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DESCRIPTION

BACKGROUND OF THE INVENTION

Field of the Invention

[0001] The present invention relates generally to a prostate treatment system for treating prostatic tissue in combination with a photoactive agent, and more specifically a transurethral device in combination with a light-activated drug for use in treating benign prostatic hyperplasia (BPH).

Description of the Related Art

[0002] Benign prostatic hyperplasia (BPH) and prostate cancer are common conditions in the older male population. For people with BPH, the enlarged prostate can compress the urethra causing obstruction of the urine pathway, which results in difficulty urinating. The enlarged prostate can also cause urethral stones, inflammation, infection and in some instances, kidney failure.

[0003] Major treatment methods for BPH include surgical treatment such as a prostatectomy or transurethral resection of the prostate. These treatments require the patient to be hospitalized, which can be a financial burden to the patient. Additionally, surgical procedures can result in significant side effects such as bleeding, infection, residual urethral obstruction or stricture, retrograde ejaculation, and/or incontinence or impotence. Patients who are too old or who have weak cardiovascular functions are not good candidates for receiving these treatment methods.

[0004] Photodynamic treatment (PDT) methods are new methods for treating cancers. In light-activated drug therapy, also known as PDT, light of a specific wavelength or waveband is directed toward a target cell or cells that have been rendered photosensitive through the administration of a photoreactive, photoinitiating, or photosensitizing agent. The drug is commonly administered to the patient via intravenous injection, oral administration, or by local delivery to the treatment site. A light source emitting certain wavelength or waveband can be used to irradiate the cancerous tumor or the enlarged tissue by activating the photosensitizer to produce a strong oxidizing agent that can kill the cancerous tumor or enlarged tissues. As compared to surgical alternatives, the light-activated drug therapy is minimally invasive, less costly, and has a lower risk of complications.

[0005] One type of light delivery system used for light-activated drug therapy comprises the delivery of light from a light source, such as a laser, to the targeted cells using an optical fiber

delivery system with special light-diffusing tips on the fibers. This type of light delivery system may further include optical fiber cylindrical diffusers, spherical diffusers, micro-lensing systems, an over-the-wire cylindrical diffusing multi-optical fiber catheter, and a light-diffusing optical fiber guide wire. This light delivery system generally employs a remotely located high-powered laser, or solid-state laser diode array, coupled to optical fibers for delivery of the light to the targeted cells.

[0006] The light source for the light delivery system used for light-activated drug therapy may also be light emitting diodes (LEDs) or solid-state laser diodes (LDs). LEDs or LDs may be arrayed in an elongated device to form a "light bar" for the light delivery system. The LEDs or LDs may be either wire bonded or electrically coupled utilizing a "flip chip" technique that is used in arranging other types of semiconductor chips on a conductive substrate. Various arrangements and configurations of LEDs or LDs are described in U.S. Patent Nos. 5,445,608; 6,958,498; 6,784,460; and 6,445,011.

[0007] One of the challenges in design and production of light bars relates to size. The largest diameter of the light bar is defined by human anatomy and the smallest diameter is defined by the size of the light emitters that emit light of a desired wavelength or waveband at a sufficient energy level, and the fragility of the bar as its thickness is reduced, which increases the risk of breaking in the patient.

[0008] Presently, there exists a need for an apparatus for light-activated drug therapy for effectively treating prostate via the urethra that is cost effective, less invasive than other treatments, and has less risk of complications. Accordingly, there is a need for smaller LEDs or LDs and other light sources that are safe for use in a urethra tract introduced via a catheter-like device.

[0009] Further catheters are known from US 5 800 478 A, US 5 445 608 A, WO 93/04727 A1, US 5 456 661 A and US 6 146 409 A. In particular, US 5 445 608 A discloses a flexible elongated member, within which an array of LEDs are placed, which are used for PDT. The translucent elongated body with the LEDs is inserted through a lumen of a catheter and protrudes from a distal side of the catheter. US 5 800 478 A discloses a catheter having a flexible polymer material, in which an array of LEDs is provided. The LED array is used for PDT.

[0010] A catheter, which comprises a balloon that is fixed in the bladder is disclosed in WO 93/04727 A1. A similar catheter is disclosed in US 5 456 661 A. A catheter having a balloon, which is placed in the esophagus is known from US 6 146 409 A. The balloon disclosed in said document has a coated side and a treatment window.

SUMMARY

[0011] In order to solve the aforementioned problems, the present invention provides

transurethral light-activated drug therapy device having the features defined in claim 1. Further preferred embodiments are defined in the dependent claims.

[0012] The invention describes devices, methods and systems for light-activated drug therapy for treating the prostate transurethrally. One embodiment of a transurethral treatment device can include an elongated support member configured to pass through the urethra, a light delivery device, and a positioning element carried by the support member. The support member can be a catheter having at least one lumen, or in other embodiments the support member can be a generally closed body without a lumen. The light delivery device can have a light generator along the support member and a light emitting region configured to be positioned within the urethra at least proximate to a treatment site. The light generator is configured to generate light at a preselected wavelength or waveband in the range of an activation waveband of a photoactive composition. The positioning element is configured to locate the light emitting region within the urethra at least proximate to the treatment site. The positioning element, for example, can be a balloon or indicators on the support member.

[0013] In other embodiments a transurethral treatment device comprises a light delivery device positionable within or along an elongated support member for treatment of benign prostatic hyperplasia (BPH). The light delivery system may include light emitting diodes (LEDs), laser diodes (LDs), or may include a diffusion quartz fiber tip connected to an internal source of light energy. The treatment device may further include a temperature monitoring system for monitoring the temperature at the treatment site and a urine drainage system.

