A Temporary Intraurethral Prostatic Stent Relieves Prostatic Obstruction Following Transurethral Microwave Thermotherapy

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Purpose: The Spanner™, a novel prostatic stent, was evaluated for safety, efficacy and patient tolerance when used to relieve prostatic obstruction following transurethral microwave thermotherapy.

Materials and Methods: Following transurethral microwave thermotherapy and routine post-procedure Foley catheterization at 1 of 9 clinical sites 186 patients meeting study criteria were randomized to receive a Spanner (100) or the standard of care (86). Baseline evaluations included post-void residual urine, uroflowmetry, International Prostate Symptom Score and International Prostate Symptom Score quality of life question. These evaluations were repeated at visits 1, 2, 4, 5 and 8 weeks after randomization (Spanner insertion) with the addition of the Spanner satisfaction questionnaire, ease of use assessment and adverse events recording. The Spanner was removed after 4 weeks, at which time the Spanner and standard of care groups underwent cystourethroscopy.

Results: At the 1 and 2-week visits the Spanner group showed significantly greater improvements from baseline in post-void residual urine, uroflowmetry and International Prostate Symptom Score compared to the standard of care group. The Spanner group experienced significantly greater improvements in quality of life at the 5 and 8-week visits. Patient satisfaction with the Spanner exceeded 86%. Cystourethroscopy findings in the Spanner and standard of care groups were comparable and adverse events associated with previous stents were rare.

Conclusions: The Spanner is a safe, effective and well tolerated temporary stent for severe prostatic obstruction resulting from therapy induced edema after transurethral microwave thermotherapy. It may be a needed addition to the armamentarium for managing bladder outlet obstruction in a broad group of urological patients.

Key Words: prostate, stents, urethral catheterization, prostatic hyperplasia, urination disorders

Benign prostatic hyperplasia is a common chronic disease contributing to moderate to severe LUTS in approximately 40% of men 60 years old.[1] Heat based MITs, such as TUMT, deliver thermal energy to the prostate and cause coagulation necrosis of obstructive tissue, resulting in marked and sustained improvements in urinary symptom scores,[2–5] uroflowmetry[2–6] and associated QOL.[2,4,5,7] However, the usefulness of MIT has been limited by significant post-procedure edema, which temporarily exacerbates prostatic obstruction, resulting in worsening bladder emptying problems and LUTS.[8,9] AUR with extended periods of intermittent or indwelling catheterization is a common sequela to therapy induced prostatic obstruction following MIT.[6,8]

Intraprostatic stents serve to maintain luminal patency of the prostatic urethra[10] and ameliorate symptoms of prostatic obstruction.[9–11] Moreover, prostatic stents provide a rapid, easy to perform, economical alternative to passive catheter drainage.[8,9,12–14] Complications related to the design of temporary prostatic stents have precluded Food and Drug Administration approval.[9,10] Therefore, a new stent design that has proved to be effective, safe and well tolerated for relieving prostatic obstruction is highly anticipated by the urological community. In this randomized, controlled, multicenter study we evaluated how a novel prostatic stent, the Spanner, affected bladder emptying, LUTS and QOL in patients with severe prostatic obstruction resulting from therapy induced edema after TUMT.

MATERIALS AND METHODS

Study Design and Treatment Allocation

From October 2002 to December 2005, 186 men meeting study criteria at initial screening and randomization were enrolled in the study at 1 of 9 clinical sites (see Appendix). Participants underwent treatment with 1 of 3 high energy TUMT devices, including a Urologix® Targis®, Urologix Prostatron® or ProstaLund® CoreTherm®. Patients treated

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with the Targis or Prostatron TUMT system were catheterized for 3 to 5 days and those treated with the CoreTherm TUMT system were catheterized for 7 to 10 days after TUMT, as directed by instructions for use. All patients received prophylactic antibiotics for the duration of Foley catheterization.

The catheterization period for each TUMT system is based on the time necessary for serious, procedure induced adverse events to resolve in most patients, including hematuria, clotting and subsequent AUR. The Spanner was inserted after standard catheterization to minimize these adverse events during the study course. Patients were pooled irrespective of the TUMT system used (and associated days catheterized) because this factor did not significantly influence I-PSS or PVR, which were the primary efficacy and safety end points, respectively (table 1).

After catheter removal participants were randomized to a Spanner (100) and a SOC (86) treatment group based on randomized, permuted blocks by clinical site. A 1:1 Spanner-to-SOC ratio was used for the first 147 patients enrolled and a 2:1 ratio was used thereafter. SOC patients were free to return home after catheter removal until followup visits, while Spanner patients conformed to the following protocol.

