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ROUNDTABLE

UroLift[®] System Treatment: Expert Panel Discussion

FACULTY

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Introduction

The UroLift® System treatment for BPH entered the US urologist's armamentarium in September 2013 upon FDA clearance. With the issuance of Category 1 CPT coding January 1, 2015, we expect this procedure to become widely adopted. As such, we felt it important to assemble a panel of urologists with direct experience to discuss key aspects of this new procedure that could be helpful to those preparing to bring the UroLift System treatment into their practices. Members of the panel were:

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UroLift® System Treatment: Expert Panel Discussion

How robust is the UroLift® clinical data? Does your personal experience reflect the published results?

Dr. Roehrborn: As co-primary investigator of the LIFT randomized study, I was involved in protocol development and discussions with the FDA. The LIFT study was well designed and executed. A sham-controlled study is clinically important and statistically challenging because there is such a formidable sham effect in BPH. Several would-be BPH procedures, such as balloon dilation, Botox®, and Nymox's NX-1207, failed to overcome a sham control and were abandoned. Likely due to a combination of the placebo effect and temporary dilation due to rigid cystoscopy, at 3 months the LIFT sham arm showed a therapeutic response stronger than typical BPH medication. This effect wears off over time, so the earlier one makes a comparison, the more challenging. The fact that prostatic urethral lift (PUL) was superior to sham by 88% at 3 months is a significant outcome. The patients have now been followed for 2 years with durable outcomes, and these results are corroborated by a sham crossover study and other open-label studies.

Dr. McVary: The results across all studies are consistent, and this can give us a measure of confidence in the data. At 2 weeks patients demonstrate improvement; at 3 months they reach a new plateau of impact; and at 2 years there is little degradation. We also employed validated instruments to test the effect on both erectile and ejaculatory function. Unique to approved BPH/LUTS procedures, PUL has shown no new-onset sexual dysfunction. This is particularly remarkable with regard to ejaculatory dysfunction, which is an expected outcome of tissue-removing procedures, such as resection (TURP) and vaporization (laser or otherwise).

Dr. Stroup: In the 15 or so cases we've done, the mean improvement on IPSS score and quality of life were even higher than the published studies, which was impressive.

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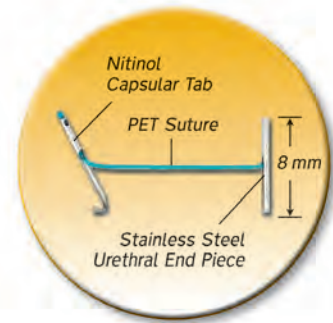
UROLIFT®
BPH Relief. In Sight.™

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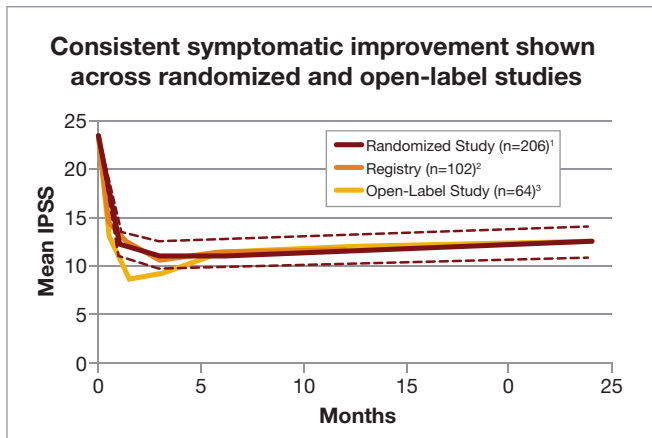


Dr. Gange: I've seen similar improvements, and it just reinforces what we learned in the trial: this is a very efficacious, minimally invasive, well-tolerated procedure.

Dr. Valenzuela: I think, as with most surgical procedures, consistently good outcomes require good patient selection. It is important to rule out the obstructive median lobes and to keep prostate size within range (<80 cc). Most importantly, this is for men with decent bladder function; outcomes can be compromised by a decompensated bladder.



UroLift® Permanent Implant



IPSS, International Prostate Symptom Score

1. Roehrborn C, et al. *Urology Practice*. 2015;(2):1–7.
2. McNicholas T, et al. *Eur Urol*. 2013;64:292–299.
3. Chin P, et al. *Urology*. 2012;79:5–11.

Why choose UroLift®?

