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Efficacy and safety of the Accordion® stone-trapping device: in vitro results from an artificial ureterolithotripsy model

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Abstract One of the challenges of intracorporeal ureterolithotripsy is undesired stone migration. Stone-trapping devices have been designed to prevent this quite common phenomenon. These devices have to be effective in terms of ureteral obstruction and safe in terms of resistance to the action of commonly used lithotriptors. This work was conducted to evaluate the efficacy and safety of the recently approved Accordion® stone-trapping device in vitro. In a rigid, submerged ureteral model with two different diameters (8 and 10 mm), artificial stones were positioned in direct contact with the engaged Accordion® device. A defined number of pneumatic pulses of the LithoClast® master at different performance levels was applied and the migration distance of the stone was measured after each single pulse. As a control, the same series was repeated without the stone-trapping device. Secondly, the Accordion device was exposed to a previously defined number of pneumatic or Ho:YAG-laser pulses, in direct contact with the lithotripsy probe, up to a total activation time of 2 min. At different time points, the device was controlled for damage and functionality. The mean stone migration distance without the Accordion® device was between 39.2 and 52.8 mm and between 37.8 and 75.4 mm in the 8 and 10 mm tubes, respectively. In comparison, the stone or fragment travelling distance with the device was in the 0–2 mm range. This difference was highly significant.

Both pneumatic and laser lithotriptor did not affect the functionality of the Accordion® device. The Ho:YAG laser causes small perforations of the film without affecting the devices' stability. The Accordion device appears to be highly efficient and safe in vitro. Clinical trials will have to assess its value in endourological practice. Randomised comparative trials comparing different stone-trapping devices are needed.

Keywords Ureter · Lithotripsy · Stone migration · Stone trapping · In vitro

Introduction

Today, there is a wide range of indications for ureteroscopic management of ureterolithiasis. Calculi of the mid and upper ureter may be managed by shock wave lithotripsy (SWL) or endoscopic stone disintegration and removal. SWL has the advantage of being a non-invasive procedure; however, it often requires repeated treatment sessions. In contrast, the stone-free rates of single-session high ureteroscopic stone management exceeds 90% [1]. Flexible ureteroscopy, especially in combination with laser lithotripsy makes endoscopic stone therapy even more favourable as compared to pneumatic ureterolithotripsy [2–4]. For the lower ureter, there is a compelling body of literature—including randomised trials—in favour of interventional endoscopy [5, 6]. Single-session stone-free rates with various disintegration modalities are excellent, complications are infrequent and predominantly of minor character. Postoperative stenting can be avoided in the majority of cases [7]. A recent Cochrane review has confirmed better stone-free rates for ureteroscopy; however, the

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number of high-quality trials on this topic is apparently small [8].

Stone migration and retropulsion during ureteroscopic lithotripsy represents a major challenge. It may be caused by irrigation flow and/or by energy transmission into the stone during stone disintegration. Undesired push back is observed most frequently in pneumatic lithotripsy; it ranges from 5 to 40% depending on stone localization [3, 9, 10]; during Ho:YAG laser lithotripsy, the risk of retromanipulation is lower [3]. An obstructed upper tract with a dilated ureter beyond the impacted stone increases the risk of stone migration considerably; moreover, a high position of the stone and surgeon's experience appear to be predictive for stone migration [11]. Centers with extensive experience in ureteroscopy report on migration rates of only 4–7% [12].

Different stone-trapping strategies have been developed to minimize stone migration to the pelvicaliceal system. Baskets have been used to fix the stone during disintegration, however, wire damage by pneumatic or laser energy has been reported [13], and removal of a damaged, engaged basket or parts of it represents a challenge, even for the experienced endourologist [14]. Obstructing balloons positioned beyond the ureteral stones are effective in non-dilated systems [15]; however, if the proximal ureter above the stone is heavily dilated, the balloon diameter might be too small for effective stone trapping. Moreover, the balloon might be easily perforated and destroyed by disintegration devices. Recently, two stone-trapping devices have been approved and are commercially available (Stone Cone®, Boston Scientific, Natick, MA, USA; N'Trap®, Cook Urological, Bloomington, IN, USA). Both Nitinol® devices are engaged cephalad to the stone, forming specifically shaped barriers that have proven their efficacy and safety in terms of preventing stone migration [16–20].

