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Christiaan F. P. van Swol, Rudolf M. Verdaasdonck, Jaap Mooibroek, Tom A. Boon, "Physical evaluation of laser prostatectomy devices," Proc. SPIE 2129, Lasers in Urology, (2 May 1994); doi: 10.1117/12.175043

SPIE.

Event: OE/LASE '94, 1994, Los Angeles, CA, United States

Physical evaluation of laser prostatectomy devices

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ABSTRACT

Transurethral laser coagulation of the prostate is a recent development in the treatment of benign prostatic hyperplasia (BPH). At present many devices are available to bring laser light energy into the prostate, but their method of action differs. In this study, the optical and thermal characteristics of the various commercially available devices for treating BPH, using transurethrally delivered Nd:YAG laser light, were evaluated. To calculate the optimal parameters for each delivery system, the created tissue effect was dynamically modeled. Optically the devices were evaluated using by measuring the three dimensional irradiance distribution in a water environment. The thermal behavior of the devices was studied by a specially developed thermal imaging technique. The optical and thermal characteristics of the devices together with optical and thermal parameters of prostatic tissue were used as an input for a theoretical model to predict the extent of laser induced permanent damage and thus the effect of the device. Results show the influence the beam profile, spot size and secondary reflections of the different devices and their consequence for the therapeutic effect. Measuring the physical characteristics of each laser prostatectomy device and modeling its therapeutic effect, will contribute to obtain an optimal dosimetry with best fitted parameters for each individual device.

1. INTRODUCTION

The use of the Nd:YAG laser in urology for the treatment of Benign Prostatic Hyperplasia (BPH) is getting widespread. Since the clinical introduction around 1991 various devices have been introduced.¹ Basically all these devices are designed to deflect the beam laterally directing the laser light energy at the urethral wall. Most of them, however, differ with regard to their optical and thermal properties, as well as to how they are applied clinically. In this study the devices, that were available to us, were evaluated with respect to their optical and thermal behavior during a laser prostatectomy.

2. MATERIALS AND METHODS

2.1. Description of the various devices

The various devices discussed here are the TULIP (Intrasonix), the UroLase (Bard), the SideFire (Myriadlase), the ADD (Laserscope), the UltraLine (Heraeus Lasersonics) and the ProLase II (Cytocare). The devices here are classified with regard to the way the laser light is deflected off axis. In the following part a general description of each device will be given, and those parts that are important for their physical behavior during clinical use are discussed. The actual measurements on the devices are presented later.

2.1.1. The TULIP probe

TULIP stands for Transurethral Ultrasound-guided Laser Induced Prostatectomy.² The equipment consists of a combined ultrasound laser probe (the delivery system). The probe consists of a rigid steel shaft that houses a 600 μm

fiber and a window for laser light delivery as well as a transducer for ultrasound imaging (figure 3, top row left). The positioning of the device is performed by ultrasound. A disposable water filled balloon, that is fitted around this probe, spreads the lobes of the prostate apart to allow efficient coupling of the ultrasound waves and the laser light into the tissue. The balloon also causes the optical properties of the prostatic tissue to change in such a way that the light penetrates deeper and the temperature at its surface to be clamped at 100 °C. The probe is slowly withdrawn in the balloon from bladder neck towards the apex, while irradiating the tissue. This process is repeated at several radial positions, thus causing stripes of coagulation necrosis. The dosimetry varies from 40 to 60 Watts power to tissue with a pull rate of the probe in the balloon of approximately 1 mm/s.

2.1.2. The UroLase (Bard) and the SideFire (Myriadlase)

The UroLase³ and the SideFire⁴ are comparable with each other with regard to the method used for deflecting the laser light that comes out of the fiber. They both consist of a 600 µm fiber with, at the end, a metal reflective mirror that deflects the beam laterally. The UroLase (figure 3 top middle) has a curved gold-coated reflector, the SideFire (figure 3 top right) a flat solid gold-alloy reflector. Further, the SideFire has a hole in the bottom of the tip near the mirror, to enhance cooling by water flow. Both devices are recommended to use in a stationary position above the prostatic tissue (i.e. delivering energy at a fixed location for a pre-defined amount of time). The powers that are currently used in the clinic are between 40 and 60 Watts with irradiation times varying from 60 to 90 seconds at 4 or 8 positions.

