

Reprinted from

VOLUME 71, NUMBER 5, MAY 2008

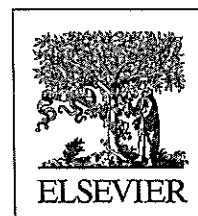
UROLOGY



OFFICIAL JOURNAL OF THE SOCIÉTÉ INTERNATIONALE D'UROLOGIE

Use of a Temporary Prostatic Stent After Transurethral Microwave Thermotherapy Reduced Voiding Symptoms and Bother Without Exacerbating Irritative Symptoms

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Prostatic Diseases and Male Voiding Dysfunction

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Martin K. Dineen, Neal D. Shore, Jeffrey H. Lumerman, Mark J. Saslawsky, and Alberto P. Corica

OBJECTIVES	To evaluate the ability of a temporary prostatic stent (Spanner [Sp]) to manage voiding symptoms, irritative symptoms, and bother after transurethral microwave thermotherapy (TUMT) for prostatic obstruction.
METHODS	Patients were randomized to the Sp (n = 100) or standard of care (SOC, n = 86) after TUMT with 3 to 10 days of routine catheterization. We evaluated International Prostate Symptom Score (IPSS) voiding subscore, IPSS irritative subscore, voiding diary data, and Benign Prostatic Hyperplasia Impact Index (BII) 7 to 10 days before TUMT and repeated them 1, 2, 4 (stent removal), 5, and 8 weeks after stent insertion.
RESULTS	After 1 week of stent use, the Sp group experienced significantly greater improvements in the IPSS voiding subscore (Sp = -4.9 versus SOC = -2.3, $P = 0.002$) and individual voiding symptoms assessed by the IPSS (intermittency, weak stream, and straining) and voiding diary data (stream strength, and strain). After 2 weeks, the Sp group showed a trend toward greater improvements in IPSS voiding ($P = 0.059$) and irritative ($P = 0.058$) subscores and reported significantly less bother (BII, Sp = -2.1 versus SOC = -1.1, $P = 0.033$). After stent removal, the Sp group reported significantly greater improvements in the IPSS irritative subscore (5 weeks: Sp = -4.0 versus SOC = -2.7, $P = 0.029$; 8 weeks: Sp = -5.0 versus SOC = -4.0, $P = 0.050$), individual voiding (stream strength and dysuria), and irritative (frequency and urgency) symptoms and bother (5 weeks: Sp = -4.0 versus SOC = -2.3, $P = 0.002$; 8 weeks: Sp = -5.0 versus SOC = -3.1, $P = 0.001$).
CONCLUSIONS	The Spanner, a temporary prostatic stent, improved voiding symptoms and bother without exacerbating irritative symptoms. Improvements in symptoms and bother were sustained after stent removal. UROLOGY 71: 873-877, 2008. © 2008 Elsevier Inc.

Benign prostatic hyperplasia (BPH) is rarely life-threatening¹ but may lead to severe lower urinary tract symptoms (LUTS) and bother, thus impacting quality of life.² Prostatic stenting improves voiding symptoms associated with BPH by opening the obstructed lumen of the prostatic urethra and allowing for

volitional voiding.^{3,4} However, the mechanical disturbance resulting from a foreign body (stent) in the prostatic urethra may worsen irritative symptoms.^{3,5,6}

The International Prostate Symptom Score (IPSS) showed that the Spanner, a temporary prostatic stent, improved bladder emptying and overall LUTS.^{3,7,8} However, the influence of prostatic stenting on IPSS voiding (intermittency, weak stream, straining, and incomplete emptying) and IPSS irritative (frequency, urgency, and nocturia) subscores was not evaluated in the past.⁸ Without this evaluation, exacerbated irritative symptoms may be masked by improvements in voiding symptoms.

The purpose of this study was to evaluate the ability of a temporary prostatic stent to manage voiding symptoms without exacerbating irritative symptoms and bother after transurethral microwave thermotherapy (TUMT).

