

Autologous Tunica Vaginalis and Subcapsular Orchiectomy: A Hormonal Therapy for Prostate Cancer

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ABSTRACT: Two novel surgical procedures that combine an autologous tunica vaginalis pedicle graft (TVG) with a subcapsular orchiectomy (SCOT) were evaluated in asymptomatic patients with rising prostate-specific antigen (PSA) values following radiation therapy, a radical retropubic prostatectomy, or a newly diagnosed prostatic cancer with bony metastasis. In the SCOT I procedure, the TVG was secured to the inner wall of the tunica albuginea. In the SCOT II procedure, the TVG was folded and secured to the external wall of the tunica albuginea. Between December 1, 1999, and July 1, 2000, 26 patients were offered hormonal therapy. Twelve patients selected the SCOT I procedure, 12 selected a luteinizing hormone-releasing hormone (LHRH) agonist, and 2 selected a bilateral total orchiectomy (BTO). Because the cosmetic outcome of the SCOT I procedure was less than ideal, this procedure was modified in December 2001. Between December 1, 2001, and July 1, 2002, 28 hormonal candidates were evaluated. Twelve patients selected the SCOT II procedure, 11 selected an LHRH agonist, and 5 selected a BTO. Preoperative measurements of the testicular area and PSA were obtained. During postoperative visits, the total testosterone, PSA, and testicular area were deter-

mined, and the Fugl-Meyer questionnaire (FMQ) and SCOT-specific questionnaire (SSQ) were completed. Between March 1, 2000, and December 1, 2002, 10 patients underwent a BTO. This group was the control for the postoperative SCOT total testosterone values. Sixty-three percent of the mean preoperative testicular area was preserved in the SCOT II group vs 43% in the SCOT I group at the 9- to 12-month visit ($P < .01$). The mean postoperative total testosterone values for the SCOT I, SCOT II, and BTO groups were in the castrate range. No statistically significant difference was noted between the preoperative and postoperative FMQ scores among the SCOT I and SCOT II groups. Eighty-three percent of the SCOT II patients experienced no change in masculine identity, and 58% noted no change in testicular size. One hundred percent of the SCOT I patients experienced no change in masculine identity and noted no change in testicular size. The SCOT II procedure preserved a greater testicular area than the SCOT I. Both SCOT procedures achieved castrate levels of total testosterone and maintained masculine identity in 83%–100% of patients.

Key words: Castration, body image.

J Androl 2004;25:375–381

Testosterone deprivation, the cornerstone for the treatment of metastatic prostate cancer, can be achieved by a bilateral total orchiectomy (BTO) or by the use of a luteinizing hormone-releasing hormone (LHRH) agonist (Huggins and Hodges, 1941). Recently, BTO has seldom been selected because of patients' aversion to an empty scrotum (Melton et al, 2001). Various surgical procedures have been designed to preserve palpable testes. These have included subcapsular orchiectomy, subcapsular orchiectomy with eversion of the tunica albuginea about the epididymis, implantation of testicular prostheses, subepididymal orchiectomy, and orchiectomy in combination with a fibrofatty graft to the tunica vaginalis (Glenn,

1990; Kihara and Oshima, 1998). These options have not gained general acceptance because of skepticism that they achieve castrate levels of testosterone and/or preserve significant testicular size. The silicone prosthesis has been costly and is associated with an increased risk of infection and a potential adverse immunological reaction. This work examines 2 novel surgical techniques designed to preserve significant testicular area and attain castrate levels of testosterone.

Materials and Methods

Between December 1, 1999, and July 1, 2000, 26 patients with increasing prostate-specific antigen (PSA) values following external beam radiation, radical retropubic prostatectomy, or newly diagnosed prostatic cancer with bony metastases were offered 3 options—an LHRH agonist, BTO, or a subcapsular orchiectomy with a tunica vaginalis graft (SCOT) procedure. Patients who were receiving a maintenance LHRH agonist therapy were ex-

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Received for publication August 20, 2003; accepted for publication December 3, 2003.

