uroTrends

VOLUME 11 NO. 2

A NEWSLETTER ON EMERGING ISSUES IN UROLOGY

CONTENTS

The Evolution of Flexible Ureteroscopes & Results of an Extended Usage Study

Vincent G. Bird, MD

Almost a full century has passed since Hugh Hampton Young's first endoscopy in the dilated ureter of a child in 1912. The evolution of ureteroscopy later continued with the introduction of small caliber rigid ureteroscopes. These instruments have for some time been used for treatment of distal ureteral pathologies with good success. The rigid nature of these endoscopes, though on a smaller scale than their cystoscopic counterparts, has given these instruments good durability and a regular place in the urologic armamentarium. However, the demands of more proximal upper tract anatomy, for which the more complicated flexible ureteroscopes have been created, has been an ongoing challenge. Many urologists have harbored reservations concerning the overall performance of flexible ureteroscopes. Now is a time for renewed interest. Here is a review of what has been learned and what these lessons have taught engineers in the creation of the latest flexible ureteroscopes.

Incredibly, manufacturers of flexible ureteroscopes have been able to address many anatomic and technical concerns related to negotiation of the upper urinary tract proximal to the iliac vessels, and have, by means of ingenious application of a variety of technologies, created the flexible ureteroscopes in use today. The most recent generation of flexible ureteroscopes are approximately 8 French in diameter, and have a 3–4 French working channel for both irrigation and introduction of working elements such as guidewires, baskets, graspers, laser fibers, and biopsy forceps. Many of these ureteroscopes also

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CyberWand: Improving PCNL with a Ground-breaking Dual Ultrasonic Lithotriptor

J. Robert Ramey, MD
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Over the past 30 years percutaneous nephrostolithotomy (PCNL) has become widely available, supplanting open stone surgery as the "gold standard" for treating patients with large stone burdens (> 2.0 to 2.5 cm). Multiple lithotrites have been employed for stone fragmentation during PCNL, including electrohydraulic (EHL), ultrasonic, pneumatic, and various laser media, each with their own inherent advantages and disadvantages. Ultrasonic lithotripters typically consist of a hand piece containing a piezoelectric crystal array which generates vibrational energy, at frequencies up to 27,000 Hz, that is then transmitted to the stone via a hollow metal probe.[1] They are able to effectively breakup most stone types and provide simultaneous removal of calculus fragments via suction tubing connected to the hollow lumen of the ultrasound probe and have thus become the instrument of choice for most urologists performing PCNL.

Unfortunately, when treating stones of very hard composition, such as calcium oxalate monohydrate or brushite, ultrasonic lithotripters become much less efficient at stone fragmentation. The holmium:YAG laser can be employed in these cases, however, fragments must then be removed manually with either a stone basket or endoscopic grasping forceps. Alternatively, a pneumatic lithotripter can be employed in conjunction with an ultrasonic probe to decrease fragmentation time but, switching between two instruments is cumbersome and the inability to suction out fragments with the pneumatic device

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have considerably exaggerated bidirectional active deflection near the distal tip to further aid maneuverability, notably in terms of accessing lower pole calyces. There are numerous reports of minimally invasive successes with these impressive instruments, such as very high stone free rates for ureteropyeloscopic stone treatment, resection of limited upper tract transitional cell tumors, and incision of ureteral and intrarenal strictures. These successes have been tempered by the fragility of these devices. The same parameters that are prerequisite for the use of these ureteroscopes are also associated with their fragility. These small diameter fiberoptic endoscopes, with their even smaller working channels and active deflection mechanisms, are at risk of degradation and damage, even when used by a skilled endoscopic surgeon. The issue of durability is of critical importance in that it directly relates to the economic practicality of the performance of ureteroscopy.

For some time, even though the fragility of flexible ureteroscopes was recognized by many, there was little understanding of the true underlying nature of this problem. The likely reason for this was the existence of limited communication between those actually using these endoscopes and the manufacturers/engineers producing them. To directly address this issue, at the University of Miami, approximately three years ago, we began prospectively collecting data that included a multitude of parameters associated with performance of ureteroscopic cases.[1] Our study and other recent studies[2,3] have begun to shed light on the nature of how these fragile instruments tend to degrade and break. Our study and similar studies can be of great value in that they highlight current weaknesses that guide engineers to where effort should be given toward the redesign of specific mechanisms of these devices and toward the creation of new paradigms in ureteroscope design that may, to a larger degree, preclude the current problems that exist.

Our study at the University of Miami is currently the largest study in terms of the number of cases and ureteroscope usages. The number of cases included in this study has uniquely created a "larger picture" of what happens to flexible ureteroscopes through extended time and use. Our database is ongoing, and now includes nearly one thousand ureteroscopic cases. Commonly cited mechanisms for damage to flexible ureteroscopes include degradation through repeated use, excessive torquing/twisting, inadvertent laser firing within the working channel, improper advancement of ancillary devices through a deflected ureteroscope, and inadvertent damage during cleaning/processing. In our study, in order to clarify these observations, damaged scopes were all returned to the manufacturer of the endoscope, for inspection by their engineers, in order to determine the specific nature of damage incurred (figure 1). A brief consideration of these possible mechanisms of damage follows here. These mechanisms are individually highlighted for the purpose of understanding possible types of damage, but it is important to keep in mind that when damaged ureteroscopes are inspected by expert engineers closely involved in their manufacture, it is often the case that damage deeming the scope further unusable is multifactorial.

Perhaps most exciting in the ongoing evolution of flexible ureteroscopes are larger shifts in the paradigm of design and construction. This is indeed the case with … the Invisio® flexible Ureteroscope DUR-D.

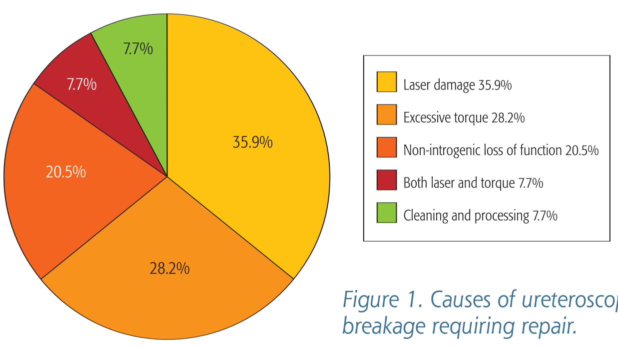

Figure 1. Causes of ureteroscope breakage requiring repair.

