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## **Maximum forces required to disengage three novel stone-trapping devices from a stone in a ureter model with a stricture**

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**Introduction and Objective:** Devices deployed in the ureter in order to limit the migration of stone fragments during laser lithotripsy produce a barrier proximal to the stone. This barrier can also be used to sweep the stone or the fragments down the ureter. If the stone or the fragments become impacted during the process, these devices are designed to passively undeploy so that they can be removed easily and with little injury to the ureter. The objective of this study was to measure the forces produced by three novel stone-trapping devices while being withdrawn past an impacted stone in a ureter model.

**Materials and Methods:** A model of the ureter was constructed from polyurethane tubing with an internal diameter of 5.7 mm. A stricture was created at the distal end of the model by tightening a plastic wire around a 3 mm pin. A metal bead 5 mm in diameter simulating the stone was placed in the tube proximal to the stricture. The three stone-trapping devices used were the Accordion occluding guidewire (PercSys Inc), the Stone Cone (Boston Scientific Corp) and the N-Trap (Cook Urological). Each stone-trapping device was advanced past the stone and deployed and then withdrawn from the ureter by first sweeping the stone down to the stricture and then undeploying around the stone and out through the lumen of the stricture. A digital force gauge was attached to shaft of each device and the maximum force (in Newtons) required to undeploy the device past the stone and out through the stricture was measured in five repetitions. The p values were calculated with Student's t-test.

**Results:** The mean maximum force measured as the devices were withdrawn past a stone impacted against the simulated stricture was 0.67 Newtons for the Accordion device and 1.13 Newtons for the Stone Cone device, a difference that was significant at the  $p = 0.01$  level. The Accordion device released around the stone with a relatively constant force, whereas the Stone Cone device produced its maximum force primarily at the end of its withdrawal as the tip of its cone was pulled past the stone, which had the tactile feel of a "pop." The N-Trap device would not disengage from the stone at all, with forces in excess of 3 Newtons measured before stopping the withdrawal.

**Conclusions:** While this was an extreme model, which is why the N-Trap device did not disengage at all, it is a scenario likely to be encountered in the operating room. Both the Accordion and the Stone Cone devices successfully undeployed from the impacted stone without the need to manipulate the devices. The significant difference between the forces produced by the Accordion and the Stone Cone devices now need to be assessed in terms of injury to the ureter and success in stone-clearing capacity in a clinical trial.

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