[0014] According to another embodiment of the invention, the treatment device has a light delivery device positioned within a catheter-like device, such as a Foley catheter or a conventional balloon catheter. In one embodiment, a light bar, sized to fit into a standard or custom optically clear Foley catheter, is inserted into the catheter which has been placed via the urethra at the prostate. The device can be used in a sterile Foley catheter or can be delivered in a sterile pack kit prepackaged with the catheter and/or an appropriate photoactive agent dose so that it is convenient for prostatic procedures, and thus facilitates treatment in a non-surgical environment leading to potential reduction in costs and medical complications.

[0015] In additional embodiments, the transurethral treatment device can have an outer diameter of about 0.8 mm to about 10 mm (e.g, 2.5 mm). The light source may have a cross-sectional dimension of about 0.5 mm to about 1.5 mm, but in other embodiments it can be larger. The size of an LED, for example, can be approximately 0.25 mm to 1 mm. In other embodiment, the transurethral treatment device, light source and LEDs can have other cross-sectional dimensions. The light bar may further include an encapsulant made from a flexible polymeric material with an appropriate refractive index to ensure efficient light coupling into the body. The encapsulant can also be made from opaque or reflective material to direct the light to the targeted tissues and to protect other tissues.

[0016] In additional embodiments, non-LED light sources such as laser diodes (LDs) can be used. Generated light can be transmitted to the treatment site via optical fibers. The light

delivery system may further include a diffusion quartz fiber tip connected to a source of light.

[0017] In additional embodiments, the light emitting region of the treatment device is fixed in place in the elongated support member. In yet another embodiment, the light emitting region of the light delivery device is movable within or along the elongated support member. For example, at the end of the treatment the light delivery device may be removed and the elongated support member left in place to act as a urine drain. The treatment device may further include printed markings or indicia on the catheter to aid in placement of the light bar within the catheter.

[0018] In additional embodiments, the catheter has a selective coating to control where light transmits to the prostatic tissue thus directing the light activate drug therapy and reducing the potential to treat adjacent tissue.

[0019] According to still further embodiments, a Y-connection with a leakage control valve is included to allow the light delivery device to be inserted into the elongated support member through a separate lumen from a urine collection lumen. The elongated support member may include one or more lumens as needed to provide light transmission source manipulation and placement. In additional embodiments, the elongated support member may include a balloon to further aid in positioning the light delivery device proximate to the prostate using non-incision type methods. In additional embodiments, the catheter may include a retractable fixation device such as balloon, umbrella, tines, disk or other means for fixation and placement within the bladder.

[0020] In additional embodiments, to make the light bar visible to ultrasound, the elongated support member and light bar may include echogenic material to reflect highfrequency sound waves and thus be imageable by ultrasound techniques. Echogenic material will aid in proper placement of the elongated support member and the light bar in operation. In additional embodiments, the light delivery system also includes temperature sensors which are electrically connected to temperature monitors for monitoring temperature at the treatment site.

[0021] Several embodiments of the present invention are expected to provide efficient, low cost, and minimally-invasive treatments of prostate conditions. The treatment device may be used to treat prostate cancer, prostatits, cystitis, bladder cancer, hypertrophic trigone, and hypertrophic urethral sphincter. The present invention utilizes light-activated drug therapy to minimally-invasively treat BPH or prostate cancer via the urethra. As a result, patients with BPH or prostate cancer can be treated using the present invention without being admitted to a hospital, undergo general anesthesia and blood transfusion, and thus have lower risk of complications.

[0022] For many of the described embodiments, a photosensitizer is administered intravenously before activating the light delivery device. The light activates the photosensitizer to promote cell death in the prostatic tissue. The device provides a minimally invasive

transurethral method for treating BPH, prostate cancer or other prostatic conditions. This type of light-activated drug therapy would treat prostatic tissue, for example, by causing cell death in the prostatic tissue. Such cell death and the absorption of the tissue by the patient's body would create an opening for urine to flow from the bladder out the urethra. Also disclosed are methods of administering light-activated drug therapy to treat targeted tissue of a human or non-human patient. In one embodiment, the method includes identifying a location of tissue to be treated in the prostate; inserting an elongated support member into the urethral tract to position a light emitting region at least proximate to the location of the targeted tissue; and administering an effective dose of a photoactive composition to the targeted tissue. The method may include confirming placement of the light source prior to treatment. The method further includes treating the targeted tissue with light-activated drug therapy for a predetermined period of treatment.

[0023] In some embodiments, the light-activated drug is mono-L-aspartyl chlorine e_6, also referred to herein as Talaporfin Sodium. This compound's absorption spectrum has several absorption bands: 400-420 nm (e.g., peak of about 411 nm), 500-520 nm (e.g., peak of about 507 nm), and 655-670 nm (e.g., peak of about 664nm). The drug could be excited at any of these bands. Alternative light-activated drugs of suitable excitation wavelengths may also be used as is known in the art. Also disclosed is a transurethral light-activated drug therapy device for the treatment of prostate diseases comprising:

a transurethral catheter having a proximal end, a distal end, and a first lumen, wherein the distal end is sized to be inserted in the urethra of a patient;

a balloon at the distal end of the catheter, wherein the balloon is sized to insert in the bladder of a patient in a deflated configuration;

a drain aperture at a distal end of the catheter and open to the first lumen; and

an array of light emitting diodes (LEDs) or solid-state laser diodes (LDs) carried by the catheter, wherein the array of LEDs or LDs light source produces light at a preselected wavelength or waveband in the range of an activation waveband of a photoactive composition.

[0024] The transurethral light-activated drug therapy device may comprise a monitoring device electrically coupled to the temperature sensor.

