Apparatus particularly, but not exclusively, useful for treating a male for impotence, includes a source of low-power light radiation, and a radiation applicator for holding the male’s penis and for applying thereto radiation from the source sufficient to induce relaxation of the walls of the blood vessels supplying blood to the corpora cavernosa of the penis.

Preferably the light radiation is monochromatic laser radiation of a wavelength of 440–950 nm, applied at a level of 20–2000 milliwatts per square centimeter, for a total exposure of 50–200 joule per square centimeter, in a total treatment time of 2–40 minutes. The applicator is coupled to the radiation source by a distributor which moves the radiation to produce at least one radiation exposure cycle including a forward stroke and a return stroke.

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RADIATION TREATMENT APPARATUS PARTICULARLY USEFUL IN TREATING FOR IMPOotence
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RADIATION TREATMENT APPARATUS
PARTICULARLY USEFUL IN TREATING FOR IMPOTENCE

FIELD AND BACKGROUND OF THE INVENTION

The invention relates to apparatus for treating objects with radiation. The invention is particularly useful in treating a male for impotence, namely a male's inability to achieve or maintain a penile erection of adequate rigidity for sexual intercourse. The invention is therefore described below with respect to this application, but it will be appreciated that the invention could also be used in other applications.

The penis consists of two longitudinal cylindrical bodies called the corpora cavernosa. These bodies are composed of sponge-like tissue that contains tiny vascular spaces (cavernous sinuses) surrounded by smooth muscle. A third cylinder is the urethra, a tube that carries the urine and the ejaculate. Blood flows to the penis via two very small arteries that come from the aorta. During erection, blood is pumped into the penis under great pressure, and is trapped in the penis to maintain the erection.

The sequence of events that initiates an erection include relaxation of the sinusoid muscle, which results in a decrease of resistance and an increase in blood flow. The events that lead to this smooth muscle relaxation are controlled by biochemical substances which are released from the nerve endings after sexual stimulation. These substances include, among others, the endothelium-derived relaxing factor (EDRF), also known as nitric oxide (NO). NO has been found to act as a neurotransmitter causing smooth muscle relaxation in the urogenital tract and seems to be a final mediator of penile erection. Penile erection is mediated by nitric oxide via cyclic guanosine monophosphate. Any medication or process which will mimic these mechanisms will enhance an erection.
Following are the main types of impotence and their causes:
- psychogenic impotence, caused by impulses from the brain which inhibit the erectile process;
- neurogenic impotence, secondary to nervous system disorders;
- arteriogenic impotence, secondary to disease of the arteries which supply blood to the penis;
- hormonal impotence, caused by a deficiency of androgens and loss of sexual interest and erections;
- venogenic impotence, caused by abnormal venous channels of communication, producing an inability to maintain an erection; and
- erectile tissue dysfunction impotence, secondary to fibrosis, trauma, diabetes, tumor infiltration and others.

Currently the following methods are used in the treatment of impotence, i.e., to enable, or to improve the ability of, a male to achieve or maintain a penile erection of adequate rigidity for sexual intercourse:
- vacuum constrictor devices; however these may be cumbersome to use and may cause pain and/or premature loss of penile tumescence/rigidity.
- transdermal administration of vasoactive drugs; however these are usually ineffective.
- transurethral administration of vasoactive drugs; however these may cause pain and insufficient erection.
- intracavernous injection of vasoactive agents; however these are frequently accompanied by side effects including hematomas, pain, formation of fibrotic nodules within the corpora cavernosa, penile curvature and priapism.
- penile prosthesis implantation; however this involves irreversible destruction of corpora cavernosa vessels, and possible complications including infection,
erosion of a component of a prosthesis, and mechanical failure of prosthesis components.

-oral medications sildenafil e.g., Viagra, the recently introduced drug, which prevents degradation of the cyclic guanosine monophosphate and thus enhances erections; however, this may be accompanied by serious, possibly fatal, side effects.