2.1.3. The Angled Delivery Device (Laserscope) and the UltraLine (Heraeus Lasersonics)

The Angled Delivery Device (ADD), consisting of a 400 µm fiber (figure 4 top left), and the UltraLine, consisting of a 600 µm fiber (figure top middle), share the same method of beam deflection. The bare fiber tip is polished at such an angle that rays inside the fiber reflect at the exit surface as their angle of incidence exceeds the angle of total reflection. Consequently the rays reflect out of the fiber side that acts as a cylindrical lens. For an air environment the tip should be polished at an angle of about 40 degrees. However, in a water environment this total reflection behavior is lost. For application in a water environment (as is inside the urethra) an optical shield is used to preserve the reflecting fiber-air interface. Both devices are recommended to be used in a scanning mode (moving the fiber over the tissue with a certain speed). Typical powers used are up to 80 Watts. The ADD is also used in combination with a KTP-laser (532 nm), which gives less light penetration and hence will enable easier vaporization of the tissue instead of thermal coagulation.

2.1.4. The ProLase II (Cytocare)

The ProLase II fiber is a 1000 µm fiber. In front of a flat polished fiber, a tip made of a highly refractive material is placed. This tip is polished at such an angle that, even in a water environment, the rays inside the fiber reflect at the angled surface as their angle of incidence exceeds the angle of total reflection. This deflection method is comparable with the one for the ADD and the UltraLine, but without the need for an optical dome placed over the fiber tip. The rays reflect out of the fiber side at an angle of about 35 degrees forward. The fiber is recommended to be used in a fixed mode, with typical power settings of 60 Watts and irradiation times of 60 seconds.

2.2. Optical characteristics

The intensity profile of the different devices was measured using a set up as shown schematically in figure 1. The beam from a 5-mW Helium Neon laser was used as a light source. A photo diode was translated circular around the device to map the distribution of the light intensity. This was done in a plane parallel to the fiber axis and

perpendicular to the fiber axis. The circle described by the diode had a radius of 10 cm. For the ProLase II device the set up was slightly different, as it had to be submerged in water, to obtain a primary beam. For the other devices the optical behavior is expected to be slightly different in water.

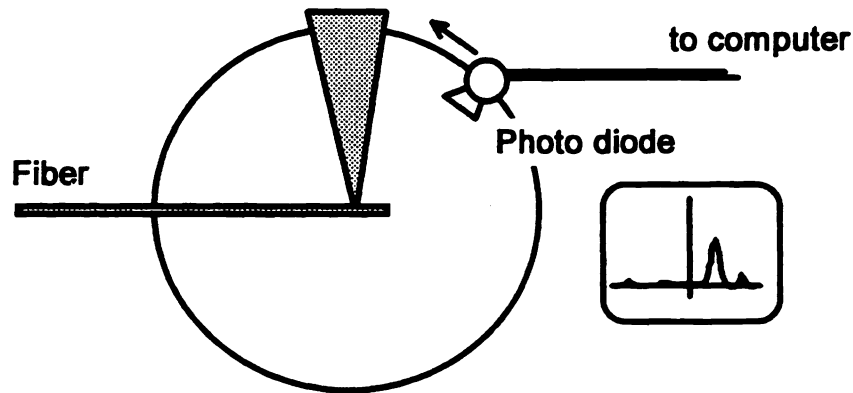


Figure 1. Experimental set up for measurements of beam profiles

The beam profile was photographed to have a direct view of the different devices. The device was submerged in water, which was stained with a special type of black ink. Photographs were taken from two viewing angles: along the fiber axis (top view) and perpendicular to the fiber axis (side view), as shown in the figure below.

