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First Experiences with the Spanner™ Temporary Prostatic Stent for Prostatic Urethral Obstruction

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Key Words
Prostate · Stent · Prostatic outflow obstruction

Abstract
Objectives: To assess the ease of insertion and removal of a temporary prostatic stent (the Spanner™) following the use of a prostatic urethral measuring device (the Surveyor™). ***Patients and Methods:*** Patients with bladder outflow obstruction or urinary retention awaiting definitive surgery were fully consented. Data were collected pre- and post-insertion and patients followed-up until definitively treated. ***Results:*** 16 patients had the Spanner inserted following use of the Surveyor. All insertions were uncomplicated. 14 patients were able to void satisfactorily immediately post-insertion with a mean Q_{max} of 15.0 ml/s and post-void residual of 51.3 ml. No symptomatic infection was reported. The stents stayed in situ for a median of 10 days. 12 stents were removed prematurely due to severe symptoms or retention. A total of 12 stents had to be removed endoscopically. ***Conclusions:*** The Spanner is easy to insert. Stent removal via the retrieval suture has been difficult necessitating the use of endoscopy in the majority of cases. Possible causes of stent failure include underestimation of the prostatic urethral length by the Surveyor leading to obstruction by apical prostatic tissue, excessive suture length between the stent and distal anchor permitting proximal migration or inadequate suture length leading to urinary incontinence. Further design modifications are suggested.

Introduction

Lower urinary tract symptoms (LUTS) and urethral catheterisation for urinary retention due to benign prostatic obstruction can adversely affect quality of life. Prostatic stents have been used either temporarily in patients with retention or permanently in patients who are poor surgical candidates [1–13]. Up to 10–15% of patients are unsuitable for surgery because of severe co-morbidities [4].

The use of a prostatic stent is based on the theory that benign prostatic hyperplasia causes mechanical or dynamic obstruction. Stents theoretically establish a patent

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lumen that allows low pressure urinary voiding [14]. The criteria for an optimal stent were identified at the Third International Consultation on Benign Prostatic Hyperplasia in 1995 (table 1) [15].

The ideal temporary prostatic stent remains elusive. The drawbacks include complex insertion and removal, tendency for migration and patient discomfort. Variations in the shape of the prostatic urethra and its relation to the bladder neck make exact measurement prostatic urethral length difficult which can compromise stability of the stent. As these stents are for temporary use, they need to be easily removed or replaced, with biodegradable stents being an exception [16]. Examples of temporary stents include the Urospiral, Prostakath, ProstaCoil, Memokath, Biofix, Intraurethral Catheter, Barnes stent and Trestle [17–20].

In 2006, the evaluation of two versions of a blind placement stent (BPS-1 and BPS-2) developed by Boston Scientific Corporation was published [21]. BPS-1 was found to be unsuitable for clinical use due to a high migration rate and BPS-2 not useful due to significant discomfort and non-significantly improved symptom and voiding parameters.

Studies evaluating temporary stents for patients with retention after non-urologic surgery and for patients temporarily unfit for transurethral resection of the prostate (TURP) are ongoing. Significant oedema following cryotherapy and brachytherapy for prostate cancer can result in difficult voiding and temporary prostatic stents can be used effectively in these circumstances.

The effect of a temporary prostatic stent (the Spanner™, AbbeyMoor Medical, Inc., Minn., USA.) following the use of a prostatic urethral measuring device (the Surveyor™; AbbeyMoor Medical, Inc., Minn., USA.) on patients with benign prostatic obstruction has been reported with significant improvement in urinary flow rates and post-void residuals [22]. In 2012, the Spanner was acquired by SRS Medical, Mass., USA.

We report our first experiences with the Spanner and Surveyor at Brighton and Sussex University Hospitals and Southmead Hospital, Bristol, UK.

