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How Rezūm Is Changing BPH Treatment
COURSE CHAIR

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Learning Objectives

- Identify the key characteristics that differentiate Rezūm from other available minimally invasive treatments for benign prostatic hyperplasia (BPH)
- Analyze the utility of common diagnostic modalities such as transrectal ultrasound and cystoscopy in a patient with suspected BPH
- Discuss pretreatment topics to cover with patients considering their BPH treatment options
- Review key Rezūm procedural steps and how to incorporate these efficiently into a practice

Disclosures

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Introduction

For many years, transurethral resection of the prostate (TURP) has been the standard by which transurethral procedures for the treatment of benign prostatic hyperplasia (BPH) have been measured. The majority of patients who undergo TURP see improvements in urinary symptom scores and a substantial improvement in urinary flow rates. However, these improvements come at a cost—namely, complications such as bleeding, hyponatremia, and sexual function. This has led researchers to explore alternative transurethral procedures that may equal or improve on the efficacy of TURP but reduce the frequency and duration of postprocedural side effects.

Rezūm is one of several new procedural modalities that has been recently introduced for BPH patients and has shown notable promise in several patient subsets.

In this Urology Times supplement, we’ll take a look at the science behind Rezūm, the nuts and bolts of the procedure, what sort of short- and long-term outcomes patients can expect following the procedure, and ways that urologists can educate their patients about this new technology.
A Look at the Science Behind Rezūm

**Dr. McVary:** What exactly is Rezūm, and how does it work?

**Dr. Dixon:** There are 3 main points that distinguish Rezūm.

First, the Rezūm technology is centered on the idea that you can get tremendous amounts of thermal energy in the form of steam from water. In this case, radiofrequency energy creates steam that stores 540 calories per gram of water. Although that may not resonate in any tangible way to a lot of people, it is a substantial amount of thermal energy.

The second point involves simple heat transfer, or the physical laws of conduction versus convection (FIGURE 1). Conduction is central to a variety of familiar BPH technologies such as Prostiva. Conduction is a relatively slow-moving process, because it relies on cell-to-cell heat transfer by heat diffusion from a higher temperature area—such as a metal electrode—toward a lower temperature area. It is also difficult to control the ablation effects. Convection, meanwhile, involves taking energy from heating fluid such as water and vaporizing it, and “blowing” that energy into the prostate at a pressure slightly above interstitial pressure. Rezūm utilizes the convective delivery of thermal energy.

The Rezūm system creates thermal energy by applying RF current to an inductive coil heater in the handle of the delivery device. Sterile water in the coil is converted into stored thermal energy in the form of steam, and then a controlled volume of steam thermal energy is convectively delivered into the prostate to ablate the targeted tissue and cause coagulative necrosis. In essence, the Rezūm system is a next-generation transurethral needle ablation (TUNA) system.

Conversely, the Prostiva system is a first-generation TUNA device that applies RF current directly to the prostate tissue. As the prostate tissue cells around the probe resist passage of the electrical RF current, thermal energy is produced by friction, thereby heating the water molecules in the tissue into vapor, or steam. This thermal energy is conducted cell by cell away from the device, which leads to heating of the tissue and, ultimately, coagulative necrosis.

In essence, both systems use steam thermal energy created with RF current to cause tissue necrosis; one by convection, one by conduction.

Another important thermodynamic consideration with Rezūm is...
that convection is accompanied by a phase change, with the energy release occurring when the water vapor changes back to its liquid state. With Rezūm, thermal energy in the form of steam is dispersed from the needle into the interstitial spaces of the tissue. It’s a much more efficient heat transfer process than conduction.

Because Rezūm produces wet thermal energy, it doesn’t desiccate or carbonize tissue like conduction technologies. Each treatment delivers 0.42 mL of water in the form of steam. Each treatment creates a 1.5- to 2.0-cm circumferential lesion.

The final point involves McNeal’s zonal anatomy of the prostate. In patients with BPH, steam can be delivered into the transition or central zone of the prostate, and it won’t escape those compartments. The reason it stays within the transition zone is because of the physical laws that govern convection. Because steam represents a mass transfer of energy, it respects the boundaries of the prostate that have a higher density. These boundaries are the “surgical” capsule, urethra, bladder neck, and what is loosely described as the outer capsule of the prostate. Those 3 distinguishing characteristics of Rezūm make it different than previous minimally invasive treatments and translate into virtually instantaneous, irreversible tissue death as steam targets the individual prostatic zones.

**Dr. Beahrs:** It is important for urologists to understand that Rezūm is different from previous technologies that some of us may be familiar with, such as Cooled ThermoTherapy™ (microwave) or Prostiva® RF Therapy. There may be some skeptics of Rezūm who have had negative experiences with those technologies and don’t understand that this is a more powerful energy transfer.

When I used Prostiva, I would try to do 12 treatments, and that would usually take care of most of the enlarged prostatic tissue. With Rezūm, fewer treatments are required because the vapor fills a much larger area, and a single treatment creates a larger lesion than a single Prostiva lesion. When a Rezūm treatment is observed under an ultrasound—which isn’t a requirement but can be educational—you see the vapor shoot through the tissue until it hits the constraints of either the transitional or the central zone, and then it stops there (FIGURE 2).

