# Management of Recurrant Bulbar Urethral Stricture – A 54 Patients Study With Allium Bulbar Urethral Stent (BUS)

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## Abstract

*Introduction and hypothesis*: The Allium Bulbar Urethral Stent (BUS) is a fully covered, self expendable, large caliber metal stent specialy designed for the treatment of bulbar urethra strictures. The stent is intended for a long term use for the purpose of opening the occluded urethral passage and to allow spontaneous urination. This study objective was to evaluate the clinical efficay of temporary placement of the Allium BUS stent.

*Patients and Methods:* This was a prospective study in 54 men with recurrent benign urethral stricture conducted between 2009 to 2012. All men underwent an internal uretrotomy or dialatation porcedure followed by an endoscopic stent placement.

*Results:* Clinical success was achieved in 44 (81.4%) of the 54 patients. No patient reported discomfort at the stent site. 2 stents migrated distally. 1 stent was occluded. All stents were removed in a mean time of 8.8 months (range 3-18 months) following implantation.

Conclusions: This experience with the Allium BUS for treating urethral strictures suggests that it is safe and reliable treatment modality..

## Introduction

Benign urethral stricture is relatively common and management remains a therapeutic challange despite recent developments in endoscopic and reconstructive surgery. Most strictures are acquired from an injury or an infection. Blunt perineal trauma causes injury to the bulbar urethra, pelvic fractures result in urethral distraction defects in the posterior urethra, but iatrojenic causes including urologic instrumentation, and placing indwelling catheter, which results in strictures anywhere in the urethra are probably the most common cause(1).

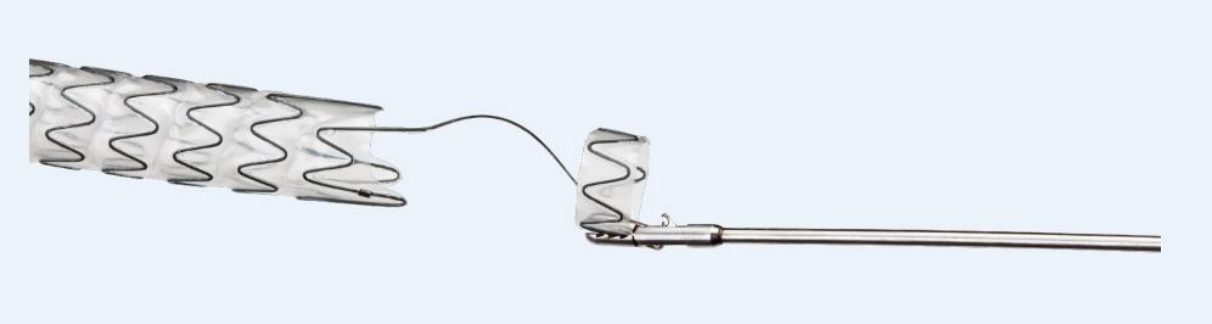
Endoscopic urethrotomy is the most performed procedure for the treatment of benign urethral stricture and has a 40-70 % reccurence rate within two years(2,3). The urethral stent was first introduced in 1988 for the treatment of recurrant urethral stricture and at that time was indicated for bulbar urethral strictures only(4). Since 1990 a lot of reports have been published regarding the efficcacy of urethral stents. However, these devices have a reported long-term efficacy of 63% in patients with recurrent urethral strictures. Retrieval stents designed for temporary placement only and several types of temporarily placed stents have been also introduced(5,6).

## Material and Methods

During the period between 2009 to 2012, 57 Allium bulbar urethral stents were endoscopically placed in 54 patients (mean age 42, range 20-64) with recurrent benign urethral strictures. Internal uretrotomy was performed prior to stent placement. All patients provided informed consent form and underwent urethral stent placement. 3 stents were

replaced because of premature migration in two and severe obstruction in one. Stricture length was documented, as well as stricture etiology and prior stricture treatment.
All 54 patients were evaluated with retrograd urethrogram and uroflowmetry. Residuel urine volume was estimated with ultrasonography. Patients who had strictures in other parts of the urethra were not included in our study, they were treated with alternative procedures.

