Innovations in surgical stone disease

Jodi A. Antonelli

Purpose of review
Urinary stone disease is a condition characterized by a rich history of surgical innovation. Herein, we review the new ideas, devices and methods that are the cornerstones of contemporary surgical innovation in stone disease, specifically flexible ureteroscopy and percutaneous nephrolithotomy.

Recent findings
The new ideas being applied to flexible ureteroscopy include extending the boundaries of surgical indications and eliminating the need for intraoperative fluoroscopy. Device advancements include disposable ureteroscopes and flexi semirigid ureteroscopes. Robotic flexible ureteroscopy, the use of magnets and mobile technology applications represent progress in methods of performing flexible ureteroscopy. Three-dimensional computed tomography and printing technology are enhancing percutaneous renal access. Novel image-guided access techniques are improving the accuracy of percutaneous surgery particularly for complex cases.

Summary
New ideas, devices and methods are continuing to reshape the landscape of surgical stone treatment and in so doing not only have the potential to improve surgical outcomes but also to cultivate further scientific and technological advancements in this area.

Keywords
fluoroless ureteroscopy, image-guided percutaneous renal access, robotic flexible ureteroscopy, surgical stone treatment

INTRODUCTION

Innovation is defined as a new idea, device or method. Throughout its history, urology has been characterized as a specialty that embraces surgical innovation. Urinary stone disease is a condition in which innovation is constantly changing the landscape of treatment options. The fact that open stone surgery is essentially obsolete exemplifies the role of innovation in the management of stone disease. Less morbid procedures such as retrograde intrarenal surgery (RIRS) and percutaneous nephrolithotomy (PCNL) have supplanted open surgery for the management of ureteral and renal stones [1,2]. Although these procedures were at one time innovative, contemporary innovations in surgical stone disease continue through new ideas, devices and methods for these procedures. Herein, we review the contemporary innovations in surgical stone disease specifically those relevant to RIRS and PCNL.

NEW IDEAS IN URETEROSCOPY

Over the last several decades, the indications for ureteroscopy (URS) have broadened in large part because of technological advances in ureteroscopes and adjunctive equipment. Historically, URS with laser lithotripsy was considered an alternative to shockwave lithotripsy (SWL) for the management of ureteral stones and small renal stones [3] and had little role in the management of large renal stones [1]. More recently, investigators have demonstrated that URS outcomes, both stone-free and complication rates, are comparable or superior to SWL and PCNL for large renal stones. These results have substantially broadened the 'scope' of stones for which URS is considered a safe and effective surgical option.

There have been a number of mainly retrospective studies comparing RIRS and PCNL for the management of large renal stones [4–15]. De *et al.* [16▪▪] performed a systematic review and meta-analysis

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KEY POINTS

- Technological advances in ureteroscope design and adjunctive tools for the procedure have extended the indications to include the safe and effective treatment of large renal stones.
- Fluoroless ureteroscopy is safe and effective particularly for those at highest risk of radiation exposure (pregnant women, children and recurrent stone formers).
- Robotic-assisted ureteroscopy with laser lithotripsy and stone extraction is feasible and improves surgeon ergonomics.
- Three-dimensional CT reconstructions and printing are being used as reference tools to improve percutaneous renal access planning in both training and clinical practice.
- Laser 3D CT-guided renal access and optical tracking on ultrasound are just some of the proposed image-guided advances to improve percutaneous renal access particularly in difficult cases.

comparing RIRS and PCNL for the management of renal stones that included two randomized and eight nonrandomized studies. Overall, PCNL had a significantly higher stone-free rate [odds ratio (OR) 2.19, 95% confidence interval (CI) 1.53–3.13, $P < 0.001$] as well as a higher complication rate (OR 1.61, 95% CI, 1.11–2.35, $P < 0.001$), and a greater decrease in hemoglobin [weighted mean difference 0.87 g/dl, 95% CI 0.51–1.22, $P < 0.001$] compared with RIRS. These findings support RIRS as a viable alternative to PCNL for the treatment of large renal stones particularly those less than 2 cm

As the indications for URS expand, the number of these procedures performed annually in the USA has risen dramatically. A review of case logs submitted to the American Board of Urology by candidates for certification and first and second recertification from 2003 to 2012 showed that URS procedures rose from 40.9 to 59.6% in both young and older urologists [17▪]. An analysis of Medicare data over a 10-year period ending in 2010 showed that URS surpassed SWL as the most frequently performed procedure for ureteral stones [18].