Fugl-Meyer Questionnaire						
Thank you for taking the time to complete this survey.						
This is a two part survey. We want you to mark "X" on the number that best describes how you felt about yourself <u>BEFORE</u> surgery on each of the questions. Then once you are done, go over all the questions again and mark "O" on the number that best describes how you feel about yourself <u>TODAY</u> . We understand that in some circumstances you might mark the same number in response to how you felt before and after surgery. See below for examples of how the answers might look.						
1 = Very dissatisfying						
2 = Dissatisfying						
3 = Rather dissatisfying						
	4 = Rather satisfying					
	5 = Satisfying					
	6 = Very satisfying					
Life as a whole is	1	2	3	4	5	6
My sexual life is	1	2	3	4	5	6
My partnership relation is	1	2	3	4	5	6
My family life is	1	2	3	4	5	6
My contacts with friends and acquaintances are	1	2	3	4	5	6
My leisure situation is	1	2	3	4	5	6
My vocational situation is	1	2	3	4	5	6
My financial situation is	1	2	3	4	5	6
<hr/>						
Name and last 4						

Figure 1. The Fugl-Meyer questionnaire (FMQ) that was designed to assess the patient's satisfaction with various aspects of his life.

cluded from the study. The patients were informed that the SCOT procedure offered the potential of preserving testicular size. Twelve patients selected LHRH agonists, 2 patients selected simple bilateral orchidectomy, and 12 patients selected SCOT. Preoperative PSA values and testicular area determination were obtained. Vernier calipers were used to obtain the longitudinal axis and the maximum diameter of each testis of the SCOT group. Testicular measurements of the LHRH group were not obtained. The testicular area was determined by a calculation of the area of the intersection of a plane with the median axis of the testis. This area was calculated by the following formula: longitudinal axis (cm) \times diameter (cm) - [diameter \times diameter] - (π $\frac{1}{2}$ diameter²). The testicular area, rather than the testicular volume, was selected because it offered a more precise measurement. Accurate volume measurements were not possible using the Prader orchidometer or goniometry because the postoperative testes did not have curvilinear, symmetric walls.

Testicular area and total testosterone determinations were performed at the 3- and 9-month postoperative visits. Total testosterone was determined by the chemiluminescent method with the IMMULITE 2000 Analyzer (Diagnostic Products Corp, Los An-

geles, Calif). For this study, we arbitrarily assigned a value of 20 ng/dL to any laboratory value reported as less than 20 ng/dL. Postoperative PSA values were obtained within 8 months of surgery. At the 6-month postoperative visit, each patient completed a Fugl-Meyer questionnaire (FMQ) comparing his life satisfaction before and after his surgical procedure (Fugl-Meyer et al, 1997) (Figure 1). Patients rated their current satisfaction for each item on a 6-point scale from 1 (very dissatisfying) to 6 (very satisfying). For each of the 8 items on the checklist, scores after surgery were subtracted from scores before surgery. These different scores were the dependent variables in the analyses. A series of 1-way analyses of variance were then used to compare group differences in improvement for each of these 8 satisfaction items. Each patient was also asked 3 SCOT-specific questions (SCOT-specific questionnaire [SSQ]): 1) Were your testes *smaller* after the operation?, 2) Did the operation make you feel *less* of a man?, and 3) Would you counsel another patient, who required hormonal therapy for advanced prostatic cancer, *against* this operation? The negative wording of these 3 questions was designed to eliminate the potentially favorable bias introduced