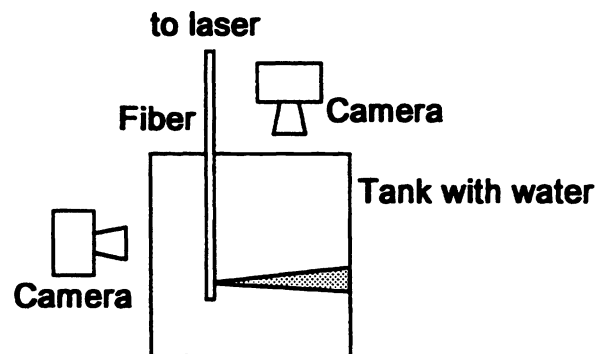


Figure 2. Recording of a beam profile from two directions.

2.3. Thermal behavior

The thermal behavior of the devices was studied during clinical use and in vitro in a water environment. Both new and used probes were used. The effect of self absorption was studied using an optical technique, introduced by Verdaasdonk et al.⁵ This technique makes it possible to visualize density changes induced by temperature gradients. The geometrical set up was matched with the clinical use. The created heat distribution in the model tissue provided a color coded thermal image. The whole configuration was submerged in water. The images were recorded with a video camera.

2.4. Numerical model

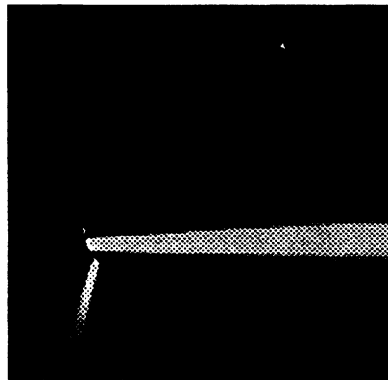
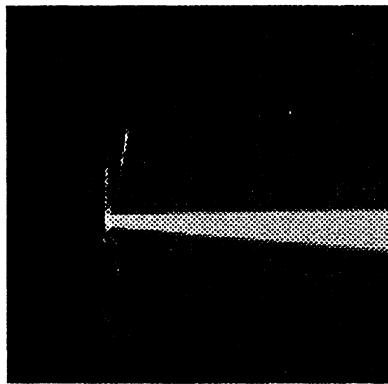
The optical characteristics of the devices and the different ways of application (static or moving) are used as parameters in a numerical model. It consists of an optical part where the light distribution is calculated, a thermal part where the created temperature distribution is calculated and a thermal response part where this temperature distribution is converted into the extent of tissue necrosis (permanent damage). Hence it is possible to compare different ways of application and to evaluate the influence of prostate specific properties, like the amount of blood flow. This model is discussed in a separate paper.⁶

3. RESULTS

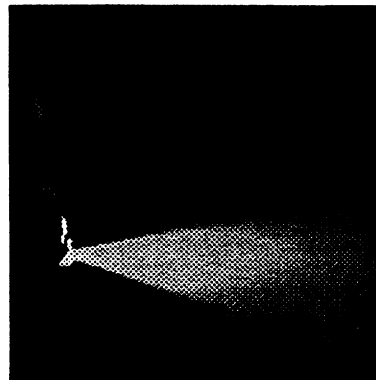
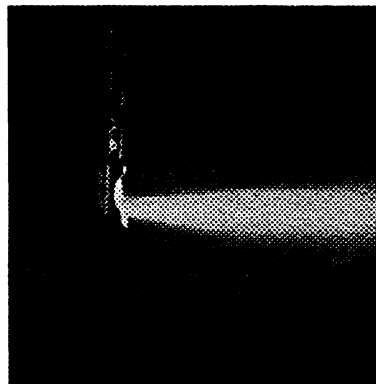
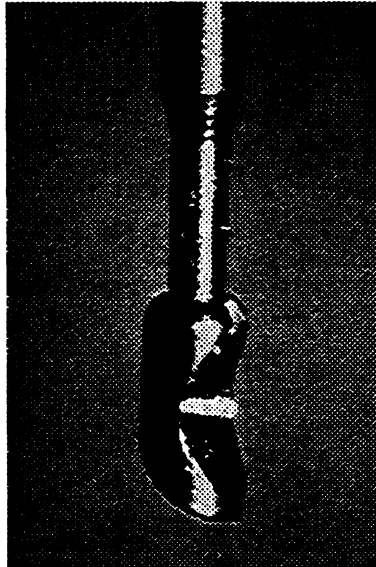
3.1. Optical characteristics

A series of photographs taken from the different devices is displayed in the figures 3 and 4 below. The magnification of the pictures is the same, so the dimensions of the probes and the beam profiles can be compared with each other.