With increasing utilization of this procedure have come increasing attempts to improve its safety including the novel idea to eliminate fluoroscopy. Although radiation exposure during URS is generally quite small the potentially deleterious biological effects exist at any exposure level [19] and most urologists, operating room staff and stone patients are at risk for cumulative exposure. Olgin *et al.* [20▪] developed a novel technique of fluoroless URS. The authors compared complication, stone-free and repeat procedure rates for 50 patients who underwent fluoroless URS and 50 patients who underwent conventional URS for a stone indication.

The fluoroless technique involves initial use of an angled glidewire and assessment of tactile cues to determine if the wire is advancing into the kidney [21]. A dual lumen access catheter is used to place a second wire. The flexible scope is then advanced initially under tactile feedback and then under vision until the stone is encountered (Fig. 1). Stent size is chosen by assessing ureter length during flexible ureteroscopy (fURS) by separately marking the ureteroscope with tape at the levels of the ureteropelvic and ureterovesical junctions and measuring

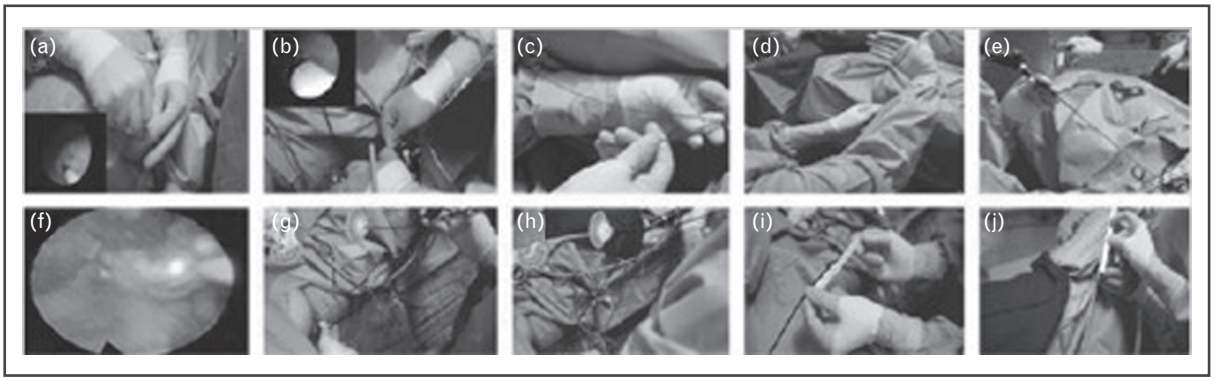

FIGURE 1. Fluoroless technique for flexible ureteroscopy with laser lithotripsy (a) 6F catheter passed over glidewire. (b) Dual-lumen catheter to dilate ureteral orifice. (c) Two working wires placed through dual-lumen catheter. (d) Distal ends of wires are same length indicating appropriate position in kidney. (e) Ureteroscope advanced over wire. (f) Holmium laser lithotripsy. (g) For stent sizing, external mark placed on the ureteroscope at ureteropelvic junction. (h) For stent sizing, second mark placed on ureteroscope at ureterovesical junction. (i) Stent length determined by measuring the distal between these marks. (j) Stent measured.

the distance between markings. The stents are placed under direct endoscopic vision. The operative times (60.6 and 59.2 min), stone-free rates (92 and 92%), postoperative complications (4 and 4%) and repeat procedure rates (4 and 8%) were not significantly different for conventional versus fluoroless URS, respectively. These results demonstrate the safety and efficacy of this novel technique and support its use particularly for those at highest risk of radiation exposure (pregnant women, children and recurrent stone formers) [20▪].

NEW DEVICES FOR URETEROSCOPY

A significant advancement in fURS occurred with the evolution from a fiber-optic to a digital platform, however, one of the drawbacks of these small diameter digital devices is fragility and the resultant costs associated with the need for inevitable scope repair and replacement [22–24]. Another disadvantage of digital URS is sterilization that can incur both direct and indirect costs particularly if it is not done properly [25].