The Spanner is a temporary (30 days or less) intraurethral prostatic stent available in 2 diameters (20Fr and 22Fr) and 6 lengths (4 to 9 cm) (fig. 1). Spanner diameter was determined by physician preference and it showed no effect on PVR or I-PSS (table 1). Spanner length was determined using a Surveyor (fig. 2). Figure 3 shows Spanner insertion and removal. Before patient discharge home a trial void and PVR were evaluated. Prophylactic antibiotics were prescribed for the course of Spanner use. Unless early removal was necessary the Spanner was removed 4 weeks after insertion.

End Points Evaluated

Baseline evaluations at initial screening and/or randomization visits included PVR, uroflowmetry (peak flow, time to peak flow, average flow, total void time and voided volume), I-PSS and the I-PSS QOL question. Voiding efficiency (percent of bladder emptying) was calculated using the equation,

TABLE 1. *Poolability of end points across patient subgroups*

Characteristic	Interaction p Value	
	I-PSS	PVR
9 Clinical sites	0.686	0.113
4 Protocol amendments	0.439	0.490
Age (older/younger than 60 yrs)	0.551	0.323
Baseline I-PSS (above/below 20)	0.258	0.442
Baseline max urine flow (above/below 10)	0.217	0.634
Baseline PVR (above/below 100)	0.598	0.755
History of urinary retention (yes/no)	0.536	0.727
LUTS onset (more/less than 1 yr)	0.248	0.991
Baseline prostatic vol (above/below 40 cc)	0.626	0.535
Bleeding after TUMT (yes/no)	0.448	0.975
Recurrent UTI (yes/no)	0.151	0.688
Bacteriuria at Foley removal (above/below 10,000 cFU)	0.242	0.237
α-Blockers at baseline (yes/no)	0.165	0.341
TUMT system	0.581	0.500
Spanner size (20 Fr/22 Fr)	0.190	0.101

From interaction test assessing significant difference in Spanner vs SOC efficacy between patient groups, except for size of Spanner used, which was a t test in Spanner patients only.

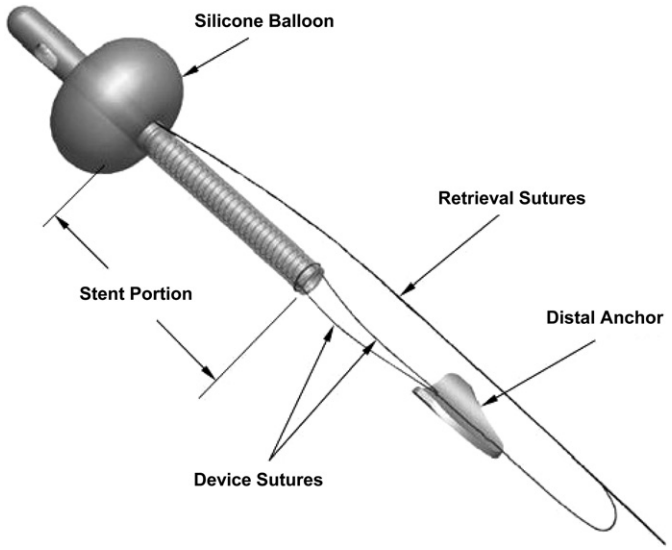

FIG. 1. Spanner balloon (proximal end) and distal anchor extend from bladder neck to distal side of external sphincter with suture crossing sphincter to maintain continence.

[voided volume/(voided volume + PVR) × 100] in all patients.[15] The Spanner and SOC groups participated in followup visits 1, 2, 4, 5 and 8 weeks after randomization (Spanner insertion), which included end points evaluated at baseline and additional cystourethroscopy, and adverse event recording. Adverse events are expressed as the percent of men reporting the condition 1 or more times at any point during the study.

Spanner patients underwent additional followup, including the Spanner satisfaction questionnaire and ease of use assessment. The Spanner satisfaction questionnaire was created for this study to determine patient perception of 1) overall Spanner performance, 2) comfort, convenience and pain, 3) leakage and emptying, and 4) sexual activity. Ease of use assessment was reported by physicians which included ease of Spanner use (very easy, easy, slightly difficult, moderately difficult or difficult), and patient assessed discomfort (none, mild, moderate or severe) at Spanner insertion and removal. Spanner device malfunctions were also noted. Table 2 lists study activities done at initial screening, randomization and followup visits.

