve that is loosely wrapped and sutured around each nerve. The leads are tunneled subcutaneously between the costal margin and the iliac crest, and are attached to the implanted receiver-stimulator, which is inserted in a subcutaneous pocket in the anterior abdominal wall through a separate incision.

Posterior sacral rhizotomy is performed through a T11 to L2 laminectomy to expose the conus medullaris and the cauda equina. The tip of the conus is identified. The posterior S5 nerve root is usually the smallest one in the cauda equina. Starting with this nerve root, and by using electric stimulation to ensure that it is a posterior root rather than an anterior root, a rhizotomy is performed. Progressing rostrally, posterior rhizotomy is performed up to the S2 root bilaterally. This usually encompasses a region 3.5cm from the tip of the conus.

Patient Selection

Patients with complete suprasacral SCI and a history of documented problems from the use of other bladder management techniques were considered for the study. Documented problems included 3 or more urinary tract infections (UTIs) in the year before study enrollment, uncontrolled reflex incontinence, or intolerance of medications prescribed to prevent incontinence. Many patients also reported autonomic dysreflexia and an inability to perform intermittent catheterization. Patients were required to be skeletally mature (as indicated by fused growth plates), be at least 1-year postinjury, and be willing and able to participate in the follow-up investigation.

The presence of intact parasympathetic preganglionic axons from the spinal cord to the bladder was confirmed in all patients by eliciting a reflex contraction of the detrusor on cystometry. A rise in detrusor pressure of 50cm of water in men and 35cm of water in women was required before a patient could be included in the study. Patients in whom urethral erosion had caused intractable incontinence, or in whom urethral trauma had led to urethral stricture, were excluded, as were those who declined to undergo posterior rhizotomy. Also excluded were patients with cardiac pacemakers, cardiac arrhythmias, epilepsy, or other neurologic diseases that affect bladder control.

Study Design

The study was a prospective, multicenter trial in which each patient served as his/her own control. The protocol was ap-

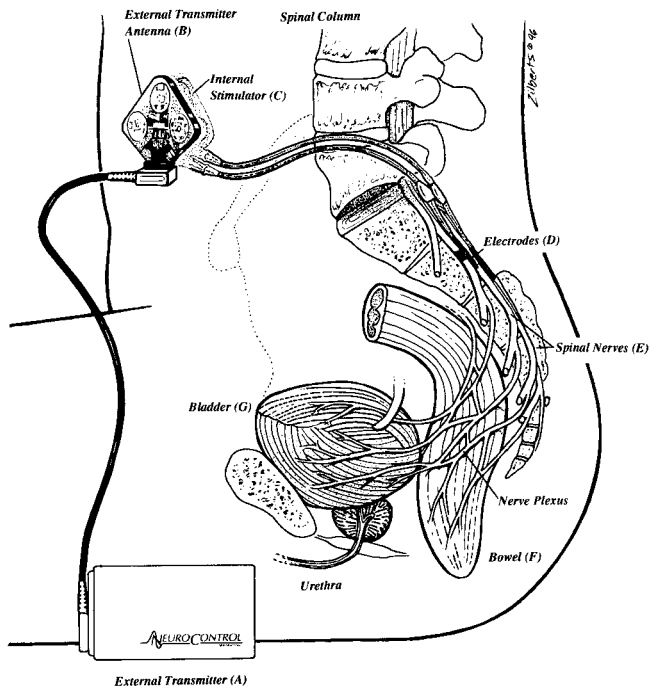

Fig 1. Components of the neurostimulation system. Reprinted with permission of NeuroControl Corp.

proved by the institutional review boards (IRBs) of all participating centers, and written informed consent was obtained from all patients.