With repeated uses the active deflection mechanism tends to degrade in terms of range of active deflectability. This observation is well documented.[1–3] This degradation likely occurs due in part to very fine parts that are subjected to relatively large repetitive forces through ongoing use of the ureteroscope. However; these deflection mechanisms may also be iatrogenically damaged by inappropriate movement of the scope while held in the deflected configuration. As such, proper orientation and training for the performance of flexible ureteroscopy is critical, foremost for good patient care, but also for maintenance and preservation of the equipment.

Similarly, the fiberoptics along the shaft of the endoscope may be damaged in a variety of ways. After repeated uses, one may often see small black dots in the field of view, each dot representing a disrupted fiber somewhere along the shaft of the ureteroscope. Mechanisms of damage and degree to which damage occurs are variable. Fibers within the shaft may be disrupted by inordinate twisting/ torquing of the scope, inappropriate laser firing with the ureteroscope, inadvertently compressing/crushing the shaft of the scope while it is on the backtable, or even during the processing/cleaning process.

The use of lasers in conjunction with ureteroscopy merits significant attention. As shown in figure 1, laser damage in and of itself is a highly significant factor. Inadvertent laser firing within the working channel of a ureteroscope may result in direct fiber disruption and/or fluid leakage. Furthermore, advancement of a laser fiber or other devices through the working channel of a deflected ureteroscope can cause substantial damage not only to the working channel, but also to the fibers alongside in the shaft. It is also imperative that the operator understand the nature of laser fibers and how laser energy is transmitted through them. Laser fibers, especially those of small diameter (e.g. 200 microns), are quite fragile. Considerable care should be taken to avoid weakening or fracturing these fibers at their time of introduction. This includes introducing them into the working channel in an atraumatic manner and avoiding use of relatively high-energy output for a fiber of a given diameter. Fibers that break can not only result in damage to the ureteroscope, but also to the operator if the break results proximal to fiber insertion into the working channel.

Attention should also be given to the cleaning and processing. Damage to flexible ureteroscopes during this process has been known to occur, and is certainly avoidable. Each institution must individually address this issue as many hospitals have policies concerning which methods of cleaning are allowable. In our facility, ureteroscopes are processed within the urology suite through use of the Steris System 1® processor (STERIS Corporation, Mentor, OH, USA) by those who are knowledgeable and experienced with the instrumentation. This has led to only very rare instances of damage.

After identification of the aforementioned mechanisms of damage, the important question at hand concerns what can be done about these problems. The answer is that many things can be done, and are being done, in a variety of different ways. As ureteroscopy becomes more commonplace, urologists are becoming more familiar with regular use and care of these instruments. Teaching institutions must always maintain vigilance when new residents are being trained. It is likely that orientation sessions prior to actual patient procedures are useful in this regard. Training operating room personnel in regular cleaning and maintenance

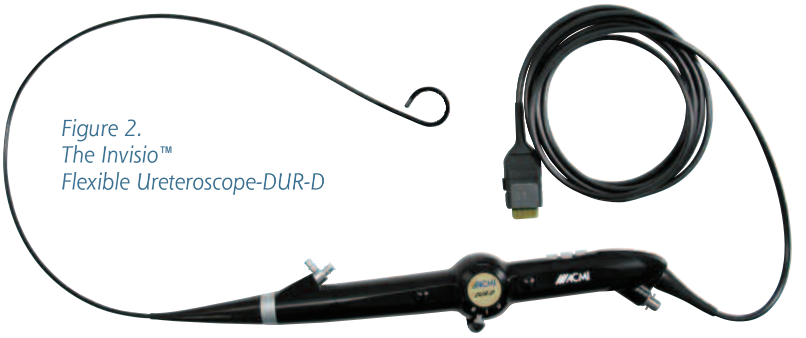

Figure 2.
The Invisio™
Flexible Ureteroscope-DUR-D

is also highly recommended. Our most recent study demonstrated that newly purchased scopes, including the DUR®-8 and DUR®-8 Elite (Gyrus ACMI, Southborough, MA, USA) lasted 40–48 uses prior to significant damage. In this study these scopes were all subjected to general use by a large number of residents and staff, attesting to the assertion that this last generation of ureteroscopes are of a relatively more durable construction.

Perhaps most exciting in the ongoing evolution of flexible ureteroscopes are larger shifts in the paradigm of design and construction. This is indeed the case with the latest generation flexible ureteroscope available, the Invisio® Flexible Ureteroscope DUR®-D (Gyrus ACMI, Southborough, MA, USA) (figure 2). Engineers have applied new technologies to this ureteroscope that not only allow for ease of use, and excellent visualization, but perhaps even more importantly, to increased durability, in terms of total usages. These modifications and technologies include integration of the endoscope, digital camera, and light source that allows for easy "plug and play" use. This new ureteroscope also has a complementary metal oxide semiconductor (CMOS) imaging sensor at its distal tip, replacing the previous generation's highly susceptible and lower resolution fiberoptics. This new scope also employs the use of a light emitting diode (LED), a "cool" light that eliminates potential patient/physician and/or drape burns that are possible with use of xenon light sources. This new light source also may last 10 – 20 times longer than xenon lamps. It is likely that this latest generation ureteroscope will augment the performance of ureteroscopy in a variety of different manners that include ease of use, less investment in equipment, superior visualization, increased safety, and improved durability. There is little doubt that in our world of rapidly evolving technologies many more exciting advances in flexible ureteroscope design are on the way.

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THE DISTAL SENSOR DIGITAL FLEXIBLE URETEROSCOPE: AN OPTICAL EVALUATION

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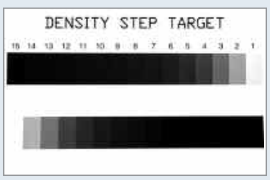
INTRODUCTION: Advances in electro-optics continue to improve the Urologist's ability to perform minimally invasive procedures. While the development of flexible fiberoptic ureteroscopes has greatly facilitated upper tract procedures, distal sensor, digital technology (DSDT) may represent the next step in the evolution of endoscopy. We compared a new DSDT ureteroscope to two standard, new fiberoptic flexible ureteroscopes *in vitro* and *in vivo*.

