

# Critical appraisal of the Spanner™ prostatic stent in the treatment of prostatic obstruction

Patrick McKenzie<sup>1</sup>  
Gopal Badlani<sup>1</sup>

<sup>1</sup>Department of Urology, Wake  
Forest University School of Medicine,  
Winston-Salem NC, USA

**Abstract:** The Spanner™ stent was first used in patients to relieve bladder outlet obstruction (BOO), and has recently been used in patients following transurethral microwave thermotherapy and men unfit for surgical intervention. We review the current literature on the role of the Spanner stent in treating prostatic obstruction compared to previously reported cases involving the use of temporary stents. The Spanner stent has been found to be successful in treating patients with bladder outlet obstruction from benign prostatic hyperplasia and following high-energy transurethral microwave thermotherapy (TUMT). Patients with the Spanner stent had an increase in peak flow rate and a decrease in post void residual and International Prostate Symptom Scores. In patients treated with TUMT, quality of life measures indicate that the Spanner stent shows increased ease of bladder drainage, decreased leakage, and no adverse effect on daily activities. In patients unfit for surgery, however, there was increased retention and pain requiring stent removal in 63% of cases. The Spanner stent offers ease of insertion with a decrease in voiding symptoms in selected patients. Based on limited data, the Spanner stent has been recommended as a treatment option for men with BOO following TUMT. However, it is not a good treatment option for men unfit for surgery based on an increased incidence of urinary retention and dysuria. The Spanner stent is the only currently approved temporary stent and, based on a literature review, it does not offer significant advantage over previously used temporary stents. It is notable that most researchers have not evaluated the role of detrusor function on the outcomes.

**Keywords:** benign prostate hyperplasia, Spanner stent, urethral stent, minimally invasive therapy

## Introduction

Benign prostatic hyperplasia (BPH) is a prevalent chronic condition affecting aging men. Specifically, BPH contributes to moderate to severe lower urinary tract symptoms (LUTS) in approximately 40% of men over the age of 60.<sup>1,2</sup> While most of these men will initially be treated with medical therapy consisting of  $\alpha$ -blockers with or without 5- $\alpha$  reductase inhibitors, a significant number of these men will ultimately fail pharmacologic therapy, necessitating more invasive intervention. While transurethral resection of the prostate (TURP) remains the gold standard for surgical intervention in these patients, it is not without complications. Surgical treatment can carry a reported 0.2% mortality and 18% morbidity rate.<sup>3</sup> The difficulty in treating these men with LUTS secondary to BPH arises from comorbidities that may lead to an increased risk of surgical complications from TURP.

Correspondence: Gopal Badlani  
Wake Forest University School of  
Medicine, Department of Urology,  
Medical Center Boulevard,  
Winston-Salem, NC 27157, USA  
Tel +1336-716-5702  
Fax +1336-716-5711  
Email gbadlani@wfubmc.edu

From these difficulties with current surgical therapies there arises a dual need: (i) a device that will maintain prostatic luminal patency following minimally invasive prostate therapy, and (ii) a device that can be used in men unfit for treatment. The device should also be easy to insert and should provide an economical alternative to indwelling Foley catheters, while improving quality of life measures. Prostatic stents, both permanent and temporary, have been an attractive solution to these problems because they serve to alleviate the symptoms of prostatic obstruction while being cost effective.<sup>4,5</sup> Over the past 30 years there have been numerous permanent and temporary stents introduced for the treatment of BPH and acute urinary retention following surgical treatment for BPH. Since the first description by Fabian<sup>6</sup> in 1980 of an indwelling intraprostatic stent, the treatment of bladder outlet obstruction including urethral stricture, detrusor sphincter dyssynergia, and BPH has evolved.<sup>7-9</sup>