[0025] The monitoring device may include an output device, wherein the output device provides a visual indicator, audible indicator or other temperature indicator for the temperature at the treatment site.

[0026] The catheter may have a selective coating to control where light emits from the distal end. The transurethral light-activated drug therapy device may comprise a second lumen in which the array of LEDs or LDs is contained and can move axially within the catheter.

[0027] The array of LEDs or LDs may be fixed at a selected location within the catheter during treatment.

[0028] The transurethral light-activated drug therapy device may comprise a fixation device for releasably retaining the catheter in the urethra tract during treatment.

[0029] The fixation device may be a balloon, umbrella, tines, and/or disk.

[0030] The fixation device may be retractable.

[0031] The transurethral light-activated drug therapy device may comprise echogenic markings on the distal end of the catheter or on the light source or both.

[0032] The transurethral light-activated drug therapy device may comprise positioning indicia on the proximal end of the catheter.

[0033] Also disclosed is a method for light-activated drug therapy of benign prostate hyperplasia, comprising:

positioning a support member of a transurethral treatment device in the urethra such that a light emitting region of the transurethral treatment device is at least proximate to a treatment site;

providing a photoreactive agent to the treatment site; and

generating light from a light generator along the support member of the transurethral treatment device and passing the light through the light emitting region, wherein the light has one or more wavelengths or wavebands substantially equal to a waveband of absorption of the photoreactive agent.

[0034] The method may comprise monitoring the temperature of the treatment site with a temperature sensor.

[0035] The method may comprise modifying the administration of light therapy based on the temperature at the treatment site.

[0036] The method may comprise releasably fixing the support member prior to administering the light therapy.

[0037] The method may comprise monitoring echogenic marking on a distal end of the support member to position the support member in the urethra tract.

[0038] The method may comprise moving the light emitting region during administration of the

light therapy.

[0039] The method may comprise controlling the emission of light from the light generator according to a predetermined pattern.

[0040] In the method, the support member may comprise a catheter, and the method may comprise moving the light generator and the light emitting region along the catheter to position the light emitting region at least proximate to the treatment site.

[0041] In the method, the light generator and the light emitting region may be fixed to the support member, and the method may comprise moving the support member within the urethra to position the light emitting region at least proximate to the treatment site.

BRIEF DESCRIPTION OF THE DRAWINGS

[0042] The following drawings are intended as an aid to an understanding of the invention to present examples of the invention, but do not limit the scope of the invention as described and claimed herein. In the drawings, identical reference numbers identify similar elements or acts. The sizes and relative positions of elements in the drawings are not necessarily drawn to scale. For example, the shapes of various elements and angles are not drawn to scale, and some of these elements are arbitrarily enlarged and positioned to improve drawing legibility. Further, the particular shapes of the elements as drawn, are not intended to convey any information regarding the actual shape of the particular elements, and have been solely selected for ease of recognition in the drawings.

Figure 1 is an elevational side view of a prostate treatment system having a transurethral treatment device according to one embodiment of the invention.

Figure 2 is a cross-sectional view taken along line 2-2 of Figure 1 illustrating one embodiment of lumens in the transurethral treatment device.

Figure 3 is side view of a transurethral treatment device positioned in the urethra tract of a patient according to an embodiment of the invention.

Figure 4 is a cross-sectional view of a transurethral treatment device in accordance with another embodiment of the invention.

Figure 5 is a cross-sectional view of a transurethral treatment device in accordance with yet another embodiment of the invention.

Figure 6 is a cross-sectional view of a transurethral treatment device in accordance with still another embodiment of the invention.

Figure 7 is a cross-sectional view of a transurethral treatment device in accordance with another embodiment of the invention.

DETAILED DESCRIPTION

[0043] In the following description, certain specific details are set forth in order to provide a thorough understanding of various embodiments of the invention. However, one skilled in the relevant art will recognize that the invention may be practiced without one or more of these specific details, or with other methods, components, materials, etc. In other instances, well-known structures associated with light sources, catheters and/or treatment devices have not been shown or described in detail to avoid unnecessarily obscuring descriptions of the embodiments of the invention.

[0044] Generally, a prostate treatment system can include a transurethral treatment device having a light delivery device positioned within or along an elongated support member for treatment of benign prostate hyperplasia (BPH) and other prostate conditions. In one embodiment, the treatment device includes a light delivery device disposed on the surface of the elongated support member, or in other embodiments, the light delivery device is within a lumen of the elongated support member. The light generator can be optically connected to a light emitting region via optical fibers or light guides. Alternatively, the light generator and the light emitting region may be positioned together at the distal end of the elongated member at least proximate to a treatment site. Thus, the light generator may include a laser, an LED, a thin plastic sheet material which produces light at a selected wavelength or waveband, or other suitable light sources that can be transmitted to or placed at the treatment site. According to a further embodiment of the invention, the transurethral treatment device also includes temperature sensors which are electrically connected to temperature monitors.

A. Treatment device for treating Benign Prostate Hyperplasia (BPH)

[0045] Figure 1 illustrates a prostate treatment system 20 including a power supply 1 and a transurethral treatment device 21 having an elongated support member 2 and a light delivery device 6 positioned along or within the support member 2. The transurethral treatment device 20 may further includes a balloon 3 or other type of positioning element carried by the elongated support member 2. The support member 2 can be a catheter having a lumen 4, or the support member 2 can be a closed body without a lumen. According to an embodiment, the support member 2 has a total length of 400 to 450 mm and has an outer diameter of 3.327 mm, and the balloon 3 at the distal end of the support member 2 has a volume of 10 to 30 ml and is used to position and fix the light delivery device 6 proximate to the treatment site such as the prostate.

