Management of Recurrent Urethral Strictures with Covered Retrievable Expandable Nitinol Stents: Long-Term Results

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OBJECTIVE. The purpose of this study was to evaluate the long-term clinical efficacy of temporary placement of covered retrievable stents in the management of recurrent urethral strictures.

MATERIALS AND METHODS. During the period December 1998–December 2005, 32 men and one adolescent boy (mean age, 48.6 years; range, 16–73 years) with recurrent urethral strictures underwent fluoroscopically guided insertion of a total of 68 stents. Patients without complications underwent elective stent removal 2 or 4 months after stent insertion. Rates of clinical success (long-term clinical and radiographic resolution of urethral strictures) were assessed. The Mann-Whitney *U* test was used to compare the duration of stent placement in patients with long-term clinical resolution with that in patients with stricture relapse.

RESULTS. Clinical success was achieved in 18 (55%) of the 33 patients. The mean duration of stent placement in patients with clinical success was significantly different from that in patients who had recurrences ($p < 0.0001$). Stricture relapse did not occur in only four (20%) of 20 cases of stent placement for 2 months. All 14 stent placements lasting at least 4 months resulted in long-term resolution after a mean follow-up period of 3.6 years. The most common complications necessitating early stent removal were stent migration (33.8% of stents) and tissue hyperplasia (20.6% of stents).

CONCLUSION. Placement of a covered retrievable stent for a minimum of 4 months is effective in inducing long-term resolution of refractory urethral strictures. Stent migration remains the largest obstacle in achieving adequate duration of stent placement.

Management of recurrent benign urethral strictures remains a therapeutic challenge to urologists. Strictures managed with conventional treatments (i.e., endoscopic urethrotomy, urethroplasty) often remain resistant to therapy. Results of previous studies [1, 2] indicate that 40–70% of strictures managed with endoscopic urethrotomy recur within 2 years. Stent placement is an evolving alternative for treatment of selected patients with recurrent urethral strictures whose condition is unsuited to invasive procedures. Despite promising early results with the use of a self-expanding stent (UroLume, American Medical Systems) [3, 4], recent reports [5, 6] of long-term results have been discouraging. The complication rates reported are as high as 55%, most of the complications stemming from stent obstruction secondary to tissue hyperplasia. These stents lack a covering material and thereby become easily incorporated into the urethral wall with hyperplastic tissue ingrowth. Because it is permanent, the stent must be removed surgically if complications necessitate removal. Retrieval stents designed for temporary placement thus have an advantage. Several types of temporarily placed stents [7, 8] have been introduced. These stents, however, are not suitable for the management of bulbomembranous strictures that require stents that traverse the external sphincter. In addition, the need for use of a rigid endoscopic forceps in stent removal makes the procedure cumbersome.

The most recent design of retrievable stent was introduced by Song et al. [9], who found promising initial results in the treatment of 12 men with recurrent bulbar strictures. Evaluation after a mean follow-up period of 18 months showed that 11 (92%) of 12 patients had been successfully treated with preservation of sphincter function despite complete bridging of the external sphincter with the stent. A follow-up study [10] showed that this newly designed stent can be easily retrieved with a high technical success rate and low complication rate. The purpose of our study

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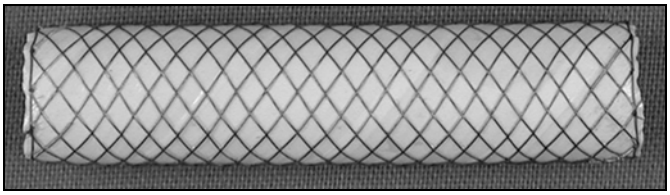

Fig. 1—Photograph shows polytetrafluoroethylene-covered retrievable nitinol stent.

was to assess the long-term effectiveness of this stent in the management of recurrent urethral strictures in 33 patients with a mean follow-up period of 3.6 years.