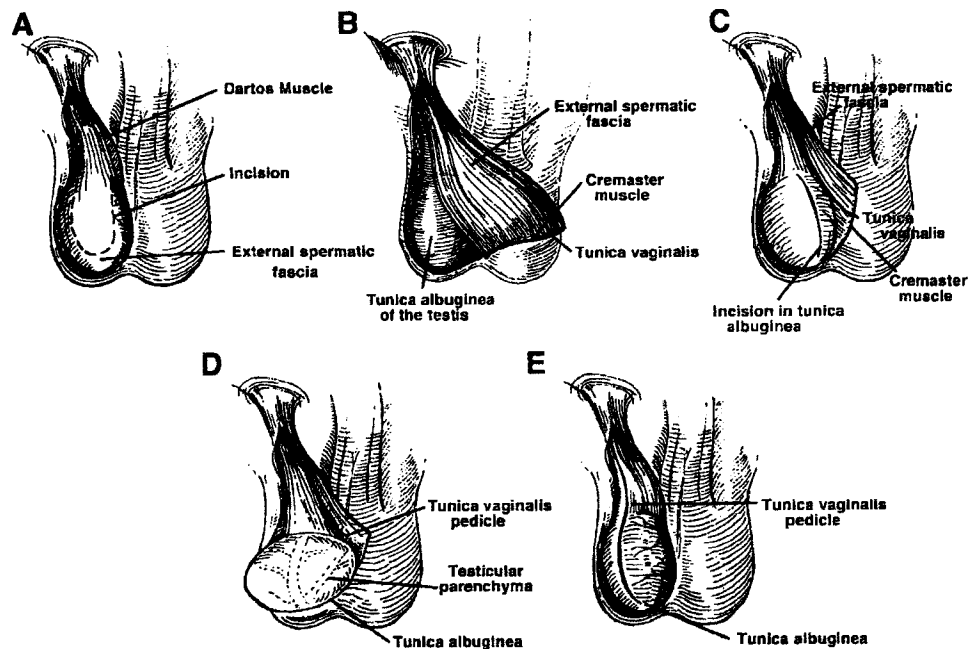


Figure 2. A sequential display of the steps involved in the SCOT I (subcapsular orchietomy with a tunica vaginalis graft) procedure.

by the natural tendency of patients to provide a positive response when asked about an outcome.

The procedure was performed as day surgery. Under spinal anesthesia, a midline vertical anterior scrotal incision, 6 cm in length, was made through the skin and dartos muscle (Figure 2A). The dartos muscle was dissected from the external spermatic fascia. A horseshoe incision, originating at the base of the testis and extending along the lateral boundaries of the epididymis, was made through the external spermatic fascia, cremasteric muscle, and underlying tunica vaginalis (Figure 2B). A longitudinal incision was made through the anterior surface of the tunica albuginea of the testis (Figure 2C). The testicular parenchyma was resected (Figure 2D). Cautery was used to achieve hemostasis. The hilar tissue was cauterized. The vascularized pedicle was secured to the inner wall of the tunica albuginea with a 3-0 chromic suture. The tunica vaginalis was then loosely approximated over the pedicle with a 3-0 chromic suture (Figure 2E). The scrotum was drained and closed.

An analysis of the data of the SCOT I patients revealed that the cosmetic outcome was less than ideal. The SCOT II procedure, performed between December 1, 2001, and July 1, 2002, was an attempt to improve this outcome through several modifications of the SCOT I. With the SCOT II, the skin incision was horizontal. The base of the horseshoe incision in the tunica vaginalis was at the superior aspect of the testis and extended inferiorly along the lateral boundaries of the testis (Figure 3A). A horizontal incision was made through the anterior surface of the tunica albuginea of the testis (Figure 3B). The vascularized pedicle was folded and secured to the external wall of the tunica albuginea (Figure 3C).

The difference between the average of the left and right testicular preoperative area and postoperative testicular area of each SCOT II patient was compared to the difference between the

average of the left and right preoperative and postoperative area of the SCOT I patients using the chi-square test.

The number of SCOT patients with a total testosterone level greater than 50 ng/dL was compared to the number of BTO patients by means of the chi-square test.

The operating time and age for each SCOT and BTO patient were noted. All charts were reviewed for postoperative complications and use of analgesics.

All analyses were run using SAS and the Georgetown statistical package. The mean presented in this work is the average obtained by adding all the values and dividing by the total number of subjects.

Results

Table 1 presents the difference between the preoperative and postoperative testicular area (cm²) for each of the SCOT I and SCOT II patients at 9 months as well as the percentage of preservation of the preoperative testicular area for each patient. At 9 months, 63% of the mean area was preserved with the SCOT II procedure vs 43% with the SCOT I. Based on the difference of the preoperative- and postoperative-averaged testicular areas, the SCOT II procedure preserved a greater testicular area ($P < .01$).

