UROLOGY OUTLOOK

CURRENT NEWS AND BACKGROUND INFORMATION

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Dear Reader

Welcome to the 2nd edition of "Urology Outlook". Continuing the tradition of the 1st edition we present a collection of relevant and up-to-date articles on recent developments in the field.

As you are aware, Boston Scientific is a major driver of excellence in urology. With the recent introduction of Rezūm water vapour therapy we offer a uniquely broad BPH portfolio to enable truly patient-centric care. With Lithovue Empower™, we moved the boundaries of single-use ureteroscopy, enabling you to #SoloBasketing in a single-handed procedure. Your benefit is increased control, reduced cognitive load and clearer focus on the patient and processes.

Erich Grösslinger
Business Unit Director
Boston Scientific
Urology & Pelvic Health
Central Western Cluster

To keep evolving care, Boston Scientific depends on your feedback and experience. I encourage you to visit our independently hosted StoneSmart discussion forum. Or tune in to the linked Twitter chats: **#StoneSmart**.

Insight-driven innovation is an unending journey into the future. I am proud to be making it together with you. But the most important beneficiaries are your patients, the group we are all dedicated to serving. On behalf of Boston Scientific I thank you for your continuing valuable collaboration and wish you a stimulating read!

Best regards
Erich Grösslinger

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Imprint

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UROPH 671602 AA SEP 2019

Demographic development and its influence on urology

Univ.-Prof.
Dr. med. Andreas Wiedemann
Universität Witten/Herdecke
Fakultät für Gesundheit
Department für Humanmedizin

From the pyramid to the urn.
Improvements in hygiene, medicine and access to clean drinking water lead to a increasing life expectancy, especially in the „developing countries". In addition, there is a lower birth rate, e.g. due to a better standard of living associated with this or the postponement of the reproductive phase of a well-trained couple.

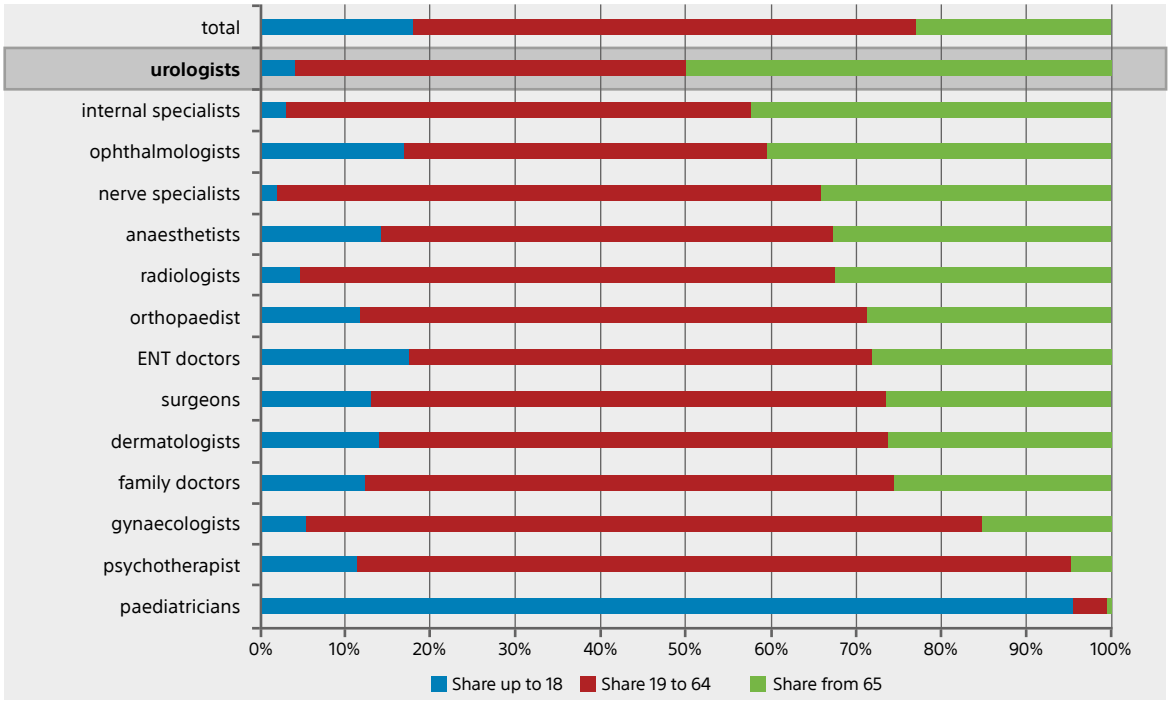
Society is outdated and „underaged".
Specialties such as Urology, which treat the elderly, have an advantage. No other specialty apart from geriatrics has older patients than Urology - With a 20% increase in the need for care by 2025.

Against the background that today ¾ the graduates at German universities are female, 2 safe tendencies can be attested for urology:

The Urology will become female; the patients geriatric.
This still leads to 2 effects:

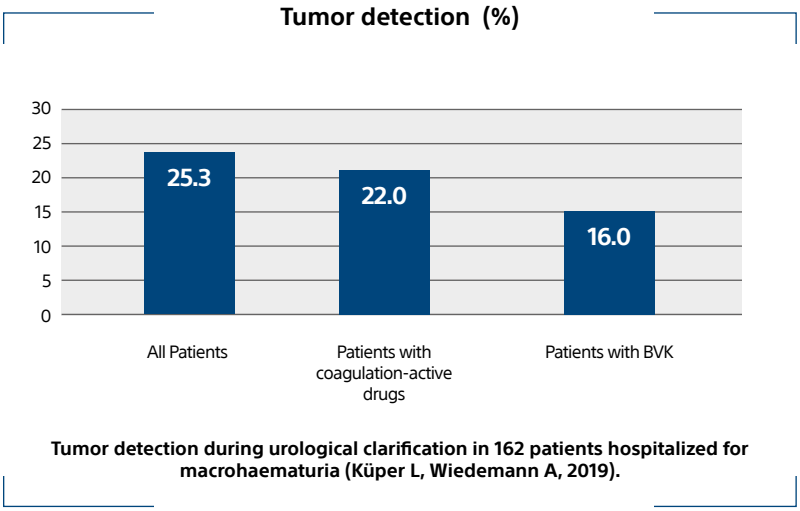
1. age-dependent urological disease patterns will increase.
A transfer of „familiar" concepts to the geriatric patient will not suffice. At the latest it is known that Tamsulosin not only causes falls, makes cataract surgery highly complicative (an effect that is irreversible after 14 days of taking it) and seems to promote dementia, conservative BPS therapy is staggering. Against the background that hormone withdrawal causes osteoporosis, sarcopenia and anaemia and thus increases the risk of falls, leads to more heart attacks and impairs cognition, new concepts are also required here.

