Research Square

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Outcomes of patients undergoing Optilume® drug-coated balloon for different locations of urethral strictures: results from a multicenter cohort

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Research Article

Keywords: Balloon-dilatation, Optilume, Urethral stricture, Outcomes

Posted Date: April 30th, 2026

DOI: https://doi.org/10.21203/rs.3.rs-9398079/v1

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Additional Declarations: No competing interests reported.

Version of Record: A version of this preprint was published at World Journal of Urology on June 21st, 2026. See the published version at https://doi.org/10.1007/s00345-026-06547-2.

Abstract

Introduction & Objectives:

The Optilume® drug-coated balloon (DCB), combining mechanical dilation with localized paclitaxel delivery, is a novel minimally invasive treatment for urethral stricture disease. However, data on its effectiveness across different stricture locations are limited. This study evaluates functional outcomes following treatment for different strictures locations.

Materials & Methods:

This retrospective multicenter study included patients treated with Optilume® DCB for urethral strictures at five European tertiary care referral centers (June 2023 - June 2025). Stricture length was assessed by retrograde urethrography, cystoscopy, or both. Recurrence was defined as any symptomatic stricture requiring treatment. A multivariable logistic regression using preoperative data was developed to predict recurrence requiring treatment.

Results:

In total 86 patients were included across four stricture locations: penile (n = 11, 13%), bulbar/penobulbar (n = 59, 68%), bulbomembranous/membranous (n = 13, 15%) and bladder neck (n = 3, 4%). Postoperative complications within 30 days occurred in 5 (5.8%) patients. Median follow-up duration ranged from 3 to 11 months. Median peak urinary flow increased from 3.5–8.8 mL/s preoperatively to 13.5–19 mL/s at 3 months. Stricture-free rates were highest in penile (91%) and bladder neck (100%) strictures, and lower for bulbar (74%) and bulbomembranous/membranous (69%) strictures. On multivariate logistic regression analysis, diabetes was an independent predictor of stricture recurrence (OR = 7.66, 95% CI 1.55–47.12, p = 0.01).

Conclusions:

Optilume® DCB showed encouraging efficacy and safety across different urethral stricture locations, achieving high stricture-free rates and improved urinary flow. Diabetes independently predicted recurrence, highlighting the value of optimizing modifiable risk factors.

Introduction

Urethral stricture disease poses a significant therapeutic challenge in the clinical practice for urologists around the world due to the high likelihood of recurrence following conventional endoscopic management (1). Endoscopic treatment options, which are routinely used, like mechanical dilatation and direct vision internal urethrotomy (DVIU), have variable success rates, with reported patency rates

between 8–77% (2–4). The gold standard for the management of anterior urethral stricture in men still is urethroplasty, with recurrence rates of approximately 15% (5).

As urethroplasty is more invasive and requires longer hospital admission, as well as greater associated risk profile and longer catheterization period (6), minimally invasive techniques are often preferred as a first step of treatment strategy. The Optilume® drug-coated balloon (DCB) is new minimally invasive treatment option, combining mechanical dilation with localized paclitaxel delivery. This is the first DCB intended for use in male urethral strictures (7, 8). The procedure can be conducted in an outpatient setting, whereby the balloon first dilating the affected area then circumferentially delivers the antiproliferative drug Paclitaxel, which inhibits smooth muscle cell proliferation and collagen production leading to reduced fibrosis (9).

Data on the effectiveness of Optilume® DCB across different stricture types and anatomical locations remain limited. This retrospective cohort study aimed to present the outcomes of patients treated with Optilume® for different types and locations of urethral stricture.

Material and Methods

Study design

We conducted a retrospective, multicenter study including data of patients treated with Optilume® DCB for anterior and posterior urethral strictures between June 2023 and June 2025 at five European tertiary care referral centers. Prior to data collection and analysis, ethical committee approval was given (BASEC 2025 – 01438). All patients included gave informed consent for anonymized data use.

Patient characteristics

Baseline patients' characteristics included age at surgery, smoking history and diabetes mellitus status. For urethral stricture disease, the type and length of stricture was classified, as well as any type of previous treatment. If there was previous treatment, the number of prior dilatations or radiation was recorded. Evaluation of stricture length was conducted by retrograde urethrography or cystoscopy, or both combined.

Intervention and follow-up

Intervention and follow-up
The Optilume® treatment was performed according to the centers protocol by trained physicians, either under general or regional anesthesia. Cystoscopically, a guidewire was placed across the stricture into the bladder under radiographic control. The following wire-guided DCB device inflation was performed at 10 atmosphere (atm) for 7 minutes. Postoperatively a catheter was placed for up to three days. The

follow-up plan was determined by the treating physician. During follow-up recurrence was detected if there was symptomatic stricture in need of any sort of treatment.