**Dr. Gonzalez:** Rezūm allows urologists to alleviate the symptoms associated with an enlarged prostate while preserving men’s sexual function. A good way to explain the Rezūm technology to patients is to tell them that there are different ways to remove or treat tissue that is obstructing the flow of urine. There are procedures that cut out this tissue by using electrocautery, a cold knife, or a laser. Alternately, we have procedures that destroy the tissue through the absorption of energy, usually with heat. Rezūm falls into that second category but uses a convective approach.

One of the benefits of Rezūm is that there is no urothelium being removed, so the urethral lining is preserved. Often, the more invasive the technology, the more likely we are to affect not only how our patients urinate but also how they ejaculate. It’s become clearer to me over the years that there are many men with BPH who are not pleased with how they urinate on a
medication, but they don’t want to jump to surgery because they don’t want to improve urination at the cost of worsening sexual function. Rezūm allows us to improve patients’ lower urinary tract symptoms, treat the enlarged prostate, and preserve their sexual function.

Dr. Shore: When I discuss Rezūm with my patients, I describe the process as a de-obstructing technique in which I use vapor or steam energy to ablate tissue without any charring effect. The blood loss risks are minimal. The expected impact on sexual function is minimal. What I find particularly compelling—and I always make a point of emphasizing this to my patients—is that the entire appointment from beginning to end is less than 2 hours. The reason I emphasize this point is that it speaks to the innate concept of “minimally invasive” procedure.

Granted, we place a rigid scope into the urethra, but it’s for a short duration of time, and thus can be accomplished with oral sedation alone. There are urologists who may prefer using a periprostatic block, IV sedation, or general anesthesia, but I have never required more than a combination of an anxiolytic and an analgesic for both my research and post-FDA-cleared patients. Of course, physician and patient preference are most important to achieve the optimal result.

Another important consideration with Rezūm is that there is no foreign body left behind once the procedure is complete, and thus no foreign material at risk for extrusion or encrustation.

Dr. McVary: Dr. Dixon, how much volume reduction can you expect when you use Rezūm? Do you see that as an important component of the technology?

Dr. Dixon: The percentage of volume reduction depends on your approach and how aggressively the transition or central zones are treated. If you look at the initial Rezūm clinical trials, magnetic resonance imaging (MRI) was performed at 1 week, 1 month, 3 months, and 6 months. From a clinical perspective, the most important results were likely those at 1 and 3 months where we saw the most significant change. At 3 months, the thermal lesions were more than 91% resorbed and overall prostate volume reduction was approximately 30% (TABLE 1).2,3

The reason volume reduction is important is that if we extrapolate from other major clinical trials, in particular the MTOPS trial, volume reduction and prevention of growth in the 5-alpha-reductase inhibitors (5-ARIs) group was one of the key factors in risk reduction of progression over time. That’s what seemed to lower the risk of needing future surgery and developing urinary retention.4

In contrast to 5-ARIs—where tissue volume is reduced only as long as the drug is administered—the ablated tissue is reabsorbed and physically “removed” during Rezūm. This results in true tissue volume reduction.

Whether fair or unfair, extrapolating from what we learned in the MTOPS and other trials,4,5 my overall impression is that

**MRI Study: Significant Lesion Creation/Resolution and Volume Reduction**

<table>
<thead>
<tr>
<th>Lesion volume</th>
<th>Time</th>
<th>N</th>
<th>Mean (cm³)</th>
<th>Mean Δ (cm³)</th>
<th>Mean % Δ</th>
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<tr>
<td>1 week</td>
<td>59</td>
<td>8.5</td>
<td>-5.0</td>
<td>-58.8%</td>
<td></td>
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<td>3 months</td>
<td>55</td>
<td>0.7</td>
<td>-12.1</td>
<td>-30.2%</td>
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<tr>
<td>6 months</td>
<td>54</td>
<td>0.3</td>
<td>-15.3</td>
<td>-38.2%</td>
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</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Transition volume zone</th>
<th>Time</th>
<th>N</th>
<th>Mean (cm³)</th>
<th>Mean Δ (cm³)</th>
<th>Mean % Δ</th>
</tr>
</thead>
<tbody>
<tr>
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<td>59</td>
<td>40.1</td>
<td>-7.0</td>
<td>-17.5%</td>
<td></td>
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<tr>
<td>1 month</td>
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<td>33.1</td>
<td>-12.1</td>
<td>-30.2%</td>
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<tr>
<td>3 months</td>
<td>55</td>
<td>28.0</td>
<td>-15.3</td>
<td>-38.2%</td>
<td></td>
</tr>
<tr>
<td>6 months</td>
<td>54</td>
<td>24.8</td>
<td>-20.6</td>
<td>-30.4%</td>
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<tr>
<th>Prostate volume</th>
<th>Time</th>
<th>N</th>
<th>Mean (cm³)</th>
<th>Mean Δ (cm³)</th>
<th>Mean % Δ</th>
</tr>
</thead>
<tbody>
<tr>
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<td>67.8</td>
<td>-9.3</td>
<td>-13.7%</td>
<td></td>
</tr>
<tr>
<td>1 month</td>
<td>57</td>
<td>58.5</td>
<td>-16.1</td>
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<tr>
<td>3 months</td>
<td>55</td>
<td>51.7</td>
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</tr>
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<td>6 months</td>
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<td>47.2</td>
<td>-20.6</td>
<td>-30.4%</td>
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</tbody>
</table>

**6-Month Measurements vs 1 Week**

- Lesion resolution: 34.9 cm³ (99.5%)
- Transition zone volume reduction: -59.5 cm³ (~52.7%)
- Prostate volume reduction: -78.1 cm³ (~46.2%)

**TABLE 1:** Clinical trial data show that Rezūm averaged 96.5% lesion resolution, resulting in a 38.2% volume reduction of the transition zone as compared to the 1-week baseline measurement. MRI, magnetic resonance imaging.
volume reduction speaks to the durability of Rezūm and likely reduces the future risk of clinical progression, in particular, urinary retention and future need for surgery.