On the other hand, Urology must also provide solutions beyond the catheter for palliative care. There is not a single study on the quality of life of catheter wearers. A multicentre study of the working group „geriatric Urology" should close this gap. In individual cases, however, a simultaneous 180-watt GreenLight



Patient structure in the department according to D. Stillfried, Zentralinstitut der Bundes-KV

laser of the prostate in men with urinary retention, who are intended for the application of a suprapubic catheter, may be able to avoid the same problem. In a retrospective study (Knoblauch M, Wiedemann A, Aktuelle Urologie 2019, accepted for publication), this concept was still able to be removed in about 50 % of indwelling catheters.



Tumor detection during urological clarification in 162 patients hospitalized for macrohaematuria (Küper L, Wiedemann A, 2019).

2. typical age-related diseases will be introduced into Urology.
Modern Urology will not be feasible without „general medical" know-how. The perioperative management of blood thinners, the treatment of diabetes complications or the management of side effects of non-urological drugs in the urinary tract is the challenge. However, this also holds future prospects: In 162 urological patients over 75 years of age who were admitted as in-patients due to macrohaematuria, an astonishing 25% of urological malignancies were detected (Küper L, Wiedemann A, Urologist A. 2019 Apr;58 (4): 381).

THE CONCLUSION IS SIMPLE AND INEVITABLE: THE FUTURE BELONGS TO URO-GERIATRY. ■

Author: Prof. A. Wiedemann

BPH

Patient-centric BPH

Individualised choice for optimised treatment outcome

Benign prostatic hyperplasia (BPH) is a disease of ageing: the average total prostate volume increases by 2.2% per year.[1] If they make it to 90 years of age, 60%-90% of men will suffer from BPH.[2] In such a large number of patients there will be an enormous variation in disease characteristics as well as life-styles and needs. There is a corresponding wealth of treatment choices available, from doing nothing ('Watchful Waiting'), prescribing a long-term regimen of pharmacotherapy in mild cases, to well-established, effective but invasive therapies for large prostates. In recent years the space between these therapies has been filling up with novel, exciting minimally-invasive options.

Patient-centric BPH empowers physicians to make the best possible treatment decisions in an informed dialogue with their BPH patients. No patient is average and patients bring invaluable expertise to the decision process: an intimate experience of their own disease.

The need for a patient-centric approach can be seen in the low satisfaction rates with pharmacotherapy. Drugs are easy to prescribe and can be discontinued or varied if the initial effect is unsatisfacory. But a number of reports show as many as 80% of patients stop their drugs within one year

and persistence rates drop ever further with time.[3–5] Younger, mildly affected and sexually active men may be put off by adverse effects of medications such as impotence or decreased libido. Other patients may be dissatisfied with the effect, or annoyed by the need to take daily pills.

Particularly relevant to older men is that pharmacotherapy may increase the risk for complications from cataract surgery. Since as many as 30% of adults over 65 have cataract[6] and a significant proportion will need surgery at some point, many individuals with BPH need to be presented with an informed choice of alternative treatment options.

Similar attention to individual needs and preferences is necessary with regard to choice of device therapy. Boston Scientific recognises the position of the patient at the core of medical decision making. Our range of device therapies was designed specifically to empower Urologists to meet their patients' individual needs.

The recent addition of Rezūm water vapour thermal therapy to the BPH portfolio has filled an important gap in the continuum between medical management and surgical approaches. As a minimally invasive therapy (80% of patients need only oral sedation) with demonstrated tolerability, safety and effectiveness, Rezūm is attractive for men keen to preserve libido, erectile, and ejaculatory functions.[7] It is also an option for patients with hyperplasia of the central zone and/or median lobe of the prostate.[2]

Other patients have other needs. Older men with BPH often have comorbidities. Such concomitant conditions must be taken into account when evaluating patients for BPH therapy, because their presence may affect the choice of treatment, its efficacy, and long-term tolerability.

Patients on anticoagulation therapy are an important example. In this group, expert opinion considers laser vaporisation of the prostate with GreenLight the treatment of choice.[8] The view has support in European and US guidelines,[9,10] which note the positive evidence for the safety of GreenLight in anticoagulated patients. European guidelines explicitly recommend physicians to offer therapy with 180-W GreenLight lasers to patients receiving antiplatelet or anticoagulant therapy with a prostate volume <80 mL.

For larger prostates >80 mL anatomical enucleation of the prostate with HoLEP laser remains the standard of care. During its long successful history HoLEP has accumulated a strong evidence base.

For physicians, patient-centric BPH presents a challenge. Not only will they need to master and deliver favourable outcomes with many therapies, but they also need the ability to explain pros and cons of the options to patients from all walks of life, and listen attentively to their needs and views. This needs dedication, time and experience.

But the potential rewards are many: durable outcomes, shorter hospital stay, lower risk of bleeding and greater scope to retain sexual function. In other words, satisfied patients with increased quality of life. For both patient and physician, this is the best possible outcome. ■

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Transurethral water vapor ablation in BPH

4-year data confirm Rezum's long-term effect

Current data is available for Rezūm - a new technology for the thermal ablative reduction of LUTS in men with benign prostate hyperplasia: They show that minimally invasive surgery is associated with effective symptom relief and an increase in health-related quality of life. Patients benefit continuously over the entire observation period without disturbances of sexual function.

For the treatment of symptomatic benign prostatic hyperplasia (BPH), minimally invasive surgical interventions such as Rezūm can also be used as an alternative to pharmacotherapy. In the transurethral convective ablation procedure, hot water vapour is generated with the aid of high frequency. Its thermal energy destroys prostate tissue on contact, which is then broken down by the body and leads to a reduction in the size of the prostate. The minimal invasive procedure perfomed in Germany as a surgical procedure under general anesthesia according to the DRG-guidelines.

The efficacy and safety of Rezūm was investigated in a prospective multicenter, double-blind, randomized, controlled study in men suffering from lower urinary tract symptoms (LUTS) due to BPH.

