In Vitro Evaluation of Nitinol Urological Retrieval Coil and Ureteral Occlusion Device: Retropulsion and Holmium Laser Fragmentation Efficiency

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Purpose: Retropulsion of ureteral stones during laser lithotripsy may result in difficult and incomplete stone fragmentation. The Stone Cone® nitinol urological retrieval coil and the NTrap® nitinol ureteral occlusion device have been introduced into clinical practice to possibly limit stone retropulsion and enhance the efficiency of holmium laser (Convergent Laser Technologies, Alameda, California) stone fragmentation.

Materials and Methods: A total of 360 BegoStone Plus phantom stones (Bego USA, Smithfield, Rhode Island) of similar mass and weight were divided into 3 groups, including control, Stone Cone and NTrap. The groups were further subdivided according to fiber size (200 or 400 μm) and pulse width (350 or 700 μsec). These stones were placed in a horizontal pipette 12 mm in diameter, submerged in normal saline and disintegrated at laser settings of 1 J and 10 Hz continuously applied for 300 seconds. Retropulsion in cm and fragmentation efficiency with mass loss in mg were measured after treatment.

Results: The 2 devices were effective for preventing retropulsion. In the control group the mean ± SD retropulsion distance using a 350-μsec pulse width with the 200 and 400 μm fibers was 18.4 ± 5.9 and 14.1 ± 4.6 cm, while it was 6.2 ± 2.6 and 5.6 ± 2.4, respectively, using the 700-μsec pulse width. There was a statistically significant higher loss of stone weight in the Stone Cone and NTrap experimental groups than in the control group ($p < 0.0001$). However, there was no difference between the 2 experimental groups across all groups ($p = 0.32$).

Conclusions: The Stone Cone and NTrap eliminated retropulsion and equally improved fragmentation efficiency. The maximum efficiency of fragmentation was seen using the 200 μm fiber at a 700-μsec pulse width.

Key Words: ureter; calculi; ureteroscopy; lithotripsy; lasers, solid state

Major advancements in flexible ureteroscopy and laser technology have propelled the holmium:YAG laser as the ideal lithotriptor for treating ureteral stones efficiently and effectively.[1–5] The holmium:YAG laser fiber is small and flexible but it has the ability to comminute all types of stones without causing significant injury to the urothelium.[5–7] However, when applied to ureteral calculi, part of the laser energy that is lost translates into uncontrollable stone retropulsion. This can lead to increased operative time and cost, and difficulty or failure of the procedure, which could potentially increase patient morbidity.[7–9]

To prevent this stone migration and minimize complications devices such as the Stone Cone and more recently the NTrap have been introduced for use in the clinical setting. We compared the 2 commercially available devices and tested their ability to prevent retropulsion and by virtue of this immobilization improve the amount of fragmentation (mass change) or the fragmentation efficiency of laser lithotripsy.

METHODS AND MATERIALS

A total of 360 BegoStone Plus phantom stones (calcium sulfate-hydrate) of a similar mean ± SD weight (776 ± 20 mg) and size (9.5 × 7.5 mm) were divided into 3 groups, including control, Stone Cone and NTrap. Each treatment group was further subdivided by the combination of laser pulse widths available (350 and 700 μsec) and laser fiber sizes (200 and 400 μsec). Overall the 360 stones were divided into 12 groups of 30 stones each and treated at each pulse width and fiber size using a holmium:YAG laser (wavelength 2,100 nm).

A 200 or 400 μm optical laser was fed through a 3.5Fr working channel of a 70 cm 7.5Fr flexible ureteroscope (Karl Storz™) and extended 5 mm beyond the ureteroscope tip. Each phantom stone was placed inside a 26 cm clear plastic pipette with an inner diameter of 12 mm that was open on each end and inscribed with distance markings with 1 ml equal to 7.895 mm. The tube was secured to a plastic tub and filled with normal saline. Each phantom stone was placed in the in vitro model to mimic a ureteral stone (fig. 1). The dry

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For another article on a related topic see page 1161.

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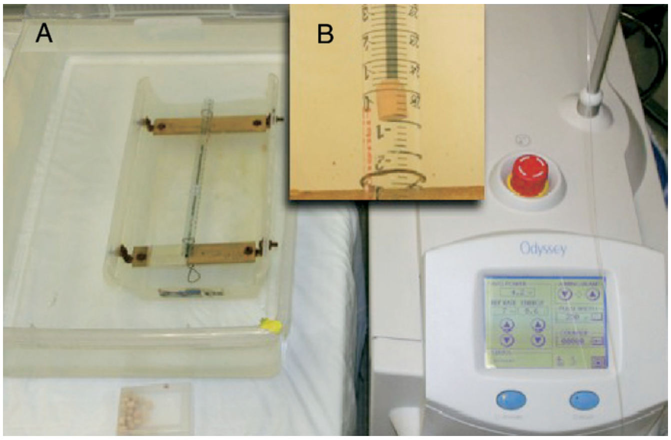

FIG. 1. In vitro ureteral model. *A*, setup and holmium:YAG laser. *B*, model with stone inside.

weight of each stone was measured before it was soaked in normal saline for 20 minutes before testing.