Outcomes

The primary endpoint of this study was symptomatic stricture recurrence during follow-up. Secondary endpoints were identifying factors leading to a higher risk of stricture recurrence, as well as treatment associated adverse events. Postoperative complications were detected by the treating physician during follow-up visits. Functional outcome was measured before treatment and during follow-up evaluating peak urinary flow (Qmax) and International Prostate Symptom Score (IPSS).

Statistical analysis

Categorical data was reported as absolute numbers and percentages. Continuous data, depending on their distribution, was reported as means and standard deviations (SD) or medians and interquartile ranges (IQR). Categorical variables were compared between groups using Kruskall-Wallis test. Continuous variables were compared between groups using One-way Anova. Multivariable logistic regression was used to identify factors predicting stricture recurrence. Statistical analysis was performed using R version 4.5.1 (R project, Vienna, Austria).

Results

Baseline characteristics

Baseline demographic and clinical characteristics are displayed in Table 1. A total of 86 patients treated with Optilume DCB were included across four stricture locations: penile (n = 11, 13%), bulbar/penobulbar (n = 11, 13%), bulbomembranous/membranous (n = 13, 15%) and bladder neck (n = 3, 4%). The median age of patients was 57 (IQR 44–64) and 58 (IQR 46–71) for those with penile and bulbar/penobulbar strictures, respectively, whereas for those with bulbomembranous/membranous and bladder neck strictures it was 74 (IQR 65–76) and 75 (IQR 72–78), respectively. Median stricture length ranged from 1 to 2 cm across groups, with no significant differences observed. Most strictures were idiopathic or iatrogenic in aetiology for all stricture types. The majority of patients had undergone prior stricture treatment, most commonly endoscopic dilation or internal urethrotomy. There were no statistically significant differences between diabetes (p = 1) and smoking history (p = 0.6) across all groups.

Table 1
Baseline characteristics of patients treated with Optilume® drug-coated balloon for the management of urethral strictures.

Variable	Penile (N = 11)	Bulbar/Penobulbar (N = 59)	Bulbomembranous/ Membranous (N = 13)	Bladder neck (N = 3)	P-value
Age at surgery [years], median (IQR)	57 (44–64)	58 (46–71)	74 (65–76)	75 (72–78)	0.04
Diabetes mellitus, n (%)	2 (18.2)	12 (20.3)	2 (15.4)	-	1
Smoking history, n (%)					
No	10 (90.9)	46 (78.0)	9 (69.2)	2 (66.7)	0.6
Ex smoker	1 (9.1)	10 (16.9)	4 (30.8)	1 (33.3)	
Active smoker	-	3 (5.1%)	-	-	
Type of stricture, n(%)					
Idiopathic	5 (45.5)	27 (45.8)	3 (23.1)	-	0.2
Iatrogenic	5 (45.5)	25 (42.4)	8 (61.5)	3 (100)	
Post-traumatic	-	5 (8.5)	-	-	
Inflammatory	1 (9.1)	1 (1.7)	-	-	
Post-radiotherapy	-	1 (1.7)	2 (15.4)	-	
Previous stricture treatment, n(%)	9 (81.8)	45 (76.3)	11 (84.6)	1 (33.3)	0.3
Type of previous treatment, n(%)					
Only dilatations	3 (27.3)	9 (15.3)	7 (53.8)	1 (33.3)	0.006
Internal urethrotomy +/- dilatations	0 (0)	20 (33.9)	1 (7.7)	0 (0)	
End-to-end urethroplasty	0 (0)	1 (1.7)	0 (0)	0 (0)	

Variable	Penile (N = 11)	Bulbar/Penobulbar (N = 59)	Bulbomembranous/ Membranous (N = 13)	Bladder neck (N = 3)	P-value
Buccal mucosal urethroplasty	6 (54.5)	15 (25.4)	3 (23.1)	0 (0)	
Missing	2 (18.2)	14 (23.7)	2 (15.4)	2 (66.7)	
Prior pelvic radiation, n(%)	0 (0)	3 (5.1)	2 (15.4)	0 (0)	0.4
Prior dilations, n(%)	6 (54.5)	19 (32.2)	11 (84.6)	1 (33.3)	0.003
Number of prior dilations, median (IQR)	1 (1–1)	2 (1–3)	4 (1–10)	-	0.2
Stricture length [cm], median (IQR)	2 (1–3)	1 (1–2)	2 (1–3)	1 (1–1)	0.1

Functional outcome

Comparison of pre- and postoperative functional outcome is displayed in Table 3. Median Qmax increased from 3.5–8.8 mL/s preoperatively to 13.5–19 mL/s at 3 months over all groups. The median IPSS was assessed before and after surgery for all stricture types except blader neck strictures. IPSS decreased after treatment for all groups, with a decrease from 8 (IQR = 8–8) to 1.5 (IQR = 1–2) for penile strictures, 15 (IQR = 11–24) to 5 (IQR = 3–9) for bulbar/penobulbar strictures and 22 (IQR = 19–26) to 5 (IQR = 3–7) for bulbomembranous/membranous strictures.

