

# Five Year Results of the Prospective, Randomized Controlled Trial of Water Vapor Thermal Therapy for Treatment of Lower Urinary Tract Symptoms Due to Benign Prostatic Hyperplasia

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# 5-Year Data Overview

## Objective

- To evaluate the safety and efficacy of the Rezūm™ System and assess its effect on urinary symptoms secondary to benign prostatic hyperplasia (BPH)
- Primary Endpoints: safety and efficacy

## Key elements of the study design

- Randomized, sham control trial (rigid cystoscopy)
- Prostates between 30 and 80g
- Patients with a median lobe were not excluded
- Durability analysis: per protocol
- 60-month follow-up

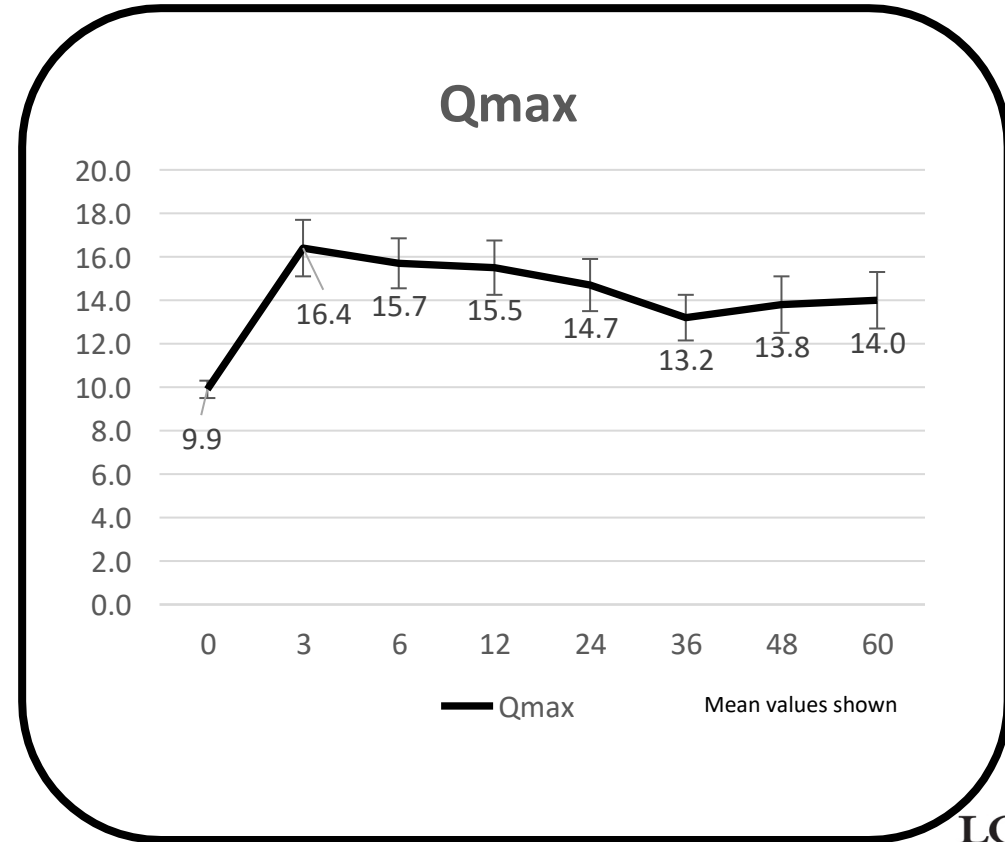
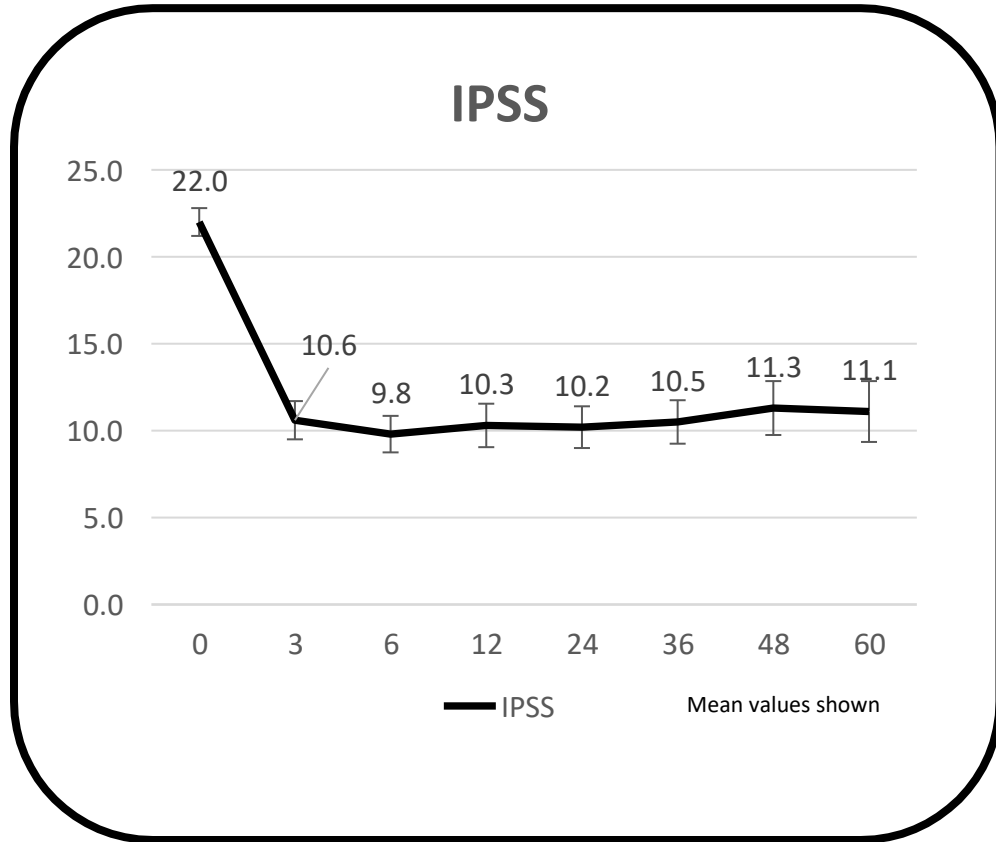
## 5-Year Data:

