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Therapy options for treating BPS

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Knife, loop, laser, implants, embolization, water... very few other diseases have such a battery of different treatment options available to them as the benign prostatic syndrome (BPS). Although many procedures have disappeared from the market over time, the development of others continues.

Transurethral resection of the prostate (TURP) is the longest established, minimally invasive procedure for prostate volumes of up to approx. 100ml. It is also the standard by which all new treatment modalities are judged. However, from a patient's perspective, it has a different reputation because it is considered to be bloody and susceptible to complications. A reputation that is only reinforced by the name it is known by in the vernacular: the "ro-to-rooter" technique.

Solid long-term data are also available for photoselective vaporization of the prostate (PVP) and holmium and thulium laser enucleation of the prostate (HoLEP and ThuLEP, respectively). A large, multicentric, randomized study found that the treatment results with 180W PVP were comparable to those achieved with TURP. A major advantage of PVP is excellent hemostasis, which makes it the therapy of choice for at-risk patients, in particular those

receiving anticoagulation treatment. Studies found that this was the only interventional procedure with an acceptable level of risk for this patient population, while all other treatment options were contraindicated. However, similar to TURP, PVP reaches its limits at prostate volumes > 80-100ml. For this reason, very large prostate adenomas have traditionally been treated with open prostatectomy.

The most solid long-term data in this area are available for HoLEP. Several randomized studies found that the largely size-independent outcomes achieved with HoLEP were comparable to TURP and open prostatectomy, but had lower complication rates and shorter hospitalization times. Over the last ten years, ThuLEP has become accepted as a comparable treatment alternative to HoLEP and was therefore approved by the German Federal Joint Committee (G-BA) for the treatment of BPS last year, which means that the decisive factor in the choice of laser will be the operator's preference. In summary, it is indisputable that TURP will continue to be a mainstay of interventional BPS therapy. However, laser procedures, no matter if PVP or HoLEP/ThuLEP, have become firmly established as alternative treatment options and are often the better choice. In contrast, other, supposedly less invasive, options still have to prove their superiority.

'Uphold' for the correction of cystocele and apical prolapse

Bernhard Liedl MD, Urological Clinic Planegg, Germany



The FDA warning concerning the use of mesh on the pelvic floor has led to uncertainty, both on the part of surgeons and patients. However, it is important to remember that mesh was introduced because conventional techniques for the correction of vaginal prolapse did not lead to satisfactory results and high prolapse recurrence rates were observed. A further, major consideration was inadequate symptom recovery, particularly in the anterior compartment. A recent study has shown that the standardization of the technique of anterior colporrhaphy was never seriously pursued and recurrence rates remain as high now as they were a century ago. Data published on the procedure reveal failure rates that range widely from an unbelievable 0% to a catastrophic 92% (1).

Over the last few years, the technique used for mesh implantation has undergone continuous improvement. For example, only macroporous monofilament mesh is used today, which leads to practically no infection and less scarring, and, although the application area has been minimalized to strategic areas on the pelvic floor, can still provide lasting support. The mesh 'Uphold' by Boston Scientific, which was developed to correct cystocele and apical de-

fects, has very large pores of 2.8mm² and a very low surface area. The mesh is easy to implant using the practical and very slim Capiro device. For apical fixation, the side arms of the mesh are secured to the sacrospinous ligament. Distal fixation by transobturator tape has been proven to be no longer required. Access through a diagonal incision approx. 1cm cranial to the bladder neck ensures very good visualization during the operation. Minimal amounts of the mesh encroach upon the incision areas, keeping erosion rates very low. The slight width and length of the mesh were adapted to fit anatomical conditions. Recent investigations have shown that a high percentage of recovery from prolapse-induced symptoms such as overactive bladder, urination disorders, fecal incontinence, defecation disorders and pain can be achieved by the use of alloplastic materials (2, 3). Adequate studies are still needed to assess conventional techniques that do not make use of alloplastic materials in terms of the symptom recovery that is required of surgical techniques today.

