A review of kidney stone ureteroscopy lithotripsy devices

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***ABSTRACT — BACKGROUND:** Surgical intervention for kidney stones which utilize ureteroscopy with laser lithotripsy can result in miniscule fragments that are irrigated out. A stone-free outcome does not occur in 42% of procedures, where "clinically insignificant residual fragments" (CIRF) can potentially be pathological. This demonstrates a need for adequate intraoperative CIRF containment methods, which can reduce CIRF pathology and follow-up procedures. This study aims to review popular devices and innovative approaches of existing devices aimed to control CIRF.*

***METHODS:** A search was conducted on MEDLINE and PubMed for articles related to kidney stone fragments and "anti-retropulsion" devices. A comprehensive list of devices and studies was created with both mechanical and gel-based devices.*

***RESULTS:** The following specific types of devices included in this study are baskets, suction devices, gels, and balloon catheters devices. Each device is either a popular device or an innovative one within each device category. A common theme among these devices is that a combination of multiple approaches, such as a balloon and a basket device together, can improve stone free rates. Similarly, using existing devices in novel innovative methods can lead to improvement as well.*

***CONCLUSIONS:** We find that innovative and effective devices can be accomplished through synthesizing existing knowledge and utilizing novel techniques. Furthermore, these approaches are open to provider modifications to facilitate intraoperative adaptations. As ureteroscopic laser lithotripsy becomes a mainstay in treating kidney stones, innovative and intraoperatively flexible devices can further improve this procedure.*

KEYWORDS
Lithotripsy, Device, Gel, Kidney stone, Fragments.

INTRODUCTION

Kidney stones or calculi refer to crystals made of organic and non-organic compounds found in highly concentrated urine. Some risk factors for kidney stones include diabetes, hypertension, pregnancy, and history of previous stones[1,2]. Kidney stones are a relatively common issue as well, with a global prevalence rate of 14.8%[3]. Beyond solely a high prevalence rate, kidney stones have unique epidemiological features that make it of particular interest. Globally, kidney stone incidence has increased over the past couple decades, with a threefold increase in the United States from 1976-2010 [3]. This could be attributed to many factors, but the most prominent explanation seems to be improved detection methods. For example, using a CT scan has shown to produce more definitive diagnoses in addition to methods such as urinalysis and urine culture[4,5]. Additionally, higher rates of obesity[6], diabetes[7], and increased dietary consumption of salt[8,9], meat[10,11], and sucrose[12,13] have also been linked to increasing rates of kidney stones. Climate has also demonstrated an association with kidney stone development, as previous studies have found higher prevalence in dry and warm areas such

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as the Southern and Southeastern US[14,15]. With rising epidemiological concern of kidney stones comes an increased financial burden, as kidney stones comprised $2.1 billion in healthcare expenditures in the year 2000, a 50% increase since 1994[16]. Even with inpatient expenditures declining in that same period[16], the rising healthcare costs of kidney stones further indicate the need for effective and economically efficient interventions.

Kidney Stone Treatment and Fragments

Currently, kidney stones are either treated medically or surgically. Medical treatment includes prevention methods such as reducing dietary sodium content, increasing water consumption, and potentially using medications such as citrate supplementation, thiazide diuretics, and allopurinol[5]. Resulting from surgical intervention, clinically insignificant residual fragments (CIRF) of the original stone are a potentially serious complication that can lead to multiple downstream issues[17,18].

CIRF presents numerous further complications that can have a serious impact on patient recovery and lifestyle post-lithotripsy. Normally left behind in the body to be cleared naturally, calling these stone fragments "clinically insignificant" has become a misnomer over time[19,20]. The kidney only clears about one-third of all CIRF post lithotripsy[21], leaving behind numerous, potentially pathologic stone fragments. CIRF can cause urinary obstruction, persistent infection, and initiate stone reformation and require further surgical intervention to ensure adequate removal[22]. CIRF have been defined as less than 4 mm, but Iremashvili et al[17] found stone fragment pathology with fragments as small as 2 mm while Emmott et al[23] found stone fragment pathology independent of fragment size. The deleterious effects and complicated nature of residual stone fragments require appropriate intraoperative containment to prevent further complications and correctional intervention. To fulfill this need, many devices have been developed to prevent CIRF migration through various mechanisms. We review commonly used and novel devices aimed at controlling CIRF and other relevant intraoperative variables.