- Co-authors:
  - Dr. Kevin McVary, Loyola University Medical Center
  - Dr. Claus Roehrborn, UT Southwestern Medical Center
- Journal: Final data with cross over groups to be submitted to a peer reviewed journal

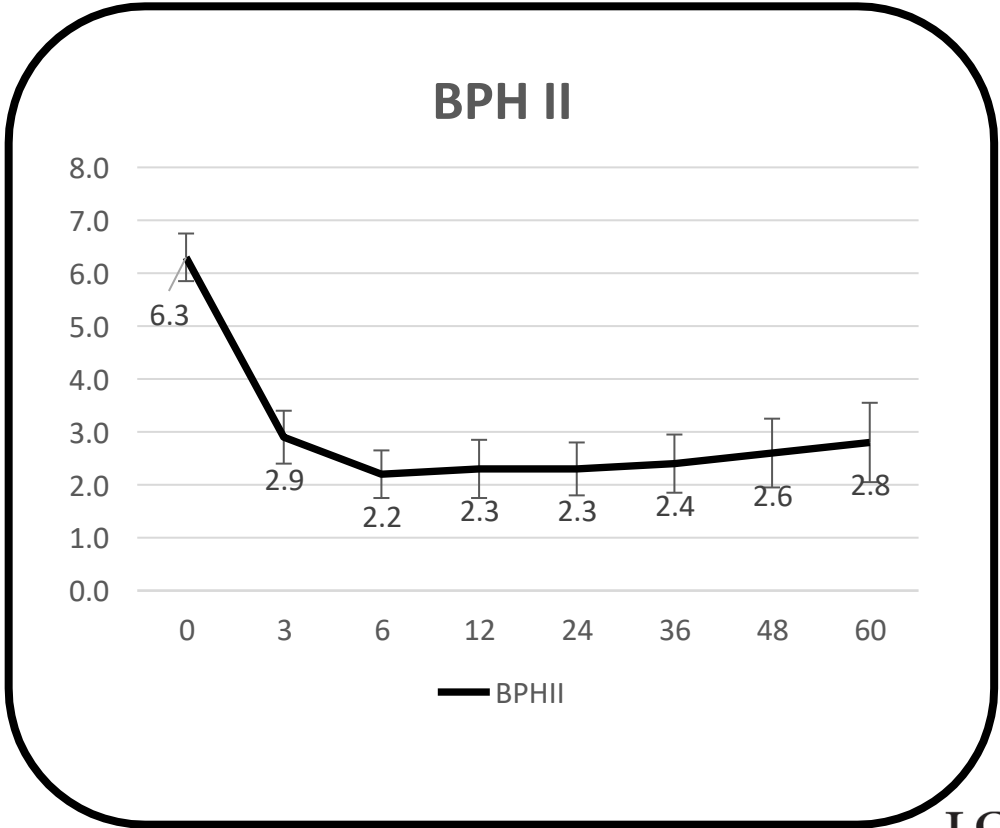