A single-use ureteroscope is a device that offers potential solutions to the aforementioned drawbacks of conventional multiuse ureteroscopes. The first single-use flexible ureteroscope was the Polyscope. This device was composed of a disposable multilumen endoscopic catheter with channels for a reusable optic cable, a light cord, a working channel and a steering mechanism [26]. The initial results with the Polyscope suggested the device was safe and effective for diagnostic and therapeutic URS including for the treatment of urinary calculi up to 3 cm, however, the biggest disadvantage was the unidirectional deflection [27–29].

The next iteration of disposable ureteroscope, the SemiFlex (MaxiFlex LLC, Baton Rouge, LA, USA), was completely disposable obviating the direct cost and concerns with sterilization. The device had a 7.85F outer diameter, a 3.4F working sheath, a G14732 Y-port adaptor for irrigation (Cook Medical, Bloomington, IN, USA) and active up/down deflection. When compared with six other commercially available multiuse flexible ureteroscopes, the SemiFlex had comparable active tip deflection, flow rate and optical qualities [30].

Most recently, the LithoVue (Boston Scientific, Marlborough, MA, USA) has been introduced as the first single-use digital ureteroscope with 270° deflection in both directions. The device's performance has not been published in peer-reviewed format, but data presented internationally suggest that it maintains the advantages of its single-use flexible ureteroscope predecessors with the additional benefits of better deflection and image quality reported as consistent with that achieved by multiuse digital ureteroscopes and superior to fiber-optic technology [31]. The performance of the single-use flexible ureteroscope could be approaching that of its reusable counterparts, but it remains to be seen whether this technology is financially feasible and environmentally sound, particularly at high-volume URS centers.

The flexible ureteroscope, be it single or multiuse, is best suited for the treatment of stones in the proximal ureter and kidney, and can be technically challenging to use in the distal ureter. The Sun's tip-flexible semirigid ureterorenoscope (SN-V, Hawk Endoscopes, China) is designed to include the aspects of both types of scopes in one device. The Sun's scope is a rigid ureteroscope with a 9 cm flexible distal tip and a retractable rigid sheath. The flexible and rigid modes are switched by releasing the flexible tip. The scope has dual 250°/270° flexion, ranges in diameter from 8.2 F distally to 9.8 F proximally. Gao *et al.* [32] tested the efficacy and safety of this device for the treatment of proximal ureteral (135) and renal (81) stones. Only three patients had stones that could not be treated and these were located in lower calyces with small angles that precluded treatment with conventional fURS as well. In this study, a low rate of insignificant complications was encountered with the use of this scope. Although further controlled studies are necessary, early results suggest that it could be a safe alternative in those situations wherein resource allocation is limited and multipurpose devices are encouraged.

NEW METHODS FOR URETEROSCOPY

Several decades of modifications to ureteroscope design have unequivocally improved the safety and functionality of this technology and in so doing extended its boundaries and consequently its frequency of use and operation duration when treating larger stones. Although this trend has been beneficial to patients, the ergonomic burden of URS is being felt by endourologists with up to 60% of respondents to a survey reporting orthopedic complaints including back, neck and hand problems, and with the majority of hand/wrist problems requiring medical or surgical intervention [33,34]. The robotic surgical platform is well suited as a potential method to alleviate the ergonomic strain of URS.

Desai *et al.* [35,36] were the first to test the feasibility of robotic-assisted URS with laser lithotripsy with the Hansen device (Hansen Medical, Mountain View, California, USA) modified from initial intracardiac indication. This specific interface