1 Halpern-Elenskaja K. et al. Int Urogynecol J 2018; 29:781-788

2 Liedl B. et al. Curr Opin Urol 2017;27:274-281

3 Liedl B. et al. BJU International 2018. Doi:10.1111/bju.14453

Advancing Men's Health together: Slavi Nestorov's Everest challenge

Moustaches and mountaineering

On May 19th, 2018, the world could see the logos of the Movember men's health association and the European Association of Urology unfurling at the top of Mount Everest, 8,848 meters above sea level. They were carried to the summit by Slavi Nestorov, a 35-year old Relationship Manager at Boston Scientific in Bulgaria.

By displaying the logos on top of the world's highest mountain, Slavi wanted to increase the visibility of men's health, as well as the importance of working together to raise awareness. "Fighting for a men's health issue and climbing a high mountain actually need similar skills," said Slavi. "You need to believe strongly in what you are doing and be prepared to overcome doubts both from others and inside yourself. It takes patience and perseverance to get to the goal. And of course, even if it is your face on the summit pictures, there is a lot of teamwork behind the

headlines." As a Relationship Manager, Slavi Nestorov spends a lot of time in hospitals and with caregivers. Being in touch with thousands of patients with urological diseases, he experiences first hand how problems such as erectile dysfunction or male urinary incontinence can still be taboo for many men. By reaching the top of the world's highest mountain in the name of men's health, Slavi merged his passions for awareness raising and mountaineering into a stunning achievement.

But it is not necessary to climb the world's highest peak to get the message across and get men to take action for their health. Inspired by the Movember logo on top of the world in May, 25,000 Boston Scientific employees have joined forces around the globe to raise awareness for men's health together with the Movember Foundation. Their actions will help the organization raise funds in the fight against prostate

and testicular cancer and stand up for men's mental health and suicide prevention.

25,000 Boston Scientific employees have joined forces to raise awareness for men's health together with the Movember Foundation.

The Movember Foundation is the only global charity focused solely on men's health. Its main awareness campaign is the annual Movember event, when men everywhere are challenged to 'Grow a Mo' [moustache] with no limits to size, shape, or colour, in order to 'Save a Bro' [brother].

A change in a man's face can change the face of men's health, as the organization states. Moreover, Boston Scientific is supporting a drive for all employees to get moving for men's health, for instance, by doing a charity walk, running a race, learning

to rock-climb or starting a new workout routine. Through discussions with friends or postings on social media, the silence can be broken around erectile dysfunction, male urinary incontinence and other issues of male health.

As testified by many men, such conversations can be life-changing. But it takes partners and team efforts to get conversations going. Slavi Nestorov's success may have required years of physical preparation and more than a month spent at high altitude.

But he emphasizes that the power to speak up for men's health is within everyone. How large would a moustache grow during the month Slavi spent on the final Everest ascent? With the power of social media, facial hair can spread at the speed of light. So can awareness of men's health, if everyone pulls together.

<https://movember.com/>

The Salzburg approach

Modern stone therapy

The development of endoscopes has made it possible to perform endourological procedures with the greatest precision while, at the same time, ensuring minimal invasiveness. This is very important for us as urologists because the growing prosperity in our area has been accompanied by a growing prevalence of patients presenting with stones. However, at the same time, patients increasingly expect to return to their normal lives as quickly as possible. Ultrasound imaging continues to be the most common technique used in making the initial diagnosis. However, a low-dose CT scan is performed on our patients to determine the exact position and size, which involves much lower radiation exposure in comparison to conventional CT scans.

Today, the majority of procedures are performed endoscopically, pushing shock wave therapy ever farther into the background. This is also the case in Salzburg. Thin endoscopes make it possible to perform a number of procedures without the prior application of a ureteral stent. In particular, the procedure used for kidney stones is largely carried out with flexible, single-use ureteroscopes. Taking all factors into account, this solution is more economical for teaching hospitals in comparison to flexible, reusable ureteroscopes. This is calculated based on the high acquisition costs as well as the steep repair costs. Urologist training has markedly improved since disposable devices became more commonly used. Under appropriate supervision, the success rates of less experienced colleagues compare well with those of experi-

enced surgeons. When used in combination with laser lithotripsy, larger concretions can also be removed endoscopically. Due to the wide range of settings offered by the modern holium laser and refinements that have been made to the technique, stones can either be primarily fragmented or undergo dusting, which is the option we prefer. The advantage of it is that no fragments have to be removed. Here, again, the single-use endoscope offers certain benefits because it allows for a good jetting flow, thus ensuring that the surrounding structures are not damaged by heat.