Dr. Gange: Urologists have been looking for a long time for a minimally invasive procedure that accomplishes near what TURP can but without the morbidities and certainly the sexual morbidity. UroLift is a procedure that can be done in the office on an outpatient basis that results in rapid recovery and significant improvement and usually without a catheter. This is what we've been waiting for.

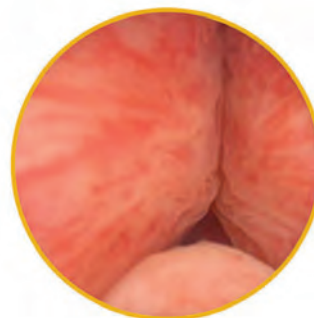
Dr. Stroup: BPH is an anatomic obstruction that needs an anatomic solution. There are 12 million men in the US with BPH: 48% are on watchful waiting, 51% take medications, and only 1% go on to surgery or another procedure. There are some benefits from medications, but those are often associated with significant side effects. Medications often fail to deliver the kind of benefits that most men would like, and the progressive natural history of BPH shows that medications will fail at some point. I think UroLift provides a highly effective, attractive, and long-term solution that gets men off the meds.

Dr. Valenzuela: With a fair amount of my practice focusing on men's health, I do find the unique preservation of sexual function really distinguishes UroLift from other BPH treatments, including most drugs.

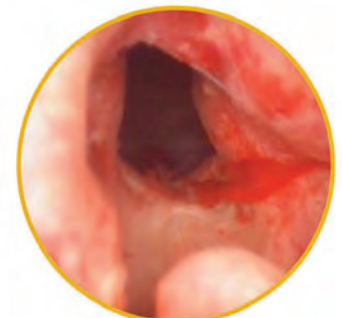
Dr. McVary: The UroLift implant procedure offers a reasonable improvement in LUTS with little risk to sexual health. Sexual preservation is possibly the single most important concern to patients with LUTS secondary to BPH.

Dr. Roehrborn: My own experience and that of the clinical studies show that PUL can be reliably conducted under local anesthesia in the office setting. In addition to offering advantages for the younger and sexually active men wishing to preserve sexual function or return to work/life rapidly, this procedure offers benefits for those with comorbidities for whom avoiding general anesthesia, fluid shifts, or potential bleeding complications is of high priority.

Dr. Gange: It's pretty novel and unique to be able to tell a patient we're going to do something significant to your prostate but we're not going to alter your ejaculation or pose any risk to your erections. We have seen no instance of de novo ejaculatory dysfunction or erectile dysfunction from UroLift implantation in the published trials and in my ongoing experience.



Pre-procedure



Post-procedure



Do you have any key technical tips to share?

Dr. Gange: UroLift is a procedure where you see what you do immediately, which is a great indicator of the outcome the patient will receive. While you do not create a true TURP-like defect, the anterior channel you do achieve is enough to give patients relief and achieve the published IPSS and flow rate improvements.



UroLift® allows you to customize the treatment to the anatomy of each patient.

—Dr. McVary

Dr. Stroup: Agreed. If you're able to visualize an open anterior channel through the bladder neck, that's an adequate and excellent result. UroLift is really a unique procedure that remedies the BPH but has no real side effects in terms of ejaculatory or erectile dysfunction. In my practice, with a number of younger patients who are still in the family planning stage or who want to maintain fertility, I definitely offer the UroLift System procedure.

Dr. McVary: UroLift allows you to customize the treatment to the anatomy of each patient. As we know, no two prostates are the same, and being able to push aside excess anterior tissue in one patient and maybe a single obstructive left lateral lobe on another is a key aspect of UroLift's versatility.

How does UroLift® fit into the treatment algorithm?

Dr. Roehrborn: I believe the PUL option is an option for most men with moderate-to-severe LUTS and the associated bother, in whom the symptoms are most likely due to BPH. Of course ruling out an obstructive median lobe is important, but otherwise it is a reasonable option in place of surgery or long-term use of medications.

Dr. Gange: I find that the fact that we can do this in the office is something that appeals to patients. When we tell them this is something that can be performed in the office, their eyes light up. They're more intrigued and they're more willing to take that step than what they perceive as a much larger step, going to a hospital and going under an anesthetic of some sort.

Dr. Stroup: I describe UroLift as a procedure, not a surgery. I'm positioning the UroLift procedure as a first-line treatment option upstream of TURP and as a real alternative to medication because of the advantages such as sexual preservation, rapid symptom relief, and a quick return to normal activity.