OBJECTS AND SUMMARY OF THE PRESENT INVENTION

An object of the present invention is to provide apparatus which is particularly useful in treating a male for impotence.

According to one aspect of the present invention, there is provided apparatus for treating a male for impotence, comprising: a source of low-power light radiation; and a radiation applicator for holding the male's penis and for applying thereto radiation from the source sufficient to induce relaxation of the walls of the blood vessels supplying blood to the corpora cavernosa of the penis.

According to further features in the preferred embodiment of the invention described below, the light radiation is preferably monochromatic, laser radiation of a wavelength of 440-960 nm, and is applied at a rate (irradiance) of 20-2000 milliwatts per square centimeter for a total energy (radiant exposure) of 50-200 joule per square centimeter for a treatment time of 1.5-40 minutes.

According to still further features in the described preferred embodiments, the radiation is applied while it is moved along the length of the penis. Preferably, the radiation is applied over one or more cycles, each including a slow forward stroke having a duration in the order of minutes, and a similar slow stroke, or a quick return stroke having a duration in the order of seconds.
Apparatus constructed with the foregoing features has been found useful in treating a male for impotence without the side effects and other drawbacks present in the currently used methods. Thus, the light radiation, particularly laser radiation, induces relaxation of vascular smooth muscle at low powers; whereas at high power, the heat generated may cause constriction, focal coaguli formation, hemostasis, and/or thermal damage to tissues. Generally, the shorter the light wavelengths, the more effective is the relaxation.

In addition, low-power, monochromatic, laser, radiation tends to reduce injury, to promote regeneration, to provide protective effects against ischemic damage, and to produce analgesia. While the mechanism is not known with certainty, one hypothesis is that the radiation produces free radicals like nitric oxide (NO), (EDRF), which have beneficial effects on impotence at low concentrations. Suggested causes of blood vessel wall relaxation by laser or other monochromatic light are similar to the endothelium-derived relaxation (based on endothelium-derived relaxing factor, (EDRF) and depends on the presence of nitric oxide (NO) donors.


According to another aspect of the present invention, there is provided apparatus for irradiating an object with light radiation, which apparatus is particularly, but not necessarily exclusively, useful in the above method. The novel apparatus comprises: a radiation source outputting a radiation beam; a radiation applicator including a holder for holding the object to be irradiated;
and a radiation guiding conduit guiding the radiation beam from the light source to the radiation applicator. The radiation guiding conduit includes a plurality of optical fibers having inlet ends for receiving the radiation beam from the radiation source, and outlet ends distributed along the length of the holder. The apparatus further includes a radiation distributor between the radiation source and the inlet ends of the optical fibers for sweeping the radiation beam across the inlet ends of the optical fibers and thereby for distributing the radiation beam across the length of the holder.

According to further features in the described preferred embodiments, the outlet ends of the optical fibers are arrayed in a matrix extending axially and transversely of the holder for the object to be irradiated. The inlet ends of the optical fibers are also arrayed in a matrix extending axially and transversely of the radiation distributor.

Further features and advantages of the invention will be apparent from the description below.

**BRIEF DESCRIPTION OF THE DRAWINGS**

The invention is herein described, by way of example only, with reference to the accompanying drawings, wherein:

Fig. 1 illustrates one form of apparatus constructed in accordance with the present invention;

Fig. 2 illustrates a rotating-mirror type of radiation distributor in the apparatus of Fig. 1;

Fig. 3 is a longitudinal sectional view of the radiation distributor of Fig. 2;

Fig. 4 is a view similar to that of Fig. 3 but illustrating a conical-deflector type of radiation distributor;
Fig. 5 is a view similar to that of Fig. 3 but illustrating a light-modulator type of radiation distributor;

Fig. 6 is an exploded view illustrating the radiation applicator in the apparatus of Fig. 1;

Fig. 7 is a view, partly broken away, more particularly illustrating the structure of the radiation applicator of Fig. 6;

Figs. 8 and 9 illustrate two further types of radiation distributors that may be used;

Fig. 10 illustrates another type of radiation applicator that may be used; and

Fig. 11 is a bottom plan view of the upper plate in the applicator of Fig. 10.