M. K. Dineen, N. D. Shore, J. H. Lumerman, and A. P. Corica are paid consultants to, and study investigators funded by AbbeyMoor Medical, Inc. M. J. Saslawsky is a study investigator funded by AbbeyMoor Medical, Inc.

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Submitted: August 9, 2007, accepted (with revisions): December 5, 2007

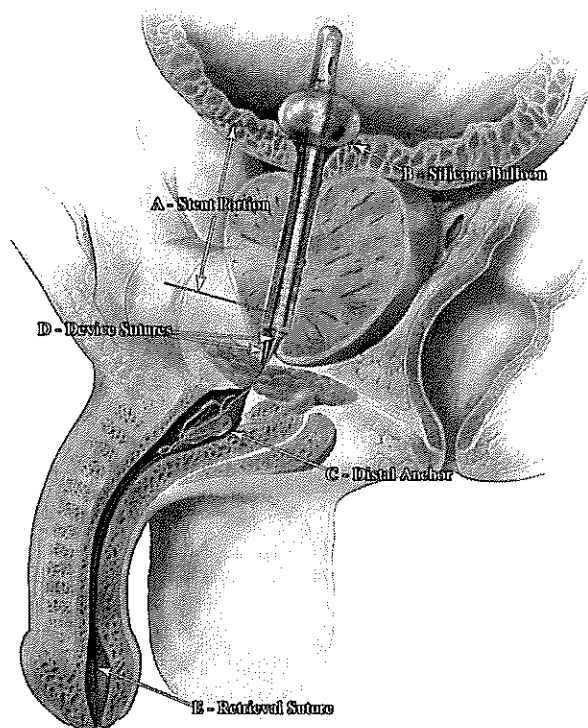


Figure 1. Spanner balloon (proximal end) and distal anchor extend from bladder neck to distal side of external sphincter with suture crossing sphincter to maintain continence.

MATERIAL AND METHODS

Study Design

The design and methods of the study comparing patients treated with the Spanner or standard of care (SOC) after TUMT and routine catheterization have been described previously.⁸ In brief, from October 2002 to December 2005, 186 men meeting study criteria⁸ were randomized to the Spanner (n = 100) or SOC (n = 86) at 9 participating centers.

Treatment Protocol

All patients received routine Foley catheterization (3 to 10 days) and prophylactic antibiotics after TUMT. BPH-specific medications (alpha-blockers and 5-alpha-reductase inhibitors) were not administered as a part of the study protocol and did not differ between the Spanner and SOC groups. Patients with an adequate trial void (PVR of 250 mL or less with a voided volume of 100 mL or more after catheter removal) were randomized into either the Spanner or SOC group. After catheter removal, the SOC group received no further treatment until follow-up visits. The Spanner group received the Spanner (Fig. 1), an intraurethral prostatic stent, and prophylactic antibiotics for the 4 weeks of stent use. The "Surveyor" was used to measure the prostatic urethra and determine the appropriate size Spanner (1 of 6 lengths from 4 to 9 cm) for individual patients.⁸

Endpoints Evaluated

We evaluated symptom severity (IPSS voiding subscore and IPSS irritative subscore) and bother (Benign Prostatic Hyperplasia Impact Index [BII]) in Spanner and SOC patients at the initial screening 7 to 10 days before TUMT (baseline), during

Spanner use (1, 2, and 4 weeks) and after Spanner removal (5 and 8 weeks). The voiding diary assessed stream strength, strain, dysuria, frequency, urgency, feeling of incomplete emptying, terminal dribble, and leakage for the 7 days before TUMT (baseline) and follow-up visits (1, 2, 4, 5, and 8 weeks). Data were averaged on a per-subject and per-visit basis, and then averaged a second time over all subjects in each randomization group (Spanner and SOC). This allowed each subject to count equally in the analysis regardless of the number of urinations per individual, per day. The impact of TUMT alone (SOC) versus TUMT with the Spanner on these endpoints was determined by comparing symptoms at each follow-up visit with baseline IPSS subscores and baseline voiding diary data (Table 1). Device malfunctions were rare, and as previously reported, none required treatment or was associated with an adverse event.⁸