[0046] The light delivery device 6 can have a light generator 6a and a light emitting region 6b. In the embodiment shown in Figure 1, the light generator 6a and the light emitting region 6b

are at approximately the same location of the elongated member, but in other embodiments shown below, the light generator 6a may not be coincident with the light emitting region 6b. As shown below, the light generator 6a may be located towards the proximal end of the support member 2. When the support member 2 is a catheter with a lumen 4, the light delivery device 6 can move within the lumen to be positioned relative to the treatment site. In other embodiments, the light delivery device 6 can be disposed on the surface of the catheter 2 below the balloon 3 or other type of positioning element. The power for the light generator can be transmitted to the light delivery device 6 via a lead wire 7 coupled to the power source 1. According to an embodiment of the invention, light could be emitted by a light emitting diode (LED), a laser diode, light-emitting polymer, or a quartz fiber tip optically coupled to another internal source of light energy.

[0047] As illustrated in Figure 2, the support member 2 can include a plurality of lumens therein. For example, the balloon 3 is connected to a fluid inlet 5 via lumen 4. Gas or liquid can be pumped into inlet 5 and through lumen 4 to inflate balloon 3. Referring to Figures 1 and 2 together, the transurethral treatment device 21 can optionally have a urine aperture 11 positioned at the distal end of the support member 2 that is connected to a urine collection bag 13 via a urine lumen 12. The urine aperture 11 can be used to collect the patient's urine during treatment.

[0048] The transurethral treatment device 21 can also optionally include a temperature measuring system having at least one of a temperature sensor 8 and a temperature monitor 10. The temperature sensor 8 can be a thermocouple or other sensor as is known in the art. The temperature sensor 8 is disposed on or thermally coupled to a surface of the support member 2 and is electrically connected to the temperature monitor 10 via wires 9 disposed within the support member 2. The temperature sensor 8 measures a temperature at the treatment site, for example, proximate to the prostate during treatment. A control loop (not shown) may further be connected to the temperature monitor 10 to automatically shut the treatment device off in the event that the temperature at the treatment site exceeds a predetermined value. Alternatively, the temperature monitor 10 may further include a warning device (not shown), such as a visual indicator or audible indicator, to provide an operator with a warning that a predetermined temperature has been reached or is being exceeded during treatment.

[0049] As illustrated in Figure 3, the treatment device is positioned transurethrally to allow access to the prostate, followed by administration of a photoactive drug, by injection, intravenously, or orally. The transurethral treatment device 21, and more specifically a portion of the support member 2, can be directed into the urethra under topical anesthesia. Once the support member is positioned, 4 to 10 ml of saline or air can be pumped into the balloon 3 via the air pumping channel 4 to inflate the balloon 3. After inflation of the balloon 3, the support member 2 can be pulled slightly proximally such that the balloon 3 can be fixed at the inner opening of the urethra . Accordingly, the light delivery device 6 can be positioned at least proximate to or within the prostate. The photoactive drug can then be administered to the patient, and the light generator 6b can be activated.

[0050] The support member 2 has a proximal portion and a distal portion relative to a power controller. The distal portion of support member 2 includes the light delivery device 6. In one embodiment, the light delivery device comprises a plurality of LEDs in electrical communication with the power supply via lead wires 7 as shown in Figure 1. The lead wires may be selected from any suitable conductor that can be accommodated within the dimensions of the support member, for example: a bus bar that electronically couples the LEDs to the controller; flexible wires; a conductive film or ink applied to a substrate, and the like. Additionally or alternatively, the light delivery device may include Bragg reflectors to better control the wavelength of the light that is to be transmitted to the target cells.

[0051] A power controller 1 may be programmed to activate and deactivate LEDs of a light delivery device in a pulsed sequence or a continuous sequence. For example, the LEDs may form two halves of the light array that may be turned on and off independently from each other. Alternatively, the system may be programmed to selectively activate and deactivate (e.g., address) different selected individual or groups of LEDs along the length of the bar. In this manner, a treatment protocol, for example causing the LEDs to be lit in a certain sequence or at a particular power level for a selected period of time, may be programmed into the controller. Therefore, by selectively timing the pulses and/or location of the light, the system delivers light in accordance with a selected program. Alternatively, LEDs can be powered by DC continuously. Examples of addressable light transmission arrays are disclosed in U.S. Patent No. 6,096,066. Exemplary light transmission arrays which include shielding or distal protection are disclosed in U.S. Patent Nos. US 2005/0228260 A1 and US 2005/0131510 A1.

[0052] Without being bound by any theory, applicants believe that by delivering light in pulses, the efficacy of the light-activated drug therapy is improved, given that the treated tissue is allowed to reoxygenate during the cycles when the light is off. Applicants further believe that tissue oxygenation during therapy is improved by using a lower frequency. In one embodiment the operational frequency is 50 Hz - 5 kHz, and in one embodiment, is 50 - 70 Hz.

[0053] According to a further embodiment of the invention, the treatment device may further include a temperature monitoring system for monitoring the temperature at the treatment site.

[0054] In one embodiment, the support member 2 is a Foley catheter and the light delivery device 6 is disposed in the Foley catheter. Alternatively, the treatment device has a light delivery device disposed in a conventional balloon catheter. Foley catheters are available in several sub-types, for example, a Coude catheter has a 45° bend at the tip to allow easier passage through an enlarged prostate. Council tip catheters have a small hole at the tip which allows them to be passed over a wire. Three-way catheters are used primarily after bladder, prostate cancer or prostate surgery to allow an irrigant to pass to the tip of the catheter through a small separate channel into the bladder. This serves to wash away blood and small clots through the primary arm that drains into a collection device.