Data Analysis

Valid randomization was confirmed by analysis, which showed that the majority of demographic characteristics,

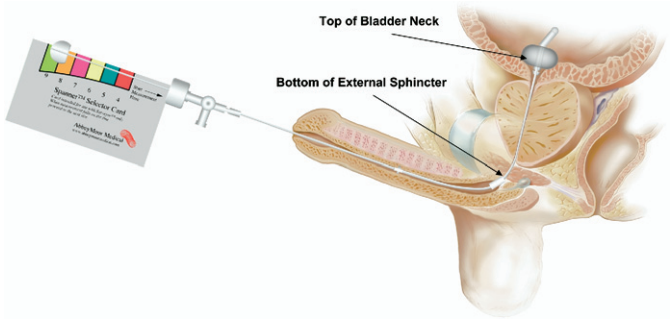

FIG. 2. Surveyor is used to measure distance between bladder neck and distal side of external sphincter.

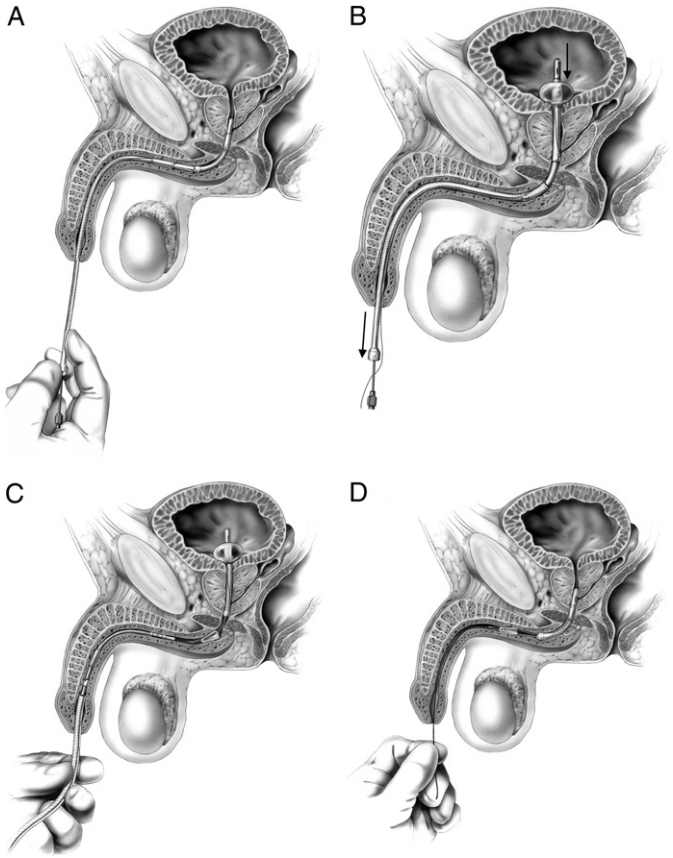

FIG. 3. *A*, Spanner is mounted on insertion device and advanced along urethral meatus and pendulous urethra until tip is well within bladder. *B*, Spanner balloon is inflated with 5 cc sterile water and seated in bladder neck. *C*, distal anchor is deployed distal to external sphincter and insertion tool is withdrawn from urethra. *D*, applying gentle traction to retrieval suture deflates proximal balloon and allows Spanner removal.

TABLE 3. *Test for randomization*

	p Value
*Demographic characteristics**	
Race (%):	
Black (3.2)	
White (73.1)	0.800
Hispanic (23.1)	
Other (0.5)	
Age	0.935
Ht	0.424
Wt	0.439
Lower urinary tract history†	
Prior AUR event	0.304
PVR	0.756
Symptoms:	
I-PSS	0.446
LUTS	0.661
Post-void dribbling	0.862
Frequency	0.373
Hesitancy	0.627
Incomplete emptying	0.667
Intermittent stream	0.710
Nocturia	1.000
Urgency	0.862
Weak stream	0.480
Relevant urological history†	
Prior surgery	0.467
Bladder stones	0.250
Prior devices or implants	0.212
Recurrent UTI	1.000
Gross/microscopic hematuria	0.722
Upper tract disease	0.602
Prostate volume	0.110
Prostate specific antigen‡	0.005

* Pearson's chi-square test for race and t test for other variables.
† Fisher's exact test for categorical variable and t test for continuous variables.
‡ Mean ± SD Spanner vs SOC prostate specific antigen 4.3 ± 4.5 vs 2.5 ± 2.3 ng/ml.

