Drug-Coated Balloon Treatment for Urethral Strictures: Is This the Future?

Kapriniotis K. et al., J Clin Med 2025;14:2854

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Background

- Urethral stricture: fibrotic narrowing of anterior urethra.
- Incidence ~0.6%; increases with age.
- Etiologies: idiopathic, iatrogenic, traumatic, inflammatory, infectious.
- Consequences: urinary retention, stones, renal impairment, QoL reduction.

Alwaal A. Transl Androl Urol 2014;3:209
Mundy AR. BJU Int 2011;107:6–26

Current Management

- Endoscopic options: Dilation, DVIU (success ≈60% for <2 cm bulbar strictures).
- Recurrence common, success near 0% after 3rd attempt.
- Urethroplasty: gold standard (>90% success), invasive and expertise-dependent.

Heyns CF. J Urol 1998;160:356–358
Barbagli G. World J Urol 2019;37:1165–1171

Rationale for Drug-Coated Balloon (DCB)

- Fibrosis and collagen deposition cause recurrence.
- Paclitaxel inhibits fibroblast proliferation and TGF-β activity.
- Used in angioplasty to prevent restenosis.
- Aim: prolong urethral patency, reduce recurrence.

Weaver BA. Mol Biol Cell 2014;25:2677–2681
Scheller B. N Engl J Med 2006;355:2113–2124

The Optilume™ Device

- Combines mechanical dilation and local drug delivery.
- Paclitaxel-coated balloon: lengths 3–5 cm, diameters 18–36 Fr.
- Indicated for recurrent anterior bulbar strictures <3 cm.
- Drug remains active 3–7 days due to lipophilicity.

