

# A RANDOMIZED PHASE 3 STUDY OF INTRAOPERATIVE CAVERNOUS NERVE STIMULATION WITH PENILE TUMESCENCE MONITORING TO IMPROVE NERVE SPARING DURING RADICAL PROSTATECTOMY

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## ABSTRACT

**Purpose:** We determine if mapping of the cavernous nerve during radical prostatectomy using intraoperative cavernous nerve stimulation with tumescence monitoring results in improved erectile potency compared to conventional nerve sparing.

**Materials and Methods:** A prospective, randomized, single blinded study was performed on 61 patients at 6 centers. Patients had elected to undergo nerve sparing prostatectomy and had normal preoperative erectile function documented by the Sexual Function Inventory Questionnaire (SFIQ) and RigiScan|| testing. Patients were randomized between conventional nerve sparing and nerve sparing assisted by the CaverMap Surgical Aid.¶ In all patients neural continuity was assessed immediately after prostate removal by proximal cavernous nerve stimulation. All patients were blinded according to their allocation cohort.

**Results:** At 1 year there was substantial improvement in erectile function in the CaverMap group as measured by RigiScan. This group had a mean of 15.9 minutes of greater than 60% nocturnal tumescence compared to 2.1 minutes in the conventional nerve sparing group ( $p < 0.024$ ). By SFIQ there was a nonsignificant trend to improved potency in the CaverMap group (71% versus 62%,  $p = 0.17$ ). Of patients who had bilateral, unilateral and no response to stimulation after resection erectile function assessed by SFIQ recovered in 68%, 27% and 0%, respectively ( $p = 0.016$ ).

**Conclusions:** CaverMap assisted prostatectomy led to improved erectile function as assessed by RigiScan testing with no associated adverse events. A response to stimulation immediately after removal of the prostate accurately predicted return of erectile function.

**KEY WORDS:** prostatic neoplasms, prostatectomy, impotence

The rate of erectile failure after radical prostatectomy varies from 30% to 100% in physician reported series<sup>1</sup> and 11% to 86% of cases as measured by patient questionnaire.<sup>2</sup> Bilateral nerve sparing yields higher rates of return of function than unilateral sparing. Patients in whom both bundles have been removed have the lowest rates of erectile function.

The advent of phosphodiesterase inhibitors like sildenafil has strengthened the case for nerve sparing during radical prostatectomy. A recent study of 28 patients placed on the drug after surgery reported that 12 of 15 (80%) treated with a bilateral nerve sparing procedure responded to the drug compared to 0 of 3 treated with a unilateral and 0 of 10 treated with a nonnerve sparing procedure.<sup>3</sup> A larger study of

150 men following radical prostatectomy reported that of men younger than 55 years erections were achieved at 1 year in response to sildenafil in 83%, 25% and 0% with 2, 1 and 0 bundles preserved.<sup>4</sup> Two other series of more modest responses to sildenafil after prostatectomy also reported that nerve sparing status was highly predictive of response.<sup>5,6</sup> In the study that used the International Index of Erectile Function erections improved in 58% of men with bilateral nerve sparing and 20% with no nerve sparing.<sup>6</sup> These results emphasize the importance of sparing nerves to increase the probability of responding to sildenafil. Although cavernous nerve sparing techniques as first described by Walsh have become standard procedures for many urologists, there is a wide diversity in rates of erectile function postoperatively, depending on surgical skill as well as the method of reporting erectile function.

We evaluated the effectiveness of a technique of intraoperative cavernous nerve stimulation performed in conjunction with a sensitive measurement of penile circumference using the CaverMap Surgical Aid.<sup>7</sup> In 65% of cases nerve stimulation identified nerve fibers at the site of dissection at least once. Of 19 patients who were potent preoperatively and in whom there was no confounding adjuvant therapy administered 16 reported erections postoperatively, including 5 who reported normal erectile function and 11 who reported partial erectile function, defined as occasional erections sufficient for intercourse. There were no apparent adverse effects. In this study we used the CaverMap device in a

Accepted for publication May 12, 2000.