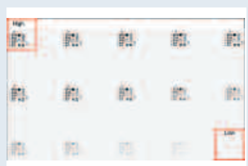
METHODS: Seven subjects compared each ureteroscope across 6 test parameters

Ureteroscope	Optics	Camera	Light Source	Pixels
Gyrus ACMI DUR-D	Distal-sensor	Intrinsic Digital	Intrinsic LED	>60,000
Fiberoptic # 1	Fiberoptic	Snap-on 3-chip	External Xenon	<5,000
Fiberoptic # 2	Fiberoptic	Snap-on 3-chip	External Xenon	<5,000

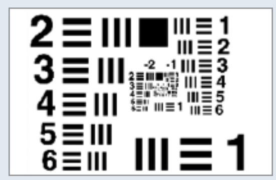
Contrast: the ability to see different intensities, shades of white, gray and black. The variation between density steps is linear (0.1 density increments). Each ureteroscope was positioned at a distance of 1 cm from the target, directly over the darkest square, and advanced slowly along the 15-step grayscale gradient towards the lightest square until the observer noted a difference in the amount of contrast.



Density step gradient (contrast)



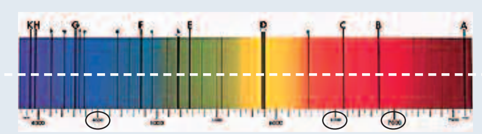
1981 USAF Resolution Target



Magnified view of resolution Square

Resolution: the ability to discern fine detail. Resolution at high and low contrast was measured 1 cm above the target.

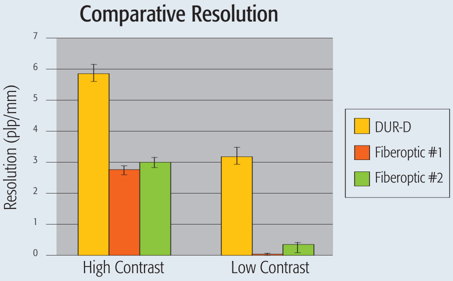
Color Discrimination: the ability to discern different shades of one color. A standard color spectrum chart was transected longitudinally. With the ureteroscope poised at wavelengths of 7000 Angstroms (dark red), 6500? (light red) and 4500? (blue), the top portion of the chart was slowly moved to the left, so that the shade of red or blue increased in intensity until the observer noted a difference in the reference color (bottom portion of the chart) and the test color (top of the chart). The difference in these two values was recorded and the process was repeated, this time moving the upper portion of the chart to the right so that the color became lighter.



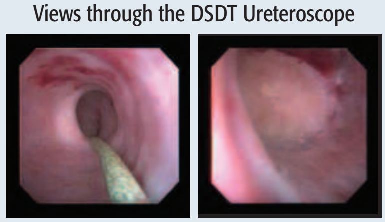
Visible postion of the Solar Spectrum

RESULTS: The DUR-D DSDT ureteroscope was statistically superior to one or both fiberoptic ureteroscopes across 5 of 6 tests, including contrast discrimination and resolution at high and low contrast. Unlike the fiberoptic ureteroscopes, the DSDT image was never affected by pixelation, glare or Moiré effect (wavy-line pattern).

Comparative Resolution

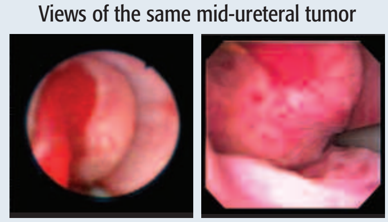


Views through the DSDT Ureteroscope



Upper pole calyx | Renal papilla

Views of the same mid-ureteral tumor



Fiber Optic | Distal Sensor Digital

CONCLUSIONS:

- The DUR-D distal sensor, digital technology ureteroscope demonstrated superior resolution *in vitro* in comparison to two state of the art, new fiberoptic ureteroscopes.
- Better image quality could translate into greater precision and shorter procedures.

CyberWand, continued from page 1

increases operative time due to more tedious stone removal. The Lithoclast Ultra™ (Boston Scientific) overcomes this problem by combining both modalities into a single instrument and *in vitro* testing has shown this to be a more efficient lithotrite than lithotripters which employ ultrasonic energy alone.[2] However, since the pneumatic probe passes through the ultrasonic probe the effective lumen size for suctioning out stone fragments is significantly decreased and the dual hand pieces makes for a bulky, somewhat clumsy instrument.

The CyberWand™ (Cybersonics) is a new dual ultrasonic lithotripter from ACMI Gyrus (Southborough, MA) which combines an inner fixed probe conventional ultrasonic lithotripter vibrating at 21,000 Hz with a concentric outer "floating" probe that uses technology initially developed for NASA planetary rovers to enable stone sampling from distant planets. The outer probe is powered by the same ultrasonic generator but, vibrates at 1,000 Hz. Meanwhile, the concentric arrangement of the two probes allows the "floating" outer probe to glide over the inner probe and impact the stone as it is driven by the free mass positioned at the base of the outer probe. A spring loaded over the "floating probe" limits its excursion, keeping the outer probe from extending beyond the inner probe thus preventing tissue damage. Additionally, built-in software in the ultrasonic generator allows the probes pulse-rates to be varied to efficiently treat both large and small stones. The CyberWand's™ concentric alignment also keeps the entire lumen of the inner probe free, allowing for evacuation of stone fragments in a more expeditious fashion than combination ultrasonic/pneumatic lithotriptors. The advanced engineering and software combined in the CyberWand™ result in an ergonomic instrument that is easy to use powered by a small, low-profile generator that slips into the smallest endourology suite with ease.

The CyberWand™ Dual Ultrasonic Lithotriptor

In vitro studies confirm the theoretical advantages of these design advances. Kim, *et al.* from Indiana University found that the CyberWand™ was nearly twice as efficient in a hands-free stone penetration assay compared to the Lithoclast Ultra™ (4.77 seconds vs. 8.09 seconds, $p < 0.0001$).[3] Clinically we have found a similar improvement in stone fragmentation rates, especially for complex calcium oxalate monohydrate stones whose inherent hardness might otherwise have necessitated a staged procedure with previously available lithotrites. Figures 1 & 2 show the CyberWand™ *in vivo* during PCNL for a complete stag horn calcium oxalate monohydrate/calcium phosphate stone. At the onset of the procedure (Fig. 1) the large stone setting is utilized to rapidly break-up the bulk of the stone burden, while the small stone setting allows for efficient retrieval of fragments toward the end of the procedure (Fig. 2) thus allowing more patients to become stone free following a single procedure. With these impressive clinical results the CyberWand™ has readily become the instrument of choice for all PCNLs performed at our institution.

