



Two-year Outcomes of a Paclitaxel-Coated Balloon for treatment of male bulbar urethral stricture

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Background

- Dilation and DVIU are the most common treatments for urethral stricture but have poor long-term success compared to urethroplasty
- Steroid and Mitomycin C injection have inconsistent results and can be user-dependent
- Optilume™ is a drug-coated balloon that combines urethral dilation with circumferential delivery of paclitaxel
- We have reported 70% 1-year anatomic success (lumen >14F) and herein report 2-year safety and functional success (i.e., by IPSS) .

Methods

- Single-arm prospective, open-label study
- Eligibility
 - Men >= 18 years
 - Single bulbar stricture
 - <12 F
 - Stricture length <= 2.0cm
 - IPSS >= 13
 - Qm < 10 cc/s
 - 1 to 4 prior treatments
- Procedure
 - Pre-dilation or DVIU before Optilume inserted
 - Balloon size 3cm long and 24F or 30F
 - Inflated for 5 minutes
- Follow-up
 - Catheter for 3 days
 - IPSS and Qm at 3, 6, 12 months and annually until year 5
 - Cystoscopy at 6 and 12 months
- Outcomes
 - Safety
 - Success = IPSS improvement ≥ 50% after 24 months in the absence of re-treatment
 - Failure = no IPSS improvement ≥ 50% at the time of study exit; or re-treatment

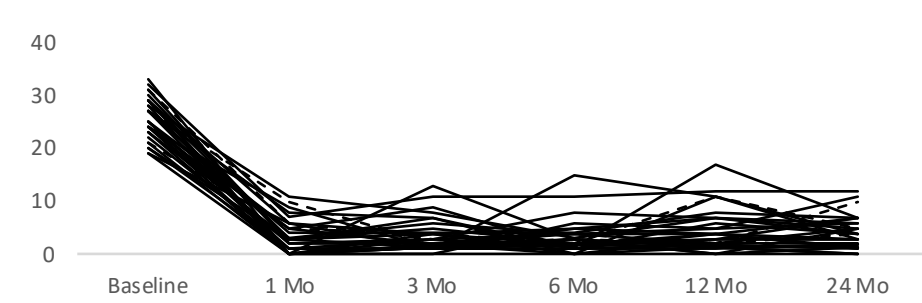
Baseline Characteristics

Patient Demographics	Total N = 53
Age (years)	
Mean ± SD	50.7 ± 15.47
Range	22.0 to 81.0
Median	50.0
Male Gender, n/N (%)	53 / 53 (100.0 %)
Race of Subjects, n/N (%)	
Black or African Origin	8 / 53 (15.1 %)
Hispanic or Latino	44 / 53 (83.0 %)
Other	1 / 53 (1.9 %)
Suprapubic catheter at baseline	7/53 (13.2 %)
Stricture Etiology, n/N (%)	
Iatrogenic	24/53 (45.3%)
Idiopathic	2/53 (3.8%)
Traumatic	27/53 (50.9%)
Stricture Measurements in mm, Mean ± SD (N)	
Stricture length	9.00 ± 5.20 (53)
Urethral diameter at stricture in mm	2.47 ± 1.97 (53)
Urethral diameter in normal urethra in mm	10.20 ± 3.62 (53)
Pre-treatment	
Uncoated balloon	31/53 (58%)
DVIU	8/53 (15%)
Uncoated balloon + DVIU	14/53 (26%)
No. of Prior Endoscopic Treatments, n/N (%)	
1	30/53 (57%)
2	13/53 (25%)
3	9/53 (17%)
4	1/53 (2%)

Safety Outcome – Adverse Events

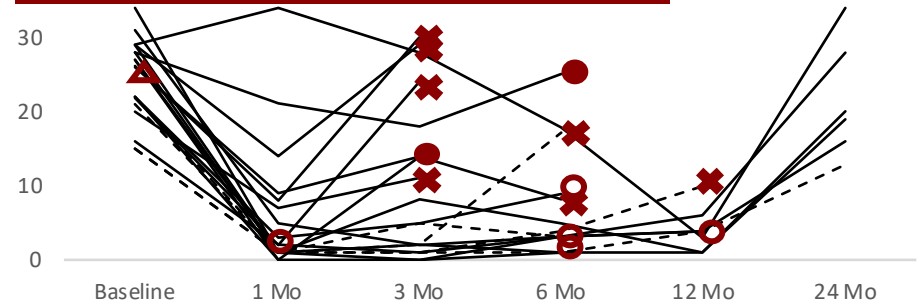
Related to Treatment?	Degree of Adverse Event			Total
	Mild	Moderate	Severe	
Not related	30	13	6	49
Unlikely related	4	2	0	6
Possibly related	2	3	0	5
Probably relate	5	3	0	8
Definitely related	2	1	0	3
Total	43	22	6	71

IPSS Over Time Among Successes (32/46 = 70% success)



Success defined as IPSS improvement ≥ 50% after 24 months in the absence of re-treatment. 3 had anatomic recurrence (<14F) at 6 or 12 months but still met criteria for functional success at 24 months.
 ---- = Failed ULT

IPSS Over Time Among Censors (n=7) and Failures (n=14)



Failure defined as (1) no IPSS improvement ≥ 50% at the time of study exit or (2) re-treatment. 4 had anatomic recurrence (<14F); 1 underwent re-treatment, 1 was censored at 6 months with an IPSS of 1, and 2 exited the study without ≥ 50% IPSS improvement.
 --- Anatomic recurrence ○ Early exit with ≥ 50% IPSS improvement
 △ Lost to follow-up before 1st visit ● Early exit without ≥ 50% IPSS improvement; one exit at 12-months had open urethra on cystoscopy and was censored without failure because symptoms judged to be due to BPH
 ✕ Re-treatment

Subset analyses

- 29/34 men with anatomic success at 12 months continued to be functionally successful at 24 months
- Of the 7 with anatomic recurrence at 12 months, 3 continued to be functionally successful at 24 months
- 24F balloon was successful in 12/23 (52%)
- 30F balloon was successful in 20/23 (87%)

Conclusions

- Optilume is safe
- 70% functional success at 2 years
- Outcomes are better with the larger 30F balloon
- Randomized trial is underway