The primary study hypothesis was that the neuroprosthesis system would improve a patient's ability to urinate on demand and reduce postvoid residual volumes of urine. A successful outcome was defined as (1) the patient having the ability to urinate more than 200mL on demand in less than 5 minutes, resulting in (2) a postvoid residual volume of 50mL or less. Each patient had his/her bladder filled to a maximum of 400mL of saline and was then asked to empty it within 5 minutes. Preimplantation, and with the neuroprosthesis turned off, the patient could use any noncatheter method to void (eg, straining, tapping). Postimplantation, the task was attempted with and without the neuroprosthesis turned on. The voided volume was measured, and a catheter was then inserted into the bladder to drain the residual volume, which was also measured. For both measures, the median value of 3 trials was used to determine success or failure. Patients who were unable to void during the first trial were not required to do the second or third trials.

Several secondary measures of bladder function were assessed. Specifically, each patient was monitored for changes in urinary catheter use, incontinence, UTI, anticholinergic medication use, and autonomic dysreflexia. Urinary incontinence episodes (small and large leaks) were documented in 30-day patient diaries, which were completed before surgery and before each follow-up visit. Patients estimated the number of symptomatic UTIs they had experienced in the year before study enrollment and reported the number of infections they had between each follow-up visit. Upper tract status was monitored through voiding cystograms, ultrasound evaluations, and plain radiographs of the kidneys, ureters, and bladder obtained preoperatively and at 3 and 12 months postoperatively.

To assess the impact of the neuroprosthesis as an aid in bowel management, patients were asked to record in their 30-day diaries the time spent in that activity and their use of the neuroprosthesis, suppositories, and other evacuation techniques. Patients were provided with a timer and were instructed not to include in their recorded bowel management time the minutes or hours they spent dressing, undressing, or transferring to and from the toilet.

Complications and adverse events were documented throughout the study. Satisfaction with the neuroprosthesis was assessed through a user satisfaction survey administered once during the study to participants who were at least 6 months postimplantation. Patients were asked to respond to statements regarding their satisfaction with the neuroprosthesis on a 5-point Likert scale. Responses of "strongly agree" or "agree" were counted as positive responses and "strongly disagree" and "disagree" were interpreted as negative responses, unless the question was worded in the negative, in which case "strongly disagree" and "disagree" were interpreted as positive responses. The surveys were mailed to patients and answers were retrieved by telephone by an independent interviewer.

Data were collected between June 1996 and December 1998 at 6 centers: MetroHealth Medical Center, Cleveland, OH; Bronx VA Medical Center, Bronx, NY; Stanford University Medical Center, Stanford, CA; San Diego VA Medical Center/University of California San Diego Medical Center, San Diego, CA; Hines VA Medical Center, Hines, IL; and Shriners Hospital for Children, Philadelphia, PA. Data were collected preoperatively and at 3, 6, and 12 months postoperatively.

Statistical Methods

Data are presented for 3 time points: baseline before implantation and at 3 and 12 months after implantation. Continuous data are summarized as medians and ranges with comparisons made by using Friedman's test statistic. Proportions were compared by using the McNemar chi-square test statistic. Alpha was set at .05 and all tests were 2-tailed.

RESULTS

Study Population

Twenty-three individuals were enrolled in the clinical study and received the neuroprosthesis; 16 (70%) were men; 17 were paraplegic, and 6 were tetraplegic. Median time between injury and implantation was 7 years (range, 2–26yr). Patients ranged in age from 14 to 67 years at the time of implantation (median, 40yr). Patient demographics and key bladder characteristics are detailed in table 1. All patients were followed-up for at least 1 year, but follow-up data were incomplete on some occasions. For each study endpoint, data are presented for those individuals for whom they are available. Table 2 provides an accounting of available data for each reported measure.

Bladder Management

At 3 months postimplantation, 19 of 21 patients (91%) for whom data were available were successful in voiding more than 200mL of urine on demand with the neuroprosthesis, and no patients voided more than 200mL with the neuroprosthesis turned off (table 3); 17 of the 21 (81%) patients successfully achieved residual volumes of less than 50mL, and 1 patient (5%) was successful with the neuroprosthesis turned off. At 3 months postimplantation, urodynamic data were unavailable for 2 of the 23 patients, neither of whom completed the 3-month follow-up visit. One had an incomplete rhizotomy that left her unable to void effectively with the device. The other person could void with the device, but no measurements were made on this occasion. These effects were maintained at 12 months postimplantation for the majority of patients (table 3). The 4 patients who could void more than 200mL on demand before implantation did so as a result of reflex contractions. Similarly, all 3 patients who had residual volumes less than 50mL before implantation had bladder capacities less than 80mL. No patient met both criteria before implantation, whereas 15 of 21 patients for whom urodynamic data were available met both criteria after using the neuroprosthesis for 1 year.

