

**Study Title:** REZŪM SYSTEM WATER VAPOR TREATMENT FOR LOWER URINARY TRACT SYMPTOMS/BENIGN PROSTATIC HYPERPLASIA: VALIDATION OF CONVECTIVE THERMAL ENERGY TRANSFER AND CHARACTERIZATION WITH MAGNETIC RESONANCE IMAGING AND 3-DIMENSIONAL RENDERINGS

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## Objective

To evaluate by magnetic resonance imaging the physical effects of convective thermal energy transfer with water vapor as a means of treating lower urinary tract symptoms due to benign prostatic hyperplasia (BPH).

## Methods

Sixty-five men with lower urinary tract symptoms were treated with the Rezūm™ System by transurethral intraprostatic injection of water vapor. A group of 45 of these men consented to undergo a series of gadolinium-enhanced magnetic resonance imagings of the prostate after treatment to monitor the size and location of ablative lesions, their time course of resolution, and the corresponding change in prostate tissue volume. Visualization was conducted at 1 week, and 1, 3, and 6 months after treatment.

## Results

Outcomes were available for 44 patients. Convective thermal lesions were limited to the transition zone and correlated with targeted treatment locations. At 1 week after treatment, the mean volume of ablative lesions was 8.2 cm<sup>3</sup> (0.5-24.0 cm<sup>3</sup>). At 6 months, whole prostate volume was reduced by a mean of 28.9% and transition zone volume by 38.0% as compared with baseline 1-week images. At 3 and 6 months after treatment, the lesion volumes had reduced by 91.5% and 95.1%, respectively. Lesions remained within the targeted treatment zone without compromising integrity of the bladder, rectum, or striated urinary sphincter.

## Conclusions

This imaging study confirms the delivery of convective water vapor technology to create thermal lesions in the prostate tissue. Lesions generated underwent near complete resolution by 3 and 6 months after treatment, with a concomitant one-third reduction in overall prostate and transition zone volumes.

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