Table 2 presents the total testosterone values for each patient and the mean total testosterone for the 3 groups. The mean total testosterone value for all 3 groups was in the castrate range. Using the total testosterone value of 50 ng/dL as the upper limit of the castrate range, the total testosterone value for the SCOT I and SCOT II categories

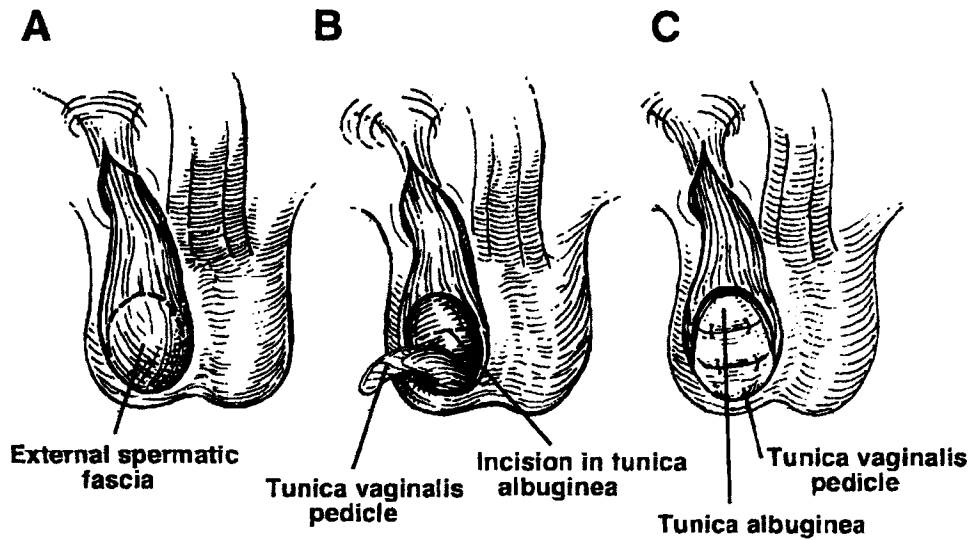


Figure 3. A display of the modifications made in the SCOT I (subcapsular orchiectomy with a tunica vaginalis graft) procedure. With these modifications in place, the procedure is the SCOT II.

was compared to the total testosterone value for the BTO group. The distribution was not significant ($P = .20$). The total testosterone of patient 11 in the SCOT I group was 112 ng/dL at 9 months.

Table 3 presents the preoperative and postoperative PSA values for each SCOT and BTO patient and the mean PSA for the SCOT I, SCOT II, and BTO groups.

Table 4 includes the difference between the mean preoperative and postoperative domain scores of the FMQ for each SCOT group. None of the comparisons (7 domain-specific comparisons and 1 overall comparison) between the groups were statistically significant.

Figure 4 presents each patient's answers to the 3 SCOT-

specific questions. All patients in the SCOT I group would recommend their operation to another patient and noted no change in their masculine identity or testicular size.

The SCOT I group had a mean age of 71 years (range, 48–80 years) vs 70 years (range, 54–80 years) for the SCOT II group and 75 years (range, 61–84 years) for the BTO group. The mean operative time for the SCOT I group was 67 minutes (range, 56–78 minutes) vs 70 minutes (range, 60–90 minutes) for the SCOT II group and 47 minutes (range, 26–90 minutes) for the BTO group.

Table 5 provides a list of factors that could have influenced the SCOT II patient's perception that his testes

Table 1. The difference and percent difference between the testicular area before and 9 months after the SCOT procedure for each patient**†

Patient	SCOT I				Patient	SCOT II			
	Preop	9 mo	Diff	%		Preop	9 mo	Diff	%
1	20.88	14.44	6.44	69	1	20.43	7.34	13.09	36
2	16.87	5.94	10.92	35	2	11.90	10.46	1.44	88
3	17.35	3.50	13.85	20	3	8.28	4.06	4.22	49
4	18.63	4.33	14.30	23	4	13.78	7.84	5.94	57
5	17.88	8.80	9.08	49	5	10.80	4.07	6.74	38
6	15.71	9.70	6.01	62	6	19.65	9.33	10.32	47
7	10.28	12.56	-2.28	122	7	7.38	5.97	1.41	81
8	8.28	3.17	5.11	38	8	11.78	10.02	1.76	85
9	21.56	8.28	13.28	38	9	10.60	12.56	-1.97	119
10	24.48	1.57	22.91	6	10	7.25	4.66	2.58	64
11	19.36	4.88	14.47	25	11	15.16	7.01	8.15	46
12	20.13	8.82	15.25	24	12	12.21	5.52	6.68	45
Mean			10.78	43				5.03	63
Mean-c/o			10.87	38				4.92	60

* The "mean-c/o extremes" is the mean for the individual study group after exclusion of the highest and lowest difference and percent preserved values.