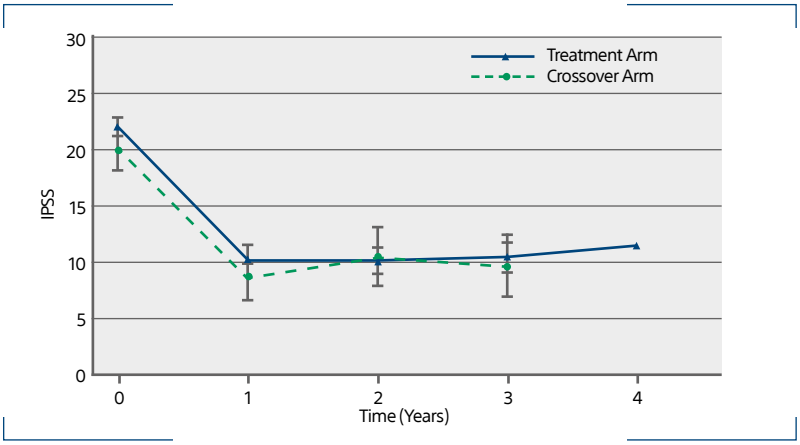
Rezūm versus rigid cytoscopy

A total of 188 participants aged ≥ 50 years were included in the evaluation. Before treatment with Rezūm, the IPSS (International Prostate Symptom Score) of the participants was at least 13, the maximum urinary flow rate (Qmax) was 15 ml/s and the prostate volume was between 30 and 80 cm^3. The participants were stratified according to IPSS and randomly subjected to thermal water vapor ablation (n=135) or rigid cytoscopy (n=61) 2:1. The study was unblinded after 3 months and suitable patients were able to cross-over to the Rezūm group (n=53). The 135 participants who were primarily treated with Rezūm (observation period 48 months) and 53 cross-over patients (observation period 36 months) were included in the present evaluation.

Significant improvements, good tolerability

The study met its primary and secondary endpoints. Within three months of using Rezūm, symptoms in the lower urinary tract improved: IPSS decreased by 46%, the maximum flow rate increased by 50% and the BPH index decreased by 51%. The significant improvements compared to baseline ($p< 0.0001$) remained consistent throughout the observation period. This also applied to the post-operative improvement in health-related quality of life, which had increased by 42% at Rezūm The therapy proved to be safe and tolerable: there were no perioperative device- or process-related complications. The men treated with Rezūm reported limited impact on sexual function, and there were no de novo cases of erectile dysfunction. The 4-year rate for a new surgical procedure was 4.4% - significantly lower than other minimally invasive procedures in this indication.

The authors see an early intervention with Rezūm as an alternative to pharmacotherapy or invasive surgery, especially for men with moderate to severe LUTS and a risk of BPH progression. ■



McVary KT et al., Urology 2019; 126: 171-179; doi.org/10.1016/j.urology.2018.12041

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Offer patients more than a lifetime of pills.

When your patients depend on BPH medications, it can add up to hundreds of pills a year. Quit the bottle and help patients find lasting relief with Rezūm™ Water Vapor Therapy. It treats the problem, not just the symptoms, and gives your patients the freedom they had lost.

Effective: 11-point IPSS symptom improvement maintained through 4 years[1]

Durable: 4.4% procedural retreatment rate at 4 years[1]

Flexible: Ability to treat prostates with hyperplasia of the lateral lobes, central zone and / or a median lobe

QoL: Preserves sexual function[1,2]

Rezūm Water Vapor Therapy

For more information visit **www.bostonscientific.eu/bph**

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Practical experience confirms study data

Recent study results show that men with benign prostatic syndrome (BPH) can benefit significantly from minimally invasive surgery using Rezūm. With the thermal ablative reduction of the prostate volume, a sustained relief of symptoms was achieved with good tolerability - among other things without a negative influence on sexual function.[1] Dr. Evangelista Martinelli, Hannover, Germany, has the greatest experience with the use of Rezūm in Germany.

Do your experiences with Rezūm agree with the study results?
Dr. Martinelli: The results of the currently published studies reproduce reality fairly accurately. This statement is based on a three-digit number of patients whom I have treated with Rezūm since July 2017, i.e. a sufficiently representative patient collective. What is particularly striking is the very high level of patient satisfaction. The quantitative reduction of symptoms as well as the improvement of urodynamic parameters reflect the data of the current literature.

How is the postoperative course in your clinic compared to the study results?
Dr. Martinelli: The postoperative course is comparable: many patients already feel a relief of symptoms within the first two to three weeks. The best postoperative results are achieved after about two to three months when the prostate shrinkage is complete. Volume reduction may vary depending on the initial prostate volume. Side effects may occur during the first four to six weeks after surgery. Our re-operation rate of approx. 4 % is also comparable with the study results in the literature.

What do you expect from further long-term studies on Rezūm?
Dr. Martinelli: Without any scientific evidence: I can imagine that if the studies continue, the re-surgery rate will not deviate significantly from the current 4-year data in the coming years.

What significance does it have for patients that the risk of impaired sexual function at Rezūm is very low?
Dr. Martinelli: The maintenance of undisturbed sexual function and the avoidance of retrograde ejaculation plays a relevant role in the therapy decision, especially in younger patients.

How do you assess the feasibility of the procedure?
Dr. Martinelli: The technique is very simple per se. Nevertheless, a certain learning curve is necessary, since often an individualized adaptation and a deviation from the standard procedure depending on the respective prostate morphology are necessary.

For which patients is Rezūm particularly suitable from your point of view?
Dr. Martinelli: The Rezūm procedure is actually suitable for all patients with symptoms of the lower urinary tract (LUTS) due to benign prostate enlargement. In my opinion, future study results will lead to an expansion of the indication. Irrespective of the prostate volume, Rezūm is basically suitable for two patient groups:

- Young“ patients in first-line treatment.
  They have so the possibility, on a medicamentous therapy and their possible to dispense with side effects.
- Sexually active“ patients with a definite indication for deobstruction of the lower urinary tract, who want a gentle treatment regardless of age.

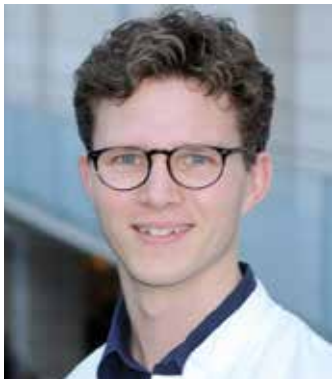
Many thanks for the interview! ■

Dr. Evangelista Martinelli, Clinic for Urology and Urological Oncology at the Medical School, Hannover

1 McVary KT et al., Urology 2019; 126: 171-179; doi.org/10.1016/j.urology.2018.12041

Vaporization and enucleation with the GreenLight laser

With the green light of the GreenLight-Laser XPS, a simultaneous coagulation of the prostate tissue can be achieved by photoselective vaporization of the prostate next to a cavity within the gland.



Priv.-Doz Dr. Hannes Cash,
Clinic for Urology,
Charité -university medicine, Berlin

The use of minimally invasive laser systems for the treatment of benign prostatic syndrome (BPS) is continuously increasing. What do you see as the most important advantages of these procedures compared to transurethral prostate resection (TURP)?