Results of secondary measures of bladder function are provided in table 4. The number of patients using catheters dropped substantially and most patients adopted the neuroprosthesis as their routine method of voiding.

Urinary incontinence was reduced for 12 of the 17 patients for whom 12-month diary data were available. The number of large leaks, which can soak clothing and furniture and are the most socially and occupationally inhibiting, was substantially reduced after surgery. Some patients experienced more small leaks postoperatively, though such leaks are generally less noticeable and usually easily managed with pads. As reported in patient diaries at 1 year, 6 of 17 patients were completely continent; 5 of the 6 had been incontinent preoperatively. Four patients were completely continent preoperatively.

In the year before implantation, all 23 patients reported UTIs, and 19 reported having 3 or more (table 4). A year after implantation, 18 of 23 reported fewer UTIs, 2 had no change, and 3 reported more infections. Two of these patients are nonusers of the neuroprosthesis. Five patients reported no infections during the year after implantation.

After implantation, only 2 of 17 patients who had previously taken anticholinergic medications continued to require them. One takes the medications to control sweating, not inconti-

Table 1: Patient Demographics and Key Bladder Characteristics

Patient	Sex	Level of Injury	Years Between Injury and Implant	Age at Implant (yr)	Preoperative Bladder Capacity (mL)	Preoperative Bladder Volume at First Contraction (mL)	12-Month Postoperative Bladder Capacity (mL)*	12-Month Postoperative Residual Volume (mL)
1	F	T2	20	26	197	116	≥400	8
2	M	C6	7	26	30	30	≥400	550
3	F	T10	2	33	340	117	≥400	30
4	M	T12	21	47	400	106	≥400	150
5	F	T10	8	22	410	160	≥400	400
6	M	C5	6	38	80	75	420	15
7	M	T8	5	40	193	150	≥400	6
8	M	T11–12	2	47	100	94	≥400	1
9	M	T12	3	50	230	130	≥400	18
10	M	T10	6	41	450	400	≥400	0
11	M	T11	9	67	310	52	≥400	400
12	M	T8	3	40	450	250	≥400	0
13	M	T7	19	48	370	370	≥400	55
14	F	T7–8	5	14	37	37	350	0
15	F	T10	10	14	52	50	NA	NA
16	M	T9–10	26	59	150	150	NA	NA
17	M	T9	5	26	223	205	≥400	0
18	F	T6–7	6	21	234	88	450	13
19	M	C6	22	40	400	234	≥400	90
20	M	C6–7	11	45	120	62	≥400	20
21	F	T9	3	23	117	117	≥400	8
22	M	C4–5	21	50	450	400	≥400	15
23	M	C5–6	23	42	254	158	≥400	20

Abbreviations: M, Male; F, Female; NA, not available.
* Bladder filling during postoperative urodynamics was usually limited to 400mL to avoid overdistension of the areflexic bladder.

nence, and the other, whose rhizotomy was incomplete at that time, took them to control reflex incontinence. Two of the 8 patients who had autonomic dysreflexia before implantation, reported single events in the first postoperative year.

Few patients participating in this study experienced vesicoureteral reflux, hydronephrosis, stones, or other upper urinary tract complications, either pre- or postoperatively. Two patients who had reflux preoperatively improved after surgery. One of the 2 had a recurrence of reflux 7 months after becoming a nonuser of the neuroprosthesis. One other patient who had no definite evidence of reflux preoperatively showed unilateral reflux during the later stages of voiding postoperatively. Before surgery, reflux was evaluated during filling but not usually during voiding, because most patients were unable to void on demand. Postoperatively, reflux was usually evaluated during filling and during voiding with the neuroprosthesis, which is a more stringent test.