Materials and Methods

Patients

All patients provided informed consent to undergo urethral stent placement, and the retrospective review was approved by our institutional review board. During the period December 1998–December 2005, 70 retrievable expandable nitinol stents were fluoroscopically placed in 35 consecutively enrolled male patients with recurrent benign urethral strictures. Two patients were lost to follow-up immediately after stent removal and were excluded. The final study population included 32 men and one adolescent boy (mean age, 48.6 years; range, 16–73 years) who had undergone placement of a total of 68 stents. Seventeen patients received a single stent; seven patients, two stents; four patients, three stents; three patients, four stents; one patient, six stents; and one patient, seven stents. The causes of stricture included trauma in 31 cases (traffic accident, $n = 10$; fall, $n = 14$; and indwelling Foley catheter, $n = 7$), surgery (prostatectomy for prostate cancer) in one case, and an unknown factor in one case. Before stent placement, all patients had undergone previous treatments that failed, including one or more of visual internal urethrotomy, urethroplasty, and balloon or sound dilation. These patients were referred to the interventional radiology service by the urology service for fluoroscopic stent placement. The stricture site was determined to be in the bulbomembranous region in all but four patients. In those patients, the primary lesion was located in the penile urethra in three cases and in the prostatic urethra in one case. The mean length of the strictures managed with stent placement was 2.69 cm (range, 1–10 cm).

Stent Insertion and Removal

The stent has been described previously [9]. In brief, the stent was developed from a 0.1-mm-diameter nitinol wire filament in a tubular configuration and was covered with either polyurethane (Chronoflex, Cardiotech International) ($n = 25$) or polytetrafluoroethylene (AG Fluoropolymer) ($n = 43$) to prevent mucosal hyperplasia through the stent wires (Fig. 1). The stent also featured drawstrings attached to the lower inner margin, allowing the stent to be easily retrieved with a hook catheter. The stent was 10 mm in diameter when fully expanded and 40–55 mm long. The stent and introducer set were made by a local manufacturer (Taewoong).

Before stent placement, the site, severity, and length of the stricture were evaluated with urethrography and uroflowmetry. Oral prophylactic antibiotic therapy was begun 1 day before the procedure and continued for at least 1 week. With the patient placed in the left anterior oblique position with knees bent, disinfection of the external urethral orifice and anesthesia of the urethra were achieved with 0.05% chlorhexidine and 10 mL of lubricating jelly containing 2% lidocaine. Retrograde urethrography was performed with fluoroscopic guidance with the sites of the stricture and the external sphincter marked on the patient's skin with radiopaque markers. The skin markings were made to estimate the stricture length and its location in relation to the external sphincter.

A 0.035-inch guidewire (Radifocus M, Terumo) was inserted through the urethra across the stricture into the urinary bladder under fluoroscopic guidance. The stent was placed through a straight 5-French graduated sizing catheter (Cook) to the proximal part of the stricture to measure the length of the stricture. A 9-French sheath with a dilator was then passed over the guidewire in the urethra and was advanced according to a technique described previously [9]. Retrograde urethrography was performed to verify the position of the stent.

On the basis of our experience of stenting benign strictures of the esophagus [11], it was initially our policy to electively remove the stent after 2 months of placement. However, reports of frequent stricture recurrences in a previous study [9] prompted extension of the duration of stent placement to 4 months. The stent was removed under fluoroscopic guidance with a 9-French retrieval set according to the technique reported previously [9, 10].

Follow-Up and Analysis

In all patients, retrograde urethrography, uroflowmetry, estimation of postvoiding residual urine volume, and urine cultures were performed 1 week after stent insertion and then every 4 weeks until the stent was removed. Follow-up studies with retrograde urethrography were performed 1, 3, and 12 months after removal of the stent to assess recurrence. When the findings on urethrography showed full expansion of the stent, urethroscopy was performed to verify the patency of the stent. Patients were questioned with regard to the frequency and urgency of micturition and level of continence. All patients were contacted by telephone every 6 months until the end of the study.

The rate of clinical success, defined as long-term clinical and radiographic resolution of urethral strictures after stent removal without the need for additional intervention (i.e., balloon dilation, urethrotomy) was assessed. To determine whether duration of stent placement and primary stricture length play a role in the achievement of long-term resolution, we classified the patients into a group with recurrence and one without recurrence. We used the Mann-Whitney U test to compare the groups with regard to mean duration of stent placement and stricture length. Clinical success rates were analyzed according to location of urethral stricture. A two-sided $p < 0.5$ was considered to indicate statistical significance. All statistical analysis was performed with the SPSS program version 11.5.