**Dr. Gonzalez:** I think that symptom relief and prostate volume reduction, in general, run parallel to each other, at least in patients with large prostates.

If someone has a very large prostate that is obstructing urine flow, reducing the volume either with surgery or tissue destruction is more likely to produce an improvement in symptoms. It’s more durable.

**Dr. McVary:** When we look back at previous technologies such as transurethral microwave thermotherapy (TUMT) or Prostiva, reports generally showed an acceptable volume reduction and response in the first 6 months to 1 year, but there was then some degradation in response as patients got farther down the road. At least with TUMT, within 3 to 4 years, approximately 70% of men required further treatment either by medication or, in some cases, crossover to TURP.

It seems possible that ablation of the tissue is the corresponding mediator for a durable impact, and that by not ablating it, we’re going to run this risk of revisiting the underperforming technologies of days gone by. In the longer-term follow-up studies of the UroLift implant, for instance, there is a signal lack of response over time depending on how a nonresponder is defined. No one wants to be the TUMT of 2017, so it’ll be important to evaluate longer-term studies of the newer minimally invasive surgical therapies (MISTs) and determine whether the promising initial responses seen over 24 months are durable.

**Dr. Dixon:** The other side issue with the UroLift implant is that it’s a metal insert, and that plays havoc when trying to use MRI as a diagnostic tool to evaluate the possibility of prostate cancer and fusion biopsy. It basically eliminates multiparametric MRI as an effective imaging tool.

**Dr. McVary:** Dr. Shore, how much improvement in the International Prostate Symptom Score (IPSS) do you like to see when you treat a patient for BPH, and how much does that depend on your treatment approach?

**Dr. Shore:** To some degree, the response can certainly vary depending on the patient and the severity and subjective impact of the symptoms that any one patient has. In clinical trials, we typically get an IPSS score at baseline and then during subsequent periods after treatment to gauge any improvements. Improvements are generally more substantial in patients who successfully respond to interventional therapies versus pharmacologic treatment.

It’s important when talking to a patient who has opted for or is considering Rezūm that they understand they are not going to see immediate improvement for at least 3 to 5 weeks and that they will need to have a catheter and a leg bag for anywhere from 1 to 5 days after the procedure. Although that is not always welcome news to patients, once they understand the postprocedure expectations, there is a really marked improvement in their IPSS scores at 3 and 6 months.

**Dr. Gonzalez:** I think it’s important that we look beyond volume reduction and other objective markers and consider patient quality of life when assessing the efficacy of specific treatment approaches. Even as we improve symptom scores and flow rates, we should be able to also offer options that do not cause a new problem such as ejaculatory or erectile dysfunction.

**Dr. McVary:** For well-validated reasons, our community has been fixated on considering that a treatment modality is successful if a patient’s IPSS score improves by 3 or more points, but I don’t think that is true or sensible. For a patient whose symptoms and corresponding IPSS score are substantially higher at baseline, the threshold for improvement has to be greater.

For instance, a man who comes in with an IPSS baseline score of 18 has to be assessed differently than a man whose initial IPSS score is in the low 30s. For that latter patient, you are going to have to have a more significant impact to be able to qualify his treatment as a success. The idea of a clinically meaningful improvement must be indexed to the level of initial symptoms, not the minimally perceptible change of 3 points on the IPSS. It’s a harder task to achieve, but we’re here to do the hard, but right, things.

When we look at pharmacologic therapy for BPH, there are exceptions, but it’s unusual that it will have a substantial impact on IPSS score. The impact is modest. When we look at a TURP or open prostatectomy, you can see a pretty rapid plummeting of the IPSS score when those procedures succeed.

When we look at the impact of MISTs, I think we need to compare outcomes to those surgical procedures. Based on the data we currently have available, Rezūm looks to be competitive, with its overall symptom improvement typically in the neighborhood of 50% at 2 years.

**Dr. Dixon:** Granted, the comparative trials aren’t there, but many of us have now handled so many Rezūm cases that I think it’s reasonable to anatomically summarize our experience.

If you have a new, symptomatic patient looking for some type of intervention and you are confident in your diagnosis of BPH, there are 2 options you can present to them—take 1 to 2 pills for the rest of your life or deal with 2 to 3 weeks of recovery time.
from Rezūm. Regarding long-term side effects and things like symptoms, quality of life, and flow improvement, Rezūm is clearly the better option.

In my opinion, Rezūm is poised to replace pharmacologic therapies as first-line therapy for BPH, with perhaps the exception of the gentleman who has erectile dysfunction and is happy with once-a-day tadalafil (Cialis®).

Dr. Beahrs: In my experience, there are a large percentage of men who do not want to go on another lifelong medication, or perhaps they have initiated pharmacologic therapy at the recommendation of their primary care physician. When you tell them that they can avoid taking another pill for an extended duration of time, they jump at the chance. I’m not quite sure why that is, but my guess is that when you are in middle age and start taking medication for your prostate, it’s a signal that you’re getting older, and nobody likes that.