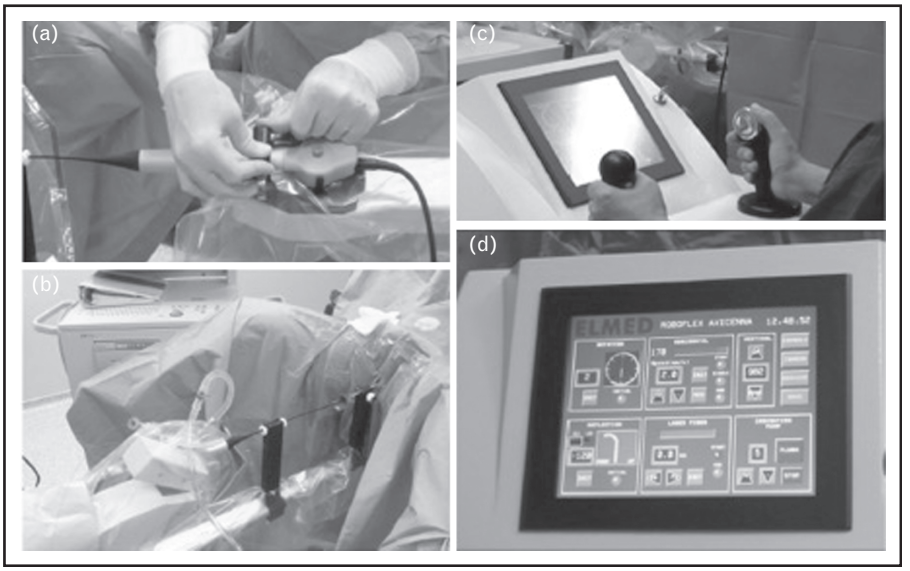

FIGURE 2. Avicenna roboflex robot-assisted flexible ureteroscopy. (a) Ureteroscope in robotic arm. (b) Manipulator with a motor and robotic arm that can fit any ureteroscope and can rotate 210° in either direction. (c) Console joysticks: right joystick controls the direction of scope deflection and the left controls the rotation, advancement and retraction of the scope. (d) Touch screen allows advancement/retraction of a laser fiber and adjustment of irrigation flow.

has not been further pursued but a URS specific robotic interface, Avicenna Roboflex (ELMED, Turkey), has since been developed and continues to be investigated. The console consists of an adjustable seat and armrests and two joysticks. The right joystick controls the direction of scope deflection and the left controls the rotation, advancement and retraction of the scope. A touch screen additionally allows advancement/retraction of a laser fiber and adjustment of irrigation flow and foot pedals control the laser and fluoroscopy. There is also a manipulator with a motor and robotic arm that can fit any ureteroscope and can rotate 210° in either direction (Fig. 2) [37▪▪].

Saglam *et al*. [37▪▪] reported on the results of fURS with laser lithotripsy using this novel platform for the treatment of stones up to 3 cm in total diameter in 81 patients. Stones were treated with high-frequency, low-energy 'ablation' or 'dusting'. The mean operative time was 74 (range: 74–182) min with a mean robot dock time of 59.6 (range: 35–124) s. No significant complications occurred. Only two cases required secondary conventional fURS, and ergonomic questionnaire scores significantly favored the robotic platform over conventional URS in seven queried surgeons ($P < 0.01$). Data from 90 cases performed by three surgeons in Heilbronn, Germany, reproduced these initial results and further demonstrated that fragment extraction was possible [38]. These results support that the robotic platform may be a safe and effective alternative method to conventional URS with potential advantages for both the patient and the surgeon. Further investigations are warranted to substantiate these claims and delineate the risk/benefit ratio of this technology particularly including a cost-benefit analysis.

Magnetic navigation is another novel method that has been proposed to improve the safety of ureteroscopy for both the patient and the surgeon. A magnetic tracking system (3D-Guidance medSAFE; Ascension Technology Corp., Milton, VT, USA) coupled to sensors on a ureteroscope was developed with the intent of improving navigation accuracy and simultaneously reducing or eliminating the need for fluoroscopy. Yoshida *et al*. [39▪] evaluated the performance of urologists at various levels of experience with ureteroscopic maneuvers in a phantom. The accuracy and time to complete the tasks were better with the magnetic navigation system compared with tradition fluoroscopic-guided navigation [40▪]. This concept is novel and could have future clinical application if the simulation program could accommodate organ deformation and positional changes that are a reality *in-vivo*.

