Instrumentation in endourology

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Rakesh Khanna and Manoj Monga

***Abstract*:** Success with endourological procedures requires expertise and instrumentation. This review focuses on the instrumentation required for ureteroscopy and percutaneous nephrolithotomy, and provides a critical assessment of *in vitro* and clinical studies that have evaluated the comparative effectiveness of these medical devices.

***Keywords*:** endourology, ureteroscopy, nephrolithotomy, instrumentation, technology

Correspondence to:
Manoj Monga, MD
Director, Stevan B. Streem Center for Endourology and Stone Disease, Glickman Urological and Kidney Institute, 9500 Euclid Avenue, Q10-1, Cleveland, OH 44195, USA
mongam@ccf.org

Rakesh Khanna, MD
Department of Urology, Glickman Urological and Kidney Institute, Cleveland Clinic, Cleveland, OH, USA

Introduction

The field of endourology has advanced considerably over the past three decades. The development of semirigid, fiberoptic, and actively deflecting ureteroscopes has allowed all areas of the collecting system to be accessed. With the development of novel ancillary equipment, it has evolved primarily from a diagnostic tool to become also a therapeutic procedure used to treat nephrolithiasis, ureteral strictures, and transitional cell carcinoma.

Endourology is highly dependent on advanced equipment to obtain satisfactory outcomes. Industry is constantly developing smaller instruments and scopes with improved vision and increasing deflection. The objective of the current review is to summarize new technological developments in the field, and to provide a review of the literature to support an evidence-based model on instrument selection.

Ureteroscopy

Advances in ureteroscope design have resulted in smaller scopes with increasing deflection capabilities and easier access to lower pole calices. Functionality is highly dependent on the size and type of accessory instrument in the working channel [Bach *et al.* 2008]. The flexible ureteroscope remains one of the most fragile instruments in medicine and should be handled carefully by experienced personnel. Indeed, a recent study suggests that scope longevity can be increased by sterilization within the urology core personnel rather than relegating that responsibility to a central supply area [Semins *et al.* 2009].

Flexible fiberoptic ureteroscopes

Paffen and colleagues compared the optical and physical characteristics of four new generation ureteroscopes including the Gyrus ACMI DUR-8 Elite, Storz Flex-X^2, Olympus URF-P5, and Wolf 7325.076 [Paffen *et al.* 2008]. The Wolf scope had the smallest tip size at 6.0 Fr while the ACMI had the largest shaft size at 10 Fr. The Storz and Wolf scopes had superior deflection and torsion stiffness, whereas irrigation was superior with the shorter ACMI scope and inferior with the longer Olympus scope. It was noted that the dual-lever deflection of the ACMI increased the complexity of scope manipulation. The Olympus and Wolf scopes had the best optical quality although the Olympus scope had poorer illumination.

Knudsen and colleagues evaluated the durability of the Wolf Viper, Olympus URF-P5, Gyrus ACMI DUR-8 Elite, and Stryker Flexvision U-500 in a randomized, multi-institutional trial [Knudsen *et al.* 2010]. The ACMI required major repair after the fewest mean number of cases (5.3). While the Stryker and Wolf scopes each experienced early catastrophic failure (fewer than 10 cases) in one of three sites, this occurred at all sites for the ACMI. In an older study published in 2007, the ACMI was noted to be one of the most durable scopes [Holden *et al.* 2008]. It can be seen that the ACMI has lost its status as the most robust scope with the improvement in scope design from other manufacturers.

Haberman compared the Wolf Cobra dual-channel (3.3 Fr each) ureteroscope to the Wolf Viper single channel (3.6 Fr) scope [Haberman *et al.* 2010]. They noted that the dual-channel scope provided superior flow and deflection when larger instruments were deployed. In addition, they reported utilizing the second channel to stabilize stone or tissue while laser ablation was applied through the dedicated laser channel [Ortiz-Alvarado *et al.* 2010].

