

Sexual Function/Infertility

POTENCY FOLLOWING ROBOTIC RADICAL PROSTATECTOMY: A QUESTIONNAIRE BASED ANALYSIS OF OUTCOMES AFTER CONVENTIONAL NERVE SPARING AND PROSTATIC FASCIA SPARING TECHNIQUES

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ABSTRACT

Purpose: Anatomical nerve sparing radical prostatectomy provides excellent cancer control, although the recovery of sexual function is variable. We recently described a technique to preserve the prostatic fascia (veil of Aphrodite) that appears to enhance the quality of nerve preservation during robotic prostatectomy. In January 2003 we initiated a prospective study comparing patients undergoing prostatic fascia preservation with those undergoing conventional nerve sparing robotic radical prostatectomy. We report results at 12 months of followup

Materials and Methods: From January to August 2003, 58 potent men with a Sexual Health Inventory for Men score (SHIM) of greater than 21 without phosphodiesterase 5 inhibitors underwent Vattikuti Institute prostatectomy, including 35 with preservation of the prostatic fascia (study) and 23 with conventional nerve sparing (control). Potency was assessed with self-administered SHIM questionnaires 12 months after surgery. The primary end point was achievement of erections strong enough for penetration with or without oral medications. The secondary end point was the ability to achieve normal erections (SHIM greater than 21) with and without medications.

Results: At 12 months of followup 17 of 23 control (74%) and 34 of 35 study (97%) patients achieved erections strong enough for intercourse ($p = 0.002$). Four control (17%) and 18 study (51%) patients achieved normal erections (SHIM greater than 21) without medication ($p < 0.0001$). Six control (26%) and 30 study (86%) patients achieved normal erections with or without phosphodiesterase 5 inhibitors ($p < 0.0001$).

Conclusions: Potency rates after radical prostatectomy vary with the measure used to define potency. Irrespective of the definition used patients undergoing prostatic fascia preserving radical prostatectomy have significantly better potency outcomes than patients undergoing conventional nerve sparing robotic prostatectomy at 12 months of followup.

KEY WORDS: prostate, robotics, prostatectomy, impotence, questionnaires

Radical prostatectomy (RP) is associated with excellent long-term cure rates for organ confined prostate cancer, although many men have erectile dysfunction following the operation. Despite technical refinements to the nerve sparing (NS) technique the recovery of erectile function (EF) (potency) following radical prostatectomy is far from uniform with potency rates of 10% to 86%.^{1–3} Steineck et al thought that variation in the reported prevalence of erectile dysfunction following radical prostatectomy may depend on the wording of questions and the cutoff value used to define preserved erectile function.⁴ In most contemporary series groups have defined potency as the ability to achieve inter-

course (penetration) with or without phosphodiesterase 5 inhibitors (PDE5Is)¹ and the prevalence of potency is high if this definition is used. However, this definition underestimates the extent of erectile dysfunction (ED) because it does not incorporate the measurement of quantitative changes in erectile frequency or quality.

Recognizing this, the National Institutes of Health recommended the development and use of validated questionnaires that examine erectile function in more detail.⁵ One such questionnaire, the International Index of Erectile Function (IIEF), has a high degree of sensitivity to detect changes in sexual function with the response to treatment. IIEF-5, also called the Sexual Health Inventory for Men (SHIM), is a 5-item abridged version of IIEF that was developed as a simple patient administered tool to detect ED in the clinical setting.⁶ Rosen et al reported that an IIEF-5 score of greater than 21 had a 98% negative and 89% positive predictive value for diagnosing ED⁵ and they recommended using an

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IIEF-5 score of 21 as the cutoff point for defining erectile dysfunction. If this cutoff is used for defining potency after radical prostatectomy, only 10% to 20% patients are potent.⁷

While the classic description of neurovascular bundles involves 2 well-defined structures lying in a groove between the prostate and rectum, recent studies suggest that accessory neural channels exist in the prostatic fascia that may supplement neural stimulation to the penis.⁸⁻¹⁰ We have previously described a technique of robotic prostatectomy that incorporates preservation of the prostatic fascia (veil of Aphrodite) and any putative accessory neural channels.¹¹ In the current communication we detail potency outcomes at 12 months of followup in the first patients undergoing this operation (study) in comparison to those in a group of patients who underwent conventional bilateral nerve sparing robotic radical prostatectomy (control) during the same period.