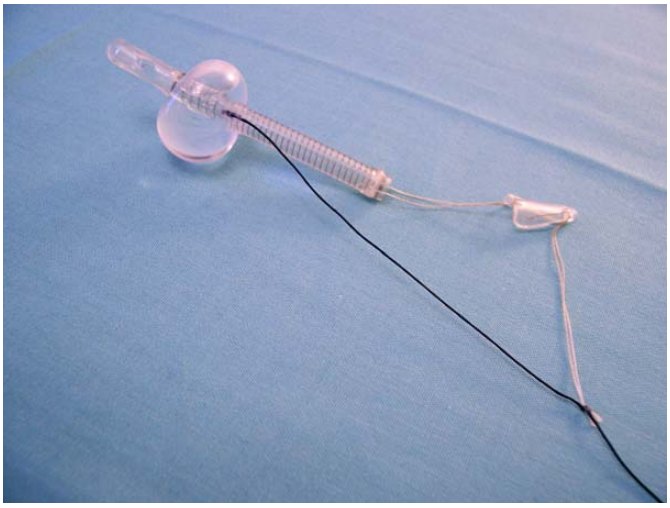

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Fig. 1. The Spanner temporary prostatic stent.

Table 1. Criteria for an optimal stent

– Easy insertion/removal with standard catheter procedures avoiding imaging or visualisation (blind placement)
– Bi-directional stabilisation to prevent migration or expulsion
– Soft and flexible to provide for patient comfort
– Thin walls for minimal urodynamic resistance to improve voiding efficiency
– Resistance to encrustation
– Improvement in LUTS
– Maintaining continence
– Causes minimal tissue irritation
– Minimal urinary tract infection rate
– Cost-effective

Materials and Methods

The Spanner Temporary Prostatic Stent

The Spanner is designed to overcome variations in the shape of the prostatic urethra as it is very similar to the proximal 4–6 cm of a Foley catheter. The Spanner device positioned in situ consists of a short stent that spans the prostatic urethra with a balloon at its proximal end which sits at the bladder neck. This stent is connected at its distal end by sutures traversing the external sphincter to a distal anchor that lies in the bulbar urethra which prevents proximal migration. A retrieval suture, which extends from the distal anchor to the external meatus, is connected to the proximal balloon which deflates when pulled and facilitates removal of the stent (fig. 1).

Prior to insertion, the Spanner is mounted on an insertion tool which allows positioning of the stent and inflation of the proximal balloon (fig. 2). Following insertion, the insertion tool detaches leaving the stent, distal anchor and retrieval suture in place. The retrieval suture is trimmed at the external urethral meatus.

The Surveyor

The Spanner stent insertion follows the use of the Surveyor. The Surveyor is a new prostatic urethral measuring device that comprises a 40 cm slim rigid polymer tube with an inflatable balloon proximally (which sits at the bladder neck), and an encircling short Teflon probe which slides proximally up the urethra along the length of the tube by means of a probe wire until it meets the

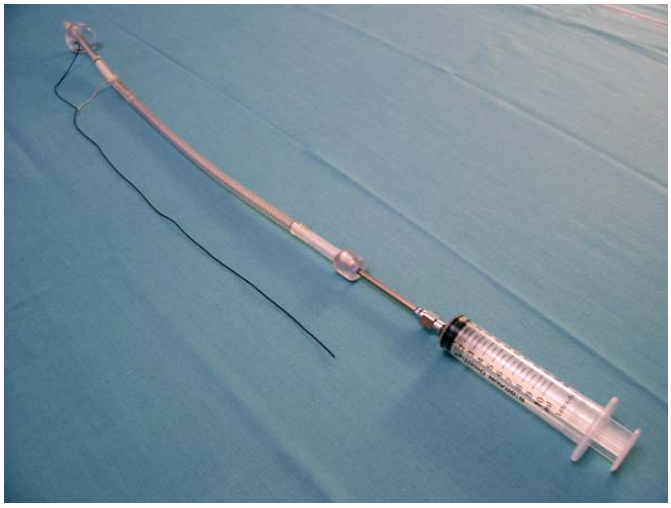

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Fig. 2. The Spanner mounted on the insertion tool.

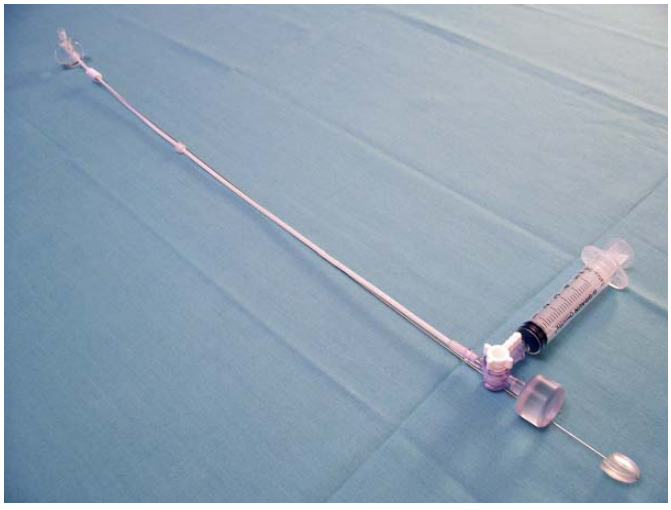

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Fig. 3. The Surveyor prostatic urethral measuring device.

resistance of the external sphincter (fig. 3). The measurement between the bladder neck and external sphincter (with the aid of a sizing card) determines the size of the Spanner stent that is inserted. The Spanner stent comes in six sizes from 4 to 9 cm.