There are still numerous unresolved issues surrounding prostatic stents including optimal stent design, materials, and indication.<sup>10</sup> Both permanent and temporary stents have similar initial improvements in urine flow and both have similar retreatment rates. A major problem with both treatment modalities is migration of the device, limiting their use in men with benign prostate obstruction (BPO). There is a need for a stent that alleviates obstruction and does not migrate. While temporary prostatic stents provide short-term relief from BPO in patients after minimally invasive thermotherapy,<sup>11-14</sup> there is still a need for a stent that can be used in patients unfit for surgery. The Spanner™ Temporary Prostatic Stent (AbbeyMoor Medical, Inc., Minnesota, USA) was developed as a more reliable and cost effective solution to permanent stents such as the Urolume Wallstent™ (American Medical Systems, Minnetonka, Minnesota, USA) and Memokath™ (Engineers and Doctors A/s Hornbaek, Denmark) in both surgical and nonsurgical patient populations. This review is focused on the use of the Spanner stent in relieving prostatic obstruction in patients, as compared to previously developed temporary prostatic stents.

## Temporary stents

Temporary prostatic stents have been utilized to provide short-term relief from BOO after minimally invasive thermotherapy including interstitial laser coagulation (MIT),<sup>13</sup> visual laser ablation (VLAP),<sup>15</sup> and high-energy transurethral microwave thermotherapy (TUMT).<sup>11</sup> After each of these procedures BOO occurs due to postoperative prostatic edema, which requires catheterization. Initial reports, in which biodegradable polyglycolic acid (PGA) stents were predominantly

used, suggested temporary prostatic stents were helpful in relieving BOO following MIT. While these biodegradable stents do not need to be removed, their rate of resorption can vary from patient to patient. This results in unpredictable degradation as well as the emergence of obstructive symptoms. Another major disadvantage of temporary prostatic stents, especially when placed in the immediate post-TUMT treatment patient, is that they have a small lumen that can lead to urinary retention secondary to clot-induced impairment of catheter patency. A stent with a larger lumen of 10 mm, the expandable nitinol stent, has been used with some success in patients with recurrent urethral strictures,<sup>16</sup> but it has not been evaluated in post TUMT patients.

A randomized control study of biodegradable polyglycolic acid stents<sup>13</sup> showed significant improvements in peak flow rate and symptoms score as soon as 1 month post prostate visual laser ablation. This same group also compared a biodegradable polyglycolic acid spiral stent to a suprapubic catheter after visual needle ablation of the prostate,<sup>15</sup> and found significant flow rate improvement by 1 month and symptom improvement by 3 months. Urinary tract infection occurred in 41% of the spiral stent recipients, however, which was managed by antibiotics. One drawback noted regarding the biodegradable stent was the incidence of diminished stream force and increased obstructive symptoms three weeks after stent placement. This was attributed to fragments that resulted from the biodegradation of the stent. Overall these two reports showed there were advantages to using a biodegradable stent as a temporary endoprosthesis that does not require subsequent removal, but there were still problems with infection and obstruction after stent insertion.

Devonect et al<sup>11</sup> examined two types of temporary stents following high-energy TUMT: a silicone transurethral prostatic bridge and a self-reinforced polyglycolic acid biodegradable spiral. Patients were assessed at 1 week as well as at 1, 3, 6, and 12 months post TUMT. There were significant improvements observed in the symptom score, peak flow rate, and voided volume, and the improvement was sustained during the entire follow up period. In the patients receiving the silicone tube the improvement was significant as early as the first week for peak flow rate, and at 1 month for symptoms. Patients receiving the spiral stent, however, did not show a significant improvement until 3 months for symptoms and 1-3 months for flow. These authors also compared stents of various diameters in their study and found that there was no clear relationship between diameter of the stent and improvement in flow rate in patients with comparable flow rates prior

to stent insertion. In this study, these two types of temporary stents did not relieve BOO in a timely fashion, necessitating further work to develop a stent that would allow for immediate relief of BOO.