Data Analysis

To compare Spanner with SOC performance, we calculated change from baseline at each follow-up visit and analyzed mean values using *t*-tests. We analyzed data on an intent-to-treat basis. The "last value carried forward" was used to handle missing IPSS and BII data; therefore, the number of patients was 100 for the Spanner group and 86 for the SOC at every time point. All *P*-values were two-sided with values less than 0.05 considered statistically significant. Statistical analyses were carried out using SAS software version 9.1 (SAS Institute, Cary, NC).

RESULTS

IPSS Voiding and IPSS Irritative Subscores

The IPSS voiding subscore improved in the Spanner group compared with the SOC at 1 week (Fig. 2A). Both IPSS voiding and IPSS irritative subscores showed a trend toward greater improvement in the Spanner group at 2 weeks (Fig. 2A and 2B). The IPSS irritative subscores were significantly better in the Spanner group at 5 and 8 weeks, 1 and 4 weeks after Spanner removal (Fig. 2B).

Individual IPSS Voiding and Irritative Questions

Individual IPSS voiding questions showed improvement in the Spanner group compared with the SOC at the earliest visits after stent insertion (Table 2). Intermittency, weak stream, and straining improved in the Spanner group at 1 week. Weak stream continued to show greater improvement in the Spanner group at 2 weeks. Incomplete emptying did not differ significantly between the Spanner and SOC groups at any visit.

Overall, individual IPSS irritative questions did not differ significantly between the Spanner and SOC groups 1, 2, and 4 weeks after stent insertion. We observed small but statistically significant differences in urgency (improved in the Spanner group at 2 weeks) and nocturia (improved in the SOC at 1 week; Table 3). Nocturia was the only IPSS question (irritative or voiding) to favor the SOC at any visit. After Spanner removal, frequency (5 weeks) and urgency (5 and 8

Table 1. Spanner use and symptomatic evaluations per visit

	Initial Screening	TUMT	Randomization	Visit (wk)				
				1	2	4	5	8
Spanner use*	None	None	Inserted	In situ	In situ	Removed	None	None
IPSS								
Voiding subscore	x			X [†]	x [†]	x	x	X
Irritative subscore	x			x	x	x	X	X
Voiding diary								
Voiding symptoms	Issued	x		X	X	X	X	X
Irritative symptoms	Issued	x		x	x	x	x	X
BII	x			x	X	x	X	X

BII = Benign Prostatic Hyperplasia Impact Index; IPSS = International Prostate Symptom Score.

* Stent use for patients randomized to the Spanner group.

[†] Bolded X indicates significantly greater ($P < 0.05$) symptomatic improvement in the Spanner group compared with the SOC. SOC did not show greater improvement than the Spanner group at any visit.

[†] Lowercase x indicates no significant difference ($P < 0.05$) between Spanner and SOC groups.

