Endourology and Stones

Systematic Evaluation of Ureteral Occlusion Devices: Insertion, Deployment, Stone Migration, and Extraction


OBJECTIVES
To compare 4 ureteral occlusion devices in terms of insertion force, maneuverability, radial dilation and extraction forces, ability to prevent stone migration, and tip stiffness.

METHODS
The devices tested were the PercSys Accordion, Microvasive Stone Cone (7 and 10 mm), and Cook N-Trap. Using a ureteral model with an artificial stone in place, the insertion force, number of attempts, and time to pass the impacted stone were measured. Using a Teflon block model, radial dilation and extraction and axial extraction force were measured with a load cell. Holmium lithotripsy was performed in the ureteral model with a canine stone in place to test the ability of the devices to prevent stone migration. In a similar model, the force applied to retrieve the canine stone was measured. The stiffness of the tip was measured as the force to compress a 5-mm length of the tip in a clamp-clamp configuration on a linear motion stage driven by a stepper motor with a resolution of 8-μm/step.

RESULTS
The devices were significantly different statistically from each other in terms of insertion force, number of attempts and time to pass the impacted stone, radial dilation, radial extraction, and axial extraction force in the Teflon block model. No proximal migration of the stones occurred with any of the devices. The devices were similar in terms of preventing proximal stone migration, force applied to retrieve stones, and tip stiffness.

CONCLUSIONS
The differences in the physical characteristics of stone migration devices might help to predict their safety and efficacy in clinical use.

Ureteroscopic lithotripsy is a modality commonly used to treat ureteral calculi. Retrograde stone migration during ureteroscopic lithotripsy occurs in 5%-40% of cases. The risk of proximal fragment migration is influenced by the pressure of the irrigant fluid, type of energy source used for intracorporeal lithotripsy, site and degree of calculus impaction, and degree of proximal ureteral dilation. Pneumatic and electrohydraulic lithotrites cause more retrograde propulsion of the ureteral stones than holmium:yttrium-aluminum-garnet lasers and ultrasonic lithotrites. However, stone repulsion increases with an increase in holmium:yttrium-aluminum-garnet pulse energy and optical fiber diameter. Retropropulsion is more likely with smaller stones and greater proximal ureteral dilation or hydronephrosis.

During intracorporeal lithotripsy, retrograde migration of fragments can lead to increased patient morbidity and cost. Migrating stone fragments can necessitate additional procedures involving flexible ureterorenoscopy with additional fragmentation or extraction with retrieval devices, ureteral stenting, or secondary procedures such as shock wave lithotripsy.

Additionally, residual stone fragments can serve as a nidus for recurrent stone growth, persistent infection, and renal colic. Various accessory instruments have been developed that are deployed above the calculus to prevent proximal migration of stone fragments during ureteroscopy and to facilitate fragment extraction on removal of the device. The Stone Cone (Boston Scientific, Boston, MA) consists of a 0.43-mm nitinol wire with a 3F polytetrafluoroethylene sheath, with the distal tip shaped in concentric coils that, when placed proximal to calculi, prevent proximal retropropulsion of stone fragments during lithotripsy. The Stone Cone has been shown clinically to reduce the incidence of residual stone fragments >3 mm in size. The Cook N-Trap (Cook Urological, Spencer, IN) is a 2.6F device with a 7-mm deployable backstop composed of 24 interwoven nitinol wires that has...
been shown in ex vivo pig ureters to prevent the migration of plastic beads as small as 1.5 mm (Fig. 1).

The PercSys Accordion (Percutaneous System, Palo Alto, CA) is a 2.9F multifold polyurethane film backstop that forms a 7-mm barrier when the film occlusion is deployed. In vitro evaluations can delineate differences in endourologic devices that predict their clinical performance. The Microvasive Stone Cone and the Cook N-Trap have been demonstrated to prevent migration of fragments as small as 1.5 mm in a porcine model; however, the N-Trap was capable of blocking smaller fragments than the Stone Cone. The Stone Cone and N-Trap have comparable low loads to release a stone fragment in the event that resistance is met as the device is withdrawn to minimize the risk of ureteral injury. To our knowledge, no clinical trials have been done comparing the efficacy of stone migration devices.