Table 3
Comparison of preoperative and postoperative functional outcomes of patients treated with Optilume® drug-coated balloon for the management of urethral strictures.

Peak urinary flow (Qmax) before surgery [ml/s], median (IQR)	**Penile (N = 11)**	**Bulbar/ Penobulbar (N = 59)**	**Bulbomembranous/ Membranous (N = 13)**	**Bladder neck (N = 3)**	**P-value**
	3 (3–5)	**7 (5–10)**	**9 (4–12)**	**5 (5–5)**	**0.3**
Post-void residual (PVR) before surgery [ml], median (IQR)	13 (0–46)	78 (30–196)	0 (0–45)	0 (0–0)	0.1
IPSS before surgery [0–35], median (IQR)	8 (8–8)	15.0 (11–24)	22 (19–26)	-	0.2
Peak urinary flow (Qmax) at 3 months [ml/s], median (IQR)	13 (12–20)	19 (15–25)	18.8 (17–21)	18 (15–21)	0.7
Post-void residual (PVR) at 3 months [ml], median (IQR)	0 (0–12)	20 (0–50)	0 (0–5)	50 (25–75)	0.3
IPSS at 3 months [0–35], median (IQR)	1 (1–2)	5 (3–9)	5 (3–7)	-	0.2

Stricture-free survival

Median follow-up duration ranged from 3 to 11 months depending on stricture location. Stricture free survival for different types of urethral stricture is displayed in Table 4. Stricture persistence was observed in 20 (23%) patients, with no persistence among bladder neck strictures. Stricture persistence was most frequently observed in patients with bulbomembranous/membranous strictures (30.8%, n = 4), followed by bulbar/penobulbar (25.4%, n = 15) and penile strictures (9.1%, n = 1). There was no significant difference between persisting stricture during follow-up for the different types of urethral stricture (p = 0.5).

Table 4
Stricture-free survival of patients undergoing Optilume® DCB for different types of urethral stricture.

Months of follow-up [months], median (IQR)	**Penile (N = 11)**	**Bulbar/Penobulbar (N = 59)**	**Bulbomembranous/ Membranous (N = 13)**	**Bladder neck (N = 3)**	**P-value**
	3 (1–6)	**5 (3–7)**	**9 (6–13)**	**10 (10–11)**	**0.07**
Persisting stricture during follow-up, n(%)	1 (9.1)	15 (25.4)	4 (30.8)	0	0.5

Postoperative complications

Postoperative data is displayed in Table 2. Postoperative complications within 30 days occurred in 5 (5.8%) patients. 3 patients (5.1%) with bulbar/penobulbar stricture and 2 patients (15.4%) with bulbomembranous/membranous stricture without a significant difference between them (p = 0.4). There were no postoperative complications detected for patients treated with penile or bladder neck strictures.

Table 2
Postoperative data of patients treated with Optilume® drug-coated balloon for the management of urethral strictures.

Postoperative complications within 30 days, n(%)	**Penile (N = 11)**	**Bulbar/ Penobulbar (N = 59)**	**Bulbomembranous/ Membranous (N = 13)**	**Bladder neck (N = 3)**	**P-value**
	-	**3 (5.1)**	**2 (15.4)**	**-**	**0.4**
Length of indwelling urethral catheter [days], median (IQR)	0 (0–0.5)	2 (0–3)	1 (0–2)	0	0.02
Months of follow-up [months], median (IQR)	3 (1–6)	5 (3–7)	9.5 (6–13)	10.5 (10–11)	
Persisting stricture during follow-up, n(%)	1 (9.1)	15 (25.4)	4 (30.8)	0	0.5

Factors predictive of stricture recurrence

Factors predicting stricture recurrence are displayed in Table 5. On multivariate logistic regression analysis, diabetes was the only independent predictor of symptomatic stricture recurrence (OR = 7.66, 95% CI 1.55–47.12, p = 0.01).

Table 5
Multivariable logistic regression predicting stricture during follow up.