Supported by a grant from Uromed Corp.

\* Financial interest and/or other relationship with Uromed Corp. and Zeneca.

† Financial interest and/or other relationship with Abbott Pharmaceuticals, RPR (Rhone Poulenc Rohrer), TAP Pharmaceuticals and Vaxis.

‡ Financial interest and/or other relationship with Uromed Corp.

§ Financial interest and/or other relationship with Abbott Pharmaceuticals, Bio-Advantex Pharmaceuticals, Protein Technology and Hoechst Marion Roussel.

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**Editor's Note:** This article is the fourth of 5 published in this issue for which category 1 CME credits can be earned. Instructions for obtaining credits are given with the question pages 1714 and 1715.

prospective multicenter, single blinded, randomized trial to determine whether intraoperative use of this novel device leads to better patient outcome compared to conventional nerve sparing technique, and whether an objective measure of the degree to which nerves have been spared correlates to return of erectile function.

#### MATERIALS AND METHODS

The study was restricted to patients with normal erectile function by questionnaire and RigiScan testing who were to undergo nerve sparing prostatectomy. Study inclusion criteria were age 70 or less, stage, T2c or less disease, prostate specific antigen, less than 20, Gleason score 8 or less, patient and physician elected nerve sparing radical prostatectomy, history of normal erectile function, and RigiScan testing demonstrating 60% or greater rigidity for a minimum of 10 minutes on 1 of 2 successive nights. Nine surgeons from 6 Canadian sites participated in the study. All surgeons had been in practice greater than 5 years, regularly performed more than 50 radical prostatectomies each year and indicated that they were experienced in performing nerve sparing prostatectomy.

At the time of surgery patients were randomized to intraoperative nerve stimulation with tumescence monitoring (study arm) or conventional nerve sparing approach (control arm). Randomization was performed by opening a preprepared envelope at the time of surgery that contained the randomization allocation for that patient. Patients were blinded to their randomization group throughout followup.

In the study arm initial nerve stimulation was performed on each side posterolateral to the urethra (baseline) before dividing it. If an initial tumescence response could not be demonstrated at baseline by stimulation at this site, an attempt to induce tumescence by stimulation more posterior, lateral and anterior was made. If a tumescence response could still not be elicited the stimulation procedure was discontinued. The rationale for this approach was that in the absence of a demonstrated response to stimulation before beginning dissection, a tumescence response to subsequent stimulation was unlikely to occur. In most cases where a tumescence response did occur each lateral pedicle was then stimulated before mobilization and division of the pedicle. If tumescence occurred as a result of stimulation, the tissue at the site of stimulation was spared if possible without compromising cancer control. The lateral pedicle was then mobilized closer to the prostate, taking care to remain extracapsular. Where the stimulation of the pedicle produced a tumescence response but mobilization closer to the prostate would have transgressed the capsule or palpable cancer, the pedicle was ligated and divided independent of the tumescence response.

In both groups, following removal of the prostate and achievement of hemostasis, proximal stimulation was performed to determine whether there was a tumescence response to efferent stimulation. A minimum change in tumescence of 0.5% was considered a tumescence response. This response reflected the minimal detectable increase in penile girth in response to nerve stimulation, indicating continuity between the area of stimulation and erectile bodies.

Study end points were change in the Sexual Function Inventory Questionnaire (SFIQ) (see Appendix) and RigiScan evaluation. Degree of potency was determined by examining 12-month responses to SFIQ question 3 ("Over the past 30 days, how often have you had partial or full erections when you were sexually stimulated in any way?"). Patients who responded "Not at all" were considered to have severe erectile dysfunction. A response of "A few times" indicated moderate erectile dysfunction. Responses of "Fairly often" and "Usually" represented patients with minimal erectile dysfunction. A response of "Always" indicated completely potent patients.

Within each domain the answer to question 3 of the SFIQ and minutes greater than 60% tumescence by RigiScan were identified as the primary outcome measures. Between group comparisons were performed with Fisher's exact test. The limited numbers of patients precluded a logistic regression analysis for other risk factors, that is age.

