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# Allium™ Bulbar Urethral Stent: An Updated Long-Term Multi-Center Study with New Treatment Modality for Bulbar Urethral Stricture

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## Abstract

***Objectives*: To report the 2-years follow-up of patients with bulbar urethral strictures treated with the new Allium™ Bulbar Urethral Stent (Allium BUS). *Methods*: The stent is a fully covered, self-expendable, large caliber metal stent specially designed for the treatment of bulbar urethral strictures. The stent is comprised of a coiled super-elastic structure covered by a polymeric coating designed to prevent mucosal hyperplasia. The indwelling time is 12 months, after which the stent should have been removed. Sixty-four patients with recurrent bulbar stricture were treated with Allium BUS in 3 worldwide centers. *Results*: All stents were successfully inserted with no peri-operative complications. In a median follow-up of 25.5 months, the mean maximal flow rate following stent insertion was significantly higher compared to the pre-surgical flow rate (14 ml/sec vs 6.6 ml/sec, $p < 0.0001$). Longer indwelling time and shorter stricture length were significantly related to success rate. The main complications were stent migration, stent re-stenosis and urinary tract infections. *Conclusions*: The temporary placement of the Allium™ BUS showed encouraging results with long-term failure rate of only 25%.**

## Keywords

**Allium BUS, Bulbar Stricture, Urethral Stent, Urethral Stricture, Urethroplasty**

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## 1. Introduction

Urethral stricture is a relatively common disease in men with a rate of as high as 0.6% in some populations [1]. The leading causes are urethral injury and infections. Iatrogenic etiology accounts for more than 45% of stricture cases, especially in patients older than 45 years old. Iatrogenic causes include transurethral resection (TUR), cystoscopy, brachytherapy, hypospadias surgery and urethral catheterization. Of all urethral strictures, bulbar stricture is the most common type accounting for almost half of the cases. The most common etiologies underlying bulbar strictures are idiopathic, iatrogenic, post-infections and traumatic [2]. Treatment options for bulbar urethral stricture include urethral dilation, endoscopic urethrotomy, urethral stents and urethroplasty.

Endoscopic internal urethrotomy is the most common surgery performed for treating bulbar urethral stricture. However, it carries a recurrence rate of 40% - 70%. Most of the failures of internal urethrotomy occur in the first year. Patients who undergo three or more internal urethrotomies have a likelihood of 0% of being stricture-free in 2 years [3].

Urethroplasty is considered as the gold-standard treatment for urethral strictures, but requires surgical experience and adequate operating room facilities [4]. Moreover, its complications rate varies from 9.1% for anastomotic urethral reconstruction and up to 40% in substitution urethral reconstruction [5].

Urethral stents were first introduced in the late 1980s, and since then various reports for various stent types have been published. The first introduced stent was a permanent urethral stent for the treatment of bulbar stricture [6]. This stent had major disadvantages; one of these was the fact that it was permanent.

Conceptually, temporary urethral stenting following urethral dilation or internal urethrotomy could maintain urethral patency and decrease stricture recurrence, and all this without the need for permanent implantation.

In the current study, we present the results of long-term follow-up of patients treated with Allium™ Bulbar Urethral Stricture (Allium BUS) stent.

## 2. Methods

### 2.1. Stent

The Allium Bulbar Urethral Stent (Allium BUS) (Allium LTD, Caesarea, Israel) is a fully covered, self-expendable, large caliber metal stent specially designed for the treatment of bulbar urethral strictures.

The stent is comprised of a coiled, super-elastic structure covered by a polymeric coating designed to prevent mucosal hyperplasia as well as to reduce encrustation, stone formation and calcification.

The main body (**Figure 1(B)**) acts as a mold to allow forming a large urethral lumen. The dynamic sphincteric segment (**Figure 1(A)**) prevents sphincteric dysfunction that may cause incontinence. The last portion of the stent is its soft distal segment (**Figure 1(C)**). The Allium BUS is intended for temporary use and is designed to be removed easily and safely even after long indwelling periods. The stent is available in 3 different lengths: 50 mm, 55 mm, and 60 mm, all of which have a 45Fr caliber.