Results

Stent Placement and Removal

All patients voided well after stent placement. Whereas the mean maximum urine flow rate was 5.0 mL/s (range, 3–7 mL/s) before stent placement, the flow rate 1 week after stent placement was 27.1 mL/s (range, 16–40 mL/s). All patients reported mild urgency and discomfort at the site of stent placement. These problems resolved spontaneously within 1 week after stent placement. Fifteen patients reported minor postmicturition dribbling and nine patients reported difficulty with continence, but spontaneous resolution of these symptoms occurred within 4 weeks of stent placement. Mild hematuria occurred after removal of seven stents, but bleeding resolved spontaneously within 4 hours in these patients.

A total of 68 stents were removed from a total of 33 patients (Table 1). Of the 68 stents placed, only seven stents were electively removed after 2 months, and 20 were removed after 4 months. The other 41 stents were prematurely removed because of complications. The most common complication necessitating premature retrieval was stent migration, occurring in the cases of 23 (33.8%) of 68 stents. In three patients, three stents migrated proximally into the urinary bladder and were removed via cystostomy. Tissue hyperplasia of the urothelial epithelium resulting in luminal narrowing

TABLE 1: Urethral Stent Placement in 33 Patients

Patient No.	Age (y)	Location	Stricture Length (cm)	Total No. of Stents	First Stent			Second Stent			Third Stent			Clinical Success	Follow-Up Period (wk)
					Duration (wk)	Reason for Removal	Recurrence After Removal	Duration (wk)	Reason for Removal	Recurrence After Removal	Duration (wk)	Reason for Removal	Recurrence After Removal		
1	37	Bulbar	3.0	7	1	Stent deformity	Yes	2	Migration	Yes	3	Migration	Yes	Yes	318
2	54	Bulbar	3.0	3	3	Tissue hyperplasia	Yes	9	Routine	Yes	18	Routine	No	Yes	335
3	23	Membranous	2.5	1	8	Routine	No	—	—	—	—	—	—	Yes	374
4	59	Membranous	2.0	2	9	Routine	Yes	20	Routine	No	—	—	—	Yes	343
5	61	Bulbar	2.0	1	8	Tissue hyperplasia	No	—	—	—	—	—	—	Yes	335
6	16	Bulbar	2.0	3[a]	17	Routine	No	16	Routine	No	—	—	—	Yes	297
7	43	Membranous	4.0	1	10	Routine	No	—	—	—	—		—	Yes	257
8	58	Bulbar	1.5	6[a]	8	Routine	Yes	10	Tissue hyperplasia	Yes	8	Tissue hyperplasia	Yes	Yes	194
9	54	Membranous	3.0	2	4	Migration	Yes	10	Routine	Yes	—	—	—	No	233
10	43	Membranous	2.0	1	7	Tissue hyperplasia	Yes	—	—	—	—	—	—	No	241
11	67	Bulbar	2.0	1	9	Routine	Yes	—	—	—	—	—	—	No	235
12	60	Bulbar	1.5	1	17	Routine	No	—	—	—	—	—	—	Yes	214
13	44	Bulbar, membranous	3.0	4	10	Migration	Yes	8	Tissue hyperplasia	Yes	1	Migration	Yes	No	150
14	43	Bulbar	2.0	1	18	Routine	No	—	—	—	—	—	—	Yes	186
15	47	Bulbar	2.5	1	1	Migration	Yes	—	—	—	—	—	—	No	153
16	41	Bulbar, membranous	2.5	3	6	Tissue hyperplasia	Yes	25	Tissue hyperplasia	No	22	Routine	No	Yes	81
17	56	Membranous	3.5	1	9	Tissue hyperplasia	No	—	—	—	—	—	—	No	143
18	33	Bulbar, membranous	3.5	3	7	Migration	Yes	5	Pain	Yes	8	Routine	Yes	No	100
19	41	Bulbar	2.5	1	17	Routine	No	—	—	—	—	—	—	Yes	131
20	63	Membranous	1.5	2[a]	17	Routine	No	—	—	—	—	—	—	Yes	129
21	64	Penile	2.0	1	10	Tissue hyperplasia	Yes	—	—	—	—	—	—	No	125
22	26	Penile	1.0	1	19	Routine	No	—	—	—	—	——	—	Yes	120
23	73	Penile	3.0	2[a]	8	Tissue hyperplasia	No	—	—	—	—	—	—	Yes	132
24	63	Bulbar	2.5	2	1	Migration	Yes	7	Migration	Yes	—	—	—	No	106
25	61	Bulbar	1.0	1	17	Routine	No	—	—	—	—	—	—	Yes	116
26	68	Bulbar	1.0	1	3	Tissue hyperplasia	Yes	—	—	—	—	—	—	No	130
27	34	Bulbar	4.0	4	1	Migration	Yes	5	Migration	Yes	9	Migration	Yes	No	102