Dr. Cash: The different laser systems have different modes of action. What they all have in common is that they can be used to treat prostate volumes of any size, including prostate volumes larger than 80 ml. In these cases, the enucleation of the prostate using a holmium laser (HoLEP) or the GreenLight laser can be a good option to relieve the patient of his micturition problems.

What are the special benefits of a laser procedure compared to TURP for patients?

Dr. Cash: Compared to TURP, the use of a laser procedure usually shortens postoperative hospital stays by at least one day and reduces the risk of bleeding complications. This applies to the holmium as well as the GreenLight laser. With the GreenLight laser, it can also be performed during continued therapy with anticoagulants without increasing the risk of bleeding complications.

What is your clinical experience with the GreenLight XPS?

Dr. Cash: At the Charité, we have been using the GreenLight laser since 2010. Initially, it was mainly used for vulnerable patients or smaller prostate volumes. However, this has changed significantly in recent years. We are currently using the laser especially for prostate volumes of 50 ml and more, as well as for more complex patients (e.g. under anticoagulation). Patients can be treated regardless of their age. The average length of stay in the clinic is two days; the irrigation is often completed as early as the evening of the operation. This relieves the hospital staff and also the feedback of the patients is very positive. A number of patients contact us explicitly because of the GreenLight laser, and we are receiving more and more patients because of the GreenLight laser. This has been especially true since we switched to Vapo enucleation 1.5 years ago.

How has the use of the GreenLight laser changed in recent years?

Dr. Cash: In addition to classic vaporization „from the inside to the outside", surgical techniques have been developed in recent years that are oriented to the anatomy of the respective prostate and thus enable more radical tissue ablation without losing the advantages of the GreenLight laser with regard to the bleeding risk. The anatomical vaporization represents an intermediate step towards vapo enucleation, which corresponds to the enucleation with the holmium laser.

What is the advantage of the variability between vaporization and enucleation?

Dr. Cash: Enucleation is at the upper end of the process of maximum desobstruction of the prostate. With the GreenLight laser, the radicality can be adjusted to the needs of the individual patient. You can also proceed more gently. This applies in particular to older patients where the risk of postoperative incontinence is higher or to patients who wish to have ejaculation protection. With the GreenLight laser it is possible to operate more radically if necessary - up to enucleation. A further advantage is that with the graduated procedure, the surgeon can also be successively introduced to enucleation when learning the method.

Many thanks for the interview! ■

Laser therapy today and tomorrow

Dr. Armin Secker,
Clinic for urology and pediatric urology
at the university hospital, Münster

Even today, electronic simulators support the learning of techniques for the use of lasers in prostate surgery. In the future, it is conceivable that the surgeon will be supported in the recognition of structures, for example by augmented reality.

To what extent can BPS affect the lives of men?
Dr. Secker: BPS can cause a variety of problems of an obstructive or iriitative nature: The frequency of micturition increases - not only during the day, but also at night, which can considerably disrupt sleep. A permanently disturbed night's sleep can have a variety of consequences, including an increased risk of stroke. Some patients therefore drink almost nothing in the evening. However, reduced fluid intake can cause further problems, such as circulatory disorders or the development of kidney stones. Another possible complication of BPH is acute urinary retention, the chronic consequences of which can be kidney damage. An enlarged prostate or BPH can also promote erectile dysfunction.

A number of different procedures are available today for minimally invasive therapy of BPH. What are the advantages of modern laser procedures for you in everyday clinical practice compared to a transurethral prostate resection (TURP), the current therapy standard?
Dr. Secker: The great advantage of modern laser procedures is that they can treat the prostate through the urethra regardless of its size. Laser therapy reduces the risk of bleeding complications and shortens post-operative recovery times. One advantage of this is that more patients can be treated with the same number of beds.

Which patients benefit most from laser therapy of their BPS?
Dr. Secker: First and foremost, patients with a very large prostate who would otherwise have had an incision would benefit. But comparatively young patients also have advantages: The minimally invasive, gentle therapy usually lasts a lifetime, as the entire glandular body is removed as in open surgery. It is known that enucleation with the laser method reduces the PSA value by 80 to 90 %. With a TURP one arrives at only 40 to 50 %.

What does it mean to you that several laser options are available?
Dr. Secker: We at the University Hospital Münster have two lasers available, the holmium and the thulium laser. There is also the GreenLight laser. Other laser procedures are not so important at the moment. The results of the lasers we use are comparable worldwide. Regardless of which type of laser you choose, it is important that you have a good command of the technology.

How do you see the future of laser therapy?
Dr. Secker: I personally assume that the proportion of laser therapy will continue to increase compared to standard methods, even though TURP is currently still ahead. With laser procedures, it takes a while until the learning curve has been passed. But there are good programmes in which you can train with simulators. Once you've learned it, operating is really fun. And the patients are really satisfied. I also assume that augmented reality or artificial intelligence will play a certain role in the future. This would make it easier to identify structures on the screen during surgery, for example the sphincter, the bladder neck, the capsule or the adenoma. Whether the data for this comes from magnetic resonance imaging or ultrasound, or whether it will be a kind of facial recognition of the prostate gland, is up to the technology to decide.

Thank you very much for the interview! ■

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SpaceOAR™ Hydrogel

Designed to reduce side-effects associated with prostate cancer radiation therapy[1-3]

73% relative reduction in rectal V70[1*]

0% late grade 2+ rectal toxicity at median 3 year follow up[2]

67% maintained potency[4***]

Significantly **LESS DECLINE** in urinary and bowel QOL[2**]

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* Average reduction when comparing pre- and post-spacer treatment plans

** compared to control group; median 3 years

*** compared to 38% in control group; of men who had erections sufficient for intercourse at baseline; median 3 years

As with any medical treatment, there are some risks involved with the use of SpaceOAR Hydrogel. Potential complications associated with SpaceOAR Hydrogel include, but are not limited to: pain associated with SpaceOAR Hydrogel injection; pain or discomfort associated with SpaceOAR Hydrogel; needle penetration of the bladder, prostate, rectal wall, rectum or urethra; injection of SpaceOAR Hydrogel into the bladder, prostate, rectal wall, rectum or urethra; local inflammatory reactions; infection; injection of air, fluid or SpaceOAR Hydrogel intravascularly; urinary retention; rectal mucosal damage, ulcers, necrosis; bleeding; constipation; and rectal urgency.

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Prostate cancer: Hydrogel spacer reduces side effects of radiotherapy

In prostate radiotherapy, rectal toxicity is largely due to the proximity of the prostate to the rectum. A recent study has shown that the use of the SpaceOAR Hydrogel peri-rectal spacer is associated with lower intestinal and quality of life impairments after radiotherapy.[1]

SpaceOAR® Hydrogel is a soft gel of resorbable polyethylene glycol that creates space between the prostate and rectum. It reduces the radiation exposure of the organs surrounding the prostate during radiotherapy and can thus reduce possible long-term side effects of radiotherapy such as rectal bleeding and impairments of intestinal function, urinary incontinence and potency.2,3 The gel is absorbed by the patient's body within three to six months.