DESCRIPTION OF PREFERRED EMBODIMENTS

The apparatus illustrated in Figs. 1-5 is particularly useful for treating a male for impotence by applying low-power light radiation, preferably monochromatic, laser radiation, to the penis of the male sufficient to induce relaxation of the walls of the blood vessels supplying blood to the corpora cavernosa of the penis. The manner in which the illustrated apparatus is used is described below following the description of the structure of the apparatus.

Fig. 1 illustrates the overall apparatus. It includes a housing 2 for a monochromatic light source, preferably a laser, coupled to a radiation applicator 4 via a radiation guiding conduit, in the form of a bundle of optical fibers 6, for applying the radiation to the male's penis P held within the applicator. Housing 2 further includes a programming panel 7 enabling the apparatus to be programmed as will be described more particularly below, and a display panel 8 displaying information regarding the operation of the apparatus. Electrical power to the
radiation source, and to a radiation distributor within housing 2, is supplied by a cable 9.

Figs. 2 and 3 illustrate the monochromatic light source and also a radiation distributor, within housing 2. Thus, as shown in Figs. 2 and 3, housing 2 includes a laser 20 (or other, preferably monochromatic, light source) outputting a laser beam 21, a power supply 22 for laser 20, and a control board 23 for controlling the energization of the laser.

The radiation distributor within housing 2 includes a cylindrical tube 24 formed with a plurality of openings 24a-24f, each receiving the inlet end of an optical fiber 6a-6f, and a mirror 25 which is moved both rotatably and axially for sweeping the laser beam 21 successively across the inlet ends of the optical fibers 6. Thus, distributor tube 24 is coaxial with the laser beam 21; and mirror 25 is movable, both rotatably and axially, within tube 24. Mirror 25 includes a 45-degree reflecting face to the laser beam 21 so that as the mirror is rotated, it reflects the beam around the inner circumference of tube 24; and as the mirror is moved axially, it reflects the beam to a different circumferential surface of the tube.

Mirror 25 is driven in the rotary direction by a motor $M_1$, and in the axial direction by a motor $M_2$. Motor $M_1$ is directly coupled to mirror 25. Both are carried on a nut 26 movable along a lead screw 27 rotated by motor $M_2$, such that the rotation of motor $M_2$ moves motor $M_1$, and mirror 25 with it, axially within tube 24.

Preferably, both motors $M_1$ and $M_2$ are step motors, or other intermittently driven motors, for driving mirror 25 in steps. Thus, motor $M_1$ steps mirror 25 in the rotary direction to successively reflect the laser beam 21 to the inlet ends of the optical fibers 6 around the circumference of tube 24 at one axial position of the mirror; and motor $M_2$ steps the mirror 25 in the axial direction to reflect the
laser beam to the inlet ends of the optical fibers at different axial positions of the mirror.

Fig. 3 illustrates six circular arrays 24a-24f of openings in the distributor tube 24, with the inlet ends of the optical fibers 6 fixed within these openings to form six circular arrays 6a-6f of fiber inlet ends. In the illustrated axial position of mirror 25, the energization of motor $M_1$ will cause mirror 25 to reflect the laser beam 21 successively to each of the fiber ends 6d at one axial location of the distributor tube 24; whereas the energization of the axial motor $M_2$, will move mirror 25 axially to align it with a different circular series of fiber ends, according to the direction and amplitude of this axial movement of the mirror.

It will thus be seen that the inlet ends of the optical fibers received within the openings of the distributor tube 24 are arranged in a matrix extending axially and transversely of the distributor tube, and that by controlling rotary motor $M_1$ and axial motor $M_2$, mirror 25 may be moved within distributor tube 24 to sweep the laser beam 21 successively to the inlet ends of all the fibers 6.