[0055] Figure 4 is a cross-sectional view of still another embodiment of a transurethral

treatment device 21. In this embodiment, the light delivery device includes a light generator 6a along the support member 2 at a location that is either within or external (shown) to the patient. The light delivery device can further include a light emitting region 6b positioned at least proximate to the treatment site and a light transmitting region 6c (e.g., fiber optic) between the light generator 6a and the light emitting region 6b. In Figure 4, the support member 2 can be a catheter through which the light delivery device 6 can be moved for positioning, or the support member can be a closed body to which the light delivery device 6 is attached (e.g., fixed at a set position).

[0056] Figures 5-7 are cross-sectional views showing additional embodiments of portions of transurethral treatment devices. Figure 5, more specifically, shows a device having a closed body support member 2 and a light delivery device fixed to the support member 2. The light delivery device has a light generator 6a, a light emitting region spaced apart from the light generator 6a distally along the support member 2, and a light transmitting region 6c between the light generator 6a and the light emitting region 6b. The light transmitting region 6c conducts light from the light generator 6a to the light emitting region 6b. Figure 6 illustrates a device having a solid or otherwise lumen-less support member 2 and a light delivery device 6 with a light generator 6a and a light emitting region 6b at the same location longitudinally along the support member 2. In Figure 5 and 6, the light generator is within the support member 2. Figure 7 shows still another embodiment in which the light delivery device is on a surface of the support member. More specifically, the light delivery device 6 has the light generator 6a and the light emitting region 6b disposed on an external surface of the support member.

[0057] In one embodiment, a light delivery system that is sized to fit into a standard or custom optically clear Foley catheter is inserted into that catheter which has been placed via the urethra at the prostate. The light delivery device can be used with a sterile Foley catheter or can be delivered in a sterile pack kit prepackaged with the catheter and/or an appropriate photoactive agent dose so that it is convenient for prostatic procedures.

[0058] The light bar or light array may include a plurality of LEDs contained in a catheter assembly or otherwise attached to a closed elongated support member. The support member 2 may have an outer diameter of about 0.8 to about 10 mm. Example of LED arrays are disclosed in U.S. Patent No. US 2007/0260295 A1 entitled "Light Transmission system for Photo-reactive Therapy," and U.S. Patent No. US 2007/0002582 A1 entitled "Medical Apparatus Employing Flexible Light Structures and Methods for Manufacturing Same,".

[0059] Additional embodiments have a power controller drive circuit capable of producing constant current D.C., A.C., square wave and pulsed wave drive signals. This is accomplished by combining a constant source with a programmable current steering network allowing the controller to selectively change the drive wave form. For example, the steering network may be modulated to achieve the various functions described above, for example, producing the desired impedance to fully discharge the battery. Furthermore, use of an A.C. drive allows for a two-wire connection to the LEDs, thereby reducing the cross-sectional diameter of the catheter, while still permitting use of two back-to-back emission sources, that when combined,

produce a cylindrical light source emission pattern.

[0060] Therefore, as discussed above, the transurethral treatment device 21 can comprise a unitary, single use disposable system for light-activated drug therapy. It should be noted that in certain embodiments the catheter is fused to the power controller to form an integrated single unit. Any attempt to disconnect the support member in this embodiment results in damage to either the catheter, or module, or both.

[0061] The prostate treatment system can be used in connection with any light-activated drug of which there are many known in the art and some of which are listed in U.S. Patent No. 7,015,240. In one particular embodiment, the light-activated drug is Talaporfin Sodium. Talaporfin Sodium is a chemically synthesized photosensitizer, having an absorption spectrum that exhibits a maximum peak at 664 nm. In one embodiment, the Talaporfin Sodium is presented as a lyophilized powder for reconstitution. One hundred milligrams of Talaporfin Sodium is reconstituted with 4 milliliters of 0.9% isotonic sterile sodium chloride solution, to give a solution at a concentration of 25 mg/ml.

[0062] The drug must be activated with light, and light energy is measured here in Joules (J) per centimeter of length of the light transmitting array. Likewise the fluence of light is measured in milli-watts (mW) per centimeter of length of the light emitting array. Clearly, the amount of energy delivered will depend on several factors, among them: the photoactive agent used, the dose administered, the type of tissue being treated, the proximity of the light array to the tissue being treated, among others. The energy (E) delivered is the product of the fluence (F) and the time period (T) over which the fluence is delivered: E=FxT. The fluence may be delivered for only a fraction of the treatment time, because the light array may be pulsed, for example in a frequency such as 60 kHz, or may be controlled by a timing pattern. An example of a timing pattern is that the array is at full fluence for 20 seconds, then off for 10 seconds in a repetitive cycle. Of course, any pattern and cycle that is expected to be useful in a particular procedure may be used. The control module may further be programmable in embodiments for such fractionated light delivery.

[0063] In accordance with an embodiment, fifteen minutes to one hour following Talaporfin Sodium administration, light energy in the range from about 50 to about 1000 J/cm of light array fluence in the range from about 5 to about 50 mW/cm of light array is delivered to the treatment site. As may be expected, the equation discussed above relating energy time and fluence plays a role in selection of the fluence and energy delivered. For example, depending upon the patient, a certain time period may be selected as suitable. In addition, the nature of treatment might dictate the energy required. Thus, fluence F is then determined by F=E/T. The light array should be capable of providing that fluence in the allotted time period. For example, if a total of 200 J/cm of light array must be delivered to the treatment site at 20 mW/cm of light array, then the treatment period is approximately 2.8 hours.

[0064] In additional embodiments, the support member further has a selective coating to control where light transmits to the prostatic tissue thus directing the light activate drug therapy

and reducing the potential to treat adjacent tissue.