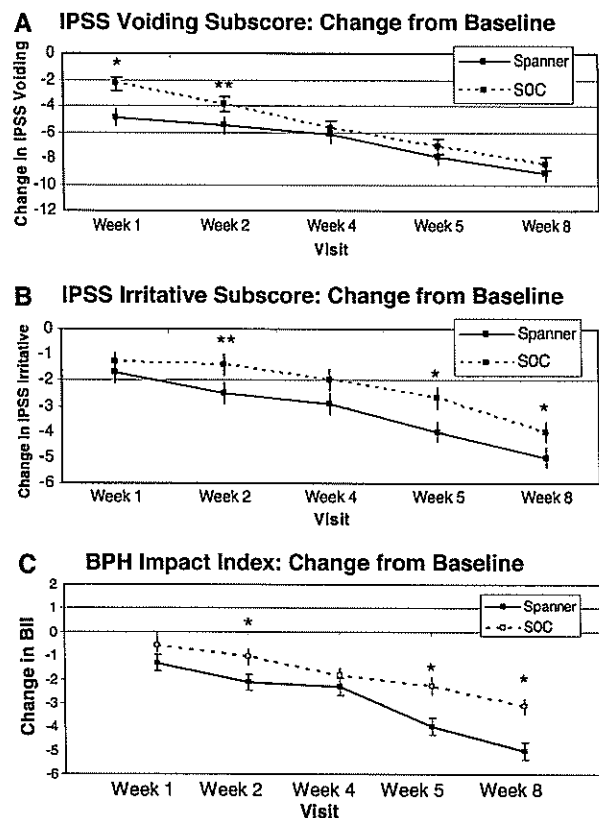


Figure 2. *t*-Test of superiority comparing Spanner and SOC change in (A) IPSS Voiding Subscore, (B) IPSS Irritative Subscore, and (C) BII from baseline. Baseline is at initial screening 7 to 10 days before TUMT. * $P < 0.05$, ** $P = 0.06$.

weeks) improved in the Spanner group compared with the SOC (Table 3).

Voiding Diary Data

Voiding symptoms including stream strength (1, 2, and 4 weeks) and strain (1 week) improved in the Spanner group compared with the SOC at early follow-up visits (Table 2). The feeling of incomplete emptying, terminal dribble, and leakage were not significantly different between the Spanner and SOC groups at any visit.

Irritative symptoms (frequency and urgency) were similar between the Spanner and SOC groups during the time of Spanner use. Dysuria (5 and 8 weeks) and frequency (8 weeks) improved in the Spanner group compared with the SOC after stent removal (Tables 2 and 3).

Benign Prostatic Hyperplasia Impact Index (BII)

Compared with the SOC, the Spanner group was less bothered both during the time of stent use (2 weeks) and after stent removal (5 and 8 weeks) (Fig. 2C). The decrease in the bother index reported at 2 weeks occurred when both IPSS voiding and IPSS irritative subscores showed a trend for improvement in the Spanner group (Fig. 2A and 2B).

COMMENT

The Spanner temporary prostatic stent improved voiding symptoms and bother without exacerbating irritative symptoms. As anticipated, the stent provided the greatest improvement in voiding symptoms immediately after TUMT, when procedure-induced edema caused severe bladder emptying problems⁸ and voiding symptoms in the SOC group. Prior stent designs also improved bladder emptying and overall LUTS after thermotherapy.⁹⁻¹¹ However, a significant number of patients experienced persistent discomfort resulting from increased urgency, frequency, and dysuria.^{5,6} These symptoms have limited the use of previous stents to high-risk BPH patients unsuitable for other treatments.⁵

Surprisingly, while the Spanner was in place, irritative symptoms and bother were similar or improved in the Spanner group compared with the SOC group. Therefore, effectively stenting the prostatic urethra with the Spanner did not generate additional irritation beyond that of TUMT (1, 2, and 4 weeks). After stent removal (5 and 8 weeks), the Spanner group experienced improvements in irritative symptoms (IPSS and voiding diary data) and bother (BII) compared with the SOC group. Future studies are needed to examine whether these improvements in irritative symptoms and bother

Table 2. Voiding questions: IPSS and diary data

Treatment Outcome	Time Period					
	Baseline		1-wk Visit		2-wk Visit	
	Spanner	SOC	PValue*	Spanner	SOC	PValue
IPSS voiding questions						
Intermittency (0-5)	3.4 ± 1.5	3.2 ± 1.4	0.584	-1.5 ± 1.9	-0.9 ± 1.6	0.032
Weak Stream (0-5)	3.5 ± 1.4	3.7 ± 1.3	0.320	-1.1 ± 2.1	-0.1 ± 1.5	0.001
Straining (0-5)	2.4 ± 1.6	2.5 ± 1.6	0.610	-1.2 ± 1.7	-0.6 ± 1.9	0.031
Incomplete emptying (0-5)	3.4 ± 1.5	3.2 ± 1.4	0.416	-1.2 ± 2.2	-0.7 ± 1.9	0.103
Diary voiding questions						
Stream strength (1-3)†	1.7 ± 0.4	1.7 ± 0.5	0.558	0.1 ± 0.5	-0.2 ± 0.4	0.001
Strain (%)	28.0	25.0	NA	-1.0	18.5	0.002
Dysuria (1-4)*	1.4 ± 0.6	1.3 ± 0.5	0.572	0.7 ± 0.8	0.6 ± 0.8	0.248

SOC = standard of care. Other abbreviation as in Table 1.