The recently FDA and CE approved Accordion® device (PercSys, Mountain View, Ca, USA) consists of a smooth film, 7 mm in width, that is attached to an applicator sheath–wire system. Radiopaque markers define the borders of the film. Engaging the device, the film folds up densely like an accordion, forming a soft yet quite stable plug, obstructing the ureter cephalad to the stone (Fig. 1). The tip of the applicator wire is very soft and atraumatic and therefore the device can be used as a guide wire that is positioned cystoscopically, under fluoroscopic control, before entering the ureter with an endoscope. Thus, it follows a "first in, last out" philosophy.

The work presented here was conducted as an in vitro proof of principle study to verify the efficacy of the Accordion® stone-trapping device in a simple, artificial ureteral model. Secondly, the durability and functionality of the device was tested in vitro under pneumatic and laser-lithotripsy conditions.
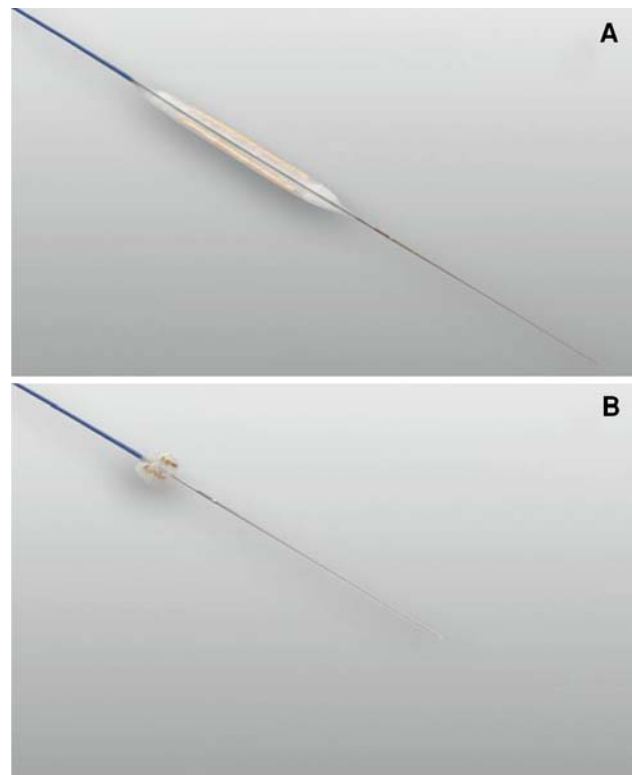
Fig. 1 Accordion® stone-trapping device. **a** Disengaged, for positioning and removal; **b** engaged, film folded for ureteral occlusion

Materials and methods

Accordion® device

The device consists of a sheath–wire system, 150 cm in length and with an outer shaft diameter of 0.038 in. Introduced through the working channel of cystoscope, both the available 7 and 10 mm films attach to the shaft very smoothly. The 6-cm tip section of the device is very soft and has a hydrophilic coating to ease the passage beyond impacted stones. When the ureteral diameter is smaller than the outer diameter of the film, the latter conforms to and fills the ureteral lumen, forming a flexible plug.

Experimental setting and ureteral model

For all experiments, a 7 mm Accordion® device was used. In the 10 mm tube, this was to try and simulate the setting of a dilated ureter with a relatively "too small" device.