Variable	**Odds Ratio (95% CI)**	**p-value**
Age	1 (0.97–1.04)	0.8
Diabetes	7.66 (1.55–47.12)	**0.01**
Smoking	0.48 (0.12–1.5)	0.2
Stricture site	5.35 (0.74–115)	0.1
Prior radiation therapy	1.02 (0.08–13.74)	0.9

Discussion

In our multicentre, retrospective study we provide real-world data on effectiveness and functional outcomes of Optilume® DCB treatment of urethral stricture according to stricture location. Our results show favourable short- and mid-term results regarding stricture free rate and safety profile for all stricture locations. In our patient cohort, stricture-free rate during follow-up was the highest for bladder neck stricture, with no recurrence occurring, followed by penile strictures, bulbar/penobulbar and lastly bulbomembranous/membranous strictures.

The follow-up time was variable between the groups ranging from 3 months to 13 months. Functional outcomes, assessed by IPSS and Qmax before and after surgery, demonstrated symptom reduction and improvement in peak urinary flow across all stricture type groups. The rate of postoperative complications within 30 days after surgery was low with a total of 5 patients (5.8%) experiencing complications. In line with the current literature our data supports the high safety profile of Optilume® treatment across different stricture types.

Our study adds valuable real-word data for not only anterior urethral strictures but also posterior stricture types such as bulbomembranous/membranous and bladder neck strictures. As the recommendation for Optilume® use nowadays mainly relies on the results of the ROBUST III study, presenting a 83% stricture free rate for short anterior urethral strictures after 1 year (11), it is important to further investigate the effectiveness of Optilume® for also posterior urethral stricture disease to extend the use of application. Although only 3 patients in total were included in our analysis with bladder neck stricture, reducing the generalizability due to low patient count, it is notable that none of these patients developed a stricture recurrence, suggesting that patient with bladder neck stricture might benefit from Optilume® DCB treatment. These findings are in line with the results of Tosev et al. who reported a no stricture recurrence for their 16 patients with bladder neck stenosis and vesicourethral anastomosis stenosis treated with Optilume® DCB after 12 months (12).

Patients in our cohort with posterior urethral strictures were older than those with anterior strictures, with a median age of 74 years in the bulbomembranous/membranous group and 75 years in the bladder neck group. Given the greater comorbidity burden often associated with advanced age, minimally invasive approaches such as Optilume® may be particularly beneficial in this population. However, in a single-centre retrospective study, Karanjia et el. found no significant association between age and treatment failure after Optilume® treatment, suggesting that advanced age alone may not negatively impact treatment outcome (13). Thus, elderly patients may benefit from this minimally invasive, which can also be performed under local anaesthesia.

To optimize patient selection for different treatment modalities it is essential to look at comorbidities that could influence treatment effectiveness and functional outcome. On multivariant logistic regression analysis, diabetes was the only independent predictor of symptomatic stricture recurrence in our patient cohort. Diabetes mellitus is known to negatively influence wound healing due to impaired microvascular circulation, as well as promoting hypertrophic scar formation (14), which may plausibly contribute to recurrent urethral fibrosis and reduce treatment success following Optilume® treatment. Given the

importance of appropriate patient selection and individualized patient consulting, it is important that further studies evaluate the influence of comorbidities on treatment success.

This study has several limitations, which need to be acknowledged. The retrospective design of this study is a limitation itself leading to selection bias. Furthermore, the variability of the follow-up time between stricture type groups, ranging from 3 to 13 months, needs to be addressed because it limits comparability for stricture-free rates. In addition, the relatively short follow-up time in some stricture type groups only allows assessment of short-term outcomes so that conclusions regarding durability of treatment effects cannot be made. Moreover, the evaluation of stricture recurrence was defined as any symptomatic stricture in need of re-treatment, which may lead to underestimation of stricture recurrence due to the lack of cystoscopic confirmation.

Despite these limitations, our study adds important real-world data on the effectiveness and safety of Optilume® DCB dilatation for different stricture types as well as looking at factors influencing stricture recurrence.

Conclusion

Optilume® DCB showed encouraging efficacy and safety across different urethral stricture sites, achieving high stricture-free rates and improved urinary flow. Diabetes was the only factor independently associated with recurrence, highlighting the value of optimizing patient selection and individualized consultation. In the future larger, prospective, long-term studies are needed to validate these findings and define ideal candidates for Optilume® treatment.

Declarations

Conflict of Interest:

The authors declare that they have no conflict of interest.

Statement of human rights

All persons gave their informed consent to use their data (deidentified).

Compliance with Ethical Standards:

Ethical committee approval was given (BASEC 2025 – 01438).

Funding:

No funding was received for this study.

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Data Availability

The data supporting the findings of this study are not publicly available due to patient privacy and institutional restrictions. De-identified data may be made available from the corresponding author upon reasonable request and with permission of the participating institutions.

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