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Optilume® Drug-Coated Balloon May Lower the Re-Treatment Rate Postintervention for Challenging Urethral Stricture Disease in Long-Term Follow-Up: A Prospective Cohort Study

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Abstract

Background: Urethral stricture disease is a common and at times unsatisfying condition that can lead to complications severely impacting a patient's quality of life (QOL). Open urethroplasty remains the gold standard treatment, however it is an invasive and highly specialized procedure. Strictures between 2 and 4 cm in length have been shown to recur at a rate of 50% within 12 months, a rate that typically decreases with each subsequent treatment. The Laborie Optilume drug-coated balloon (DCB) is the first of its kind developed for adjunct treatment of urethral strictures in men. The DCB initially treats the stricture through balloon dilatation and subsequently aims to prevent recurrence via the localized application of Paclitaxel. Our study assesses the safety and efficacy of the DCB in an Australian population with strictures exceeding 2 cm, who have undergone at least two prior procedures for urethral stricture disease.

Methods: Patients were prospectively recruited from November 2019 to September 2021. International prostate symptom score (IPSS), IPSS QOL, and voiding parameters were collected at baseline, and again at 1, 6, 12, and 18 months. The DCB was applied by a single consultant urologist under rigid cystoscope with shallow direct vision internal urethrotomy with a cold knife prior to application of the DCB.

Results: Seventeen patients were recruited with an average of 7.7 prior urethral procedures for recurrent stricture disease. In total, 76% were stricture free at 30 months follow-up. There were improvements in almost all parameters including max flow, average flow, IPSS, and IPSS QOL scores at 12 and 24 months. There were no complications.

Conclusion: The DCB is a safe and effective method at reducing the rates of recurrence for high-risk stricture disease and can delay or prevent the need for urethroplasty in what remains a very challenging cohort of patients.

Keywords: drug-coated balloon, Optilume, prospective cohort study, urethral stricture, recurrence

Introduction

Urethral stricture disease is a common and potentially challenging presentation in urology. Urethral stricture disease may lead to recurrent urinary tract infections, detrusor dysfunction, kidney failure, and can severely impact a patient's quality of life.[1] Open urethroplasty remains the gold standard of treatment but is an invasive and technically specialized procedure. Minimally invasive treatment of urethral strictures includes direct vision internal urethrotomy (DVIU) or dilatation but their procedures are associated with high recurrence rates.[2]

Management of urethral strictures depends on size, location, etiology, and whether it is primary or recurrent. Patients with a stricture 2–4 cm in length have shown a stricture recurrence rate of 50% at 12 months. Furthermore, the long-term reported success rate of initial DVIU is 32% and decreases with repeated treatment.[3] Recurrent urethral stricture disease

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has remained challenging for urologists to manage, there is a need for novel techniques to manage these strictures suitable for the general urologist. Adjunctive treatment with paclitaxel in combination with endoscopic management of strictures has shown promise in reducing recurrence rates.[4–6]

The Laborie Optilume drug-coated balloon (DCB) (Laborie, Inc., Plymouth, MN, USA) is the first DCB developed for the adjunct treatment of urethral strictures in men. The DCB initially treats the stricture via balloon dilatation, and then aims to stop stricture recurrence via the local application of Paclitaxel. Paclitaxel has been used in vascular anastomosis to prevent restenosis due to its antimitotic properties which inhibit cell proliferation and migration.[7] The ROBUST trials[4–7] have explored the safety and efficacy of the Laborie Optilume DCB and have demonstrated a 72–73.7% stricture free rate at 1 year[5,7] and a 67% stricture free rate at 3 years.[7] As a result of these promising outcomes, the Optilume DCB has been recommended in the European Urology guidelines for use in patients unsuitable for urethroplasty, who have had 2 prior endoscopic treatments and have bulbar urethral strictures less than 3 cm in length.[8]

Our study examines the safety and efficacy of the DCB in an Australian population with strictures greater than 2 cm, who have undergone at least two prior procedures for their urethral stricture disease.