In addition, there can be bothersome side effects as well as questions regarding durability of effect of medications. For some patients, they may do OK on medication for 3 to 5 years, but then its effectiveness is blunted, and they need to try something else.

My experience with medication is if I have a patient who’s been on it for more than a year, I will ask, “Would you like to try something new?” Ninety percent of the time, they’ll sign on to something minimally invasive.

Dr. Gonzalez: We know that 5-ARIs can affect a patient’s libido and by doing so also impact erectile function and ejaculatory volume. There are strong data that show Rezūm preserves overall sexual function.

Dr. McVary: When you have the initial discussion with a patient with BPH, what are some of the concepts and potential tradeoffs that you make sure to discuss with him?

Dr. Shore: Based on my personal experience, the easiest thing for most patients to consider is a daily oral medication. Many of my patients are already on 4 or 5 other medications, so it’s not a significant leap for them to consider another one. As we’ve already touched on, though, there are a variety of considerations with alpha blockers or 5-ARIs, such as sexual side effects, cost, and adherence.

Men may initially cringe when they hear about the need to undergo rigid cystoscopy with Rezūm or any other endoscopic procedure. It’s also important to go through the list of potential side effects such as bleeding, anesthetic issues, retrograde ejaculation, and erectile dysfunction, as these may or may not be relevant with various treatment options. Although those aforementioned side effects are not necessarily common, they are legitimate concerns that should be discussed.

I ask my patients, “How would you feel about a minimally invasive in-office procedure that would allow you to taper off or stop your oral medications? You’d still have the option later on for a more invasive TURP, if required, but Rezūm, in my experience, is better tolerated, with markedly less anesthetic requirement, and very minimal likelihood of ejaculatory or erectile dysfunction.

Dr. Beahrs: In my practice, I tend to be referred patients with BPH who are already on medication, so I don’t do a lot of the primary workup. I have been performing minimally invasive procedures for about 20 years, so I’m historically the “Minimally Invasive MD” in the group. When Rezūm came along, it was a natural fit for my practice.

When I see a new patient, it’s usually either because they are unhappy with medication or because they want to learn more about Rezūm or other minimally invasive options. My role is to explain to the patient what is likely to happen if they stop taking medication and move to something with more permanence. I talk through the pros and cons of Prostiva, TUMT, Rezūm, TURP, and laser. I don’t perform UroLift procedures at this point.

The BPH Patient Workup

Dr. McVary: Let’s move on and talk about the appropriate workup of a patient with BPH. Dr. Gonzalez, what does your initial evaluation look like? What parts of American Urological Association (AUA) clinical guidelines (TABLE 2) do you adhere to and which do you find your approach conflicts with?

Dr. Gonzalez: In terms of evaluation, I pretty much stick to the AUA guidelines if there is not a complicated past medical history. The medical history, physical exam, and urinalysis are important, and the IPSS score is also key.

If there are items in the medical history that sound atypical, such as isolated nocturnal polyuria, that is important to tease out. Any prior therapies that the patient has tried and/or failed are also important to consider.
Within the physical exam, at a minimum, you need to do a digital rectal exam. Where my approach may then veer off from the AUA guidelines is in the patient for whom I am considering a MIST. In those patients, I always perform a transrectal ultrasound (TRUS) to help understand the anatomy and be more confident in my discussion of therapy options. I like to tell my patients, “A good tailor will measure twice and cut once.” It should be similar for surgeons—we have to know exactly how much tissue we need to address.

If I have a patient who has had an inadequate response to medical therapy, I will often perform a cystoscopy and/or urodynamics to assess intravesical median lobe enlargement. For example, if the patient is prescribed an alpha blocker and does not experience any improvement, I would consider that a mechanical obstruction (eg, stricture or intravesical lobe) or a functional problem (eg, impaired bladder contractility) is at play.

Here is a simple breakdown: A man comes in complaining of nocturia, hesitancy, and dribbling. He has no prior history of BPH medication. For him, at a minimum, you need a history and physical. If he has never had a prostate-specific antigen (PSA) test, that is important to include. A urinalysis is also typically warranted to ensure that there is no microhematuria infection. Assuming normal results on the workup, I will typically offer that patient medical therapy before MIST or an invasive operation.

**Dr. McVary:** That approach is absolutely reasonable, though it is important for our colleagues to understand that the AUA BPH guidelines don’t suggest a preference for front-line medical versus surgical interventions. What they say is that patients should be provided with all options before making a decision. It gives us a little bit more versatility in terms of approaching patients as individuals and taking their preferences into consideration during the decision process.

OK, so Dr. Gonzalez, you mentioned that you do a volume measurement on everybody. Dr. Shore, how about you?

**Dr. Shore:** No, I don’t do a volume measurement on everyone. I don’t do a TRUS. I will get a flow rate and then sometimes do a bladder ultrasound. Depending on the patient’s anatomy, I may then consider a gland volume measurement. It’s not as accurate as a TRUS, but I have preferred to avoid the invasiveness of the TRUS.

**Dr. Dixon:** I utilize the same approach—getting a volume transabdominally. It is not intrusive and, I think, is good enough in most cases. It’s not until I’ve decided on a surgical procedure that I’ll commit to TRUS. In those instances, TRUS can help you to get a sense of size and shape of the prostate. You can sometimes get fooled endoscopically. The Rezūm device is not intended to be a cystoscope; its diagnostic quality outside of the urethra is limited.