lower urinary tract history and relevant urological history were balanced between Spanner and SOC groups at baseline (table 3). Poolability of primary end points (PVR and I-PSS) across patient subgroups was verified by tests of interaction effects (table 1). The patient population ensured a representative and adequately powered (greater than 80% power) study for evaluating primary end points. When feasible, analyses of end point data were done using changes from the baseline initial screening or randomization visit, as appropriate. Analyses were based on the intent to treat principle, that is subjects were analyzed by the group to which they were randomized irrespective of the actual treatment delivered. The last value carried forward method was used to interpolate missing end point data for primary end points (I-PSS and PVR). Except as noted, hypothesis tests for continuous variables were done using the t test, while Fisher's exact test was used for binary categorical variables. Pearson's chi-square test was used to analyze multinomial categorical variables. All tests were 2-sided and $p \leq 0.05$ was

TABLE 2. *Study activities done at each visit*

	Visit						
Standard Activities	Initial Screening	Randomization	1-Wk	2-Wk	4-Wk	5-Wk	8-Wk
Informed consent	X						
History, physical examination + digital rectal examination	X						
UA/UC	X	X	X	X	X	X	
PVR + uroflowmetry	X	X*	X	X	X	X	
I-PSS and I-PSS QOL	X*		X	X	X	X	X
Randomize/Spanner insertion		X					
Spanner satisfaction/questionnaire			X	X	X		
Insertion ease		X					
Removal ease					X		
Spanner removal					X		
Cystourethroscopy					X		
Adverse event		X	X	X	X	X	X

Initial screening was done 7 to 10 days before planned TUMT and randomization was done after Foley catheter removal 3 to 10 days following TUMT.
* Baseline for comparison with followup values.

considered statistically significant. Statistical analysis was done using SAS®, version 9.1.

RESULTS

Bladder Emptying

The increase in PVR from baseline was significantly greater in the SOC group at the 1 and 2-week visits compared to the Spanner group. By the 5-week visit the change in PVR was similar between the SOC and Spanner groups (fig. 4). Following this pattern, the percent of patients in the SOC group with abnormally increased PVR (100 ml or greater)[16] was approximately double that in the Spanner group at the 1 and 2-week visits but it was not significantly different by the 4 and 5-week visits (fig. 5).

At the 1, 2 and 4-week visits 2 or more uroflowmetry end points (peak flow rate, time to peak flow, average flow, total void time and voided volume) showed significantly greater improvement from baseline in the Spanner group compared to the SOC group (table 4). By 5 weeks no uroflowmetry end point differed significantly between the Spanner and SOC groups. Calculated voiding efficiency in the SOC group decreased significantly from baseline at the 1 and 2-week visits compared to that in the Spanner group, in which subjects continued to have values (approximately 80%) similar to or greater than baseline. By the 4 and 5-week visits the Spanner and SOC groups showed efficiency similar to baseline values (table 4).

Symptoms and QOL

The Spanner group showed superior I-PSS decreases from baseline at the 1 and 2-week visits (fig. 6). Using the Mantel-Haenszel test of ordinal trend to analyze the clinical perceptibility of symptom improvement a significantly greater percent of patients in the Spanner group reported marked (8 point I-PSS decrease)[17] improvement compared to the SOC group (44.0% vs 27.9%, $p = 0.026$). The I-PSS QOL question showed no significant differences between the groups at the 1, 2 and 4-week visits. However, the Spanner group had significantly greater mean ± SD improvements in QOL at the 5-week (-2.23 ± 1.92 vs -1.52 ± 1.67, $p = 0.014$) and 8-week (-2.73 ± 1.69 vs -1.99 ± 1.62, $p = 0.006$) visits, which were 1 and 4 weeks, respectively, after Spanner removal. There was a trend toward a greater percent of patients in the Spanner group reporting being satisfied, pleased or delighted on the I-PSS QOL question at the 1 and 2-week visits, and a significantly greater percent at the 5 and 8-week visits (fig. 7).

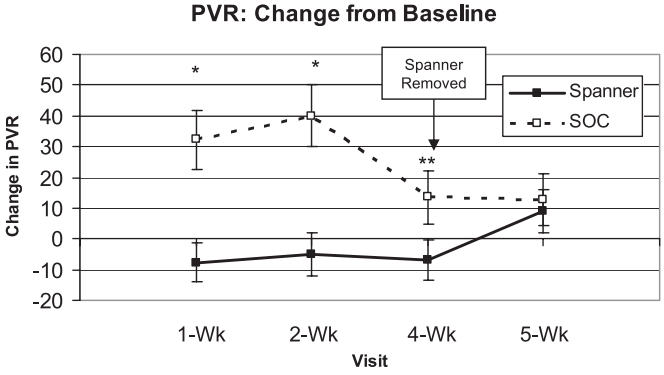

FIG. 4. Change in PVR in ml from baseline (randomization visit after TUMT following Foley catheter removal) at followup visits. Mean ± SE baseline Spanner and SOC measurements were 60.0 ± 62.3 ml (range 0, 291) and 60.3 ± 88.9 ml (range 0, 641), respectively ($p = 0.984$). Single asterisk indicates t test $p = 0.001$. Double asterisks indicate t test $p = 0.061$.