Methods

After institutional ethics approval, the data were collected prospectively from Nov 2019 to Sep 2021. We identified patients who required dilation for their urethral strictures, who had undergone previous treatments, and who could provide informed consent and agreed to comply with the follow-up schedule. All subjects had to meet the inclusion criteria and had to not meet any of the exclusion criteria (Appendix 1) to be enrolled to this study. Namely, subjects were eligible to enroll into the study if they had urethral strictures longer than 2 cm in length and have undergone at least two prior interventions (DVIU or urethral dilatations) and have had recurrence of disease as confirmed on retrograde urethrogram and have decided against urethroplasty. Etiology, number of prior treatments, basic demographic features, baseline voided volume, peak flow rate (Qmax), voiding time, international prostate symptom score (IPSS), and mean flow rate were recorded prior to treatment and measured posttreatment at 30 days, 12 months, and 24 months. All subjects were followed up up to 48 months in duration to determine stricture retreatment rate alone.

Every procedure was performed by a single consultant urologist under general anesthesia and rigid cystoscopy. Each subject underwent shallow DVIU with a cold knife in at least five areas circumferentially prior to treatment via Optilume DCB dilatation. A 30F 5 cm Optilume DCB was inflated across the incised stricture for at least 5 minutes. Cystoscopy was performed to the stricture at the end of the procedure to confirm the presence of paclitaxel flakes circumferentially within the incised and dilated stricture. The paclitaxel coating adheres to the dilated stricture in flakes. These flakes need time in contact with the tissue to be absorbed. These flakes are clearly visible coating the dilated stricture at the end of the procedure and can be dislodged with irrigation or by mechanical means (further cystoscopy or indwelling catheter (IDC) insertion). To give the patient the longest period of tissue contact between the paclitaxel flakes and the dilated stricture, no IDC was inserted at the end of the procedure to minimize the potential for mechanical dislodgment of the flakes. The bladder was emptied prior to insertion of the Optilume DCB, and minimal irrigation utilized during deployment of the balloon, ensuring low bladder distention. During deployment, the urethra is completely blocked by the Optilume DCB, thus the bladder remains relatively empty. Detailed information regarding the technique with intraoperative imaging can be found in Appendix 2.

Note that predilation of the stricture was not performed as a standard practice prior to insertion of Laborie Optilume DCB in this cohort. The recommendation is that a balloon diameter is selected that is larger than the distal urethral size by a maximum of 30% of the lumen diameter and extends 0.5–1 cm proximal to the stricture segment prior to inflation. Predilation of the stricture tends to result in a single dilation defect (tear) across the weakest portion of the stricture. By performing circumferential shallow cold knife incisions and creating multiple "weak" areas in the stricture, the subsequent dilatation with the Optilume DCB allows the paclitaxel to be in contact with multiple circumferential defects in the stricture, potentially improving the absorption and decreasing subsequent recurrence of the stricture at those points.

Effectiveness was defined as an objective improvement in uroflow study results or improvement in IPSS scores at 1 month, 6 months, 12 months, and 24 months where voided volumes greater than 150 mL were considered valid results. The efficacy was also subjectively measured via an improvement in the IPSS QOL scores at the same time points. Safety was measured as the rate of major device or procedure-related complications within 90 days of the procedure. Re-treatment was defined as any urological procedure for stricture treatment including DVIU, repeat DCB, urethroplasty, and urethral dilatation. Insertion of indwelling catheters was not considered treatment for urethral strictures. The results were analyzed with Mann–Whitney test with the statistical significance set at $p < 0.05$.

Results

Between November 2019 and January 2022, 21 patients underwent dilation via the Optilume DCB at our institution. All patients passed the initial trial of void postprocedure and no patient required an IDC postdilatation or within 30 days of the procedure. Four patients were repeated treatments (with Optilume DCB) during this timeframe and therefore were excluded from this study. Twelve of the 17 (71%) patients had a follow-up time of 24 months or greater, with the median follow-up time of 30 months (Table 1). The mean age of the cohort patients was 61. Twelve subjects had bulbar urethral stricture disease, 3 had bladder neck scarring postradical prostatectomy, and 1 subject had a penile urethral stricture (Table 1). All patients had multiple prior urethral surgeries which included three urethroplasties and one