State-of-the-art clinical trial

A prospective multicenter controlled trial included 222 patients with T1 or T2 stage prostate cancer who were scheduled for radiotherapy. They were randomly assigned either to a resorbable spacer (SpaceOAR® system) or to the control group. The safety of the spacer and its effects associated with irradiation (image-assisted intensity-modulated radiotherapy with 79.2 Gy in 1.8 Gy fractions) as well as the quality of life of the patients were evaluated.

Simple and safe placement

The physicians involved in the study rated the application of the spacer as „easy" or „very easy" in 98.7% of the cases - hydrogel placement was successful in 99% of the cases. The perirectal distances after placement were 12.6 ± 3.9 mm or 1.6 ± 2.0 mm in the spacer or control group. The spacer was well tolerated, there were no spacer-related side effects such as rectal perforations, serious bleeding or infections.

Reduction of V70 in the rectum

The spacer was associated with a significant reduction in median rectal radiation exposure (V70; 12.4% vs. 3.3%; p<0.0001). From three months after irradiation through a median follow up of 3 years, the rectal side effects of irradiation were significantly less pronounced in the spacer group than in the control group: the cumulative incidence of rectal adverse events was 0% in the spacer group vs. 6% in the control group (p=0.01). Furthermore, men who received SpaceOAR reported significantly less decline in bowel and urinary quality of life at a median three year follow up.[2] According to the authors, the spacer is an effective tool that could enable expanded radiotherapy protocols for patients with prostate cancer.

Application of the hydrogel spacer in everyday clinical practice[4]

SpaceOAR is applied transperineally under local anesthesia and supported by a transrectal ultrasound device.[4]

Helpful tips can be found in the review paper of a Canadian working group[4]

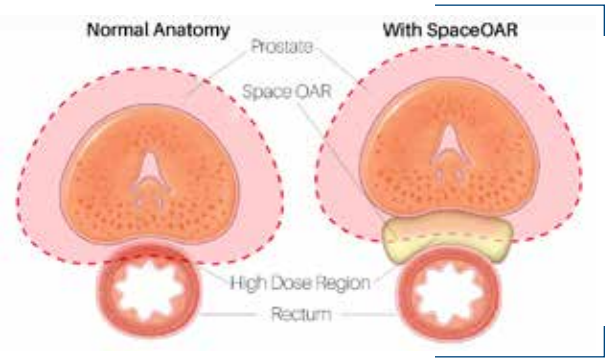

Figure 1: The hydrogel spacer ensures a distance between the rectum and prostate during irradiation.

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StoneSmart™: Insights to Innovation for the Treatment of Nephrolithiasis

The problem in kidney stones

Urologists and their patients today have access to a larger armoury of better treatment options than ever before. As a partner for Urologists around the globe, one of our focus areas is the treatment of Nephrolithiasis. However, globally, including in established markets, the growth of kidney stone prevalence[1] has been outpacing surgical volume growth[2] – potentially leaving behind a large number of untreated stone sufferers. Additionally, surgical complexity is increasing with rising BMIs and other co-morbidities. All of this leads to undeveloped potential in managing urologic care.

To bridge the gap, healthcare providers need the right innovations to effectively solve procedural challenges to be able to treat more patients in efficient and profitable ways.

For an innovation-driven company such as Boston Scientific, the challenge is uncovering the types of meaningful innovations needed to help drive urologic care forward. We are investing in Urology in unique ways: In 2016 we launched LithoVue™, the first digital single-use flexible ureteroscope, that addressed unmet needs related to the use of reusable flexible ureteroscopes, which have inconsistent performance and are associated with operational challenges and high costs for maintenance, sterilisation and reprocessing.

We studied flow and set up in ORs

Today we are introducing StoneSmart™, our approach to developing meaningful innovation in stone therapy. Using an insight-driven ethnographic approach, we sent cross-functional teams to over 40 hospitals in nearly 30 cities around the world observing a diverse set of ureteroscopy and PCNL procedures to deeply understand urologists' and their staffs' greatest challenges.

Our teams observed and documented procedures and techniques and interviewed many of the stakeholders involved in providing Urologic care. This deep body of knowledge was actionable. Instead of looking at a device in isolation, we looked at the network of how everything works together and asked where can we make a change that will have an impact? And, ultimately, to identify the roadblocks and the problems we should be solving that will truly impact the efficiency of procedure.

Within ureteroscopy, we found three powerful insights that really seem to be important considerations to future innovations. First, is to increase the surgeon's control during procedures, because that leads to greater efficiency and improved outcomes.[2] Second, is reducing the cognitive load and minimizing distractions, so performing surgical tasks can become easier. And third, we recognise that the operating room is an ecosystem of its own with a large team that needs to be orchestrated during procedures. Reducing the effort required to coordinate people, tools and movements would enable the surgeon to focus on the patient and processes.

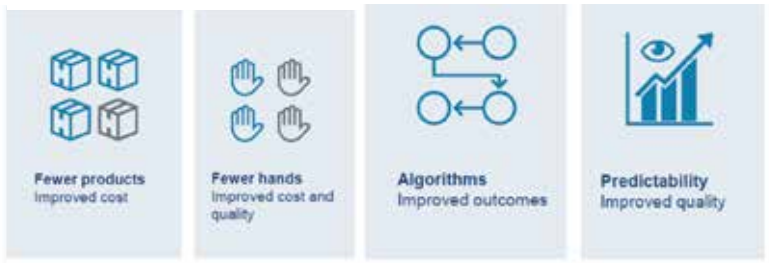
Solving for the largest problems

These three insights came together for stone fragmentation procedures. Data from this research showed, on average, basketing stone fragments accounts for more than 20% of procedural time when employing a stone fragmentation strategy.[2] A great example of how this process forced us to challenge our assumptions about innovation is with stone baskets. In the past, we have thought a lot about how to change the shape and flexibility at the basket end. And this makes sense, a basket needs to access, capture and release stones efficiently – it's a basket, that's what it does. But when you really watch a basket being used you realize that to move the scope, manipulate the basket and maintain a clear field of view, depending on where you are in the world, you can have 4 to 6 hands and from 2 to 4 people involved. This led to our first StoneSmart Innovation.