Flexible digital ureteroscopes

Despite technical advances in ureteroscopic design, the scopes continue to have problems with vision and durability. It has been proposed that digital ureteroscopes with a 1 mm digital camera at the tip and dual light-emitting diode-driven light carriers may provide significant advantages in this regard [Andonian *et al.* 2008b]. The elimination of fiber optic bundles also allows for a larger working channel for instrument passage and irrigation.

Shah and colleagues compared the Gyrus ACMI/Olympus Invisio DUR-D and the Olympus URF-V digital ureteroscopes in a prospective, randomized trial [Shah *et al.* 2010]. The URF-V offered better visibility and maneuverability compared with the DUR-D. In 9% of cases (7% for the DUR-D and 11% for the URF-V), the stone could not be reached with the larger digital scopes and a conventional URF-P5 fiberoptic scope was required to complete the case.

Multescu and colleagues compared the performance of the Storz 11274AA flexible fiberoptic ureteroscope to the Olympus URF-V digital flexible ureteroscope [Multescu *et al.* 2010]. The digital scope was found to have superior maneuverability and visibility. However, it was noted that a narrow infundibular width (<4 mm) may predict failure of the larger tip digital scope to access segments of the upper urinary tract. After 22 procedures in each group, a deflection loss of 10 degrees was present for the fiberoptic ureteroscopes whereas no change was present with the digital ureteroscope.

Xavier and colleagues evaluated the efficacy of a laser fiber protection system in preventing damage to the DUR-D ureteroscope [Xavier *et al.* 2009]. The system functions by recognizing the outer blue covering of the Dornier DURHL-20 laser fiber and disabling the laser generator if the fiber is drawn into the scope preventing inadvertent firing. The system was 100% effective in shutting down the laser prior to entry into the ureteroscope. However, the authors noted that the effectiveness of the system may be decreased if significant bleeding is present or if blue dyes, such as indigo carmine, have been used. In addition, although the system prevents damage at the tip of the scope if the laser fiber is inadvertently drawn into the working channel, damage within the working channel may still occur if the laser fiber breaks within the scope as commonly occurs at the point of maximal deflection. While this system may potentially increase the longevity of flexible ureteroscopes, it is designed specifically for the DUR-D and cannot be applied to other digital scopes.

Guidewire

While it has been proposed by some groups that routine use of a safety wire is not required [Dickstein *et al.* 2010; Eandi *et al.* 2008], we believe that the presence of a safety wire adds no inconvenience yet maintains emergency access to the upper urinary tract throughout the procedure.

Numerous guidewires are commercially available. In general they differ in size, tip design, surface coating, and shaft rigidity. An ideal guidewire requires little force to flex in response to resistance and requires a large force to perforate tissue. A slippery hydrophilic guidewire is used to obtain access to the ureter or to bypass an impacted calculus, whereas a stiffer guidewire that is less likely to slip out is used to straighten a tortuous ureter, or to pass instruments and access sheaths into the upper collecting system [Holden *et al.* 2008].

Clayman and colleagues compared nine available guidewires: the Roadrunner PC and polytetrafluoroethylene (PTFE) wire (Cook Urological, Spencer, IN, USA), Glidewire, Bentson-type 15 cm flexible tip PTFE-coated wire, and Amplatz super stiff Urowire XF (Boston Scientific Microvasive, Miami, FL, USA), Bentson guidewire, and Amplatz guidewire (Applied Medical, Rancho Santa Margarita, CA, USA), and PTFE-coated Bard guidewire (Bard Urological Division, Covington, GA, USA) [Clayman *et al.* 2004]. They found that the Glidewire required the greatest force to puncture in an *in vitro* model whereas the Amplatz super stiff was the most resistant to bending. This indicated that in this *in vitro* model, the Glidewire would be the safest wire for initial access and the Amplatz super stiff would be the best wire for passing instruments.