The Allium Bulbar Urethral Stent, BUS, (Allium, Allium LTD, Caesarea, Israel) is fully covered; self expendable, large caliber metal stent specially designed for the treatment of bulbar urethra strictures. The stent is comprised of a coiled super-elastic structure covered by a polymeric coating designed to prevent mucosal hyperplasia through the stent wires and into the lumen as well as reduce encrustation, stone formation and calcification. Once inserted into the urethra with the aid of its special inserter, the stent is released to allow its self-expansion. The BUS high radial force along the stent body and soft sphincteric ends were specially designed to fit and adapt to the shape and dimensions of the normal bulbar urethra. A special unraveling feature allows stent retrieval by unraveling it into a thread-like strip and enabling a non-traumatic removal.
1.



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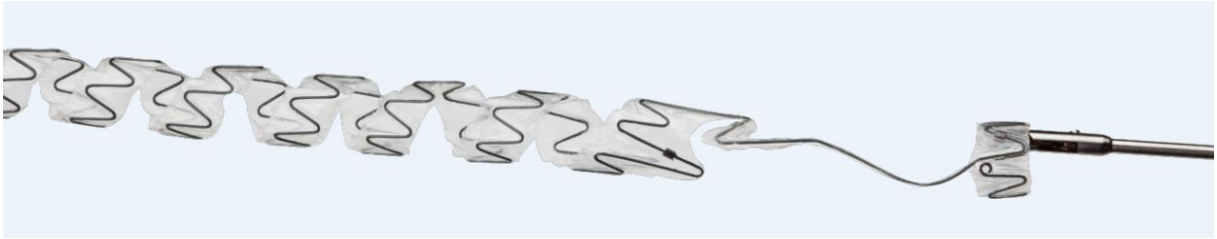

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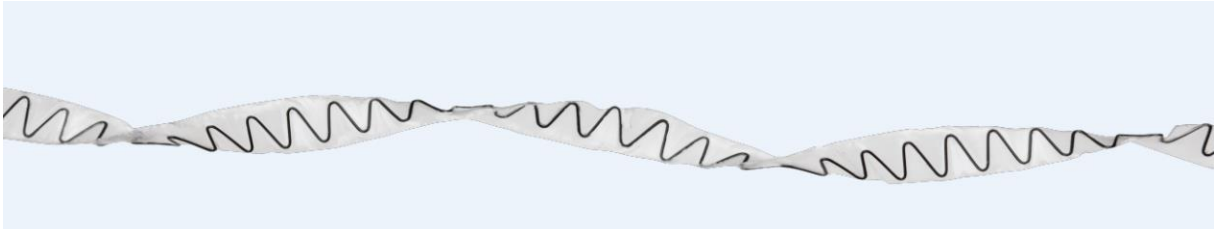
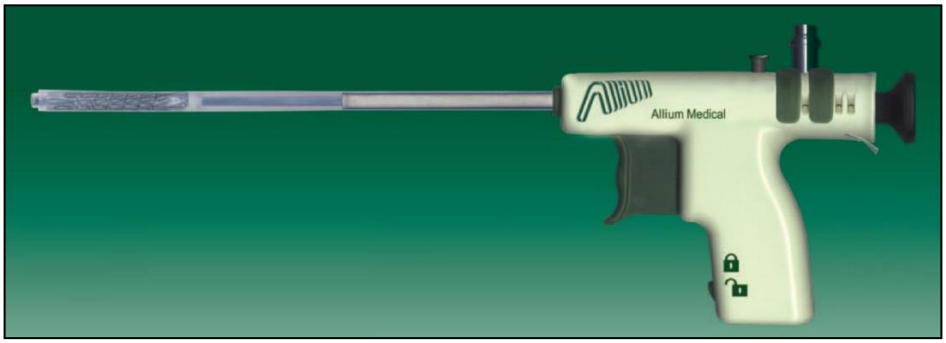


Stent insertion was done using a gun-like delivery system on which the stent in mounted and is deployed gradually. The patients were placed in lithotomy position under general anesthesia, internal urethrotomy was first performed and after measuring the length of the stricture, the stent was placed endoscopically, under vision, just beneath the external syphincter.




