

# 4 Years of the Optilume® Drug Coated Balloon for recurrent anterior urethral strictures: a summary of ROBUST I, II and III

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Introduction

Methods

The Optilume Drug Coated Balloon has been studied in three clinical investigations (ROBUST I, II and III). ROBUST I, the first in man trial conducted as a single arm, prospective multicenter study in Latin America (4 sites, 53 subjects) followed by ROBUST II, early feasibility (5 sites, 15 subjects), and ROBUST III, the randomized controlled pivotal trial (79 Optilume, 48 Control). Data combined from all three studies is presented here.

A total of 148 subjects were treated with Optilume in ROBUST I, II and III in Latin America, Canada, and the United States. Follow-up was completed at 3 months, 6 months and annually thereafter. All studies were designed to follow subjects through 5 years with RB1 at 4-year follow-up, RB2 at 3-year follow-up and RB3 at 2-year follow-up, currently.

**Eligibility criteria included:**

- adult males with anterior strictures
- $\geq 1$ -4 prior treatments
- stricture length  $\leq 3$ cm

**Endpoints included:**

- freedom from repeat intervention
- International Prostate Symptom Score (IPSS)
- peak urinary flow rate (Qmax)

Results

International Prostate Symptom Score (IPSS) improved in all patients treated with Optilume from 22.5 at baseline to 7.8 at 4 years. Peak urinary flow rate (Qmax) had a sharp improvement and is sustained through follow-up (7.1 to 14). Freedom from repeat intervention is approximately 73% at 4-year follow-up. There were no serious treatment related adverse events.



Conclusion

Subjects with recurrent bulbar strictures treated with Optilume® paclitaxel-coated balloon exhibited significant improvement in symptomatic and functional outcomes through 4 years post treatment with demonstrably improved recurrence rates. There was no impact on erectile function and there were no serious adverse events.