The PGA biodegradable stent has been reported as having been used in diagnostic procedures. Knutson et al<sup>14</sup> utilized a biodegradable stent to assess LUTS after relief from BOO in an effort to predict postsurgical outcomes in a better way in the difficult patient population that exhibits a combination of BPO, severe detrusor overactivity, and urge urinary incontinence. Stents were placed in 37 patients and disintegrated after 3–4 weeks. At 2 months patients were interviewed and if they had no urinary leakage while the stent was in place, they were recommended to undergo TURP. The patients who experienced profuse urge incontinence while the stent was in place were encouraged not to undergo surgery. Twenty-five of the 37 patients did not experience urge incontinence during this 2 month period. The postoperative results, after an undisclosed amount of time, in the 18 patients who underwent TURP showed no episodes of postprostatectomy incontinence along with improvements in international prostate symptom score (IPSS), post void residual (PVR), and peak flow rates (PFR). While this study was used to mimic a TURP, it was only a diagnostic study and did not test the effectiveness of PGA biodegradable stents for treatment of BOO.

There have recently been two studies of novel temporary stents in animal models. Crisostomo et al<sup>17</sup> evaluated the use of a retrievable polytetrafluoroethylene (PTFE)-covered nitinol stent in a canine model. They found that of the eight dogs implanted, two had complete stent migration at 1 month requiring deployment of an additional stent. At 30 days post implantation, three dogs showed slight urethral hyperplasia (grade 1) while on day 60 four dogs displayed moderate hyperplasia (grade 2). Urinary flow was not impaired in any of the animals. Histologic findings included chronic inflammatory cell infiltrates, prostate glandular atrophy, periurethral fibrosis, and dilation of the prostatic urethra. The other animal study was by Kotsar et al<sup>18</sup> in which they utilized a biodegradable polylactic glycolic acid self-expandable stent in a rabbit model. They found that the stents were easy to insert and they degraded smoothly over a period of 1–2 months. This stent design was then used in a pilot study along with dutasteride in the treatment of acute urinary retention due to BPH.<sup>19</sup> Ten men with acute urinary retention due to BPH were treated in an outpatient setting. The braided PLGA biodegradable urethral stent was inserted into the prostatic urethra, under visual control, using a specially designed insertion device. Dutasteride treatment was then initiated

and the patients were followed up for 3 months after stent insertion. After stent placement all men were able to void. At a 1 month follow up 5 patients voided freely with a low residual urine volume, while 2 voided but had a high residual urine volume; in these two patients a suprapubic catheter was inserted. Three patients needed a suprapubic or an indwelling catheter before the 1 month follow up meeting, due to acute urinary retention or other comorbidities. The authors noted that while the new polylactic glycolic acid stent overcame the earlier problems of migration and sudden breakage into large particles associated with previous biodegradable spiral stents, the mechanical properties of the new stent still required improvement.

Since temporary stents rely on intact detrusor function there is a need to study the effect of temporary stents in patients with and without detrusor dysfunction. Corujo et al<sup>20</sup> described the use of the ContiCath in the management of post-operative and temporary BOO. These authors used 3 groups of patients for their study: patients with nonneurogenic causes of retention and retention less than 1 week (37 patients), patients with nonneurogenic causes of retention and retention longer than 1 week (19 patients), and patients with neurogenic causes of retention (eg, diabetes mellitus) and retention longer than 1 week (5 patients). Of the 37 patients with nonneurogenic retention for less than 1 week 89% were able to void after placement of the catheter. However, of the patients with nonneurogenic retention longer than 1 week and with neurogenic retention (24 in total), only 3 were able to void after the catheter was placed. The authors also reported urodynamic data from 8 patients in their study group who had urodynamic study (UDS) after catheter insertion. Six of the 8 patients had confirmed retention by UDS with a mean detrusor pressure of 89.7 cmHg at maximum flow, while the other 2 patients had hypocontractile bladders (mean detrusor pressure 12.8 cmHg). The 2 patients with hypocontractile bladders were unable to void with the catheter in place. These results indicate that patients with detrusor dysfunction will not benefit from temporary stenting and that an intact detrusor reflex is needed for the stent to function properly.