METHODS

Patient selection. From January to August 2003, 126 consecutive patients underwent Vattikuti Institute prostatectomy (VIP),¹¹ as performed by a single surgeon (MM) who developed the technique. Sexual function was measured preoperatively and 12 months after surgery with a validated third party questionnaire (SHIM).⁷ Of the patients 76 had normal erectile function (SHIM greater than 21 without medication) and 50 had erectile dysfunction (SHIM 21 or less and/or potency enhancing medication). Patients with normal erectile function and low risk disease according to the D'Amico classification, that is prostate specific antigen (PSA) 10 ng/ml or less, clinical stage T1c and Gleason sum 6 or less,¹² were offered the prostatic fascia sparing procedure and they represent the study group. All others were treated with conventional bilateral nerve sparing VIP and they represent the control group. There were 10 exceptions to patient allocation. Eight young patients with a mean age of 49.6 years with intermediate risk disease (PSA greater than 10 and 20 ng/ml or less, clinical stage T2b and Gleason sum 7) elected fascia preserving surgery. Two patients with low risk disease elected conventional nerve sparing because of a strong family history of prostate cancer. Thus, 46 patients underwent the prostatic fascia preserving procedure, whereas 30 underwent conventional nerve sparing (fig. 1). The study protocol was approved by the Institutional Review Board at Henry Ford Hospital. Data collection and followup correspondence were done in accordance with the Health Insurance Portability and Accountability Act.

Surgical technique. Conventional nerve sparing was performed using the previously described VIP technique¹¹ with certain modifications. After the bladder neck was divided the prostatic pedicles were controlled with Hem-o-Lok® clips applied well anterior to the major neurovascular bundles.

From this point no monopolar coagulation was used. Articulated cold da Vinci® robotic scissors were used for separating the bundles and bipolar coagulation was done only when absolutely necessary. In the study group clips were not used and individual vessels were coagulated using articulated da Vinci® bipolar forceps as they entered the prostate. Scissor dissection was used to separate the prostatic fascia from the capsule after the proper plane of dissection was identified.

The radical prostatectomy specimen was submitted for pathological analysis and examined as reported previously.¹³ Patients were encouraged to start PDE5I as needed 4 weeks after surgery. However, medications were not given on a routine basis.

End points and statistical analysis. The primary end point of analysis was a history of sexual intercourse at least once in the last 4 weeks. There were 2 secondary end points, namely attainment of a SHIM of greater than 21 with or without PDE5I and the maintenance of normal erectile function (SHIM greater than 21) without potency enhancing medications 12 months after surgery. These end points were chosen because they were used in other studies of potency after radical prostatectomy.^{1,7,14} The 2 groups were compared using the 2-tailed Fisher exact test with $p < 0.05$ considered statistically significant. All statistical analyses were performed using SPSS, version 11.5 (SPSS, Chicago, Illinois).

RESULTS

Seven patients in each of the 2 groups could not be contacted after several followup communications. Four patients in the study group indicated that they achieved full erections but were not sexually active because of intercurrent medical problems (2) or lack of partner interest (2). A total of 35 patients in the study group and 23 in the control group completed the preoperative and followup questionnaires (fig. 1).

The 2 groups were well matched in terms of preoperative PSA, body mass index and operative time. Patients in the study group were younger and had lower risk disease than the control group, as expected. However, the 2 groups were evenly matched for factors that adversely affect erectile function, namely smoking, diabetes, hypercholesterolemia and cardiac disease (table 1).