Table 1. Patient Characteristics

n	17
Mean age	61.6 years
Stricture location	
Bulbar	12
Bladder neck	4
Penile urethra	1
Prior urethral surgery (Excluding DVIU/Dilatation)	4
Number of prior urethral procedures	
<5	8
5–10	6
11–20	1
>20	2
Mean number of prior urethral procedures	7.7
Prior RTx	4
Stricture length (cm)	4
2	8
3	7
4	1
5	1
Median length of follow-up (months)	30

DVIU, direct vision internal urethrotomy, RTx, Radiotherepy.

excision of a urethral diverticulum in a female. Four different subjects had a history of pelvic radiotherapy. All patients had a stricture of 2 cm or longer, with the majority (15/17) having a stricture of 2 or 3 cm in length. The longest stricture was 5 cm. The mean number of prior urethral procedures in our cohort was 7.7.

Overall, the re-treatment rate was 24% at a median follow-up of 30 months. In our study, only one patient had a history of a penile urethral stricture, which did not necessitate further treatment. Among the four patients with bladder neck strictures, one recurrence (25%) occurred in a female patient with a history of prior urethral diverticulum excision, the other three had undergone radical prostatectomy. Of the 12 patients with bulbar urethral strictures, 9 (75%) did not require additional treatment at a median follow-up of 30 months (Table 2). Overall, four patients developed stricture recurrence posttreatment, three of which were bulbar urethral strictures, and one bladder neck stricture postexcision of urethral diverticulum in a female (Table 3). Two bulbar urethral stricture recurrences had a history of pelvic radiotherapy. The average time to stricture recurrence was 9.5 months.

Statistically significant improvement was seen in almost all parameters in postprocedural measures of effectiveness, with a more pronounced effect at 12 months which declined with time as seen at 24 months follow-up. IPSS improved from 18.50 at a baseline to 8.0 at 12 months ($p < 0.001$) and 13.5 at 24 months ($p = 0.031$). The max flow improved from 5.4 mL/s at baseline to 13.4 mL/s ($p = 0.001$) at 12 months and 11.25 mL/s at 24 months ($p = 0.041$). There was statistically significant improvement in IPSS QOL at 12 months that was seen to decrease at 24 months, however it still remained greater than the pretreatment IPSS QOL score.

There were no device-related complications in the immediate postoperative period or within 30 days of the procedure. No participant went into urinary retention in the postoperative period necessitating insertion of an indwelling catheter.

No patient needed to perform intermittent self-dilatation subsequent to the procedure. The decision on whether to retreat or not was made jointly between the surgeon and patient based on multiple factors. All patients had multiple previous interventions for recurrent urethral strictures. Slowing of stream and return of symptoms of obstruction were common patient subjective factors. Reduced flow rate, incomplete emptying, and IPPS deterioration compared to initial post-Optilume DCB dilatation were objective indicators of recurrence of a stricture. Patients were all given an option for a urethroplasty due to recurrence of symptoms and signs of obstruction and recurrence of stricture. All these factors were taken into account when deciding if and when to perform a re-treatment with Optilume DCB.

Table 2. Summary of Effectiveness of Treatment with Optilume Drug-Coated Balloon

Re-treatment-free rate (median follow-up 30 months)	*13/17 = 76%*		
Average time to repeat intervention (months)	*9.5*		
Uroflow & IPSS scoring (pre- and posttreatment comparison)	*Pretreatment*	*Posttreatment*	p *value*
Max flow mL/s (median)	5.4 (n = 15)		
12 months		13.4 (n = 11)	0.001
24 months		11.5 (n = 8)	0.041
Average flow mL/s	3.50 (n = 15)		
12 months		7.4 (n = 11)	0.003
24 months		6.55 (n = 8)	0.056
IPSS	18.50 (n = 16)		
12 months		8.0 (n = 11)	<0.001
24 months		13.50 (n = 16)	0.031
IPSS QOL score	4.000 (n = 15)		
12 months		2.0 (n = 11)	<0.001
24 months		3.000, n = 16	0.002

IPSS, prostate symptom score; QOL, quality of life.