## Spanner stent Design and placement

The initial shortcomings of the temporary biodegradable stents including variable rates of resorption leading to premature and unpredictable degradation along with obstructive symptoms, and small intraluminal diameters that result in urinary retention necessitated the development of a better temporary prostatic stent. Corica et al<sup>21</sup> described a novel

temporary prostatic stent, focusing on voiding function and quality of life among patients with prostatic urethral obstruction. The Spanner stent design incorporates elements of an indwelling Foley catheter: (i) the proximal balloon, similar to a Foley catheter, assists to prevent distal displacement, (ii) the urine port proximal to the balloon allows for adequate bladder drainage, (iii) the reinforced stent of various lengths spans the majority of the prostatic urethra to ensure prostatic urethral patency.

The insertion of the Spanner stent was described in detail by Shore et al<sup>22</sup> The Spanner stent is mounted on the insertion device and advanced along the urethral meatus and pendulous urethra until the tip is well within the bladder. The Spanner balloon is then inflated with 5 mL of sterile water and seated in the bladder neck. The distal anchor is deployed distal to the external sphincter and the insertion tool is removed from the urethra. Removing the stent involves applying gentle traction to the retrieval suture which deflates the proximal balloon.

## Pilot study data

In the initial trial by Corica et al,<sup>21</sup> the Spanner stents remained in situ for a mean duration of 57 days. The mean PFR at baseline and after insertion were 8.2 and 11.6 mL/s respectively, which represented a 42% improvement, while the PVR and IPSS demonstrated a 64 and 68% decrease respectively. The stability, patency, and lack of migration of the device were confirmed radiographically and through satisfactory functioning up to 12 weeks post implantation. These pilot results indicated that the Spanner stent was a feasible treatment modality for BOO from BPH, and subsequently this treatment was applied to LUTS following TUMT and brachytherapy of the prostate.

## Effects on uroflowmetry and PVR

Shore et al studied the effect of the Spanner stent on bladder emptying following TUMT.<sup>22</sup> These data, however, are difficult to put into context because no concrete numbers were disclosed for any parameter measured; only percentages were reported. Based on the percentages reported, the patients with the Spanner stent showed a significant improvement over Foley catheter in both PVR and uroflowmetry endpoints (peak flow rate, time to peak flow, average flow, total void volume, and voided volume) at 1 and 2 weeks post stent insertion. At 4 weeks, however, these parameters were no longer significant, and following Spanner stent removal the 5 and 8 weeks, PVR and uroflowmetry end points did not differ significantly between groups. The authors point out

the shortcomings of supporting their hypothesis since flow rates and post-void residual volumes were only calculated up to 1 week after Spanner stent removal and not followed for 12 months, as reported in previous studies.<sup>11</sup> In order to support their hypothesis there is a need long-term follow-up PVR and uroflowmetry data from these patients, which, to date, has not been reported.

## Quality of life with spanner stent

In the study by the Corica group a novel questionnaire (not validated) was used to assess quality of life parameters with the Spanner stent.<sup>22</sup> Termed the Spanner Satisfaction Questionnaire, it was aimed at assessing various modalities of the stent on the patient including comfort with insertion and removal, ease of bladder emptying, interference with daily activities, and effects on sexual activity. Of the 100 patients surveyed, most experienced mild to no pain with Spanner insertion and removal (81.8% and 82.3% respectively). Patients displayed an increased preference for the Spanner stent over the standard of care (Foley catheter, personal communication), and there was an increased ease in bladder emptying with minimal to no urine leakage. Patients also felt that the stent was comfortable, convenient, and rarely interfered with normal activity. During Spanner use, the percentage of sexually active men increased along with percentage that could achieve an erection while the Spanner stent was in place; additionally, the patients reported no pain during sexual activity and erections.