In the case of very large concretions, or those that are very difficult to reach endoscopically, the general procedure of choice at our hospital is mini-percutaneous nephrolithotomy (mini-PCNL). Much smaller incisions are required because of the miniaturization, which has improved our complication rate, even though only little published evidence is available. However, from the patient's perspective, the much shorter hospitalization times are a key advantage.

In summary, ESWT is being phased out at our hospital due to technological advances in endoscopy. The use of single-use endoscopes has allowed us to significantly improve the quality of training for our assistants. In times of limited staff, the capability of offering sound urologic and surgical training has become vital in remaining attractive to young physicians.

Thomas Kunit MD, Hubert Griebner MD
University Clinics for Urology and Andrology, Salzburg

Dakota™ Stone Retrieval Basket edges NGage™ in head-to-head comparison

OpenSure™ handle shows its value

The Dakota™ nitinol end-engaging tip-less basket demonstrated greater versatility in releasing larger stones in a recent in-vitro head-to-head comparison with the NGage™ nitinol stone extractor (1). Dakota™ demonstrated better versatility in handling and releasing larger stones, aided by the OpenSure™ aspect. Durability characteristics were similar for both baskets. Although these bench tests need clinical confirmation, the comparison provides valuable information to guide physician's choice. The introduction of end-engaging tip-less nitinol baskets has made it easier and more controllable to capture, reposition, extract and release stones. This has a direct impact on effectiveness, safety and procedure times.

Dakota™ and NGage™ are the only tip-less nitinol baskets available at present and the comparison is thus highly relevant. All baskets captured each standardized stone model up to 8mm (8mm baskets) and 10mm (11mm baskets). The 11mm Dakota™ basket captured 100% of 11mm stones, but NGage™ did not capture any stone of this size.

Dakota™ was also more successful when releasing stones: the 8mm basket released all 7mm stones after simple opening of the basket, whereas NGage™ required shaking with 87% of stones. The 11mm Dakota™ basket released all 9–10mm stones after simple opening, whereas with NGage™ 33% of stones required shaking. For larger stones, the

8mm Dakota™ released 87% of 8mm stones after simple opening or shaking. NGage™ released only 13% of 8mm stones after shaking.

The OpenSure™ handle of the Dakota™ basket made a difference with large stones which were not always disengaged with either passive release or shaking. The OpenSure™ handle enlarges by 50% and 39% in diameter for 8 or 11mm baskets, respectively. This provides additional release power for trapped stones. The OpenSure™ mechanism released captured 11mm stones with 100% success with the 11mm Dakota™ basket, without the need for manual removal. NGage™ required manual removal of all stones that could not be shaken free.

On durability, all baskets maintained performance over 20 repetitive cycles, but 8 out of 30 NGage™ baskets showed visible breakdown, typically splitting of the end effector tube and kinking at the strain relief site. No visible breakdown was observed with the Dakota™ basket. As the comparison was done under laboratory conditions it is not possible to extrapolate the results directly to performance in actual patients. The authors concluded that the potentially better performance of the Dakota™ is something "both clinical practice and trials should evaluate".