#### RESULTS

A total of 61 patients were entered into the study at 6 institutions. Patient ages ranged from 39 to 70 years, with a mean of 60.5. Of the patients 5 were not evaluable due to absence of post-prostatectomy removal proximal stimulation data and 3 due to device failure. The clinical characteristics of the remaining 53 patients are presented in table 1. Two patients had no baseline response to stimulation, including 1 in the device failure group, and 1 who received adjuvant irradiation therapy and was excluded from the 12-month evaluation.

Bilateral nerve sparing was attempted in 45 and unilateral nerve sparing in 8 patients. Of the 53 patients 7 were treated with radiation and 1 with hormonal therapy following surgery for positive margins or seminal vesicle involvement. No patients had lymph node metastases. These 8 patients were excluded from evaluation at 12 months, leaving 45 evaluable patients. Of the 45 patients 10 declined to have RigiScan testing at 1 year postoperatively for unknown reasons which left 35 patients with 1-year RigiScan data, including 18 in the study arm and 17 in the control arm.

Estimated blood loss ranged from 200 to 4,000 ml. Mean blood loss in the study and control groups was 1,420 and 1,035 cc, respectively. There was no difference in transfusion requirements. Mean duration of surgery for the study and control groups was 183 and 160 minutes, respectively.

The pathological margin rate in the 2 groups is summarized in table 2, and the overall rate was 41.7%. There was no difference in the rate of positive margins between the groups. In 7 patients unilateral nerve sparing only was performed due to concerns about the risk of positive margins on the side of the nodule. In 6 (87%) of these cases there was in fact a positive resection margin.

A tumescence or detumescence response was elicited in 93% of the patients at least once during the prostate removal (table 3). A tumescence response occurred on 1 or both sides in 67% of the patients during distal stimulation, 60% with proximal stimulation and 70% with stimulation around the base of the prostate. A tumescence response to proximal cavernous nerve stimulation following prostate removal occurred bilaterally in 31 patients, unilaterally in 27 and on neither side in 3 (table 4). A tumescence response, particularly when bilateral, was predictive of eventual recovery of erectile function as measured by SFIQ (chi-square  $p = 0.016$ ) and RigiScan (chi-square  $p = 0.006$ ).

Erectile function was evaluated by RigiScan and SFIQ. At baseline before surgery nocturnal tumescence, defined as

TABLE 1. Patient characteristics

	No. Controls	No. Study Group	Total No.
Gleason scores:			
2-6	19	22	41
7	6	4	10
8	1	1	2
Stage:			
T1B	2	2	4
T1C	4	6	10
T2A	13	13	26
T2B	6	5	11
T2C	1	1	2
PSA:			
Less than 4	6	8	14
4-10	12	13	25
Greater than 10	8	5	13

TABLE 2. Rate of pathological margins by cohort and nerve sparing strategy

	No. Pos. Margin/Total No. (%)	
	Unilat. Bilat. Attempt	Unilat. Attempt Only
Control	14/32 (43.8)*	4/5 (80.0)
Cavernmap	11/28 (39.3)	3/3 (100.0)
Totals	25/60* (41.7)	7/8 (87.5)

At surgeon discretion when disease was suspected by palpation to be close to neurovascular bundle on 1 side only contralateral nerve sparing was attempted.

\* Margin data were unavailable for 1 patient.  
 † No association between study group and positive margins (chi-square 0.12, df 1, p = 0.73).