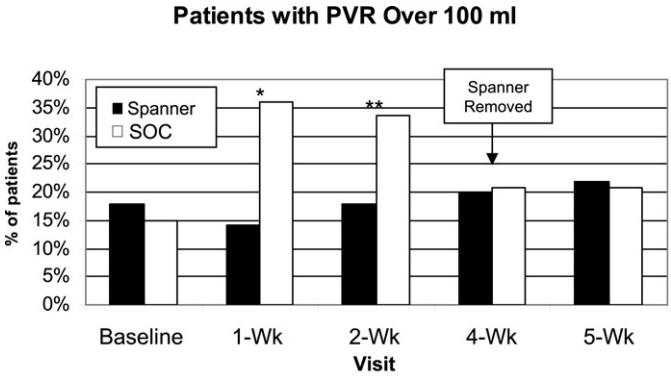

FIG. 5. Percent of patients with increased PVR (100 ml or greater) at baseline (randomization visit after TUMT following Foley catheter removal) and followup visits. Single asterisk indicates Fisher's exact test $p = 0.001$. Double asterisks indicate Fisher's exact test $p = 0.018$.

The Spanner Satisfaction Questionnaire and Ease of Use Assessment

The Spanner satisfaction questionnaire showed that respondents preferred the Spanner over the Foley catheter, which was worn by the Spanner and SOC groups for 3 to 10 days after TUMT. The majority of men reported that bladder emptying was easy or very easy with no leakage or leakage that caused mild or no bother. The Spanner was also reported to be comfortable or very comfortable, convenient or very convenient and it rarely or never interfered with activities. In addition, the majority of respondents stated that they would recommend the Spanner to a friend and they were satisfied or very satisfied with the Spanner.

The percent of sexually active men increased with the percent able to achieve erection during the course of Spanner use. The majority of these respondents reported no pain during sexual activity or erection (table 5).

Ease of use assessment showed that 101 patients (1 had 2 Spanners inserted and removed) experienced mild or no pain during Spanner insertion (81.8%) and removal (82.3%). Similarly physicians assessed the majority of Spanner insertions (87.8%) and removals (73.0%) as easy or very easy.

Adverse Events

The rate of adverse events between the Spanner and SOC groups was not significantly different except for perineal pain (26.0% vs 12.8%, $p = 0.028$). Adverse events of particular importance for evaluating Spanner safety were rare and, when comparable, they did not vary between the Spanner and SOC groups (table 6). Cystourethroscopy was completed in 94 Spanner and 77 SOC patients, and it showed no significant differences between the groups in the percent of overall bladder or urethral abnormalities ($p = 0.298$ and 0.531, respectively). Individual bladder and urethral abnormalities were also similar between the groups ($p > 0.05$). However, urethral erosion was significantly lower in Spanner vs SOC patients (2.1% vs 13%, $p = 0.007$). Withdrawal of

