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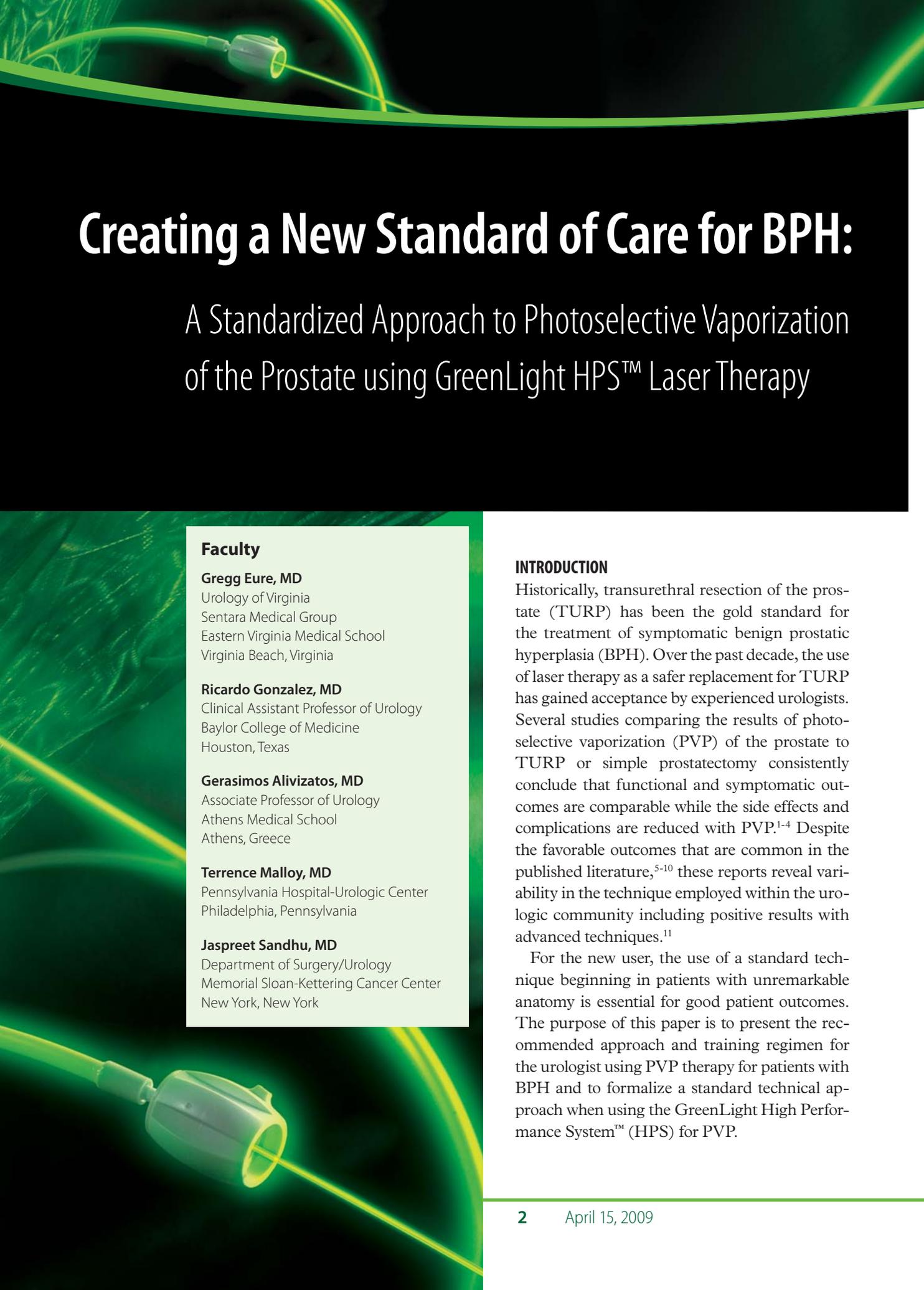
Creating a New Standard of Care for BPH

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A green laser probe is shown at the top and bottom of the page, emitting a bright green beam of light. The background is dark with green light trails and a curved green line.