1 Bechis SK. et al. Transl Androl Urol 2017.
Doi: 10.21037/tau.2017.11.30

Reusable versus single-use ureteroscopes

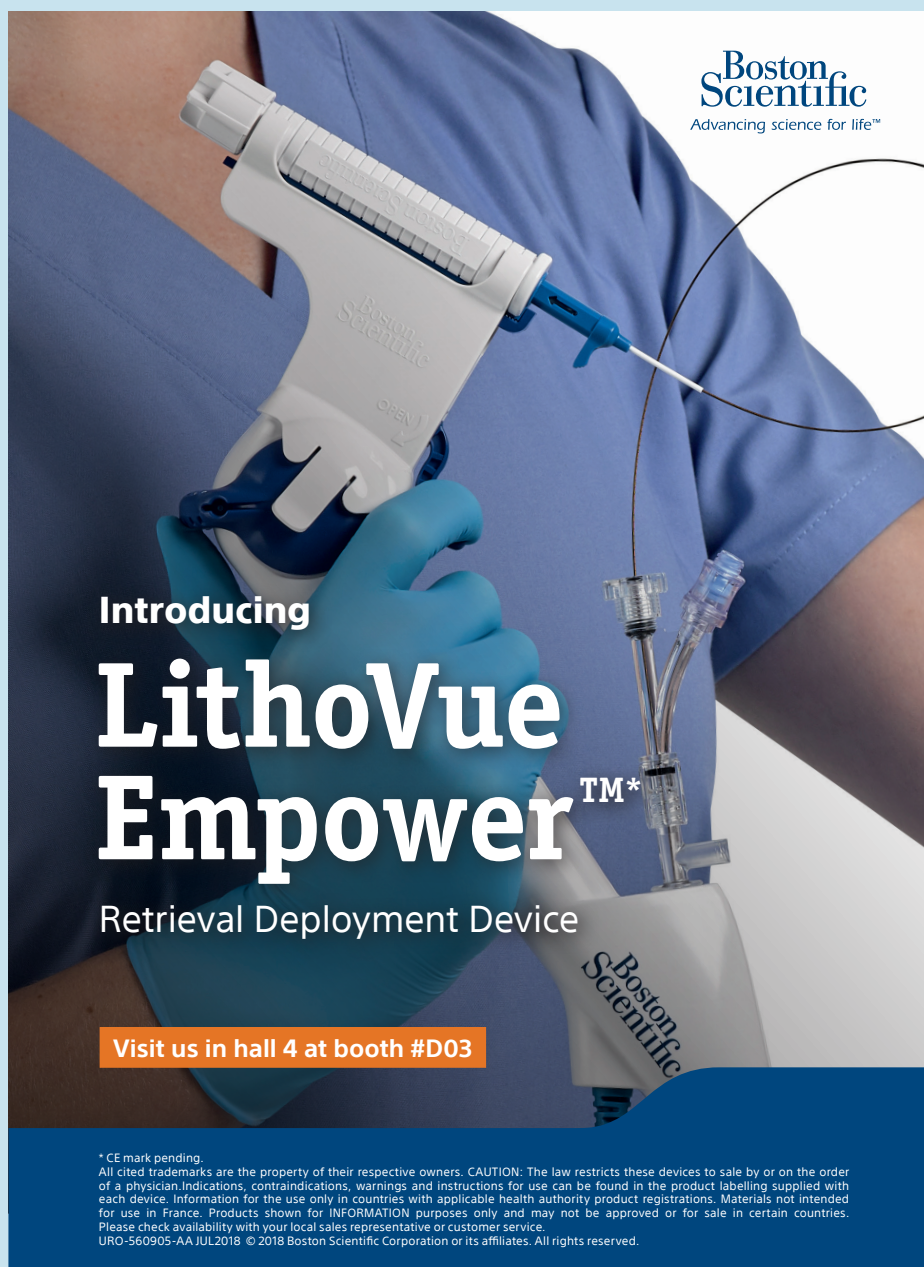
LithoVue™ validated as alternative in one study

The LithoVue™ flexible single-use system aims to eliminate many of the steps required to use, maintain and handle reusable ureteroscopes. A recent study* (1) evaluated the clinical effectiveness of LithoVue™ compared to reusable ureteroscopes. The research in this study may suggest that LithoVue™ is economically equivalent to reusable instruments. Reusable ureteroscopes require reprocessing and sterilization and repair when damaged, which can lead to inconsistent performance, operational challenges and increased costs. After performing 68 flexible ureterorenoscopy procedures in each of two groups at a tertiary referral center in Germany, the researchers concluded that LithoVue™ matched reusable instruments regarding success rate, stone-free rate, complications, operation times and radiation exposure. All p values indicated no statistically significant differences for the study endpoints. The researchers also concluded that further analysis of stone treatments revealed no difference in stone-free rates (adjusted to stone burden) between the two types of instrument groups. The study team modeled costs in different scenarios. The more procedures that can be performed before repairing or replacing a reusable ureteroscope, the more economical it becomes. But while a new flexible ureteroscope may perform 3–40 procedures before need-

