

# Initial Safety and Efficacy outcomes of a novel drug-coated balloon (DCB) for treatment-refractory stricture disease—The ROBUST I Study



DRUG-COATED UROLOGY BALLOON

R. Virasoro, MD, J. DeLong, MD, R. Estrella, MD, M. Pichardo, MD, R. Rodriguez Lay, MD, G. Espino MD, G. Suarez, MD, S. Elliott, MD—Urotronic, Minneapolis, Minnesota, USA

## Objective

Determine the safety and effectiveness of a novel drug-coated balloon (Optilume™ DCB) in the treatment of recurrent urethral strictures

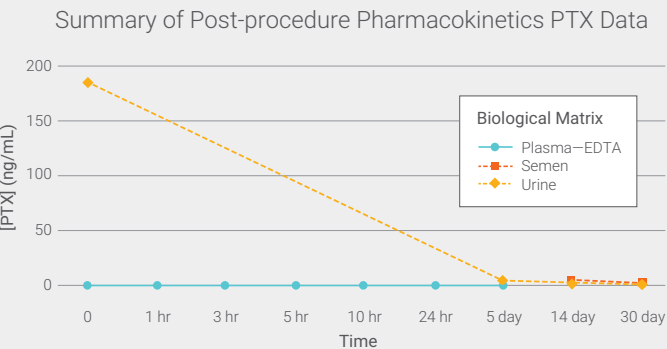


## Methods

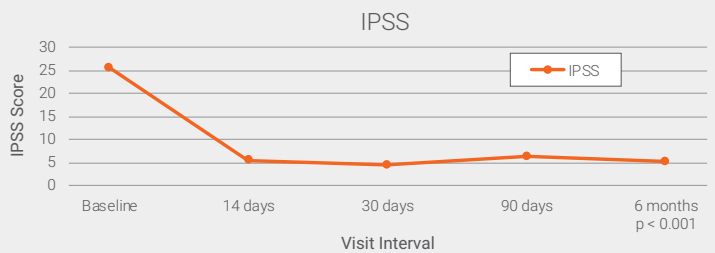
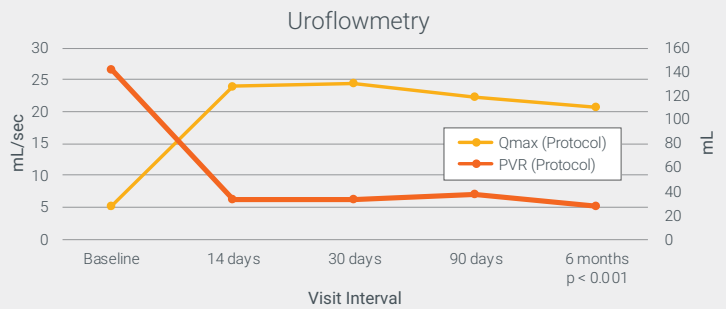
- 4 sites in Latin America (Panama and Dominican Republic)
- 53 male subjects enrolled with bulbar urethral stricture ≤2cm with 1–3 prior treatments
- Optilume DCB procedure inflated under cystoscopic vision, placement confirmed via fluoroscopy
- Subject follow-up at 2–5 days, 14 days, 3 and 6 months post-treatment
- Primary outcome: anatomic success at 6 months—defined as urethral caliber >14F
- Secondary outcomes: International Prostate Symptom Score (IPSS) and uroflowmetry

## Pharmacokinetics

- 21 subjects participated in paclitaxel pharmacokinetic testing (PK)
  - Blood plasma, urine and semen samples taken post-treatment
- PK testing confirmed paclitaxel levels below the lower limit of quantification (BLQ) in both plasma and semen
- Paclitaxel present in urine as expected
  - Reduced to near the detectable limit around day 14



AGE	50 ± 15.5	22–81
RACE	83% Hispanic, 5% Black, 2% Other	
LUTS SYMPTOMS	100% (53/53)	
URETHRAL STRICTURE ETIOLOGY	Iatrogenic	45.3% (24/53)
	Idiopathic	3.8% (2/53)
	Traumatic	50.9% (27/53)
ANATOMIC LOCATION	Bulbar	100% (53/53)
RETENTION (LUMINAL OBLITERATION)	Near total occlusion	50.9% (27/53)
	Patent urethra	49.1% (26/53)
STRICTURE LENGTH (CM)	Mean ± SD	0.9 ± 0.52



- No serious or unexpected adverse events (AEs)
- Anatomic success in 73.2% of subjects (30/41)

## Conclusion

At 6 months, the Optilume drug-coated balloon:

- 73% anatomical success (stricture free)
- 310% increase in peak flow rate (Qmax)
- Significant decrease in IPSS (p<0.001)
- Demonstrated an acceptable safety profile
- Had a low re-treatment rate (9%) in a challenging (≥2x previous dilations) patient population