TABLE 3. Likelihood of response to stimulation by anatomical site

	No./Total No. (%)		
	Tumescence	Detumescence	No Change
Lt. base	18/28 (64)	8/28 (29)	2/28 (7)
Rt. base	19/27 (70)	5/27 (19)	3/27 (11)
Lt. proximal	29/51 (57)	14/51 (28)	8/51 (16)
Rt. proximal	31/52 (60)	8/52 (15)	13/52 (25)
Lt. distal	8/12 (67)	2/12 (17)	2/12 (17)
Rt. distal	9/16 (56)	5/16 (31)	2/16 (13)

TABLE 4. Return of erectile function measured at 12 months postoperatively according to tumescence response to nerve stimulation at end of surgery

	Bilat.	Unilat.	None
SFIQ:*			
No. pts./total No.	21/31	3/11	0/3
% Pts.	68	27	0
95% CI	0.52-0.84	0.01-0.53	
RigiScan:†			
No. pts.	17	11	2
Mins. greater than 60% rigidity (95% CI)	15.71 (0-33.35)	4.59 (0.86-8.33)	0

\* Bilateral versus unilateral plus none p = 0.016.  
 † Bilateral versus unilateral plus none p = 0.006.

greater than 60% rigidity by RigiScan, occurred for a mean of 31.75 and 29.88 minutes in the study and control groups, respectively (table 5). A year after surgery nocturnal tumescence occurred for a mean of 15.9 minutes (median 3.0) in the study group and 2.09 minutes (median 1.0) in the control group (p = 0.024). The distribution of minutes with greater than 60% nocturnal tumescence is shown in table 6. Tumescence of greater than 10 minutes in duration was demonstrated by 45% of the study group and 10% of controls.

On SFIQ both groups reported a substantial degree of erectile dysfunction at 1 year (table 7). There was no difference in the proportion of patients with no or minimal erectile dysfunction. There also was no significant difference in the

TABLE 5. Erectile function at 12 months by SFIQ and RigiScan

	Study Group	Control Group
Greater than 60% rigidity on RigiScan preop. (p = 0.163):		
Mean mins.	31.75	29.88
No. pts.	27	26
Greater than 60% rigidity on RigiScan 12 mos. postop. (p = 0.024):		
Mean mins.	15.92	2.09
No. pts.	18	17
95% CI	2.27-29.57	0.47-3.71
Erectile potency on SFIQ 12 mos. postop. (p = 0.789):		
No. pts./total No. (%)	17/24 (71)	13/21 (62)
95% CI	0.53-0.89	0.41-0.83

TABLE 6. Distribution of minutes of greater than 60% nocturnal tumescence by allocation cohort

Mins. Greater Than 60% Rigidity	No. Control Group (%)	No. Study Group (%)
0	7 (41)	3 (17)
0.1-5.0	7 (41)	6 (34)
5.1-10.0	2 (12)	1 (6)
10.1-20.0	1 (6)	4 (22)
20.1-30.0	0	2 (11)
30-100	0	1 (6)
120	0	1 (6)
Totals	17	18

TABLE 7. Severity of erectile dysfunction by allocation cohort

Erectile Dysfunction	No./Total No. (%)	
	Control Group	Study Group
Severe	8/21 (38)	7/24 (29)
Moderate	5/21 (24)	9/24 (38)
Minimal	7/21 (33)	6/24 (25)
None	1/21 (5)	2/24 (8)

likelihood of patients reporting erections adequate for intercourse, as indicated by 71% and 62% in the study and control groups, respectively. Of the 5 additional patients not included in the original SFIQ analysis due to lack of postprostatectomy stimulation data 2 reported minimal erectile dysfunction, 1 moderate erectile dysfunction and 2 severe erectile dysfunction at 12 months. An intent to treat analysis incorporating these patients did not indicate any change in the results. There were no trends suggestive of an interaction between the surgeon performing the procedure and use of the CaverMap, which may be due in part to the small number of patients at some of the sites.

DISCUSSION

Erectile impotence has been recognized as a sequela of radical prostatectomy since the operation was first reported. After Walsh and Donker described the anatomical course of the neurovascular bundle containing the cavernous nerve,<sup>8</sup> and Walsh defined the anatomical radical prostatectomy,<sup>9</sup> potency preservation has been sought by urologists and patients. Initial reports by Quinlan et al of potency rates as high as 80% contributed to a rekindling of interest in the operation.<sup>10</sup> Coincidentally, a sharp increase in the incidence of localized prostate cancer due to the advent of prostate specific antigen screening afforded unprecedented numbers of patients for whom prostatectomy was a treatment option. The nerve sparing prostatectomy is now offered routinely to patients with localized prostate cancer throughout North America.