Figs. 4 and 5 illustrate two other types of radiation distributors that may be used instead of the rotating-mirror of Fig. 3.

In Fig. 4, the radiation distributor includes a beam expander 30 outputting an expanded beam of parallel arrays to a conical reflector 31, e.g., a conical mirror, which reflects the expanded beam laterally towards the outlet ends of the optical fibers 6a-6f. Thus, the conical reflector 31 needs to be driven only in the axial direction, this being done by motor $M_2$, to sequentially sweep the laser radiation from the conical deflector 31 across the six circular arrays 6a-6f of the fiber inlet ends. The arrangement illustrated in Fig. 4 thus obviates the need of motor $M_1$ for rotating the laser beam about the beam axis
from the laser, and therefore motor $M_1$ of Fig. 3 is replaced merely by a head 32 supporting the conical deflector 31 and moved axially by motor $M_2$.

Fig. 5 illustrates a radiation distributor which includes a plurality of light modulators 35a-35f axially-aligned with the laser axis, and axially-spaced from each other, for distributing the laser beam with respect to the inlet ends 6a-6f of the optical fibers. Light modulators 35a-35f may be in-line modulars to produce an axial sweep of the laser beam with respect to the fiber ends, or matrix modulators to produce also a rotary sweep of the laser beam with respect to the fiber ends. The arrangement illustrated in Fig. 5 thus obviates the need for both motors $M_1$ and $M_2$ in the rotary flat-mirror distributor illustrated in Fig. 3.

The optical fibers 6 in all the above-described arrangements guide the laser radiation from housing 2 to the radiation applicator 4 to distribute the radiation over the surface of the penis $P$ held by the radiation applicator.

Thus, as shown in Figs. 6 and 7, the radiation applicator 4 includes a lower supporting plate 40 formed with a semi-cylindrical groove 41 to receive the lower part of the penis $P$, and with an upper plate 43 similarly formed with a semi-cylindrical recess 44 for engagement with the upper part of the penis. The two plates may be clamped together, e.g., by straps 45, to define a cylindrical cavity for the penis. The upper plate 43 is formed with a plurality of openings or passageways 47 for receiving the outlet ends of the optical fibers 6.

The outlet ends of the optical fibers 6 are fixed within openings 47 of the radiation applicator 4, and are thus also arrayed in a matrix extending axially and transversely of the applicator. In the radiation applicator, however, the outlet ends of the optical fibers are arrayed in a semi-cylindrical pattern, rather than in a cylindrical
pattern as in the distributor tube 24 receiving the inlet ends of the optical fibers. This is because the radiation is applied only to the upper part of the penis P, proximal to the two corpora cavernosa bodies of the penis.

The radiation applicator 4 further includes a transparent convex lens 48 at the outlet end of each optical fiber 6. Each lens 48, (e.g., spherical or convex-convex) converges the laser radiation applied by its respective optical fiber 6, and also provides a smoother surface for contact with the penis.

Preferably, the upper part 43 of the radiation applicator 4 should be made of a somewhat resilient material, such as silicon rubber, for comfort purposes. The lower part 40 may be made of the same material, or conceivably could even be omitted.

In order to reduce radiation hazards, particularly when a laser is used as the monochromatic light source, the applicator illustrated in Figs. 6 and 7 is provided with an interlock switch, schematically shown at 49, which must be closed, by the clamping of plate 43 to plate 40, to enable energization of the light source. Thus, whenever the two plates are not clamped together, the light source (e.g., laser) is disabled in order to minimize possible eye injury or other radiation hazards.

Preferably, the surfaces of one or both plates 43, 40, coming into direct contact with the object being irradiated, includes temperature sensors, shown at 50 in Fig. 7. Such sensors will also automatically disable the laser (or other light source) upon the temperature of the irradiation surface exceeding a predetermined value, e.g., by more than 2-3 degrees C from its normal value.