One patient who had mild caliectasis preoperatively showed no hydronephrosis postoperatively. One patient showed chronic pyelonephritic changes with no hydronephrosis preop-

Table 2: Data Collected

	Number of Individuals with Data Collected		
	Preoperative	3 Months Postoperative	12 Months Postoperative
Voided volume	23	21 (pts 14, 15)*	21 (pts 15, 16)*
Residual volume	23	21 (pts 14, 15)*	21 (pts 15, 16)*
History			
Catheter user	23	23	23
UTIs	23	23	23
Anticholinergic medication use	23	23	23
Autonomic dysreflexia episodes	23	23	23
Diary			
Urinary incontinence episodes	23	20 (pts 2, 14, 15)*	17 (pts 2, 5, 11, 14–16)*
Bowel diary (bowel time, suppository use, manual evacuation use)	22 (pt 16)*	20 (pts 2, 14, 15)*	17 (pts 2, 5, 11, 14–16)*
User satisfaction survey		18 (pts 10, 11, 14–16)*	

Abbreviations: pts, patients.
* Data unavailable: (1) patient 2: incomplete data collection, unable to void with the device; (2) patient 5: incomplete voiding with device; (3) patient 11: had a compression fracture between 3 and 6 months postoperatively, rendering nerves unresponsive to stimulation; (4) patient 14: incomplete data collection and device effective at prior follow-up; (5) patient 15: incomplete data collection, continued hyperreflexia caused by incomplete rhizotomy, and device was ineffective because of temporary use of anticholinergic medication; and (6) patient 16: incomplete data collection, developed terminal lymphoma, and device effective at prior follow-up.

Table 3: Characteristics of Bladder Voiding for Patients With and Without the Neuroprosthesis

Endpoint	Preimplantation (n = 23)	3-Month Follow-Up (n = 21)*	12-Month Follow-Up (n = 21)*
Patients who voided > 200mL on demand			
Neuroprosthesis off	4	0	1
Neuroprosthesis on	NA	19	18
p		<.001	<.001
Patients with residual volumes of < 50mL			
Neuroprosthesis off	3	1	1
Neuroprosthesis on	NA	17	15
p		<.001	<.001
Median voided volume, mL (25%–75%)			
Neuroprosthesis off	60 (0–144)	0 (0–0)	0 (0–0)
Neuroprosthesis on	NA	405 (365–425)	400 (350–420)
p		<.001	<.001
Median residual volume, mL (25%–75%)			
Neuroprosthesis off	135 (73–240)	400 (400–400)	400 (323–400)
Neuroprosthesis on	NA	22 (10–35)	15 (6–55)
p		<.001	<.001

* Data were incomplete.

eratively and mild unilateral hydronephrotic changes postoperatively; another showed minimal hydronephrosis on the right preoperatively and mild pelvocaliectasis on the left postoperatively. Thus, only 1 patient showed a slight increase in hydronephrosis.

Bowel Management

The neuroprosthesis also helped patients with bowel management (table 5). Of 17 patients for whom 12-month diary data were available, 15 reduced the time they spent on bowel management; the median time was halved ($p < .001$). Of 4 patients who spent more than 25 minutes on their bowel routines postoperatively, 3 had had preoperative times longer than 1 hour, and all had substantial reductions in time spent after implantation.

All 23 patients reported that they used the neuroprosthesis in bowel management. At 1 year, 14 used it every time in conjunction with other methods, and 1 used it only to produce bowel movements. Several patients who did not use the neuroprosthesis for every bowel movement, nevertheless, commented that its regular use for bladder control improved the movement of stool into the rectum, thus, improving their overall bowel routine. Ten patients reduced their use of suppositories, but most continued some use of manual evacuation (table 5). Several patients reported that adjustment to a new pattern of bowel function required a period of experimentation with different techniques of bowel management.