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TABLE 1: Urethral Stent Placement in 33 Patients (continued)

Patient No.	Age (y)	Location	Stricture Length (cm)	Total No. of Stents	First Stent			Second Stent			Third Stent			Clinical Success	Follow-Up Period (wk)
					Duration (wk)	Reason for Removal	Recurrence After Removal	Duration (wk)	Reason for Removal	Recurrence After Removal	Duration (wk)	Reason for Removal	Recurrence After Removal		
28	41	Bulbar	4.0	2	7	Migration	Yes	5	Migration	Yes	—	—	—	No	107
29	55	Bulbar, membranous	3.0	1	16	Routine	No	—	—	—	—	—	—	Yes	96
30	49	Bulbar	2.0	2	1	Migration	Yes	3	Migration	Yes	—	—	—	No	96
31	60	Prostatic	2.0	1	1	Migration	Yes	—	—	—	—	—	—	No	98
32	26	Bulbar	1.5	4	4	Migration	Yes	1	Migration	Yes	1	Migration	Yes	No	8
33	40	Bulbar	2.5	1	17	Routine	No	—	—	—	—	—	—	Yes	46

Note—Dash [—] indicates not applicable. Some patients underwent more than three trials of stent placement; the results of trials beyond the third are not included.

[a]More than one coaxial stent placed; duration is longest placement. In patient 8, the fifth and sixth stents were placed coaxially with the fourth stent.

at the proximal or distal ends of the stent or both and concomitant obstructive symptoms were the primary reasons for premature removal of 14 (20.6%) of the 68 stents. Other complications resulting in premature stent removal included stent deformity ($n = 3$) and severe pain ($n = 1$). In three patients (patients 6, 8, and 20 [Table 1]), additional stents were inserted coaxially to overlap one or both ends of the primary stent to stem the growth of hyperplastic tissue (Fig. 2) to allow extension of the duration of stent placement to at least 16 weeks, resulting in long-term resolution of the stricture.

Follow-Up and Analysis

Patients were followed up for a mean of 174 weeks (range, 8.4–374 weeks) after the last stent removal. Clinical success was achieved by 18 (55%) of the 33 patients. Four of the patients had a stent in place for 2 months, and 14 patients had a stent in place for of 4 months (Table 1). The mean duration of stent placement in patients with clinical success (15.8 ± 4.57 weeks; range, 8–22 weeks) was significantly different from that of patients with recurrence (6.46 ± 5.09 weeks; range, 1–11 weeks) ($p < 0.0001$). Only four (20%) of 20 stents in place for 2 months did not result in stricture relapse. All 14 stents in place for at least 4 months resulted in long-term resolution (Fig. 3). One patient underwent six 1- to 3-month stent placements because of stricture relapse and complications necessitating early stent removal. This patient achieved long-standing resolution after placement of a seventh stent for 17 weeks.

The mean stricture length in the patients successfully treated (2.2 ± 0.08 cm) was not statistically significantly different from that of patients who experienced relapse (3.38 ± 2.25 cm) ($p = 0.0715$). With regard to stricture location, 15 (52%) of 29 patients with bulbomembranous strictures and two (67%) of three patients with penile strictures had long-term resolution with stent placement. The one patient with a prostatic stricture also had successful long-term resolution.