The clinical success rate was related to the stent indwelling period. The stents remained in the body for as long as possible with the longest indwelling period being 18 months. Progressive decreasing of urinary peak flow rate during this time period, recurrant urinary infection and stent migration were the removal criteria. The cause for early stent removal in the period of 3 to11months after implantation was migration in 6, chronic urinary infection in 4 and progressive decreasing of urinary peak flow rate in 3 patients.
The success criteria after stent removal were no evidence of stricture on urethrogram or endoscopy, urinary peak flow greater than 15ml/sec. and no recurrent urinary tract infection. Median follow-up was 8.3 months (4 to 19) after the last stent removal.
We also investigated the correlation between the success rate of stent indwelling period and stricture length. We used Mann-Whitney U test to compare the groups. A two-sided $p< 0,5$ was considered to indicate statistical significance.

**Results:**
During the period between 2009 to 2012, 54 patients were enrolled, 57 stents were placed.
The causes of the stricture included trauma in 39 patients, surgery in 12 patients, infection in 1 and unknown cuases in 2 cases. Before stent placement, all patients underwent more than one internal urethrotomy or dilatation procedure. The mean length of the stricture was 2.44 cm (range 1.1 to 4.3). All stents were inserted succesfully and positioned correctly just beneath the external sphincter. No adverse events related to the stent or the procedure were recorded.
No patient reported discomfort at the site of the stent. 3 patients complained of mild urinary stress incontinence but the problem resolved within one week. All patients reported good urinary flow after stent placement. Whereas the mean maximum urine flow rate was 4,3 ml/sec before the procedure, the mean flow rate five days after the stent placement was 20ml/sec.
Stents were removed 3 to 18 months after implantation (mean 8.8 months). Stent removal was easy, without anesthesia, and the duration of the removal procedure was short. There was no post procedure complication. Median follow-up time after the removal of the stent was 8.3 months (range 4 to19).

2 stents migrated distally, one and three weeks after placement. Severe obstruction was obserbed in one stent after four weeks of implantation.We replaced these three stents immediately after removal of the previous ones.

The indwelling period of the stent was statistically related with clinical success. Clinical success was achieved in 44 (81.4%) of the 54 patients. Clinical success was determined as 14/22 (63.6%) with the mean duration time of 4.8 months (ranged 3 to 8). After longer

duration mean 10.6 months ranged (9 to18), estimated success rate was 30/32(93%) and, p< 0.001.

| Length of stricture | 1-2cm | 2-3cm | 3-4cm | 4cm> |
|---|---|---|---|---|
| # of patients | 39 | 8 | 5 | 2 |
| % of patients | 72 | 15 | 9 | 4 |

| # of previous surgeries | 1 | 2 | 3 | 3> |
|---|---|---|---|---|
| # of Patients | 6 | 17 | 11 | 20 |
| % of Patients | 11 | 32 | 20 | 37 |

Clinical success was also related with the length of the stricture. The stricture length was measured 2cm< in 39 patients and clinical success was 35/39 (89.7%) in these patients. The estimated clinical success was 9/15(60%) in the other group with longer stricture (more than 2 cm) and p value was < 0.001.

**Discussion**

When urethral stents were first introduced for the management of recurrent urethral strictures, results suggested excellent outcomes (2,7). The procedure was considered as an option for minimally invasive treatment. However, longer follow-up period began to cast doubt on the usefulness of urethral stenting as a primary treatment modality particularly for urethral strictures (8,9). High rates of recurrent urethral strictures of up to 45% was observed in the follow-up period (8,10). In our study, mean follow-up period was 8.8 months and and the recurrence rate was 18.6%.