Figure 2 shows preoperative and postoperative SHIM scores in all 58 patients. Figure 2 also demonstrates the ability of the operations to achieve the predetermined end points. The primary end point, that is achieving sexual intercourse in the 4 weeks before completing the questionnaire, was achieved by 17 control (74%) and 34 study (97%) patients ($p < 0.002$). Six control (26%) and 30 study (86%) patients attained the secondary end point of normal potency with or without PDE5I medications ($p = 0.0001$). The maintenance of normal erections

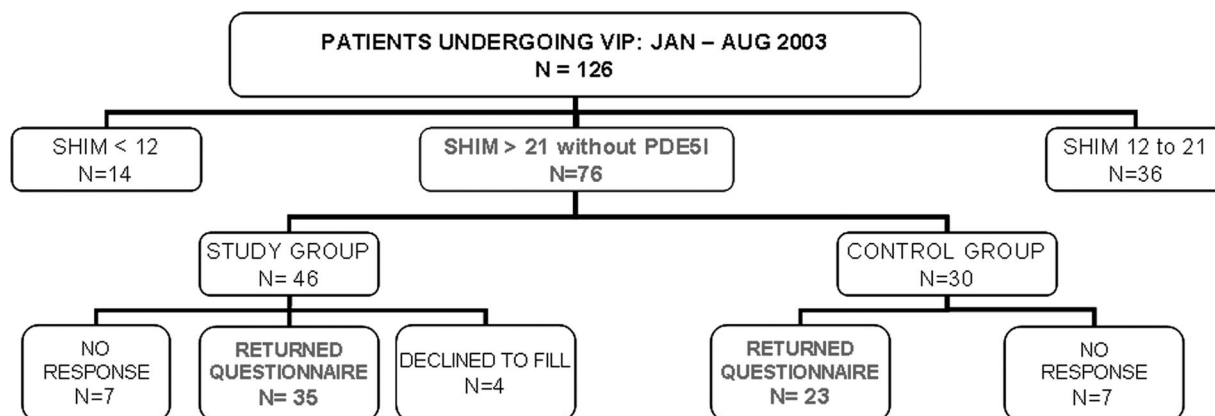


FIG. 1. Study design

TABLE 1. Demographic characteristics of control and study groups

Variable	Control	Study	p Value
Preop parameters:			
Mean age ± SD	60.5 ± 7.0	57.4 ± 6.3	0.03*
Mean ng/ml preop PSA (range)	5.8 (2.8–11)	4.9 (0.9–8.9)	0.10
Mean biopsy Gleason sum ± SD/median	6.5 ± 0.5/7	6.2 ± 0.4/6	0.02*
Mean body mass index ± SD (kg/m ²)	27.1 ± 3.4	26.9 ± 3.1	0.79
No. D'Amico classification (%):†			
Low risk group	2 (7)	38 (83)	<0.0001*
Intermediate risk group	28 (93)	8 (17)	<0.0001*
No. comorbidities (%):			
Diabetes mellitus	1 (4)	2 (6)	0.65
Hypertension	6 (24)	6 (18)	0.51
Coronary artery disease	1 (4)	2 (6)	1.0
Abnormal lipid profile	7 (28)	8 (24)	0.55
Smoking	0	2 (6)	0.15
Other	2 (8)	3 (9)	1.0
Operative parameters:			
Mean operative time ± SD (mins)	117 ± 23	113 ± 22	0.36
Mean operative blood loss ± SD (ml)	89 ± 45	111 ± 66	0.19
Mean pathological Gleason sum ± SD	6.7 ± 0.8	6.4 ± 0.5	0.16
% Pathological stage T2	90	98	0.29
No. pos surgical margins (%)	1 (3)	1 (2)	1.0

* Statistically significant difference between control and study groups.

† Low risk—clinical stage T1c, PSA 10 ng/ml or less and Gleason sum 6 or less, intermediate risk—clinical stage T2b, PSA greater than 10 to 20 ng/ml or less, and Gleason sum 7, and high risk—clinical stage T2c, PSA greater than 20 ng/ml and Gleason sum 8 or greater.

