Visual laser ablation of the prostate

Background

Transurethral resection of the prostate (TURP) has become the primary choice for the treatment of benign prostatic hyperplasia (BPH) over the past 50 years. BPH, an enlargement of the prostate causing urinary tract obstruction, is a major international health problem, affecting 50% of men 55 years of age and older. Several clinical studies have shown that TURP has a success rate of about 75%. Yet, with a morbidity rate of 18%, TURP is not a surgical procedure that is free of risks. This, in addition to the high costs and lengthy healing period associated with TURP, has forced the medical community to seek alternative methods of therapy.

Many new treatment modalities and minimally invasive techniques have emerged over the past decade. Visual laser ablation of the prostate (VLAP) can be performed by using either a contact laser or free beam (non-contact) laser. Using a special quartz fiber and reflector with a Neodymium:YAG (Nd:YAG) laser and conventional cystoscopic equipment, the procedure involves passing a laser into the prostatic channel under telescopic guidance. Laser energy is then used to heat up the obstructing portions of the prostate. Prostate tissue dies, and depending on the type of laser used, is either melted or sloughed in the urine, and discarded during voiding. Since the system seals blood vessels, preventing both bleeding and intraoperative fluid absorption, physicians can treat BPH more quickly.

VLAP, originally anticipated to replace TURP, has not lived up to such expectations. It has fallen out of favor in recent years partially because of the discomfort caused in urination during the 48 hours following VLAP (free beam) when the dead prostatic tissue is voided. While still used by physicians, it now competes with more recent procedures such as transurethral needle ablation, transurethral microwave thermotherapy, transurethral electrovaporization of the prostate, and other laser therapies such as interstitial laser coagulation.

Involved specialists

Urologists.

Positions of societies and academies

AUA

The American Urological Association Inc. (AUA) believes that, based upon a review of available data, laser treatment of the prostate appears to be a safe, effective, and reasonable therapeutic modality for the treatment of bladder neck obstruction.
Visual laser ablation of the prostate secondary to BPH. The AUA has no specific criteria for privileging urologists in VLAP.

**Positions of other interested parties**

**FDA**
The Food and Drug Administration (FDA) has changed its policy regarding the approval route of lasers used for BPH, according to Dan Schultz, MD, chief medical officer for the office of device evaluations. Prior to 1995, lasers for BPH were on a pre-market approval (PMA) path, a stringent classification in which more data is required to prove a product’s safety and effectiveness before it is allowed on the market. After 1995, these lasers were switched to a 510(k) route, a much faster way of getting a product to the market by claiming equivalency to another product already out on the market.

“There is a big difference between a 510(k) and a PMA in the amount of time, effort, and money involved,” explains Schultz. “We [FDA] spent a lot of time looking at the amount of information and evidence we had accumulated over the years. In 1995, we decided we had enough information to allow lasers for BPH to be marketed under 510(k) as long as sufficient ‘confirmed clinical trials’ were performed.”

A “confirmed clinical trial” for a BPH laser would be a comparison trial run by testing about 50 patients with the new device and 50 patients using the TURP treatment, which is considered the “gold standard” in BPH operations, says Schultz.

The FDA has cleared the Nd:YAG laser and the side-firing laser fibers produced by Trimedyne Inc., for the treatment of BPH.

**Surgical Laser Technologies Inc., Oaks, PA**
The FDA has given clearance to Surgical Laser Technologies Inc. (SLT), in the use of its technology—the SLT Contact Laser Delivery System—for soft tissues and genital urinary surgeries, with specific clearance for prostatectomy and TURP.

**Trimedyne Inc., Irvine, CA**
The FDA has given clearance to Trimedyne Inc., in the use of its side-firing lasers and laser fibers for the treatment of BPH.

**Mid-Dakota Clinic, Bismarck, ND**
There are several different methods for performing VLAP procedures, according to Chris J. Adducci, MD, a urologist at the Mid-Dakota Clinic in Bismarck, ND. In the past, only the right angle or non-contact laser was employed, but in recent years, the contact laser has come into favor.
“The advantage is direct visualization of the tissue on contact,” Adducci says. “A contact laser allows you to see a cavity as soon as it’s created.”

The contact laser also eliminates the 48-hour voiding period because the tissue is immediately melted on contact. Patients tend to experience less pain because they do not have to pass the floating tissue that is usually created when a non-contact laser is used.

**John N. Kabalin, MD, FACS,** of Scottsbluff Urology Associates, PC, in Scottsbluff, NE, is a well-versed researcher and surgeon in the use of the Nd:YAG laser for BPH treatment. According to Kabalin, in addition to minimal formal training, physicians should have the following qualifications before being granted privileges for VLAP:

- Experience in urologic endoscopy and general transurethral surgery, including TURP
- A detailed knowledge of endoscopic instrumentation and endoscopic anatomy in the male
- A general knowledge and clinical experience with the surgical use of lasers
- A basic knowledge of laser physics and laser tissue interactions, laser safety procedures in the operating room, and familiarity with the physical characteristics and tissue effects of the Nd:YAG laser in particular
- Specific didactic and practical training in the scientific basis of the use of the Nd:YAG laser to perform VLAP and the technical aspects of proper operative technique to perform VLAP should be required

Dr. Kabalin also recommends that certification of training in laser surgery and in the VLAP procedure in particular, is documented either by the course director of the continuing medical education (CME) training program(s), or, if the experience is acquired during residency, from the director of residency training (usually a department chair).