Dr. McVary: An in-office treatment is something that appeals to many patients.

Dr. Valenzuela: Given the truly remarkable lack of serious adverse events, I feel UroLift is a viable option for most men suffering from BPH/LUTS with an appropriate prostate anatomy.

Can UroLift® be performed under local anesthesia?

Dr. McVary: I have only performed it as such.

Dr. Gonzalez: Early on, I did a few under local with sedation and some under a heavier conscious sedation like propofol instead of just an IV sedative. I found that it was important for the patient to be as comfortable as possible because during the procedure we need them to be very still; millimeters of distance can make a big difference in this operation and placement and creating that anterior urethral channel is very important.

Dr. Valenzuela: I did my first several cases in the operating room to offer the most control when learning the technique. Since then, I have begun offering the procedure in the office setting. I think a lot of men would prefer an office treatment over outpatient.

Dr. Gange: I've done over 50 cases and have had tremendous success with local anesthesia for this procedure, and I haven't had a patient ask to be put to sleep for this. We use chilled lidocaine in the bladder and we use lidocaine jelly in the urethra for approximately 20 minutes. And those patients have all been pre-medicated with hydrocodone, alprazolam, and ketorolac.

Dr. Roehrborn: The US clinical studies were performed using a local anesthesia protocol. This was done to test, and ultimately validate, the feasibility of conducting PUL under local anesthesia. I see this as a key advantage of the PUL procedure, and I would intend to conduct it primarily in the office.



What's the learning curve for the UroLift® procedure?

Dr. Gonzalez: For those who are just starting out, it helps to do several cases with oversight from someone who's had some experience with the procedure. The company is very good about providing that early support.

Dr. Gange: A practicing urologist can learn UroLift quickly, as it is not overly challenging; that said, there are some nuances. For example, getting just far enough from the bladder neck to stay out of the bladder while still achieving a good proximal opening for the first 2 implants just takes a little practice. And then where you place your additional implants is also something that one learns with experience.

Dr. Stroup: I would say it takes 5 cases to be comfortably self-sufficient.

Dr. McVary: I was very comfortable after the first 3 procedures.



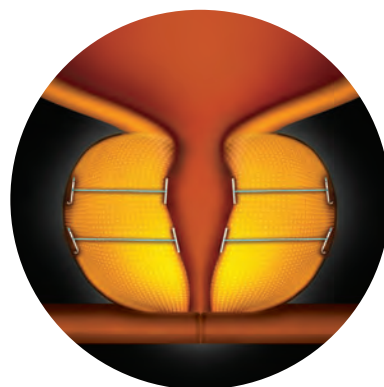
I've done over 50 cases and have had tremendous success with local anesthesia for this procedure.

—Dr. Gange

Dr. Roehrborn: One objective with the clinical study was to work with the company to develop an effective training program for new surgeons to come up the learning curve quickly. The company has been very diligent in developing and implementing a solid training program that gives us confidence in terms of maintaining good outcomes as urologists become involved who are new to the procedure.

How many implants are typically placed? Does prostate size make a difference?

Dr. Stroup: I haven't really correlated the number of implants I place with prostate size. I rely on visual appearance. I'll place the first 2 implants at the bladder neck level, and then I'll take a look to see if more are needed. If so, then they are placed more distally but before the veru. I have found that



for most of the prostates we've needed to place 4 implants. However, we have done a couple in the 70 to 80 gram range, and in those cases we have placed 5 or 6 implants. We've also seen that a lot of the prostates are not symmetrical all the time. There may be a little bit of a bulge in one area in the mid gland, so you may put in 2 on one side and 3 on the other to achieve the ideal opening you want.

Dr. Roehrborn: Reviewing the clinical trial data, there was no definitive algorithm we could create for number of implants versus prostate size or length. The most common number was 4, while the overall mean was about 5.

Dr. Gange: The average number of implants used in the trial population was about 5, but my current average is more around 4 in average-sized glands.

Dr. McVary: The number of implants placed is related to the urethra length and size, but again, this is a customizable procedure. You adjust the number of implants used according to the contours of the gland you are presented with.

Dr. Valenzuela: I find that my most common number is 4 for a broad range of prostate sizes. Occasionally, you get an odd number like 5 so as to address a bulge that may occur from the other compression zones.