The present study systematically measured the physical characteristics and in vitro performance of the 4 devices to evaluate their safety and efficacy during ureteroscopic lithotripsy.

MATERIAL AND METHODS

Devices
The devices tested were the 7-mm Cook N-Trap, the 7-mm PercSys Accordion, and the 7- and 10-mm Microvasive Stone Cone (Boston Scientific) (Fig. 1). Five samples of each device were provided new and sterile by the manufacturers.

Artificial Stones
Artificial kidney stones (BegoStones, Bego USA, Smithfield, RI), 10 × 5 mm in size, were fabricated in a wooden mold with 5-mm holes lined with 5-mm straw so that the stone emerged with a smooth, cylindrical surface. A 3F catheter was placed between the straw and hole to form an indentation in the stone. The stone mix was de-aerated with a vacuum pump before being poured into the mold.

Insertion Force and Maneuverability
The artificial stone was placed in a 15F silicone tube as an in vitro model of the ureter. The stone was located 5 mm from the distal end with its 3F indentation oriented to the 3-o’clock position. The ureteral model was secured in a clamp, and 4 mL of water was used to submerge the stone. The stones were replaced every 10 trials. An experienced endourologist maneuvered the occlusion device passed the stone under direct vision through the 4F working channel of a 6F-7.5F Wolf semirigid ureteroscope. The insertion force to pass the device beyond the stone was measured with a miniature 1000 g load cell. The load cell signal was sampled by a data acquisition unit and digitally low-pass filtered to eliminate noise. The insertion force was defined as the peak compressive force during the insertion maneuver. The time to pass and number of attempts to maneuver beyond the indentation were recorded. The procedure was repeated in random order for each of the 4 occlusion devices, and for a glidewire and a Sensor wire (Boston Scientific).

Radial Dilation and Axial Extraction Forces
Two Teflon blocks were positioned with the lower block on a digital scale, and the upper block was secured to a plastic frame. A 0.01-in. gap separated the blocks. Alignment pins secured the position of the lower block in relationship to the upper block. The occlusion device being tested was passed through a 5.375-mm cylindrical hole in the center of the block and deployed to its fully extended length. The occlusion device was slowly retracted through the hole, and the maximal radial dilation force was recorded. Simultaneously, the axial extraction force was measured using the load cell (Fig. 2). Eight repetitions were performed for each occlusion device. The results were analyzed using one-way analysis of variance followed by a Tukey multiple comparison test.

Ability to Prevent Stone Migration
Canine kidney stones (average weight 0.092 plus 0.01 g, length 5.88 plus 0.67 mm; width 4.76 plus 0.42 mm) were positioned in the middle of a 15F, 20-cm silicone ureteral model. The canine stones had been surgically retrieved from 1 animal, were approximately uniform in shape, and were 100% calcium oxalate. The ureteral model was secured in a clamp. The occlusion device being tested was passed through the 4F working channel of a semirigid ureteroscope. Two mesh strainers were placed at the proximal and distal end of the ureteral model to collect the stone fragments. The device was deployed beyond the stone site. Gravity endoirrigation (22 cm H2O) was passed through the accessory 2F working channel of the ureteroscope. A
365-μm Lumenis holmium:yttrium-aluminum-garnet laser fiber (Lumenis, Santa Clara, CA) was advanced through the scope and lithotripsy performed at 0.8 J and 15 Hz. After lithotripsy, the fragments were collected from the distal and proximal strainers, representing distal and proximal stone migration. The stones were also collected separately as the device was retracted from the model, representing extracted stones, and from the ureteral model after removal of the device, representing retained fragments. The procedure was repeated in random order for 5 trials for each of the 4 occlusion devices.

**Force Applied to Retrieve Stones**
A canine kidney stone (average weight 0.091 plus 0.01 g, length 5.07 plus 0.44 mm, width 4.56 plus 0.65 mm) was positioned in the middle of a 15F, 20-cm hydrated silicone ureteral model.