Our in vitro ureterolithotripsy model is shown in Fig. 2. Briefly, rigid acryl tubings (diameter 8 and 10 mm were positioned horizontally and fixed in a plastic container (5 cm in height). In the front wall of the container, drilling holes in concentric position with the tubes were established and armed with rubber seals. Thus, the Accordion® device
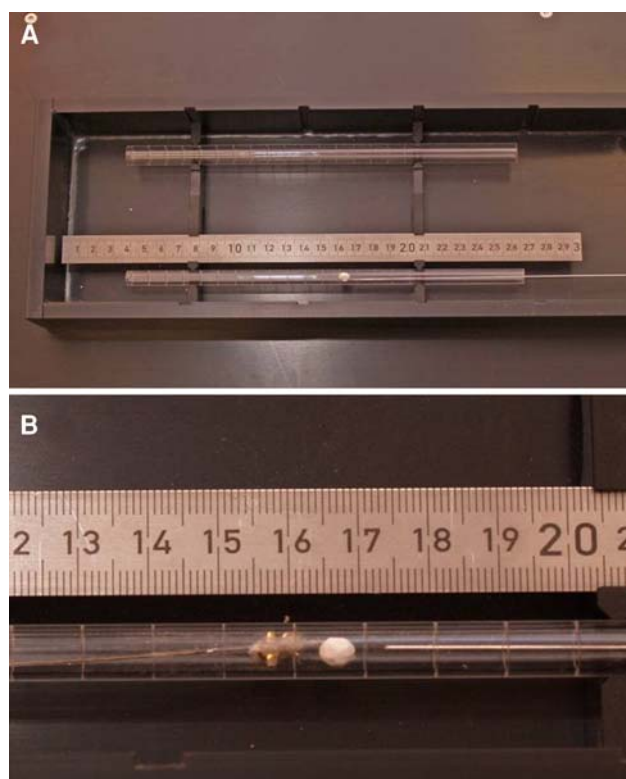
Fig. 2 Setting of in vitro model. **a** Overview with stone, LithoClast® and disengaged Accordion® in position. **b** Detail of 8-mm tube with tip of LithoClast® probe, stone and deployed, obstructing Accordion® device in position

and the lithotriptors could be positioned in-line inside the tubes without bending the devices. The complete system was submerged in physiological saline. No continuous irrigation was used in these experiments. For LithoClast® experiments, the lithotriptor was fixed by a clamping system attached to the water container to keep it in position during lithotripsy.

We used artificial Plaster of Paris (semihydrated calcium sulphate), nearly spherically shaped stones with diameters of 6.5 and 8.5 mm.

Stone retropulsion experiments

After submersion of the complete tubing system, the Accordion® device was positioned and engaged in the mid portion of the 8 and 10 mm tubes, respectively. According to tube size, a 6.5 or 8.5 mm stone was positioned in contact with the engaged stone-trapping device. A standard, 1-mm pneumatic lithotripsy probe (LithoClast® Master, EMS, Nyon, Switzerland) was positioned in contact with the stone. Three power settings of the LithoClast® (60, 80 and 100%) were chosen and in single-shot mode, 20 pulses were applied to the stone or the resulting fragments. For each power setting, the experiment was repeated 5 times,

using a new stone for each sequence. After each hit, the maximal distance travelled by the stone or a fragment of it was measured by a precision calliper rule and documented.

For the control, the same sequence of experiments was repeated without the accordion device. After each hit, the stone or its largest fragment was repositioned in contact with the probe.

For each power setting, the mean stone travelling distance after 100 disintegration pulses (5 stones × 20 hits) was calculated and the difference between Accordion® and control group was tested for statistical significance by a conventional unpaired Student's t test (SPSS 15.0, Chicago, IL, USA).

Safety assessments under pneumatic and laser-lithotripsy conditions

The same submersible tubing system was used. The Accordion® device was positioned and deployed in the 8-mm tube. Thereafter, a 1-mm LithoClast® probe or a 650-μm holmium laser fibre were placed with their tips in the folds of the Accordion®. The LithoClast was activated at a power of 100% and a pulse frequency of 5 Hz. The holmium laser (Auriga® StarMedTech, Starnberg, Germany) was used with a pulse frequency of 8 Hz and a performance of 800 mJ. Each disintegration device was activated for 5 s, immediately thereafter, the Accordion® was removed and controlled for damage, i.e. rupture or perforation of the film or wire disruption, using diaphanoscopy and a 5× magnification loop and functionality of the system, i.e. smooth and complete folding and unfolding. The 5-s action cycles were repeated 24 times for a complete activation time of 2 min, which is more than usually needed to treat a typical ureteral stone of 1 cm or less. For both the LithoClast® and the Ho:YAG Laser, 5 Accordion® devices were tested.