User Satisfaction

A user satisfaction survey was sent to 20 patients during the study who had completed the 6-month follow-up milestone, and 18 responded. One person could not be reached and 1 declined to respond because he became dissatisfied after nerve compression resulting from a vertebral fracture prevented him from using the system. Before the fracture, he met both criteria for successful use of the neuroprosthesis. Of the remaining 3 users who were not surveyed, 1 was terminally ill and the other 2 were from 1 center that was omitted because it had not received IRB approval for the survey at the time that it was performed. One of the 3 individuals was unable to use the system because of an incomplete rhizotomy, and the others were regular device users, according to follow-up histories.

Overall, patients reported high satisfaction with the system (table 6). Of the 18 respondents, 15 were using the neuropros-

Table 4: Bladder Management: Secondary Results

Secondary Outcomes	Preimplantation (n = 23)	3 Months Postoperatively (n = 23)	12 Months Postoperatively (n = 23)
Method of voiding* (n)			
Intermittent catheter	18	6	5
Indwelling catheter	2	0	1
Reflex	5	0	0
Neurostimulation system	0	20	18
Episodes of urinary incontinence in previous 30 days, median (25%–75%)			
Small leaks	3 (0–13)	4 (0–13)	3 (0–8)†
Large leaks	4 (1–13)	0 (0–25)	0 (0–0)†
Urinary tract infections per patient per year, median (25%–75%)	3 (3–5.5)	NA	2 (1–3)†
Patients using anticholinergic medications	17	2	2
Patients experiencing autonomic dysreflexia	8	1	2

* Some patients used more than 1 method.
† n = 17.

Table 5: Bowel Management: 30-Day Diary Reports

Endpoint	Preimplantation (n = 23)	3-Month Follow-Up (n = 20)*	12-Month Follow-Up (n = 17)*
Time for bowel evacuation, in minutes, median (interquartile range)	26 (15.25–60)	13 (5–24.25)	12 (5–37.5)
p		<.001	<.001
Patients using suppositories	16	6	6
Patients using manual evacuation	20	17	15

* Diaries were incomplete or unavailable for some patients.

thesis an average of 5 times a day for bladder voiding. All patients surveyed reported using the system for their bowel routines an average of 4 times per week.

Complications

During the study, there were no infections caused by the device, and no implantable device failures. One individual implanted since this study was concluded developed an infection from the device, requiring its removal during the first postoperative week. Two patients experienced temporary nerve damage from the implantation surgery; both recovered function within 3 months. Two patients reported increased lower limb spasticity postoperatively. The most common adverse event after surgery was stress incontinence. Four patients reported some persistent increase in incontinence: 1 patient who previously had reflex incontinence now has stress incontinence and continues to wear a condom; 1 person with paraplegia who was previously dry now wears a condom, though he is very satisfied overall with the system; 2 other patients have had some increased incontinence but remain satisfied overall.

Three patients discontinued using the neuroprosthesis. One, the oldest patient at 67 years, experienced a pathologic fracture of the second lumbar vertebra 5 months after surgery, which caused compression of the cauda equina and prevented stimulation from reaching the bladder. Osteomyelitis was suspected and radiologically guided needle biopsy was performed, but no organisms were grown. The patient was treated empirically with antibiotics and bed rest, and fusion occurred, but the nerves have not recovered and the patient has reverted to a Foley catheter. It is possible that the fracture was related to the thoracolumbar laminectomy and the removal of Harrington rods to allow rhizotomy, but not related to the sacral laminectomy performed to implant the neuroprosthesis. Another patient had terminal lymphoma and was hospitalized for more than 6 months. During hospitalization, a condom catheter was used to facilitate nursing care, and he did not use the neuroprosthesis regularly, though it continued to function properly. A third patient continued to experience reflex bladder contractions after implantation, indicating an incomplete rhizotomy. An anticholinergic drug administered to treat the incontinence diminished the response of the bladder to the neuroprosthesis. The patient initially declined surgery to complete the rhizotomy and reverted to intermittent catheterization during the study. She has since undergone a revision of the rhizotomy and has become a user of the system.

DISCUSSION

The efficacy of sacral anterior root stimulation via intrathecal electrodes, combined with sacral posterior rhizotomy, has been documented in numerous publications.[2,3,5,8,12,14] This study showed similar efficacy via extradural electrodes. The safety of the intrathecal technique has been documented in long-term follow-up studies[15,16] that also report that the implantable components are reliable, with an average of 1 failure every 19.6 implant years. The safety of the extradural technique, though evaluated in smaller numbers of patients over a shorter period, is comparable.