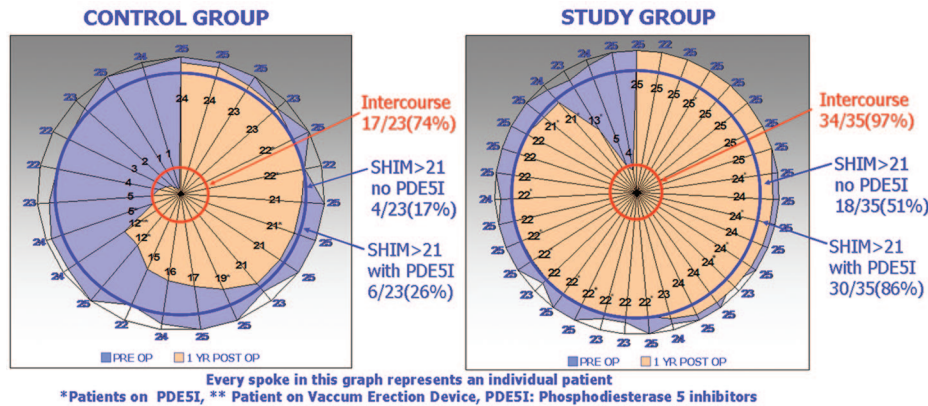


FIG. 2. Radar graph shows preoperative and postoperative SHIM scores in each patient (spokes) and ability of procedure to preserve sexual function. Extent of blue areas correlates with postoperative loss of potency.

TABLE 2. Erectile function outcomes in control and study groups

Outcomes	Control	Study	p Value
No. erection adequate for intercourse (SHIM 2 or greater) with/without PDE5I (%)	17 (74)	34 (97)	0.002*
Normal erections (SHIM greater than 21) with/without PDE5I	6 (26)	30 (86)	0.0001*
Normal erections (SHIM greater than 21) without PDE5I	4 (17)	18 (51)	0.0001*
Preop SHIM:			
Mean ± SD	24 ± 1.8	24.5 ± 0.8	0.12
Median	25	25	
Postop SHIM:			
Mean ± SD	14.8 ± 8.6	21.9 ± 4.8	0.0001*
Median	19	22	
Mean SHIM change (%)	9.1 (38)	2.6 (11)	0.0002*
No. pts on PDE5I (%)	7 (30)†	15 (43)	0.57

* Statistically significant difference between control and study groups.

† Including 1 patient using a vacuum device.

without PDE5I was achieved by 4 control (17%) and 18 study (51%) patients (p <0.0001). A total of 15 of 35 study (43%) and 7 of 23 control (30%) patients were on PDE5I or were using a vacuum device (1 control) at 12 months (p = 0.57). Postoperative mean and median SHIM scores in control and study patients were 14.8 and 19, and 21.9 and 22, respectively. This represents a 38% decrease from preoperative levels in control subjects and 11% in patients who underwent prostate fascia sparing (p <0.0001, table 2).

Histological analysis showed that 1 study patient (2%) had a focally positive margin at the apex. No patients had posi-

tive margins in the region of the veil and, hence, the veil did not compromise margin status in this series. There was 1 positive margin (3%) posterolaterally at the location of the main neurovascular bundle in the group of patients undergoing conventional nerve sparing. The 2 patients had undetectable PSA at 12 months of followup.

DISCUSSION

The main objective of performing radical prostatectomy is cancer control, although an important secondary goal is the

maintenance of the quality of life. Many studies have shown that the most common detractor of quality of life following radical prostatectomy is a decrease in erectile ability.^{2,3,7} While conventional nerve sparing radical prostatectomy leaves most men with some erectile function, it is the exceptional individual who emerges from the operation with erectile ability unscathed.

