

GreenLight XPS[™] Laser Therapy System

A SYSTEMATIC APPROACH TO VAPORIZATION INCISION TECHNIQUE (VIT) FOR THE REPRODUCIBLE TREATMENT OF LARGER PROSTATES



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TECHNIQUE SPOTLIGHT

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Focusing on key fundamentals of laser fiber handling and following a systematic approach referencing the surgical capsule, anatomical GreenLight Laser Therapy laser vaporization can enhance clinical outcomes and procedural experience. Dr. Kevin Zorn has used GreenLight Laser Therapy effectively in his practice for over 15 years and has performed well over 2000 procedures using the technology. The following technique summary was developed based on his experience with the technology and his patient outcomes.

Patient selection

Most patients with moderate-to-severe benign prostatic hyperplasia (BPH) are GreenLight Laser Therapy candidates for urologists with adequate experience. First cases are best performed using the classic systematic vaporization (PVP) technique on patients with prostate volumes <50cc, with minimal median lobe component and not taking anticoagulation medication.

Many patients, however, present with larger prostates. With additional experience with the GreenLight system, additional advanced fiber handling techniques can be employed to help provide these patients an endoscopic, minimally invasive therapeutic treatment.

Traditionally, for prostates over 80 grams, many would consider the rule book standard of care to be an open prostatectomy. Given the prolonged hospitalization, incision-related morbidities, high blood transfusion rate and especially the low surgical volumes, in my practice, I do not feel that that is a safe, modern option for benign disease. For larger prostates, I typically use Anatomical Photoselective Vaporization of the Prostate (aPVP), also known as Vaporization Incision Technique, to remove transition zone prostate tissue more thoroughly and in a more efficient standardized approach. This systematic approach uses anatomical landmarks, committing to getting to the capsule and removing as much tissue as possible. In our experience using the XPS system, we have demonstrated comparable outcomes to enucleation techniques that require morcellation.

Patient workup

Patient examination: Flexible cystoscopy and transrectal ultrasound (TRUS) are strongly encouraged. These methods:

- Help with surgical planning and timing/choice of anesthesia
- Allow for easier capsule recognition intra-operatively
- Aid in patient counseling
- Help rule out other pathology

American Urological Association (AUA) guidelines also recommend: AUA symptom score, PSA when appropriate, flow rate and post void residuals. Formal urodynamics are optional but helpful in select cases.

OR preparation

- Broad spectrum antibiotic
- DVT prophylaxis
- B & O Supprettes[™] suppository (B & O 16A) at the time of surgical prep
- Hold anticoagulation when safe and in consultation with cardiologist
- Make sure to include prostate volume and any anatomical considerations in the record when scheduling the GreenLight procedure this will help the OR scheduler/anesthesia team prepare properly for the case.

OR equipment and anesthesia

- Spinal is preferred but use general anesthesia for larger prostates or if the OR time will be longer
- Comfortable rolling chair to perform the procedure while seated
- Continuous flow resectoscope (24F-26F) with laser bridge for MoXy[™] Liquid Cooled Fiber, and visual obturator to avoid traumatizing mucosa upon scope insertion
- Continuous flow resectoscope (26–28F) with a separate laser bridge for MoXy Fiber provides greater flow rates and may be helpful for larger, bloody glands
- Dedicated urology HD camera (pendulum style) recommended



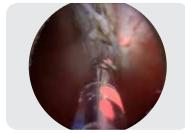
Cystoscope set with visual obturator

Resectoscope set with visual obturator

- Camera filter or 30-degree telescope with built-in GreenLight system filter preferred
- Two to four 3-liter bags of normal saline with large irrigation tubing
- Additional 3-liter bag of saline with pressure cuff set to 80mmHg for irrigation of the MoXy Fiber; ensure this is connected utilizing IV tubing and irrigating prior to fiber insertion into the scope
- GreenLight MoXy Fiber
- Graspers or a 24-27F versacut TURP loop for mechanical tissue removal at the end of the procedure

GreenLight[™] PVP Laser Therapy fundamentals

• Fiber-to-tissue distance: 1–3mm away from tissue is optimal, but not in contact with tissue. The MoXy Fiber tip is 2.1mm and provides a good visual to help determine proper fiber-to-tissue distance.



Optimal fiber-to-tissue distance

- Sweep speed: adjust sweep speed to maximize vaporization efficiency. The key is to heat the tissue to 100 degrees Celsius for vaporization to occur. 0.5Hz rotation speed has been shown to deliver the optimal vaporization ablation.
- Sweep arc: 30 degrees is optimal
- **Power settings:** start low, 80W to create an initial working space, and increase to maintain maximal vaporization while maintaining visibility, usually 120W for incisions and 180W for vaporizations
- Avoid emptying the bladder during the procedure, as this can result in undesired venous bleeding with impaired visualization due to reduction of pressure within the bladder
- aPVP or VIT: advanced close-contact fiber dragging along the tissue to provide efficient, homogenous dissection. This close contact maneuver is started at the bladder neck and pulled back to the apex to 1) create the initial floor grooves down to the surgical capsule and 2) dissection of the adenoma from the capsule while treating/releasing along the point of cleavage.

