



# Outcomes of drug-coated balloon urethral dilation in patients with stricture recurrence after urethroplasty

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**Background:** Stricture recurrence after urethroplasty can be challenging to manage. Endoscopic intervention has been used with low success within this population. Optilume is a paclitaxel coated balloon dilator that has demonstrated high urethral patency rates and low risk of adverse events in patients with recurrent anterior urethral strictures when compared to endoscopic intervention. The objective of this study was to evaluate the utility of Optilume for treatment of stricture recurrence after urethroplasty.

**Methods:** We performed a retrospective cohort study of patients who underwent paclitaxel drug-coated balloon (DCB) dilation for urethral stricture recurrences after urethroplasty at two institutions between June 2022 and September 2024. Baseline patient characteristics were recorded including age, stricture etiology, and prior repair. The primary outcome was freedom from any repeat intervention.

**Results:** Of the 146 men who underwent DCB dilation at our institutions, 19 had stricture recurrence after urethroplasty and were included in our analysis. The mean age was 55 years (standard deviation, 18 years; range, 34–82 years). Idiopathic strictures were most predominant (42%), followed by iatrogenic (21%), lichen sclerosis associated (16%), radiation induced (11%), and trauma induced (11%). Stricture locations were bulbar (47%), penile (32%), membranous (16%), and prostatic (5%). Prior urethroplasties were: 9 buccal mucosal graft (BMG) augmentation, 7 excision and primary anastomosis (EPA), 1 scrotal skin graft, 1 prior hypospadias repair and 1 rectourethral fistula repair with EPA and gracilis flap interposition. Sixty-three percent of patients underwent endoscopic intervention prior to DCB dilation. Average time from urethroplasty to DCB dilation was 43±42 months. The median follow-up was 228 days with interquartile range of 182 to 369 days. Two patients with idiopathic and iatrogenic bulbar strictures, previously treated with BMG and EPA respectively, had recurrence after Optilume and opted for repeat DCB dilation. Average time between DCB treatments was 464 days in these two patients. DCB dilation resulted in a freedom from reintervention rate of 89% in our cohort.

**Conclusions:** DCB dilation was effective for treatment of urethral stricture recurrence after urethroplasty at a median follow-up of 228 days in our cohort. This minimally invasive intervention may be an option for patients who are not ideal surgical candidates or refuse repeat urethroplasty. Data on longer-term outcomes in this cohort is needed and is forthcoming.

**Keywords:** Optilume; stricture recurrence; urethroplasty failure

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## Introduction

Urethroplasty is the definitive gold standard surgical treatment for management of urethral stricture disease. The success rates of urethroplasty range from 80% to 90% depending on the complexity of the stricture and technique used for repair, whereas endoscopic intervention has a failure rate greater than 50% at 1 year (1-3). Despite this, stricture recurrence after urethroplasty can occur in up to 20% of patients leading to significant morbidity and a decrease in quality of life for patients and family members (4).

Endoscopic management with urethral dilation or direct vision internal urethrotomy (DVIU) is the most common intervention for stricture recurrence after urethroplasty, however reported success rates in literature vary widely from 10–70% with failure rates in this cohort often two times higher when compared to those without a history of urethroplasty (5-9).

Optilume is a drug-coated balloon (DCB), which has been approved by the Food and Drug Administration for the management of urethral stricture disease (10). The balloon works by radial force dilation of the stricture area with simultaneous circumferential delivery of paclitaxel—an anti-fibrotic agent, that is most widely used in vascular surgery to prevent restenosis of endovascular stents (11). The Re-Establishing Flow Via Drug Coated Balloon For The Treatment Of Urethral Stricture Disease (ROBUST) trials have shown the efficacy of Optilume DCB dilation in the treatment of recurrent anterior urethral strictures (12-15). The ROBUST III trial demonstrated that, when compared to standard endoscopic dilation, Optilume had a

higher freedom from reintervention rate at 2 years (77.8%) than standard dilation (23.6%). The American Urological Association and European Urology Guidelines endorse the use of DCB dilation in patients with bulbar urethral strictures less than 3 centimeters (cm) who have failed prior endoscopic management and for whom urethroplasty is not an option. Current areas of further investigation for DCB dilation include its utility in posterior urethral stricture disease, bladder neck contractures, and post-urethroplasty stricture recurrence (16).

Our study reports on the efficacy and utility of Optilume in patients with recurrent strictures after urethroplasty by drawing upon our experiences at two high volume tertiary care centers as well as the current reported outcomes in the literature. We present this article in accordance with the STROBE reporting checklist (available at <https://tau.amegroups.com/article/view/10.21037/tau-2025-49/rc>).