Table 3. Characteristics of Participants who Developed Stricture Recurrence

Re-treatment patients	*Previous intervention (radiotherapy or surgery not including dilatation/DVIU)*	*Length of stricture (cm)*	*Number of prior treatments (DVIU or dilatations)*	*Length between treatments prior to DCB (months)*	*Time to recurrence post-DCB (months)*	*Location of stricture*	*Initial stricture diameter (Fr)*
1	Prior radiotherapy	3	6	3	8	Bulbar	3
2	Prior excision urethral diverticulum	3	6	9	4	bladder neck	3
3	Nil	2	4	5	13	Bulbar	1
4	Prior radiotherapy	2	21	8	13	Bulbar	2

DCB, drug-coated balloon; DVIU, direct vision internal urethrotomy.

Discussion

In urethral strictures, our study found that at a median follow-up of 30 months, 76% of patients did not require re-treatment for their recurrent strictures with no complications.

Our study investigated the efficacy of the Optilume DCB in a notoriously difficult cohort of patients. A study by Pal and colleagues demonstrated that stricture recurrence rate greatly increases with the number of repeat treatments.[9] In their cohort of 187 patients, 30% of patients were stricture-free at 24 months following one DVIU, 23% after two treatments at the same time point, and 13% after three treatments. This is reinforced by Kluth and coworkers who found that a history of previous DVIU was their only strong risk factor for recurrence in a cohort of 128 patients.[10] Moreover, longer strictures greater than 2 cm have been shown to have a much higher risk of recurrence compared to strictures less than 2 cm with studies demonstrating a 50–75% risk of recurrence for strictures 2–4 cm in length compared to 40% recurrence of strictures 2 cm or less at 48 months follow-up.[11–13]

The "ROBUST" trials performed across Latin America and the United States of America investigated the safety and efficacy of the Optilume DCB. ROBUST I evaluated 53 patients with strictures 2 cm or less with an average of 1.7 previous dilations.[4,7] The authors found that at 3 years follow-up, 77% were free from re-treatment and had a large reduction in IPSS from an average of 25.2 at baseline to 5.5.[7] However, the authors discuss that balloon size was a significant predictor of success and the decision to choose a balloon size was based on its availability and thereby could not completely attribute the differences to the DCB alone. ROBUST II was the first study to investigate the DCB in an American population.[5] In their cohort of 16 patients, the average stricture length was 2.1 cm and on average had undergone four previous dilations. They found similar results to the ROBUST I trial with a reported stricture free rate of 73.3% at one year and a large reduction in IPSS from 18.4 to 6.0.[5] The ROBUST III trial compared a DCB and DVIU group to a control DVIU alone group in strictures less than 3 cm in length with an average of 3.2 prior endoscopic treatments for stricture disease. In 127 trial patients, the treatment group reported significantly greater anatomical stricture-free rates at 6 months (75 vs. 27%) and IPSS at 6 months with an average of 9.0 in the treatment group and 19.9 in the control group. Patients in the DCB plus DVIU group demonstrated a 83.2% patency rate at 1 year compared to 21.7% in the DVIU alone group. The authors note that the DCB group used 30 Fr balloons to dilate whereas the control arm had heterogenous balloon sizes which may have impacted the findings. However, the authors contest that in their post-treatment urethrogram the estimated lumen diameters were not different between the groups, and in a subset analysis of patients in the control group who had been dilated to 30 Fr the results were similar to the overall analysis and thereby don't believe this difference would have had a significant impact on their results.

The results of our study demonstrated a similar stricture re-treatment-free rate and improvement in max flow to the ROBUST trials, although our patients demonstrated that in a similar trend in IPSS improvement it was smaller in magnitude.