* From ttest of superiority comparing groups change from baseline (baseline is at 7 to 10 days before TUMT). Data are expressed as means plus or minus standard deviations.

† Four-week visit, Sp = 0.3 ± 0.6 versus SOC = 0.1 ± 0.5, P = 0.024 and 8-week visit, Sp = 0.7 ± 0.5 versus SOC = 0.5 ± 0.6, P = 0.036.

‡ Five-week visit, Sp = -0.0 ± 0.8 versus SOC = 0.2 ± 0.7, P = 0.052 and 8-week visit, Sp = -0.3 ± 0.7 versus SOC = 0.1 ± 0.6, P = 0.047.

Table 3. Irritative questions: IPSS and diary data

Treatment Outcome	Time Period					
	Baseline		5-wk Visit		8-wk Visit	
	Spanner	SOC	PValue*	Spanner	SOC	PValue
IPSS irritative questions						
Frequency (0-5)	3.8 ± 1.1	3.4 ± 1.3	0.015	-1.8 ± 1.8	-1.1 ± 1.9	0.005
Urgency (0-5)†	3.4 ± 1.3	3.0 ± 1.5	0.086	-1.6 ± 1.8	-1.0 ± 1.7	0.021
Nocturia (0-5)*	2.9 ± 1.2	3.1 ± 1.3	0.273	-0.6 ± 1.0	-0.7 ± 1.2	0.444
Diary irritative questions						
Frequency (mean/day)	8.1	8.4	0.583	0.2	0.7	0.334
Urgency (%)	48.5	39.6	NA	-12.9	-5.4	0.247

Abbreviations as in previous tables.

* From ttest of superiority comparing group change from baseline (baseline is at initial screening 7 to 10 days before TUMT). Data are expressed as means plus or minus standard deviations.

† Two-week visit, Sp = -1.3 ± 1.9 versus SOC = -0.5 ± 1.8, P = 0.009.

‡ One-week visit, Sp = -0.1 ± 1.1 versus SOC = -0.3 ± 1.1, P = 0.023.

are related to sustained improvements in bladder emptying. This hypothesis is supported by a previous study showing that flow rates and symptoms improved for at least 12 months with the use of a prostatic bridge catheter for 1-month post-TUMT (Prostatron, 2.5 protocol¹¹). The study presented here has limited potential to test this hypothesis because flow rates and post-void residual urine were evaluated only 1 week after stent removal (5 weeks).

Determining the relationships among stent use and patient-reported symptoms and bother is challenging because both prostatic stenting and thermotherapy are associated with worsening LUTS and bother.^{12,13} Previous studies have relied on historic-control trials, with their inherent problems including comparisons with pretreatment values, disparate patient populations, differing stent designs, and varying thermotherapies.¹² To our knowledge, this prospective, randomized, controlled study is the first to report that a prostatic stent after TUMT improved voiding symptoms and bother without exacerbating irritative symptoms compared with the SOC.

CONCLUSIONS

The Spanner, a novel temporary prostatic stent, has clinical utility owing to its demonstrated ability to improve patient-reported voiding symptoms and bother without exacerbating irritative symptoms after TUMT.

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The Spanner™
Prostatic Stent

Indication for Use: The Spanner™ Temporary Prostatic Stent is intended for temporary use (up to 30 days) to maintain urine flow and allow voluntary urination in patients following minimally invasive treatment for benign prostatic hyperplasia (BPH) and after initial post-treatment catheterization.

Caution: Federal law restricts this device to sale by or on the order of a physician.

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