The occlusion device being tested was deployed past the stone and attached to a 50g Sensotec load cell. The load cell was positioned on a linear motion stage driven by a stepper motor with a resolution of 8-μm/step. The procedure was repeated in random order for 5 trials for each of the 4 occlusion devices.

**Tip Stiffness**
The occlusion device was attached to a linear motion stage driven by a stepper motor. Force was measured at a sampling rate of 5 Hz with a Wagner FDIX digital force gauge. The stiffness of the tip was measured as the force required to compress a 5-mm length of the tip of the device in a clamp-clamp configuration during a 2-cm move. This procedure was repeated 5 times for each occlusion device. The results were analyzed using one-way analysis of variance followed by a Tukey multiple comparison test.

**RESULTS**

**Insertion Force and Maneuverability**
The devices differed significantly in the insertion force required (P = .0001). The insertion force for the 10-mm Stone Cone (56.6 ± 49.0g) was similar to that for the 7-mm Stone Cone (29.8 ± 25.4g, P = .21) but required more force than did the Accordion (14.6 ± 9.8g, P = .01) or N-Trap (3.7 ± 5.8g, P = .0006). The insertion force for the Sensor wire and glidewire was 5.0 ± 4.38g and 6.6 ± 7.1g, respectively.

The number of attempts to pass the impacted stone was significantly different among the devices (P = 1.44 × 10⁻³). The 10-mm Stone Cone (3.7 ± 0.9) and 7-mm Stone Cone (3.4 ± 0.8) required more attempts than the N-Trap (2.0 ± 0.8, P < .05), PercSys Accordion (1.4 ± 0.5, P < .05), Sensor wire (1.1 ± 0.4, P = 3.9 × 10⁻⁶), and glidewire (1.1 ± 0.4, P = 4 × 10⁻⁷). The PercSys Accordion (P = .97) and N-Trap (P = .20) were similar to the Sensor wire and glidewire.

Significant differences were found in the time required to maneuver beyond the stone (P = .0036). The PercSys Accordion (14.9 ± 5.1 seconds), 10-mm Stone Cone (11.6 ± 1.8 seconds), 7-mm Stone Cone (10.3 ± 2.3 seconds), and Boston glidewire (10 ± 5.6 seconds) performed similarly. In contrast, only the PercSys Accordion performed differently than the Sensor wire (6.3 ± 2.8 seconds, P = .002) and N-Trap (8.1 ± 2.7 seconds, P = .022).

**Radial Dilation and Extraction Forces**
Significant differences were noted in the radial dilation forces on deployment (P = 2.2 × 10⁻¹⁰) and extraction (P = 1.2 × 10⁻¹⁵). The PercSys Accordion (0.9 ± 0.6g) and N-Trap (7.6 ± 2.3g) were similar in performance on both tests (P = .93 and P = .96, respectively). The 10-mm Stone Cone had the greatest radial dilation force on deployment (252.0 ± 40.5g) and extraction (226.2 ± 20.4g) and the 7-mm Stone Cone demonstrated intermediate forces for each test (55.2 ± 17.7g and 92.9 ± 52.6g, respectively). Significant differences were noted in the axial force required to extract the devices (P = .0012). The PercSys Accordion (4.7 ± 3.5g) required less force for extraction than did the N-Trap (17.2 ± 3.0g, P = .0012).
.002), 10-mm Stone Cone (16.6 ± 6.1g, P = .004), or 7-mm Stone Cone (14.5 ± 9.8g, P = .019).

Ability to Prevent Stone Migration and Residual Stone Fragments After Device Removal
No significant differences were noted in the length (P = .207), width (P = .125), or weight (P = .134) of the residual stone fragments remaining in the ureteral model after removal of the devices (Fig. 3). The lengths of the residual stones were as follows: PercSys Accordion, 3.7 ± 1.3 mm; N-Trap, 2.6 ± 2.0 mm; 10-mm Stone Cone, 2.1 ± 0.28; and 7-mm Stone Cone, 1.1 ± 1.1 mm. The 7- and 10-mm Stone Cone performed similarly (P = .99), and N-Trap and PercSys Accordion performed similarly (P = .99). No stone fragments were collected from the proximal end of the tubing for any of the devices, indicating that all devices were effective at prevention proximal migration.

