

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

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# 2-year analysis of 5-year single-arm open-label study of Paclitaxel-coated balloon for <2cm bulbar stricture

Previously presented 1-year anatomic success. Now 2-year functional success

## Eligibility and Procedure

### Eligibility

- Men  $\geq$  18 years
- Single bulbar stricture
- $<12$  F
- Stricture length  $\leq$  2.0cm
- IPSS  $\geq$  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 and Outcomes

### 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

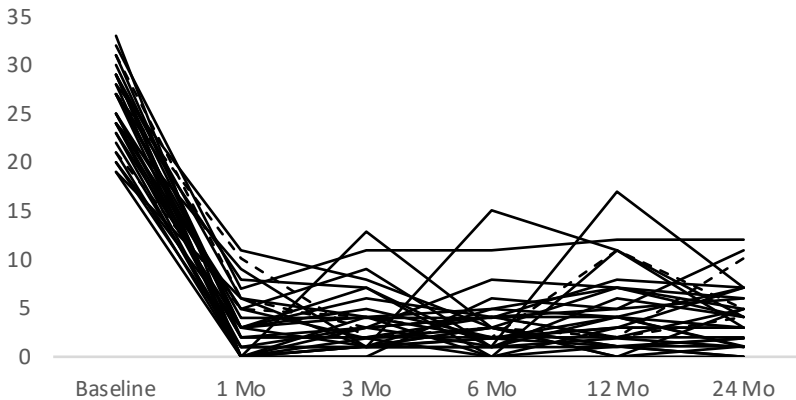
- Safety
- Success = IPSS improvement  $\geq$  50% after 24 months in the absence of re-treatment
- Failure = no IPSS improvement  $\geq$  50% at the time of study exit; or re-treatment



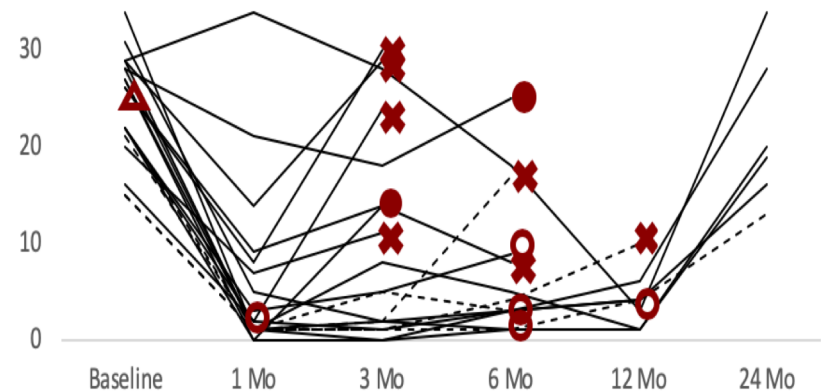
# 70% 2-year functional (i.e., symptomatic) success

No severe adverse events attributable to the device

## Successes: IPSS over time (32/46 = 70%)



## Failures (n=14) and Censors (n=7): IPSS over time



## Conclusions

- Optilume is safe
- 70% functional success at 2 years
- Outcomes are better (87%) with the 30F balloon than the 24F (52%)
- Randomized trial is underway