The subjects enrolled into our study come from a notoriously difficult to treat cohort of patients given that they all have strictures greater than 2 cm in length and an average of 7.7 prior urethral dilatations across the cohort. Compared to the ROBUST trials, the number of average dilatations in our cohort is far greater. Therefore, the outcomes in our patients reflect the efficacy of the DCB in a cohort of much more treatment-resistant disease than what has previously been investigated. In addition, four patients had prior radiotherapy, and a further four had previous urethroplasty. This represents a real-world cohort of all comers in a urological practice. Outcomes in these patients often leave urologists feeling unsatisfied, and thus, the high re-treatment-free rate in our cohort of patients suggests a strong treatment effect from the DCB as opposed to DVIU or dilatation alone. This difficult group of "heartsinker" patients with high recurrent urethral stricture disease would normally be referred for a urethroplasty as a definitive treatment option. For a multitude of reasons, these patients did not proceed to urethroplasty, but elected to have repeat dilatations or DVIU. The Optilume DCB significantly reduced the stricture re-treatment rate in this cohort of patients and broke the cycle of repeat dilatations and DVIU in these patients, delaying the need for urethroplasty.

The lack of a control group comparing DVIU alone to DCB dilatation in our study potentially limits any definitive findings to be made based off the outcomes in our subjects. By saying this, the findings in this study are comparable to the ROBUST III trial that had randomized their 127 patients into a control and treatment group with a similar cohort of patients in regard to prior urological procedures for stricture disease and stricture length.

Limitations to our study include the lack of power which limits the ability to perform any subgroup analysis. Four

patients had a history of radiotherapy, and an additional four patients have had previous urethroplasty, which could have affected the outcome, although typically patients with these interventions tend to have higher stricture recurrence rates and it would be expected to lower the re-treatment-free rates. Future studies with larger cohorts may be able to determine if the DCB has a particular increased effect based on the particular etiology of stricture disease, although it's clear in the results of this trial and ROBUST trials that most subjects tend to see a clear benefit with treatment. Furthermore, the heterogenous follow-up of patients could affect the reliability of the findings. Nevertheless, at each time point investigated in this study, there were clear benefits at each time point in almost all measures of efficacy. A larger study with more compliance from subjects would be more definitive in confirming the results seen in our patients. In addition, the pre-Optilume procedures received by patients for their recurrent urethral stricture or bladder neck contracture disease was not standardized. In our institution's general practice, patients typically undergo DVIU or urethral dilation initially and for subsequent recurrence depending on their treating surgeon. The impact of not recording the specific type of treatment received for each recurrence is likely nondifferential as no high-quality trials have demonstrated a difference in outcomes between urethral dilation and DVIU techniques.

Conclusion

In a notoriously challenging group of patients with a far greater average prior dilatations than previously investigated, the Optilume DCB has demonstrated a 76% re-treatment-free rate and improvement in almost all measures of treatment effect in long-term follow-up. This makes the novel DCB a very exciting addition to a field of urology that can often leave urologists and their patients feeling unsatisfied. Larger studies are required to validate the results seen in this study and to investigate the efficacy and durability of the Optilume DCB in much larger study populations.

Authors' Contributions

All authors contributed to the write-up of this article.

Author Disclosure Statement

There is nothing to disclose, no conflict of interests.

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Abbreviations Used

DCB = Urotronic Optilume drug-coated balloon
DVIU = direct vision internal urethrotomy
IPSS = International prostate symptom score
IPSS QOL = International prostate symptom score quality of life

(*Appendix follows* →)