**Dr. McVary:** Dr. Shore, what does the optimal BPH patient for Rezūm look like?

**Dr. Shore:** The optimal patient is a man with a 30- to 60-g gland, classic BPH symptoms, no significant comorbidities, and a moderate-to-severe symptom score, who wants to maintain sexual function and is not interested in taking daily medications.

**Dr. Gonzalez:** I’d also include patients who are highly sexually active. If they are interested in maintaining their sexual performance, Rezūm is an ideal option.

**Dr. Dixon:** To me, the “sweet spot” is a gland somewhere around 40 to 70 g in size. When you get into glands that are much smaller than that, the question of whether the patient has BPH versus something else can get a bit murky unless there is an obvious, obstructing median lobe or prostatic urethral angle. For larger glands, it isn’t that Rezūm is any more challenging to perform, but the postprocedure recovery time is likely to be longer if more vapor is delivered. Most men will be OK with that, but there are some who may get a little frustrated if they aren’t properly informed ahead of time. Knowing the volume and procedure plan in advance helps me manage patient expectations regarding possible catheter time and general recovery.

In treating patients with prolonged, catheter-dependent retention, or larger prostates where more treatment is delivered, I will routinely leave a Foley for 2 days and then place a Spanner® Temporary Prostatic Stent as an alternative. Patients have described the Spanner as much more comfortable than a Foley and leg bag.

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**TABLE 2: AUA Recommended Tests in the Evaluation of Patients with Noncomplicated Lower Urinary Tract Symptoms (LUTS)**

<table>
<thead>
<tr>
<th>Relevant medical history</th>
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<tbody>
<tr>
<td>Assessment of LUTS</td>
</tr>
<tr>
<td>Severity and bother (ie, AUA-SI)</td>
</tr>
<tr>
<td>Physical examination including digital rectal exam</td>
</tr>
<tr>
<td>Urinalysis</td>
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<tr>
<td>Serum PSA, in accordance with the guidelines</td>
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<tr>
<td>Frequency/volume chart</td>
</tr>
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</table>

AUA-SI, American Urological Association-Symptom Index; PSA, prostate-specific antigen.
Dr. McVary: What about patients in retention? Does that make a difference?

Dr. Beahrs: I see 3 types of retention patients. The first is the guy who just had hip or knee surgery, went into retention, and now has a catheter in. He’ll typically fare well with Rezūm, because he will be motivated to be weaned off the catheter without needing long-term medication.

The second is the man who has been struggling with BPH for 20 years, has a very large bladder, and finally went into retention. That patient often has an atonic bladder and is on self-catheterization. This patient might do somewhat better after Rezūm, because he’ll often need to self-catheterize only twice a day after the procedure versus his current 4 times a day. I find that those are actually my happiest patients, because now they can go to church or play cards with their friends without carrying a catheter in their pocket.

The third is the patient with “silent prostatism.” His problem is only recognized when finding a large, postvoid residual on scan or perhaps a rising creatinine level. He is often on unmonitored BPH medications.

Dr. Gonzalez: I have treated several patients in retention. When we’re talking about Rezūm, it’s important to clarify that the data in the printed materials I have in my office are based on trials that did not include patients in retention.

That said, I have seen some of these patients urinate as early as 3 to 4 weeks after the procedure, while others may take 2 months to be able to urinate spontaneously. I think that intermittent catheterization after the first official trial void is the best way for the patient to figure out when they’re able to fly on their own.

I agree that if you try to do intermittent catheterization early on in men with large prostates, there’s a potential for bleeding not necessarily due to the procedure but due to traumatic catheterization and edema after the procedure.

Dr. McVary: Dr. Shore, when you have a treatment-naïve BPH patient come into your office, where does Rezūm fit into the conversation?

Dr. Shore: I think it’s perfectly reasonable from a clinical perspective to have Rezūm in the dialogue for first-line therapy, but because of the medicolegal environment in the United States, you should certainly discuss pharmacologic therapy upfront as well.

Dr. Dixon: For the typical BPH patient seeking symptomatic treatment, I think Rezūm represents a new era, and I now recommend Rezūm as a first-line option along with medical therapy. Although the direct comparative trial has not and is not likely to be performed, we have 25+ years of BPH data that gives us a firm grasp on what we’d expect regarding efficacy, side effects, symptom score, and quality of life with BPH therapies. In all of those categories, Rezūm is likely going to beat the standard combination of an alpha blocker and 5-ARI. Rezūm is likely going to lose in the first 2 weeks after treatment in regard to catheter time and other transient issues, but that would seem to be a minor issue in the long term.

Clinically, it comes down to deciding between taking 1, 2, or sometimes 3 pills once per day for the rest of the patient’s life versus a Rezūm treatment that will likely result in better symptom relief and flow improvement without negatively impacting erections or urinary control.

Although I certainly won’t tell patients that there is no risk with Rezūm, the risk of any permanent serious adverse event is extremely remote. To me, the key is that I can confidently tell patients that efficacy will likely exceed medical therapy, and it is extremely unlikely that Rezūm will negatively impact erectile function. With the exception of PDE5 inhibitors, you can’t say that about medications, and 5-ARIs in particular. In fact, from the published Rezūm sexual function data, it seems more likely that erectile function will remain the same or improve than cause any de novo loss of erectile function.11

Dr. Gonzalez: if you have a patient who’s not on medical therapy and they come in asking about MISTs like Rezūm, it’s reasonable to consider it as front-line therapy. I think it’s perfectly reasonable for the patient who opts for MIST to have them initiate an alpha blocker prior to the procedure and then ask them to stay on it until they improve following the procedure. Improvement doesn’t start the day after MIST procedures, and I think that the use of alpha blockers can help patients improve more quickly.