What is the best way to select UroLift® candidates?

Dr. Stroup: Patient selection is key to achieving good outcomes. I evaluate all patients with a uroflow, cystoscopy, and TRUS volume study. I think a useful guideline has been the patients that were eligible for the study—men with up to 80-gram prostates, who are not in retention and who do not have a middle lobe. These patients have the most to gain from the PUL.

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—Dr. Stroup

Dr. Gange: Agreed. I also think patients with a high bladder neck make it a little harder to achieve a good anterior channel. And smaller prostates are easier to do this on than larger prostates. So, starting with the 30-cc prostates and doing a few of those will greatly enhance the comfort level as you move toward larger, more challenging glands.

Dr. Gonzalez: We all see older patients who are at risk of having falls when they get up so many times during the night. If we can offer those patients a low-risk procedure and get them off a medication that may make them unstable or potentially increase their fall risk, then I think we're doing a service to these men without having to do a very invasive operation.

Dr. McVary: A patient population that can tolerate a minor sedation procedure or even just a local procedure is who I target.

Dr. Roehrborn: It is important to select UroLift candidates using TRUS and cystoscopy. TRUS assures you are in the right prostate volume range, and flexible cystoscopy is arguably more helpful in determining whether the prostate anatomy is suitable. "Median lobe" is a broad term. While conducting the cystoscopy, it is important to ask yourself, "If I part the lateral lobes, will this prostate be less obstructed?" If a median lobe or very high bladder neck would continue to obstruct the prostatic fossa, then the answer is, "No."

Have you treated anticoagulated patients?

Dr. Gange: I have not treated men with active anticoagulation, and clearly I would have to accept some level of increased risk associated with that. I'm comfortable on baby aspirin, but beyond that I prefer patients to be off the anticoagulant for the procedure and then resume it after.

Dr. Stroup: I've been comfortable treating several patients on low-dose aspirin and have had good outcomes. I've held other anticoagulation in 2 other patients who were at low

cardiovascular risk for 3 days, resuming it on postoperative day 2 when the majority of gross hematuria had resolved.

Dr. Gonzalez: A large proportion of my patients come to see me because of obstructive symptoms, and they are on anticoagulation. I've treated patients with UroLift without stopping their anticoagulation, and I've not had bleeding that needed fulguration during the procedure or postoperative bleeding yet in approximately 16 patients.

Do the implants get encrusted?

Dr. Gange: In the trials, we conducted follow-up cystoscopies in all patients and did not see a single urethral endpiece calcify. In fact, by 3 to 6 months the implants are not visible any longer; they're covered over with epithelium. The only encrustation we've seen has been when the implant was inadvertently deployed into the bladder. It can happen if you're too close to the bladder when you make the proximal deployments. If that does happen, it's important to remove those components and replace them, which is easy to do.

Dr. Roehrborn: This is a good point. Unlike the early studies with urethral stents, the UroLift FDA study required video capture of cystoscopies at 1 year, followed by review by an independent urologist, specifically assessing for encrustation, inflammation, and edema. There was no encrustation on any implant within the prostatic urethra. One important safety aspect is to avoid having the distal end of the device enter the bladder inadvertently. This can, and has, happened if the device is deployed too close to the bladder neck and if the angle is not quite right. Flexible cystoscopy with 180 degree retroflexion should be considered at the end of the procedure to make sure this has not happened. It is a very important training point to carefully place the proximal implants and to assess their positioning cystoscopically before removing instrumentation.

Is a catheter required post-op?

Dr. Roehrborn: Catheterization rate appears to be something that may be reduced with increased experience. In the randomized study, the patients were the first ever treated by most of the investigators, and 30% of patients required a catheter after void trial testing. This was followed by a study of 51 patients in 7 US centers, and catheterization dropped to 20% with a mean duration less than 1 day. This reduction in catheter usage is probably associated with both a learning curve and with proper patient selection.



Dr. Stroup: We typically place a catheter in the OR and remove it an hour later.

Dr. Gange: In the trial population, in 2 different trials, there was a 20% to 30% catheterization usage. In my personal experience, it has been less than that. I try to leave the bladder full when I've finished the procedure, and if the patient passes a voiding trial we don't leave a catheter in.

Dr. Gonzalez: In my experience, 90% of patients go home without a catheter. And in cases with slight hematuria, the less manipulation or rotation you do within the prostate, the less likely they are to bleed.