ing repair, refurbished instruments manage only 3–11 procedures. In addition to reprocessing and maintenance costs the study team added the initial purchasing price. For single-use devices this is almost the only driver of procedure costs. In the final estimate, reusable instruments only had a cost advantage for an institution if they could be used in at least 61 procedures per year. In some pricing scenarios up to 118 procedures were needed. This means that for centers with a limited number of procedures, LithoVue™ would be potentially economically competitive or may even lead to cost savings. Centers that perform a large number of procedures and have access to a central reprocessing core for sterilization may find reusable flexible ureteroscopes the more economical alternative. The aim of the study was to emphasize the importance of knowing the expenses and case load when considering the choice of ureteroscopes. The final price tag will be determined by purchase price and repair costs as well the institution's reprocessing infrastructure and the volume of procedures.

1 Mager R. et al., Urolithiasis, 2018

* In-vivo device comparative studies are not necessarily representative of clinical outcomes in all cases as individual results may vary.



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LithoVue Empower™
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GreenLight: an effective and safe treatment option for BPO

Interview with Claus Brunken MD, Asklepios Westklinikum Hamburg, Germany

Dr Brunken, you have extensive experience with GreenLight laser photoselective vaporisation of the prostate (PVP). What is the attitude of your patients to their illness?

Patients today are not willing to accept a major reduction in their quality of life from a treatable disease like benign prostatic obstruction (BPO). As we know, 70 is the new 60: men in their 70s want to continue their active lifestyles. They expect an effective therapy requiring minimal time in hospital for the procedure and they want to recover rapidly after discharge.

What drives your choice of technology for BPO treatments?

We base our therapeutic decisions on comorbidities, use of anticoagulation therapies and the size of the prostate. In our experience, GreenLight PVP is an excellent option in all patients who require rapid recovery.

Any type of patient you would think twice about treating with GreenLight?

The only group we routinely treat with holmium laser enucleation surgery are younger patients with large prostates who are not on anticoagulation therapy.

You are talking about personal experiences from your work in the clinic. How deep is this experience?

I have been using laser technologies for over a decade. At our center we perform 160–180 GreenLight laser PVP and holmium laser enucleation procedures per year. So we are discussing experience of more than 1,000 procedures here.

In your view, what is the greatest advantage of GreenLight over transurethral resection of the prostate (TURP)?

The safety profile is very impressive, in particular the excellent hemostasis and coagulation efficiency. For the patient it means he experiences more rapid recovery.

The German G-BA and NICE in the UK have both acknowledged GreenLight's non-inferiority to TURP and recommended its use. This must add to your confidence with the system?

GOLIATH is the largest randomized trial that has compared GreenLight with TURP. In my view it verifies GreenLight's position as a modern, effective and safe treatment option for BPO. Especially the safety results with fewer complications and reintervention procedures were encouraging. The reduced need for flushing liquid increases patients' comfort during recovery.

As with all procedures, operator experience is crucial for safe and effective therapy. In your experience, how steep is the learning curve with GreenLight?

In our experience, operators learn rapidly. The safety of PVP with GreenLight and the low risk of bleeding accelerate the learning process. After 30–40 procedures most operators have mastered the intervention, although it is perfected by continual experience. Beginners or less experienced colleagues may be more cautious or slower at removing the necessary amount of tissue, but this changes with increasing practice.

Original interview published in Akt Urol 2018; 49: 236

LithoVue™ S18 has arrived

An Illuminating Experience

Boston Scientific boldly changed the world of flexible ureteroscopy when the LithoVue™ Single-Use Digital Flexible Ureteroscope made its first in-human debut in December 2015. In the next step of the LithoVue™ evolution, we are pleased to announce that LithoVue™ S18 has arrived.