Creating a New Standard of Care for BPH:

A Standardized Approach to Photoselective Vaporization of the Prostate using GreenLight HPS™ Laser Therapy

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INTRODUCTION

Historically, transurethral resection of the prostate (TURP) has been the gold standard for the treatment of symptomatic benign prostatic hyperplasia (BPH). Over the past decade, the use of laser therapy as a safer replacement for TURP has gained acceptance by experienced urologists. Several studies comparing the results of photoselective vaporization (PVP) of the prostate to TURP or simple prostatectomy consistently conclude that functional and symptomatic outcomes are comparable while the side effects and complications are reduced with PVP.¹⁻⁴ Despite the favorable outcomes that are common in the published literature,⁵⁻¹⁰ these reports reveal variability in the technique employed within the urologic community including positive results with advanced techniques.¹¹

For the new user, the use of a standard technique beginning in patients with unremarkable anatomy is essential for good patient outcomes. The purpose of this paper is to present the recommended approach and training regimen for the urologist using PVP therapy for patients with BPH and to formalize a standard technical approach when using the GreenLight High Performance System™ (HPS) for PVP.

PRE-PROCEDURE CONSIDERATIONS

Several factors are important for achieving positive patient outcomes and a favorable clinical experience for the physician: patient selection, patient education, and acquiring the needed expertise to effectively utilize the GreenLight HPS system.

Patient Selection

Patients with BPH and lower urinary tract symptoms (LUTS; mild to severe) are appropriate candidates for the procedure. However, proper patient selection is imperative while gaining experience with PVP using the GreenLight HPS laser. The authors recommend starting with patients who have the following characteristics: prostate sizes ≤ 40 cc as measured by transrectal ultrasound (TRUS); symptomatic; not taking anticoagulants; no urinary retention; and no intravesical median lobes.

Several factors are important for achieving positive patient outcomes and a favorable clinical experience for the physician: patient selection, patient education, and acquiring the needed expertise to effectively utilize the GreenLight HPS system.

The goal of a new operator of the Greenlight HPS should be to achieve a level of mastery with fiber handling, vaporization techniques, identification of surgical end points and coagulation of bleeding tissues before proceeding to more difficult procedures. It takes time to develop technical competence in these areas. Performing early cases on simple anatomy is crucial for translating technical competency into mastery of the technique.

Setting Patient Expectations

To ensure patient satisfaction with the PVP procedure, it is important to manage patients' expectations, including: expected post-pro-

Abstract

The use of laser therapy has evolved over the past decade as a safer replacement for transurethral resection of the prostate (TURP). The objective of this article is to discuss a standardized, methodical approach to photoselective vaporization of the prostate (PVP) in men with benign prostatic hyperplasia. Developing the initial technical competence when using the GreenLight HPS laser system is paramount to achieving good patient outcomes and procedural efficiency.

cedure symptoms, potential adverse events, and a likely timeline for improvement. This discussion can set the stage for patient satisfaction and a successful recovery.

Following the PVP procedure, the patient will likely experience immediate improvement in flow and symptoms, but possibly have mild short-term

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urgency and frequency or mild dysuria. Hematuria occurs less frequently, however, retrograde or diminished ejaculate volume is common. The patient may require a Foley catheter, which is dependent on the physicians' discretion.

INTRAOPERATIVE APPROACH AND TECHNIQUE

Proficiency with PVP may be achieved with unremarkable anatomy and appropriate patient selection as discussed earlier. Physicians can expect to be more comfortable with the technique after 10 cases using the GreenLight HPS, which may result in reduced operating room (OR) and laser time. At this point the physician may be confident enough to select more difficult cases such as those with comorbidities, larger gland size, or patients taking anticoagulants.^{4,12-13}

TISSUE VAPORIZATION

PVP occurs by laser light absorption within the prostatic tissue. The laser light is directed at the tissue and is absorbed by the hemoglobin. The temperature of the hemoglobin increases and as a result dissipates the heat into surrounding tissue. The water in the tissue is heated until pockets of steam or vapor bubbles form. The vapor bubbles create pressure in the connective tissue and then burst. This vaporization process is

repeated throughout the various layers of prostatic tissue until there is complete debulking of the prostatic tissue.