† SCOT indicates subcapsular orchiectomy with a tunica vaginalis graft (procedure).

Table 2. The postoperative total testosterone values in ng/dL for each SCOT I, SCOT II, and BTO patient*

Patient	SCOT I		SCOT II			BTO	
	3 mo	9 mo	Patient	3 mo	9 mo	Patient	2-8 mo
1	112	38	1	64	20	1	27
2	20	20	2	20	20	2	20
3	46	20	3	58	28	3	20
4	32	20	4	23	58	4	20
5	20	20	5	68	34	5	20
6	48	32	6	33	37	6	20
7	62	57	7	38	40	7	20
8	39	20	8	20	20	8	20
9	23	20	9	20	20	9	20
10	20	20	10	20	20	10	20
11	71	112	11	20	51		
12	20	20	12	59	30		
Mean	43.0	33.0	Mean	37.0	31.5	Mean	21.0

* BTO indicates bilateral total orchiectomy; SCOT, subcapsular orchiectomy with a tunica vaginalis graft (procedure).

were smaller after the operation. The subgroup of SCOT II patients who believed their testes were smaller is compared to the subgroup who believed their testes had not been affected by the SCOT II procedure.

During the 14-month SCOT I and SCOT II study periods, 44% of the candidates for hormonal therapy selected the novel surgical procedures, 43% selected an LHRH agonist, and 13% selected BTO. This preference was present at all ages.

There were no significant immediate or delayed complications. There were no wound infections, scrotal hematomas, or problems from epididymitis. Oral analgesics were used for less than 4 days. Scrotal-wall ecchymosis occurred in 2 patients.

Discussion

An LHRH agonist is the preferred first option to treat patients with advanced prostatic cancer. However, clinical studies have suggested that a BTO is superior to an LHRH agonist in that it more rapidly achieves castrate levels of testosterone, avoids the testosterone flare, is less expensive, and has superior therapeutic compliance (Chadwick et al, 1991; Bonzani et al, 1998). If there were a castration procedure that did not adversely affect life satisfaction and the male image, this option might become more frequently recommended and chosen. Several attempts have been made to achieve this goal. In 1942, Riba pioneered the subcapsular orchiectomy, a procedure that involved the removal of the testicular parenchyma and the simple closure of the tunica albuginea (Riba, 1942). Controversy began when cells that were similar to Leydig cells of the testicular parenchyma were found within the tunica albuginea after a subcapsular orchidectomy

Table 3. The preoperative and postoperative PSA values in ng/mL for each SCOT I, SCOT II, and BTO patient*

Patient	SCOT I		SCOT II			BTO		
	Preop	2-8 mo	Patient	Preop	2-8 mo	Patient	Preop	2-8 mo
1	42.5	1.7	1	8.8	0.1	1	23	0.33
2	2.5	0.1	2	9.1	1.1	2	3	0.59
3	6.8	0.8	3	2.3	1.0	3	2.9	0.1
4	14.6	0.5	4	1.4	0.4	4	63	1.71
5	7.9	0.2	5	52.1	0.0	5	667	25.3
6	5.4	0.3	6	2.7	0.4	6	22	0.7
7	3.9	1.7	7	6.7	0.5	7	2.6	2
8	4.1	5.5	8	5.8	2.6	8	1.43	0.1
9	142	7.8	9	4.9	0.2	9	495	15.07
10	59	2	10	38.8	1.9	10	71.5	2.19
11	8	3.2	11	31.5	8.2			
12	9.2	2.3	12	10.2	3.9			
Mean	25.5	2.2	Mean	14.5	1.7	Mean	135.1	4.8

* BTO indicates bilateral total orchiectomy; SCOT, subcapsular orchiectomy with a tunica vaginalis graft (procedure).

(McDonald and Calams, 1959). These concerns were eliminated by studies that compared human chorionic gonadotropin-stimulated plasma testosterone levels in patients who underwent a bilateral orchiectomy with patients who underwent a subcapsular orchiectomy (Burge, 1976). No difference was found in testosterone levels. Subsequently, no difference was observed between patients who underwent a BTO and a subcapsular orchiectomy in preoperative and postoperative testosterone or luteinizing hormone levels (Chapman, 1987). Most importantly, serum PSA and 3-year survivals for patients undergoing a BTO and a subcapsular orchiectomy were determined to be similar (Zhang et al, 1996).