The improvement in both voiding and continence is primarily related to stimulation and rhizotomy, respectively. The complete voiding provided by the neuroprosthesis also contributes to the improvement in continence by reducing infection and by allowing longer periods between voids.

In this study, a few patients were able achieve low residual volumes preoperatively as a result of detrusor hyperreflexia, but for the same reason they had a low bladder capacity and could not hold or void substantial volumes. A few patients held and voided more than 200mL on demand by straining or reflex contraction, but they had substantial residual volumes. None could void substantial volumes with low residual volumes preoperatively, but 15 of 21 could do so after the procedure. The 50-mL target for postvoid residual volumes was deliberately demanding. Three patients who did not meet this target had residual volumes between 50 and 150mL, which are sometimes acceptable.

Some patients initially used intermittent catheterization occasionally to check their residual volumes after using the neuroprosthesis, and some continued to do so at 3 and 12 months. Four patients continued to use intermittent catheterization regularly; 1 woman had an incomplete rhizotomy that was revised more than 1 year later. Another woman chose to continue a lower dose of anticholinergic medication to control sweating, thereby reducing the response of the bladder to

Table 6: Responses to Key Questions from the 6-Month User Satisfaction Survey from 18 Patients Using the Neuroprosthesis

Question	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
I am satisfied with my bladder system.	12	5	0	1	0
The bladder system has improved the quality of my life.	8	9	1	0	0
The bladder system has met my expectations.	5	10	0	2	0
I am more independent since I had the bladder system implanted.	7	7	4	0	0
The bladder system is easy and convenient to use.	5	11	0	2	0
I have had fewer bladder infections since I had the bladder system implanted.	8	6	1	2	1

stimulation; she continued to use the neuroprosthesis for bowel function. One patient with residuals over 100mL supplemented the stimulator with intermittent catheterization, and 1 patient with high residuals used only intermittent catheterization.

The number of large leaks, which probably represents reflex incontinence, decreased substantially after rhizotomy. Patients recorded small leaks, which may represent stress incontinence, in similar total numbers pre- and postoperatively. However, 1 man who had been continent preoperatively experienced urine leakage postoperatively, and 3 other patients reported some increase in incontinence. Stress incontinence of urine may have been masked preoperatively in some patients by the more profound reflex incontinence, or it may have been prevented preoperatively by spasticity of the external urethral sphincter, which was abolished by the rhizotomy.

In a study of continence after posterior rhizotomy, MacDonagh et al[17] reported that patients whose bladder neck was seen to be open in a preoperative cystogram had a greater likelihood of stress incontinence than did those with a closed bladder neck. We now routinely obtain a preoperative cystogram and if the bladder neck is open, we inform the patient of the risk of stress incontinence. This risk does not necessarily deter the patient from undergoing surgery because of the other advantages of the procedure.

Some tetraplegic men who became continent continued to wear condom and leg-bag collection systems for convenience in collecting urine when voiding with the stimulator; some of the paraplegic men occasionally did so when travelling or at work.

We performed urinalysis and urine culture and sensitivity on 3 occasions preoperatively and before each follow-up visit, but these points in time were not necessarily representative of the overall pattern of infection. We therefore chose to also record the patients' self-reported history of symptomatic UTIs during the preoperative year and between each follow-up visit. Eighteen patients reported a decrease in UTIs in clinical follow-up histories.

The time spent in bowel care was reduced most dramatically for those who had prolonged bowel care preoperatively. Some patients reported that the frequency of bowel emptying increased slightly, resembling more closely their bowel habits before SCI. Other studies of this technology have reported improved bowel function[18-20] that is presumably related to the stimulation of sacral parasympathetic nerves and the reduction of anticholinergic medication. The response to suppositories and digital stimulation of the rectum may be reduced by posterior rhizotomy, and this possibility could be a consideration for tetraplegic patients who can insert a suppository but cannot do manual evacuation. Some patients were able to defecate by using only the neuroprosthesis, but most also checked the contents of the rectum digitally and removed any remaining stool manually. Stress incontinence of feces might have been expected to be a problem, given the fact that posterior rhizotomy rendered the external anal sphincter areflexic, but overall, the procedure did not increase the frequency of fecal incontinence in these patients.