To ensure patient satisfaction with the PVP procedure, it is important to manage patients' expectations.

The degree of tissue effect is dependent on a number of factors: tissue composition, laser wavelength, power or energy settings, and the mode of laser operation. Glandular tissue will vaporize faster than stromal tissue. Fibrous tissue has a higher ultimate tensile strength. Therefore, a higher pressure must build up inside the tissue before the tissue matrix breaks apart and vaporization begins. This can be achieved with a slower sweep speed during the procedure. Very fibrous glands, such as those in patients taking long-term 5-alpha reductase inhibitors (finasteride and dutasteride), may take longer to treat. However, short-term use of 5-alpha reductase inhibitors preoperatively may actually be beneficial in reducing perioperative bleeding.¹⁴

The tissue effect will also be dependent on the laser wavelength. Different wavelengths are absorbed into tissue differently depending on the tissue structure. Power settings play a role in the laser-tissue interaction in that a higher power generally results in a more dramatic effect (Figure 1). The GreenLight HPS is a quasi-continuous wave laser and is capable of vaporizing a large bulk of tissue. Finally, laser tissue interaction depends on how the fiber is handled by the physician, including working distance, sweep speed, and sweep arc.

Managing Vaporization Efficiency

During the procedure, there is an increase in the tissue temperature. When the tissue temperature remains below 100°C, a photothermal effect is achieved and coagulation occurs. When the tissue temperature exceeds 100°C, photoablation is achieved and vaporization of the tissue occurs.

Figure 1. Vaporization Efficiency



Vaporization efficiency comparing the 80W GreenLight HPS and the 120W laser in bovine prostatic tissue (ex vivo).

Courtesy of American Medical Systems

Bubbles should be evident at all times during vaporization as they provide continuous feedback with regard to vaporization efficiency.¹⁵⁻¹⁷

Vaporization relies on sufficient exposure of the tissue to laser energy and is affected by both sweep speed and length of sweep arc. Proper sweep speed should not be too fast or too slow, and the arc should not be too wide. An optimal sweeping motion creates efficient vaporization, demonstrated by the presence of bubbles. Excessive coagulation may result from a sweeping motion that is too fast, while a slow sweeping motion may result in bleeding that is more difficult to control. Sweep speed and sweep arc should be adjusted depending on tissue response to laser energy.

During PVP, proper cleaning of the fiber throughout the procedure may maintain fiber efficiency and reduce procedure time. Maintaining the condition of the fiber will lead to time savings in the OR and consistently better outcomes for the patient. If tissue adheres at or near the exit beam, the fiber should be cleaned immediately. To clean the fiber cap and remove any debris, the physician should wipe from the distal to proximal end or from the tip of the cap back. This can be done by putting the laser in the standby mode, removing the fiber and the inner sheath of the scope, and wiping the fiber cap with wet sterile gauze. In some situations, the cap may be cleaned by gently rubbing it against prostatic tissue for approximately 2 seconds. The goal throughout the procedure is to keep the fiber cap clean, avoid tissue contact, and maintain good cooling flow around the fiber cap. The optimal working distance to tissue is 0.5 to 3 mm; one fiber cap width's (i.e. 1.8 mm) is a good visual cue. If these conditions are not met, there may be premature degrading of the fiber.

PERFORMING PVP: A STANDARDIZED APPROACH USING THE GREENLIGHT HPS LASER

Developing a standardized, methodical approach to the treatment of the prostate gland using the

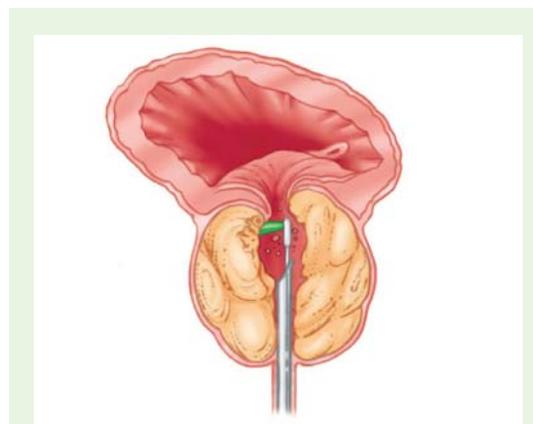
GreenLight HPS laser system is an integral part of developing positive experiences and ensuring positive patient outcomes.