#Solobasketing

Thinking about how to make the use of a retrieval device much more

StoneSmart Ecosystem Goals



efficient, as well as how it fits into the whole flow of the procedure to improve efficiency, we developed the LithoVue Empower™ Retrieval Deployment Device, providing physicians with a revolutionary way to streamline basketing from start to finish. The Lithovue Empower™ Device takes stone removal procedures to the next level. The critical task of controlling the basket is now in the surgeon's hand while seamlessly integrating with our LithoVue Ureteroscope and nitinol baskets allowing surgeon to use the #Solobasketing-approach.

Integrating the Lithovue Empower™ Device with the LithoVue Flexible Ureteroscope simplifies team orchestration and increases surgical control by turning a multiple-person task into a one-person operation, eliminating the need to coordinate with an assistant during stone retrieval and reducing the chance of miscommunication during stone basketing.[2]

Sharing procedural techniques

StoneSmart™ innovations such as the Lithovue Empower™ Device is only a first step forward. While improved technology plays an important role in evolving the future of urology, so does developing technique and surgical strategy best practices. With the launch of the StoneSmart™ video series hosted by Urology Times, international thought leaders are able to share and discuss procedural case studies and innovative surgical techniques for the treatment of stone diseases. Each month, a new featured video is released, as well as linked Twitter conversation under the #StoneSmart tag, which enables clinicians to discuss the video and debate in real time. These conversations generate additional important insights and considerations for future innovations and solutions.

The insights from StoneSmart™, and the future innovations that come from them, will continue to result in better technology and fuel the momentum in specialty urology by delivering improved financial health, quality outcomes and provider engagement. ■

Further information is available at https://stonesmart.urologytimes.com/

1. Prevalence of Kidney Stones in the United States. Charles D. Scales, Jr.,a,* Alexandria C. Smith,b Janet M. Hanley,b Christopher S. Saigal,c and Urologic Diseases in America Project. 2012.
2. Data on File at Boston Scientific. Internal Boston Scientific Market Model.

Important disposables in the minimally invasive percutaneous nephrolitholapaxy (MIP)

Stonefree, low complications and short-term treatment that can be planned today are the standards demanded by patients and health systems in urinary stone therapy.

Percutaneous stone treatment shows the highest stone clearance rate of all treatment modalities even in times of computer tomographic stone control.[1] This seems to play an essential role in the avoidance of recurrent stone episodes, especially in the case of low-risk stone formers.[2]

While in earlier times the high absence of stones was bought at the price of considerable morbidity[3] , technical improvements have made it possible to significantly reduce complications to a level tolerated by patients and the health system.

In 2008, the term „minimally invasive percutaneous nephrolithotomy" (MIP) was defined for the first time.[4] The ultrasound-assisted puncture used here is superior to pure radiological puncture due to the lower radiation exposure and the avoidance of perforation complications. The use of an „Open-Tip" mono-J catheter, such as the Chr. 8 Percuf-

lex™ Urinary Diversion Stent for the representation of the cavity system. Furthermore it helps in combination with a needle with a sharp pyramid tip and a special ultrasound-visible surface structure at the tip, such as the NaviGuide™ Percutaneous Needle, to further facilitate the exact puncture and can be left as a drainage after the operation has been completed. The lower blood loss with the „Mini-PNL" has been attributed in many studies to the diameter of the access tract. However, it is important to remember that all „Mini-PNL" procedures are performed with a single-step dilatation, while the standard PNL mainly uses telescopic or balloon dilatation. This one-step technique leads to a significantly lower access trauma and could indirectly explain the lower blood loss. It is also responsible for a lower radiation exposure of patient and surgeon.[5] Thus, even if a larger nephroscope adapted to the stone size is used, a lower blood loss seems to be achievable with the corresponding one-step dilatation. The decisive factors for problem-free dilatation are an appropriate guide wire, a hydrophilic tip and a certain degree of digitality, which is offered, for example, by the Sensor™ wire. This allows safe placement in the ureter without sacrificing good kink-free guidance of the dilator. Although the literature on low-pressure irrigation and thus the reduction of fever or sepsis caused by intrarenal reflux is inconclusive, there are strong indications that an intrarenal increase in pressure only leads to one of the above symptoms after a certain period of time.[6] Hydrodynamic stone recovery mechanisms, in particular the vacuum cleaner effect[7] working with a low-pressure system, facilitate rapid stone recovery. Fragment residues that get caught in the fornices and blood clot obstructing the view can be removed with a tipless nitinol basket such as the atraumatically functioning Zero Tip™.

The closure of the access tract to avoid postoperative bleeding and the reduction of the need for painkillers by avoiding a urinoma could not be proven to be advantageous, but the comfort for the patient seems to be attractive and can reduce the length of stay.

A modular nephroscopy system (K. Storz, Tuttlingen) currently available in 4 sizes, which meets all the above requirements, was developed to perform a MIP and enables therapy to be adapted to the patient and stone size. With the MIP L-System, for example, a stone up to approx. 7 mm in size can be removed from low-risk stone formers without any residual fragments potentially remaining in the patient. The risk of a new stone episode is thus reduced. In case of a frustrating retrograde access despite the most modern technology, the flexible ureterorenoscopy can be changed to a percutaneous access with the MIP S-System and the intervention can be terminated in one session without significant rearrangement in supine position. ■

Prof. Udo Nagele,
Hall in Tyrol

Disclaimer

The opinions expressed in this article are those of the author. They do not purport to reflect the opinions or views of Boston Scientific.

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Solobasketing – Salzburg's Experiences with LithoVue Empower™

Complete stone extraction is essential to guarantee sustainable stone freedom.[1] One reason why ESWL has lost importance in recent years is that residual concrements can occur more frequently than with RIRS (retrograde intrarenal surgery). However, the higher stone clearance rate with RIRS is associated with a significant additional effort for the surgeon and a longer operation time.[2] Especially in flexible ureterorenoscopy with laser lithotripsy, concretions often remain in the renal and have to be extracted at a later stage. By improving laser technology and the laser process itself, the amount of concrements to be extracted can be significantly reduced, but complete dusting, which does not require basketing at all, is still not always possible.[3]

However, the goal of a flexible ureterorenoscopy should always be complete stone clearance. Remaining residual concrements lead to an increased rate of new stone formation.[1] Nor can the effort and cost of a flexible ureterorenoscopy be justified if the patient is not completely stone free.[4,5] The process of stone extraction via the flexible ureterorenoscope is a coordinatively demanding process because the kidney moves with breathing displacement, the flexible ureterorenoscope is moved by the surgeon and the basket is operated by an operating assistant. It is therefore not surprising that several attempts are often required to capture and extract a concrement.

Guiding the Ureterorenoscope and of the basket for stone extraction is in the hands of the surgeon.

