Case - Novel approach to complex female urethral stricture using paclitaxel-coated balloon dilation

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INTRODUCTION

KEY MESSAGES

- In male stricture disease, adjuvant technologies, such as the Optilume drug-coated balloon, have shown promise, but remain largely unexplored in women.
- This report is the first to evaluate the efficacy of Optilume in a female panurethral stricture, as well as in a patient with prior urethroplasty.
- Findings suggest that this minimally invasive approach may be a promising therapeutic option in women with recurrent urethral stricture.

Female urethral stricture (FUS), especially when recurrent, can severely impact quality of life via urinary retention, weakened stream, and increased risk of urinary tract infections and renal failure[1]—highlighting the need for effective treatment. However, given its rarity and the limited body of research, treatment guidelines for female patients are not well established—notably, the International Consultation on Incontinence omits FUS.[2] Moreover, most treatment modalities—including urethral dilation, direct visual internal urethrotomy and urethroplasty—are invasive or result in high recurrence and reintervention rates.[2–5] In male urethral stricture disease, adjuvants such as intralesional steroids, mitomycin C, and drug-coated devices have been suggested to address these limitations.[6] Among these, Optilume Drug-Coated Balloon Dilation (DCB) has demonstrated superior outcomes to standard endoscopic management, yet remains largely underexplored in women. By combining flexible balloon dilation with paclitaxel delivery—an anti-fibrotic and anti-mitotic drug—it reduces restenosis risk.[3]

This study presents the case of a female patient with recurrent FUS who had undergone multiple treatments using various modalities. To our knowledge, although a few cases of Optilume-treated FUS have been previously reported,[7–9] this is the first to provide extended follow-up and to evaluate its efficacy in both a panurethral stricture and in a patient

with prior urethroplasty. This work was prepared in accordance with the Consensus-based Clinical Case Reporting Guideline Development (CARE Guidelines).[10] Written informed consent for publication was obtained from the patient.

CASE REPORT

The patient, a now 70-year-old otherwise healthy woman, was diagnosed at 52 with idiopathic FUS following cystoscopy for voiding lower urinary tract symptoms. Between diagnosis and 2017, she underwent multiple urethral dilations and intermittent self-dilation.

In 2017, videourodynamic testing revealed signs suggestive of bladder neck stenosis, along with recurrent FUS. A bladder neck incision was performed with satisfactory initial results, and the patient was instructed to continue self-dilation. Her symptoms recurred six months later due to non-compliance, and she consented to undergo buccal mucosa graft (BMG) urethroplasty. While awaiting surgery, she developed acute urinary retention requiring suprapubic catheter placement.

In 2018, she underwent BMG dorsal onlay urethroplasty. She remained well until 2021, when voiding and storage symptoms recurred. Repeat cystoscopy revealed no significant obstruction; she was diagnosed with underactive bladder and prescribed twice-daily intermittent catheterization.

In 2023, now aged 70, she was unable to pass a 12 Fr catheter despite proper technique, due to complete urethral obstruction. A redo BMG urethroplasty was planned. However, the patient had resumed tobacco use after years of abstinence, prompting reconsideration of surgical risk. Additionally, during cystoscopy, the guidewire could only be advanced antegrade—via the suprapubic route. Optilume Drug-Coated Balloon (DCB) dilation was therefore selected over repeat urethroplasty. A 5 cm, 30 Fr balloon was deployed to span the panurethral stricture, and a 16 Fr urethral catheter was left in place for two weeks.

Overall, Optilume-DCB provided substantial symptom relief and improved quality of life, with no adverse events. Urodynamic assessments were performed at multiple time points. One month prior to treatment, her baseline parameters—maximum flow (mL/s)/voided volume (mL)/postvoid residual (mL)—were 2/40/180. At three months post-procedure, the uroflow had improved to 23/350/76, while at twenty months it was 10/59/120. Two years after surgery, a detailed interview was conducted. She reported: "If my voiding function were always like this, it would be wonderful. (…) I am very satisfied with how things are currently going" (Free translation). She described Optilume-DCB as significantly less invasive than urethroplasty, with comparable results, but expressed concern about the slight re-stenosis that had been detected at the 20-month follow-up. The patient chose to postpone the second Optilume-DCB dilation was then offered.

DISCUSSION

This report has limitations. A key limitation of its design is that it describes a single patient, which limits the generalizability of its findings. The lack of prior research on Optilume-DCB

in women also introduces the risk of overinterpretation. Nevertheless, the present findings underscore Optilume-DCB as promising for managing complex FUS.

The study's strengths lie in the detailed patient history, offering valuable insights into individualized care, and in the extended follow-up period of over two years. Previous reports of Optilume-DCB in women documented outcomes only up to an average of six to twelve months post-intervention.[5,8,9] We are also the first to report post-urethroplasty Optilume-DCB use for a female panurethral stricture and in a patient with prior urethroplasty.[5,8,9] This case thus contributes novel and critical data to a field where treatment options remain limited and often ineffective.

Among women with voiding lower urinary tract symptoms, only 2.7–8% have bladder outlet obstruction, and of these, 4–13% are attributed to FUS.[1] Unlike male urethral stricture, FUS is therefore rare and understudied.[6] Consequently, whether Optilume-DCB is suitable for women remains uncertain. Approved by the U.S. *Food and Drug Administration* (FDA) in 2022 for recurrent anterior strictures in men,[3] Optilume-DCB has been proposed as a safe and superior alternative to standard endoscopic treatments, supported by investigations such as the ROBUST trials.[3,11–13] Its minimally invasive nature and cost-effectiveness[14] have further contributed to its popularity, underscoring the importance of evaluating its use in women. This study helps fill that gap by suggesting the potential efficacy of Optilume in this population.

Results in the context of what is known

Although Optilume-DCB has been studied almost exclusively in males, these findings are consistent with the existing literature. The three-year results of the ROBUST III randomized controlled trial showed sustained symptomatic improvement in 67% of patients,[13] while the five-year outcomes from the ROBUST I study demonstrated sustained therapeutic success in 54%.[11] It is therefore unsurprising that this patient experienced a mild recurrence of symptoms just under two years post-procedure, yet remained overall satisfied with the outcome.

To the best of our knowledge, only a few cases of Optilume-treated FUS have been reported to date.[7–9] Stuehmeier et al. reported that their patient, who had a 1.8 cm stricture, experienced no complications and demonstrated significant improvement: urinary flow increased to 26 ml/s with no residual urine, a 16 Fr catheter passed without resistance, and the patient expressed satisfaction.[7] Thomas et al. found that six months post-procedure, their patient voided 135 ml with a peak flow of 5 ml/s and slightly prolonged flow time.[9] However, she had no residual urine, no bladder outlet obstruction symptoms, and no adverse events.[9] Finally, Jelisejevas et al. reported that, at a mean follow-up of 12 months, 11 of 12 patients remained free of stricture recurrence—defined as anatomical success (≥14 Fr on cystoscopy or calibration) and no reintervention.[8] No new incontinence or adverse events were observed.[8] The present study builds upon these initial findings by addressing their limited follow-up periods, and by being the first to evaluate Optilume-DCB in a female with panurethral stricture and prior urethroplasty. It also further supports the potential efficacy of this novel modality in female patients. Despite these promising results, further investigations with more robust designs are needed to draw reliable and generalizable conclusions.

CONCLUSIONS

FUS remains a therapeutic challenge, particularly in complex and recurrent cases. Optilume-DCB appears promising and may represent a valuable addition to the current treatment armamentarium. Further studies are warranted to confirm its efficacy.

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