## Methods

### Study design

After institutional review board approval, we performed a retrospective cohort study of patients who underwent Optilume DCB urethral dilation for urethral stricture recurrence after urethroplasty at our respective institutions from June 2022 to September 2024.

Baseline patient characteristics were recorded including age, stricture etiology, prior urethroplasty, and current form of bladder management. All patients who were candidates for urethroplasty were offered urethroplasty. DCB dilation was offered to patients who were not urethroplasty candidates based on the judgement of the primary surgeon, who had a failed urethroplasty repair, or did not want to undergo repeat urethroplasty. In general, all patients who had unifocal strictures, regardless of location, were offered DCB dilation.

Informed consent, with patient understanding that guidelines may recommend repeat urethroplasty, was obtained for Optilume DCB for the management of their urethral stricture disease. As per manufacturer guidelines, patients were counseled to wear a condom for sexual intercourse for 30 days after procedure and to utilize contraceptive for at least 6 months post procedure due to the possible teratogenic effects of paclitaxel (12).

### Data collection and endpoints

All patients had a retrograde urethrogram in the operative

### Highlight box

#### Key findings

- At a median follow-up of 228 days, 89% of patient treated with Optilume drug-coated balloon dilation (DCB) for urethral stricture recurrence after prior urethroplasty were free from any repeat interventions.

#### What is known and what is new?

- The ROBUST trials have shown superior outcomes of Optilume DCB in the management of recurrent anterior urethral strictures when compared to standard endoscopic intervention.
- Optilume is safe and efficacious in the management of urethral stricture recurrence after urethroplasty.

#### What is the implication, and what should change now?

- Based on our findings, studies with larger patient populations and longer-term follow-up should be performed in this population.

room or in clinic prior to intervention. The primary outcome of our study was freedom from any repeat intervention after DCB urethral dilation. This was determined by patient's symptomatic burden after initial intervention and post operative postvoid residual if obtained. Secondary outcomes included postoperative complication rates. At the discretion of the surgeon, a subset of patients underwent surveillance cystoscopy at follow-up to evaluate for urethral patency, which was defined as a urethral lumen patent enough to pass a 16-French (Fr) cystoscope. Follow-up was obtained via chart review of the electronic medical record. The date of last follow-up was the time the patient had last been evaluated in clinic. Patients who had significant urethral narrowing on cystoscopy which caused bothersome urinary symptoms that necessitated repeat intervention were considered treatment failures.

### *Statistical analysis*

Descriptive statistical analysis was performed for the cohort. Patient variables including age, gender, ethnicity, and prior interventions were retrospectively evaluated. Stricture characteristics were also evaluated including etiology and anatomic location. Measurements of central tendency and dispersion were calculated to quantify length of postoperative catheterization and follow-up period for the cohort, respectively. Rate of treatment failure, defined as need for repeat intervention after Optilume, was also determined for the overall cohort.

### *Surgical technique*

Two methods for operative intervention were done based on the institution at which it was performed. One institution performed plain balloon pre-dilation of the stricture and maintained a urethral catheter for 14 days post-procedure. The longer duration of catheter placement was based on surgeon preference and standard practice for all patients undergoing DCB dilation at that institution. In the other institution, no pre-dilation was done and a urethral catheter was left in place for 3 days.

Patients underwent a retrograde urethrogram to identify the stricture length and location. Then, a 16-Fr flexible cystoscope was advanced until just distal to the stricture, and a guidewire was advanced through the stricture under direct vision. Entrance of the wire into the bladder was confirmed on fluoroscopy. The cystoscope was then removed. The retrograde urethrogram image defining the

stricture was used to guide balloon placement. In the DCB dilation technique, where pre-dilation was employed, a 30 Fr × 4 cm plain balloon dilator was placed across the stricture and inflated to 20 atmospheres (atm). For strictures located in the penile urethra, a 24 Fr × 4 cm plain balloon dilator inflated to 20 atm was used.

Optimal diameter and length of the DCB used was chosen by the operating surgeon based on the retrograde urethrogram findings. In general, 24-Fr dilators were used for more distal strictures, and 30-Fr for more proximal strictures. The paclitaxel DCB was then advanced over the wire to the area of the stricture, based on retrograde urethrogram images that defined the stricture. A flexible cystoscope was advanced up to the distal end of the DCB to ensure adequate coverage across the stricture. The paclitaxel coated balloon was subsequently inflated to the manufacture recommended burst pressure, then held in place for a minimum of 5 minutes prior to deflation and removal. A 16-Fr or 18-Fr council tip catheter was then placed over the guidewire into the bladder per surgeon preference.