Hybrid wires incorporating features of different glidewires (a hydrophilic distal tip for bypassing an obstructing stone, a kink-resistant body, and a flexible proximal tip for backloading of instruments) have been developed [Weiland *et al.* 2006]. In an abstract presented at the 28th World Congress of Endourology and SWL, Hendlin and colleagues evaluated two hybrid wires, the Bard NiCore and Boston Scientific Sensor [Hendlin *et al.* 2010]. They reported that neither hybrid wire was as stiff as the Boston Scientific Amplatz super stiff, suggesting the importance of continued reliance on this wire for passage of ureteral access sheaths and large stents.

Ureteral access sheath

Use of a ureteral access sheath has been shown to lower irrigation pressure, decrease costs, reduce operative time, facilitate ureteral re-entry, and improve ureteroscope longevity [Weiland *et al.* 2006].

Factors that are important to clinical application include a lubricated outer coating to facilitate entry, a low friction inner coating for easy ureteroscope insertion, and a reinforced wall to decrease sheath kinking and buckling.

While Shields and colleagues reported no significant difference in the overall successful placement of the applied reinforced and nonreinforced access sheaths, it is important to note that in this study 82% of patients were previously stented, which assists in easier stent placement [Shields *et al.* 2009].

In contrast, Monga and colleagues compared the 12/15 Fr Applied Access Forte XE (Applied Medical) and the 12/14 Fr Cook Flexor (Cook Urological, Bloomington, IN, USA) access sheaths in a clinical setting [Monga *et al.* 2004a]. These two sheaths were chosen based on *in vitro* studies. They noted that the device failure rate was 44% for the applied sheath and 0% for the Cook sheath. In each case of device failure, the Cook sheath allowed successful completion of the procedure. Furthermore, the Cook sheath was rated superior with regards to placement, instrument passage, and stone extraction. *In vitro* studies further demonstrated that the Cook and Gyrus ACMI UroPass access sheaths have the largest inner diameter in a straight and 30° bend position. In a subsequent analysis, the Cook Flexor remained the most resistant to buckling while the Gyrus ACMI Uropass was most resistant to kinking when compared with the Boston Scientific Navigator and the Bard AquaGuide [Pedro *et al.* 2007].

Harper and colleagues compared a novel balloon expandable ureteral access sheath with a conventional access sheath in a porcine model [Harper *et al.* 2008]. They noted that the balloon expandable sheath was easier to insert and resulted in less subjective trauma to the ureter compared with the conventional sheath. A balloon expandable sheath was released then withdrawn from the market; one concern was the ease of sheath removal at the end of the procedure, in particular if deployed across an area of ureteral narrowing.

Intracorporeal lithotripsy

Different intracorporeal lithotrites, including electrohydraulic, pneumatic, ultrasonic, and laser, are utilized in endourology. Electrohydraulic was the first modality developed. This was followed by the development of different laser energies, with presently the Holmium:YAG being the standard. The Holmium:YAG is effective against stones of all compositions and produces smaller fragment sizes compared with pneumatic or electrohydraulic lithotripsy. It is considered safer than electrohydraulic lithotripsy (which has the narrowest margin of safety), with a depth of penetration of less than 0.5 mm and provides higher stone-free rates. The Holmium:YAG causes less stone retropulsion compared with pneumatic lithotripsy [Garg *et al.* 2009].

Laser fibers exist in varying sizes and uses (single use *versus* reusable). Factors important in their use include durability and flexibility. Typically what is gained in durability is lost in flexibility. In general for flexible ureteroscopy, one uses the smallest fiber in order to maximize deflection and irrigant flow.

Mues and colleagues evaluated 24 Holmium:YAG laser fibers of different sizes from various manufacturers [Mues *et al.* 2009]. They compared small (150–300 μm) and medium (300–400 μm) fibers separately. They noted that of the small core fibers, the SureFlex LLF-150 and LLF-273, OptiLite SMH1020F, and Dornier LG Super 270 had the highest thresholds for failure. In the medium fiber group, the SureFlex LLF-365 and Accuflex 365 had the highest failure threshold. They also noted that the reusable Lumenis 365 fiber had a higher failure threshold compared with the single-use fiber.