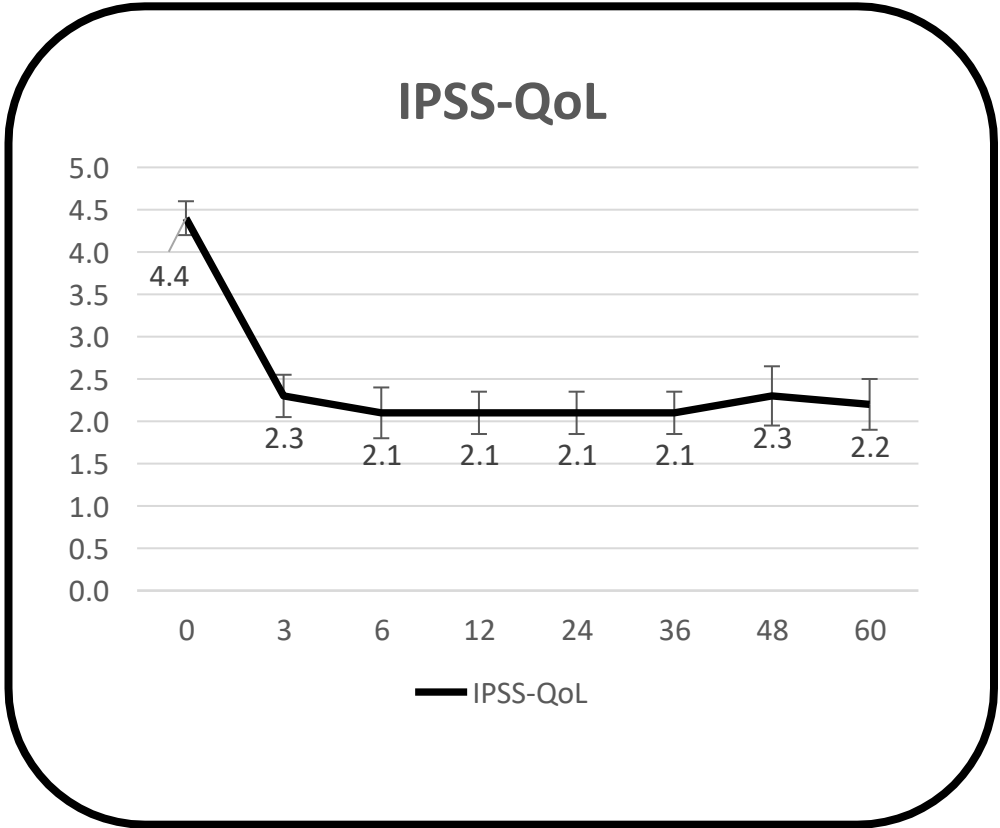


# IPSS and Qmax

Significant improvement from baseline through 5 yrs



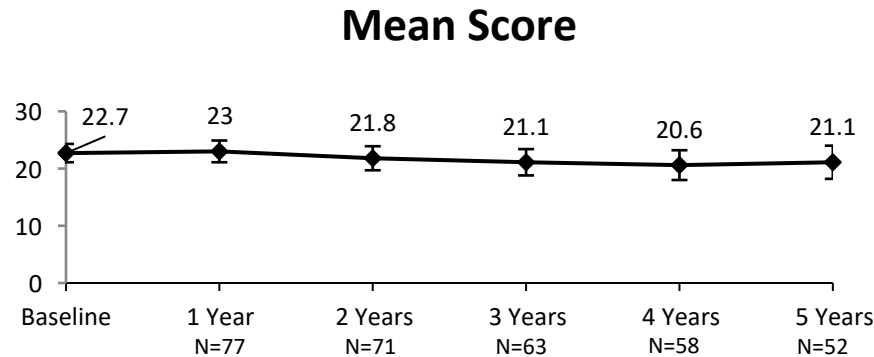
# IPSS QoL and BPH II: Significant improvement from baseline through 5 yrs



