IN VITRO EVALUATION OF THE STONEBREAKER™, A NOVEL CORDLESS PNEUMATIC LITHOTRIPTER

Abhay Rane[1] , Chris Kyle[2], Robert Carey[2], S Bhalani[2], Raymond Leveillee[2]
[1]East Surrey Hospital, Redhill, UK and [2]University of Miami, Miami, USA

ABSTRACT

Aims

To evaluate the safety of the StoneBreaker™ (LMA Urology, Switzerland) in an acute ureteral perforation model. Secondly, we compared the fragmentation efficiency of the StoneBreaker™ to the Swiss LithoClast™ (EMS, Switzerland) in an ex-vivo model.

Methods

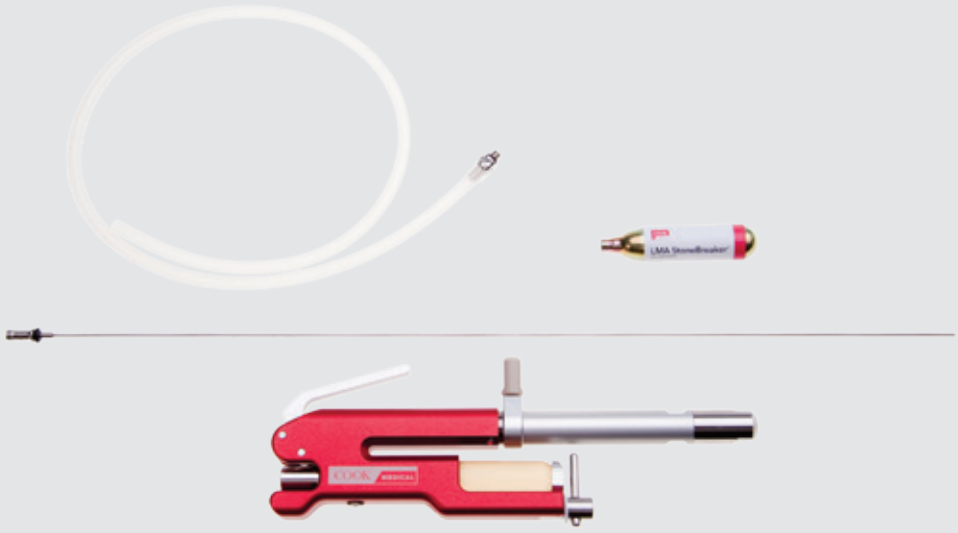
1. A freshly harvested porcine ureter was ligated and distended with methylene blue. The 1 mm StoneBreaker™ probe was advanced under endoscopic vision to the wall and fired one hundred times. The number of pulses required to perforate were recorded.
2. The StoneBreaker™ was set at an artificially high pressure and the device was fired directly at a distended ureter in a live pig. Serial segments were harvested for histology.
3. To compare fragmentation efficiency, the number of hits required to break Ultracal-30 stone phantoms to fragments smaller than 7 mm was recorded for both the StoneBreaker™ and the Swiss LithoClast™.

Results

No evidence of perforation was seen even at high pressure settings. For large stone phantoms (mean 7.4 gms), the LithoClast™ required an average of 307 fires, as compared to 77 for the StoneBreaker™ ($p<0.001$).

Conclusions

In the porcine model, the StoneBreaker™ does not perforate the ureter. The StoneBreaker™ is more efficient than the Swiss LithoClast™ at fragmentation of stone phantoms ex vivo.



Methods:

1. For the perforation models, a freshly harvested porcine ureter was ligated at its distal end. The proximal end was introduced over a 6.9 French semi-rigid ureteroscope (Circon ACMI, Santa Barbara, California, USA). A mixture of methylene blue and normal saline were infused through the irrigation port from a height of 90 cm to maintain a constant intraluminal pressure of 90 cm H2O. The ureteroscope and ureter were affixed to an underwater apparatus and the angle of incidence was manipulated such that the working channel was directly opposite the ureteral wall. The pneumatic probe was advanced under vision to the wall and fired 100 times. Under similar conditions, a holmium laser perforates the wall with fewer than 20 pulses (visible as a jet of blue irrigant).
2. A segment of the right ureter in a 40 kg male anaesthetised pig was isolated, and artificially distended with dilute methylene blue. The StoneBreaker with the 1 mm and 2 mm probe attached was set at an artificially high pressure (see chart) and the device was fired directly at the distended ureter, under direct vision. Serial segments were harvested and sent off for histology. The contralateral left ureter was used as a control and a segment was sent off for histology as well.
3. To compare fragmentation efficiency, the number of hits required to break 10 large, 10 medium, and 10 small Ultracal-30 stone phantoms to fragments smaller than 7mm (large and medium) or 3 mm (small) was recorded for both the StoneBreaker and the Swiss LithoClast. These sizes were chosen to reflect pelvic, calyceal, and ureteral stones, respectively. T-test was used to compare the results.

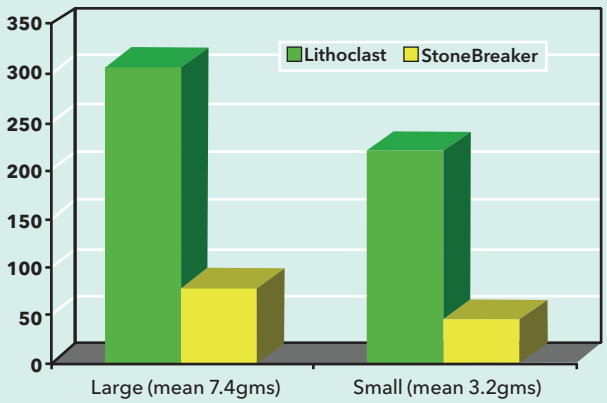
Results:

1. The StoneBreaker did not perforate the ureteral wall, even after more than one hundred fires.
2. There was no naked eye evidence of perforation, even at artificial high pressure settings; histology confirmed no microscopic evidence of trauma.
3. For large stone phantoms (mean 7.4 gms), the LithoClast required an average of 307 fires, as compared to 77 for the StoneBreaker ($p<0.001$). For medium stones, (mean 3.2 gms), the LithoClast needed an average of 221 fires, as compared to 46 for the StoneBreaker ($p<0.001$). Small stones (mean 0.50 grams), required an average of 72 hits for the LithoClast as compared to 26 for the StoneBreaker ($p<0.01$).

Conclusions:

In porcine ex vivo and in vivo models, the StoneBreaker does not perforate the ureter, even after multiple direct hits. The StoneBreaker is more efficient than the Swiss LithoClast at fragmentation of stone phantoms ex-vivo.

Number of fires required to fragment stone phantoms



Artificial high settings used to evaluate perforation

Probe used	Pressure Setting	Number of shocks/ pressure recorded
1 mm	55/60 bar	4@60 bar 8@40-55 bar
1 mm	55/60 bar	14
1 mm	55/60 bar	6@50-60 bar 8@40-50 bar
2 mm	55-60	6@50-60 bar 8@40-50 bar
2 mm	55-60	6@50-60 bar 10@40-50 bar
2 mm	55-60	6@50-60 bar

Reprinted by permission. Poster presented at: Engineering and Urology Society 22nd Annual Meeting; May 19, 2007; Anaheim, CA. URO-BM-SBP-EN-200906