All of the surgical and nonsurgical techniques for managing the neurogenic bladder and bowel have both advantages and disadvantages. Intermittent catheterization has many advantages but is sometimes limited by hand dysfunction, inconvenience, infection, urethral trauma in men, or adductor spasm in women, and it can be costly long term, particularly if it requires skilled assistance. Indwelling catheters have well-known risks of causing chronic infections, stone formation, and, in the longer term, bladder cancer; nonetheless, their convenience sometimes leads to their adoption. Bladder augmentation can produce continence without rhizotomy, but commits the individual to lifelong use of catheters. Urinary diversion, such as augmenting the bladder with bowel tissue, requires extensive surgery. If diversion restores continence, it can be useful for some individuals (eg, tetraplegic women); however, it still requires catheterization.

The combination of sacral nerve stimulation and posterior sacral rhizotomy can improve both voiding and continence, and offers important advantages over existing methods. Effective voiding, with low residual volumes and reduced infection, should lead to reduced use of antibiotics and medical services. Reduced catheter use is likely to further reduce infection and urethral damage and, in patients with limited hand function, the need for an attendant. It also greatly reduces the cost of bladder care supplies, which can account for nearly half of the costs of conventional bladder and bowel care. A companion article[21] reports the potential cost savings of the technique, compared with conventional management. Avoiding reflex incontinence further reduces costs; of the patients for whom 12-month diary data were available, 4 had an increase in stress incontinence, but 12 had a reduction of incontinence and 6 of the 12 were completely continent because of the abolition of reflex bladder contraction. The reduction of autonomic dysreflexia has implications for both the safety and quality of life.

The technique has the disadvantage of requiring surgery, though the surgery is no more invasive than that required for some other methods of bladder and bowel management. The implantable receiver-stimulator is reliable and has no internal batteries and therefore rarely requires revision surgery.[16] Posterior rhizotomy has major advantages in reducing reflex incontinence, increasing bladder capacity and compliance, decreasing sphincter spasticity, and reducing the pressure at which urine is stored in the bladder. These advantages can protect the upper urinary tracts against reflux and hydronephrosis.[2-7,22,23] The rhizotomy also has the disadvantages of abolishing reflex erection and reflex ejaculation, which can be a deterrent for some men; however, the implant can produce erections in some patients.[2,3,5,24] Reflex erection and ejaculation are, unfortunately, often poorly functional after SCI, but methods of improving erection, such as intracavernosal injection, external appliances, penile prostheses, or improving seminal emission by electroejaculation, can still be effective after posterior rhizotomy. Men should be educated about these methods for assisting sexual function, and offered an opportunity to test them as a part of the discussion about bladder and bowel management options.

User satisfaction with the device is high and most patients indicate that they would choose the system again and recommend it to others.

CONCLUSIONS

In this study, the neuroprosthesis substantially improved bladder control for almost all patients, and it was a useful adjunct in bowel management. For selected patients with complete suprasacral SCIs, the use of an implanted neuroprosthesis, together with posterior sacral rhizotomy: (1) restored the ability to micturate on demand with low residual volumes of urine; (2) reduced UTI; (3) reduced use of intermittent and indwelling catheters; (4) reduced reflex incontinence; (5) reduced use of anticholinergic medications; (6) reduced autonomic dysreflexia; (7) reduced the amount of time spent in bowel management; and (8) reduced use of suppositories.

In addition, patient satisfaction with the device was very high, and the rate of adverse events was low. We conclude that sacral anterior root stimulation combined with posterior sacral

rhizotomy is an effective alternative to conventional bladder management techniques for appropriately selected patients.

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Supplier

a. VOCARE™ Bladder System; NeuroControl Corp, 8333 Rockside Rd, Valley View, OH 44125.