Appendix 1: Inclusion and exclusion criteria

Inclusion criteria
Subjects ≥18 years old
Visual confirmation of stricture via cystoscopy or urethrogram
Single, tandem, or diffuse anterior urethral stricture
Two or more prior dilation treatments of the same stricture, including DVIU (Direct Vision Internal Urethrotomy). Note: Catheterization is not considered a dilation treatment.
Significant symptoms of stricture such as frequency of urination, dysuria, urgency, hematuria, slow flow, feeling of incomplete emptying, and recurrent UTIs.
Lumen diameter ≤12 F by urethrogram
QMax <15 mL/s at baseline
Guidewire must be able to cross the lesion
Exclusion criteria
Subjects with diffuse stricture length > 6 cm. (Stricture length is defined as the distance between the most distal edge of the stricture to the most proximal edge of the stricture).
Subjects with a history of hypersensitivity reactions to TAXOL, on medication that may have negative interaction with paclitaxel, with solid tumors who have a baseline neutrophil counts of 8.0%) or evidence of poor wound healing due to diabetes.
Subjects who had an indwelling suprapubic catheter prior to enrolment.
Stricture dilated or incised within the past 6 weeks (urethral catheterization is not considered dilation).
Presence of local adverse factors, including abnormal prostate making catheterization difficult, urethral false passage, or fistula.
Presence of signs of obstructive voiding symptoms not directly attributable to the stricture at the discretion of the physician.
Diagnosis of untreated and unresolved benign prostatic hypertrophy or bladder neck contracture.
Untreated stress urinary incontinence (SUI).
History of diagnosed radiation cystitis.
Diagnosis of carcinoma of the urethra, bladder, or prostate within the past 5 years.
Active kidney, bladder, urethral, or ureteral stone passage in the past 6 weeks or concern of stone passage in the next 6 weeks at the discretion of the investigator.
Diagnosis of chronic renal failure and treatment with hemodialysis.
New diagnosis of OAB (overactive bladder) within the past 6 months.
Use of alpha blockers, beta blockers, OAB (overactive bladder) medication, anticonvulsants (drugs that prevent or reduce the severity and frequency of seizures), and antispasmodics where the dose is not stable. (Stable dose is defined as having the same medication and dose in the past 6 months.)
Dependence on Botox (onabotulinumtoxinA) in the urinary system.
Presence of an artificial urinary sphincter, slings, or stent(s) in the urethra or prostate.
Known neurogenic bladder, sphincter abnormalities, or poor detrusor muscle function.
Diagnosed with lichen sclerosis or stricture due to balanitis xerotica obliterans (BXO).
Previous hypospadias repair.
History of cancer in nongenitourinary system which is not considered cured (except basal cell or squamous cell carcinoma of the skin). A potential participant is considered cured if there has been no evidence of cancer within 5 years of enrolment.
Any cognitive or psychiatric condition that interferes with or precludes direct and accurate communication with the study investigator regarding the study or affect the ability to complete the study quality of life questionnaires.
Unwilling to abstain or use protected sex for 90 days posttreatment if sexual partner is of child-bearing potential.
Inability to provide informed consent form (ICF) and/or comply with all the required follow-up requirements.
Participation in other premarket studies or treatment with an investigational drug or device. Long-term follow-up or postmarket study of an approved device is allowed.
Current active infection in the urinary system.
Current uncontrolled diabetes (hemoglobin A1c >8.0%) or evidence of poor wound healing due to diabetes.
Diagnosed or suspected primary neurological conditions such as multiple sclerosis or Parkinson's disease or other neurological diseases known to affect bladder function, sphincter function, or poor detrusor muscle function.
Visible hematuria in subject's urine sample without known contributing factor.
Invisible hematuria (or significant microscopic hematuria, i.e., hematuria of ≥3 RBC's/HPF) that may be caused by a clinically significant disease unless it is attributed to the urethral stricture disease or other causes which are benign and not requiring treatment.

Appendix 2: Supplemental information regarding surgical technique and intraoperative imaging

The Urotronic Optilume™ drug-coated balloon (DCB) is a 0.038" guidewire compatible over-the-wire catheter with a tapered atraumatic tip. The distal end of the catheter has a semi-compliant inflatable balloon coated with a proprietary coating containing the drug paclitaxel and carriers that facilitates the drug's transfer to the urethral wall upon inflation.

Paclitaxel is an anti-inflammatory and antiproliferative drug commonly used to prevent arterial restenosis. The drug coating evenly coats the working length of the balloon body only. The device has two radiopaque marker bands that indicate the drug-coated working length of the balloon under fluoroscopy (Fig. A1). The device is provided sterile, and is intended for single use only.

The device is available in multiple diameters and balloon body lengths. The full matrix of device availability is described in the instruction for use. Table A1 shows the current device sizes available. This device is approved for use to treat urethral strictures in Australia via a special access scheme under TGA.

The 30F 5 cm Optilume DCB was utilized in all cases in this study.