TABLE 4. *Uroflowmetry data*

	Mean ± SD (range)		p Value (t test of superiority)
	Spanner	SOC	
Baseline:			
Peak flow (ml/sec)	8.9 ± 4.2 (3.3,29.0)	9.2 ± 5.4 (2.0,39.0)	0.691
Time to peak flow (secs)	9.6 ± 6.5 (0.0,36.0)	10.4 ± 10.9 (1.0,77.0)	0.546
Av flow (ml/sec)	5.2 ± 2.5 (1.8,16.1)	5.4 ± 3.3 (1.5,20.1)	0.678
Total void time (secs)	41.6 ± 19.3 (7.0,119)	45.5 ± 31.5 (10.0,250)	0.336
Voided vol (ml)	170 ± 58.0 (70.0,331)	186 ± 78.1 (70.0,470)	0.126
% Voiding efficiency	79.1 ± 17.6 (30.7,100)	81.3 ± 15.5 (39.2,100)	0.388
1 Wk:*			
Peak flow (ml/sec)	1.8 ± 5.2 (−13,22.0)	−0.3 ± 4.5 (−12,11.0)	0.010
Time to peak flow (secs)	−2.1 ± 7.7 (−25,21.0)	3.1 ± 21.3 (−75,104)	0.048
Av flow (ml/sec)	1.3 ± 3.5 (−5.0,11.6)	−0.4 ± 2.6 (−8.1,7.0)	0.002
Total void time (secs)	−5.5 ± 29.6 (−88,88.0)	4.3 ± 43.4 (−176,210)	0.111
Voided vol (ml)	11.6 ± 102 (−188,290)	0.0 ± 104 (−210,386)	0.483
% Voiding efficiency	3.9 ± 20.7 (−49.6,52.1)	−10.2 ± 20.8 (−78.0,49.5)	0.001
2 Wks:*			
Peak flow (ml/sec)	2.5 ± 5.6 (−19,18.7)	0.0 ± 4.8 (−11,14.0)	0.005
Time to peak flow (secs)	−0.5 ± 20.4 (−23,167)	−0.3 ± 15.4 (−75,52.2)	0.937
Av flow (ml/sec)	1.5 ± 3.5 (6.0,12.6)	−0.2 ± 2.7 (−6.0,6.0)	0.001
Total void time (secs)	−5.1 ± 29.2 (−62,153)	1.0 ± 24.5 (−121,47.0)	0.170
Voided vol (ml)	26.3 ± 104 (−232,323)	5.9 ± 96.7 (−201,269)	0.207
% Voiding efficiency	3.4 ± 20.9 (−38.6,55.9)	−10.1 ± 21.4 (−75.1,43.7)	0.001
4 Wks:*			
Peak flow (ml/sec)	2.8 ± 5.7 (−16,24.0)	1.7 ± 5.5 (−11,19.1)	0.206
Time to peak flow (secs)	−2.8 ± 7.1 (−29,12.0)	−0.5 ± 12.8 (−71,32.0)	0.175
Av flow (ml/sec)	1.8 ± 3.3 (−6.0,15.1)	0.6 ± 2.9 (−5.0,9.0)	0.030
Total void time (secs)	−11 ± 19.4 (−65,36.0)	0.0 ± 30.5 (−176,46.0)	0.008
Voided vol (ml)	4.1 ± 89.8 (−150,325)	38.5 ± 108 (−260,294)	0.034
% Voiding efficiency	1.5 ± 20.8 (−56.3,53.1)	−0.9 ± 18.7 (−47.3,45.8)	0.476

* p value change from baseline randomization visit immediately before Spanner insertion.

18 Spanner subjects was required under various clinical situations, including adverse events (table 7). However, under the intent to treat principle data were imputed using the last value carried forward for the primary efficacy (I-PSS) and safety (PVR) end points.

Device Failure

Five device malfunctions were reported and none required treatment or was associated with an adverse event. Two malfunctions were due to the retrieval suture coming untied during the removal process. A design change, which added a second suture knot to prevent the retrieval suture from coming untied, was implemented and no further events of this type occurred. Two malfunctions were due to the Spanner not deploying. Each instance was addressed with additional physician training. One balloon deflated before removal.

DISCUSSION

The benefits of TUMT and other MITs have been limited by therapy induced edema and resulting prostatic obstruction following the procedure. Catheterization is the only commonly used treatment for bladder emptying problems and LUTS during what can be a lengthy post-MIT recovery period. This extended catheterization negatively affects QOL, subjecting men to the continued discomfort of the Foley catheter/leg bag and the risk of complicated, symptomatic UTIs.[9,18] With no ideal treatment currently available phy-

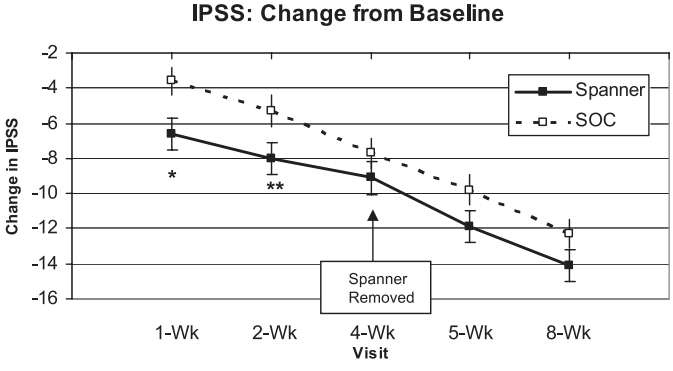

FIG. 6. Change in I-PSS from baseline (initial screening before TUMT) at followup visits. Mean ± SE baseline Spanner and SOC measurements were 22.7 ± 5.4 (range 10, 34) and 22.1 ± 5.0 (range 13, 35), respectively (p = 0.446). Single asterisk indicates t test p = 0.016. Double asterisks indicate t test p = 0.036.