[0065] In another embodiment, the light delivery device is fixed in place in the catheter. In yet another embodiment, the light delivery device is movable within the catheter. According to this embodiment, the treatment device may further include printed markings or indicia on the catheter to aid in placement of the light bar within the catheter. The light delivery device can also have asymmetric light delivery to protect the colon or rectum. For example, the light deliver device can be double sided and/or shielded so that one side of the light bar emits light at a higher intensity than another side. Exemplary light delivery devices are disclosed in U.S. Patent No. 5,876,427.

[0066] In additional embodiments, a Y-connection with a leakage control valve is included to allow the light transmission source to be inserted into the catheter through a separate lumen from a urine collection lumen. The catheter may include two or more lumens as needed to provide light transmission source manipulation and placement.

[0067] In additional embodiments, the catheter includes a balloon or other positional element to further aid in positioning the light source transmission end proximate to the prostate using non-incision type methods. In additional embodiments, the catheter may include a retractable fixation device such as balloon, umbrella, tines, disk or other means for fixation and placement within the bladder.

[0068] In additional embodiments, to make the light bar visible to ultrasound, the light source catheter and/or the light bar may include echogenic material to reflect highfrequency sound waves and thus be imageable by ultrasound techniques. In operation, echogenic material will aid in proper placement of the catheter and the light source.

[0069] In additional embodiments, the light transmission source also includes temperature sensors which are electrically connected to temperature monitors.

[0070] Several embodiments of the prostate treatment systems are expected to provide highly efficient, low cost, and minimally-invasive treatment of prostate conditions. The treatment device may be used to treat prostate cancer, prostatis, cystitis, bladder cancer, hypertrophic trigone, and hypertrophic urethral sphincter. The present invention allows for utilization of light-activated drug therapy methods to minimally-invasively treat BPH or prostate cancer via the urethra. As a result patients with BPH or prostate cancer can be treated using the present invention without being hospitalized, undergo general anesthesia and blood transfusion, and thus have lower risk of complications.

B. Methods of Treating BPH Using the Treatment Device

[0071] Also disclosed are methods of administering photoactive therapy to treat targeted tissue of a human or non-human patient. In one embodiment, the method includes identifying a

location of tissue to be treated in the prostate; inserting a catheter into the urethra tract; inserting a light delivery device at least proximate to the location of the targeted tissue; and administering an effective dose of a photoactive drug. The method may include confirming placement of the light source prior to treatment. The method further includes treating the targeted tissue by activating the light delivery device for a predetermined period of treatment. In some embodiments, the light-activated drug is mono-L-aspartyl chlorine e_6, also referred to herein as Talaporfin Sodium. Compositions and methods of making Talaporfin Sodium are disclosed and taught in co-pending U.S. Patent No. US 2008/0021210 A1 entitled "Compositions and Methods of Making a
Photoactive Agent". This compound has an absorption spectrum that exhibits several peaks, including one with the excitation wavelength of 664 nm, which is the wavelength favored when it is used in photoreactive therapy. Alternative light-activated drugs of suitable excitation wavelengths may also be used as is known in the art.

[0072] The method further includes monitoring a temperature at treatment site. The temperature measuring system includes a temperature sensor for monitoring the temperature at the treatment site. The temperature sensor may be a thermal couple or any suitable device for providing temperature information at the treatment site. The temperature sensor may be disposed at the surface of the support member and is further electrically connected to the temperature monitor via wires. Alternatively, the temperature sensor may be wirelessly connected to the temperature monitor. The temperature sensor provides the temperature proximate to the treatment site during treatment to ensure safe operating temperatures during the treatment at the treatment site.

[0073] The above description of illustrated embodiments, including what is described in the Abstract, is not intended to be exhaustive or to limit the invention to the precise forms disclosed. Although specific embodiments of and examples are described herein for illustrative purposes, various equivalent modifications can be made without departing from the spirit and scope of the invention, as will be recognized by those skilled in the relevant art. The teachings provided herein of the invention can be applied to light sources, catheters and/or treatment devices, not necessarily the exemplary light sources, catheters and/or treatment devices generally described above.

[0074] Unless the context requires otherwise, throughout the specification and claims which follow, the word "comprise" and variations thereof, such as, "comprises" and "comprising" are to be construed in an open, inclusive sense that is as "including, but not limited to."

[0075] Reference throughout this specification to "one embodiment" or "an embodiment" means that a particular feature, structure or characteristic described in connection with the embodiment is included in at least one embodiment of the present invention. Thus, the appearances of the phrases "in one embodiment" or "in an embodiment" in various places throughout this specification are not necessarily all referring to the same embodiment. Further more, the particular features, structures, or characteristics may be combined in any suitable manner in one or more embodiments. The headings provided herein are for convenience only

and do not interpret the scope or meaning of the claimed invention.

[0076] The various embodiments described above can be combined to provide further embodiments. Embodiments of the invention can be modified, if necessary, to employ systems, circuits and concepts of the various patents, applications and publications to provide yet further embodiments of the invention.

[0077] These and other changes can be made to the invention in light of the above-detailed description. In general, in the following claims, the terms used should not be construed to limit the invention to the specific embodiments disclosed in the specification and the claims, but should be construed to include all catheters, light transmission sources and treatment devices that operate in accordance with the claims. Accordingly, the invention is not limited by the disclosure, but instead its scope is to be determined entirely by the following claims.

[0078] From the foregoing, it will be appreciated that specific embodiments of the invention have been described herein for purposes of illustration, but that various modifications may be made without deviating from the scope of the invention. Accordingly, the invention is not limited except as by the appended claims.