METHODS

A search for articles related to kidney stone fragments and lithotripsy devices was conducted on PubMed and MEDLINE. Search terms included "kidney stone fragments", "stone fragment migration", "kidney stone baskets", "kidney stone fragment balloons", "kidney stone suction devices", "kidney stone fragment gel", and "kidney stone guide wire". Titles and abstracts were first assessed for relevance, and then full text articles were as well. A cohesive list of commonly used and novel devices was determined from search results. These include both mechanical and gel-based devices.

The following types of stone containment devices will be reviewed: baskets, suction devices, gels, balloon catheters devices, and guide wire devices.

RESULTS/DEVICES

Stone baskets

Ncircle®

Ncircle® (Cook Medical, Bloomington, IN, USA) is the first nitinol-based basket removal device (Cook), as previous devices were made of stainless steel. The tipless version of Ncircle® has a 2.4 French (F) sheath four-wire basket with Delta wire® technology (cook-pdf). The tipless design minimizes trauma and bleeding while the Delta wire® design increases flexibility to work on a variety of stone sizes. This design captures large stone fragments and secures them as they are pulled out of the ureter. Hausmann et al[24] found that surgeons who used the Ncircle® and many other commonly used basket devices *in vitro* were unable to grasp sand grains (kidney stone fragment substitute) in a kidney model. While baskets were designed to secure large fragments for removal, the advent of holmium: YAG lasers in lithotripsy can deliver more powerful forces to stones, leading to smaller fragments that are inaccessible to basket devices. From an intraoperative perspective, a 2004 clinical trial [25] investigated the stone capture rate and time for Ncircle and other similar tipless basket devices, where it was found other devices performed better than the Ncircle®. For 2 mm fragments, the Halo (14 +/- 9 seconds) and Vantage (19 +/- 12 seconds) were significantly faster at fragment removal than the Ncircle (73 +/- 60 seconds, $p = 0.006$). Similarly, the Halo was superior to other basket devices for 5 mm fragments and the Microvasive Zerotip was the fastest for 8 mm fragments.

Peralta Stone Extraction System

The Peralta Stone Extraction System is a novel device which combines a nitinol wire stone basket and 5 mm diameter balloon to enhance stone fragment extraction. The catheter is 3 F wide while the balloon is 30 mm in length and can be inflated with up to 1.25 cc to a pressure of 1 atm[26]. This device has an identical stone removal mechanism as conventional basket devices, but the addition of a balloon to dilate the ureter further aims to facilitate stone removal and reduce intraoperative time. Preoperative studies demonstrated reduced extraction force and no significant trauma[26]. Because of its ability to dilate the ureter, it is proposed that small to medium size stone fragment removal is facilitated through regular irrigation, while the basket removal mechanism will benefit from the increased ureteral diameter to remove large fragments.

Suction devices
Lithovac®

The Lithovac® (EMS Urology, Nyon, Switzerland) was developed to create a consistent suction force during lithotripsy, particularly in conjunction with the Lithoclast® probe that was already in use. The Lithovac® is a probe either 1.6, 3.5, or 4.0 mm in diameter through which the Lithoclast® probe can be inserted, and a suction force is generated which can be controlled by a valve. The aim of the Lithovac® mechanism is to avoid stone migration and control stone fragment direction during lithotripsy. *In vitro* studies found 3.5 mm (10.5 F) and 4.0 mm (12 F) diameter probes to have "excellent" aspiration, and with the Lithoclast®, had the largest passable fragment of only 1.3 mm and 1.5 mm[27]. *In vivo*, this combination had a robust finding of 100% stone free rates in ureter and bladder stones with 0% residual fragments. However, this study was conducted in the context of percutaneous lithotripsy. Delveccio et al[28] assessed the Lithovac®/Lithoclast® combination with laser lithotripsy, and found that although demonstrating similar stone free rates, this approach would require additional procedures and repeated ureteral entry for basket fragment removal, greatly increasing ureteral trauma. Furthermore, the role of suction in laser lithotripsy is further complicated by a small working space as the ureteroscope and suction device simultaneously in the ureter and can obstruct a natural pathway for fragment expulsion[29].