Another study by Henderson et al<sup>23</sup> reported quality of life measures in of five patients with unusually high morbidity following brachytherapy of the prostate. Two of the patients developed urinary retention while the other 3 had severe LUTS. The mean time to implantation was 40 days post brachytherapy (range 25–90 days). In these patients, 1 stents were introduced using topical anesthetics without complication. All patients were able to void spontaneously with no PVR, and in all patients, PFR and IPSS significantly improved after stent insertion. All patients experienced some degree of pain or dysuria during stent use. Two patients (early post brachytherapy group) requested stent removal at 1 week and the other 3 patients continued using the stent for 30 days until planned removal. Overall, bladder outflow obstruction was effectively treated with the Spanner stent in these patients; however the patients found that there was gradual reversion of their urinary symptoms to present levels after stent removal. The pain and dysuria associated with the Spanner stent was relieved within a few days after stent removal.

The Corica group<sup>24</sup> described the use and effectiveness of the Spanner stent in patients treated with TUMT on reducing voiding symptoms, irritative symptoms, and bother (Benign Prostatic Hyperplasia Impact Index) compared with standard of care (SOC). SOC was not specifically defined by the authors. Also, it is unclear from the article how the Corica group was able to measure IPSS in patients with an indwelling Foley catheter. The patients treated with the Spanner stent showed significant improvement in IPSS voiding subscores at 1 week after stent implantation, and improvement in individual voiding symptoms assessed by IPSS (intermittency, weak stream, and straining) compared to patients treated with SOC. At 2 weeks, however, there was a trend toward greater improvement in IPSS voiding scores in the Spanner stent patients, but these results were not statistically significant. After 2 weeks the IPSS voiding subscore was not significantly different between the Spanner stent group and the Foley catheter group, indicating that Spanner only assisted in relieving voiding symptoms within the first 2 weeks following TUMT. IPSS irritative and BPH impact index scores were not initially significantly different for either group, demonstrating that implanting the Spanner stent did not generate additional irritation beyond the TUMT procedure. Following Spanner stent removal at 4 weeks post TUMT, there was a significant decrease in IPSS irritative subscore and BPH Impact Index which the authors hypothesized was related to sustained improvements in bladder emptying. The hypothesis proposed by the authors, that the Spanner stent improves bladder emptying leading to an improvement in IPSS irritative and BPH Impact Index, appears to be evident initially following stent placement, but after 1 month there is no improvement when compared to conventional therapy.

## Adverse events and device failure

The Spanner temporary stent does carry a risk of adverse events following insertion, although the majority of these events are not significantly different when compared to patients treated with only Foley catheter.<sup>22</sup> Adverse stent related events included symptomatic urinary tract infection, stent migrations, stent expulsion, stent encrustation, acute urinary retention, clot retention, and increased PVR. Other events that occurred which required patients to withdraw from the study included congestive heart failure and gross hematuria, but these events were not specifically device related. When comparing the Spanner stent group to the Foley catheter group there was no significant increase in the number of symptomatic UTIs (15 versus 10,  $P = 0.527$ ),

acute urinary retention (6 versus 12,  $P = 0.083$ ), or clot retention (1 versus 2,  $P = 1.000$ ). When evaluating Spanner stent safety, for the Shore et al series,<sup>22</sup> the risk of major adverse events were particularly rare, and they did not vary between the Spanner stent and Foley catheter group. What was more prevalent in patients treated with Spanner stent was perineal pain (26.0% versus 12.8%  $P = 0.028$ ).<sup>22</sup>