### *Ethical statement*

The study was conducted in accordance with the Declaration of Helsinki and its subsequent amendments. The study was approved by the institutional review board at the University of Florida (study ID #202301505) and the institutional review board at the Indiana University (study ID #20299). There was no informed consent obtained, as it was not necessary given the retrospective nature of this study.

## **Results**

Of the 146 patients who underwent Optilume DCB at our institutions, 19 had a stricture recurrence after urethroplasty and were included in our analyses. The mean age was 55 (standard deviation, 18 years; range, 34–82 years). Within the cohort there were 15 Caucasian, 3 Black, and 1 Hispanic patients. Sixteen patients had strictures less than 2 cm in length. The average stricture length for the 3 patients with strictures greater than 2 cm in length was 3.5 cm. The original stricture etiology was idiopathic in 8 cases, followed by iatrogenic in 4 patients. Three patients had inflammation/lichen sclerosis associated (LSA) stricture, 2 patients had radiation associated strictures, and another 2 had trauma-associated strictures. Stricture locations included 9 bulbar, 6 penile, 3 membranous and 1 prostatic urethral. Prior urethroplasty types in this

**Table 1** Patient demographics, stricture characteristics, and treatment outcomes

Variables	Value
Age (years)	
Mean ± SD	55±18
Range	34–82
Gender (male), n [%]	19 [100]
Stricture etiology, n [%]	
Idiopathic	8 [42]
Iatrogenic	4 [21]
LSA	3 [16]
Radiation	2 [11]
Trauma	2 [11]
Prior intervention types, n [%]	
BMG	9 [47]
EPA	7 [37]
Scrotal skin graft	1 [5]
Hypospadias repair	1 [5]
Rectourethral fistula	1 [5]
Endoscopic	12 [63]
Ethnicity, n [%]	
Caucasian	15 [79]
Black	3 [16]
Hispanic	1 [5]
Stricture location, n [%]	
Penile	6 [32]
Bulbar	9 [47]
Membranous	3 [16]
Prostatic	1 [5]
Length of catheterization (days), median	7
Rate of treatment failure, n [%]	2 [11]
Length of follow-up (days), median [IQR]	228 [182–369]

BMG, buccal mucosal graft; EPA, excision and primary anastomosis; IQR, interquartile range; LSA, lichen sclerosus associated; SD, standard deviation.

cohort included 9 buccal mucosal graft (BMG), 7 excision and primary anastomosis (EPA), 1 scrotal skin graft, 1 prior hypospadias repair failure and 1 rectourethral fistula repair with EPA and gracilis flap interposition. Twelve of 19 patients (63%) in our cohort had undergone

an endoscopic procedure (urethral dilation or DVIU) prior to DCB dilation (*Table 1*). No patient had more than one urethroplasty prior to DCB dilation. The median time from urethroplasty to DCB dilation was 28 months [interquartile range (IQR), 15–55 months] for 17 of our patients. The date of urethroplasty was unknown in 3 patients. Pre-treatment with plain balloon dilation was performed in 26% of patients (n=5). Within the cohort, 11 (58%) patients had a catheter for 3 days. The rest of the cohort had a catheter in place for 8 days. The median follow-up was 228 days (IQR, 182–369 days) (*Table 1*). Postoperative post-void residual was measured in 16 patients, averaging 48.6±116.6 milliliters. There were no postoperative complications noted after DCB in our cohort.

Freedom from repeat intervention at a median follow-up of 228 days was achieved in 89% of patients (17/19). The 2 patients who had failure after DCB dilation had bulbar urethral strictures previously treated with BMG and EPA, respectively. Both patients elected to undergo repeat DCB dilation as they were satisfied with the success they experienced after initial DCB dilation and wished to avoid repeat urethroplasty. The average time from initial DCB dilation to repeat intervention in these patients was 464 days. The stricture etiology in these patients who had repeat DCB dilation was idiopathic and iatrogenic. Only one patient had a stricture measuring greater than 3 cm. This patient underwent pre-dilation with an uncoated balloon at time of initial DCB dilation and had a catheter in place for 14 days postoperatively, the other patient was not dilated and had a catheter in place for 3 days.

### Discussion and review of literature

We describe our early experience using DCB urethral dilation for the treatment of post-urethroplasty stricture recurrence. Within our cohort, DCB dilation for strictures after urethroplasty had an 89% freedom from repeat intervention at a mean follow-up of 8 months. Urethroplasty remains the gold standard management for urethral stricture disease. Success rates for repeat urethroplasties is lower than the initial repair, with some studies reporting success rates as low as 67% after a repeat procedure (17). This is in part due to the decreased vascularity and scarring that occurs after the initial repair, which makes endoscopic intervention by DCB dilation attractive in this setting.