REFERENCES CITED IN THE DESCRIPTION

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- US6958498B **[0006]**
- US6784460B **[0006]**
- US6445011B **[0006]**
- US5800478A **[0009]** **[0009]**
- WO9304727A1 **[0009]** **[0010]**
- US5456661A **[0009]** **[0010]**
- US6146409A **[0009]** **[0010]**
- US6096066A **[0051]**
- US20050228260A1 **[0051]**
- US20050131510A1 **[0051]**
- US20070260295A1 **[0058]**

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- US7015240B **[0061]**
- US5876427A **[0065]**
- US20080021210A1 **[0071]**

PATENTKRAV

1. Indretning (20) til transurethral lysaktiveret lægemiddelterapi til behandling af prostatatilstande, omfattende:

et aflangt støtteelement (2) indrettet til at passere gennem urethra, hvor det aflange støtteelement har en proksimal ende og en distal ende;
en lysafgivelsesindretning (6) med en lysgenerator (6a) langs støtteelementet og et lysemitterende område (6b) indrettet til at være positioneret inde i urethra mindst nær et behandlingssted, hvor lysgeneratoren er indrettet til at generere lys ved en prævalgt bølgelængde eller bølgebånd i området af et aktiveringsbølgebånd af en fotoaktiv sammensætning;
et positioneringselement (3) båret af støtteelementet, hvilket positioneringselement er indrettet til at være fikseret og beliggende inde i en patients blære, hvor positioneringselementet er indrettet til at lokalisere det lysemitterende område (6b) inde i urethra; og hvor støtteelementet er et kateter med mindst en lumen (4) og en selektiv coating til at styre, hvor lyset transmitterer til prostatavævet.

2. Indretning til transurethral lysaktiveret terapi ifølge krav 1, hvor lysgeneratoren omfatter mindst en eller flere af en lysemitterende diode (LED), en faststoflaserdiode (LD), en lysemitterende polymer, en laser, en lysemitterende transistor eller en anden lyskildetransmitterende fiber, hvorigennem kan ledes lys.

3. Indretning til transurethral lysaktiveret lægemiddelterapi ifølge krav 1, hvor lysgeneratoren omfatter et array af LED'er med en størrelse fra cirka 0,25 mm til cirka 1 mm.

4. Indretning til transurethral lysaktiveret lægemiddelterapi ifølge krav 1, hvor lysgeneratoren omfatter et array af LED'er med en størrelse fra cirka 1 mm til cirka 5 mm.

5. Indretning til transurethral lysaktiveret lægemiddelterapi ifølge krav 3 eller 4, hvor arrayet af LED'er er indrettet til at levere fra cirka 5mW til cirka 50 mW pr. centimeter arraylængde.

6. Indretning til transurethral lysaktiveret lægemiddelterapi ifølge krav 3 eller 4, der endvidere omfatter en strømstyringsenhed (1) indrettet til at pulsere arrayet ifølge en frekvens eller ifølge et tidsbestemt mønster.

7. Indretning til transurethral lysaktiveret lægemiddelterapi ifølge krav 3 eller 4, hvor arrayet af LED'er har en driftsfrekvens i området fra cirka 50 Hz til cirka 5 kHz.

8. Indretning til transurethral lysaktiveret lægemiddelterapi ifølge krav 1, hvor lysgeneratoren omfatter en laser indrettet til at generere lys langs støtteelementet og en lyskanal indrettet til at transmittere lyset til det lysemitterende område.

9. Indretning til transurethral lysaktiveret lægemiddelterapi ifølge krav 7, hvor lysafgivelsesindretningen endvidere indbefatter en diffusionskvartsfiberspids.

10. Indretning til transurethral lysaktiveret lægemiddelterapi ifølge krav 1, der endvidere omfatter en temperatursensor (8) og en temperaturmonitor (10), der er elektrisk koblet til temperatursensoren (8).

11. Indretning til transurethral lysaktiveret lægemiddelterapi ifølge krav 10, hvor temperaturmonitoren indbefatter en visuel indikator, en akustisk indikator og/eller en automatisk afbryder, når temperaturen stiger over en prævalgt værdi.

12. Indretning til transurethral lysaktiveret lægemiddelterapi ifølge krav 1, hvor støtteelementet omfatter et kateter med en første lumen, hvori lysafgivelses-systemet kan positioneres, og en anden lumen indrettet til at transmittere en fluid mellem et sted inde i en patients krop til et sted uden for en patients krop.

13. Indretning til transurethral lysaktiveret lægemiddelterapi ifølge krav 1, der endvidere omfatter ekkogent materiale på eller i en fast forbindelse i forhold til lysafgivelsesindretningen på forudbestemte steder for at levere positionsinformationer om lysafgivelsesindretningen.

14. Indretning til transurethral lysaktiveret lægemiddelterapi ifølge krav 10, hvor temperatursensoren er et termoelement elektrisk forbundet med et reguleringskredsløb, hvor temperatursensoren er indrettet til at måle temperaturen ved behandlingsstedet under behandling.

15. Indretning til transurethral lysaktiveret lægemiddelterapi ifølge krav 1, hvor lysafgivelsesindretningen er fastgjort til støtteelementet.

16. Indretning til transurethral lysaktiveret lægemiddelterapi ifølge krav 1, hvor positioneringselementet indbefatter en ballon ved den distale ende af kateteret.