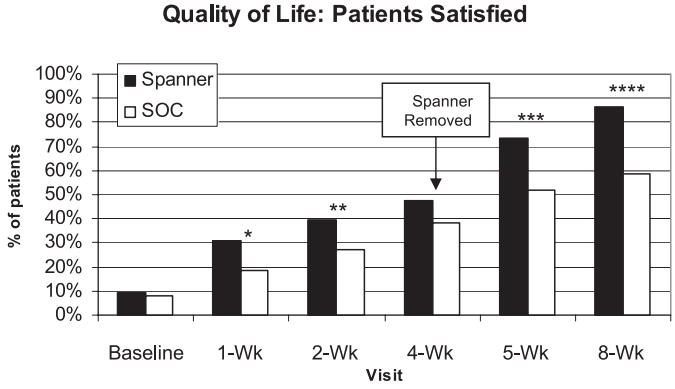

FIG. 7. Percent of patients reporting that they were satisfied, pleased or delighted on I-PSS QOL question at baseline (initial screening before TUMT) and followup visits. Single asterisks indicates Fisher's exact test p = 0.072. Double asterisks indicate Fisher's exact test p = 0.10. Triple asterisks indicate Fisher's exact test p = 0.008. Quadruple asterisks indicate Fisher's exact test p = 0.001.

TABLE 5. *Spanner satisfaction questionnaire*

Parameter	No. Pts (%)		
	1 Wk	2 Wks	4 Wks
Overall satisfaction (very satisfied or satisfied)	72 (82.7)	68 (79.0)	71 (86.6)
Recommend to friend (yes)	63 (73.3)	64 (74.4)	68 (85.0)
Comparison to Foley catheter (greatly prefer or prefer Spanner)	75 (87.2)	77 (89.5)	72 (88.9)
Emptying ease (very easy or easy)	58 (66.6)	64 (74.4)	61 (74.4)
Bother due to leakage (no leakage or no to mild bother)	78 (91.7)	74 (88.1)	70 (87.6)
Comfort (very comfortable or comfortable)	48 (55.1)	50 (58.1)	42 (51.3)
Convenience (very convenient or convenient)	59 (68.6)	63 (74.2)	65 (79.3)
Interfered with activity (never or rarely)	66 (75.8)	69 (80.3)	62 (75.6)
Erection (yes)	43 (49.4)	45 (52.3)	48 (58.5)
If erection, pain or discomfort (no)	29 (63.0)	36 (80.0)	38 (77.6)
Sexual activity (yes)	11 (12.6)	20 (23.5)	21 (25.6)
If sexually active, pain or discomfort (no)	8 (66.7)	14 (66.7)	15 (71.4)

sicians and patients anticipate the development of a safe, temporary prostatic stent that would effectively relieve prostatic obstruction.

Two early Spanner studies indicated that the stent design preserved volitional voiding and significantly improved bladder emptying and LUTS.[12,14] The 2 studies also showed that the Spanner was easily inserted and removed with minimal to no problems associated with migration or encrustation. This multicenter study confirms these early studies and shows that the Spanner meets criteria for an acceptable stent by allowing immediate volitional voiding and improving bladder emptying, LUTS and QOL in patients with severe prostatic obstruction. The Spanner design provided a high degree of patient comfort and satisfaction, blind insertion and removal as well as minimal migration, expulsion and encrustation. Furthermore, Spanner use resulted in urethral and bladder irritation, and UTI similar to those of the SOC.

Spanner use eliminated the dramatic, temporary increase in PVR observed in the SOC group after TUMT and it significantly decreased abnormally increased PVR (100 ml or greater). Corroborating uroflowmetry results showed that the Spanner group experienced significantly greater improvements in bladder emptying, indicating that the stent may decrease AUR, which is the most significant adverse event associated with treatments for prostatic obstruction. Indeed, trends showed that the Spanner group experienced less than half of the urinary retention events ($p = 0.083$) and a third of the days catheterized to treat retention ($p = 0.11$, table 6). Men with a proclivity for urinary retention (PVR more than 250 ml or voided volume less than 100 ml at initial screening or randomization following Foley catheter removal after TUMT) were excluded from study to prevent these patients in the SOC from going into retention. However, Spanner use with its demonstrated ability to improve bladder emptying after TUMT may significantly benefit this subpopulation of patients by decreasing their risk of AUR. This should be evaluated in future studies.

