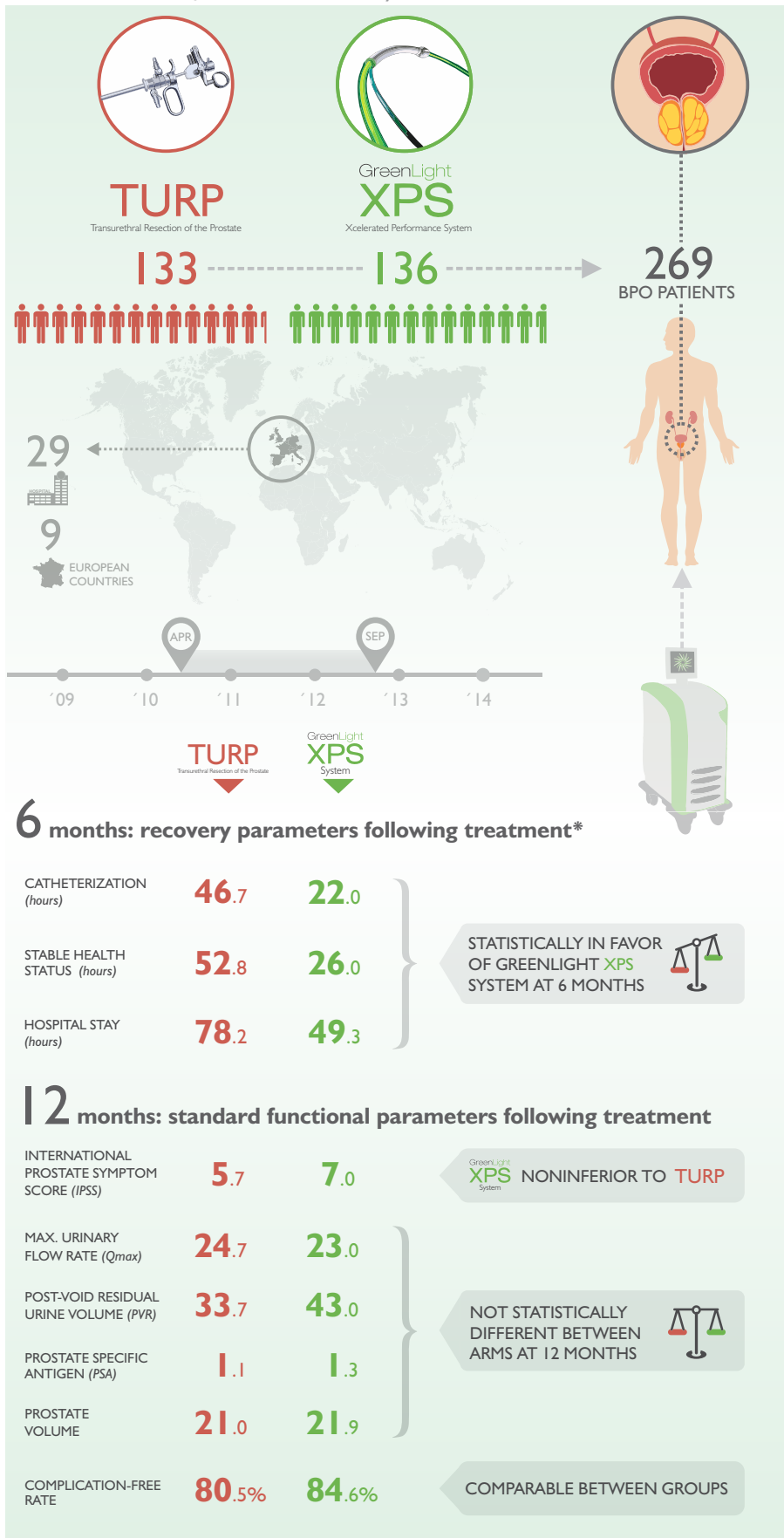


A European Multicenter Randomized Noninferiority Trial Comparing 180 W GreenLight XPS Laser Vaporization and Transurethral Resection of the Prostate for the Treatment of Benign Prostatic Obstruction:

12-Month Results of the GOLIATH Study



6-month values shown in median.  
12-month values shown in mean.



**Study Method**

- Oxford level 2 evidence
- Prospective, randomized, multi-center
- 291 patients enrolled from 29 sites in 9 European countries
- 269 patients treated: 136 GreenLight XPS™ Laser Therapy System; 133 TURP
- Period: April 2011 and September 2012

**Study Objective**

- Evaluate the hypothesis that GreenLight XPS is noninferior to TURP on the International Prostate Symptom Score at 6 months. Several objective parameters were assessed, including maximum urinary flow rate, post-void residual urine volume, prostate volume and prostate specific antigen, in addition to functional questionnaires and adverse events at each follow-up.

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**Authors:**

- Alexander Bachmann, Andrea Tubaro, Neil Barber et al.

**Materials and Methods:**

- The primary end point of the study was I-PSS at 6 months. The study also evaluated Q<sub>max</sub>, PVR, PSA, prostate volume and AEs, and used validated questionnaires to assess erectile function, continence, bladder symptoms and quality of life issues (IIEF-5, ICIQ-SF and OABq-SF, SF-36).

**Key Results:**

- Noninferiority of GreenLight XPS was maintained at 12 months.
- Maximum urinary flow rate, post-void residual urine volume, prostate volume and prostate specific antigen were not statistically different between the treatment arms at 12 months.
- The complication-free rate at 1 year was 84.6% after GreenLight XPS vs 80.5% after transurethral resection of the prostate.
- At 12 months, 4 patients treated with GreenLight XPS and 4 who underwent transurethral resection of the prostate had unresolved urinary incontinence.
- More than 90% of the patients in both arms would go through the procedure again and would recommend the therapy.
- Time until stable health status, length of catheterization, and length of hospital stay were superior with GreenLight XPS (p < 0.001).\*

**Limitations:**

- Blinding of the subject, treating surgeon, and all site personnel was not attempted in the present study due to significant technological and procedural differences between GreenLight XPS and TURP. However, AEs were blindly adjudicated by an independent CEC.

\* Bachmann A, Tubaro A, Barber N et al: 180-W XPS GreenLight laser vaporisation versus transurethral resection of the prostate for the treatment of benign prostatic obstruction: 6-month safety and efficacy results of a European Multicentre Randomised Trial - The GOLIATH study. Eur Urol 2014; 65: 931.

The GreenLight™ laser system is intended for incision/excision, vaporization, ablation, hemostasis and coagulation of soft tissue, including photoselective vaporization of the prostate for benign prostatic hyperplasia (BPH). The laser system is contraindicated for patients who: are contraindicated for surgery, contraindicated where appropriate anesthesia is contraindicated by patient history, have calcified tissue, require hemostasis in > 2mm vessels, have uncontrolled bleeding disorders, have prostate cancer, have acute urinary tract infection (UTI) or severe urethral stricture. Possible risks and complications include, but are not limited to, irritative symptoms (dysuria, urgency, frequency), retrograde ejaculation, urinary incontinence, erectile dysfunction, hematuria - gross, UTI, bladder neck contracture/outlet obstruct, urinary retention, perforation - prostate, urethral stricture.

Prior to using these devices, please review the Operator's Manual and any accompanying instructions for use for a complete listing of indications, contraindications, warnings, precautions and potential adverse events.

**Rx Only**