Fig. 8 illustrates another radiation distributor, generally designated 60, which may be used instead of those of Figs. 2-4. The distributor 60 includes a plate 61 formed with a rectangular matrix of opening 62 receiving the inlet
ends of the optical fibers 63. Each row of the optical fibers may be irradiated by a laser 64 driven by a motor 65; alternatively, one laser driven along both axes may be used for irradiating the inlet ends of the optical fiber 63. Another alternative is to have the laser or lasers 64 fixed, and to move plate 61 of the distributor 60 relative to the laser or lasers.

Fig. 9 illustrates another radiation distributor, generally designated 70, also including a plate 71 formed with a matrix of openings 72 receiving the inlet ends of the optical fibers 73. In this case, the inlet ends of the optical fibers are irradiated by one or more lasers 74 via a 45 degree mirror 75 which is driven by a drive 76 to sequentially scan the inlet ends of the optical fibers.

Figs. 10 and 11 illustrate another type of applicator, generally designated 80, for holding the penis P and for applying the radiation to it. In this case, the applicator 80 includes an upper plate 81 and a lower plate 82 for receiving the penis P between them. The upper plate 81 has a planar lower surface 83 engageable with the upper surface of the penis, and is formed with a matrix of openings 84 receiving the outlet ends of the optical fibers 85. The openings 84 may be of any desired number, size and spacing. Preferably, they are arranged in groups of two, as shown in Fig. 11, or in groups of three or four.

When the illustrated apparatus is used in treating for impotence, the monochromatic light source 20 is preferably a laser having a wavelength of 440-960 nm, more preferably 632-808 nm. A preferred laser is a helium-neon one having a wavelength of 632 nm, since such lasers are today readily available at relatively low cost. Other lasers that may be used are the helium-cadmium laser having a wavelength of 440 nm, and the diode laser having a wavelength of 780 nm or 808 nm. However, other monochromatic
light sources may be used, such as an Xenon lamp with an appropriate collimator, filter, and converging lens.

The light radiation is applied at a rate (irradiance) of preferably 20-2,000, more preferably 300-600, milliwatts per square centimeter, for a total exposure of 50-200 joules per square centimeter and for a total treatment time of 1.5-40 minutes. For example, when using the helium-neon laser of 632 nm, a preferred irradiance is 100 milliwatts per square centimeter, and the preferred treatment time is approximately 2 minutes.

The light radiation is preferably applied in one or more cycles, wherein in each cycle the light radiation is moved slowly through a slow forward stroke along the penis from one end to the other, and then through a similar slow return stroke, or a fast return stroke, back to its original position. This cyclical movement of the radiation is effected by the radiation distributor, as described above. Preferably, each slow forward and return stroke has a duration in the order of minutes, and when a fast return stroke is used, it may have a duration in the order of seconds. As one example, a treatment may include four such cycles, in which each forward stroke is about 5 minutes, and each return stroke is about 6-12 seconds, thereby providing a total treatment time of about 21 minutes.

Preferably, the bundle of optical fibers should include from 20 to 150 optical fibers, all enclosed within a jacket sufficiently stiff to avoid sharp bends in the fibers. As one example, there could be 49 fibers arranged in a 7 X 7 matrix; and as another example, there could be 20 fibers arranged in a 2 X 10 matrix. Each fiber is preferably from 1-2.5 mm in diameter.

In the Fig. 3 radiation distributor, motor $M_1$ is preferably a stepper motor, operated at 3 RPM, and motor $M_2$ is preferably a stepper motor operated to produce a dwell time for each fiber of 4-8 seconds, but no more than 10
seconds. The radiation distributors illustrated in Figs. 4, 5, 8 and 9 could be correspondingly operated. Distributor tube 24 (Fig. 4) is preferably of aluminum, blackened on both surfaces, having an inner diameter of 25 mm, an outer diameter of 50 mm, a thickness of 12.5 mm, and a length of 65-85 mm.