For the basic intraoperative procedure, insert the cystoscope into the bladder using a visual obturator to minimize any tissue trauma and visualize all essential landmarks, including the ureteral orifices. Allow the bladder to adequately distend and maintain the continuous flow of irrigant throughout the procedure, taking care not to over distend the bladder.

A step-wise approach to the procedure should be taken starting at the bladder neck, proceeding to the median lobe working proximal to distal (bladder neck to veru), then progressing to the lateral lobes. Remove one lobe first, then the other. Finally, evaluate the anterior lobe and treat, if needed.

1. Beginning the Procedure

Advance the cystoscope into the bladder to evaluate anatomical landmarks and determine the degree of obstruction of the bladder neck. Once the physician has determined the amount of tissue that needs to be removed from the bladder neck, lasing may begin. Using a 60W laser setting



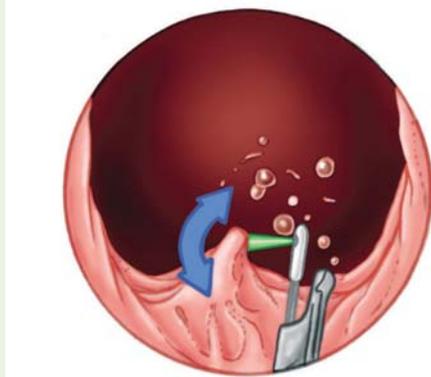
Carefully introduce the cystoscope to minimize bleeding and visualize landmarks such as the ureteral orifices. Lasing should begin at the bladder neck.

Courtesy of American Medical Systems

around the bladder neck is recommended to avoid inadvertent damage to critical structures (ureteral orifices or trigone). As the physician progresses in the procedure, the power setting can be adjusted by 10W increments up to 120W to achieve efficient vaporization.

2. Removal of the Median Lobe Tissue

Start removing the median lobe at the bladder neck by slowly rotating the fiber side-to-side no more than 30 to 40 degrees. Continue lasing tissue at the bladder neck until capsular fibers are visualized before progressing towards the apex and verumontanum (veru).

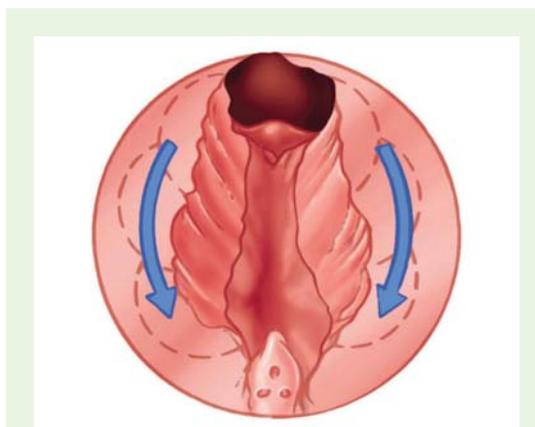


Removal of the median lobe progressing from bladder neck towards the apex and veru.

Courtesy of American Medical Systems

3. Removal of the Lateral Lobes

Systematically lase the lateral lobe from bladder neck to verumontanum (first one side and then the other). The general objective is to create a concave surface. Start high at the bladder neck using a sweeping motion downward. Rotate the cystoscope 60 to 90 degrees while keeping the video camera on a fixed vertical plane. Once the lateral lobe has been sufficiently debulked, gently rotate the scope to the contralateral lobe and repeat the same process.



Systematic approach by removal of lateral tissue from bladder neck to veru on one side and then moving to the contralateral wall.

