MP15-18 THULIUM LASER LITHOTRIPSY OF RENAL CALCULI AUGMENTED WITH A NOVEL REVERSE THERMAL HYDROGEL IN THE PORCINE KIDNEY

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INTRODUCTION

We sought to evaluate the benefits of a novel reverse thermal gel (Hydrogel®) developed by UroGen Pharma to augment retrograde ureteroscopic laser lithotripsy and stone removal. Hydrogel® is a liquid at room temperature and transforms into a viscous, transparent, semisolid gel at body temperature. We hypothesized that the gel would entrap fragments and thereby enhance stone removal.

METHODS

Preparation

- Two pigs (four renal units) were studied.
- Each kidney was randomized to experimental (with Hydrogel) or control (without Hydrogel).
- Pre-weighed canine calcium oxalate stones were implanted, via an open pyelotomy, into an upper pole calyx **(Figure 1A)**.
- A temperature probe was placed percutaneously into the stone-bearing calyx.
- Pressurized saline irrigation at 100 mmHg was instilled via a Thermedx machine at either 4ºC (transform gel into liquid form) or 37ºC (transform gel into semi-solid form).

Procedure

- In the experimental kidneys, 5 cc of Hydrogel® was instilled in the calyx with the stone via a 5 Fr molded Kumpe catheter. A 14 Fr 35 cm ureteral access sheath was passed **(Figure 1B)**.
- Next, laser lithotripsy with a superpulse thulium fiber laser was performed using an 8.5 Fr Storz® video flexible ureteroscope utilizing a 200-micron fiber (settings of 0.2 J and 80 Hz) **(Figure 1C)**.
- Once the stone was sufficiently dusted, the fragments were basketed with a 1.7 Fr NCompass basket to remove any visible fragments. We then passed an ureteroscopic brush to entrap any residual dust or fragments entrapped in the gel.
- At the conclusion of the experiment, the animal was euthanized. The kidneys and ureters were harvested. The kidneys were then bivalved and washed to capture any residual stone fragments while also liquefying any residual gel. The fragments were then dried, sieved, and weighed.

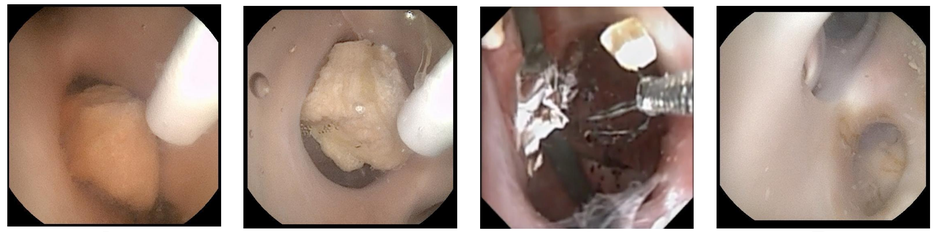

Figure 1.

A. Stone implanted in calyx prior to Hydrogel administration
B. Stone implanted in calyx after instillation of Hydrogel
C. Stone fragments entrapped in Hydrogel
D. Calyx after ablation and washout of Hydrogel

RESULTS

- 98.9% and 99.7% of the stone was removed from the experimental Hydrogel® kidneys compared to 85.5% and 98.8% of stone removed in the control kidneys **(Table 1).**
- In the control kidneys, peak intra-calyceal temperatures were 35ºC and 55ºC; temperatures > 44ºC (threshold for urothelial injury) occurred for a total of 0 and 4 times in both kidneys, respectively.
- In the Hydrogel kidneys, peak intra-calyceal temperatures were 36ºC and unmeasured in one kidney; temperatures > 44ºC occurred 0 times in the measured kidney.

Table 1. Stone Clearance in Hydrogel Treated and Control Kidneys

	Experimental Kidney 1	Experimental Kidney 2	Control Kidney 1	Control Kidney 2
Starting Stone Mass (mg)	731	791	724	704
Mass Retrieved (mg)	69.8	71.7	47.6	31.8
Mass Remaining in Kidney (mg)	8.3	2.6	105.9	8
Mass Cleared via Sheath (mg)	652.9	716.7	571.2	664.2
Percent Mass Cleared (%)	98.9	99.7	85.5	98.8
Procedure Time (minutes)	76	70	92	70
Peak Intracalyceal Temperature (ºC)	N/A*	36	35	55
Times Peak Temperature Exceeded 44ºC	N/A*	0	0	4

***Unmeasured**

CONCLUSIONS

In this pilot study, the use of Hydrogel to augment thulium laser ureteroscopic stone removal resulted in >99% clearance of stone fragments/dust from both kidneys while also having a possible insulating effect from intracalyceal temperature spikes.