The Spanner and the Surveyor are both CE-marked.

Patients and Methods

Urologists from Brighton and Bristol were trained on the use of the Spanner and Surveyor by representatives of AbbeyMoor Medical, Inc. A demonstration video was provided and representatives demonstrated the use of the Surveyor, and the insertion and removal of the Spanner on a training model. This was followed by repeated model insertions by the clinicians and supervised insertion on patients. This was with the intent of proceeding with a pilot study and a formal trial in both Brighton and Bristol to assess the efficacy of the Spanner and Surveyor in patients who presented acutely with urinary retention in the emergency setting.

Patients with bladder outflow obstruction or urinary retention awaiting definitive surgery were approached. All patients were fully consented and provided with information leaflets and contact details. Patients were aware of the novelty of the device and its efficacy as reported in the sole publication of the device at the time [22].

Clinicians inserted the Spanner stent into these patients following use of the Surveyor under the supervision of representatives of AbbeyMoor Medical, Inc. Wherever possible, pre- and post-insertion data were collected including International Prostate Symptom Scores (IPSS), uroflowmetry and residual volume measurements. Patients were followed up until definitively treated.

All collated data was analysed and we present the respective group analysis. Clinicians and engineers of AbbeyMoor Medical, Inc. used these observations and results to draw conclusions and to improve techniques and stent design.

Results

Between May 2004 and April 2005, a total of 16 patients had the Spanner inserted. Four patients were from Brighton and 12 from Bristol. The average age was 72.8 years (range 64–83). The main presenting problems were acute or chronic urinary retention (n = 13) and LUTS (n = 3). Two patients had prostate cancer and two suffered from detrusor overactivity (table 2).

The 4 patients from the Brighton centre voided well immediately post-insertion. However, the first patient returned the following day in retention. The stent was removed via the retrieval suture and was found to be occluded by a blood clot. The following 2 patients developed severe LUTS requiring removal on day 10, one of whom had proximal migration of the stent into the bladder. The fourth patient complained of a slow stream and severe LUTS on day 7 and subsequently went into retention 3 days later. On rigid cystoscopy, the distal anchor was in the prostatic urethra indicating proximal migration.

Of the initial 7 patients from Bristol, 4 devices subsequently failed. The first patient was able to void well initially but returned within 48 h with retention. The retrieval suture could not be seen and the Spanner was subsequently pushed into the bladder. The second, third and sixth patients who had the stent inserted were all successful and subsequently underwent TURP 5–6 months later. The fourth patient voided well post-insertion but went into retention 4 days later. The fifth and seventh patients also voided well initially but both returned within 24 h and at 14 days, respectively, in retention.

Table 2. Patient demographics and data analysis

Total patients/age	Presentation	Stent size (n patients)	Post-insertion (n = 10)	Outcome/ complications	Removal details	Days in situ	UTI
Total patients: 16 Mean age: 72.8 Range: 64–83 Median: 72	retention: 13 LUTS: 3	6 cm (1) 7 cm (4) 8 cm (6) 9 cm (3)	mean Q_{max}: 15.0 mean PVR: 51.3	successful: 4 retention: 8 worsening LUTS: 3 incontinence: 1 proximal migration: 5 stent blockage: 1	removal via endoscopy: 12 removal via retrieval suture: 4 premature removal: 12 removal at TURP: 4	median: 10 mean: 41.9	no cases recorded

PVR = Post-void residual (ml); Q_{max} = maximum flow rate (ml/s); UTI = urinary tract infection.

Following the insertion of the initial 4 Spanners in Brighton and 7 Spanners in Bristol, it was noted that all devices in Brighton and 4 devices in Bristol subsequently failed. A trend of patients returning in retention following good voiding post-insertion was noted. It was acknowledged that all patients voided successfully initially and many had large prostates. It was thought that the Surveyor may be underestimating prostatic urethral length especially with larger prostates and in these cases, a longer Spanner size would be more appropriate.