Courtesy of American Medical Systems

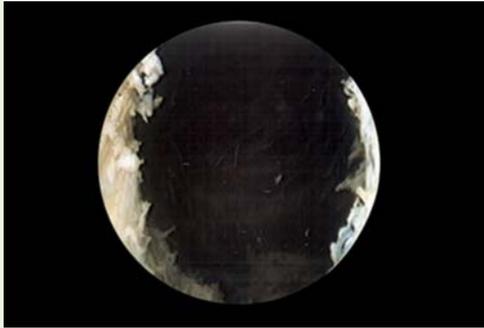
4. Treating Anterior Tissue

Treating anterior tissue is at the discretion of the physician. Turn the cystoscope upside down (180 degrees) so that the telescope is looking at the 12 o'clock position, keeping the video camera at its original fixed vertical plane. Consider reducing the power and begin lasing at the bladder neck, sweeping left to right, lasing down to the capsule. Anterior apical tissue should be vaporized with caution, while maintaining awareness of sphincteric position.

Developing a standardized, methodical approach to the treatment of the prostate gland using the GreenLight HPS laser system is an integral part of developing positive experiences and ensuring positive patient outcomes.

5. Confirm Endpoint

When the tissue removal has been completed, retract the cystoscope to the verumontanum and look towards the bladder. Confirm a TURP-like cavity and empty the bladder to verify prostatic fossa remains open without coapting tissue.



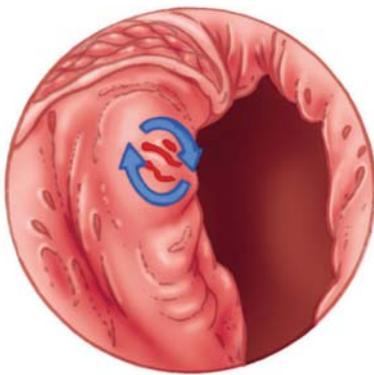
Final cystoscopic visualization confirming endpoint of laser vaporization of the prostate.

Courtesy of Dr. M. Hai

Long-term durability may be optimized by vaporizing down to the surgical capsule. It is not unusual to have small strands of tissue in the prostatic fossa; these will slough off or reabsorb over a few weeks.

6. Check for bleeding issues

Despite the superior hemostasis of PVP when compared to TURP, there is potential for bleeding. To check for bleeding, turn off the inflow and outflow valves. Check the prostate care-



If bleeding is evident, coagulate the bleeding site by using the laser in coagulation mode to paint around the bleeding source.

Courtesy of American Medical Systems

fully for bleeding in the same manner following a TURP. If bleeding is found, turn the inflow back on and coagulate the tissue surrounding the site of bleeding. This may be accomplished by using the coagulation mode of the GreenLight HPS and painting around the bleeding site. By directing the laser energy around the periphery of the bleeding site, the heat will diffuse into the vessel and surrounding tissue, creating vasoconstriction and sealing of the bleeding source. Directly lasing on the bleeding vessel may create a crater and worsen the bleeding.

7. Check Ureteral Orifices

Check both the ureteral orifices and the trigone to ensure no damage has occurred from the laser procedure. Fill the bladder with saline, remove the cystoscope, and check the draining flow and color of the emptying fluid. At this time, a Foley catheter may be inserted. Generally, continuous bladder irrigation is not necessary.

8. Evaluating Patient Outcomes

Upon completion of the GreenLight HPS laser procedure, there are a number of factors to consider when evaluating patient outcomes (Table 1).

Table 1. Factors to Consider for Optimal Patient Outcomes

Completeness of tissue removal
Size of prostate
Clarity of urine
Status of bladder function
Type of anesthesia
Time of day procedure was performed
Urinary retention pre-procedure
Physician comfort level with GreenLight technology

Courtesy of American Medical Systems



POST-PROCEDURE CONSIDERATIONS

Postoperative care will vary dependent on the physician and facility. It is recommended that some type of antibiotic be given. Nonsteroidal anti-inflammatory drugs and mild analgesic such as Pyridium® (Parke-Davis) are optional. Typically, the patient may return to normal activities

in about 2 to 3 days following the procedure. The patient should not engage in strenuous or sexual activities for 2 weeks post-procedure (Table 2).