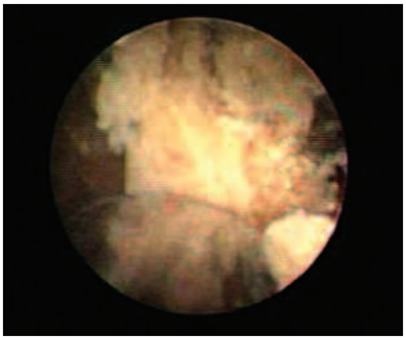


Figure 1: CyberWand™ fragmenting stag horn calculus

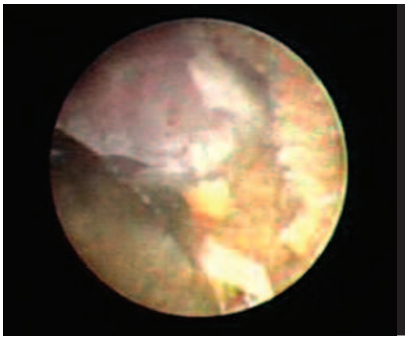


Figure 2: Cleaning up small fragments, note the concentric arrangement of the dual ultrasonic probes

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Versatile use of the PK™ Technology Cutting Forceps and Plasma Trissector in the Laparoscopic Radical Prostatectomy

Gerald H. Yoon, MD, and Gary C. Bellman, MD

Since the first description of the laparoscopic radical prostatectomy (LRP) in 1997 by Schuessler *et al*. and the standardization of operative technique widely popularized by the group from the Institut Montsouris in France, LRP has been established as a viable surgical approach for the management of localized prostate cancer.[1,2] As was the case following the introduction of the open radical retropubic prostatectomy, a number of endeavors describing refinement of technique to improve overall oncologic, continence, and potency rates were generated, LRP is currently undergoing a similar process of "fine tuning." Much has been published on the use of different energy types as it pertains to performing an effective nerve-sparing dissection. Ong *et al.* elegantly showed the detrimental effects of thermal and electric energy sources on parasympathetic nerves in peri-prostatic neurovascular bundles in a dog model.[3] Despite this, instruments utilizing electrical or ultrasonic thermal energy remain a vital tool in the performance of laparoscopic radical prostatectomy as they provide hemostasis and aid in precise dissection.

The PK™ Cutting Forceps (top) and the PK™ Plasma Trissector (bottom)

The PK™ Cutting Forcep and PK™ Plasma Trissector™ (from Gyrus ACMI Minneapolis, MN) are two laparoscopic instruments using bipolar energy we commonly utilize during laparoscopic radical prostatectomy. The PK™ Cutting Forceps employs vapor pulse coagulation energy and serves multiple purposes such as grasping, coagulating and cutting in a single instrument. This provides valuable savings in time and physical motion as the exchange of instruments is minimized. Pietrow *et al.* have already demonstrated the vessel sealing capability of the PK™ Cutting Forceps in a porcine model.[4] Arteries measuring 5mm or less and veins measuring up to 12mm were reliably sealed and cut as demonstrated by high burst pressures. The degree of thermal spread was also assessed and determined to be approximately 0.4–3.5mm from the cut edges of the vessels. Similar demonstrations of the versatility of the PK™ Cutting Forceps have also been shown by Santa-Cruz *et al*.[5]

The Plasma Trissector™ also employs adaptive bipolar energy for hemostasis and tissue sealing properties with the ability to effectively dissect tissue planes by virtue of its curved, atraumatic tip. Again, an advantage with cost-savings in time and instrumentation is afforded by the design of the instrument.

Our LRP technique closely mimics that of the Montsouris technique with a few modifications. The PK™ Cutting Forcep and Plasma Trissector™ are utilized in several key steps of the operation:

As the technique of laparoscopic radical prostatectomy continues to be refined and new advances are made in instrumentation, visualization and tissue dissection, the use of some energy source will inevitably be a mainstay in the surgeon's armamentarium.

1. Anterior Dissection – The peritoneum as it courses along the anterior abdominal wall is incised lateral to the medial umbilical ligaments which the incision carried caudally to the level of the vas deferentia as it courses from lateral to medial and cephalad to approximate level of the umbilicus. The PK™ Cutting Forcep provides a convenient method of coagulating structures such as the medical umbilical ligaments as well as dividing it with a single instrument. *(Figures 1 & 2)*
2. Exposure of prostate – As the space of Retzius is exposed and important landmarks are identified, the PK™ Cutting Forcep is utilized to first de-fat the anterior surface of the prostate. Again, hemostasis and division of small perforating vessels which course throughout the fat layers in the space of Retzius is effectively achieved. This will then provide wide and clear exposure of the endopelvic fascia on either side of the prostate. *(Figure 3)*
3. Superficial dorsal vein – The PK™ Cutting Forceps effectively coagulates the superficial dorsal vein and divides it in one single motion.
4. Bladder neck division – Prior to division of the prostatovesical junction, the PK™ Cutting Forceps is utilized to coagulate superficial venous channels from Santorini's plexus which emanate cephalad onto the bladder. *(Figure 4)*
5. Prostatic pedicles – Prior to clipping the main prostatic vascular pedicle, the PK™ Cutting Forceps or the Plasma Trissector™ can be used to divide lateral bladder wall attachments from the base of the prostate. When single vessels are isolated each device provides a means to quickly control and divide vessels without exchanging instruments.
6. Dorsal venous complex – The DVC may be controlled either with vas-

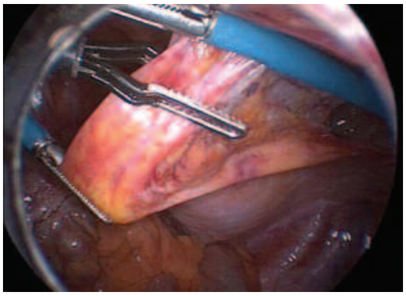

Figure 1. PK Cutting Forcep used to cauterize medical umbilical ligament prior to division.

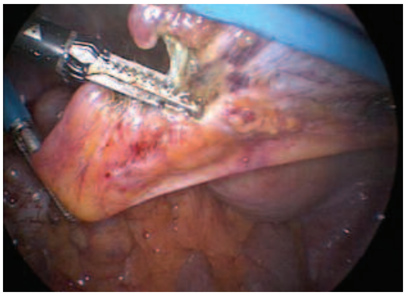

Figure 2. PK Cutting Forcep used to divide medial umbilical ligaments.

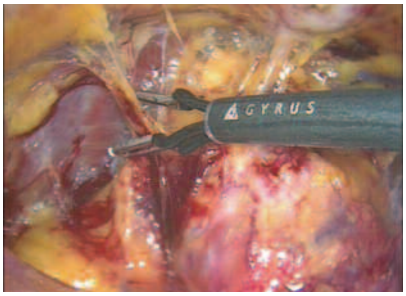

Figure 3. PK Cutting Forcep used to expose anterior and lateral surfaces of prostate.