How the procedure is performed in detail:

The procedure is performed under general anesthesia utilizing a rigid cystoscope. A baseline retrograde urethrogram is preformed (Fig. A2). The surgeon may predilate the lesion first. In all cases in this study, 6X small shallow incisions were performed at 12, 2, 4, 6, 8, and 10 o'clock in the stricture prior to dilation with the Optilume DCB. A guidewire is placed through the urethra. The size of the predilation equipment and Optilume balloon is based on the urethral lumen and stricture length. In all cases in this study, a 30F 5 cm Optilume DCB was utilized.

Prior to dilation with Optilume, air is purged from the system. Fill a standard inflation device (rated for at least 15 atmospheres) with saline or a 50:50 contrast mix, and attach it to the Optilume. Remove air by drawing back the plunger, then turn the stopcock to "off" to prevent more air from entering.

Insert a cystoscope and place a 0.038" guidewire through its working channel, positioning the tip within the bladder (Fig. A3). Flush the guidewire lumen with water or saline. Remove and discard the balloon protector. Minimize handling and avoid wiping the balloon with any materials that could damage the drug coating.

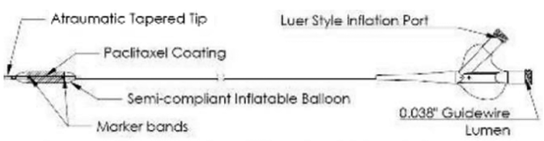

FIGURE A1. Schematic diagram of the device.

Table A1. Different Sizes of the Device

Diameter (Fr/mm)	*Length (mm)*	
18.0/6.0	30	50
24.0/8.0	30	50
30.0/10.0	30	50

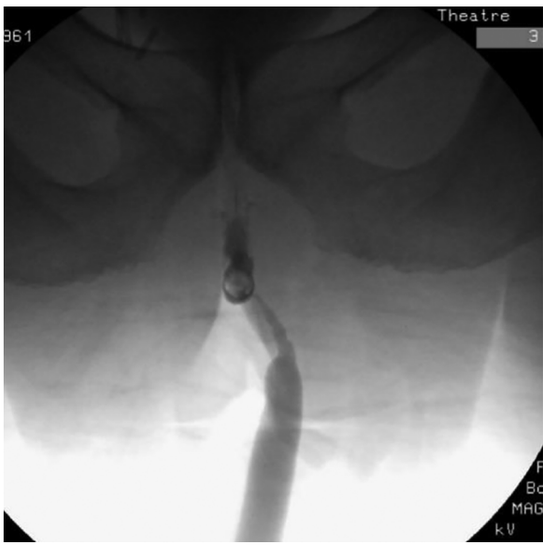

FIGURE A2. Retrograde urethrogram demonstrating stricture.

The Optilume is then passed over the guidewire through the working channel of a rigid cystoscope. The cystoscope is used to guide the balloon placement across the stricture, ensuring the balloon extends at least half a centimeter beyond the stricture and is aligned at its midpoint. Fluoroscopy was used to confirm proper positioning (Fig. A3). Check that the balloon's radiopaque markers are correctly placed distal and proximal to the stricture.

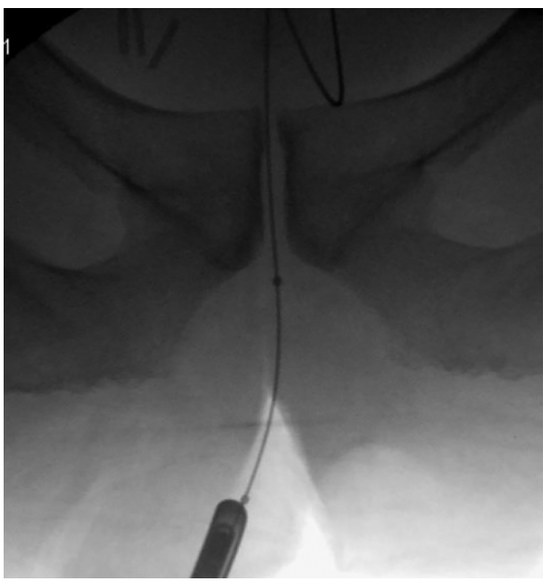

FIGURE A3. Positioning of Optilume Guidewire beyond the stricture, with a radio-opaque tracer at location of balloon.