Knudsen and colleagues further evaluated multiple reusable fibers including the Laser Peripherals 270, Laser Peripherals 365, Lumenis Slimline 270, and the Lumenis Slimline 365; 37 laser fibers were required for 541 endoscopic procedures [Knudsen *et al.* 2011]. The 365 μm fibers had significantly more uses than the 270 μm fibers and the total cost savings was US$64,125. Of all the fibers used, only the reusable Lumenis Slimline 270 was found not to be cost effective owing perhaps to the cost of the fiber and the smaller number of cases in which it was used.

Stone migration/occlusion devices

Whereas advancements in scope design and technique of lithotripsy have allowed increasingly complex stones to be treated in an ureteroscopic fashion, stone migration remains a significant challenge. The risk of stone migration is affected by the pressure of the irrigant fluid, modality of lithotripsy, location of calculus, degree of impaction, and amount of proximal hydroureteronephrosis. A variety of devices have been designed to minimize stone retropulsion and increase ureteroscopic efficiency.

The Escape nitinol stone retrieval basket (Boston Scientific, Natick, MA, USA) is designed to capture calculi and allow for simultaneous laser lithotripsy. Kesler and colleagues reported on 23 patients who underwent ureteroscopic laser lithotripsy using the Escape basket [Kesler *et al.* 2008]. Twenty patients were rendered completely stone free, two patients had residual fragments smaller than 3 mm, and one patient had fragments larger than 3 mm. In three patients however, damage to the basket by the laser fiber prevented adequate closure requiring insertion of a new basket. Laser ablation of a stone while secured in a basket decreases stone migration, however it also impedes manipulation of the tip of the ureteroscope. In general, it is a technique that is recommended if a stone becomes entrapped in the basket at the time of extraction as opposed to a primary approach to stone management [Teichman and Kamerer, 2000].

The Stone Cone (Boston Scientific) is a ureteral occlusion device used to prevent retropulsion of stones larger than 2–3 mm during lithotripsy. It consists of a 0.43 mm nitinol wire with a 3 Fr PTFE cover with the distal sheath shaped in a concentric coil fashion. The stone cone is resistant to pneumatic or electrohydraulic lithotripsy, but can also be disrupted by the Holmium laser.

Eisner and Dretler retrospectively reviewed the use of the Stone Cone at an academic center over a 3-year period [Eisner and Dretler, 2009]. One hundred and thirty-three patients were identified and only two cases of residual retropulsed fragments greater than 2 mm were recognized. Of 105 cases of semirigid ureteroscopy, no case required conversion to flexible ureteroscopy secondary to stone migration. However, it was emphasized that patients with ureteropelvic junction stones or proximal hydroureteronephrosis greater than 10 mm were not included.

The Cook NTrap (Cook Urological, Spencer, IN, USA) is a 2.6 Fr device with a deployable backstop. In the laboratory setting it has been shown to prevent migration of plastic beads as small as 1.5 mm. Clinical experience has not been reported in the literature.

Lee and colleagues evaluated the Stone Cone and Cook NTrap in an *in vitro* model [Lee *et al.* 2008]. While they noted no difference between either device, they noted that stone retropulsion was decreased and fragmentation efficiency increased compared with a control group in which no device was used.

An additional evaluation by Ahmed and colleagues compared four ureteral occlusion devices, including the PercSys Accordion (Percutaneous System, Palo Alto, CA, USA), Stone Cone (7 and 10 mm) and the Cook NTrap, in a ureteral model [Ahmed *et al.* 2009]. The PercSys Accordion is a 2.9 Fr polyurethane film backstop. The Cook NTrap had the stiffest tip, which in a clinical scenario of an impacted stone may increase the risk of ureteral perforation. The force required for insertion and number of attempts at insertion was greater for the Stone Cone compared with the other devices; a finding that correlates with a softer tip. The total time for passage of the device was greatest for the PercSys Accordion. All devices were effective in preventing stone migration, and no significant difference in extraction force during fragment removal was seen for any of the devices.