Elterman DS. Can J Urol 2020;27:10322–10328

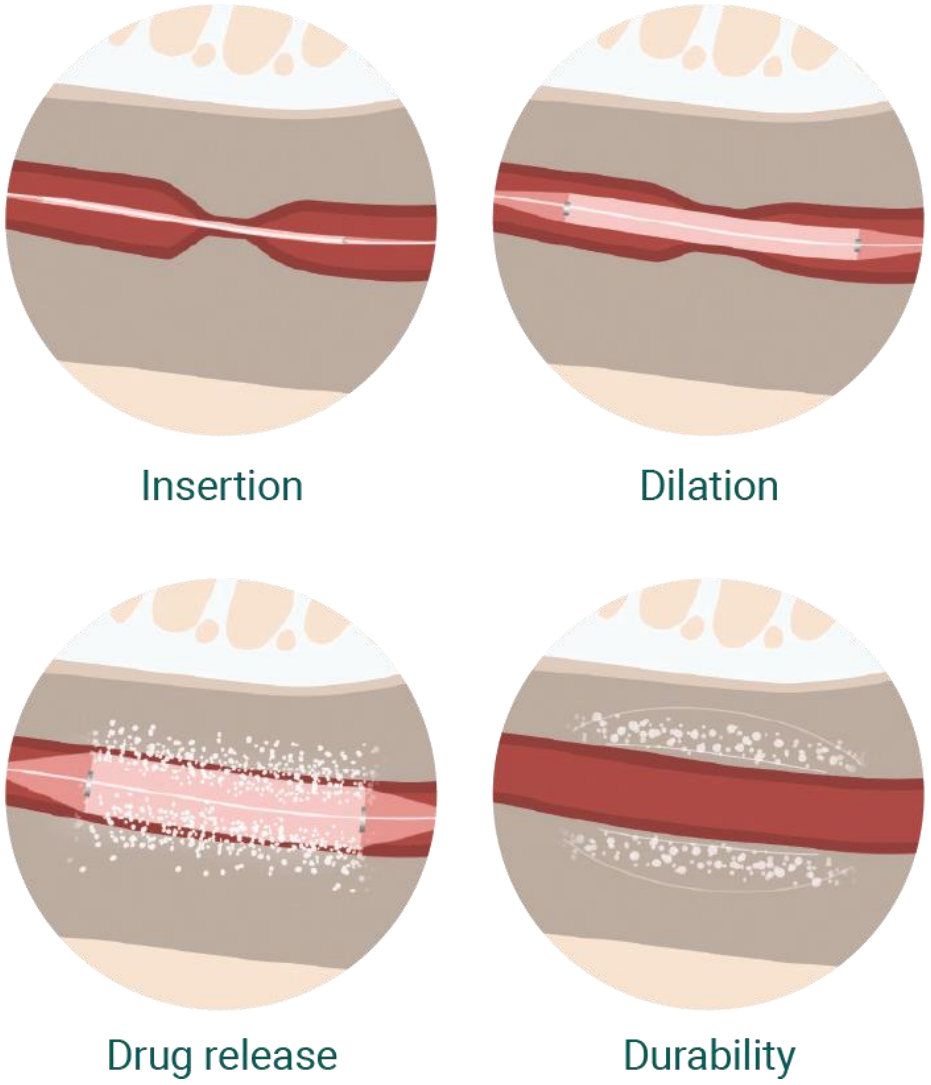
The Optilume device

Surgical Technique (Overview)

- Performed under local or general anesthesia.
- Cystoscopic/fluoroscopic guidance recommended.
- Guidewire → Balloon inflation (5 min) → Catheter 3–5 days.
- Barrier contraception advised for 1–6 months.

Virasoro R. Can Urol Assoc J 2020;14:187

The Optilume device



Technical Tips

- Pre-dilation optional.
- Balloon diameter slightly > healthy urethra (30 Fr typical).
- Avoid cystoscopy after inflation to prevent drug washout.

VanDyke ME. BJUI Compass 2024;5:366–373

Clinical Efficacy

- ROBUST I: IPSS ↓ 25.2→7.2 (5 yrs), Qmax ↑ 5→19.9 mL/s.
- ROBUST III: IPSS ↓ 22→10.1, Qmax ↑ 7.6→12.6 mL/s.
- Meta-analysis (457 pts): mean IPSS ↓13, Qmax ↑10 mL/s.

DeLong J. J Urol 2024;213:90–98
VanDyke ME. BJUI Compass 2024;5:366–373

Durability

- ROBUST I: 71% free from reintervention (5 yrs).
- ROBUST III: 77.8% reintervention-free (2 yrs).
- Most recurrences within first year.

DeLong J. J Urol 2024;213:90–98
VanDyke ME. BJUI Compass 2024;5:366–373

Safety

- Mild/transient AEs: hematuria (14%), dysuria (6–9%), UTI (6%).
- No severe complications.
- Sexual function preserved; paclitaxel detected in semen up to 6 months.

DeLong J. J Urol 2024;213:90–98
Elliott SP. J Urol 2022;207:866–875

Repeat DCB Use

- Recurrence rate ≈19%.
- Limited retreatment data; AUA advises against repeat DCB.
- Some partial successes reported.

Mahenthiran AK. Transl Androl Urol 2024;13:1498

Economic and Clinical Benefits

- Minimally invasive, fast recovery.
- NHS analysis: cost saving over 5 yrs (£243 vs urethroplasty, £2502 vs endoscopy).
- Cost-effective with minimal adverse events.

Kelly L. BJUI Compass 2023;4:430–436

Guidelines

- EAU 2024: weak recommendation for recurrent bulbar <3 cm, after ≥2 failed endoscopic.
- AUA 2023: grade B recommendation for palliative use when urethroplasty not feasible.

Wessells H. J Urol 2023;210:64–71
EAU Guidelines 2024

Future Directions

- Evaluate DCB in penile, post-radiation, and female strictures.
- Explore combined drug-eluting technologies and antifibrotic agents (mitomycin C, ROCK inhibitors).
- Need standardized definitions and long-term RCTs.

Luo H. Asian J Androl 2024;26:1–9

Conclusions

- DCB (Optilume) is effective, safe, durable for recurrent short bulbar strictures (<3 cm).
- Alternative for patients unfit for urethroplasty.
- Urethroplasty remains gold standard for complex/long strictures.