Tip Stiffness
No significant differences were found among the devices in tip stiffness (Fig. 4). The stiffness of the tips was as follows: PercSys Accordion, 78.5 ± 42.7g; N-Trap, 150.7 ± 61.5g; 10-mm Stone Cone, 74.2 ± 41.9g; and 7-mm Stone Cone, 86.3 ± 36.9g. The 7- and 10-mm Stone Cone and PercSys Accordion are similar in performance on this test (P = .99), and the stiffness of the N-Trap did not achieve statistical significance (P = .09).

Force to Retrieve Stones During Device Extraction
No significant difference was found in the force to remove stone fragments from the ureteral model during device extraction (P = .9491). The average force for the devices to retrieve the stone was 39.2 ± 3.86g.

COMMENT
The present study compared the Microvasive Stone Cone and Cook N-Trap to a new device, the PercSys Accordion, specifically studying the characteristics that predict for safety and efficacy.

Differences were noted in the physical characteristics that would predict for ease of placement. Although the force required and the number of attempts required to place the Stone Cone were greater than for the other devices tested, the time required for passage of the device was greatest with the PercSys Accordion. When considering safety, the primary concerns are ureteral perforation during passage of the device around an impacted stone and ureteral avulsion during extraction of the device with or without a stone fragment.

The risk of ureteral perforation correlates with the stiffness of the tip of the device. Although the N-Trap was double the stiffness of the other devices tested, this did not reach statistical significance. A greater insertion force could increase the risk of perforation or proximal migration of a stone during placement of the device. In the present study, the Stone Cone had the greatest insertion force (57g). We previously reported that ureteral perforation of a normal human ureter can occur at a force of 372g; however, this was measured at a perpendicular angle to the ureteral wall.5 It is possible that perforation could occur at lower forces if applied tangentially or if the ureteral wall was weakened by the disease (eg, inflammation, edema).

The risk of ureteral avulsion is related to the axial extraction force.5 The present study found no significant difference in extraction force during stone fragment removal. We previously reported that 1 kg of force is required to avulse a normal pig ureter, a force that is 20 times lower than the extraction forces identified in the present study. These findings suggest that the risk of ureteral avulsion using an occlusion device is low, although our forces were measured without a stone trapped in the device.8

Our in vitro model has a number of potential limitations and pitfalls. The insertion forces and maneuverability of the devices were tested in an in vitro ureteral model to facilitate reproducibility in testing. However, it is
possible that the responses to the devices measured and ease of maneuverability would differ in an in vivo model, in which the tissue properties of the ureter, including the presence of edema and bleeding, could have a significant effect. Second, although the in vitro studies can establish comparative values for such measures as tip stiffness and radial dilation force, the “ideal value” for in vivo applications (ie, what tip force predisposes to perforation) remains to be determined.

Occlusion devices have the primary function of preventing stone migration. The results of the present have shown that all devices were effective because no proximal migration occurred with any device. The secondary function of occlusion devices is to capture and extract residual stone fragments from the ureter during extraction. As reflected by the greater radial dilation of the Stone Cone on deployment and extraction, the flexible configuration of the Stone Cone conforms to the shape of the ureter, which helps to prevent the escape of stone fragments during extraction. In contrast, the PercSys Accordion had the lowest radial dilation force. As such, although the size of the residual stones after removal of the 10-mm Stone Cone (1 mm) was smaller than that with the other devices tested, this did not reach statistical significance.

CONCLUSIONS

Occlusion devices represent a new generation of technology that minimize proximal ureteral stone migration. The results of the present study have identified the radial dilation force, ease of placement, and efficacy for stone extraction as parameters that might predict the clinical efficacy of the currently available commercial alternatives.

References