TULIP



UroLase



SideFire

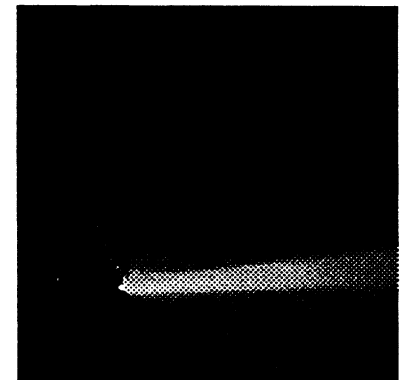
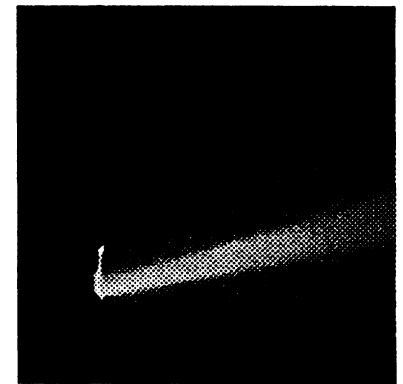
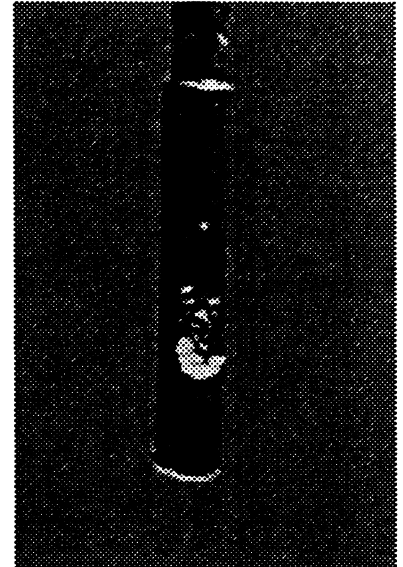
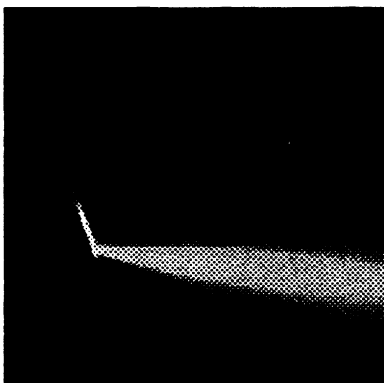
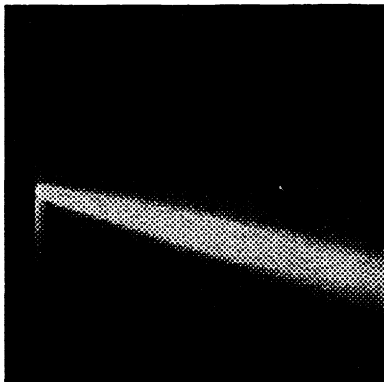
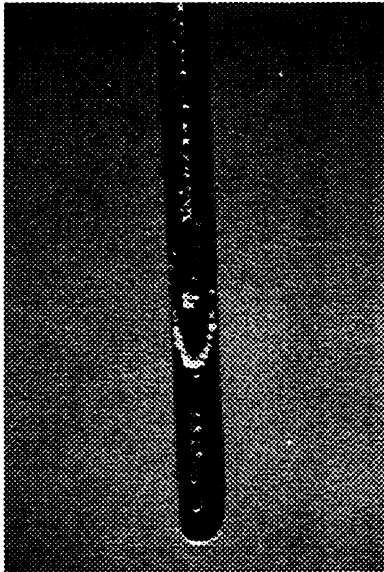
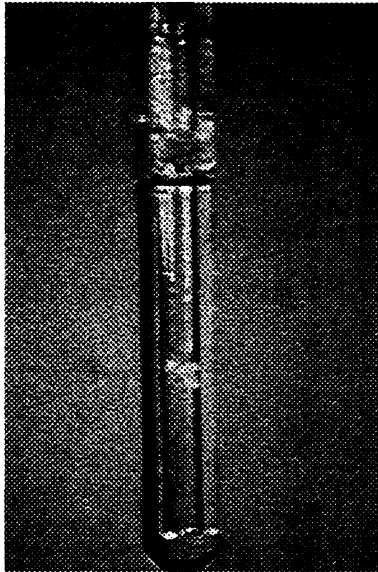