Outcomes of endoscopic intervention in patients with recurrent urethral strictures vary significantly, with some studies reporting success rates as low as 10% with standard

urethral dilation alone and as high as 60% to 70% when DVIU is used (5,7,8). Morey *et al.* and Barbagli *et al.* proposed that the success rate of DVIU in this setting is dependent upon the prior area of fibrosis having been previously excised at initial urethroplasty and the presence of less than 1cm fibrous ring strictures (18,19). When comparing DVIU to standard dilation after urethroplasty, Sukumar *et al.* noted a 10% success rate with standard dilation alone versus 49% for DVIU (7). The authors used the inability to pass a 17-Fr flexible cystoscope as their strict definition of stricture recurrence, which likely explains the lower success rates compared to our findings. Notably, many other studies, including ours, use patient reported symptoms as the definition of failure (6,9,20).

When using a standard 8-cm, 24-Fr balloon dilator, Morey *et al.* noted that patients undergoing salvage treatment for stricture recurrence following urethroplasty had a 78% failure rate when compared to those without a prior repair of 51% (18). The median time to recurrence within this cohort was 4 months (IQR, 2–12 months). Based on this, we infer that the success rate of 89% at a median follow-up of 8 months within our cohort is likely due to the addition of paclitaxel to the re-stricture area after balloon dilation. Furthermore, in 6/19 (32%) of our patients who had follow-up greater than 12 months post-procedure (median, 13 months; IQR, 12–36 months), there was an observed success rate of 83%, which is higher than reported in some DVIU cohorts and similar to the 1-year ROBUST III freedom from repeat intervention rate of 83.2% (7,13).

VanDyke *et al.* have published their early experiences with Optilume DCB in patients with stricture recurrence after urethroplasty. Notably within their cohort they noted a freedom from repeat intervention rate was 80.0% at a median follow-up of 3.5 months (21). Our coauthors (Mahenthiran *et al.*) from Indiana University have also described initial efficacy of DCB for patients with treatment-naïve strictures of varying locations and etiologies (22). Alhamdani *et al.* have also published their outcomes using Optilume DCB dilation (20). Within their cohort, four patients had a history of prior urethroplasty and all patients had strictures greater than 2 cm. Their freedom from repeat intervention at 30 months was 76%. Another investigator has also reported success at 1 year follow-up using Optilume DCB dilation for a recurrent 1-cm bulbar urethral stricture after BMG urethroplasty (23).

Our data demonstrates promising results for the use of DCB urethral dilation for post-urethroplasty stricture recurrences. Limitations of our study include

the retrospective nature of this study, the limited sample size, and the short median follow-up. Additionally, we did not use a strict objective measure of urethral patency to determine success of the DCB dilation procedure. However, many patients remain satisfied with their voiding habits after urethroplasty, even when they are found to have urethral lumens that are not quite patent enough to accept a 16-Fr flexible cystoscope. For these patients who have patent, but less than 16-Fr urethral lumens, other parameters such as bothersome obstructive voiding symptoms, elevated post-void residuals, or development of bladder stones or infection are the typical indicators of urethroplasty failure necessitating repeat intervention and are the same criteria that we used to determine success after DCB balloon dilation.

Furthermore, not all patients in our cohort were pre-dilated prior to DCB dilation, as was standard in the ROBUST trials. We hypothesize that pre-dilation allows for an adequate stricturotomy to maximize the urethral lumen while creating enough micro-fissures in the tissue to enhance drug absorption which may improve clinical outcomes (24). Some of our patients had a prolonged catheter placement after DCB dilation, which was a deviation from the standard 48 to 72 hours as recommended by the manufacturer. This deviation of length of catheterization from the ROBUST trial was based on surgeon practice patterns and our findings do not suggest this impacted outcome. Additionally, given our limited sample size, we are unable to draw conclusions on the impact of prior urethroplasty repair type and location of stricture on DCB dilation outcomes. However, the primary goal of this article was to describe our early experiences and success using DCB dilation in an often difficult to treat population, with a primary focus on the need for repeat intervention. Future studies should seek to further study outcomes in these patients in a standardized manner as well as elucidate the success rate of DCB dilation when using more objective definitions of stricture recurrence.

## Conclusions

DCB urethral dilation is effective in the management of post-urethroplasty stricture recurrence. In our cohort, patients had a freedom from repeat intervention rate of 89% at median follow-up of 228 days. Our results are promising, providing patients a minimally invasive option for the treatment of post-urethroplasty stricture recurrences, which can be technically difficult to retreat with another

urethroplasty. Longer-term outcomes in this cohort are forthcoming and future larger studies will further elucidate the efficacy of DCB dilation in this cohort.

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