Discussion

There is a high predilection for recurrence of urethral strictures with the conventional treatments of endoscopic urethrotomy and dilation. The ideal management of recurrent strictures, therefore, would entail a noninvasive procedure that would result in long-term elimination of the obstruction with minimal complications. The stent would also have to be well tolerated at and around the external sphincter, especially given the resultant complications of incontinence in cases of stent-induced injury to the sphincter [3–6]. The results of this study indicate that placement of a retrievable covered expandable stent may be such an option as long as stent placement of long-term duration (> 4 months) is achieved. We hasten to point out that multiple trials of stent placement do not appear to be additive with regard to treatment; that is, continuous stent placement with a duration of 4 months is not equivalent to four separate trials of stent placement of 1 month. This issue is exemplified by the patient who achieved long-term resolution only after achieving a stent placement duration of 4 months after previously undergoing six separate trials lasting 1–3 months. This finding suggests that long-term urethral stenting achieves stricture resolution in a stricture-remodeling process that if not allowed sufficient time to proceed to completion results in complete stricture relapse to the initial state. For a minority of patients, 2 months of stenting was sufficient. A majority of patients, however, needed at least 4 months of stent placement irrespective of the number of previous trials of stent placement.

A complication of prolonged stent placement is induction of luminal narrowing at the stent ends. Tissue hyperplasia resulting in recurrence of obstructive symptoms was a major complication resulting in premature stent removal and eventual recurrence of the primary stricture. We were able to circumvent this complication in three cases by inserting additional stents at one or both ends of the primary stent, thereby achieving the sufficient duration of stent placement that is essential for long-term resolution. Although addition of multiple stents can induce new sites of tissue hyperplasia, resolution of stent-induced hyperplasia after stent removal, as found in a previous study [12], should not make this a major concern. Moreover, it has been reported that patients who had needed multiple stents for a variety of reasons (i.e., recurrent stricture adjacent to stent, stent migration, underestimation of stricture length, tissue hyperplasia within and at the ends of the stent) achieved the same efficacious and durable results as reported for patients with single stents [13].

We emphasize that the use of covering material and ease of retrievability are important features integral to the effectiveness of a stent. The polyurethane or polytetrafluoroethylene covering material minimizes the risk of tissue ingrowth through the stent lumen. In comparison, the widely used bare