Lithassist®

Lithassist® (Cook Medical, Bloomington, IN, USA) is a combination of a holmium: YAG laser along with a suction device. This device aims to reduce the number of devices crowding the ureteral space which can allow for facilitated passage of stone fragments through consistent irrigation. A 11.6 F diameter outer catheter houses a 5 F internal canal for the laser, so the outer portion can provide suction of fluid and stone fragments. Okhunov et al[30] compared Lithassist to the Swiss Lithoclast® Ultra (SLU), a device combining ultrasound fragmentation technology with suction. Okhunov et al[30] discovered that for soft stones the SLU device was superior for disintegration levels of "2 mm (2.83±0.41 *vs.* 4.15±0.70 minutes, $p=0.049$), complete disintegration (3.18±0.20 *vs.* 6.40±1.95 minutes, $p=0.038$), and complete removal (3.30±0.22 *vs.* 8.82±1.05 minutes, $p=0.001$)". However, SLU could not disintegrate hard stones, while LA could, with a "mean time for first disintegration, disintegration to 2 mm, complete disintegration, and complete removal was 3.60±1.36, 7.25±3.33, 7.54±2.94, and 8.64±2.78 minutes, respectively"[30].

Gel
Backstop™

A reverse thermosensitive water-soluble polymer, Backstop™ (Boston Scientific Corp., Marlborough, MA, USA) aims to prevent stone fragment migration during lithotripsy by temporarily obstructing the ureter. Dispensed with either a 3 F or 5 F catheter, Backstop™ is a liquid below temperatures of 16°C and solidifies at body temperature[31]. Due to being inserted immediately proximal to the stone, Backstop™ is compatible with lasers or other ureteral probes. This gel aims to absorb stone fragments and contain them while saline irrigation dissolves it for removal. A randomized controlled trial found the group assigned to Backstop™ significantly reduced stone retropulsion but did not improve stone free rate at all[31].

Biocompatible Adhesive

Building upon the foundation and parameters of using a gel to prevent stone fragment migration, a novel adhesive device has recently been developed. Using a flexible ureteroscope, the adhesive will attach stone fragments and still be small enough to be removed without changing the state of matter of the adhesive. Hausmann et al[24] tested a bioadhesive adhesive *in vitro* by assessing the gel's ability to contain sand grains which it unfortunately was not significantly better than a normal basket approach. However, further development of this device, especially in contrast to the Backstop™, could yield promising results.

Balloon
Passport®

A simple combination of a non-compliant balloon and a catheter, the Passport® (Boston Scientific Corp., Marlborough, MA, USA) device aims to dilate the ureter to prevent stone retropulsion. A 3 F wide catheter, Passport® is also coated with Hydroplus®, a polymer, which prevents friction against the ureteral wall and can support inflation up to 8.5

ATM of pressure[32]. Expanding proximal to the targeted calculi, this device allows for stone fragment and irrigation control by blocking backward flow. An early study of 42 patients into the effectiveness of Passport® by Dretler[33] found 29 had the balloon successfully placed behind the kidney stone, of which 26 were stone free after one treatment. Dretler [33] also argues for the cost efficiency of this device, as it is relatively inexpensive and saves costs on repeat procedures. With a lack of serious complications, the Passport® emerged as a worthy device to control stone fragments. However, its use is limited by the size of the ureter: a ureteral diameter larger than 12 F (the maximum diameter of the balloon) allowed stone fragments to flow proximally, around the balloon. This would reintroduce the complications of CIRF, establishing Passport® as a potential solution in a small subset of patients.

Uromax Ultra®

Building upon the basic model of a balloon catheter to prevent kidney stone retropulsion, the Uromax Ultra® (Boston Scientific Corp., Marlborough, MA, USA) has a few unique features that establish it as an innovative balloon device. It can inflate up to a pressure of 20 ATM, contains radiopaque bands to facilitate visualization under fluoroscopy, and a kink resistant shaft with a tapered distal end which eases passage through tight, tortuous ureters [34]. While an improved balloon dilation mechanism seems to only add on to merits of earlier devices such as the Passport®, it must be understood that there are serious side effects associated with balloon use in ureteroscopic lithotripsy. Chang et al[35] looked specifically at Uromax Ultra® use in laser lithotripsy to assess its relationship with acute kidney injury and renal tubular damage, where they found a strong association with Uromax Ultra® use. As lithotripsy procedures head towards an outpatient setting, side effects such as acute kidney injury and renal tubular damage would require further inpatient admission and monitoring. That not only negates the cost effectiveness of balloon catheters due to further hospitalization costs but can also cause adverse effects for patients with previous kidney damage.