The technologic advances that have made URS a more attractive surgical technique have simultaneously dissuaded or prohibited its use for some because of cost considerations. Methods that could extend the availability of URS without increasing the cost have become more appealing particularly in developing countries. The application of mobile technology to ureteroscopy has been explored by

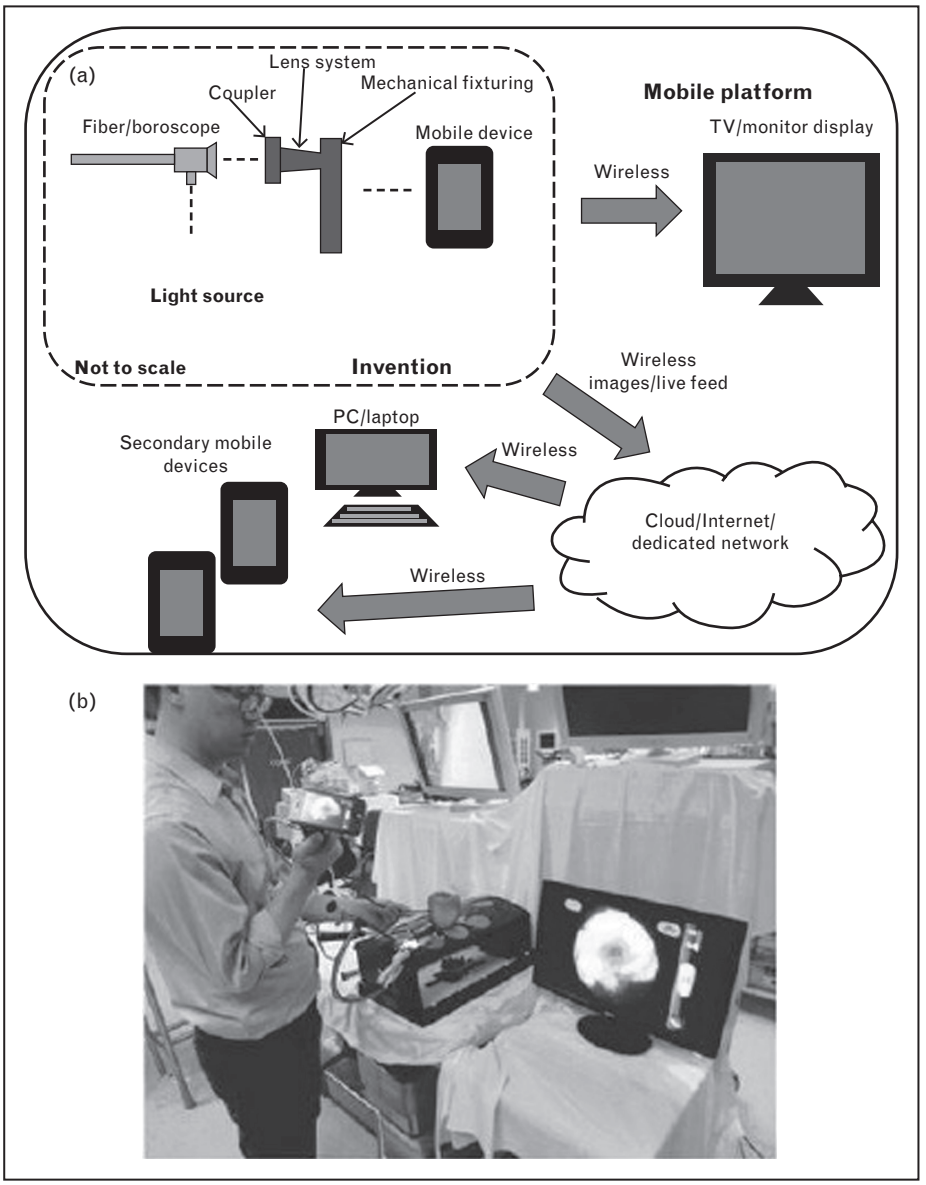

FIGURE 3. (a) Custom-machined components fit an off-the-shelf prescription lens to a smartphone allowing for the cystoscopic image to be displayed on the camera mode screen. Images can then be wirelessly sent to monitors or to other devices through cloud based transfer. (b) Endockscope a specialized lens and docking system, to convert a smartphone into a mobile endoscopic viewing system.