Results

The mean retropulsion distance of the stones stratified by power setting conditions and tube/stone diameter are displayed in Fig. 3. It is clearly shown, that the Accordion® device efficiently and significantly reduces stone migration in this model. The stone-trapping performance is effective in a ureteral model with an inner diameter (10 mm) exceeding the diameter of the deployed Accordion® device (7 mm) by 43%. In no case an unfragmented stone passed the occlusion device; all fragments that passed through the Accordion® or were pushed into its folds were 3 mm or smaller.

After a 2-min activation interval of the LithoClast® at a frequency of 5 Hz, i.e. 600 pulses delivered, neither perforation of the Accordion® film nor breakage of the guidewire or sheath were detected. Under diaphanoscopy

Mean stone migration distances at different power-settings with and without Accordion device
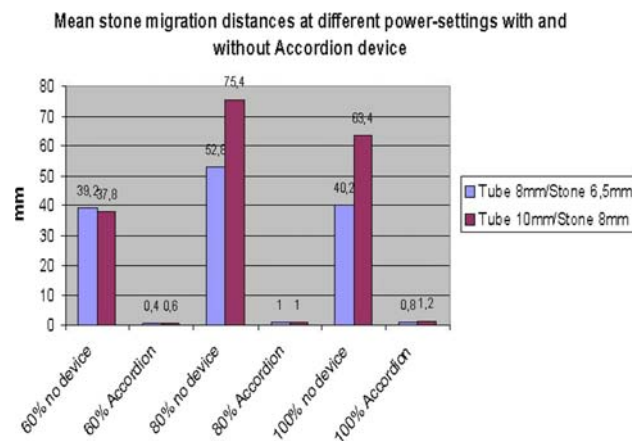
Fig. 3 At each power setting and tube size, the difference in stone migration with and without Accordion® device is highly significant [$p<0.005$, unpaired t test (SPSS, Chicago, IL, USA)]

and magnification, the unfolded device showed some superficial scratchy alterations of the film surface. Functionality was not affected.

After a 2-min activation interval of the Ho:YAG laser at a frequency of 8 Hz, i.e. 960 pulses delivered, multiple, small (<1 mm) perforations of the film were detected, visible only under magnification. The number of perforations increased with activation time. Macroscopic appearance or stability of the wire–film system was not affected and there was no visually detectable wire damage at all. Functionality of the complete device in terms of proper folding and unfolding was not affected with laser lithotripsy either.

Discussion

There are three essential requirements a stone-trapping device for ureteroscopic lithotripsy has to fulfil: of course, it has to prevent stone migration effectively, not allowing stones or fragments of any size to pass. Second, it should be easy to handle for the surgeon, minimizing the need for assisting staff. And last but not least, it should be designed to be resistant to damage by intracorporeal lithotriptors. However, if damage to the system occurs, this must not affect the ability to be disengaged and removed easily. The work presented here was conducted to cover some of these aspects and examine efficacy and safety of the Accordion® stone–trapping device in vitro. We were able to demonstrate that the Accordion® wire–film system effectively prevents stone migration using pneumatic lithotripsy, the modality that has the highest probability to cause undesired push back according to the literature. Upper ureteral position appears to be a risk factor for migration and high surgeon and center volume seem to produce lower stone migration rates [11, 12]. The engaged device is stable

enough to withstand the forces of the LithoClast® although it was in direct contact with the probe or the stone. Stone migration was completely prevented with LithoClast® lithotripsy in this simple, rigid model consequently, the experiments were not repeated using laser lithotripsy, a stone disintegration modality with lesser risk of push back. There are two major drawbacks of our experimental setting: first, it cannot simulate the clinically typical situation of a heavily dilated ureter proximal to the stone. This situation might dramatically reduce the efficacy of stone-trapping devices in general; however, it is hardly reproducible in an experimental setting. In vivo experiments or clinical studies will have to address this issue. Secondly, our model is rigid and uses quite large internal lumina of the experimental tubes. This is far from a natural ureter or from an ex vivo, e.g. porcine ureteral model. However, it can be expected, that in a normal sized ureter the efficacy of ureteral-occlusion devices might even be better than in a large-bore rigid system. A major concern with the Accordion® might be poor vision during lithotripsy due to complete obstruction, when the ureter is plugged completely. Of course, this problem was not addressed by our experiments, but clinical experience from our first clinical cases showed that the device passes impacted stones easily and—being deployed—does not perform complete, water-tight obstruction; vision is not compromised during stone disintegration.