Scope handling and maneuvering

This is important and differs somewhat from transurethral resection of the prostate (TURP):

- Rotate the fiber as described in the Fundamentals section with the dominant hand
- Hold the scope and camera system by the camera head with the non-dominant hand
- Move both hands together and rotate the scope, as one would with TURP, to circumferentially treat the prostate
- Utilize the light cord connection with the camera and rotate accordingly to position the GreenLight fiber for optimal visualization/tissue angulation

Identifying landmarks

• Atraumatically, locate the ureteral orifices (UOs) using a visual obturator. (Fig. 1)



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V3



Figure 1 - Left ureteral orifice

- If they cannot be seen, at least try to identify the ureteric ridge. After vaporizing down the bladder neck, the UOs can usually be found.
- Assess how much median lobe is present and assess the amount of intravesical tissue to be vaporized. (*Fig. 2*)



Figure 2 - Assessment of median lobe

- Introduce the laser fiber in the visual field, confirm irrigation for both scope and laser fiber, and activate aiming beam.
- Identify the verumontanum. Using coagulation, you may demarcate the limits of distal dissection (3 and 9 o'clock position) at the level of the verumontanum. (*Fig. 3*)



Figure 3 - Verumontanum

• The bladder should be kept moderately distended. This helps identify the prostate from the bladder anteriorly and laterally, and also helps control bleeding. Do not use any suction during the procedure; use gravity for outflow instead.

Create a Working Channel

• Activate aiming beam by putting the laser on "ready." (Fig. 4)



Figure 4 - Aiming beam

• Begin the procedure using the 30W coagulation setting, with demarcation of a distal border at the apex mucosa of the prostate, just proximally from the verumontanum. Increasing the margin can be considered in the elderly patient or those seeking to preserve antegrade ejaculation (apical sparing). This initial step sets the distal line of treatment. (*Fig. 5*)



Figure 5 - Marking distal line of treatment

- Begin with low power (80–120W) with the goal to turn up the power quickly as a working channel is created and good flow is established.
- If the lateral lobes are touching, make a working channel between 9 and 3 o'clock on low energy with a fast sweep. Once there's good flow with the continuous flow cystoscope, I can visualize the median lobe.

Efficient vaporization remains the key goal and is confirmed with the creation of large, "scuba-like" bubbles. Small, "champagne-like" bubbles result from a combination of vaporization and coagulation. Vaporizing without the creation of bubbles is evidence of coagulation and is the biggest cause of postoperative irritative symptoms.

Bubbles = Feedback

- Bubbles are an indicator of vaporization efficiency
- Greater distance results in more coagulation; less vaporization

Lack of bubbles = Trouble (coagulation, edema)

- You will notice increased bubbles during vaporization when using the system at higher power
- You may need to make adjustments to manage increased bubble formation and maintain good visualization

Median lobe

• Using the 120W vaporization setting, start at the 5 o'clock sulcus at the bladder neck, and create a groove from the bladder neck towards the verumontanum apex. Repeat the treatments to deepen and widen the groove down to the surgical capsule. (*Fig. 6*)





Figure 6 - Creating 5 o'clock grooves

• Repeat this same process at the 7 o'clock sulcus at the bladder neck to the apex, deepening to capsule. Increasing to 120W may be needed to maintain efficient vaporization. (*Fig. 7*)

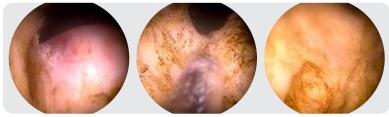


Figure 7 - Creating 7 o'clock grooves

- Once these grooves have been created you will have demarcated the median lobe from other prostate tissue.
- Remove the isolated median lobe tissue with medially directed lasing along the surgical capsule on both sides (180W). (*Fig. 8 & 9*)



medially to resect the median lobe

Figure 8 - Directing the laser beam Figure 9 - Reserved



Figure 9 - Resected tissue in the bladder

Ensure that the resected tissue is small enough to be remove with graspers at the end of the procedure. If not, cut the median lobe into smaller sections before resecting.

• Push the tissue sections into the bladder for removal later in the procedure.

Bleeding may be encountered during the procedure, especially at the 5 and 7 o'clock locations where the vasculature enters the prostate. Vaporizing around and through these areas to control it is important. If needed, utilize the TruCoag[™] feature and "paint" around the bleeder to create hemostasis.