Comparison of potency outcomes among published studies is confounded by the different definitions of postoperative potency used by reporting surgeons. Most groups use data from chart reviews and physician interviews to assess potency but this approach may overestimate potency compared to patient administered validated questionnaires.⁴ In most series that equate potency with the ability to achieve intercourse (penetration) potency rates are 20% to 40%.⁷ However, in a small series of patients Walsh et al reported a 73% intercourse rate with or without PDE5I.¹

A somewhat different picture emerges when potency is measured using validated questionnaires. In perhaps the most comprehensive study to date Schover et al reported that 33% of patients undergoing bilateral NS RP (BNSRP) had a score of greater than 22 on the IIEF erectile function domain 4 years after surgery, including 15% spontaneously and 18% with PDE5I.⁷ In their analysis a score of greater than 25 indicates normal erectile function and a score of greater than 22 includes not only normal patients, but also patients with mild ED. Using the same questionnaire Rabbani et al reported normal erectile function in only 8% patients 12 months following BNSRP.¹⁵ Using an equally stringent definition (SHIM 22 or greater) we achieved a potency rate of 26% in the control group and 86% in the study group.

Parsons et al reported a potency rate of 71% at 12 months in young men with a mean age of 50.1 years undergoing BNSRP with preoperative IIEF-5 scores greater than 20.¹⁶ Potency was defined as SHIM 16 or greater. We repeated our analysis using the Parsons criteria. A total of 27 patients with SHIM 21 or greater underwent conventional nerve sparing and 41 underwent the veil. A postoperative score of 16 or greater was achieved by 14 control (52%) and 38 study (93%) patients (data not shown).

To our knowledge the erectile function outcomes that we achieved using our technique of prostatic fascia preservation are the highest reported in the literature (table 3). However, there are several caveats. Although our study was prospective, we did not randomize patients. While patients self-administered the mail-in questionnaires, data collection (SK and AB) and analysis (MM) were done by individuals directly involved with surgical treatment. All patients were operated on by a single surgeon (MM), who was responsible for the development of the surgical techniques described.

Can the apparent superiority in potency outcomes be explained by patient selection? Patients in this analysis were younger than those in many other studies, although they were considerably older than those reported by the Johns Hopkins group.¹⁶ As in that study, we deliberately included only patients fulfilling the Rosen criteria of normal erectile function (SHIM greater than 21) in this analysis and these results may not be applicable to men with preexisting erectile dysfunction. Thus, our patients were selected to achieve a high potency result. However, they are representative of the patient population that we see and no selection was done for comorbidities that predispose to erectile dysfunction.

There are 2 cautionary notes. In this series recovery of potency required 9 to 12 months. Thus, even men destined to have a good outcome must be patient for about a year and patience is not a quality that this select group of patients possessed. Finally, only 76% of the patients returned the questionnaire despite our best efforts to contact them. While this compares with the 49% and 70% response rates noted by other investigators,^{3,8} it nevertheless raises the possibility that our results would have been different had all patients responded. Therefore, we calculated ranges of potency in the 2 groups, assuming the worst and best case scenarios. If all nonrespondents were considered to be impotent, the potency rates would be 60% in the control group and 74% in the study group. If all nonrespondents were deemed potent, the rates would be 83% and 98%, respectively. In this series potency following conventional nerve sparing robotic radical prostatectomy is comparable with that in the best reported results of open radical prostatectomy. However, outcomes were sig-