However, major doubts remain about the efficacy of the nerve sparing approach by most urologists. Despite the adoption of Walsh's surgical modifications, numerous studies have reported considerably lower rates of potency preservation than he reported. The American Urological Association Prostate Cancer Clinical Guidelines Panel reviewed the published literature before 1995 and found a rate of potency preservation between 15% and 80%.<sup>1</sup> A meta-analysis of treatment outcomes in prostate cancer by Wasson et al revealed the probability of retaining erectile function after surgery to be 15%.<sup>11</sup> This analysis was performed on studies published between 1966 and 1991. However, it included many studies performed before the nerve sparing era and did not include studies published since 1991. Furthermore, many of the articles included patients with sexual dysfunction before surgery. A more recent attempt to model the effect of treatment on erectile function based on the published literature derived a probability of maintaining normal erectile

function after prostatectomy of 42% (95% confidence interval (CI) 40 to 43.3).<sup>2</sup> This calculation was based on studies up to 1995, with 15 additional studies since the earlier meta-analysis and 14 studies specifically using a nerve sparing prostatectomy.

Injury to the neurovascular bundle may occur during urethral dissection where nerves may be transected with the urethra, along the base of the prostate during division of the lateral pedicles or during dissection of the seminal vesicles. Identification of the neurovascular bundles by anatomical landmarks may be obscured by bleeding, overlying tissue, surrounding fat or blood vessels. Recent data have also suggested that the course of the nerve is considerably more variable than initially described.<sup>12</sup> Several animal and human studies have demonstrated that intraoperative stimulation of the cavernous nerves causes elevation of intracavernous pressure and induces erection.<sup>13-21</sup> The terminal branches of the nerves innervate the helicine arteries and trabecular smooth muscle. Stimulation results in smooth muscle relaxation and expansion of the corporeal sinusoids causing an increase in blood flow and penile girth and length.

Cavernous nerve stimulation in humans during surgery was first reported by Lue et al in 16 patients under going retropubic prostatectomy.<sup>13</sup> Cavernous nerve stimulation was accomplished using an oval of stainless steel mesh with a 10 × 5 mm. stimulating surface. Stimulation produced a visible erection in 8 of 11 patients (73%) who were potent preoperatively. End point was a visible change in the length and girth of the penis as assessed subjectively. However, this information was not used during surgery and postoperative outcome was not described. There was no evidence of injury to the cavernous nerve resulting from the stimulation. The limitation of the technique was that a broad stimulating surface would not be useful in localizing the position and course of a single fiber.

Successful cavernous nerve stimulation has been reported by Watson et al using an objective change in penile circumference as the end point.<sup>22</sup> In 15 patients they described eliciting tumescence responses during and immediately after prostate resection with proximal and distal nerve stimulation. Intraoperative stimulation with measurement of intracorporeal pressure has been used to improve nerve identification.<sup>23</sup> Pressures could be augmented by administration of an  $\alpha$  blocker during surgery, and confirmed the variable functional anatomy of the erectile nerves. No followup data were provided.

The CaverMap Surgical Aid has been developed to exploit the ability to identify the course of the cavernous nerve by using electrical stimulation to stimulate a tumescence response. The CaverMap assisted technique is based on the observation that stimulation of a single nerve fiber may produce a real but subclinical increase in penile volume. The device can detect a 0.5% increase in penile girth. This degree of enlargement is not apparent visually, although it is often accompanied by some movement of the penile skin. The device consists of a control unit, reusable probe handle, a probe tip with 8 stimulation electrodes in a 1 cm. linear array and a penile tumescence sensor. The device operates by applying a low current to a small area of tissue and monitors for a feedback response in the penis. The feedback response is measured by detecting minute alterations in penile circumference measured by the strain gauge placed at the base of the penis. Based on the presence or absence of a confirmed response, a decision can be made regarding the dissection strategy in an attempt to preserve the neurovascular bundles better.