Solobasketing

In order to simplify this surgical step, the Department of Urology and Andrology at the University Hospital Salzburg is currently testing a surgical aid, the so-called LithoVue Empower™ Retrieval Deployment Device from Boston Scientific.

This surgical aid makes SoloBasketing possible. The guidance of the ureterorenoscope and the basket for stone extraction is now in the hands of the surgeon. The aim is to accelerate the surgical step and to simplify the coordinatively demanding stone extraction through the interaction of the surgical team as all steps are now in one hand. A holder for the basket is attached to the flexible ureterorenoscope and the control unit of the basket is clamped in the holder. The surgeon can now open and close the basket with one finger without having to rely on outside help. Initial personal experience has shown that a concrement can be more easily grasped in solo basketing with just a few attempts. This can speed up the operation. Less experienced colleagues, in particular, seem to benefit in particular, although clinical studies and data are still lacking. Especially for larger stones with a large number of stones that have to be extracted, the LithoVue Empower™ Retrieval Deployment Device seems to be a great help for the surgeon. All in all, the LithoVue Empower™ Retrieval Deployment Device provides the endourologist with a new set of useful instruments to make the procedure faster and easier.[6] ■

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6. Data on File at Landeskrankenhaus Slalzburg

Artificial bladder sphincter AMS-800™

Promising data for women with stress incontinence

Peyronnet, Benoit, et al. „Robot-assisted AMS-800 artificial urinary sphincter bladder neck implantation in female patients with stress urinary incontinence." European urology 75.1 (2019): 169-175; https://www.ncbi.nlm.nih.gov/pubmed/30139632

The AMS 800™ bladder control system restores continence with occlusive cuff pressure and a patient-controlled pump. AMS 800™ is often used to treat stress incontinence in men after prostate surgery.

The system mimics normal sphincter function by opening and closing the urethra according to the patient's control.[1] The widespread use of the artificial bladder sphincter in women has been hampered by the morbidity associated with the open procedure required for implantation.

Mission: Standardized technique in women

A French working group therefore set itself the goal of describing a standardized technique for robot-assisted implantation of AMS 800™ on the bladder neck of female patients and presenting perioperative and functional results. For this purpose, the medical records of 49 women who underwent a robot-assisted implantation of an artificial bladder sphincter between March 2012 and March 2017 were retrospectively evaluated. Women with an intrinsic dysfunction of the bladder sphincter were median 75 years old, the vast majority had an incontinence-related surgical intervention in their anamnesis (mostly midurethral loop system). The 10 participating surgeons from five centers were generally not very experienced in the implantation of artificial sphincters or in robot-assisted surgery.

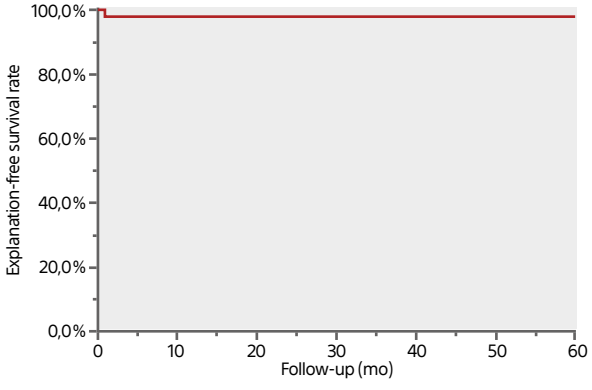
In transperitoneal surgery, the artificial sphincter is inserted into the bladder neck using a robot. An important role is played by the assistant surgeon, who uses the fingers inserted into the vagina to expose the vesicovaginal space and guides the surgeon through the preparation of the bladder neck at the robot.

High continence rates after 3 months

The primary endpoint of the investigation is incontinence - categorized as complete incontinence (e.g. no more use of templates), reduced or unchanged incontinence. The evaluation of the available data shows that 3 months after the procedure 40 patients were completely continental (81.6 %), six women had reduced incontinence (12.2 %) and three women were unchanged (6.1%). Intraoperative complications (bladder neck or vaginal injuries) occurred in 16.3% of women. In nine patients (18.3%) postoperative complications occurred (only 2 cases Clavien-Dindo-Classification ≥ 3). After a median follow-up of 18.5 months, explantation (vaginal erosion) and three revisions (1 mechanical, 2 non-mechanical) were necessary.

Conclusion: In this first multicenter series of robot-assisted implantations of AMS 800™ in women, the technique used was feasible, safe, reproducible and associated with promising results. ■

1 AMS 800TM System zur Blasenkontrolle – Gebrauchsanweisung American Medical Systems, Inc. 2012

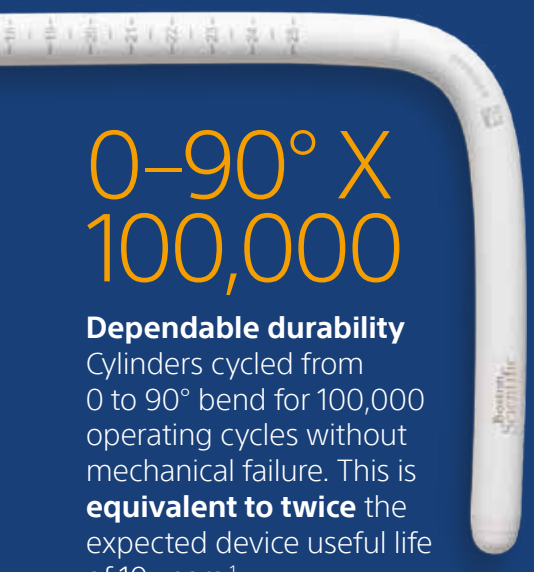


Only one of the implants had to be can be removed again. Background was a vaginal erosion.

Tactra™ Malleable Penile Prosthesis

The Natural Choice.

A natural feeling malleable penile prosthesis constructed around a Nitinol core to optimize rigidity, durability and concealment.[1]



0–90° X 100,000

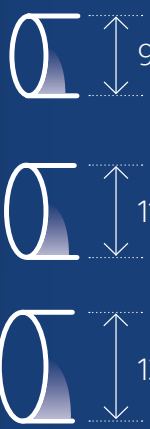
Dependable durability
Cylinders cycled from 0 to 90° bend for 100,000 operating cycles without mechanical failure. This is **equivalent to twice** the expected device useful life of 10 years.[1]

Dynamic Nitinol core for optimal rigidity, durability and concealment[1]

Proprietary dual-layer silicone construction for **authentic, natural feel**[1]

Soft, rounded silicone distal tip designed to provide maximum patient comfort and satisfaction[1]

Simplified sizing to address the widest spectrum of patient anatomy[1]



Insertion-fit Rear Tip Extenders for a secure connection and stable foundation[1]

Laser-etched markings trimmable to corporal length intraoperatively

6.1 lbs.