Rane and colleagues reported the use of a thermosensitive polymer, Backstop, to prevent stone retropulsion [Rane *et al.* 2010]. The polymer is deployed proximal to the stone to occlude the ureter. Lithotripsy is then performed. At the completion of the procedure, the polymer is dissolved using saline irrigation. In a randomized study of 68 patients (34 with Backstop and 34 without any antiretropulsive device), patients in the Backstop group had a significantly lower rate of stone retropulsion. No adverse events were encountered in either group.

Retrieval devices

Many different stone baskets are commercially available. These differ in size, configuration, wire material and stiffness, radial dilation force to open in the ureter, and ability to capture/retain or disengage a stone. Baskets may also be tipped or tipless, with tipless baskets being superior for stone extraction from renal calices. In flexible ureteroscopy, the most commonly used baskets are composed of nitinol, which is less rigid compared with stainless steel and allows for greater deflection.

Evaluations of basket configuration and dilation force have demonstrated that the Cook NCircle has a more linear opening and closing dynamic that may lend itself to more controlled opening and closing [Monga *et al.* 2004b]. Radial dilation force of small <1.9 Fr baskets was strongest for the Sacred Heart Halo, while the Cook NCircle 3.2 Fr had the strongest force for application through a semirigid ureteroscope [Hendlin *et al.* 2004]. It was previously shown that the Cook NCircle 3.0 Fr facilitated efficient stone capture in ureteral models while the Sacred Heart Halo was more efficient in calyceal models [Lukasewycz *et al.* 2004a, 2004b]. For stones less than 1 mm in size, the Cook NCompass has a webbed configuration to assist with stone capture [Holden *et al.* 2008].

There has been a continuing trend to further miniaturization of devices to improve deflection and flow. Compared with the larger Microvasive Zerotip 1.9 Fr or the Cook 3 Fr laser flat wire baskets, the 1.5 Fr Sacred Heart Halo allowed for significantly higher irrigant flow rate [Weiland *et al.* 2006].

Chotikawanich and colleagues searched the MAUDE database for trends in stone failure over a 14-year period [Chotikawanich *et al.* 2011]. It was noted that with the increasing use of stone baskets, an increasing rate of device malfunction was noted. Compared with 1996–2004, a sixfold increase in rate failure was noted from 2008 to 2009. One possible explanation for this is that the newer 1.9 Fr or smaller baskets may be less durable for complex procedures compared with the larger size baskets.

In an abstract presented at the 28th World Congress of Endourology and SWL Korman and colleagues evaluated the radial dilation capabilities of three small stone baskets including the Boston Scientific Optiflex (1.3 Fr), the Cook NCircle Nitinol Tipless Stone Extractor (1.5 Fr), and the Sacred Heart Halo (1.5 Fr) [Korman *et al.* 2010]. While the Sacred Heart Halo had the highest radial dilation force compared with the other baskets, all baskets had four times lower radial dilation compared with the larger stone baskets [Hendlin *et al.* 2004]. This factor may impact deployment of these smaller baskets and, in the face of ureteral edema or stricture, use of these baskets may not be ideal.

Percutaneous nephrolithotripsy

Percutaneous nephrolithotripsy (PCNL) is the surgical procedure of choice for the management of large, complex, or multiple renal calculi. Similar to flexible ureteroscopy, since its initial description, technological innovation in accessory equipment and lithotripsy have focused on improving safety and efficiency.

Rigid nephroscope

The standard rod lens nephroscope has traditionally been the workhorse in PCNL. Andonian and colleagues reported the use of a new digital nephroscope, the Invisio Smith nephroscope from Gyrus ACMI, for the removal of caliceal stones in two patients [Andonian *et al.* 2008a]. With its integrated light source and camera, they reported the new scope was lighter, and provided improved ergonomics. The scope also has a large working channel (15 Fr) that permits the insertion of a wide variety of accessory instruments.

