

Study Title: THREE-YEAR OUTCOMES OF THE PROSPECTIVE, RANDOMIZED CONTROLLED REZŪM SYSTEM STUDY: CONVECTIVE RADIOFREQUENCY THERMAL THERAPY FOR TREATMENT OF LOWER URINARY TRACT SYMPTOMS DUE TO BENIGN PROSTATIC HYPERPLASIA

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Objective

To report 3-year outcomes of a prospective, multicenter, randomized, blinded control trial after treatment with convective radiofrequency (RF) water vapor thermal therapy for moderate-to-severe lower urinary tract symptoms (LUTS) due to benign prostatic hyperplasia (BPH).

Materials and Methods

Fifteen centers enrolled and randomized 197 men ≥ 50 years old with International Prostate Symptom Score (IPSS) ≥ 13 , maximum flow rate (Q_{max}) ≤ 15 mL/s, and prostate volume 30 to 80 cc to thermal therapy with Rezūm™ System or control (2:1). Rigid cystoscopy with simulated active treatment sound effects served as the control procedure. Convective RF thermal energy was delivered into obstructive prostate tissue including the median lobe as needed. After randomized comparison at 3 months, thermal therapy subjects were followed annually for 3 years.

Results

Convective RF thermal therapy yielded IPSS improvement of 160% compared with control subjects at 3 months ($P < .0001$). Maximal symptom relief of at least 50% improvement in IPSS, quality of life, Q_{max}, and BPH Impact Index remained durable throughout 3 years ($P < .0001$). Subjects with a treated median lobe had similar responses. No late-related adverse events occurred, and no de novo erectile dysfunction was reported. The surgical retreatment rate was 4.4% over 3 years.

Conclusions

The minimally invasive convective RF thermal therapy is an office or ambulatory outpatient procedure with minimal transient perioperative side effects. It provides early, effective and durable relief of BPH symptoms with preservation of sexual function in subjects followed up for 3 years, and is applicable to treatment of the median lobe and hyperplastic central zone tissue.

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