Klotz and Herschorn performed a phase 2 feasibility study with 1-year followup.<sup>7</sup> In two-thirds of the cases nerve stimulation led to a modification of the dissection at least once during the operation. Postoperatively, 84% of the patients had erections sufficient for intercourse. There were no appar-

ent adverse effects. Their phase 2 experience prompted our current randomized study, which demonstrates that the ability to produce a tumescence response by stimulation of the proximal cavernous nerve following prostate removal is predictive of recovery of erectile function. In patients with bilateral, unilateral and no intraoperative stimulation erectile function was present at 1 year in 68%, 27% and 0%, respectively. Performance on RigiScan at 1 year was also predicted by the response to stimulation intraoperatively. This finding indicates conclusively that the demonstration of neural continuity after resection is an important predictor of recovery of erectile function.

Our study demonstrated substantial improvement in erectile function as measured by RigiScan 1 year after surgery in patients treated with the CaverMap assisted technique. Duration of nocturnal tumescence (greater than 60% rigidity) was 15.9 minutes versus 2.09 minutes in the control group. Compared to the preoperative state, RigiScan performance decreased in both groups, which likely reflects the multifactorial etiology of post-prostatectomy erectile dysfunction.

The rate of positive margins in our study was 40%, which is lower than the rate of margin positivity in the control arm of the randomized neoadjuvant hormone therapy study performed in Canada (56%). While this rate is high, the absence of a difference between the 2 groups suggests that the use of the CaverMap was not a significant factor in the positive margin rate.

Although there was a trend to improved erectile function as measured by SFIQ in the study group, this did not achieve significance. There are several possible interpretations to explain the differences between the RigiScan and SFIQ data. As the objective measure of erectile function showed dramatic improvement, failure to reach statistical significance on the subjective SFIQ may reflect the lack of power of the study. Another explanation is that patient self-reporting of sexual function may lag behind the physiological recovery of erection due to the impact of other factors on sexual behavior, including urinary incontinence, stress of surgery or depression related to the diagnosis of cancer and its perceived impact on quality and quantity of life. The SFIQ data are based on an intent to treat analysis and include all patients, whereas the RigiScan data by definition excluded patients who declined to be tested at 1 year, which is a potential source of bias. Alternatively, the RigiScan assessment may be a misleading indicator of recovery of erectile function. This question cannot be assessed in the context of this study.

The strengths of our study are: the use of intraoperative randomization between conventional nerve sparing and CaverMap assisted technique, which to our knowledge is the first time randomization has been used to study surgical technique of radical prostatectomy; blinding patients to allocation cohort postoperatively; objective assessment of erectile function preoperatively and postoperatively by RigiScan testing; use of the technique by multiple surgeons at multiple centers; and absence of confounding influences, that is sildenafil postoperatively, which was not available in Canada at the time of the trial. The weaknesses of our study are the relatively small size (61 patients) and lack of standardization of the nerve sparing technique among the 9 surgeons involved. Thus, the results reflect a broad rather than a closely controlled base of experience. It may also reflect the Hawthorne effect, which refers to the tendency for patients in the control arm of a study to have outcomes superior to those that would normally be expected.<sup>24</sup> There may be an interaction between the use of the device in the study cases and the outcome in patients having conventional nerve sparing performed by the same surgeon but this cannot be quantitated in the context of this clinical trial.

CONCLUSIONS

We have demonstrated the feasibility of conducting a prospective, randomized blinded trial of surgical technique during radical prostatectomy to evaluate objectively differences in outcome related to surgical methodology. To our knowledge this is the first time surgical technique of radical prostatectomy has been subjected to evaluation by a randomized trial design. The study has demonstrated that the use of intraoperative cavernous nerve stimulation with tumescence

monitoring permits rapid identification of the course of the cavernous nerves during radical prostatectomy. A response to stimulation immediately after removal of the prostate accurately predicted return of erectile function. CaverMap assisted prostatectomy led to improved erectile function as assessed by RigiScan testing with no associated adverse events. Further studies of this approach are warranted to confirm the benefit of this technique with respect to preservation of erectile function.