It was also noted that the length of the suture between the stent and distal anchor increased with increasing stent length which permitted some degree of proximal migration (but with the distal anchor still in the bulbar urethra), thus allowing apical prostatic tissue to obstruct. The suture length was thus standardised across stent sizes to 2 cm and this Constant Suture Length Spanner was inserted in 5 subsequent patients in Bristol.

Of these, the first patient voided well initially but after 3 weeks, began to develop frequency, urgency and urge incontinence. The Spanner was removed but the distal anchor was proximal to the external sphincter thus indicating proximal migration. The second patient managed to void satisfactorily until TURP but suffered from mild urinary incontinence exacerbated by bending forward. The third patient suffered from intractable urinary incontinence. However, this was thought to be due to sphincter weakness following radiotherapy as the stent position was satisfactory on flexible urethroscopy and bladder scanning. The following 2 patients were unable to void following insertion, but one of them experienced urinary incontinence on bending forward. At flexible urethroscopy, this patient was asked to bend forward and during this manoeuvre, the distal anchor moved proximally to impinge on the external sphincter.

Discussion

In the past, the use of temporary prostatic stents for bladder outlet obstruction and urinary retention had to overcome hurdles of accurate measurement of the prostatic urethra, stent sizing, stent insertion which normally requires the use of a cystoscope, and accurate placement with minimal incidence of migration.

The Spanner and its measuring tool, the Surveyor, appear to be an elegant and long-awaited solution. One is impressed with the ease of use of both for the operator during insertion. A publication by Corica et al. [22] supports this first impression. They assessed the use of the Spanner in patients with prostatic obstruction in Mendoza, Argentina. 30 patients were investigated with 5 patients catheterised for urinary retention. The Spanner remained in situ for a mean of 57 days (1–98 days) with a statistically significant improvement in Q_{max} of 42% (mean 8.2–11.6 ml/s). Improvements were also seen in mean post-void residual (PVR) (312.1–112.3 ml, $p = 0.004$) and mean IPSS (22.3–7.1, $p < 0.001$). Only minor adverse events were reported. Stability, patency and lack of migration were observed up to 12 weeks.

However, in our experience, the clinical use of the Spanner in situ for bladder outlet obstruction and urinary retention has not been without difficulties.

Measurement of the Prostatic Urethra

The Surveyor is an ingenious device used for measuring the length from the bladder neck to the external sphincter. From our experience, this device is easy to use in an outpatient or ward setting. All Surveyor measurements were performed under local anaesthesia and were uncomplicated. The accuracy of measurement is questionable and is discussed below.

Insertion of the Spanner

Insertion of the Spanner with the aid of an insertion tool is very similar to insertion of an ordinary Foley catheter, with the learning focused on deployment of the stent following inflation of the proximal balloon. We found that stent insertion is easy to perform in outpatients or on the ward. All Spanner stent insertions were performed under local anaesthesia and were uncomplicated.

Function of the Spanner

No symptomatic urinary tract infection was reported by any of the 16 patients. The mean flow rate of 15.0 ml/s (n = 10) and the median post-void residual of 51.3 ml (n = 10) were acceptable. The median time in situ of the Spanner was 10 days and therefore well short of the planned use. In 12 patients, the Spanner was removed prematurely, in 5 cases for migration.

The possible causes of failure include:

(1) Underestimation of the prostatic urethral length by the Surveyor leading to obstruction by apical prostatic tissue.

(2) Excessive suture length between the stent and distal anchor permitting proximal migration of the stent.

(3) Inadequate suture length between the stent and distal anchor which allowed the distal anchor to impinge on the external sphincter leading to urinary incontinence.

To assess the accuracy of the Surveyor, it was used following measurement of the prostatic urethra with a flexible cystoscope and/or TRUS measurement in subsequent patients to determine the correlation between all three methods of measurement. As a result, alterations in sizing guidelines were made which resulted in a modified sizing card for Spanner size selection.

It was recognised that in the original stent design, the suture length between the stent and the distal anchor increased with increasing stent size. A modification was made to standardise this suture length to 2 cm. However, this led to problems with urinary incontinence due to impingement of the external sphincter by the distal anchor. The suture length was thus deemed too short and modifications have been made to increase this length to 2.5 cm to comfortably accommodate the external sphincter.