TABLE 6. *Adverse events*

	No. Spanner (%)	No. SOC (%)	p Value (Fisher's exact test)
Symptomatic UTI	15 (15.0)	10 (11.6)	0.527
Spanner migration	5 (5.0)	—	—
Spanner expulsion	2 (2.0)	—	—
Spanner encrustation	1 (1.0)	—	—
AUR*	6 (6.0)	12 (14)	0.083
Clot retention	2 (2.0)	1 (1.2)	1.000
Increased PVR†	3 (3.0)	3 (3.5)	1.000
No. days catheterized	50	151	0.110 (Wilcoxon nonparametric rank sum test)

* During Spanner wear and not related to blood clots.
† Greater than 200 ml with voided volume at least 100 ml on 2 measurements made within a few hours of each other.

TABLE 7. *Spanner patient withdrawal*

	No. Pts (%)
UTI	1 (1.0)
Spanner migration	3 (3.0)
Spanner expulsion	2 (2.0)
Urinary retention	6 (6.0)
Clot retention	1 (1.0)
Withdrew consent*	3 (3.0)
Congestive heart failure†	1 (1.0)
Gross hematuria†	1 (1.0)
Total	18 (18.0)

Subset with adverse events and other clinical situations requiring study withdrawal.
* Not device related (1 lost to followup).
† Not device related.

Clinical management of BPH is often elective and driven by the desire to improve LUTS, which limit basic activities of daily living and negatively impact quality of life.[19] Therefore, patient satisfaction and willingness to recommend the Spanner were likely the result of the stent providing clinically perceptible improvements in LUTS and QOL without exacerbating the adverse events associated with TUMT. Interestingly the Spanner group experienced significant QOL improvements compared to the SOC at followup visits after Spanner removal (5 and 8-week visits). This indicates that the Spanner may improve QOL beyond the evaluation time of this study, corroborating the results of Devonec and Dahlstrand, who noted that symptoms and flow rates improved for at least 12 months with a prostatic bridge catheter for 1 month after TUMT (Prostatron 2.5 protocol).[11] Accurate interpretation of these data emphasize the importance of including the SOC as a control, which allowed a clear distinction between changes in bladder emptying, LUTS, QOL and adverse events due to Spanner use in conjunction with TUMT vs changes due to the TUMT procedure alone (SOC).

CONCLUSIONS

The Spanner ameliorated bladder emptying problems, LUTS and QOL during the healing period after TUMT without the complications that have limited the usefulness of previous stent designs, including difficult insertion and removal, migration, expulsion and poor patient tolerance. Therefore, the Spanner safely and effectively relieved severe prostatic obstruction resulting from therapy induced edema after TUMT. It may be a needed addition to the armamen-

tarium for managing bladder outlet obstruction in a broad group of urological patients.

APPENDIX

Criteria for Study Participants*

Inclusion Criteria

Underwent TUMT for BPH
Age older than 45 years
I-PSS greater than 13
Signed informed consent form
Ability and willingness to complete followup protocol

Exclusion Criteria

Current, recent or symptomatic urinary tract disease
Surgery altering normal urogenital anatomy or abnormal urethral anatomy
Previous MIT or surgery for BPH†
History of or conditions associated with (spinal cord injury, multiple sclerosis or Parkinson's disease) neurogenic bladder
Prostate cancer
Prior pelvic irradiation therapy
Prostatic urethral length less than 2.4 or greater than 5.4 cm
Any change in prostate specific medications 30 days before TUMT
Intravesical enlargement of the median lobe of the prostate
PVR greater than 250 ml
Voided volume less than 100 ml
Evidence of UTI or positive urine culture
Gross hematuria at the time of or 24 hours before Foley catheter removal (randomization)
PVR greater than 250 ml with voided volume less than 100 ml after Foley removed (randomization)‡
Signs and symptoms of active UTI after Foley catheter removed (randomization)

* Criteria were assessed at initial screening 7 to 10 days before TUMT unless noted as randomization, which was completed after Foley catheter removal 3 to 10 days after TUMT.
† Amendment 2 allowed TUMT using CoreTherm system.
‡ Amendment 3 increased PVR to 250 from 200 ml.

Abbreviations and Acronyms

I-PSS	=	International Prostate Symptom Score
LUTS	=	lower urinary tract symptoms
MIT	=	minimally invasive therapy
PVR	=	post-void residual urine
QOL	=	quality of life
SOC	=	standard of care
TUMT	=	transurethral microwave thermotherapy

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