In the experimental groups we deployed an NTrap (2.8Fr wire diameter and 145 cm long with a 7 mm basket diameter and basket wires less than 2 mm apart) or a Stone Cone (2.8Fr wire diameter and 145 cm long with a 9 mm coil diameter and a central pore size of less than 2 mm) behind the stone to prevent retropulsion (fig. 2). In all groups the laser fiber was positioned at a normal incident (perpendicular to the stone face) angle and in contact with the stone surface as the laser was applied continuously for a total fragmentation time of 300 seconds with laser settings of a pulse energy of 1 J and a frequency of 10 Hz (fig. 3). Each stone was initially placed at the 0 ml mark of the clear plastic pipette and, if retropulsion occurred, the ureteroscope was advanced to follow the stone up to the 19 ml mark (15 cm). After the stone migrated to the 19 ml mark the laser was stopped, the stone was returned to the initial starting position (0 ml) and fragmentation was continued. This sequence was repeated until 300 seconds of actual laser time were achieved. Each stone was air dried overnight and weighed to determine the dry weight after laser fragmentation. After the dried weight of each stone was determined fragmentation efficiency was determined by calculating the mass change from the original mass of the stone. After each trial the laser fiber was cleaved to ensure the maximal transmission of energy in every trial.

The procedure was monitored under direct vision through the clear plastic pipette. Air bubbles and stone fragments were flushed from the pipette between trials. Only 1 investigator applied laser energy in all trials. Data were analyzed using Student's paired t test and 1-way ANOVA with statistical significance considered at $p < 0.05$.

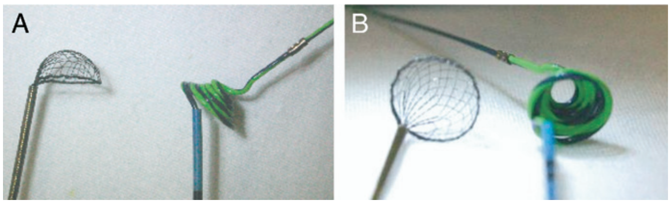

FIG. 2. Deployed NTrap (left) and Stone Cone (right). *A*, side view. *B*, end view.

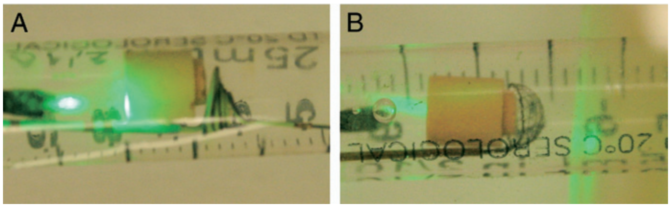

FIG. 3. Deployed device behind phantom stone in in vitro ureter model. *A*, Stone Cone. *B*, NTrap.

RESULTS

Stone Fragmentation

There was greater fragmentation efficiency (mass change) in the Stone Cone and NTrap groups compared to that in the control group ($p < 0.001$), while there was no significant difference between the 2 devices across all pulse widths and fiber sizes ($p = 0.32$, tables 1 to 3). Stone fragmentation was more effective using 200 μm, as reflected by the greater mass loss for the 2 pulse widths when comparing this fiber to the 400 μm fiber across all 3 groups ($p = 0.0084$). In addition, when using the 700-μsec pulse width, there was a greater loss of stone mass compared to that of the 350-μsec pulse width regardless of fiber size ($p < 0.001$, fig 4).

Retropulsion

There was no retropulsion when the Stone Cone and NTrap were deployed proximal to the stone. Each device held all stones in place, preventing retropulsion. However, in the control group when there was no device proximal to the stone, retropulsion occurred at all times. In the control group stone migration was greater with the 350-μsec pulse width than with the 700-μsec pulse width regardless of fiber size ($p < 0.001$). In relation to laser fiber size migration was greater with 200 μm than with 400 μm, which was statistically significant for the 350-μsec pulse width ($p < 0.003$). However, this difference was not observed when using the 700-μsec pulse width ($p = 0.36$). Furthermore, when the distance of retropulsion was normalized by the amount of fragmentation in each group, the 400 μm fiber showed 0.058 and 0.019 cm/mg for 350 and 700-μsec pulse widths, and the 200 μm fiber showed similar values of 0.065 and 0.019 cm/mg, respectively (fig. 5).

DISCUSSION

Laser technology has been incorporated into the urological armamentarium to treat various urological pathologies, such as benign prostatic hyperplasia, urothelial carcinoma, ureteral and urethral stricture, and urolithiasis.[1–10] Lasers

TABLE 1. *Fragmentation efficiency at variable fiber sizes*

	Mean ± SD Mass Loss (mg)		
Pulse Width (μsec)	200 μm Fiber	400 μm Fiber	p Value
350:			
Control	294.1 ± 46.0	243.3 ± 17.0	<0.0001
Stone Cone	345.0 ± 39.1	339.2 ± 24.8	0.5
NTrap	356.0 ± 45.4	343.3 ± 22.1	0.17
700:			
Control	328.5 ± 45.0	291.8 ± 22.8	0.0002
Stone Cone	387.3 ± 42.2	361.7 ± 31.7	0.01
NTrap	393.1 ± 23.1	364.1 ± 35.1	0.0004