Figure 3. The TULIP (left), UroLase (middle) and SideFire device (right). The top row shows the tip of the devices in detail, the middle row shows the light distribution seen from the side, perpendicular to the fiber axis and the bottom row shows the light distribution seen from the top along the fiber axis.

ADD



UltraLine



ProLase II

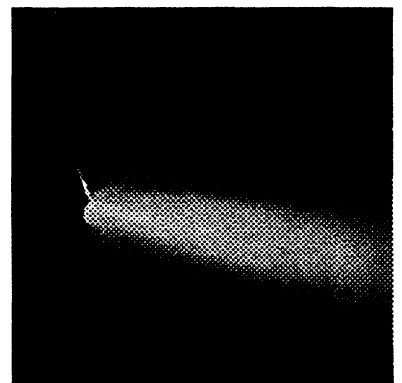
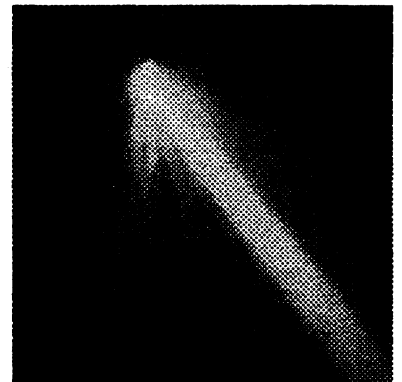
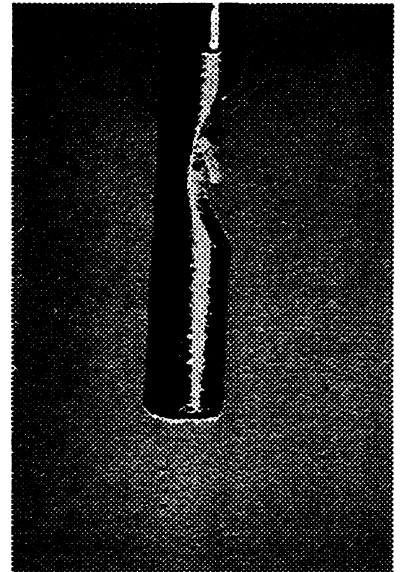


Figure 4. The ADD (left), UltraLine (middle) and ProLase II device (right). The top row shows the tip of the devices in detail, the middle row shows the light distribution seen from the side, perpendicular to the fiber axis and the bottom row shows the light distribution seen from the top along the fiber axis.

The dimensions of the different tips vary between 1.0 (ADD) up to 3.0 mm (UroLase). The TULIP device has far larger dimensions since it also incorporates an ultrasound antenna. The pictures show clearly that each device has its own specific beam profile. The angle at which the beam exits the fiber and the beam divergence was quantified using the set up of figure 1. The results are presented in table 1. The measured exit angles are with respect to the end of the tip of the device, i.e. a beam of a bare ended fiber has an exit angle of 0 degrees.

Device name	Exit angle	Divergence (in air [*])	
		perpendicular	parallel
TULIP	90	25	25
UroLase	95	25	60
SideFire	105	15	15
ADD	70	14	42
UltraLine	75	21	30
ProLase II	35	20	not measured

Table 1. Exit angle, with respect to the fiber axis, and divergence for the prostatectomy devices (*: except for ProLase II expected to be comparable with water)

The angle at which the beam is deflected is for most fibers around 90 degrees, the SideFire deflects the light a little backwards (105 degrees), the others slightly forward, except the ProLase II that deflects the beam 35 degrees forward. The divergence of the beam profiles in the two viewing planes (as can be also appreciated by comparing side on top view of the photographs in figure 3 and 4) is striking, except for the TULIP device. Due to this, the shape of the spot on the urethral wall will not be circular but will be elliptical. The size of the spot on the prostatic tissue varies strongly with the distance. The UroLase has the highest divergence. However, as the light is emitted with a 35 degree forward angle the ProLase II will produce the largest spot size on the urethral wall that is parallel to the fiber axis. The amount of scattered light, due to secondary beams, around the tip is most pronounced for the UltraLine. The ProLase II and the ADD may also produce scattered light, but the metal shaft around the tip shields the scattered light.