Patients who have been catheterised for prolonged periods prior to stent insertion may lack the necessary external sphincter tone required to keep the distal anchor from migrating proximally through the sphincter. It is also possible that the design of the distal anchor may not be optimal for maintaining stent position in this population of patients. In addition, the stent may be too rigid to enable it to conform to the shape of the prostatic urethra especially in larger prostates and the distal end of the stent may embed in the posterior curve of the distal prostatic urethra thus obstructing the stent lumen. If this is indeed true, stent rigidity is another aspect worth investigating and design modifications have since been made. A further issue to consider is the intraprostatic portion of the external urethral sphincter complex which has a role in urinary continence. Miano et al. [23] have shown that evaluation of the external urethral sphincter complex is feasible by TRUS and that the intraprostatic portion can be determined similarly. The latter has a stronger correlation with prostatic volume ($r = 0.60$, $p < 0.001$). Further functional evaluation of the Spanner should take this into account as stent placement or impingement of the intraprostatic external urethral sphincter complex may affect success rates.

Removal of the Spanner

Removal of the Spanner stent via the retrieval suture has been difficult. Of the 4 patients who had their stents removed in this manner, 1 patient had the stent removed via the retrieval suture which was grasped with forceps following milking of the urethra. In 2 other patients, the suture was not trimmed immediately post-insertion and, when they subsequently failed to void 3 h later, the untrimmed suture was used for stent retrieval.

It has been observed that the end of the retrieval suture tends to retract into the urethra thus necessitating the use of endoscopy to locate the suture for subsequent removal in the remaining 12 cases. Retraction of the retrieval suture into the urethra is possibly due to the suture curling or sticking to the lining of the urethra, proximal retraction following erections, or proximal migration of the stent. Techniques to draw the retrieval suture out such as asking the patient to void and milking the urethra following instillation of local anaesthetic gel have not been terribly effective. Therefore, it is now recommended that the retrieval suture is left extended 5 cm beyond the meatus with the penis on stretch to compensate for erections and suture retraction. Cystoscopic stent removal will be required if these measures fail.

The use of the Spanner in symptomatic benign and malignant prostatic obstruction in patients unfit for surgery has been investigated. In the series by Grimsley et al. [24], 43 consecutive patients who were unfit for surgery were treated with the Spanner between March 2004 and November 2005. If tolerated, the stents were replaced ev-

ery three months. 63% had immediate or delayed retention or stent removal due to symptoms. The remaining 37% had satisfactory outcomes with the Spanner in situ after a mean of five changes or became stent-free following a trial of voiding. 21% of patients had the stent in situ at the end of the study period.

The Spanner has been used in patients with unusually severe urinary symptoms following prostate brachytherapy [25]. In their series, all 5 patients treated with the Spanner were able to void spontaneously with no PVR. Significant improvements in IPSS and flow rates were seen in all cases but pain and dysuria associated with the stent were poorly tolerated. Two patients requested stent removal at one week and the remaining three had theirs removed at thirty days as planned. No problems with stent blockage, migration or encrustation occurred.

In a trial of the Spanner versus standard of care after initial urethral catheterisation following transurethral microwave thermotherapy, 186 men were recruited in nine centres in the USA and Puerto Rico from October 2002 to December 2005 [26, 27]. Significant improvements in IPSS, uroflowmetry and PVR at 1 and 2 weeks were seen in the Spanner group. Greater improvements in quality of life were seen at 5 and 8 weeks. Patient satisfaction was >86% and cystourethroscopy findings in both groups were comparable. Adverse events were rare.

In the USA, the FDA has approved the Spanner for temporary use (up to 30 days) in patients following minimally invasive treatment for benign prostatic hyperplasia (BPH) and after initial post-treatment catheterisation.

Conclusions

There is limited data in the literature on the Spanner but there is potential for its use for prostatic urethral obstruction following transurethral microwave thermotherapy, and FDA approval has been given for this indication. The Spanner has allowed volitional voiding in patients post-brachytherapy but there was associated bothersome pain and dysuria. Although the design of the Spanner and the accompanying Surveyor is a step forward, we believe that for patients with bladder outlet obstruction or urinary retention awaiting definitive surgery, careful patient selection, assessment of detrusor function, modifications in stent design and further clinical evaluation with longer term parameters are required.

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