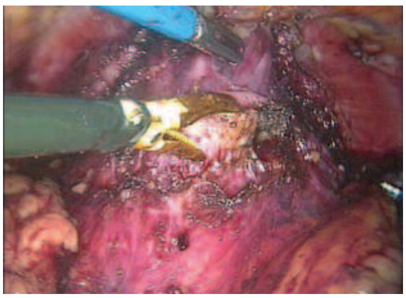

Figure 4. Plasma Trissector used to divide prostatovesical junction.

cular staplers such as an Endo GIA or with suture ligature. In the event that incomplete hemostasis is achieved, we have found the PK™ Cutting Forceps to be effective in selectively cauterizing bleeding channels.

7. Neurovascular Bundle – The lateral fascia overlying the prostatic capsule is bluntly dissected to enter the important plane between the neurovascular bundle and posterolateral prostatic capsule. Care is taken to avoid injudicious use of energy, however, when perforating vessels are well isolated, the Plasma Trissector™ is utilized to seal and cut them. This instrument also serves to dissect the planes in a blunt fashion without undue trauma or tissue tearing.

As the technique of laparoscopic radical prostatectomy continues to be refined and new advances are made in instrumentation, visualization and tissue dissection, the use of some energy source will inevitably be a mainstay in the surgeon's armamentarium. The surgeon must avoid unscrupulous utilization of such instruments especially during nerve-sparing dissections which may ultimately result in suboptimal patient outcomes. Instruments such as the PK™ Cutting Forceps and Plasma Trissector,™ which utilize adaptive bipolar energy, can be employed effectively in key steps of a laparoscopic radical prostatectomy. The advantages lie in the ability of the instrument to grasp, coagulate and cut in one single motion with ease.

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Learning Curves: Acquiring New Surgical Skills in Residency & Private Practice

Carson Wong, MD, FRCSC, FACS, and Po N. Lam, MD

The Challenge

The advent of technological advances in endourology, laparoscopy and computer-assisted robotic surgery have led to increased demand for specialized training of residents and practicing urologists. Increasing scrutiny from both the litigious public and governing medical authorities for technical proficiency and documentation of qualifications further prompt this need. These requirements are becoming more and more difficult to satisfy for residents especially, with implementations of new standards set forth by the Accreditation Council on Graduate Education (ACGME) and the 80-hour work week which limits time available for surgical training.[1] The steep learning curve and technical demands of laparoscopy make it difficult for practicing urologists to take adequate time away from their clinical practices to acquire such skills. In recent years, advances in training methodology and computer functionality have made training models available for both physician groups.

Adjunct Training Options

It has been well documented that there is an inverse relationship between surgeon surgical volume and patient operative mortality.[2] For residents, no longer does the tenet of "watch one, do one and teach one" apply. Unlike open surgical procedures, endourologic, laparoscopic and robotic surgery require more than just a detailed familiarity with the procedure; they require technical mastery. For many, the "dry" and "wet" laboratories have served as prerequisites to operating on a patient. "Dry" laboratories range from the crude covered boxes within which surgical tools are maneuvered, to elaborate high-fidelity genitourinary bench models geared to enhance hand-eye coordination by performing various tasks. Several "dry" pelvic trainers are currently available for practicing endoscopic skills. At our institution, endoscopic and laparoscopic laboratory training modules (supplied by Gyrus ACMI, Southborough, MA) provide task oriented skills training for our residents. The faculty is responsible for technique training at the modules and have developed an evaluation tool to use with the residents. Basic and advanced cystoscopic skills are tested by a timed flexible cystoscope maneuvering station and the transurethral prostate resection (TURP) simulator. Complex flexible ureteroscopy is tested by basket extraction of stones from various calyceal locations in a box simulator. Laparoscopic skills are monitored by one's precision in cutting a circle and ability to "decorticate" a balloon from a second balloon within. Such task oriented stations provide an objective method to assess skills acquisition of the resident physicians, identifying their strengths and areas for improvement. The benefits of endoscopic and laparoscopic training with such inanimate models have been well documented.[3–5] Matsumoto *et al.* conducted an investigation on the effects of didactic teaching and supervised hands-on surgical skills training laboratories. They found that there is a significant positive effect on the resident physician's endourologic skills after "dry" laboratory training, which may be effective in preparation for the operating room.[3] More importantly, technical skills gained from bench models show significant retention by novice surgeon. However, to maximize the retention and further develop one's technical skills, continued hands-on practice is essential.[6]

The "wet" laboratory or use of live or freshly-killed animals provides an additional training modality. It allows for more of a "real" training experience to prepare for surgery on a patient. Several studies emphasize that live animal experience is essential for skills training.[5,7,8] Traxer *et al.* reported that experience with an animal model significantly improves all aspects of complex laparoscopic procedures, regardless of one's prior "dry" laboratory experience.[5] Despite the benefit, there are definite constraints to the animal model. One formidable obstacle is the high financial cost associated with the requirement of a specialized facility and staff to care for the animals before, during and after the training session. In other locales (i.e. United Kingdom), the use of animals for surgical training is prohibited. In the United States, there are growing ethical concerns regarding the use of animals for this purpose, making it more difficult to further develop "wet" laboratory training. Limited "wet" laboratory availability places additional constraints on residents' ability to access this training modality, as they concurrently attempt to balance clinical demands, educational need and government laws.

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For the practicing urologist, technical skills acquisition can be even more difficult. Without the mentorship resources of a tertiary/quaternary academic center, "dry" laboratory skills training has limited efficacy. Studies have demonstrated that laboratory training in conjunction with mentorship programs are much higher yield training methods for skills acquisition.[3,9,10] Available to them are mini-fellowships, which usually demand only a few days or weeks of intense training with animal or embalmed cadaver models. Shalhav *et al.* demonstrated that the mini-fellowship model provides a rapid and safe process for teaching complex laparoscopic surgery to community urologists.[10] Such programs, provided by various academic centers, product sponsored venues and the AUA (American Urological Association, Baltimore, MD) have allowed for acquisition and dissemination of new surgical techniques to urologists with various training backgrounds. In 2003, we in conjunction with IMET (Innovations in Medical Education and Training, Haddenville, NJ), developed a hands-on urologic laparoscopy training course that utilizes the unembalmed cadaver model. This training model has the benefit of being more realistic than the embalmed cadaver specimen. According to J. Stuart Wolf, MD from the University of Michigan, "the cadaver model is simply the best there is for surgical training. No experience prepares you more effectively for the OR." Both mini-fellowships and unembalmed cadaver training courses, however, are extremely costly for the community urologist, demanding time away from clinical practice and a substantial financial commitment. As well, certain complexities associated with surgery in a patient remain unmatched.