As with any surgical procedure, potential adverse events may occur following laser therapy. Table 3 represents a comparison of adverse events as reported in the literature.^{10,18}

Table 2. Post-Procedure Considerations

Antibiotic
Non-steroidal anti-inflammatory drug (optional)
Mild analgesic (e.g. Pyridium)
Avoid oral narcotics
No strenuous activities
Avoid constipation
No driving for 2 to 3 days
No sexual activity involving ejaculation for 2 weeks
Return to normal activities in a few days

Courtesy of American Medical Systems

RECOMMENDATIONS FOR TRAINING

Training recommendations vary depending on the laser experience of the physician. Proctor or preceptor physician training on three to five cases should be considered the minimum level of training. Physician education courses for new and experienced users are available through the manufacturer.

It may take more than 10 cases to achieve a level of comfort and expertise before moving on to more complex cases.

It may take more than 10 cases to achieve a level of comfort and expertise before moving on to more complex cases. Successful progression to larger glands (>60 cc) or patients taking anticoagulants can be accomplished after experience with uncomplicated cases, however, further training may be required.

This standardized clinical approach is key to developing a physician's technique and confidence when using the GreenLight HPS laser system.

Table 3. Potential Adverse Events

Adverse event	Range of Percentage Occurrence (%)
Bleeding	0–3.8
Dysuria beyond at least 2 weeks	0–2.9
Bladder neck contracture	0–0.4
Urethral stricture	0–1.5
Capsular perforation	0–1.5
Incontinence	0–1.6
Ejaculation dysfunction	14.3
Urinary retention	0–9.5

Courtesy of American Medical Systems

CONFLICTS OF INTEREST

All authors have received honoraria from American Medical Systems for meeting attendance and are paid consultants for the company.

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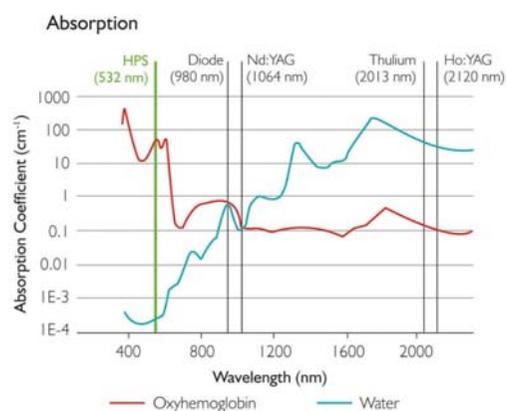
Addendum

General Principles

Laser Physics and Safety Requirements - The GreenLight HPS

The GreenLight HPS Laser System is manufactured by American Medical Systems, Minnetonka, Minnesota. This system has evolved over the past decade from the 80W potassium-titanyl-phosphate (KTP) laser to the current 120W lithium-triborate (LBO) GreenLight HPS laser. The GreenLight laser is absorbed poorly by water but absorbed extensively by oxyhemoglobin. This is unique to other laser therapies as indicated by the absorption characteristics of various laser technologies [GreenLight HPS (532 nm), Diode (980 nm), Thulium (2013 nm), and Ho:YAG (2120nm)] illustrated in Figure 2. Note that the low absorption of GreenLight in water means energy will not be lost in procedural irrigant.

Figure 2.



With laser therapies, the absorption coefficient is combined with the concentration of the chromophore (oxyhemoglobin or water) and results in a specific optical penetration depth. The application of laser energy results in the heating of tissue that causes tissue vaporization and coagulation of varying depths, depending on the optical penetration depth. Vaporized tissue is destroyed leaving behind the coagulated tissue. The coagulation

depth refers to the zone of tissue necrosis created as a result of the application of laser energy. Deep coagulation may lead to increased dysuria or irritative symptoms but may also aid in the cessation of bleeding. For the GreenLight laser, the optical properties result in tissue penetration to 0.8 mm with a coagulation depth of 1 to 2 mm. This shallow zone of coagulation provides optimal hemostasis with minimal tissue disruption.