Sohn *et al.* [41] who reported on the use of Endockscope (Orange, California, USA), a specialized lens and docking system, to convert a smartphone into a mobile endoscopic viewing system. Custom-machined components were used to fit an off-the-shelf prescription lens to an iPhone 4S (Apple Inc., Cupertino, CA, USA) allowing for the cystoscopic image to be displayed and centered on the iPhone camera mode screen in 8X optical zoom for maximal picture clarity. Images can then be wirelessly sent to monitors or to other devices through cloud-based transfer (Fig. 3). The feasibility of utilizing ubiquitous consumer-based mobile technology in endoscopy is a promising and novel method by which to extend the availability of URS in a cost conscious manner.

NEW IDEAS IN PERCUTANEOUS NEPHROLITHOTOMY

The first step to a successful PCNL is precise percutaneous renal access. The first step to a successful PCNL is precise percutaneous renal access. Two-dimensional imaging such as preoperative CT

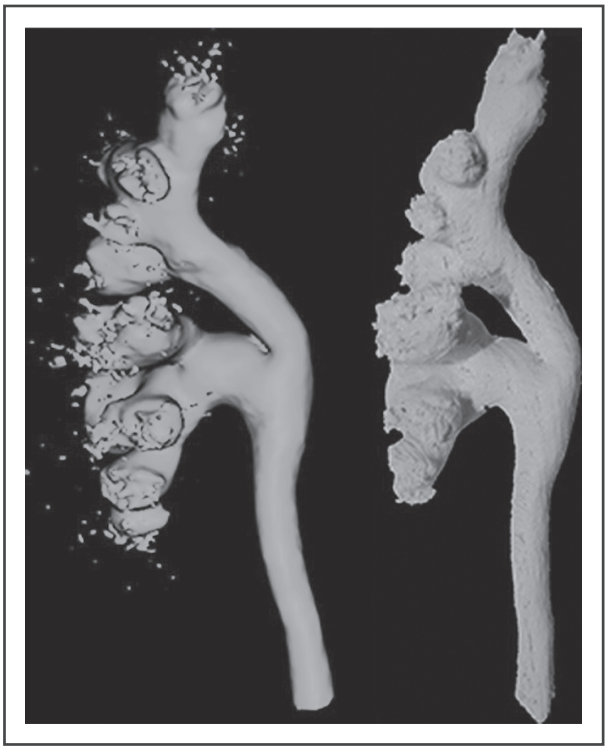

FIGURE 4. Water-soluble plastic biomodels made from 3D reconstruction images of human collecting systems.

and/or intravenous pyelography and intraoperative fluoroscopy and/or ultrasound are the conventional tools used for access placement. Advances in CT technology have led to three-dimensional (3D) CT reconstructions, however, limitations still exist with translating those images on a monitor to the spatial relations of the calyceal system in the patient on the operating room table.

Turney [42▪] used a 3D printer to transform 3D CT reconstruction images of collecting systems into water-soluble plastic biomodels that were then embedded in silicone and dissolved in water resulting in a silicone model with hollow collecting systems (Fig. 4). These 3D human collecting system biomodels are ideal training tools for percutaneous access, but the process is time prohibitive and incurs additional cost and it therefore has minimal practicality in clinical practice.

Gadzhiev *et al.* [43▪] sought to develop a more practical intraoperative tool to aid in conceptualizing the 3D nature of the calyceal system and the stone contained within it. Their technique involves specifically the surgeon using the 3D CT reconstruction images to hand sculpt the calyceal system and stone from Plasticine in an average time of 20 +/– 6 min and for an average cost of 5 dollars. The authors stress that this technique has merit not only in the model that is produced which acts as a tangible intraoperative reference tool but also in the process of the surgeon creating it and in so doing become more familiar with the collecting system.

NEW DEVICES FOR PERCUTANEOUS NEPHROLITHOTOMY

The advantage of PCNL that enables it to be so well suited for the management of large kidney stones is the unique ability to not only fragment stones but also efficiently evacuate them from the collecting system with suction that is part of ultrasonic (Cyberwand, Olympus, USA) and combined ultrasonic/pneumatic (Lithoclast Ultra, Boston Scientific, USA) lithotripters. Several studies have compared stone fragmentation with these devices to holmium-yttrium-aluminum-garnet (Ho:YAG) laser, and shown that Ho:YAG laser more effectively breaks up hard stones but has the disadvantage of requiring manual fragment extraction because of a lack of combined suction [44,45].