In the future, with further refinement, VR simulators may promise to resolve the conflict between the need to acquire and refine new surgical skills with patient safety, personal time and travel constraints as well as financial efficiency for both the private practice urologist and the urology resident in training.

Virtual Reality Systems: The Future

With advances in visual graphics, virtual reality (VR) may provide the solution for complex skills acquisition in the future. Robert Mann, who is credited with pioneering the first VR system, calls it the "ultimate surgical simulator." Since inception, several systems that focus on urologic surgery have become available. The University of Washington TURP simulator is currently under preliminary validation studies.[10,5] URO Mentor (Simbionix, Cleveland, OH) has been validated for acquisition of endourologic skills that include flexible cystoscopy, ureteroscopy and percutaneous nephrolithotomy.[11–15] Shah *et al.* reported significant reduction in flexible cystoscopy time after URO Mentor training.[11] Jacomides *et al.* demonstrated that ureteroscopic skills acquired using the simulator by medical students were comparable to those of trained urology residents.[14]

Faculty proctor assists a resident with a procedure

The MIST VR (Mentice Corp., Cincinnati, OH) system allows for practice of basic laparoscopic skills such as "pick and place," intracorporeal suturing and diathermy. Although the technology is appealing, such skills can easily be practiced on simple box trainers that are far less expensive. Nevertheless, Seymour *et al.* demonstrated that the VR trained group performed laparoscopic cholecystectomy faster and with fewer intraoperative errors than the non-VR trained group.[16] These endourologic and laparoscopic VR systems remain rudimentary in their development. VR laparoscopic cholecystectomy is the only complete surgical trainer currently available. The success of Eindhoven laparoscopic cholecystectomy training course (Catharina Hospital, Eindhoven, The Netherlands), using the MIST-VR and Xitact LS500 laparoscopy simulator platform (Xitact, Morges, Switzerland), shows the promise of the transferability of VR training into the operating room by abbreviating the learning curve. However, VR training can not yet be a substitute for clinical training. Ogan *et al.* found that VR trained novice medical students were inferior on their performance on cadavers when compared to resident physicians with no VR training. They noted that simulators provided limited anatomical variations and case scenarios.[18] Another obstacle of current VR systems is the lack of realistic haptic simulation or tactile sensation. Burdea *et al.* reported the success of the prototype PHANToM (Sensable Technology, Woburn, MA) haptic interface for prostate digital rectal examination simulation.[20] LapSim (Surgical Science, Stockholm, Sweden) and Accutouch (Immersion Incorporated, Gaithersburg, MD) have developed laparoscopic training systems with haptic interface. How-ever, their training is currently focused on basic general surgical and gynecological procedures. VR systems for more complex endourology and laparoscopy, focusing on better graphics and fine tuning haptic feedback are in their nascent development.

Potential advantages of VR systems are that they provide a more "real" training experience with the capability to objectively evaluate mastery of skills by measuring incremental improvement. This may allow for a more accessible structured learning experience for acquisition of skills and efficient use of resources. It may also prove to be a less expensive method of training. Validation studies of this technology will need to be performed.

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Learning Curves, continued from page 9

The integration of skills acquisition for both resident physicians and practicing urologists is critical. Training models offered by "dry" and "wet" laboratories can help acquire the basics of endourologic and laparoscopic surgery. There are good hands-on learning courses available today. However, to take advantage of these courses, travel, financial commitment and time away from one's practice are required. In the future, with further refinement, VR simulators maypromise to resolve the conflict between the need to acquire and refine new surgical skills with patient safety, personal time and travel constraints as well as financial efficiency for both the private practice urologist and the urology resident in training.

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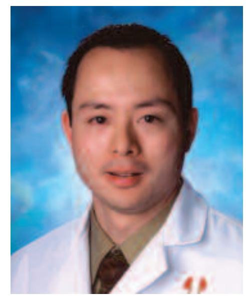

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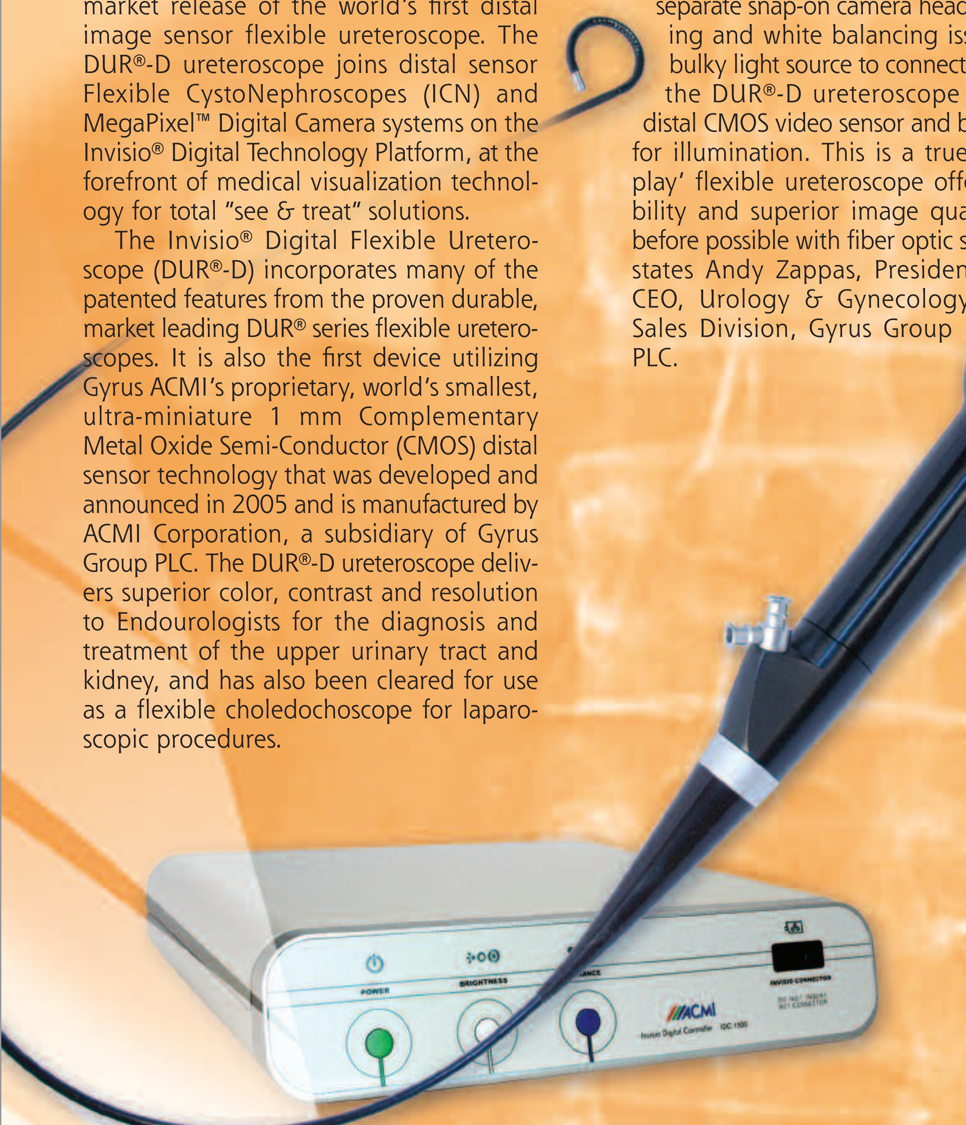
GYRUS ACMI LAUNCHES THE WORLD'S FIRST DISTAL SENSOR FLEXIBLE URETEROSCOPE