When using a laser for medicine, laser safety compliance is required for safe use and is important when using the GreenLight HPS laser. It is recommended that a facility establish a program for safety, designate a laser safety officer, institute a training program, and monitor ongoing adherence to safety standards. The standards and recommendations made are found through: Occupational Safety and Health Administration (OSHA) Regulated American National Standards Institute (ANSI), Manual Z136.3 titled: 'Safe Use of Lasers in Healthcare Facilities' Safety of laser products IEC 60825.

All laser safety education criteria and content should be in accordance with applicable standards, facility policies and procedures, and regulations for federal, state, and local requirements. Personnel would be required to demonstrate laser competency periodically and when new laser equipment, accessories, or safety equipment is purchased or brought into the practice environment. The laser safety program should provide participants with a thorough understanding of laser procedures and the technology required for establishing and maintaining a safe environment. Education activities should be documented and maintained on file in the facility.

When using a laser, there are potential safety hazards to the eyes, skin, as well as the possibility of electrical shock and fire. Protective eyewear must be worn by all OR personnel including

the surgeon, patient, and staff. The eyewear worn is specific to the 532-nm wavelength and should be printed on the eyewear frame. Extra eyewear should be hung on all access doors to the operating room to prevent personnel from entering without eye protection. If anyone enters the room without protective eyewear, the laser should immediately be put in “Standby” mode. Patient eye protection may vary dependent on the laser therapy and level of sedation. If the patient is under general anesthesia, wet pads covering the patient’s eyes and a towel over the eye pads for protection is required. If the patient is awake, eyewear (specific to the wavelength) must be provided during the procedure. Other measures include covering the windows with opaque material and all doors closed during the procedure. Each door(s) must be posted with warning signs specific to the 532 nm outside the operating room door(s). Additional considerations when using a laser include: 1) lasers should never be used in the presence of flammable materials; 2) fire extinguishers and basin of water available; 3) potential risk of electrocution as with all electrical equipment; and 4) skin injury can occur if exposed to laser energy.

PROCEDURE EQUIPMENT REQUIREMENTS

Equipment

The following equipment is needed in preparing for a GreenLight HPS laser procedure:

- Continuous Flow Cystoscope (21-23 Fr). The continuous flow cystoscope provides a constant irrigation flow through the cystoscope during the procedure to provide adequate cooling of the fiber during lasing. A visual obturator must be used during cystoscope introduction to prevent trauma to the prostatic urethra. The use of a 30-degree telescope is recommended for good visualization of the bladder neck and ureteral orifices. A 12-degree telescope is optional and dependent on physician preference.
- Video Camera. A video camera with camera

filter insert (dependent on manufacturer) is required when using a laser system. The filter insert protects the CCD chip in the camera from being damaged by the high-intensity laser light. Ensure that the video camera filter insert is clean, dry, and placed between the telescope and camera. With the filter insert in place, the camera must be white balanced prior to the procedure. To do so, the camera system should be focused against a sterile white towel (disposable) or 4×4 gauze, which may be more effective. It is recommended that pre- and post-op procedure pictures be obtained. Working with the cystoscope and video camera manufacturer will ensure proper system settings for optimizing visualization during the procedure.

STERILE SUPPLIES

Required sterile supplies for the GreenLight HPS procedure include:

- Irrigation of 0.9% normal saline (approximately 8-12 three-liter bags). Room temperature irrigation is preferred because warmer irrigation fluid may lead to increased bleeding. Water is not recommended as an irrigant due to the potential of dilutional hyponatremia (TUR syndrome). When using a good-quality video camera and scope, there is no visibility advantage in using water. With the use of 0.9% normal saline, there have been no reported incidents of TUR syndrome. Glycine or sorbitol should not be used because the heated sugar components will cause the fiber to degrade.
- Standard TUR-Y tubing, suction tubing (suction may not be needed), cystoscopy pack, and other basic procedural supplies are required. It is recommended that additional equipment such as Van Buren sounds (18 to 26 Fr), catheter stylet, sterile camera drape (optional), and Toomey syringe (with catheter tip) are available during the procedure. Post-procedure a Foley catheter may be inserted dependent on physician discretion. The catheter should be a two-way, 18 to 22 French catheter.



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