This is the first formal report about the use of this new Allium BUS stent. After longer follow-up period we will also be able to compare long term results. Previously several stents were used for the management of urethral strictures. Urolume (by American Medical Systems) was first introduced in 1988. Despite promising early results with the use of this self-expanding stent, long-term results were discoureging. The complication rates reported as high as 55% and most of these complications stemming from stent obstruction secondary to the tissue hyperplasia (8,11,12,13). These stents lack any coating or full cover, they incorporate into the urethra wall, allow tissue ingrowth which contributes to a very problematic removal at a later stage. Because it is a permanent stent, it must be removed surgically if complication necessiate removal(14). The Allium stent that was used in our study has full polymeric cover to prevent mucosal hyperplasia. It is designed for temporary use and can be removed easily even after several months of implantation. The stent dilated the strictures to the full extent of stent diameter. The Allium BUS stent has an expansile force until it reaches its preset expanded diameter. Several types of temporarily stents have been introduced up to now including fully and non-covered stents all indicating what was describe above (3,5,6). The other point we are making in our study that stent indwelling period is statistically related with clinical success. Choi and coworkers reported similar result with the use of retrievable expandable nitinol urethral stent. Majority of the patients in their study needed at least 4 months of stent implantation for achieving successsful clinical result(5). If

one reviewes the literature critically and focuses on which reports demonstrate good results using urethral stents, it become obvious that primarily short strictures(less than 3cm) have been treated successfully(12). We have also similar results. Clinical success was statistically significant with the patients who have strictures less than 2 cm in our study. However, Choi and coworkers reported that the mean stricture length in the patients successfully treated in their study (2.2±0,08) was not statistically significantly different from that of patients who experienced relapse (3.38±2.25cm)(p=0.0715)(5). The most common complication necessiating premature stent removal was stent migration in our study. Stents of 6 patients were removed before 12 months because of migration and early stent migration was also observed in our two patients a few weeks after implantation and replaced with new ones immediately. Choi and coworkers also agreed that stent migration is a known problem associated with covered stents(5)

Stent encrustation, chronic urinary infection, urethral pain and restonosis are the other complications of stent placement in the longer follow-up period (8,14). Decrease of urinary peak flow rate due to stent encrustation and chronic urinary infection were the reasons for stent removal in three and four patients respectively before 12 months in our study. Restenosis was also determined in 10 patients after the stent removal. Some authors also declared that the bulbar urethra has uniform radial forces leading to better stent fixation and epithelization and stents have been recommended only for bulbar urethral structures because its tissue has a rich spongiofibrous structure that make it less susceptible to erosion than other parts of the urethra(15). All stents in our study were also placed in bulbar urethra. We observed 14.8% migration rate. The device benefits the majority of our patients besides those with most common complications. When removal is required it can be easily done within a few minutes and no complication was observed.

**Conclusion:**

The main indication for Allium Bulbar Urethral Stent (BUS) is for the management of Bladder Outlet Obstruction (BOO) caused by bulbar urethral strictures and to avoid restenosis after direct visual internal urethrotomy for urethral stricture. The nature of biomaterials allows a 12 months indwelling period, flexibility of the metal alloy provides a good compromise between required radial force and patient tolerance, non-incorporation in the urethral wall, lack of overlay or encrustation and ease of removal make it an excellent solution for the treatment of bulbar strictures. Temporary placement of Allium covered stent for an extended duration is effective in inducing resolution of refractory urethral strictures according to this study results. A more extensive experience is necessary with a larger number of patients and a longer follow-up period to further confirm stents' efficacy.

Urethral stenting is a minimally invasive procedure that benefits some patients. Technology also brings us new devices. Certainly more experience with new stents with new technologies is needed before treatment of bulbar urethral strictures with stenting is advocated.

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