Axial load
The powerful Nitinol core gives a pair of Tactra Penile Prosthesis cylinders the column strength to withstand **5.5** times (6.1 lbs) the requirement for vaginal intromission, post durability testing[1]

1. Data on file with Boston Scientific

Caution: U.S. Federal law restricts this device to sale by or on the order of a physician.

CAUTION: The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings and instructions for use can be found in the product labelling supplied with each device. Information for use only in countries with applicable health authority registrations. This material not intended for use in France.

Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, and potential adverse events.

The Tactra™ Malleable Penile Prosthesis is intended for use in the treatment of erectile dysfunction (impotence) in adult males. Implanting a penile prosthesis will damage or destroy any remaining natural ability to have a spontaneous erection, as well as make other treatment options impossible.

Men with diabetes, spinal cord injuries, or skin infections may have an increased risk of infection. Implantation may result in penile shortening, curvature or scarring. Potential adverse events may include device malfunction/failure leading to additional surgery, device/tissue erosion, infection,and pain/soreness. MH-611819-AA

Products shown for informational purposes only – not meant as a promotion or offer for sale – certain components are pending CE Mark, not available for sale in the European Economic Area (EEA).

The testing was performed by or on behalf of Boston Scientific. Data on file. Bench Test results may not necessarily be indicative of clinical performance.

Boston Scientific
Advancing science for life™

The transobturator suburethral sling: a safe and effective option for all degrees of post prostatectomy urinary incontinence

Sullivan JF, et al. Can J Urol. 2018 Apr;25(2):9268-72

77 consecutive patients

- Stress urinary incontinence (SUI) following radical prostatectomy (RP)
- Implanted with an AdVance™ transobturator male sling
- One surgeon at a single centre

Postoperative outcomes

OVERALL
(mild, moderate and severe SUI at baseline):
73% cured

MILD SUI at baseline	Cured	82%
	Improved	12%
	Failed	6%
MODERATE SUI at baseline	Cured	73%
	Improved	13%
	Failed	13%
SEVERE SUI at baseline	Cured	60%
	Improved	7%
	Failed	33%

Effective for all degrees of post-RP incontinence

Significant improvement in quality of life scores

ICIQ-UI SF	
Baseline	6 months
17.7	8.0

ICIQ-SF, International Consultation on Incontinence Questionnaire short form

Male Incontinence: AdVance™ XP Male Sling System

Expert interview Dr. Peter Rehder from the University Hospital Innsbruck, AT

Hello, Dr. Rehder. Together with Dr. Christian Gozzi you were the developer of the AdVance™ Male Sling Systemand have successfully implanted a large number of them in more than 10 years. How did the idea for the AdVance™ Male Sling System come about?

Dr. Rehder: The female sling (Monarc) was already known, and I had made very good experiences with it with women. The principle of outside-in around the lower pubic branch was familiar to me, with a very low risk of injuring the pudendal vessels and nerves. In 2003 I was assigned a patient with complete urinary incontinence. He was shot at close range through the pelvis and pre-operated in all hospitals. However, the patient still had urinary incontinence and did not want an artificial hydraulic sphincter. First I enlarged the small scarred shrink bladder with an ileum segment in the sense of a bladder augmentation. I then discussed the case with Christian Gozzi and inserted a transobturatoric ligament. We also did this with the aim of supporting the urethra and the residual sphincter muscle. The use of templates was halved. Later I still had to implant an artificial hydraulic sphincter (AMS 800). This was our first patient whom we had treated with a transobturatoric retroluminal suspension band (in this case Monarc). Prof. Georg Bartsch from the University Hospital Innsbruck then allowed us to conduct a pilot study with 20 patients, which we were able to publish in European Urology 2007. As a „prototype" we used the female Monarc band. The company AMS then developed, patented and marketed the AdVance™ Male Sling System and later the AdVance™ XP Male Sling Systemspecifically for men.

When do you use AdVance™ XP Male Sling System?

Dr. Rehder: From the anamnesis, the most important thing is the nocturnal continence. If the patient is dry in bed and can stand up with a full bladder and hold back the urine, this is a good sign that the sphincter is still working. If there is urinary stress incontinence in such a prostate dominated patient, with the use of 2 to 4 templates, these are good conditions for a transobturatoric retroluminal suspension band to be able to restore urinary stress incontinence. In the clinical examination, the mittperineal elevation test then helps to assess whether the sphincter reacts positively to support of the urethral bulb. With the index finger, the perineal region below the urethra and parallel to the anal canal and the membranous urethra is slightly pushed in/ lifted. You should not press directly on the urethra, as you will simply compress it. The elevation test is positive if the sphincter closes spontaneously in the distal part and thus extends the closure distance to at least 1 - 1.5 cm. Postoperatively, the patient should take care of himself, since the ligament is only inserted and must first strengthen through the formation of scar tissue.

Can you tell us more about the mechanism – the Mode of Action?

Dr. Rehder: The AdVance™ XP Male Sling System is a non-compressive, transobturatoric retro-urethral sling that works by supporting the dorsal structure of the sphincter. The loop is placed proximal to the bulb and moves from vertical to horizontal at the distal end under the sphincter urethra. The bulbus is very voluminous and blood-filled between the loop and the distal sphinteric urethra. During loading, the sphincter is supported in the sense of an abutment in order to be able to seal better. Studies show the low complication rate and almost no corrosion because the ligament lies below the urethral lumen. The implantation of an artificial hydraulic sphincter continues distally.

How should the sling be tensioned?

Dr. Rehder: The tensioning technique is important. The tension is applied parallel to the lumen of the urethra on the urethral bulb – not perpendicular to the lumen as compressive implants provide, causing an increased risk of obstruction and possible corrosion. The AdVance™ XP Male Sling System causes proximal displacement of the urethral bulb, leading to circumferential coaptation of the urethral asphincter without reducing the urethral lumen through ligament placement or tension.

How can physicians learn more about the AdVance™ XP Male Sling System?

Dr. Rehder: I would like to introduce interested physicians to the planned surgical workshop with AdVance™ XP Male Sling System. I myself will lead a workshop in October 2019 in Innsbruck and look forward to the exchange with the participating colleagues. For further information please contact your local Boston Scientific employee.

Boston Scientific

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Rezūm™

Water Vapor Therapy

Transform the BPH treatment experience for your patients with a durable, minimally invasive alternative to medical management

- First-line therapy option[1]
- Low retreatment rate[2]
- Preserves sexual function[3]
- Doesn't require a permanent implant
- Able to treat prostates with hyperplasia of the lateral lobes, central zone and/or median lobe

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