# Sexual Function: IIEF, MSHQ Function & Bother

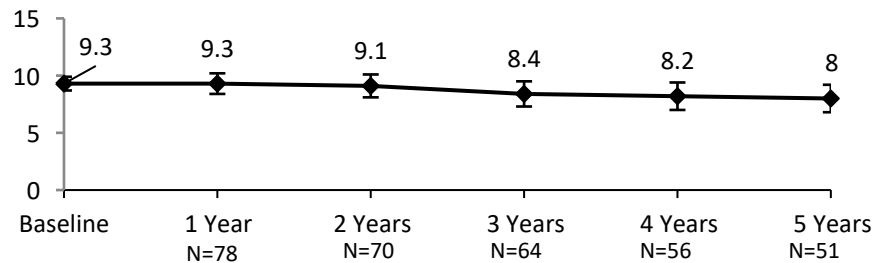
## IIEF<sup>†</sup>

Erectile function, orgasmic function, sexual desire, intercourse satisfaction and overall satisfaction



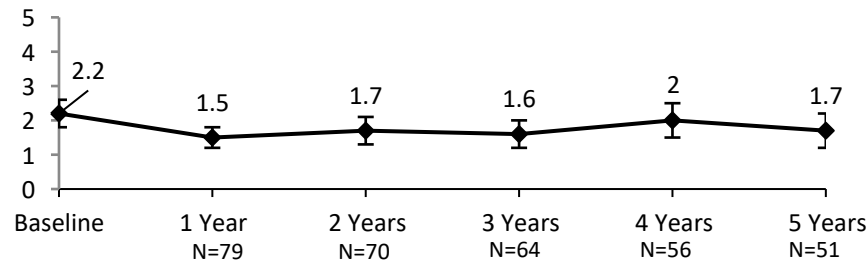
## MSHQ Function<sup>†</sup>

Frequency, strength and volume of ejaculation



## MSHQ Bother<sup>\*</sup>

Bother/satisfaction with ability to ejaculate



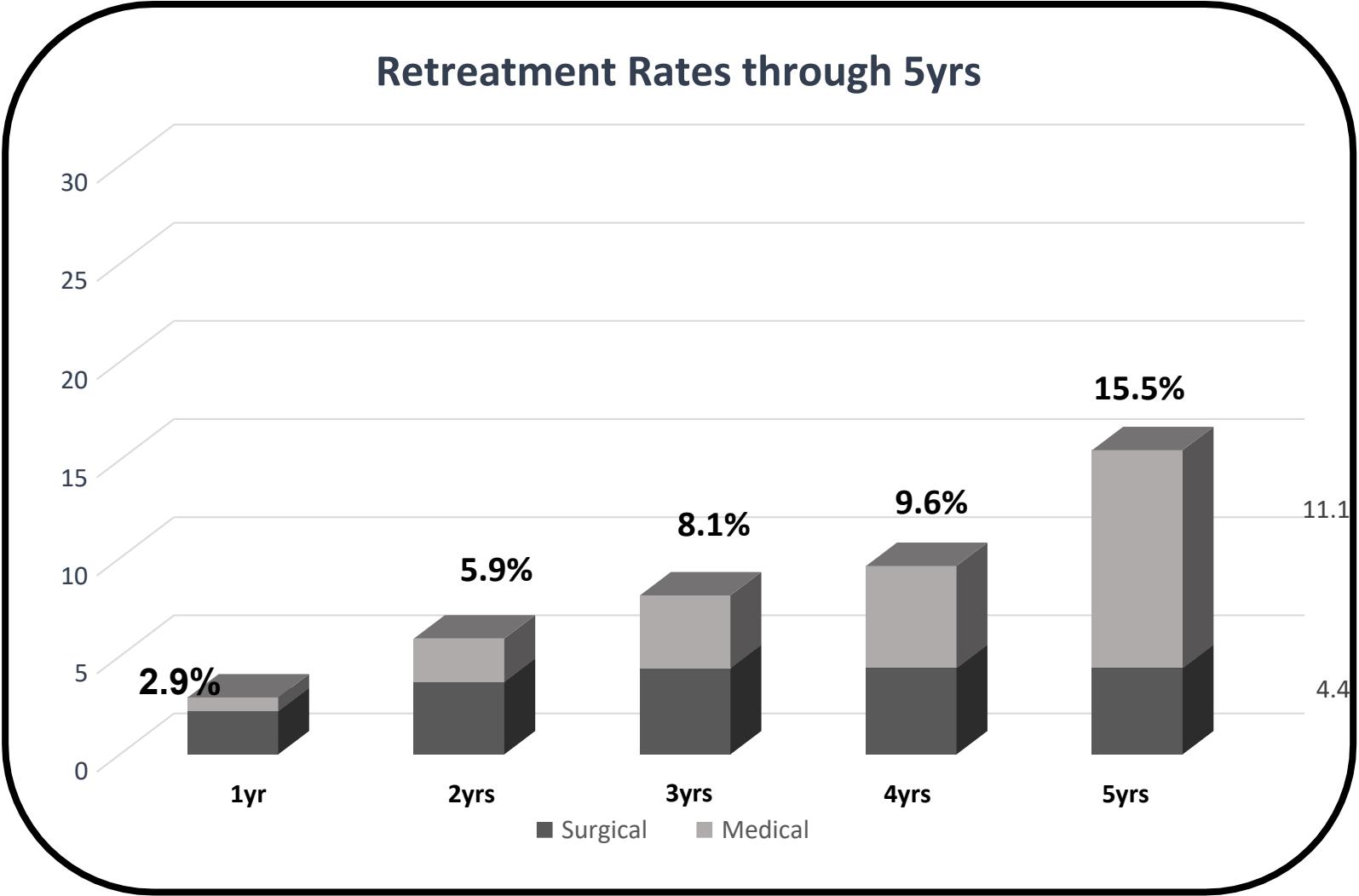
## Key Points

- 1) **No de novo erectile dysfunction & limited impact on sexual function**
- 2) **Patients had sexual function issues at baseline<sup>1</sup>**
  - 90 of 135 men were sexually active
  - 53% had history of ED
  - 25% had EjD



<sup>†</sup> Decrease indicates decline  