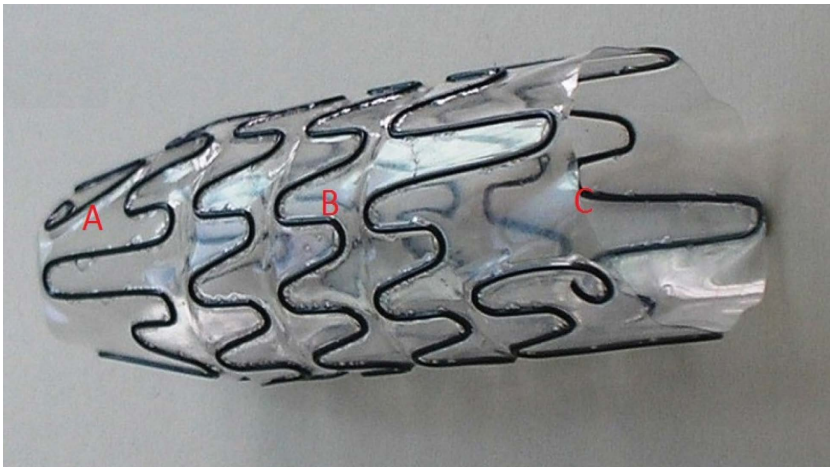


**Figure 1.** Allium bulbar urethral stent. (A) Soft sphencteric segment; (B) high radial force body; (C) soft distal segment.

Stent insertion was done using a 24Fr gun-like delivery system on which the stent is mounted and is deployed gradually. Pre-operative antibiotics were given routinely and were continued for 3 - 5 days following insertion for patients with pre-operative negative urine culture. Patients who had asymptomatic bacteriuria were treated for longer duration. Patients were placed in lithotomy position under general or regional anesthesia. Internal urethrotomy was first performed using a cold knife. The length of the stricture was then measured and the stent placed endoscopically, under direct vision, just beneath the external sphincter. After proper allocation, the stent was released allowing its self-expansion. Mean operation time was 46.4 minutes (range 20 - 70, median 45.5). It should be emphasized that these are the first patients to undergo this procedure and thus a learning curve exists.

The Allium 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 (**Figure 2**). Stent removal procedures were done under local anesthesia or general anesthesia if the patient demanded.

## 2.2. Patients

Between 2009 and 2012, 64 patients with recurrent bulbar stricture were treated with Allium$^{TM}$ BUS in the following centers: Kocaeli University in Turkey, Haseki Research and Training Hospital in Turkey and Bnai-Zion Medical Center in Israel. The inclusion criteria included patients ≥ 18 years old with bulbar urethral stricture who failed on at least one trivial treatment. Patients who had non-bulbar urethral strictures were excluded.

We planned a 12-months indwelling time for each inserted stent, after which patients were invited to remove the stent. In some patients the stent was removed prior to the planned 12-months indwelling time mainly because of progressive decrease in urinary flow, recurrent urinary tract infections or migration of the stent.

We evaluated several parameters including age, etiology of the stricture, the length of the stricture, post-void residual volume estimated by ultrasonography, uroflowmetry providing mean and peak flow, and voiding cystourethrography (VCUG). All patients had pre-surgical uroflowmetry and a diagnostic VCUG or endoscopy.