Another consideration for Spanner stent efficacy is bladder and urethral abnormalities associated with device implantation. Shore et al<sup>22</sup> presented data from 100 patients receiving Spanner stents post TUMT compared to 86 patients receiving Foley catheter. When compared to Foley catheter there was no difference in the percentage of overall bladder and urethral abnormalities, and the Spanner stent had significantly lower incidences of urethral erosion (2.1% versus 13%) in post-TUMT patients.<sup>22</sup> There were, however, 18 post-TUMT patients who withdrew from the Spanner stent group for various reasons including urinary tract infection (1), gross hematuria (1), Spanner expulsion (2), Spanner migration (3), clot retention (1), and urinary retention (6). There was no mention of patients in the Foley catheter group that withdrew from the study in the Shore et al series. Of particular importance is the mention of gross hematuria in this series which was also seen in the initial study of the efficacy of the Spanner stent.<sup>21</sup> In the initial Spanner stent study, 7 patients were noted to have hematuria within the first week of stent insertion. While these 7 patients did not withdraw because of this event, it should be noted that the Spanner stent can cause intermittent mild hematuria following device insertion.

Results of an observational study by Grimsley et al<sup>25</sup> involving patients who were unfit for surgical intervention indicate that unsatisfactory outcomes are more common in patients treated with Spanner stents than previously reported. In their series of 43 patients treated with the Spanner stent, 63% had to discontinue use of the device due to immediate or delayed urinary retention or unbearable symptoms (nocturia, dysuria, severe frequency, or incontinence). There were a higher percentage of patients who withdrew from the study due to adverse events in the Grimsley series compared to the Shore series (63% and 18% respectively). These data indicate that the Spanner stent may be a good treatment option for patients undergoing surgical prostate procedures, but it does not appear to be an efficacious treatment for unfit for surgery patients with BOO or LUTS.

There is one mention of device failure in the search of the current literature for the Spanner stent. Shore et al<sup>22</sup> noted 5 device failures for 100 patients treated with the Spanner stent,



none of which required additional treatment or was associated with an adverse event. Two device malfunctions were due to the retrieval suture becoming untied during stent removal. This led to a change in the stent design where a second knot was added to prevent the suture from coming untied. Two other malfunctions occurred because the Spanner stent did not deploy, and the fifth malfunction was due to a deflated balloon. All of these events considered, it appears that the Spanner stent, in the hands of a well trained physician, is unlikely to have a significant device failure and a subsequent adverse event related to the device.

## Conclusions

Since no stenting option, permanent or temporary, has shown 100% percent success, there still a need for a more reliable stent to relieve BOO. Temporary stents have arisen as a novel treatment for BOO following MIT, but several of the temporary stents, including PGA biodegradable stents, have had problems associated with their placement and degradation. Also, temporary stents rely on intact volitional or reflex detrusor contraction and associated pelvic floor relaxation, in order to function properly, thus patients with detrusor abnormalities are not good candidates for temporary stents.<sup>20</sup> Considering the previous shortcomings of temporary stents, the Spanner stent was created and utilized in a design similar to a Foley catheter to maintain luminal patency.

The Spanner stent is the only FDA approved temporary stent available; however based on the limited data which only includes post TUMT use, it appears that the Spanner stent does not offer significant advantage over previously designed temporary stents. It does not improve PFR or IPSS beyond 1–2 weeks after insertion and the stent causes irritative symptoms which are relieved once the stent is removed. There is also a lack of long term follow up data (eg, PVR, PFR, voided volume) after Spanner stent removal, necessitating studies that evaluate the effects of Spanner stent on urinary parameters and prostatic/urethral tissue long term. Furthermore, in non-surgical patients with LUTS the Spanner performed poorly requiring stent removal. What is not reported in the literature is bladder function for the patients treated with the Spanner stent, so we do not know if the treatment fails due to the device or based on detrusor dysfunction. Future studies are needed with the Spanner stent in these patients in order to truly test its efficacy in treating bladder outlet obstruction.

## Disclosure

The authors report no conflicts of interest in this work.

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