However, subcapsular orchiectomies have rarely been performed. In a 1988 survey of 129 randomly selected urologists, 45% felt that it was not effective in lowering testosterone levels, 18% lacked a familiarity with the procedure, and 20% felt it had no cosmetic advantage (Merrill, 1988). The SCOT I and II procedures are additional

Table 4. The difference between the mean preoperative and postoperative domain scores of the FMQ for each of the SCOT groups*

	SCOT I	SCOT II
Life as a whole	0	0
Sexual life	1	1
Partnership relation	0	0
Family life	0	1
Contacts	0	0
Leisure	0	0
Vocational situation	0	0
Economy	0	1

* FMQ indicates Fugl-Meyer questionnaire; SCOT, subcapsular orchiectomy with a tunica vaginalis graft (procedure).

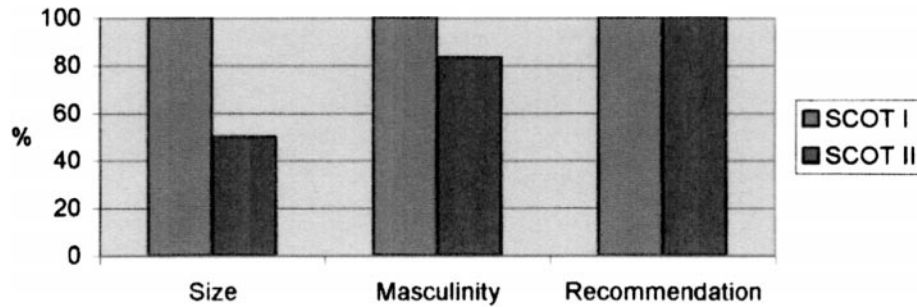


Figure 4. The percentage of SCOT I and SCOT II (subcapsular orchiectomy with a tunica vaginalis graft) patients who noted no change in testicular size or masculinity and would recommend their operation.

attempts to preserve testicular size. Nine months following surgery, the mean percentage of preservation of preoperative testicular area was 67% for the SCOT II group and 46% for the SCOT I group. If self-image were directly related to testicular area, the FMQ might detect a significant difference between the 2 SCOT groups. However, no difference in the domain-specific scores was noted. The SSQ also failed to demonstrate a direct relationship between testicular area and self-perception. While the SCOT II group had greater preservation of the testicular area ($P < .01$), all of the SCOT I patients believed their testicular size and “manliness” were unaffected by their procedure, while 58% of the SCOT II patients felt their testicular size had been unaffected, and 83% felt their masculinity had been unaffected. An analysis of Table 5 suggests that the percentage of testicular area preserved (64% vs 69%), the partner relationship (5/0 vs 4/0), and the postoperative total testosterone (28.4 vs 32.8 ng/dL) were not critical factors for the perception of loss

of testicular area. The “loss” subgroup tended to be younger (67.6 vs 73 years), had a lower post-SCOT PSA (0.9 vs 3.1 mg/mL), was less likely to have had radical prostatic surgery (1/5 vs 3/7), and was more likely to have been potent (3/5 vs 2/7) prior to the SCOT II procedure. Those who perceived a loss in testicular area were more likely to feel “less of a man.”

Subsequent to a BTO, 100% of serum testosterone is produced through the conversion of adrenal dehydroepiandrosterone by 3-beta hydroxysterone dehydrogenase and from the conversion of adrenal androstenedione through 17-beta hydroxysterone dehydrogenase. Both adrenal steroids are regulated by adrenocorticotropic hormones, and their levels do not increase following a bilateral orchiectomy (Walsh, 1975). Several studies have shown that the mean total testosterone level following a BTO was 50 ng/dL \pm 50 and that there was no late rise in plasma testosterone levels (Robinson and Thomas, 1971; Mackler et al, 1972). The *mean* total testosterone

Table 5. Potential variables affecting perception of change in testicular size and percentage of testicular area preserved between preoperative and postoperative mass*†