DRAWINGS

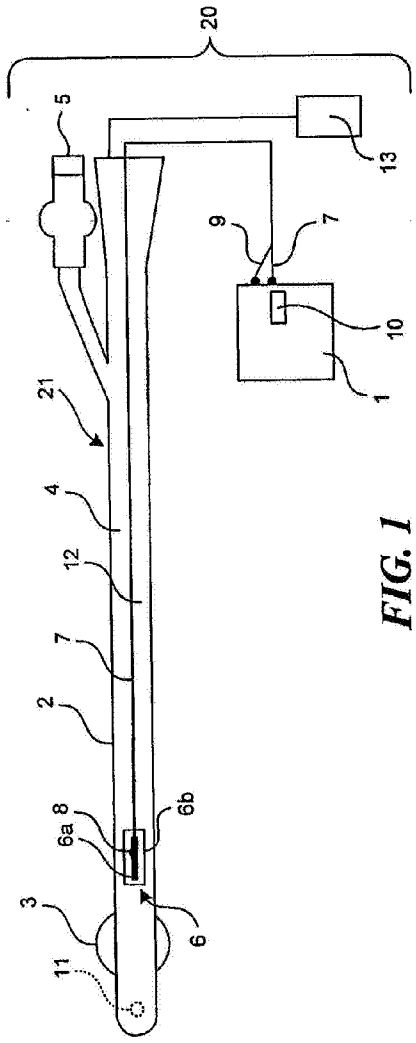


FIG. 1

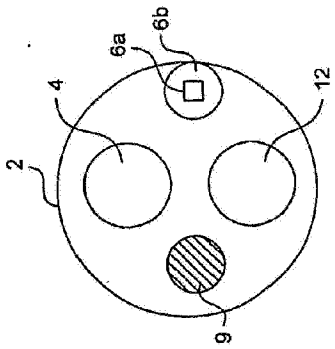


FIG. 2

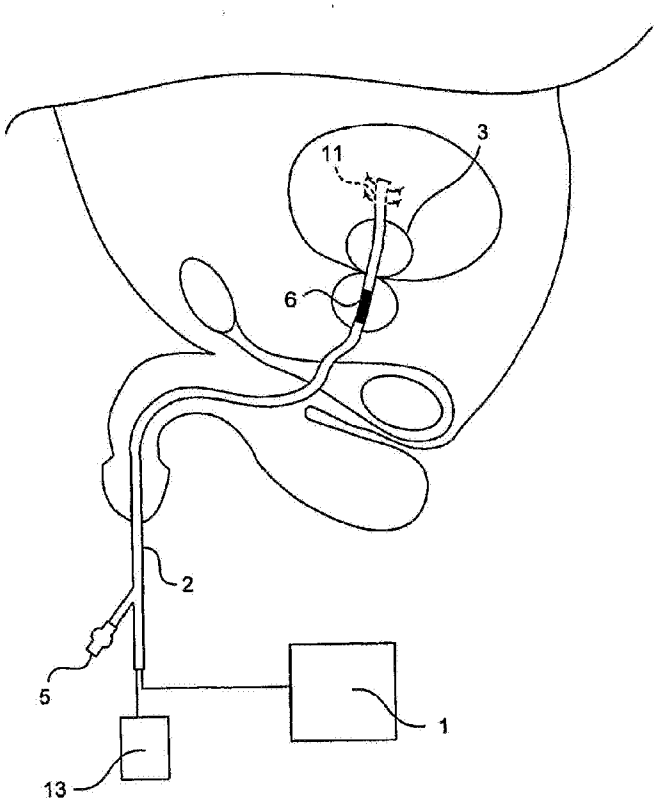


FIG. 3

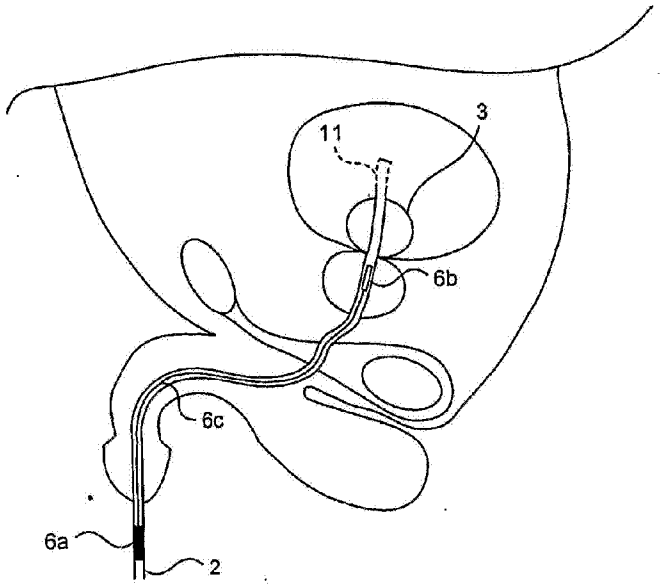


FIG. 4

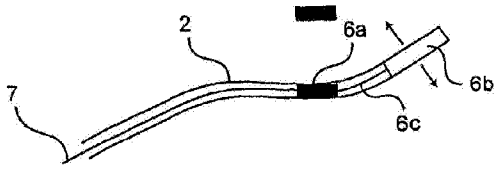


FIG. 5

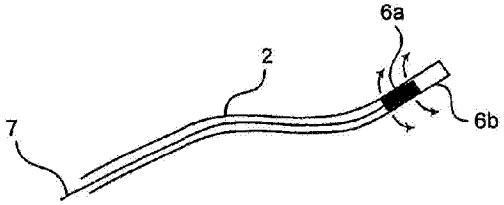


FIG. 6

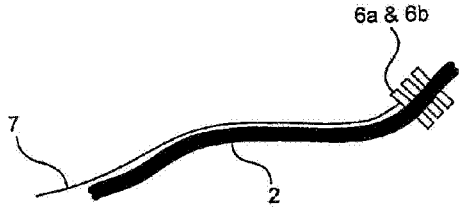


FIG. 7