September 18, 2006 – Gyrus ACMI, a leading worldwide manufacturer and supplier of diagnostic and therapeutic minimally-invasive surgical devices in the areas of Urology and Gynecology, announces the market release of the world's first distal image sensor flexible ureteroscope. The DUR®-D ureteroscope joins distal sensor Flexible CystoNephroscopes (ICN) and MegaPixel™ Digital Camera systems on the Invisio® Digital Technology Platform, at the forefront of medical visualization technology for total "see & treat" solutions.

The Invisio® Digital Flexible Ureteroscope (DUR®-D) incorporates many of the patented features from the proven durable, market leading DUR® series flexible ureteroscopes. It is also the first device utilizing Gyrus ACMI's proprietary, world's smallest, ultra-miniature 1 mm Complementary Metal Oxide Semi-Conductor (CMOS) distal sensor technology that was developed and announced in 2005 and is manufactured by ACMI Corporation, a subsidiary of Gyrus Group PLC. The DUR®-D ureteroscope delivers superior color, contrast and resolution to Endourologists for the diagnosis and treatment of the upper urinary tract and kidney, and has also been cleared for use as a flexible choledochoscope for laparoscopic procedures.

"The DUR®-D Digital Flexible Ureteroscope is the latest innovation to our Invisio® Digital Technology platform which is taking visualization to a higher level in overall performance and simplicity. Instead of a separate snap-on camera head with focusing and white balancing issues, and a bulky light source to connect and adjust, the DUR®-D ureteroscope employs a distal CMOS video sensor and built-in LEDs for illumination. This is a true 'plug and play' flexible ureteroscope offering durability and superior image quality never before possible with fiber optic systems," states Andy Zappas, President and CEO, Urology & Gynecology Sales Division, Gyrus Group PLC.



Conventional Fiberoptic Image

DUR®-D Digital Image

For more information, please contact your local GYRUS ACMI sales representative or call Customer Service at 888.524.7266

GYRUS ACMI

Getting Accurate and Cost-Effective Urodynamics Studies in your Office

Denise D'Andrea LPN, BA, Clinical Trainor

Urodynamics testing is a valuable step in the evaluation and management of bladder dysfunction. It is emerging as a reliable indicator of OAB, urinary incontinence, LUTS and as a way to rule out the presence of Interstitial Cystitis (IC). Urodynamics is a group of tests designed to reproduce symptoms while making precise measurements in order to identify the underlying causes for the symptoms, and to quantify the related pathophysiological processes. (Schäfer *et al.*, 2002)

According to Schäfer and the report from the Standardization Committee of the International Continence Society[1] a Good Urodynamic Practice is comprised of three main elements:

1. A clear indication for and appropriate selection of relevant test measurements and procedures
2. Precise measurement with data quality control and complete documentation
3. Accurate analysis and critical reporting of results

The first study done in Urodynamic testing is the Uroflowmetry, a noninvasive study measuring the peak flow rate and quickly identifying a voiding pattern for the patient. This is most often followed by a post void residual (PVR) and then documented to complete the information obtained from the Uroflowmetry.

The Filling Cystometry and Pressure Flow Studies comprise of a study whereby the bladder is filled with sterile water through a catheter at a steady rate (Pves). A second catheter is placed in the rectum or vagina and measures intra-abdominal pressure (Pabd). The abdominal pressure is then automatically subtracted from the vesical pressure (Pves) to measure true detrusor pressure (Pdet) during the study. The study is enhanced by the use of Electromyelogram (EMG) recording using patch or needle electrodes. The electrical activity of the striated muscles in the pelvic floor are monitored and recorded and provides useful information in evaluating certain voiding dysfunctions such as detrusor or sphincter dyssynergia. This is extremely helpful in assessing patients with neurologic discorders and spinal cord injury.

Leak point pressures may be performed during the study and measures the degree of pressure when leakage occurs utilizing a valsalva or other provocative maneuvers. These measurements help in assessing Stress Urinary Incontinence (SUI).

Solar SmartFlow™ Urodynamics Unit and Flowmaster Standalone Uroflow make urodynamics studies simple & convenient for office or clinic studies.

A Urethral Pressure Profile can be performed to further assess the patient with urinary incontinence. This measurement is taken either manually or by use of a puller-arm. The Urethral Pressure Profile measures closure pressure and urethral competence as well as functional length of the urethra.

The Solar™ SmartFlow™ (distributed by Gyrus ACMI, (Southborough, MA), manufactured by Medical Measurement Systems (MMS, The Netherlands) is an easy and concise way to perform Urodynamics studies and utilizes customized reports to assist in interpretation and diagnosis. One can perform multiple studies on a patient including Uroflowmetry, Cystometry, Pressure-flow study, including Valsalva Leak Point Pressures and Urethral Pressure Profile all with the capability of utilizing the monitoring of EMG.

The Solar™ SmartFlow™ is the only system with Bluetooth® Uroflow technology. A standalone Bluetooth® Uroflow, the Flowmaster, is also sold separately with Flowmaster software. The Flowmaster can operate up to 300 feet and makes it convenient and private to perform Uroflow studies. The Solar™ SmartFlow™ has a modular set-up, with easy plug-and-play design, compactly attached to a pole mounted on wheels requiring minimal space needed to perform studies. It can easily be transported in and out of a room making it a small mobile footprint ideal for office or clinic. A remote control is included for freedom from the unit during studies as well as a touch screen. It is Microsoft® Windows-based, making it easy to customize reports and studies based on user preference and then view these reports from any MS Windows-based computer.