TABLE 3. Potency outcomes in contemporary series of patients undergoing NSRP

References	No. Pts	NSRP	Potency Definition	Followup (mos)	Age	% Potency
Talcott et al ²	19	Bilat	Intercourse with/without PDE5I	12	64.5	21
Walsh et al ¹	64	Bilat	Intercourse with/without PDE5I	12	57	73
Stanford et al ³	NA	Bilat	Intercourse with/without PDE5I	18	Not available	44
Turk et al ²¹	125	Bilat laparoscopic	Intercourse with/without PDE5I	12	59.9	41
Madalinska et al ²²	102	Bilat	Intercourse with/without PDE5I	12	62.6	36
Siegel et al ²³	419	Bilat	Intercourse with/without PDE5I	6	66	10
Steineck et al ⁴	116	Bilat	Intercourse with/without PDE5I	12	64.1	20
Katz et al ²⁶	26	Bilat laparoscopic	Intercourse with/without PDE5I	12	62.8	23
Fulmer et al ²⁴	42	Bilat	Achieve preop function	18	64	18 (unknown PDE5I)
Hara et al ²⁵	52, 54	Bilat laparoscopic, Bilat	IIEF greater than 21/25	6, 6	68.2, 66.5	17 (unknown PDE5I), 27 (unknown PDE5I)
Schover et al ⁷	240	Bilat	IIEF ED greater than 22/30	52	65	18 (no PDE5I), 15 (PDE5I)
Rabbani et al ¹⁵	145	Bilat	IIEF ED greater than 25/30	12	Median 59	8
Parsons et al ¹⁶	25	Bilat	IIEF greater than 16/25	12	50.1	71 (PDE5I)
Present series:						
Control	23	Bilat conventional	Intercourse with/without PDE5I	12	60.5	74
Study	35	Veil of Aphrodite	Intercourse with/without PDE5I, SHIM greater than 21/25	12	57.4	97, 51 (no PDE5I), 86 (PDE5I)

nificantly better in patients undergoing prostatic fascia sparing technique than in control patients undergoing conventional nerve sparing irrespective of the definition of potency used. Why? Although study patients were younger than control patients by 3 years, the recovery of potency was similar in study patients who were younger and older than 60 years (data not shown). Similarly the prevalence of preexisting comorbid factors and the postoperative use of PDE5Is were comparable in the 2 groups (tables 1 and 2). Therefore, we conclude that it may be surgical technique rather than patient selection that was responsible for the salutary outcomes.

The technique of nerve preservation in anatomical radical prostatectomy is based on the autopsy studies of the pelvic plexus of Walsh and Donker.¹⁷ In 2 specimens, that is 1 fetus and 1 newborn, they determined that branches that innervate the corpora cavernosa were organized into distinct neurovascular bundles situated between the rectum and urethra. While these seminal studies laid the foundation of nerve sparing techniques, they do not account for variations in neural anatomy that may occur. Other investigators have found that distinct neurovascular bundles cannot be identified in many instances and a plexus of nerves exists that innervates the cavernous tissues, rectum and prostate, in contrast to 2 distinct neurovascular bundles.⁹ This plexus crosses the midline posterior within the layers of Denonvilliers' fascia and extends to the anterolateral surface of the prostate in the prostatic fascia.^{18,19} These studies suggest that the prostatic fascia on the anterolateral surface of the prostate is rich in nerve tissue that may be important in erectile function, at least in some men.¹⁰ We have reported that it is technically feasible to preserve the prostatic fascia in patients undergoing VIP without compromising cancer margins.²⁰ We attribute this to stereoscopic vision and magnification of the da Vinci[®] robot, which permits accurate dissection of fascial planes. We hypothesize that the excellent outcomes in study patients are related to the preservation of additional erectile nerves in the prostatic fascia. However, we have not performed microdissection studies that trace accessory nerve channels to the corpora cavernosa. Therefore, it is equally possible that the enhanced erectile function seen in study patients is the result of decreased traction or thermal injury to the nerves because the plane of dissection is far away from the putative neurovascular bundles. A third possibility is that preservation of the prostatic fascia preserves an additional blood supply to the cavernous tissue, allowing the production of more endothelial nitric oxide, which is the factor responsible for the maintenance of penile erection. In fact, all 3 factors may have a role in the realization of superior potency outcomes with prostatic fascia preserving radical prostatectomy.

CONCLUSIONS

In our hands patients undergoing prostatic fascia preserving robotic radical prostatectomy had significantly better erectile function outcomes than patients undergoing conventional bilateral nerve sparing surgery without compromising cancer control. To our knowledge our potency outcomes with this technique are the highest reported to date. We conclude that the fascial preserving technique appears to be effective in our patients, although we cannot state precisely why. Larger multi-institutional studies are necessary to determine if our results are unrealistic or reproducible.