There are two more stone-trapping/ureteral-occlusion devices that have been examined in different experimental settings and are widely accepted in clinical practice. The Stone Cone® (Boston Scientific, Natick, MA, USA) has been designed in the late 1990s by Stephen Dretler and is an effective tool for the prevention of undesired stone migration. Its efficacy was proven in artificial and ex vivo experimental settings [16, 17] as well as in clinical use. One randomised trial proved its superiority to a flat wire basket in terms of stone migration and stone-free rate [21]. Furthermore, it is safe in terms of spontaneous disengagement if traction forces are getting too high [16]. To the authors' knowledge, a clinical report on ureteral injury by the Stone Cone® has not been published until now.

The N'Trap® (Cook Urological, Bloomington, IN, USA) performs very effective as well in artificial or natural ureters of normal calibre and might be even superior to the Stone Cone in very small fragments [19]. However, recent experimental studies have raised some safety concerns because the device is somewhat rigid in the engaged status and higher forces are required to straighten it and pass, e.g. a stone or a stricture [20].

The function of "sweeping fragments" by pulling out the engaged device appears an attractive option for the Accordion® device, too, and one published abstract compared the forces of the three mentioned devices, needed to disengage when pulled over a stricture [22]. In this study, the

Accordion® had the lowest forces and thus, seems to have the widest margin of safety. However, this clinical situation cannot be simulated in an in vitro or ex vivo model and we do not encourage using this technique of stone retrieval routinely, independently of the stone-trapping device used. Ureteral avulsion is a rare, but deleterious complication that is unnecessary in the majority of cases.

To our knowledge, there is no published data on the stability and functionality of Stone Cone® and NTrap® when brought into direct and prolonged contact with pneumatic or laser driven disintegration devices. To address this issue simultaneously, we performed the second part of our study. Two safety aspects have to be considered when working with stone disintegration devices in close contact with stone catching or stone-trapping devices: the latter should be resistant to damage by the pneumatic probe or the laser energy delivered by the lithotriptor. Furthermore, the stone-trapping device should keep its functionality. If damage occurs, it has to be removable without causing injury to the ureter. There are reports on broken or damaged stone retrieval baskets causing ureteral injury or avulsion [13, 14]. Eventually, open surgery might be necessary to remove the damaged device or parts of it.

In our small series of experiments, we were able to demonstrate that the Accordion® device is durable and retains its functionality when directly exposed to an activated pneumatic or laser lithotriptor. Whereas the LithoClast® did not damage the Accordion device at all, the Ho:YAG-Laser caused small perforations (visible only under magnification) of the Accordion® film; the threedimensional stability of the device was not affected, no damage to the film–wire system was detected, and, most importantly, engagement and disengagement of the system was still possible after a maximal number of lithotripsy pulses/energy delivered. To our knowledge, comparable, systematic investigations do not yet exist for the Stone Cone® or the N'Trap® device; however, in one of the first publications of S. Dretler [15] on the Stone Cone® Laser, lithotripsy is discouraged because of the danger of melting or disruption of the coils of the device. A comparative in vitro analysis is under current investigation. Future research activities in this field should incorporate prospective, in the best scenario randomised, comparative clinical trials investigating the clinical efficacy and safety of different available stone-trapping devices. However, these trials have to be carefully designed and endpoints prudently chosen. We feel, that the only reasonable and clinically valuable endpoint for such clinical trials might be the stone-free rate in one session. Perhaps one arm where no stone-trapping device is used at all should be incorporated in such a trial, too, because the body of literature proving the advantage of any such device is somewhat small. Moreover, some tricks like proper patient positioning (head up) or fixing the stone against the ureteral wall, which have not been incorporated in our model, might even reduce the difference between using a device or not.

In summary, the Accordion® stone-trapping device shows convincing in vitro properties in terms of efficacy and safety. Clinical trials are needed to prove its value, especially in comparison with other devices.

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