LithoVue™ S18 is a new software offering designed to improve the user experience by reducing laser interference and improving illumination. LithoVue™ S18 provides enhanced image quality for supporting procedure visualization. LithoVue™ S18 shows how at Boston Scientific we continue to listen to customers' feedback and enhance our visualization offering. In 2016, we partnered with TEAC, a leading manufacturer of surgical recording, to deliver an image and video capture option so we could offer an advanced solution to fit our customers' unique visualization and recording needs. Bench studies performed by Boston Scientific have confirmed the difference in first generation software versus the new LithoVue™ S18. But the difference must be experienced to be appreciated in full. The LithoVue™ System and LithoVue™ S18 are two milestones in the history of urology innovations by Boston Scientific. Our expertise spans

several decades and encompasses all facets of ureteroscopy from stents to baskets to lasers to ureteroscopes. In fact, every 23 seconds a patient is treated with a Boston Scientific urology product. We have over 3,000 stone, BPH, erectile dysfunction and women's health patents issued or pending in 26 countries*. Through partnerships with physicians and healthcare providers around the world, we have consistently offered new evidence to support the clinical, operational and economic efficacy of the LithoVue™ System. In 2016 and 2017 alone, more than 40 supporting journal articles and studies were published.

To learn more, visit www.LithoVue.com or ask your Boston Scientific representative to show you LithoVue™ S18.

*Data on file with Boston Scientific. LithoVue™ S18 is Release Version 1.3 consisting of Software Application Version 4.1.0.0. Bench study conducted with the same LithoVue™ FlexScope and same laser in a model. The signal was split between two LithoVue™ Touch PCs carrying original and new software. Output of both monitors (video) joined using the NDS ConductOR™ system. Bench Test results may not necessarily be indicative of clinical performance. TEAC is a trademark of TEAC CORPORATION, registered in the U.S., Japan and other countries.

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Vaginal support: slings still valuable

Consensus opinion from Women's Health meeting

Vaginal support systems and midurethral slings utilizing synthetic mesh remain valuable alternatives to other systems for pelvic organ prolapse (POP) and stress urinary incontinence (SUI) surgery. This was the consensus opinion of an expert panel of German gynecologists recently meeting in Berlin for the 3rd Women's Health Delegation Club, an event hosted by Boston Scientific. In agreement with current guidelines all participants agreed that vaginal mesh is a secondary option and that sacrocolpopexy remains the gold standard for prolapse surgery. But there was a strongly expressed view that vaginal mesh has an important role in the appropriate patients. Slings made by synthetic mesh perform well when employed in the correct indication and using correct surgical procedures. The opinions are relevant for the ongoing debate following warnings some years ago related to mesh erosion and contraction with associated pelvic pain or painful sexual intercourse. The delegates emphasized that the reports which triggered concern are from a decade or more ago and did not take into account recent developments. Today, we have smaller nets and fewer fixation points. When used for stage 3 and 4 prolapse repair these appear to be very stable in place. But because of their relatively recent introduction no comparative studies have reported on benefits compared with other nets and data are still being collected. Careful

patient selection is key. Indiscriminate use of any therapy will put patients at risk. Consensus at the meeting was that younger women should opt for laparoscopic sacrocolpopexy, whereas older and sexually no longer active women could be candidates for vaginal mesh. Important risk factors for erosion should be considered, e.g., smoking, which carries a four-fold increased risk. Up to 40% of women seeking help may not need a procedure after all. A thorough discussion with the patient is essential to ensure those in need get the right therapy. Smaller slings have also been developed for stress urinary incontinence. Such single-incision minislings may be associated with lower morbidity and more rapid recovery than retropubic and transobdurator slings. Again, more data would be welcomed. As with POP, operator experience is probably more important for safety than the type of sling used. The experts thought that increasing experience with one's favourite sling will increase success rates, regardless of sling type. At the end of the discussion speakers agreed that discontinuation of synthetic mesh would reduce the therapeutic alternatives for women with prolapses who need recurrent procedures because of failing biological material. A wide choice of safe and effective options is necessary for patients to benefit safely from treatments.