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EDITORIAL COMMENT

These authors present their EF outcomes in this series and their efforts in using a validated instrument for the definition of EF. However, this study illustrates some of the complex methodological problems involved in RP outcome studies. 1) We can no longer rely on patient self-reporting because of social desirability issues (patients telling their surgeon what they think their surgeon wants to hear) and we must rely on validated questionnaires. However, when using such questionnaires, what score represents functional erections? SHIM (reference 6 in article), also known as IIEF-5, and IIEF¹ contain frequency questions that are scored 1 to 5, 1 representing never or almost never and 5 representing always or almost always. Thus, when using SHIM, which has 5 questions, a score cutoff of at least 20 is reasonable since this equates to a mean score of 4 per question, representing most of the time. The most important end point in this study is the percent of men attaining a score of 21 without PDE5I and nowhere in the National Institutes of Health definition of ED is medication assistance mentioned (reference 5 in article). 2) As pointed out by the authors, this was a nonrandomized study and demonstrating that the study and control groups were demographically matched does not account for all potential biases, in particular patient motivation to remain sexually functional. Might study group patients be more committed to remaining sexually active than those in the control group if they initially elected the study operation in an effort to preserve EF? However, we have seen many published studies that compared open vs laparoscopic renal surgery or radical vs partial nephrectomy that were not randomized and, thus, this issue is not unique to RP analyses.

The next potential bias in such studies is the assessment of nerve sparing in the 2 groups. We are at a point, especially when surgeons are integrally involved in research (no true third party independent evaluator existed in this study), when objective documentation of cavernous nerve function is critical to assessing comparative outcomes. Declaring the macroscopic integrity of the nerves does not represent the level of scientific rigor that is required to make a definitive statement regarding the advantages of 1 operative approach over another. On another note, might the 3-year difference in mean age between groups represent a factor that resulted in such a dramatic difference in EF outcomes? It is unlikely that age alone was the key factor since baseline SHIM scores were similar. However, what may be an important factor is comorbidity profiles. Stating that the comorbidity profiles are identical may not be completely accurate (table 1). Each of the comorbidities outlined is a risk factor for ED and a heterogeneous condition. For example, the degree to which a patient with hypertension has end organ (penile) vascular disease depends on the severity of hypertension. Thus, there is a need to commence assessing the severity of comorbidities because they are likely to be directly related to EF after radical pelvic surgery.

Another issue of significance is that no mention is made by the authors of accessory pudendal artery presence and preservation. This is important since accessory pudendal arteries have been identified as a potential contributor to EF outcomes.² Surely they are more easily and readily identified with the magnification that is associated with laparoscopic/robotic approaches. Might the control group have had poorer outcomes, at least partly based on the sacrifice of these vascular channels, which we know may have a major role in cavernous arterial inflow?³

One of the most significant concerns is that the authors made no effort to record PDE5I use. Rather, they state that "patients were encouraged to start PDE5I as needed 4 weeks after surgery." This has become a crucial factor in EF outcomes following radical pelvic surgery. Preliminary clinical and basic science evidence supports a protective effect of these medications, in particular sildenafil, on EF.^{4,5} More frequent and/or more prolonged use of sildenafil by patients in the study group could well have accounted for improved outcomes. Finally, while the authors statement that "the erectile function outcomes that we achieved using our technique of preservation of prostatic fascia are the highest reported in the literature" is supported by the data presented, a definitive statement regarding the superiority of 1 surgical approach over another needs a randomized trial of closely matched patients in the study and control groups with rigorous recording of severity of comorbidities, preoperative medication use, PDE5I use and cavernous nerve function at the completion of the operation.

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REPLY BY AUTHORS

Our patients had preoperative SHIM scores greater than 21, and maintenance of potency was of equal importance to all of them (whether they had undergone conventional nerve sparing or the veil procedure). Accessory pudendal arteries can be seen with exquisite clarity even with 2-D laparoscopy.¹ This is even more true with 3-D vision. Thus, they were easily preserved in these patients.

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