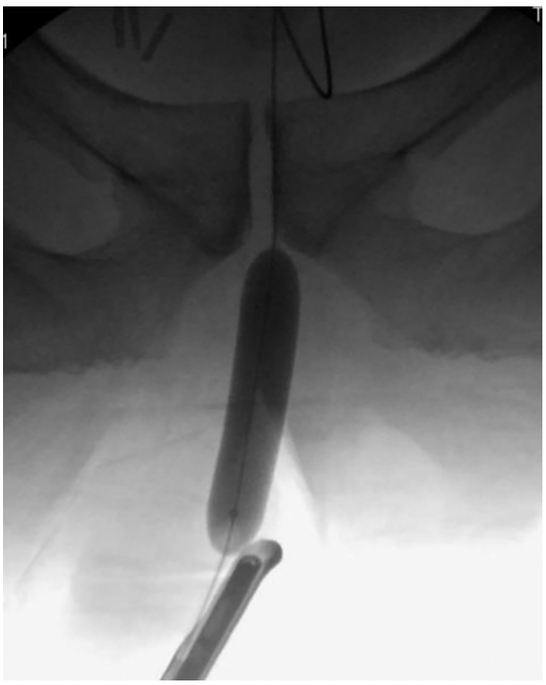

FIGURE A4. Inflated Optilume DCB (30 Fr 5 cm). DCB, drug-coated balloon.

FIGURE A5. Postdilation retrograde urethrogram with contrast entering the bladder.

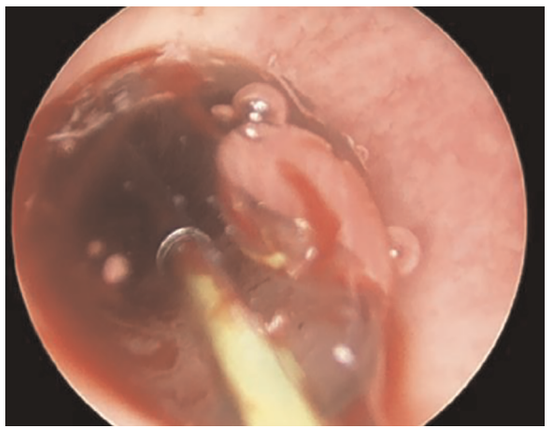

FIGURE A6. Postdilation photo with the Optilume DCB inflated within the urethra. DCB, drug-coated balloon.

Inflate the balloon slowly to 10 ATM. Although using fluoroscopy, an image is acquired at about 2 ATM to confirm placement (A4). During inflation, visually monitor the balloon and apply gentle traction to prevent migration (Fig. A6). If migration occurs, stop inflation and reposition the balloon. Positioning can be confirmed via a retrograde urethrogram (Fig. A5) or cystoscopy (Figs. A6, A7).

Do not exceed the rated burst pressure to avoid rupture. Refer to the product label for specific recommended pressures: 12 ATM for 18 and 24 French balloons, 10 ATM for 30 French, and 8 ATM for 36 French. A pressure drop indicates stricture yielding; increase pressure to the recommended pressure and maintain for at least 5 minutes to transfer the drug and achieve dilation. For dense, fibrous strictures, the surgeon may extend inflation times.

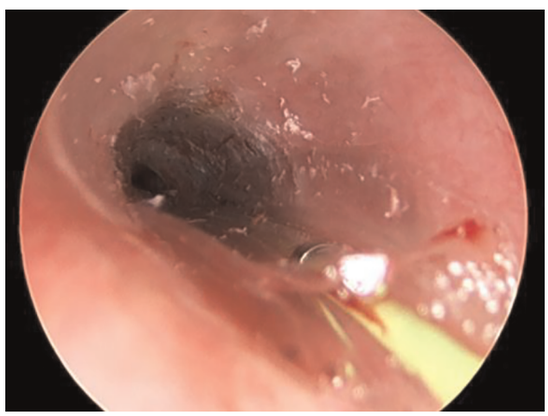

FIGURE A7. Postdilation photo of urethra with Optilume DCB. DCB, drug-coated balloon.