Berlin, May 2018 – URO 559203 AA MAR 2018

GreenLight XPS™: increasingly popular for benign prostatic obstruction

Short learning curve, preferred by patients

GreenLight XPS™ 180W is increasingly popular for photoselective vaporization of the prostate (PVP) to treat patients with benign prostatic obstruction. Besides safety and a short learning curve, a notable driver are the patients themselves, who often ask specifically for this treatment option. This was confirmed by Dr Hannes Cash from the Department of Urology at Charité in Berlin, one of the largest urological centers in Europe.

“Patients are usually satisfied after a GreenLight procedure,” observed Dr Cash in an interview with Boston Scientific in April 2018. “Quality of life is improved by the reduction in symptoms and low need of medication post-procedure. Patients also recover rapidly, with short catheter time and limited hospital stay.” Not all therapeutic solutions fit all patients equally well, but Dr Cash has found that GreenLight can be safely employed in a variety of clinical profiles and prostate sizes. One reason is the low risk for bleeding complications. This is particularly relevant when vaporizing large prostates. Dr Cash’s team has published results with GreenLight based on treating 375 patients over five years that confirm the low complication rates and high patient satisfaction (1). Procedure and laser times improve with increased experience. Although procedure times are longer for larger prostates, Dr Cash

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emphasized that adequate operator training and experience keep them reasonably short.

Prostate cancer is sometimes considered a contraindication for PVP. Dr Cash has a more differentiated view. It is true that no tissue specimens for histological analysis are available with GreenLight. But the cancer risk can be assessed on PSA tests and the age of the patient. Multiparametric MRI can be performed before the procedure, too. If this is negative, in Dr Cash’s experience, the patient can usually be

treated with GreenLight without the need for a biopsy. Interoperative biopsy can be performed in patients who would be indicated for radiation therapy in the case of a carcinoma.

The results of the pivotal GOLIATH trial demonstrated that GreenLight can match transurethral prostate resection (TURP) regarding the quality of treatment outcomes. Dr Cash was particularly impressed by the short learning curve with GreenLight in the trial. Some GreenLight operators had performed only about ten cases and others

had experience of more than 500 procedures. TURP operators were selected for long experience and high quality performance.

“GOLIATH showed that operators with very varied experience of GreenLight can achieve comparable results to what experienced operators attain with TURP,” Dr Cash concluded.

1 Reimann M. et al., Urol. Int. 2018

Original interview published in Urol Nach, 5:2018

Well-established therapies for male incontinence

Sphincters and slings still favored

Artificial Urinary Sphincter (AUS) remains the preferred therapy for male stress urinary incontinence, with slings remaining second choice and adjustable slings being a distant third. This was the common opinion of experts at the 8th Urology Therapy Update Meeting recently sponsored by Boston Scientific in Berlin. German data indicate that most patients receive an AMS800 AUS. Among popular slings are Advance or Advance XP, used in some 30% of patients. These therapies are well established with long physician and patient experience. The international DOMINO working group has studied complication rates

with AUS and slings. Rates are moderate for both. Slings are associated with more intraoperative complications. AUS are explanted more frequently, yet the speakers at the event had found that patients may accept the risk of future reimplantation if they can enjoy the benefits of the device in the meantime. Infection and dislocation rates may be higher with a double-cuff than a single-cuff AUS. For adjustable slings, the evidence is less compelling and no relevant advantages over established systems have been shown. Speakers agreed that adjustable slings can achieve high levels of continence, but this success comes at

the cost of relatively high rates of complications such as leakage, infection or dislocation. In consequence, explantation rates are high. A special session was dedicated to the needs of patients with spinal cord injuries. This is a sometimes neglected topic. A flexible approach is necessary, as paraplegic individuals vary greatly in their needs. People constrained to a wheelchair can still be physically active and it is important to listen to each patient’s needs and wishes. AUS systems can improve quality of life in paraplegic individuals, but slings are a valid alternative with their lower explantation rates. The speakers strongly re-

commended to discuss sexual needs with patients early rather than late after injury. Although sexual experiences are difficult or impossible to treat medically, tools can help achieve erection and support fertility. Similarly, therapy should not be delayed or postponed for long after the event. The faculty concluded that the risk of complications notwithstanding, AUS, slings and implants are successful options with high patient satisfaction.

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