<sup>\*</sup> Decrease indicates improvement

# Rezūm treatment remains durable through 5 yrs



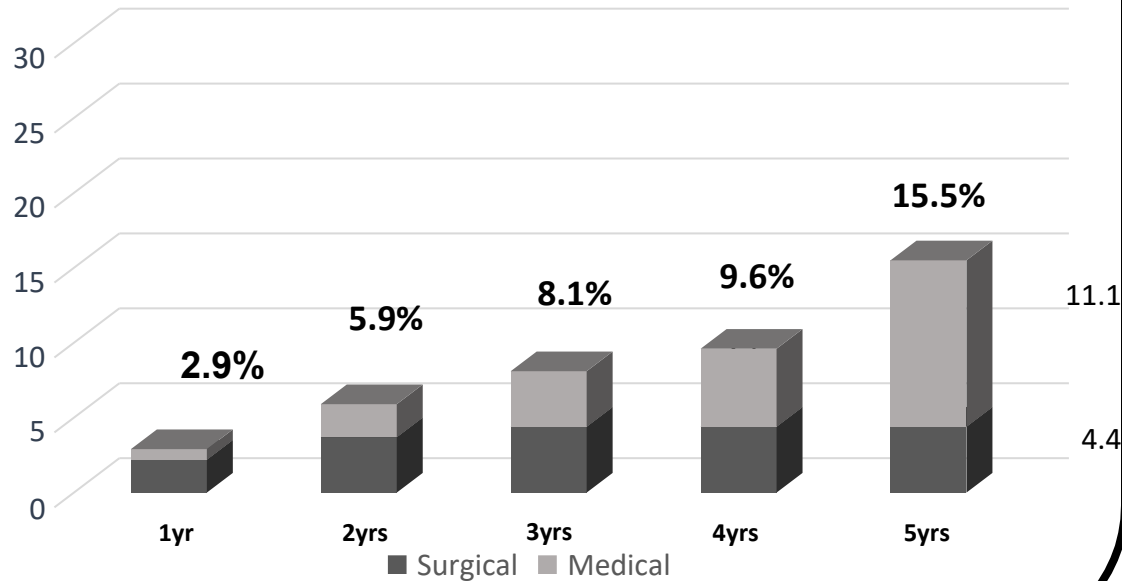
# Key Takeaways

- **Proven durability for treatment of BPH**
  - 4.4% surgical retreatment rate through 5 years
  - 11.1% medical retreatment rate through 5 years
- **Significant, sustained improvement of lower urinary tract symptom (LUTS) and quality of life for patients with BPH from baseline**
  - IPSS 48% improvement through 5 yrs
  - Qmax 49% improvement through 5 yrs
  - IPSS QOL 46% improvement through 5 yrs
  - BPH II 49% improvement through 5 yrs
- **Able to treat prostates with hyperplasia of the lateral lobes, central zone and/or a median lobe**