The Solar™ SmartFlow™ can be used with various catheters, Microtip, Water and keeping in step with plug and play technology, the disposable easy to use T-DOC air-charged catheters. All catheters can be used with respective interface cables. A quiet weight cell pump can infuse at the user's desired rate, easily increasing or decreasing the rate during the study and is accurately measured throughout the study, calculating computed residual urine. Automatic artifact detection eliminates "noise" from study results. Compliance can be automatically measured during the study, at designated intervals or at end filling and automatically placed on the report. EMG can be monitored during any study and can be extremely helpful in the diagnosis and treatment of the patient. An event marker can easily label provocative maneuvers performed during the study. The use of event markers during the study allows for documentation of vital information obtained during the study and will be placed in the final report printout. The study can be edited and the event markers moved to the appropriate areas for concise pressure measurements and calculations. The Urethral Pressure Profile performed as a separate study or done within the Gynecology Study reports vital information including the urethral closure pressure and functional length.

While considering the cost-benefit of puchasing urodynamics equipment, the cost of the equipment often pays for itself in a short time. The reimbursement levels utilizing the CPT codes for Urodynamics testing have not only proven to be an effective diagnostic tool to the physician, they also add to the bottom line of the physician's office practice.

The report can be customized so that results can be easily interpreted. There are several nomagrams that can be placed in the report. The nomagrams available are ICS, Siroky (also available on Uroflow report), CHESS and Schäfer.

While considering the cost-benefit of purchasing urodynamics equipment, the cost of the equipment often pays for itself in a short time. The reimbursement levels utilizing the CPT codes for Urodynamics testing have not only proven to be an effective diagnostic tool to the physician, they also add to the bottom line of the physician's office practice.

Summary

The interpretation of results, typically referred to as the "3Cs and 2 Ss," Capacity, Compliance, Competence, Sensations and Stability are evaluated during a Urodynamics study. By assessing these important components within a Urodynamic study, one can evaluate the interpretation and place into two categories, Failure to Store due to bladder or outlet and Failure to Empty due to bladder or outlet thus confirming a diagnosis or making a specific Urodynamic diagnosis.

The Solar™ SmartFlow™ is a cost effective and valuable diagnostic tool that complements any clinical setting. With the purchase of the Solar™ SmartFlow™ system comes Gyrus ACMI's commitment to training, service and ongoing support.

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Denise D'Andrea, LPN, BA

NEW PRODUCT RELEASE

Titan™ 3CCD Digital Autoclavable Camera

The Titan's durable, titanium housing is hermetically sealed and validated to withstand the most intense sterilization modalities, including Flash and French Autoclave Cycles. Fully internalized optics and magnetically controlled buttons are designed to eliminate the most common failure modes.

Advanced, three-chip digital imaging delivers unparalleled clarity, contrast, and color fidelity and digital zoom to 150% with no visible loss of image quality. Digital enhance set to fiberscope mode eliminates the "screen door" effect without the need to defocus.

The Titan™ 3CCD Digital Autoclavable Camera is lightweight, ergonomically designed and available in direct-coupler or right-angle configurations. Motorized optics allow for single-handed focus. Two programmable buttons allow for customi- zation and remote image/ video capture. The controller's integrated LCD displays setting status and signal.

The Complete Procedural Approach

Message from the President & CEO
Gyrus ACMI, Urology & Gynecology Division

Thank you for reading the latest edition of UroTrends, celebrating ten years of publishing emerging issues in Urology. I hope you found the articles in this issue both interesting and practical. I'm grateful for another opportunity to communicate directly with you during this exciting time for Gyrus ACMI. Research and Development, Engineering, Marketing and Sales have had an unprecedented year of new product releases and successes in 2006. Through our continued collaboration with opinion-leading Urologists around the world, we are realizing together the limitless potential for integrating "see & treat" solutions.

I've learned from Urologists, like you, that the best method for providing quality patient care is to take a comprehensive, procedural approach. Optimizing patient outcomes requires that you perform a complex analysis of your diagnosis, treatment and available clinical resources for every case. I believe that our foremost objective is to streamline this process by delivering complete, customized product programs that will consistently support your clinical and financial goals. Another major objective is to anticipate changes in the industry that influence reimbursement policies and rapidly develop technology systems that will enable you to move procedures from the operating room into your office or day-case environment without compromising patient safety and peace of mind.

Delivering state-of-the-art, modular technology is one big piece of the total solutions puzzle. We've engineered the Invisio® Digital Technology Platform to make a giant leap in visualization with this year's release of our second digital endoscope, the DUR-D Invisio Digital Flexible Ureteroscope. It dramatically improves visualization by utilizing our proprietary, ultra-miniature, CMOS imaging sensor that renders a significantly larger image with unmatched digital clarity, superior resolution and accurate color reproduction. If you haven't had an opportunity to test the DUR-D Ureteroscope, I encourage you to see the difference for yourself. It truly is changing visualization, as you know it. The same Invisio® Controller that drives the digital endoscopes also powers the newly released MegaPixel Digital Cameras that cost-efficiently bridge conventional, existing fiberoptic scopes to superior digital clarity. The Invisio® platform is the world's first fully-integrated, all-digital CMOS imaging system enabling surgeons to see more clearly, diagnose more accurately and treat more efficiently.

At Gyrus ACMI, we are uniquely positioned in the industry to deliver broad, differentiated products that support all your diagnostic and treatment needs by providing capital equipment, disposables and service programs, all from *one source. Partner with us and we'll merge the advantages of industry-leading digital visualization, advanced treatment options, and full-breadth, high quality disposables (access, dilation, stone retrieval, tissue treatment and drainage) into a package that is protected by one of our many service options. It's a value-added, asset management program called Customer First™ Total Solutions.*

We've been listening to surgeon's needs for over 100 years and that is the cornerstone of our success. We make speed, simplicity and patient safety our priorities because you told us that they are your greatest concerns. We're concentrating on providing total, procedurally focused Customer First™ programs because you asked us to deliver streamlined solutions that simplify procedures for you and add value to our partnership. I encourage you to contact me directly with your suggestions on how we can better serve your practice or institution.

Many thanks to our contributing authors: Dr. Bagley, Dr. Bellman, Dr. Bird, Nurse D'Andrea, Dr. Lam, Dr. Ramey, Dr. Wong and Dr. Yoon, for their insightful articles.

Sincerely,

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