Dr. McVary: Dr. Beahrs, you have a BPH patient in front of you. You’re about to begin counseling him about the procedure. How do you keep the discussion realistic and rational?

Dr. Beahrs: There are 4 areas I always make sure to discuss with new BPH patients, and I start with one that we haven’t talked much about, lifestyle change. I have many patients who drink 6 to 8 cups of coffee and 2 beers every day, and they are running to the bathroom constantly. I first of all strongly encourage them to cut down on their liquid intake, which can improve symptoms enough in about 10% to 15% of patients so that they don’t want or need to have anything more done.

The second conversation is around medications, the third around...
Dr. McVary: Let’s now shift into a discussion of some of the nuts and bolts of Rezūm, starting with preprocedure planning. We discussed earlier how some of us perform an ultrasound while some do not. What about a flexible cystoscopy?

Dr. Gonzalez: Yes, I’ll always do flexible cystoscopy.

Dr. Beahrs: I typically don’t. Unless it’s a patient with blood in their urine or other unusual presenting symptoms, I just look at the size and configuration of the prostate. I also visualize the bladder. With a good exam, I can usually pick up stones or tumors. I also evaluate the median lobe. I feel pretty confident that I can judge what the patient needs to have done with an ultrasound alone. At the time of Rezūm, I check the orifices and bladder base for stones.

Dr. Shore: If I have some reason to think that the patient may have a stricture, I might order cystoscopy, but for the vast majority of my patients, I do not.

Dr. McVary: Dr. Shore, walk me through your step-by-step procedure for Rezūm. What are you doing?

Dr. Shore: Once I’ve got the fluid going, using that as needed for visualization, I start to navigate the anterior/posterior urethra. Depending on the tortuosity of the prostate, I’ll then manipulate the level of Trendelenburg so that as I’m angling the Rezūm scope up, it makes it more amenable to climbing over the bladder neck. I always try to get into the bladder first so I have my landmark of the bladder neck. If there is a median lobe, I’ll treat that or any sort of floor tissue first to take some of the angulation tension off of the scope.

Dr. Beahrs: I have 2 OR tables in my office, so after the block, I place the patient in dorsal lithotomy. They watch the whole procedure, which I think helps. I always check the patient orifices first, as well as the floor of the bladder, to make sure there are no stones. I once had a patient with an ectopic orifice that drained into the prostate; one can never be too careful with the ureteral orifices.

My first treatment is just a pullback from the bladder neck, usually starting on the left side with the verumontanum as my distal point before proceeding to the right side. I save the median lobe for last.

Dr. Gonzalez: My only issue with having the patient watch the procedure is that sometimes they will see the needle go in and suddenly say “Ouch!” just as a reaction to the poke.

As for Rezūm technique, I also tend to go from the bladder neck, distally on one side first and then the other. If an area looks like it’s a little more friable and has some oozing either because of a catheter or introduction of the scope, that’s where I start to try to coagulate the bleeding and avoid impairment of my vision during the procedure.

If there isn’t any bleeding, I start on the patient’s left lobe just inside of the bladder neck, working distally. I’ll then treat the contralateral lobe before assessing the median lobe. If there’s deflection of more than 30 degrees, I’ll treat the median lobe or enlarged central zone.

Dr. Dixon: It is important to have the patient positioned low on the bed in case the scope needs to be passed over a high bladder neck or large central zone. Thermodynamically, it is best to place treatments contiguously and not jump from side to side or apex to base. During the development of Rezūm, we gained a much better appreciation for the central zone and its probable obstructive role in the pathophysiology of BPH. Consequently, I look closely for central zone enlargement during my pretreatment evaluation, and more than 50% of the time, my patients have a central zone or median lobe that I will treat with at least one treatment. We have learned from a subset of data in the Rezūm pivotal trial that patients experience a clinically meaningful improvement of at least 3 points in symptom relief when this enlarged tissue is treated in conjunction with the lateral lobes.

Dr. McVary: Dr. Beahrs, have you had any challenges in trying to get the Rezūm device either up to the level of the membranous urethra or over the bladder neck? What are some of the techniques you have learned to overcome those potential issues?

Dr. Beahrs: Just as with TURP, if you have a very overweight patient with a really deep perineum, it’s important to have them slide down on the table or even have them hang off the table in the dorsal lithotomy position. When you get through the membranous urethra and past the verumontanum, you are in the clear, because you can then start to see your landmarks. Additionally, if a patient has an enlarged central zone increasing...
the prostatic urethral angle, it may be necessary to drop your hands to reach the bladder. This is an indication that the central zone should also be treated for maximum symptom relief.

**Dr. McVary:** Dr. Gonzalez, you’re in the middle of performing a BPH procedure with Rezūm, perhaps you’ve completed a couple of treatments, but then you start to have some bleeding issues. How do you manage that?

**Dr. Gonzalez:** If I’m scoping the patient and the mucosa is friable, I initially treat wherever the bleeding is coming from. It is rarely a difficult issue to control with Rezūm. With other MIST procedures, it can be harder to control the bleeding, but I use the same approach—treat the side that is bleeding first.