The LithAssist (Cook Medical, USA) was developed as a device to deliver simultaneous laser energy for stone fragmentation and suction for evacuation during PCNL. Okhunov *et al.* [46] reported on the in-vitro results comparing the LithAssist with the Lithoclast Ultra for the treatment of artificial, gypsum cement-based soft and hard stones. They found the Lithoclast Ultra was superior to LithAssist for the treatment of soft stones, but for hard stones the LithAssist outperformed Lithoclast Ultra on all parameters including mean time for complete disintegration [3.17+/−0.20 and 6.39+/−1.95 min, respectively, ($P = 0.03$)] and mean time for complete stone removal [3.30+/−0.21 and 8.81+/−1.05 min, respectively ($P = 0.001$)]. These data support the superiority of LithAssist over Lithoclast Ultra for the treatment of gypsum-based hard stones, however, in-vivo testing is required to corroborate these results in humans.

NEW METHODS FOR PERCUTANEOUS NEPHROLITHOTOMY

Successful PCNL is predicated on accurate percutaneous renal access that safely avoids injury to the kidney or surrounding structures and provides a direct approach to the largest amount of stone. Adjuncts to traditional fluoroscopic and ultrasound-guided renal access have been developed as methods to improve the safety and efficacy of renal access and concomitantly the procedure as a whole.

An operating room-based CT unit, The Urological Dyna-CT (Siemens Healthcare Solutions, Erlangen, Germany), has been developed that includes not only CT but also 3D reconstruction images as standard X-ray and fluoroscopy [47]. It also has a

laser-guided puncture tool, the syngo iGuide, which can be used when performing 3D-guided access. Ritter *et al.* [48▪▪] presented the results of this novel access method in 26 patients with 27 punctures. The median time for image acquisition and 3D generation was less than 2 min and prepuncture review of images and planning took on average 5 min. The success rate of puncture was 89% with 88% success on the first puncture. The median time to puncture was 30 (range 30–420) s and the median fluoroscopy time was 0.7 (range 0.1–4.4) min and the mean dose area product by CT was 6113.1 (range: 1081.6–7957.2) mGym^2. Two puncture attempts were aborted because of contrast extravasation and one was converted into ultrasound-guided because of mobility of the kidney even with breath holding. Notably, image acquisition during this technique requires a higher radiation exposure compared with conventional fluoroscopy but for difficult cases where the kidney stone, kidney or surrounding anatomy pose challenges, this novel method can be beneficial.

Ultrasound-guided access is advantageous to fluoroscopy because it decreases or eliminates radiation exposure to the patient and surgical team, however, ultrasound is an imaging technique with a steep learning curve and one which most urologists, even those who obtain their own percutaneous access, might not be as familiar and therefore comfortable with using. Clear Guide One (Clear Guide Medical, Baltimore, MD, USA) is an optical tracking system that mounts on an ultrasound probe and provides real-time tracking for needles and instruments [38]. The Clear Guide Synergy adds CT image fusion capability to this technology. Although no one has published on its use in percutaneous renal access, this novel method could be the adjunct necessary to increase urologist utilization of ultrasound-guided PCNL.

Attempts at other novel image-guided methods including iPad-assisted image-guided access and electromagnetic tracking of percutaneous puncture have been shown to be feasible but of limited utility as a sole means with which to safely gain renal access. Instead, these modalities may have utility as adjuncts to existing imaging methods to improve the safety and efficacy of percutaneous renal access [38].

CONCLUSION

Technological advances in flexible ureteroscopy have extended the indications for this procedure increasing the utilization of this technique overall and specifically for the management of larger stones. New ideas, devices and methods for ureteroscopy are focused on improving not only the safety and efficacy of the procedure for patients but also for surgeons through efforts to reduce radiation exposure and ergonomic burden. The use of 3D imaging technology is being applied to percutaneous renal access planning and technique. New ideas, devices and methods are continuing to reshape the landscape of surgical stone treatment and in so doing not only have the potential to improve surgical outcomes but also to cultivate further scientific and technological advancements in this area.

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Conflicts of interest

J.A.A. is on the scientific advisory board of Boston Scientific. There are no conflicts of interest.

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