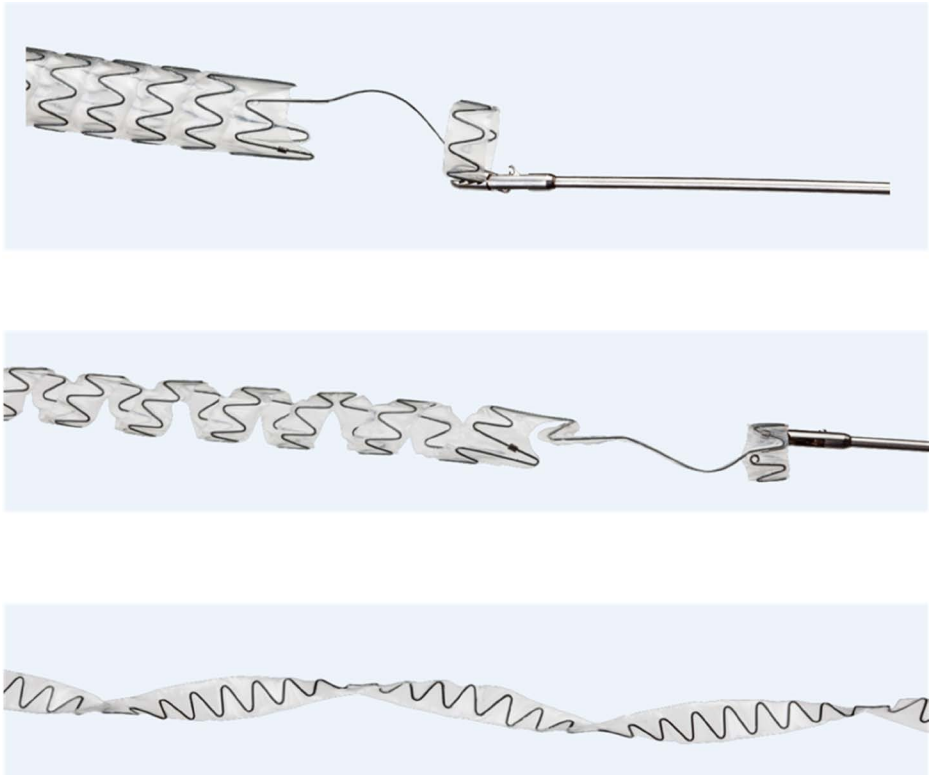

**Figure 2.** A special unraveling feature allows stent retrieval by unraveling it into a thread-like strip.

Follow-up evaluation included PVR and uroflowmetry starting one week after surgery and on each visit thereafter (3-months interval) until last follow-up. VCUG was donethree months after the removal of the stent. Patients who had abnormal VCUG were evaluated with urethroscopy. Assessing stent-related symptoms was done following surgery and on each visit by asking the patients.

The success criteria were defined as both of the following: 1) no evidence of stricture by endoscopy or VCUG and 2) significant increase in peak urinary flow compared to pre-operative value.

All patients provided informed consent form after detailed explanation of the procedure. The study was approved by each institutional review board.

## 3. Statistical Analysis

Student t-test was used to compare the post-surgical to the pre-surgical continuous variables. Mann-Whitney U test was used to analyze the categorical parameters. A two-sided $p < 0.05$ was considered as statistically significant. Statistical analysis was done using MedCalc v 13.

## 4. Results

Sixty-four patients were treated by endoscopic insertion of Allium$^{TM}$ BUS after urethroscopy and internal urethrotomy. Three patients were treated with 2 consecutive stents due to long stricture. The median age of patients was 45 (mean 43, range 20 - 68) years. All patients had a history of more than one internal urethrotomy or dilation procedure. The etiologies of strictures included trauma in 45 patients, surgery in 15 patients, idiopathic in three patients and recurrent infections in one patient.

The median length of the stricture was 20 (mean 22, range 10 - 52) mm. All stents were successfully inserted and positioned just anterior to the verumontanum. There were no complications during any of the surgeries.

Median pre-surgical peak urinary flow rate was 7 (mean 6.6, range 2 - 12) ml/sec. Median pre-surgical post-void urine residual was 90 (mean 103, range 25 - 300) ml. Median pre-surgical IPSS score was 20 (mean 20.5, range 14 - 27). Median follow-up was 25.5 (mean 27.5, range 18 - 37) months starting from stent removal. Patients' characteristics are summarized in **Table 1**.

Following stent insertion, none of the patients reported any urethral pain, urethral discomfort, or dysuria. Three patients reported stress urinary incontinence that resolved in all of these patients within one week following the procedure. All patients reported a subjective good urinary flow following the procedure.

The median peak flow rate in the first post-operative week was 14 (mean 14, range 5 - 22) ml/sec. The median peak flow rate on the last follow-up visit was 13 (mean 12.5, range 4 - 20) ml/sec. The median post-surgical post-void urine residual was 40 (mean 50, range 10 - 200) ml. The median post-surgical IPSS score was 8 points (mean 10, range 3 - 25).

There were no peri-operative complications during any of the removal procedures. Stents were scheduled to removal 12 months after insertion. The median time to removal of the stents was 12 (mean 8.8, range 3 - 18) months. Three stents were replaced: one because of distal migration one week after insertion, one because of distal migration three weeks after insertion and one because of severe obstruction four weeks after insertion.

Sixteen patients had undergone early stent removal. The causes for early removal were migration in six patients, progressive decrease in urine flow in six patients and chronic urinary tract infection in four patients. One Stent remained for 18 months because of patient's late presentation.

The overall success rate as defined earlier was achieved in 48 of 64 patients (75%). Mean peak urinary flow was significantly higher in the post-operative period compared to the pre-surgical peak urinary flow (13 vs 6.6 ml/sec, $p < 0.0001$). Mean post-operative PVR was significantly lower than pre-operative PVR (50 vs 103 ml, $p < 0.0001$), as well as mean IPSS (10 vs 20.5, $p < 0.0001$). These results are summarized in **Table 2**.