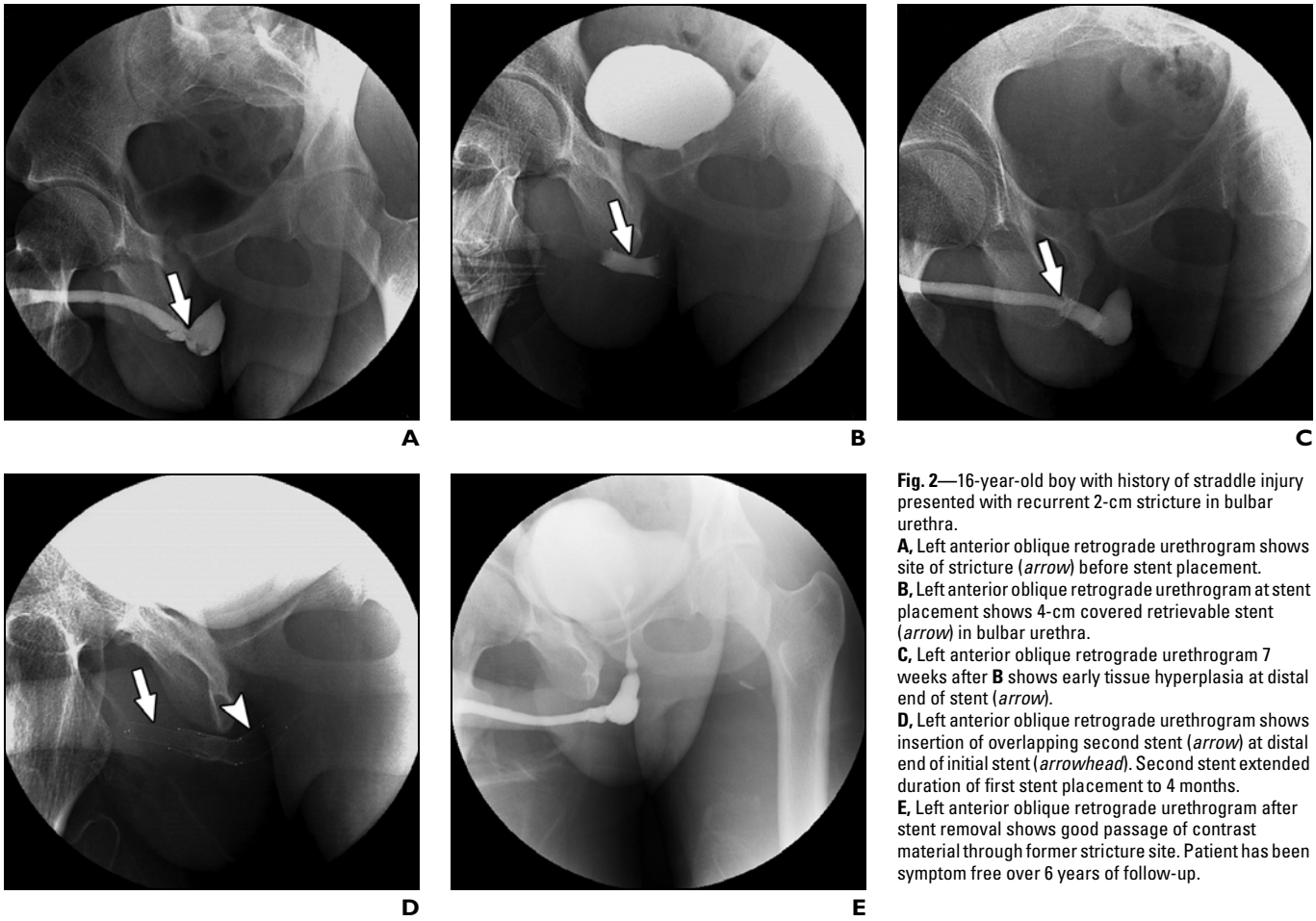

Fig. 2—16-year-old boy with history of straddle injury presented with recurrent 2-cm stricture in bulbar urethra.
A, Left anterior oblique retrograde urethrogram shows site of stricture (*arrow*) before stent placement.
B, Left anterior oblique retrograde urethrogram at stent placement shows 4-cm covered retrievable stent (*arrow*) in bulbar urethra.
C, Left anterior oblique retrograde urethrogram 7 weeks after **B** shows early tissue hyperplasia at distal end of stent (*arrow*).
D, Left anterior oblique retrograde urethrogram shows insertion of overlapping second stent (*arrow*) at distal end of initial stent (*arrowhead*). Second stent extended duration of first stent placement to 4 months.
E, Left anterior oblique retrograde urethrogram after stent removal shows good passage of contrast material through former stricture site. Patient has been symptom free over 6 years of follow-up.

UroLume stent is prone to ingrowth of tissue hyperplasia through the stent wiring, necessitating surgical intervention for removal. With the retrievable feature of our stent, we can insert a stent temporarily throughout stricture remodeling, after which the stent is removed before the occurrence of further complications (e.g., tissue hyperplasia at the stent ends). As an alternative, we can aggressively insert multiple stents to thwart hyperplastic tissue growth and then subsequently remove all stents after an optimal duration of stent placement is attained. Drug-eluting stents are under investigation to reduce tissue hyperplasia associated with stent placement and may soon obviate use of multiple stents [14]. In patients in whom stent placement is not well-tolerated, radionuclide-filled balloon dilation has been used with success in preliminary studies [15, 16].

The most common complication necessitating premature stent removal is stent migration, a known problem associated with covered stents. We have routinely used stents 10 mm in diameter. The optimal stent diameter, however, is undetermined. Using stents of a wider diameter in patients with problems with migration may help anchor the stent, and we are exploring this strategy.

An important additional advantage of the stent used in this study is preservation of external sphincter function after stent removal. Although the stent achieves sufficient radial force to dilate the stricture, its soft and flexible characteristics minimize the risk of permanent damage to the external sphincter. As a result, despite initial difficulties with continence in association with stent placement, complete resolution eventually occurred in all patients. Therefore, we propose an expansion of the indications for stent placement to include stricture near the external sphincter.

Despite a limited number of patients with penile strictures treated with stent placement, our findings suggest a potential role for use of stents in this highly mobile part of the urethra that has been conventionally treated with progressive dilations or optical urethrotomy [7]. None of the patients with penile strictures reported interference with erections or sexual activity.