While the invention has been described with respect to several preferred embodiments, it will be appreciated that these are set forth merely for purposes of example, and that many other variations, modifications and applications of the invention may be made.
WHAT IS CLAIMED IS:

1. Apparatus for treating a male for impotence, comprising:
   a source of low-power light radiation;
   and a radiation applicator for holding the male's penis and for applying thereto radiation from said source sufficient to induce relaxation of the walls of the blood vessels supplying blood to the corpora cavernosa of the penis.

2. The apparatus according to Claim 1, wherein said source of light radiation is a laser producing laser radiation of a wavelength of 440-960 nm.

3. The apparatus according to Claim 2, wherein the irradiance of said laser is 20-2000 millewatts per square centimeter and is applied for a total irradiance exposure of 50-200 joule per square centimeter in a total treatment time of 2-40 minutes.

4. The apparatus according to Claim 1, wherein said applicator slowly moves the radiation along the length of the penis.

5. The apparatus according to Claim 4, wherein said radiation applicator is coupled to said radiation source by a distributor which moves the radiation, relative to the penis, to produce at least one radiation exposure cycle including a forward stroke from one end of the penis to the opposite end, and a return stroke from the opposite end back to the one end.

6. The apparatus according to Claim 5, wherein said forward stroke has a duration in the order of minutes, and said return stroke has a duration in the order of minutes to seconds.

7. The apparatus according to Claim 5, wherein said distributor moves the radiation along the upper part, and for the length, of the penis.
8. The apparatus according to Claim 5, wherein said applicator includes a holder for holding the penis, and a plurality of optical fibers having inlet ends exposed to said distributor and outlet ends arrayed along the length of said holder and sequentially irradiated by a narrow beam of the radiation.

9. Apparatus for irradiating an object with light radiation, comprising:
   a radiation source outputting a radiation beam;
   a radiation applicator including a holder for holding the object to be irradiated;
   a radiation guiding conduit guiding the radiation beam from the light source to the radiation applicator; said radiation guiding conduit including a plurality of optical fibers having inlet ends for receiving the radiation beam from said radiation source, and outlet ends distributed along the length of said holder;
   and a radiation distributor between said radiation source and said inlet ends of the optical fibers for sweeping said radiation beam across said inlet ends of the optical fibers and thereby for distributing the radiation beam along the length of the holder and the object held thereby.

10. The apparatus according to either of Claims 8 or 9, wherein said outlet ends of the optical fibers are arrayed in a matrix extending axially and transversely of said holder.

11. The apparatus according to Claim 10, wherein said inlet ends of the optical fibers are arrayed in a matrix extending axially and transversely of said radiation distributor; and said radiation distributor distributes said radiation beam with respect to said inlet ends of the optical fibers.

12. The apparatus according to Claim 11, wherein said radiation distributor includes a cylindrical tube
having a plurality of openings therein arrayed both circumferentially and axially of said tube; said inlet ends of the optical fibers being fixed in said openings.

13. The apparatus according to Claim 12, wherein said radiation distributor includes a mirror within said cylindrical tube, said mirror being rotated by a rotary drive and moved axially by an axial drive to sequentially sweep said radiation beam across said inlet ends of the optical fibers.

14. The apparatus according to Claim 12, wherein said radiation distributor includes: a beam expander for expanding the radiation beam outputted by said radiation source; a conical deflector within said cylindrical tube for deflecting the radiation beam laterally towards said inlet ends of the optical fibers; and an axial drive for driving said conical deflector axially with respect to said inlet ends of the optical fibers.

15. The apparatus according to Claim 10, wherein said radiation distributor includes a plurality of light modulators axially-aligned with said radiation source, and axially-spaced from each other, for distributing the radiation beam with respect to said inlet ends of the optical fibers.

16. The apparatus according to Claim 10, wherein said holder includes a plate, and said outlet ends of the optical fibers are fixed in said plate.

17. The apparatus according to Claim 10, wherein a convex lens is provided at the outlet end of each optical fiber to converge the radiation beam emitted therefrom.