Most of the patients who had recurrence after stent removal were patients who have gone early stent removal or had a long urethral stricture.

Longer indwelling time and stricture length were significantly related to success rate. Patients who had longer indwelling time (≥9 months) had higher success rate compared to shorter indwelling time (<9 months) (93% vs 51.7%, $p < 0.001$). Patients who had a stricture length <2 cm had higher success rate compared with patients who had a stricture length ≥ 2 cm (84.3% vs 53.1%, $p = 0.005$). Only three patients with indwelling time of >9 months did not improve the flow rate and were considered as a failure.

**Table 1.** Patients' baseline characteristics.

| Parameter | Median | Mean | Range |
|---|---|---|---|
| **Age (years)** | 45 | 43 | 20 - 68 |
| **Stricture length ( mm)** | 20 | 22 | 10 - 52 |
| **Max. flow rate (ml/sec)** | 7 | 6.6 | 2 - 12 |
| **PVR (ml)** | 90 | 103 | 25 - 300 |
| **IPSS (points)** | 20 | 20.5 | 14 - 27 |
| **Post-removal Follow-up (months)** | 25.5 | 27.5 | 18 - 37 |

**Table 2.** Post-surgical vs. pre-surgical parameters.

| Feature | Pre-surgical | Post-surgical | p value |
|---|---|---|---|
| **Max. flow rate (ml/sec)** | 6.6 | 13 | <0.0001 |
| **PVR (ml)** | 103 | 50 | <0.0001 |
| **IPSS (points)** | 20.5 | 10 | <0.0001 |

Numbers are in mean.

## 5. Discussion

This is the largest worldwide report about the use of the new Allium™ BUS stent. It is an update of a previously published study about the use of Allium BUS [7]. When urethral stents were introduced in 1988, the concept was based on a permanent large-caliber urethral stent, an idea derived from vascular surgeries [6]. The idea of temporary large self-expanding stent was introduced several years after with the concept of sufficient time for stricture treatment and urethral healing and easily removal after 10 - 12 months [8]. When first introduced, results suggested excellent outcomes for the treatment of bulbar urethral stricture [6]. However, long-term follow-up showed a recurrence rate of up to 45% [9]. In our study, we had a median follow-up of 25.5 months with failure rate of 25%. However, only 3 patients with indwelling stent time >9 months were considered as a failure. All other failures were patients with significant shorter indwelling time.

Several previous stents were introduced, the first of which was the Urolume™—the first reported permanent stent—which had a promising short-term results, but discouraging long-term results, mainly because of as high as 55% complication rate, with stent obstruction due to tissue hyperplasia being the most prevalent complication. This stent had two main problems: the first is the lack of any covering which makes it incorporate into the urethral wall allowing tissue in growth and secondary obstruction, and the second problem is the need for complicated surgery if a removal is desired or required.

The Allium BUS has a full polymeric cover, which prevents epithelial hyperplasia. Moreover, its removal is an easy procedure, even after long-term use.

Our study showed that shorter strictures had better chances of being cured using urethral stents. This fact was also shown in previous studies [10], although others reported conflicted data [11]. This fact could help in selecting the proper candidates for the treatment with Allium BUS stent.

Another important finding was the relation between indwelling time and failure rate. We showed that the longer the indwelling time, the higher chance of being stricture-free. Choi *et al*. showed similar results with the use of retrievable, expandable nitinol urethral stent [11]. Thus, the most important pitfall in the use of urethral stents is the complications that necessitate early stent removal. The most common complication requiring removal was stent migration, which occurred in 9%, of them two patients had their stents replaced because of early migration. Other complications include chronic or recurrent urinary tract infections, urethral pain and obstruction.

It should be emphasized that urethral stents are not intended to replace surgical urethroplasty when feasible. Urethroplasty is still considered the gold standard for the treatment of urethral strictures, so patients who can be treated with urethroplasty should be referred to it, with optimal results achieved by experienced surgeons.

The main limitation of our study was the relatively small number of patients. We are still following-up pa-

tients and recruiting other patients so we could report the results with larger number of patients. A large prospective studies should be conducted to further test our results.

## 6. Conclusion

Allium™ BUS is a feasible and safe urethral stent for the treatment of recurrent urethral stricture. Our long-term results showed an acceptable failure rate of 25%.

## Acknowledgements

None.

## Declaration of Conflicting Interests

The authors declare no conflict of interest.

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