In patients who still have a little bit of oozing after the procedure, I will put in a catheter, but I’ve not had a bleeding complication yet that required a trip to the operating room, even in men who are anticoagulated. When our office gets a postprocedure call from a patient who does see blood, it is usually described as on-and-off, intermittent bleeding. I don’t often get patients complaining that they’re passing clots and having a significant hematuria after Rezūm.

**Dr. McVary:** What about oral sedation for pain management before Rezūm. Dr. Beahrs, are you using oral agents?

**Dr. Beahrs:** I have pretty much stopped using all oral agents because I like the idea that if Rezūm is truly a MIST, the patient should be able to drive himself into the office, have the procedure, and drive himself home. I do tell patients that they should take a couple of extra-strength Tylenol® as soon as they get home for discomfort and sit on a hot pad, but my prostate block is usually satisfactory enough so that they don’t need anything extra.

**Dr. Gonzalez:** My use of oral sedation depends on the patient. I will tell patients that, if they’re going to drive themselves to and from my office, they can’t be on an oral sedative or receive intravenous sedation. But if it’s a patient who found flexible cystoscopy particularly unpleasant, I will explain to them that Rezūm treatment is more stimulating than cystoscopy, and I will commonly use a transrectal high pelvic lidocaine block above the level of the seminal vesicles to limit the pain.

I tell all my patients that, “You’re going to have something placed in your rectum. I’m going to do a pelvic floor block to control the pain, but you’re going to feel a rigid scope go in after I’ve used lidocaine jelly. If that idea makes you nervous or you think it’s going to be difficult to lie still for about 6 to 8 minutes, oral or conscious sedation might be a good option.” My experience is that, in general, younger patients in their late 40s or early 50s are more likely to want the sedation.

**Dr. McVary:** Dr. Beahrs, tell us about your procedure in laying down prostate blocks.

**Dr. Beahrs:** Urologists should all be familiar with the Mount Everest or “White Mountain” block that Nash described years ago.¹³ That’s how I start on the right and left side, but then I turn the handle of my ultrasound just a little lateral until the seminal vesicle slips away. Just above what I call “the cloud above the mountain” is where I put the block—it’s right below the bladder. Looking anatomically, it’s an area near the orifice on either side that blocks the inferior hypogastric nerve. It’s the same nerve that causes pain in patients with a distal stone.

I use 1% lidocaine, 10 cc on each side, then wait 5 minutes. It’s very rare that patients do not respond to the block.

To learn more about the modified prostate block that I have found effective with my patients, visit the physician training page on rezum.com.

**Dr. McVary:** Let’s talk a little about postprocedure side effects of Rezūm. Dr. Shore, what are you telling patients to expect, and what have you seen that has or has not surprised you?

**Dr. Shore:** I tell all of my patients that they will always go home with a catheter that is going to come out no sooner than 2 days from their procedure. Three days is more common, and it’ll sometimes take 4 or 5. I tell them that they are going to feel worse before they feel better—they are going to have initial urinary frequency and urgency, and they may have some intermittent hematuria.

We send everyone home with a short course of antibiotics. When we see patients back in the office 3 to 4 weeks after the procedure, then we discuss the likelihood of symptomatic improvement.

**Dr. McVary:** Is anyone seeing any patients come in and talking about erection or ejaculatory dysfunction? If they are, what issues are they bringing up?

**Dr. Gonzalez:** I recently had a patient specifically opt for Rezūm because of fear of ejaculatory dysfunction. He had initially been interested in a UroLift procedure, but on cystoscopy, he was told by his urologist he had a large intravesical lobe and that lasers or plasma vaporization might impact his ejaculatory capabilities.

Prior to the procedure, I did counsel him that while theoretically Rezūm should not affect ejaculation, the prostate is an ejaculatory gland and it’s therefore impossible to guarantee no
effect on ejaculation. It was a good thing we had this discussion, as while he did not develop retrograde ejaculation, he claimed he did notice a 33% reduction in his ejaculate after taking careful measurements. On the flip side, he described his urination as more than 90% improved, so he was very happy overall.

Dr. McVary: One area where there is currently a lot of discussion surrounds catheterization and intermittent self-catheterization after Rezūm. How do you prepare patients for this need?

Dr. Gonzalez: When we schedule Rezūm, I tell patients that they will go home either with a catheter or they will need to do intermittent catheterization until they’re able to urinate comfortably on their own. I give them the option and show them how intermittent self-catheterization works. If they are interested and willing to learn, our staff helps to guide them through the process. We will even give them supplies and offer hope—but not promises—that they may not need a catheter for as long if they utilize intermittent catheterization. I will add that the number of my patients who opt for intermittent self-catheterization is low, probably less than 10%.

Dr. Beahrs: One strategy I have found effective is that, at the end of the procedure, I have all of my patients put their own catheter in, whether they have expressed interest in intermittent self-catheterization or not. Once they have done it, a lot of them will say, "Oh, that was pretty easy. I guess I’ll do that instead of leave one in."

I think a lot of the fear is psychological. It’s just a little barrier that once they get over, many of my patients are happy that they know how to put the catheter in, and they feel secure in doing it on their own.

Incorporating Rezūm into Clinical Practice

Dr. McVary: Dr. Gonzalez, how are you creating awareness among your patients and your community about Rezūm?

Dr. Gonzalez: I’m part of a large urology group practice, and we take turns educating the community. We post information on our website and will send occasional emails to our patients about updates in available therapies for different disease processes. We also routinely offer a public seminar on BPH at least once a year. Having discussions in a group setting like that can be extremely efficient, because if one of our future patients attends the seminar, they have already heard about the information and perhaps even taken materials home to review before coming into our office. The patient often then comes with relevant questions so, at that point, it’s just a matter of whether his evaluation confirms good candidacy for the procedure he is interested in.