Balloons

The choice of access tract dilation is important to minimize the risk of bleeding and perforation of the collecting system. Gonen and colleagues compared balloon dilatation with Amplatz dilation of the nephrostomy tract in a retrospective chart review of 229 patients [Gonen *et al.* 2008]. They noted no difference in operative time or estimated blood loss. Furthermore, there was no statistically significant difference in failure rates (2% of Amplatz dilators failed secondary to hypermobility of the kidney, whereas 1% of balloon dilations failed secondary to fibrosis from previous surgery; when failure occurred with one technique, the access was successfully dilated by the other method). They concluded that urologists should be experienced with both techniques as use of an alternative method may be required during percutaneous surgery.

This study utilized a low pressure balloon (17 atm) for access tract dilation. It is likely that the newer higher pressure balloons (30 atm) could have reduced the failure rate in the balloon cohort. Hendlin and Monga compared the expansion of balloon dilators under increasing loads of extrinsic compression simulating retroperitoneal scar tissue [Hendlin and Monga, 2008]. The Bard X-Force, Boston Scientific Microvasive Amplatz Tractmaster, and Cook Ultraxx were tested. While all balloons performed well under low constrictive forces, the Bard X-Force (30 atm) and Cook Ultraxx performed best under the higher constrictive loads.

Intracorporeal lithotripsy

A variety of intracorporeal lithotriptors are available for PCNL. Ultrasonic and pneumatic lithotripters are most commonly used secondary to their safety profile and effectiveness. An advantage of the ultrasonic device is the presence of continuous suction to aspirate stone fragments. Disadvantages of the pneumatic device include stone migration and the need for individual fragment retrieval. Devices that incorporate features of both modalities are also available. The LithoClast Master (EMS, Nyon, Switzerland), also known as the LithoClast Ultra (Boston Scientific) in North America, is a combination ultrasonic and pneumatic lithotripter. The addition of the Lithopump suction and Vario handpiece to the LithoClast Select Series is thought to improve vision and allow higher power output, respectively, while the modified suction channel (straight in pure ultrasound mode and 45° angle in combination mode) is proposed to reduce clogging).

The Gyrus ACMI CyberWand is an ultrasonic lithotripter that contains two separate probes that vibrate at two distinct frequencies to break up calculi. The probes are of different length, which is also thought to cause a ballistic effect. The CyberWand had a stone penetration time almost twice as fast compared with the LithoClast Master in an *in vitro* model [Pugh and Canales, 2010].

The Cook LMA Stonebreaker is a pneumatic lithotripter that was studied in a prospective multi-institutional trial. It is a portable lightweight device. In this trial it was successful in fragmenting all stone types. KUB stone-free rates were reported to be 100%. In no case was another intracorporeal lithotripter required nor was an antiretropulsion device used [Rane *et al.* 2007].

Zhu and colleagues compared different lithotripters, including the pneumatic lithotripter, Swiss LithoClast Master, and Holmium laser, in the percutaneous management of proximal ureteral calculi [Zhu *et al.* 2010]. While they noted that the operative time was shorter and the stone-free rates were higher with the LithoClast Master and the Holmium laser, they also noted a 16% incidence of ureteral strictures in the patients treated with the high energy Holmium laser at 1-year follow up.

Retrieval devices

The Cook Perc NCircle is a tipless, nitinol stone basket designed for PCNL. In an *in vitro* comparison with the Storz 3-prong grasper, the Perc NCircle was found to have a faster stone extraction time with less risk of inadvertent sheath removal [Hoffman *et al.* 2004].

Conclusion

The armamentarium available to the endourologist has increased dramatically over the past decade. As the cost of equipment increases, in the face of limited financial resources, there will be increasing pressure to perform minimally invasive surgery in an economical fashion. This should not occur at the expensive of high-quality patient care. It is hoped that the information available in this review will help the practicing urologist make an evidence-based decision on the appropriate equipment to be selected for the clinical situation.

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Conflict of interest statement

Dr. Monga has served as a consultant for Bard, Boston Scientific, Cook Urological, and Gyrus ACMI.

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