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Lateral lobes

- Create an anterior 1 o'clock groove from the bladder neck to the apex, deepening to the surgical capsule (120W).
- Follow the surgical capsule with the laser fiber to thin down and release the left lateral lobe from the surgical capsule. (*Fig. 10*)

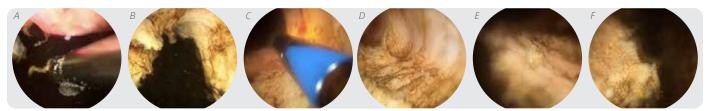


Figure 10 - Creating 1 o'clock groove and removing lateral tissue

• Complete the left lateral lobe treatment with systematic vaporization or vapor incision fragmentation of the isolated tissue (180W). (*Fig. 11*)

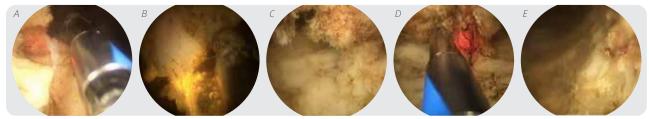


Figure 11 - Lasing anterior tissue

• Create an anterior 11 o'clock groove from the bladder neck to the apex, deepening to the surgical capsule (120W). Follow the surgical capsule with the laser fiber to thin down and release the right lateral lobe from the surgical capsule. (*Fig. 12*)

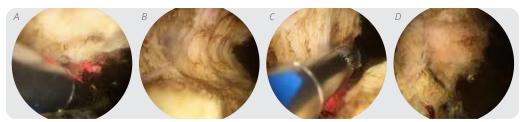


Figure 12 - Creating 11 o'clock groove and segmenting right lateral tissue

• Complete the right lateral lobe treatment with systematic vaporization or vapor incision fragmentation of the isolated tissue (180W). (*Fig. 13*)

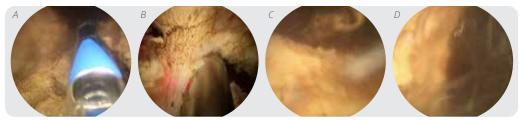


Figure 13 - Completing resection of right lateral tissue

7 8 9 10 roical



V8

THE VAPORIZATION INCISION TECHNIQUE (VIT) PROCEDURE

Apical tissue



Figure 14 - Untreated left apical tissue

- Decrease the power to lower wattage (~120W) for less effect on the external sphincter.
- Working "around the corner" at the apex is important to treat transition zone tissue that may fall into the fossa laterally and potentially cause post-op obstruction.
- To remove the distal apical tissue, work in a retrograde manner away from the sphincter.
- Vaporize alongside and even beyond the veru if adenoma extends distally in larger glands. (Fig. 15)



Figure 15 - Treated apical tissue

If possible, work away from danger so whatever the danger is, it is near you. If it's a ureteral orifice, work in the opposite direction. If it's the sphincter, also work in the opposite direction.



Completing the procedure



• 50-70% of the prostate volume should be eliminated for a durable outcome. (Fig. 16)

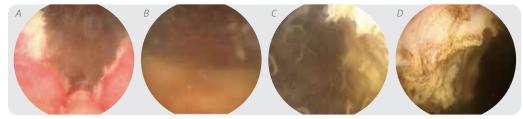


Figure 16 - Open fossa

Before completing the procedure, all tissue in the bladder must be removed. To do this, use either the graspers or versacut TURP loop.

- In my experience, PSA is reduced more than 50% after adequate healing. The fossa should look like a well-resected TURP defect.
- The remaining fossa will be relatively smooth. Within 3 to 4 weeks, there is generally smooth re-epithelialization, which is faster than conventional PVP. (*Fig. 17*)



Figure 17 - Fossa 4 weeks post-op

- Confirm the surgical endpoint, verification of anatomic landmarks and hemostasis.
- Liberated adenoma tissue in the bladder is then mechanically removed from the bladder using either alligator graspers (for small pieces) or the Karl Storz VaporCut thick endoscopic loop. (*Fig. 18*)



Figure 18 - Removal of excised tissue from bladder

- Administer Lasix[™] 20mg approximately 10 minutes prior to completing the procedure, if desired. This not only helps diuresis, but also helps irrigate the catheter.
- Atraumatic placement of a Foley catheter (20 or 22F 2-way; a 3-way Foley may be placed, but may not offer benefit for patients treated as outpatients). (*Fig. 19*)



Figure 19 - Catheter insertion

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As with all surgical procedures, there are a number of ways to successfully treat BPH using the GreenLight XPS Laser Therapy System. However one chooses to systematically approach a given procedure, adherence to the basic principles outlined below is the cornerstone to repeatable surgical success and patient satisfaction.

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The GreenLight" Laser System is intended for incision/excision, vaporization, ablation, hemostasis and coagulation of soft tissue, including photoselective vaporization of the prostate for benign prostatic hyperplasia (BPH). The laser system is contraindicated for patients who: are contraindicated for surgery, contraindicated where appropriate anesthesia is contraindicated by patient history, have calcified tissue, require hemostasis in >2mm vessels, have uncontrolled bleeding disorders, have prostate cancer, have acute urinary tract infection (UTI) or severe urethral stricture. Possible risks and complications include, but are not limited to, irritative symptoms (dysuria, urgency, frequency), retrograde ejaculation, urinary incontinence, erectile dysfunction, hematuria - gross, UTI, bladder neck contracture/outlet obstruct, urinary retention, perforation - prostate, urethral stricture.

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