Dr. Shore: Treating men with lower urinary tract obstructive symptoms is a core function for most community practice urologists. Understanding all of the approved pharmacologic and interventional modalities is clearly important in order to optimize patient outcomes. Novel therapeutic advancements, such as Rezūm, have successfully expanded my minimally invasive treatment choices for patients with symptomatic prostate enlargement.

Dr. Beahrs: Because I am in a large practice group of 35 physicians, I receive a lot of internal referrals from my colleagues who would rather be in the OR doing robotic prostatectomies or nephrectomies, so they usually send patients to me with a baseline patient history and physical. We have Rezūm brochures in every room, and when patients are “on hold” when calling the office, they hear about all of the things that our practice is currently involved in. We also have information on our website.

Dr. McVary: What about procedure schedule? Dr. Gonzalez, how do you set up your schedule in regard to Rezūm?

Dr. Gonzalez: Procedures can easily be worked into the normal flow of a clinic day with a dedicated procedure room.

Our first step with patients is to have them sign a consent form, unless they have done so previously. Then they receive oral sedation if that is going to be part of the procedure, usually about 30 minutes before they are taken into the procedure room.

Once the nurses have the equipment sterilized and ready for me, I have the patient placed in a dorsal lithotomy position. I do my block, put in the lidocaine jelly, insert the telescope, and then proceed with the procedure. After it is complete, the patients may receive instructions on use of the catheter or self-catheterization, and then they go home.

Dr. Beahrs: The timing is similar for me. I have a nurse who gets to know each patient ahead of time and instructs them in advance regarding use of antibiotics. When they show up, she walks them down the hall, and they get undressed before I come into the room. I usually meet the spouse and then discuss again what the procedure will entail. I then ultrasound the prostate.
Once the block is in, I usually step out and dictate what I’ve done so far, come back in 5 minutes later, and then perform the procedure. I have my nurse perform the teaching regarding the catheter, and then I do one final check as the patient is about to leave the office to make sure that they are doing well.

Dr. McVary: Dr. Dixon, do you set aside a specific day when you try to schedule multiple cases or do you intersperse these throughout your normal clinical practice?

Dr. Dixon: I usually set aside a full day or half day just for Rezum. That seems to help with the overall efficiency of my team. I can perform 5 to 6 procedures within half a day.

Dr. Beahrs: I will typically set aside Tuesday and Friday mornings for my Rezum patients. I’ll sometimes see other patients for Rezum at other times depending on my overall workload, but those are the 2 times I will typically set aside.

Dr. McVary: Lower urinary tract symptoms in the aging male can have a marked impact on individual health and society at large. Although LUTS secondary to BPH is not often life-threatening, its impact on quality of life can be significant.

The modern urologist has a growing armamentarium with which to tackle this diagnosis. Each currently available therapy has a unique risk/benefit profile that must be considered when advising and treating patients.

In this clinical supplement, we’ve discussed how Rezum is a valuable addition to the urologists’ toolbox and covered ways that it can be successfully incorporated into the daily workflow. It will be interesting to see how the treatment of LUTS secondary to BPH evolves as the general urology community gains experience with new technologies like Rezum that can improve outcomes for patients.

References
Approximately 30% of all urologist visits are related to BPH. Many visits involve patients who have tried and failed initial medical management of their symptoms. For some, a different approach to medication may be the best option, while for others, a minimally invasive in-office procedure such as Rezūm should be a consideration. Although writing a new prescription has no or negligible financial impact on a practice, there are a variety of economic considerations with the patient for whom Rezūm is an option.

This flowchart includes a breakdown of the common pathways for an established BPH patient who has failed on medical therapy and is considering Rezūm, as well as specific coding details and approximate reimbursement rates (reimbursements are based on 2017 Medicare unadjusted rates).

For those payers who require Rezūm be reported with CPT code 53899, there are 2 further steps—Box 19 on the CMS-1500 form must be completed with information about Rezūm for the claim to be processed, and documentation of the procedure and medical necessity needs to be submitted within 2 days of claims submission.

Providers should always check a patient’s benefits and any prior authorization requirements before scheduling a TUNA procedure using Rezūm.

References

*Medicare 2017 unadjusted rate place of service, office; multiple procedure reductions may apply.
**A UroCuff™ (CPT Code 53899) may be ordered as an alternative to these 2 tests.
†Providers should always check a patient’s benefits and any prior authorization requirements before scheduling the Rezūm procedure.
For many BPH sufferers, the road to relief goes through the central zone.

A significant number of men who present with symptoms of LUTS secondary to BPH have a median lobe and/or an enlarged central zone. An enlarged central zone increases the prostatic urethral angle and contributes to bladder outlet obstruction.

Rezūm gives you the flexibility to treat all areas of an enlarged prostate, so you can customize your BPH treatment to suit each patient's unique anatomy. This in-office/outpatient therapy does not require general anesthesia, preserves sexual and urinary functions, and eliminates the need for drug therapies and their associated side effects.

Contact us at info@rezum.com to learn more about how Rezūm is transforming the BPH treatment experience for physicians and their patients.

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Rezūm Pivotal Study
IPSS: Median Lobe (ML) Identified – Treated vs Not Treated

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