Guide Wire
Stone Cone®

The Stone Cone® is a coil-like device that prevents stone retropulsion by securing the stone distal to the laser during fragmentation. It can also facilitate stone fragment removal by grasping fragments from behind as they are pulled out. Made of nitinol like guide wire material, this device uses a guide wire approach to control stone retropulsion and remove fragments without taking up further space in the already limited ureter. Shelbaia et al[36] looked at 119 patients to assess the effectiveness of the Stone Cone®, demonstrating that the group that had the Stone Cone® used during their lithotripsy procedure had a higher success rate and fewer adverse effects. However, this study was conducted in the context of pneumatic lithotripsy, which is key to realize in assessing Stone Cone® effectiveness. Due to being available for a long time and studied under various contexts, the Stone Cone® has a strong reputation due to compatibility with various types of lithotripsy procedures. Allameh et al[37] looked at Stone Cone® effectiveness in laser lithotripsy procedures, where they found it to have a 55% stone free rate, which was the lowest compared to holmium laser dusting and a stone retrieval basket. It was also found that sans the laser group, the stone basket and Stone Cone® basket had no significant differences. Although a valid option for stone fragment containment in procedures with large stone fragments, laser lithotripsy creates miniscule fragments for which the Stone Cone® is not the most prominent option.

Guidewire-Coil method

A novel method to utilize guidewires to control stone fragmentation is the "Guidewire-Coil" approach developed by Dreger et al [38]. In patients undergoing laser lithotripsy, a hydrophilic guidewire with a nitinol core and angled tip was advanced up the ureter and after reaching the renal pelvis was "looped" to turn back into the ureter[38]. The goal of this approach was to prevent stone retropulsion and control fragments. Stone free rate, although not statistically significant, was higher in the "Guidewire-Coil" group, while stone migration was significantly reduced. Although this method was not able to significantly affect stone free rate, it is a simple and safe method that does not require new devices but rather the creative use of existing tools. Further randomized trials are needed to confirm the safety and efficacy of this method.

DISCUSSION

As current devices continue to improve patient outcomes and provide a wide variety of options for stone fragment containment, it is important to better understand the underlying need for future innovation. Sen et al[39] conducted a study comparing the effectiveness of Stone Cone™, Percsys® Accordion™ (a type of guide wire device), and a lidocaine jelly (a gel-based approach). Prospectively reviewing 100 patients who had undergone ureteroscopic lithotripsy, the researchers found that the Stone Cone™ and

Accordion™ were significantly more effective than no device or the lidocaine jelly. This study establishes that lithotripsy devices can be similarly effective and will always be more effective than not using any device. Additionally, both are guide wire devices, which offer the greatest degree of ease and operational space within the ureter compared to other, potentially bulkier devices. Ahmed et al[40] in a systematic review also found that the devices assessed had no differences in stone retropulsion but were significantly different in other aspects such as device insertion and use. These studies suggest that any lithotripsy device is equally effective, and the use of any type can provide a significantly improved stone free rate. Rather than comparing devices, it is important to adapt uses as per the type of operation and the patient undergoing the procedure. Uretersoscopy is one type of lithotripsy, and other types require the use of the devices discussed above. Furthermore, it seems that the future of stone fragment control devices lies not in improving individual devices but combining useful aspects of multiple devices to create a "hybrid" model. With co-morbid, obese, or pediatric patients, there are various mechanical and physiologic considerations that can complicate lithotripsy. Using effective existing technology and modifying it to fit the needs of such patients will lead to multiple types of use for a single device. Future device innovation can take direction from other types of devices for such use as well.

CONCLUSIONS

While our assessment of lithotripsy devices is not exhaustive, we believe it to be a representative sample of a large proportion of the urological device market. As such, these trends represent an interesting trend that could represent a unique landscape in the future. Using and combining existing technologies and knowledge to create complex stone devices can be more effective than marginally improving upon individual devices. Additionally, this gives providers flexibility as devices are more familiar and can be customized upon encountering deviations in patient anatomy. Analyzing the differences in patient outcomes using innovative combination and method-based devices against conventionally used devices can provide a deeper level of understanding necessary for intraoperative decision making. Finally, as the device market heads into territories, maintaining other existing innovative standards such as the most updated lithotripsy laser technology can provide findings with stronger clinical relevance as well.

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