Patient	%	SSQ 2	PSA	TT	Pre-SCOT Rx	POT	Age, y	FNQ 3
2	88	No	1.1	20	None	Yes	77	5/0
3	49	No	1.0	28	LND	Yes	58	5/0
5	38	Yes	0.0	34	RRP	No	67	5/0
7	81	Yes	0.5	40	XRT	No	80	6/0
10	64	No	1.9	20	LND	Yes	56	5/0
Mean	64	2/5	0.9	28.4		3/5	67.6	5/0
1	36	No	0.1	20	RRP	No	66	2/0
4	57	No	0.4	58	RRP	No	66	6/0
6	47	No	0.4	37	RRP	No	54	5/0
8	85	No	2.6	20	LND	Yes	75	1/0
9	119	No	0.2	20	None	No	76	5/0
11	46	No	8.2	57	None	No	80	5/0
12	45	No	3.9	30	None	Yes	80	6/0
Mean	69	0/7	3.1	32.8		2/7	73.0	4/0

* FNQ indicates Fugl-Meyer questionnaire; LND, lymph node dissection; POT, potent; PSA, prostate-specific antigen; RRP, radical retropubic prostatectomy; SCOT, subcapsular orchiectomy with a tunica vaginalis graft (procedure); SSQ, SCOT-specific questionnaire; and XRT, external beam radiation therapy.

† SSQ 2 “Did the operation make you feel less of a man.” Potency defines the patient’s erectile function immediately prior to the SCOT procedure. FNQ 3 provides the postoperative score for question 3 of the Fugl-Meyer questionnaire (My partnership relation is...) and the difference between the preop and postop score for question 3.

values for the SCOT I and SCOT II groups were in this castrate range. Follow-up total testosterone values for these 2 groups confirmed that the total testosterone remained in this range.

Furthermore, the distribution of total testosterone in the combined SCOT group compared with the distribution of total testosterone in the BTO group, using 50 ng/dL as the cutoff, was not significant ($P = .20$). The total testosterone of patient 11 in the SCOT I group was 112 ng/dL at the 9-month postoperative visit. It is possible that residual testicular parenchymal tissue contributed to this elevation. However, 3 factors suggest an adrenal source. First, the operation was performed in the standard fashion, making it unlikely that there was residual testicular tissue. Second, the total testosterone level increased between the 3- and 9-month follow-ups of this patient, suggesting increased adrenal production, as seen in patients on estrogens (Robinson and Thomas, 1971). Finally, Shearer et al (1973) described several patients, status post-BTO, with total testosterone values greater than 130 ng/dL.

Both SCOT groups achieved the critical objective, a reduction in PSA value at the 3- and 9-month follow-ups. This finding was in agreement with the study of Zhang et al (1996).

Historically, when patients have been given only the options of a BTO and an LHRH agonist, the surgical option has rarely been selected (Melton et al, 2001). The SCOT procedures added a third option. Although the BTO option was the least frequently selected option (8% in the SCOT I study and 18% in the SCOT II study), more than 40% of the study patients selected a SCOT procedure. The SCOT procedures were the preferred surgical option for all ages.

The use of the electrosurgical unit to cauterize the interior wall of the tunica albuginea and to incise the tunica vaginalis was a concern because of the potential for postoperative epididymitis. This complication did not occur. Our first 2 SCOT patients experienced scrotal wall ecchymosis. This problem was subsequently avoided by the use of the electrocautery to incise the scrotal skin and by a reapproximation of the scrotal skin with a running baseball stitch.

With a follow-up of greater than 1 year in many of the patients in our study, we have observed a progressive decrease in the testicular area of both the SCOT I and SCOT II patients. None of these patients have complained of "feeling less of a man" or of having shrinking testes. The gradual nature of this loss and the favorable PSA response to surgical castration may explain the acceptability of this loss. The ultimate advantage of the SCOT procedures over BTO may be that they provide a period of transition and adaptation.

Conclusion

The SCOT I and SCOT II procedures preserved 43%–63% of the preoperative testicular area, achieved castrate levels of total testosterone, and maintained life satisfaction. All SCOT patients would recommend their operation to another patient requiring hormonal therapy, and most noted no change in testicular size or masculine identity. Both SCOT procedures were more frequently selected than total orchidectomy. Either SCOT procedure may be an additional hormonal treatment option for patients with prostate cancer.

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