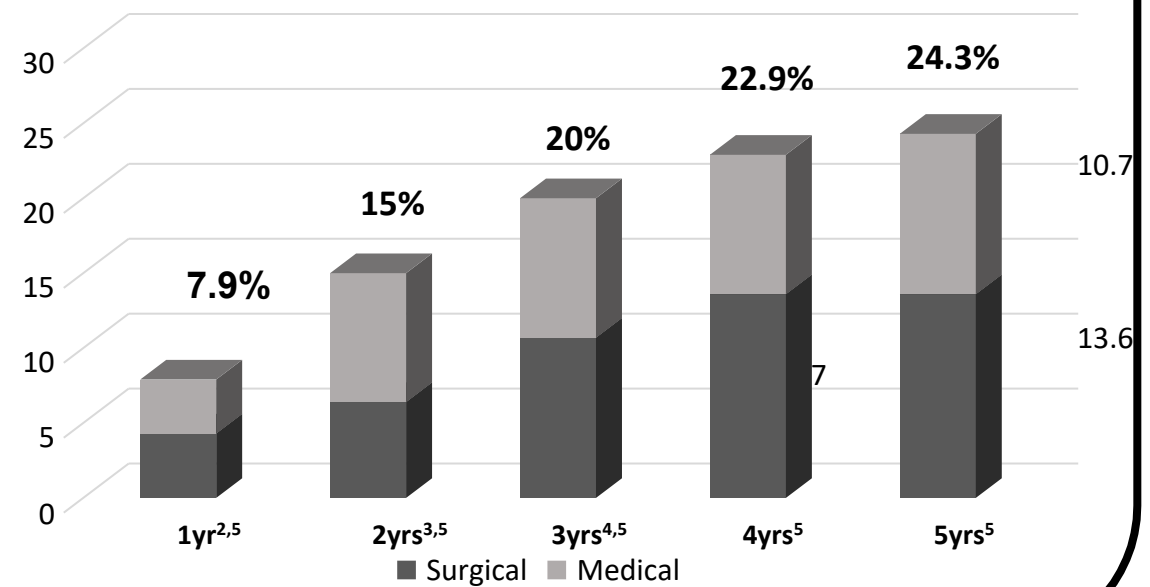


# Retreatment rates: Rezūm™ and UroLift™ Pivotal Studies

Rezūm II Pivotal Study  
Retreatment Rates through 5 yrs



LIFT Pivotal Study  
Retreatment Rates through 5 yrs



Because the data from Rezūm and the UroLift System studies was not collected in a head-to-head study, direct comparisons between Rezūm and the UroLift System cannot be made.

Results from different clinical investigations are not directly comparable. Information provided for educational purposes only.





# 5 Year Results of the Prospective, RCT of Water Vapor Thermal Therapy for Treatment of LUTS/BPH

## Clinical investigators and institutions participated in the Rezūm Clinical Study:

J. Randolph Beahrs—Metro Urology, Woodbury, MN

Chris Cantrill—Urology San Antonio Research, San Antonio, TX

Barrett E. Cowan—Urology Associates of Denver, Englewood, CO

Steven N. Gange—Western Urologic Clinic, Salt Lake City, UT

Marc C. Gittelman—South Florida Medical Research, Aventura, FL

Kenneth A. Goldberg—Texas Urology, Carrollton, TX

Jed Kaminetsky—Manhattan Medical Research, New York, NY

Richard Levin—Chesapeake Urology Research, Towson, MD

Lance A. Mynderse—Mayo Clinic, Rochester, MN

Kalpesh Patel—Arizona Institute of Urology, Tucson, AZ

Michael Rousseau—The Urology Group, Cincinnati, OH

Neal D. Shore—Carolina Urologic Research, Myrtle Beach, SC

James C. Ulchaker—Cleveland Clinic, Cleveland, OH;

**Scientific advisors:** Thayne R. Larson—Institute of Medical Research, Scottsdale, AZ;

Christopher M. Dixon—Lenox Hill Hospital, New York, NY.