Our long-term results indicate that temporary stent placement should be considered the treatment of choice in cases of recurrent urethral stricture. We have used stent placement only in patients who have undergone at least one unsuccessful trial of conventional treatment, including visualized internal urethrotomy and urethroplasty. Further investigation should involve an examination of the efficacy of stent placement as the first-line treatment of patients with urethral strictures.

Temporary placement of a covered retrievable stent for an extended duration is effective in inducing long-term resolution of refractory urethral strictures. The stent is well-tolerated in the bulbomembranous urethra, including the region surrounding the external sphincter, with minimal long-term complications. Stent migration, however, remains the largest obstacle to achieving the adequate duration of

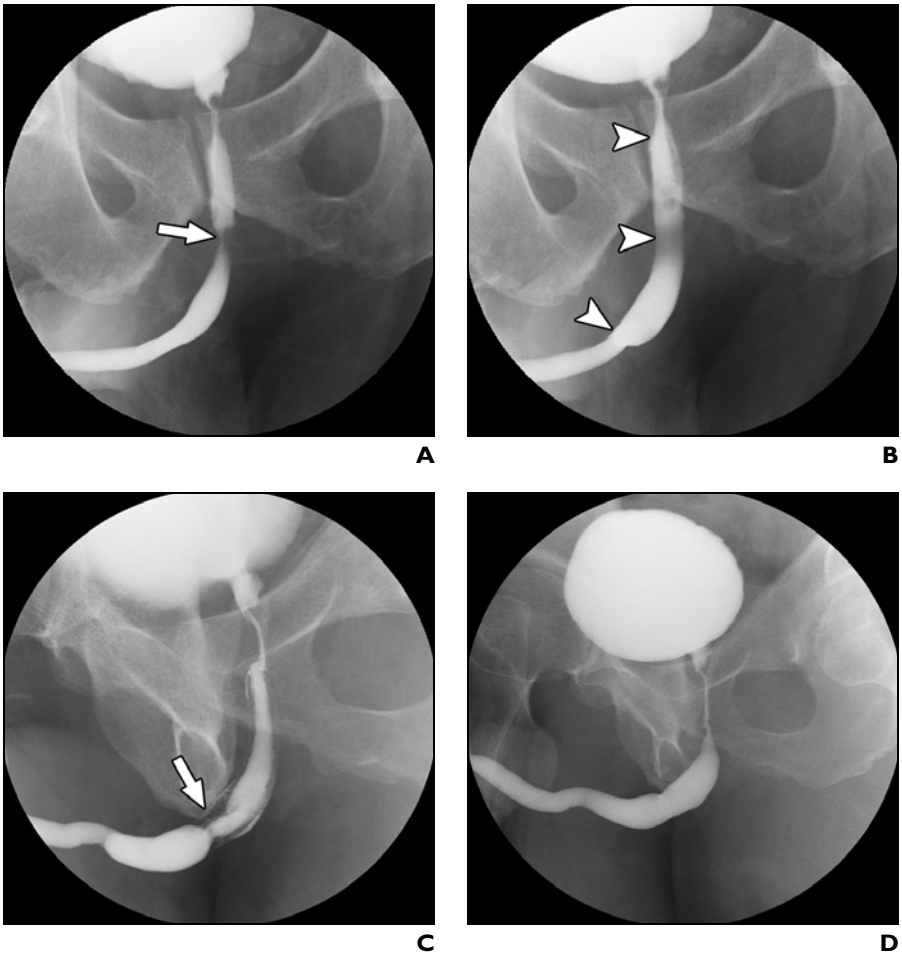

Fig. 3—60-year-old man with history of traumatic stricture of bulbar urethra underwent stent placement after three failed trials of optical urethrotomy.
A, Left anterior oblique retrograde urethrogram shows site of bulbar stricture (*arrow*) before stent placement.
B, Left anterior oblique retrograde urethrogram shows 5-cm-long covered retrievable stent (*arrowheads*) traversing external sphincter.
C, Left anterior oblique retrograde urethrogram 4 months after stent placement shows maintained patency of stent despite tissue overgrowth at distal stent end (*arrow*).
D, Left anterior oblique retrograde urethrogram obtained 3 years after **C** shows well-maintained patency at former stricture site. Patient has not had relapse after 4 years of follow-up.

stent placement critical for achieving long-term resolution.

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