3.2. Thermal behavior

The formation of bubbles around the tip is an often observed phenomenon during clinical use. The tip can get polluted with blood and tissue particles, which will absorb the laser light at the surface of the probe. As energy densities are high, these particles become very hot (exceeding the boiling temperature of the surrounding water) and induce the formation of little bubbles. Due to these bubbles the optical behavior of the device changes dramatically, either they scatter the beam or, when bigger, they act as a negative lens. The thermal behavior may change as well, as vapor bubbles insulate the probe thermally, thus preventing its surface from being cooled by the water. This phenomenon can be useful to determine the degree of deterioration of the device and it can be incorporated in a testing protocol.

The thermal imaging technique was used to visualize the self absorption of the devices, while submerged in water. The original color images of the UltraLine and the UroLase are represented in black and white in figure 5 below.



Figure 5. Thermal images of the UltraLine (left) and the UroLase (right) device, with an input power of 40 Watts.

The black background represents ambient temperature, the temperature scale ranges from dark gray to white. The pictures are taken from the side, while the laser light is emitted to the left side. The water in front (left side) of the UltraLine, where light is emitted, is heated. The UroLase is also heated at the place where light is emitted from the fiber and where it reflects on the mirror, but as scattered light is shielded and absorbed by the probe, even the back of the probe gets heated. The temperatures reached are up to 100 degrees as vapor bubbles are formed around the probe. If you compare this figure with the beam shape characteristics of figures 3 and 4, the difference is obvious. Although there is a large amount of scattered light around the tip of the UltraLine, this does not cause direct heating of the device, while for the UroLase the scattered light is not visible directly, but is responsible for heating of the entire tip. The other devices that shield the scattered light with a metal cap, show the same behavior as the UroLase.

4. DISCUSSION

The devices evaluated are unique with regard to their optical characteristics. Therefore the protocols, describing the way the devices should be applied, should differ as well, which is not always the case. The key parameter in the laser tissue interaction is the energy density at the tissue surface, which is defined by a combination of spot size and laser power. As the divergence of the light exiting the device varies, the spot size at the tissue for a certain distance of the device to the tissue, will differ. Depending on the desired tissue effects, coagulation and/or vaporization the power can be adjusted with regard to the divergence and distance to the tissue.

The thermal behavior of the devices is important, as this may influence the optical characteristics and result in a different tissue effect. The power density at the tissue may become too low, even for coagulation, when the device becomes dirty and bubbles are induced. A hot probe may cause coagulation effects on tissue which is not irradiated, because the device is sometimes in direct contact with the tissue. This is usually considered a non-desirable side effect.

All devices that are discussed are to be used in a non-contact mode, i.e. there should be always a distance between the device and the tissue. If that part of the device where light is emitted, is in contact with the tissue, the lack of cooling and the high power density will cause the temperature to rise locally above 300 degrees. As such devices are not designed to resist this high temperatures, irreversible damage can be done to the probe, even resulting in a total burn of the tip.

Our initial experience using these probes in patients show that a laser induced prostatectomy has almost the same results as the traditional Trans-Urethral Resection of the Prostate (TUR-P).⁷

5. CONCLUSION

The optical characteristics of all the side firing devices are unique, with regard to the angle at which the light is deflected off axis and to the size and shape of the spot at the urethral wall. Measuring the physical characteristics of each laser prostatectomy device and modeling its therapeutic effect, will contribute to obtain an optimal dosimetry with best fitted parameters for each individual device.

6. ACKNOWLEDGMENTS

The authors wish to acknowledge the manufacturers and local distributors in The Netherlands for their participation in this evaluation study.

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