APPENDIX: SEXUAL FUNCTION INVENTORY QUESTIONNAIRE

Directions: Please read the questions below carefully and circle the response that is closest to your experiences within the past 30 days.

SEXUAL DRIVE

Let's define sexual drive as a feeling that may include wanting to have a sexual experience (masturbation or intercourse), thinking about having sex, or feeling frustrated due to lack of sex.

- |  |             |                 |           |             |                  |
|--|-------------|-----------------|-----------|-------------|------------------|
| 1. During the past 30 days, on how many days have you felt sexual drive?   | No Days     | Only a Few Days | Some Days | Most Days   | Almost Every Day |
| 2. During the past 30 days, how would you rate your level of sexual drive? | None at all | Low             | Medium    | Medium High | High             |

ERECTIONS

- |  |                       |                     |                 |                   |               |
|--|-----------------------|---------------------|-----------------|-------------------|---------------|
| 3. Over the past 30 days, how often have you had partial or full erections when you were sexually stimulated in any way? | Not at all            | A Few Times         | Fairly Often    | Usually           | Always        |
| 4. Over the past 30 days, when you had erections, how often were they firm enough to have sexual intercourse?            | Not at all            | A Few Times         | Fairly Often    | Usually           | Always        |
| 5. How much difficulty did you have getting an erection during the past 30 days?   | Did not get erections | A lot of difficulty | Some difficulty | Little difficulty | No difficulty |

EJACULATION

- |  |                       |                     |                 |                   |               |
|--|-----------------------|---------------------|-----------------|-------------------|---------------|
| 6. In the past 30 days, how much difficulty have you had ejaculating when you have been sexually stimulated? | No sexual Stimulation | A lot of difficulty | Some difficulty | Little difficulty | No difficulty |
| 7. In the past 30 days, how much did you consider the amount of semen you ejaculate to be a problem for you? | Did not climax        | Big Problem         | Medium Problem  | Small Problem     | No Problem    |

PROBLEM ASSESSMENT

- |  |             |                |               |                    |            |
|--|-------------|----------------|---------------|--------------------|------------|
| 8. In the past 30 days, to what extent have you considered a lack of sex drive to be a problem?                    | Big Problem | Medium Problem | Small Problem | Very Small Problem | No Problem |
| 9. In the past 30 days, to what extent have you considered your ability to get and keep erections to be a problem? | Big Problem | Medium Problem | Small Problem | Very Small Problem | No Problem |
| 10. In the past 30 days, to what extent have considered your ejaculations to be a problem?                         | Big Problem | Medium Problem | Small Problem | Very Small Problem | No Problem |

OVERALL SATISFICATION

- |   |                   |                     |                  |                  |                |
|---|-------------------|---------------------|------------------|------------------|----------------|
| 11. Overall, during the past 30 days, how satisfied have you been with your sex life? | Very dissatisfied | Mostly dissatisfied | Neutral or Mixed | Mostly Satisfied | Very Satisfied |
|---|-------------------|---------------------|------------------|------------------|----------------|

