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INITIAL EVALUATION OF A NOVEL MODULATED RADIOFREQUENCY-BASED BLADDER DENERVATION DEVICE

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INTRODUCTION

We developed a novel ablation device (Denerblate) incorporating an intravesical balloon with selectively mounted electrodes, thermal and impedance sensors, a novel energy algorithm, and insulation material for highly targeted and modulated radiofrequency ablation (RFA). We hypothesized that the application of carefully modulated RFA on the urinary bladder will reduce bladder nerve density, which could ultimately result in a novel way of managing overactive bladder.

METHODS

- A total of 15 Yorkshire pigs were divided into four groups:

***In-vivo* non-survival experiments**

Group 1 (n=3): We sought to evaluate the efficiency of the modulated RF power on the bladder tissue. This group served as a control; animals were euthanized immediately following RFA.

***In-vivo* survival experiments**

Group 2 (n=4): This group underwent transurethral RFA of the bladder in order to evaluate acute tissue reaction with respect to the non-survival group; animals were euthanized 1 week after the procedure.

Group 3 (n=4): The same procedures were carried out on this group to evaluate short-term tissue reactivity; animals were euthanized 4 weeks after RFA of the urinary bladder.

Group 4 (n=4): The same procedures were carried out on this group to evaluate long-term tissue reactivity to RFA; animals were euthanized 12 weeks after RFA.

- Denerblate was deployed on the trigone and three 240-second cycles of modulated RFA were applied with 30-second intervals.
- Urinary bladders were harvested for histological evaluation; nerve count and nerve density were calculated.

Figure 1. 3D Prototype of the Device

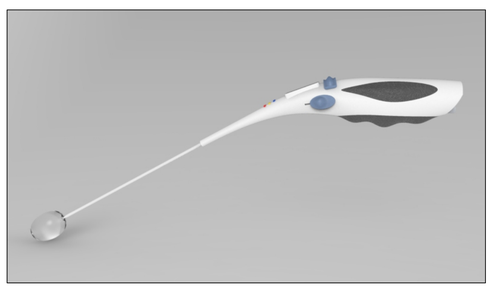
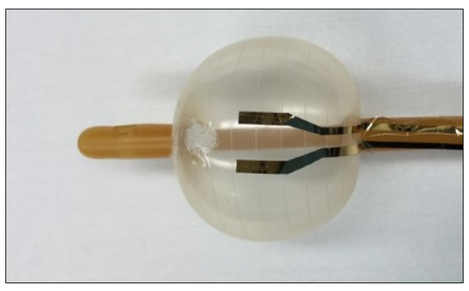


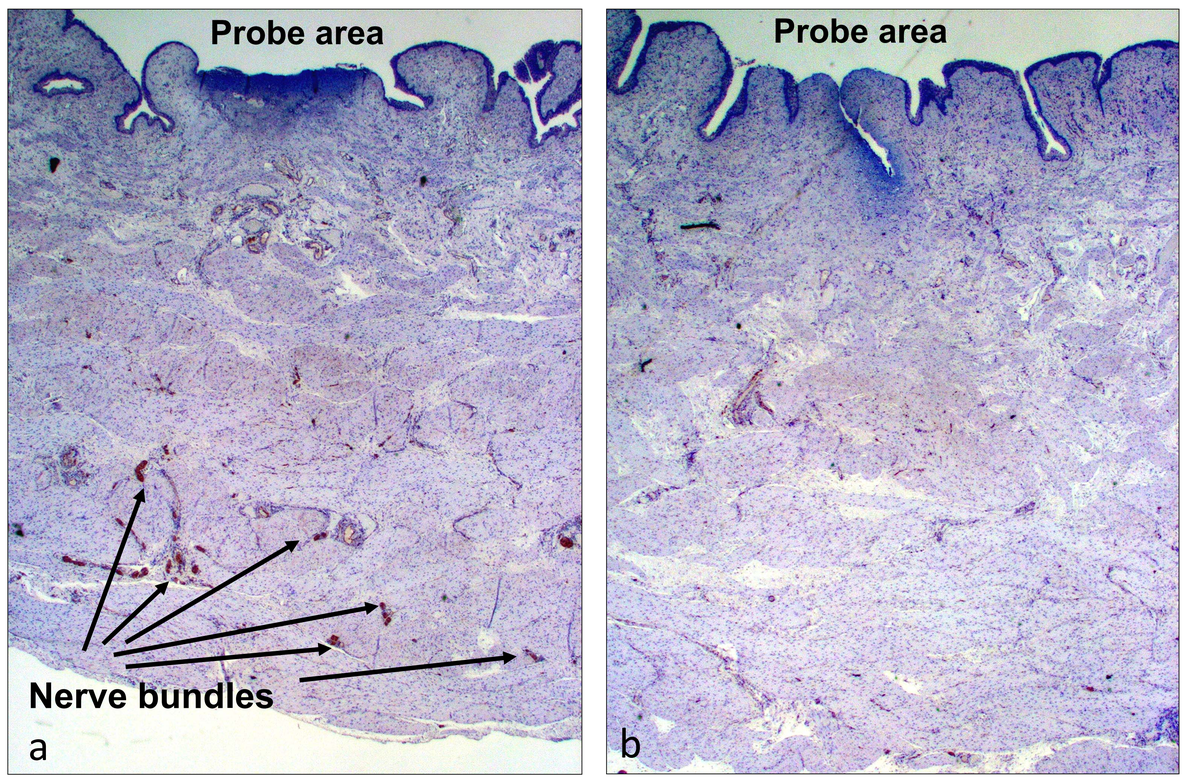
Figure 2. RF Antenna and Balloon



RESULTS

- All procedures were successfully completed, with no intraoperative or postoperative complications.
- The mean nerve density was highest at baseline (controls) and 1 week survival group compared to the 4 week and 12 week groups, which exhibited significant diminishment.
- Nerve density (nerves/mm^2) at the bladder neck (1.8 nerves/mm^2 at baseline) was reduced at 1 week, 4 weeks, and 12 weeks by 25%, 52%, 93%, respectively ($p<0.001$).
- Nerve density at the trigone (1.5 nerves/mm^2 at baseline) was reduced at 1 week, 4 weeks, and 12 weeks by 34%, 57%, 93%, respectively ($p<0.001$).
- Epithelial heat injury was observed in 14% of subjects at 1 week, 11% at 4 weeks, and 0% at 12 weeks.

Figure 3. Histopathology of the Denerblate ablation site at 1 week (a) and 12 weeks (b). Both images are depicting the location of the probe on bladder epithelium. Nerve bundles are labeled in the immunostained (S100) slide. The nerves are ~ 2 to 3 mm from the mucosa. Image b demonstrates completely healed urothelium and significantly diminished nerve density at 12 weeks post-ablation.



CONCLUSIONS

- **We developed a novel modulated RFA device for trigonal nerve ablation.**
- **Uroepithelial injury at 1-week post-RFA was completely resolved by 12 weeks post-ablation.**
- **Trigonal nerve density was decreased by 93% by 12 weeks.**
- **The Denerblate RFA device in living swine is effective, safe, and durable.**

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