What are your patient instructions and follow-up schedule?

Dr. Gange: I'm comfortable with about a week of lighter activity and tell them to avoid sexual activity for that first week. The side effects that are to be expected are urgency, hematuria, and a little pelvic ache. I don't give anyone narcotics to go home with. The urgency is relatively mild. I keep them on alpha-blockers until I see them at 2 weeks if they were on them to begin with, and then we typically discontinue them at that time. The majority of my patients have gone back to their typical day's work the day after their procedure. So, while there may be some nuisance level complaints, those haven't really seemed to get in the way of their daily activities.

Dr. Stroup: I'll describe some degree of hematuria as normal, along with mild pelvic pain or discomfort that's usually alleviated with anti-inflammatory medications, after 1 to 2 weeks. They all have a very rapid return to normal activities.

Dr. Gonzalez: I've found that it's best to mention to the patient that they're going to feel a pelvic ache that can last 7 to 10 days after the procedure. Since we are compressing the prostatic tissue, you're going to feel a bit of an ache down there. And anti-inflammatories like ibuprofen are how I manage that. I've not had to give anyone narcotics for this. I tell my patients that they can resume all activities of daily living right away.



**In my experience 90%
of patients go home
without a catheter.**

—Dr. Gonzalez

Local Anesthesia for Prostatic Urethral Lift

Steven Gange, MD, FACS

Western Urological Clinic, Salt Lake City, UT

1. Oral meds: 45–60 min pre-op

- Alprazolam (Xanax): 2 mg
- Ketorolac (Toradol): 10 mg
- Acetaminophen/hydrocodone (Lortab): 7.5 mg

2. Lidocaine instillation

- Empty bladder with catheter
- Liquid lidocaine: 2%, 30 mL, 4°C into bladder
- Viscous lidocaine: 2%, 10–20 mL, 4°C into urethra
- Penile clamp, patient sitting upright, 20 min dwell

3. Verbal anesthesia as required

4. Use a surgical screen obscuring patient's view of pelvic region.

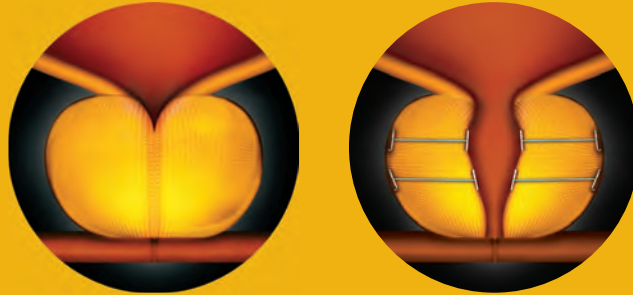
Disclaimer: This information is presented in conjunction with Steven Gange, MD. Surgical technique, medication, and anesthesia regimens are recommendations that have been successfully administered with the UroLift System. Medical practice is solely the responsibility of the treating physician and not Steven Gange, MD, or NeoTract, Inc.

Dr. McVary: I place no restrictions on my UroLift patients.

Dr. Valenzuela: I believe this is an example where a patient can determine when he is ready to resume activities. If having sex or playing a sport results in any hematuria or discomfort, he should back off a little, and resume a day or two later.

Dr. Gange: With regard to follow-up, I see my patients at 2 weeks post UroLift, as this is when they should get past whatever adverse effects they've seen from transurethral access. I then see them again at 3 months, when they should reach their full reduction in symptom score.

Dr. Roehrborn: The LIFT study follow-ups were at 2 weeks; 1, 3, and 6 months; and then annually thereafter. I do feel a 2- to 4-week follow up is a good point to assess that any adverse effects have resolved.



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A new, minimally invasive treatment that alleviates BPH symptoms **without cutting, heating or ablating**

Immediate visible results¹ • Rapid symptom relief² • Preservation of sexual function^{3,4}

Check out the data and learn more at UroLift.com

Most common adverse events reported include hematuria, dysuria, micturition urgency, pelvic pain, and urge incontinence. Most symptoms were mild to moderate in severity and resolved within two to four weeks after the procedure.

1. Data on file at NeoTract; 2. Chin, P et al., Urology 2012; 3. Woo, H, et al., Journal of Sexual Medicine 2011;

4. No instances of de novo, sustained erectile or ejaculatory dysfunction. Roehrborn, C, et al., Journal of Urology 2013, LIFT Study