## REFERENCES

1. Report on The Management of Clinically Localized Prostate Cancer. The American Urological Association Prostate Cancer Clinical Guidelines Panel. Baltimore: The American Urological Association, pp. A-20, 1995
2. Robinson, J. W., Dufour, M. S. and Fung, T. S.: Erectile functioning of men treated for prostate carcinoma. *Cancer*, **79**: 538, 1997
3. Zippe, C. D., Kedia, A. W., Kedia, K. et al: Treatment of erectile dysfunction after radical prostatectomy with sildenafil citrate (Viagra). *Urology*, **52**: 963, 1998
4. Zagaja, G. P., Mhoon, D. A. and Brendler, C. B.: Evaluation of response to sildenafil after radical prostatectomy using a confidential mail survey. *J Urol*, suppl., **161**: 154, abstract 589, 1999
5. Gilbert, W. B., Cookson, M. S., Milam, D. F. et al: Treatment of erectile dysfunction with oral sildenafil following radical retropubic prostatectomy. *J Urol*, suppl., **161**: 356, abstract 1376, 1999
6. Lowentritt, B. H., Scardino, P. T., Miles, B. J. et al: Sildenafil citrate after radical retropubic prostatectomy. *J Urol*, **162**: 1614, 1999
7. Klotz, L. H. and Herschorn, S.: Early experience with intraoperative cavernous nerve stimulation with penile tumescence monitoring to improve nerve sparing during radical prostatectomy. *Urology*, **52**: 537, 1998
8. Walsh, P. C. and Donker, P. J.: Impotence following radical prostatectomy: insight into etiology and prevention. *J Urol*, **128**: 492, 1982
9. Walsh, P. C.: Anatomic radical retropubic prostatectomy. In: *Campbell's Urology*, 7th ed. Philadelphia: WB Saunders, vol. 3, chapt. 86, pp. 2565-2588, 1998
10. Quinlan, D. M., Epstein, J. I., Carter, B. S. et al: Sexual function following radical prostatectomy: influence of preservation of neurovascular bundles. *J Urol*, **145**: 998, 1991
11. Wasson, J. H., Cushman, C. C., Bruskewitz, R. C. et al: A structured literature review of treatment for localized prostate cancer. Prostate Disease Patient Outcome Research Team. *Arch Fam Med*, **2**: 487, 1993
12. Zvara, P., Spiess, P. E., Merlin, S. L. et al: Neurogenic erectile dysfunction: the course of nicotinamide adenine dinucleotide phosphate diaphorase-positive nerve fibers on the surface of the prostate. *Urology*, **47**: 146, 1996
13. Lue, T. F., Gleason, C. A., Grock, G. B. et al: Intraoperative electrostimulation of the cavernous nerve: technique, results and limitations. *J Urol*, **154**: 1426, 1995
14. Bennett, C. J., Seager, S. W., Vasher, E. A. et al: Sexual dysfunction and electroejaculation in men with spinal cord injury: review. *J Urol*, **139**: 453, 1988
15. Creed, K. E., Carati, C. J. and Keogh, E. J.: Autonomic control and vascular changes during penile erection in monkeys. *Br J Urol*, **61**: 510, 1988
16. Lue, T. L., Fahey, M. R., Lin, S. N. et al: Effect of anesthesia on penile erection. *Surg Forum*, **35**: 628, 1984
17. Lue, T. F., Schmidt, R. A. and Tanagho, E. A.: Electrostimulation and penile erection. *Urol Int*, **40**: 60, 1985
18. Mueller, S. C., Aboseif, S., Fahey, M. R. et al: Spinal anesthesia and electroerection in dogs and monkeys. *J Urol*, **142**: 171, 1989
19. Shafik, A.: Cavernous nerve stimulation through an extrapelvic subpubic approach: role in penile erection. *Eur Urol*, **26**: 98, 1994
20. Steers, W. D., Mallory, B. and de Groat, W. C.: Electrophysiological study of neural activity in penile nerve of the rat. *Am J Physiol*, **254**: R989, 1998
21. Rehman, J., Christ, G., Melman, A. et al: Intracavernous pressure responses to physical and electrical stimulation of the cavernous nerve in rats. *Urology*, **51**: 640, 1998
22. Watson, D. L., Richie, J. P., Vickers, M. A. et al: Cavernosal nerve stimulation during radical retropubic prostatectomy. *J Urol*, **153**: 383A, abstract 620, 1995
23. Michl, U., Dietz, R. and Huland, H.: Is intraoperative electrostimulation of erectile nerves possible? *J Urol*, **162**: 1610, 1999
24. Johnson, A. G.: Surgery as a placebo. *Lancet*, **344**: 1140, 1994