**CRC draft criteria**

The following draft criteria are intended to serve solely as a starting point for the development of an institution’s policy regarding this procedure.

- **Basic education**: MD or DO
- **Minimal formal training**: The applicant must demonstrate completion of a fully accredited residency training program in
urology. The physician should be either board eligible or board certified by the American Board of Urology. Specific didactic and practical training in the scientific basis of the use of the Nd:YAG laser to perform VLAP and technical aspects of proper operative technique to perform VLAP should be required. This might be acquired either during the course of residency training in urology or through later CME programs. It is recommended that a physician who did not receive in-residency training in this area participates in a one-and-a-half day course devoted to VLAP, including both didactic and laboratory experience involving a live laboratory animal or equivalent. A longer and more extensive course might be required for those practitioners with minimal prior experience with laser surgery.

*Note: Certification of training in laser surgery and in the VLAP procedure in particular should be documented, either by the course director of the CME training program(s), or, if the experience is acquired during residency, from the director of residency training (usually a department chair).*

**Required previous experience:** The applicant must demonstrate prior performance of at least 20 conventional TURPs in the last 24 months and evidence of prior utilization of the Nd:YAG laser to perform at least 30 other procedures in the last 12 months, or provide evidence of current practical knowledge of urologic laser surgery, either through CME or course attendance reviewable on request.

*Note: A letter of reference must come from the applicant’s residency director or from the chief of surgery of the hospital with which the applicant has most recently been affiliated.*

### Reappointment

Reappointment should be based on unbiased, objective results of care according to the hospital’s quality assurance mechanisms. The applicant must demonstrate that he or she has performed at least 20 conventional TURPs in the last 24 months and provide evidence of prior utilization of the Nd:YAG laser to perform at least 30 other procedures in the last 12 months, or provide evidence of current practical knowledge of urologic laser surgery, either through CME or course attendance reviewable on request.

### For more information

For more information regarding privileging this procedure, contact:
American Urological Association Inc.
1120 North Charles Street
Baltimore, MD 21201-5559
Telephone: 410/223-4310
Fax: 410/223-4375

Food and Drug Administration
Office of Device Evaluations
9200 Corporate Boulevard
Rockville, MD 20850
Telephone: 301/594-5072
Fax: 301/480-4224

Surgical Laser Technologies Inc.
147 Keystone Drive
Montgomeryville, PA 18936
Telephone: 215/619-3600
Fax: 215/619-3211

Trimedyne Inc.
2801 Barranca Road
P.O. Box 57001
Irvine, CA 92619-7001
Telephone: 714/559-5300
Fax: 714/559-1330
Privilege request form

Visual laser ablation of the prostate

In order to be eligible to request clinical privileges for visual laser ablation of the prostate, a practitioner must meet the following minimum threshold criteria:

- **Education:** MD or DO

- **Minimal formal training:** The applicant must demonstrate completion of a fully accredited residency training program in urology. The physician should be either board eligible or board certified by the American Board of Urology. Specific didactic and practical training in the scientific basis of the use of the Nd:YAG laser to perform VLAP and technical aspects of proper operative technique to perform VLAP should be required. This might be acquired either during the course of residency training in urology or through later CME programs. It is recommended that a physician who did not receive in-residency training in this area participates in a one-and-a-half day course devoted to VLAP, including both didactic and laboratory experience involving a live laboratory animal or equivalent. A longer and more extensive course might be required for those practitioners with minimal prior experience with laser surgery.

Note: Certification of training in laser surgery, and in the VLAP procedure in particular, should be documented either from the course director of the CME training program(s), or, if the experience is acquired during residency, from the director of residency training (usually a department chair).

- **Required previous experience:** The applicant must demonstrate prior performance of at least 20 conventional TURPs in the last 24 months and evidence of prior utilization of the Nd:YAG laser to perform at least 30 other procedures in the last 12 months, or provide evidence of current practical knowledge of urologic laser surgery, either through CME or course attendance reviewable on request.

- **References:** A letter of reference must come from the applicant’s residency director or from the chief of surgery of the hospital with which the applicant has most recently been affiliated.

- **Reappointment:** Reappointment should be based on unbiased, objective results of care according to the hospital’s quality assurance mechanisms. The applicant must demonstrate that he or she has performed at least 20 conventional TURPs in the last 24 months and evidence of prior utilization of the Nd:YAG laser to perform at least 30 other procedures in the last 12 months, or provide evidence of current practical knowledge of urologic laser surgery, either through CME or course attendance reviewable on request.

I understand that in making this request I am bound by the applicable bylaws or policies of the hospital and hereby stipulate that I meet the minimum threshold criteria for this request.

Physician’s signature: ________________________________________________

Typed or printed name: ____________________________________________

Date: __________________________

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