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(54) **DEVICES AND TECHNIQUES FOR LIGHT-MEDIATED STIMULATION OF TRABECULAR MESHWORK IN GLAUCOMA THERAPY**

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Publication Classification

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(57) **ABSTRACT**

An apparatus and technique for transscleral light-mediated biostimulation of the trabecular plates of a patient's eye in a treatment for glaucoma or ocular hypertension. The apparatus includes; (i) a working end geometry for contacting the anterior surface of the sclera and cornea to insure that a laser emission reaches the trabecular meshwork from a particular location on the anterior surface of the sclera, (ii) a laser energy source providing a wavelength appropriate for absorption beneath the anterior scleral surface to the depth of the trabecular plates, and (iii) a dosimetry control system for controlling the exposure of the laser emission at the particular spatial locations. The device uses a light energy source that emits wavelengths in the near-infrared portion of the spectrum, preferably in the range of about 1.30 μm to 1.40 μm or from about 1.55 μm to 1.85 μm. The depth of absorption of such wavelength ranges will extend through most, if not all, of the thickness of the sclera (750 μm to 950 μm). In accordance with a proposed method of trabecular biostimulation, the targeted region is elevated in temperature to a range between about 40° C. to 55° C. for a period of time ranging from about 1 second to 120 seconds or more.

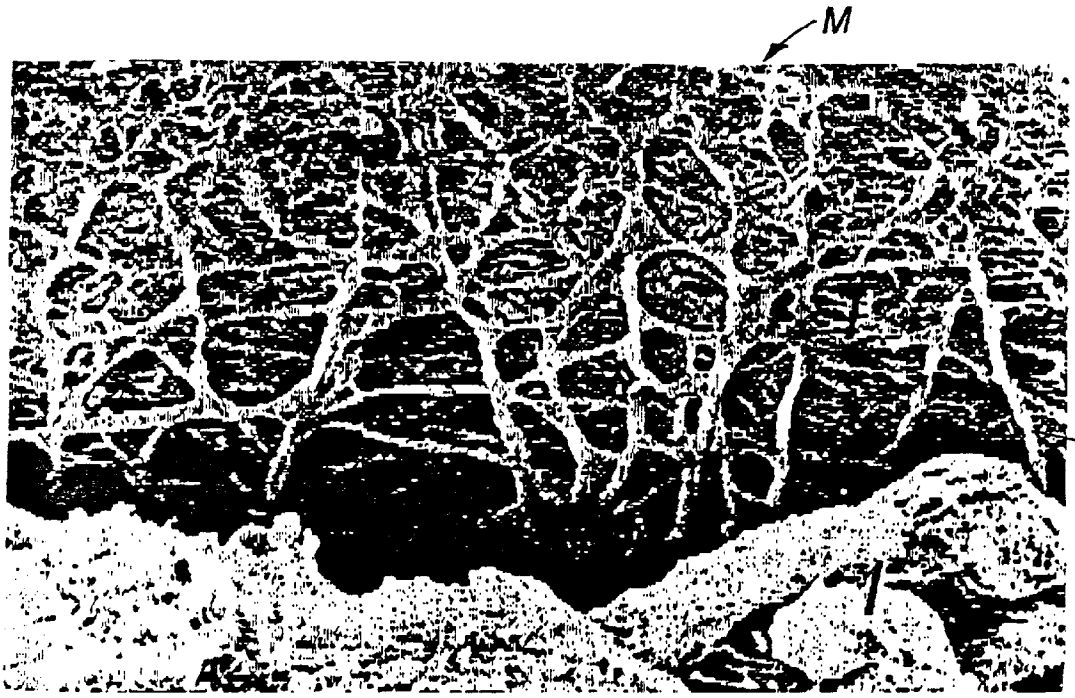


FIG. 1A

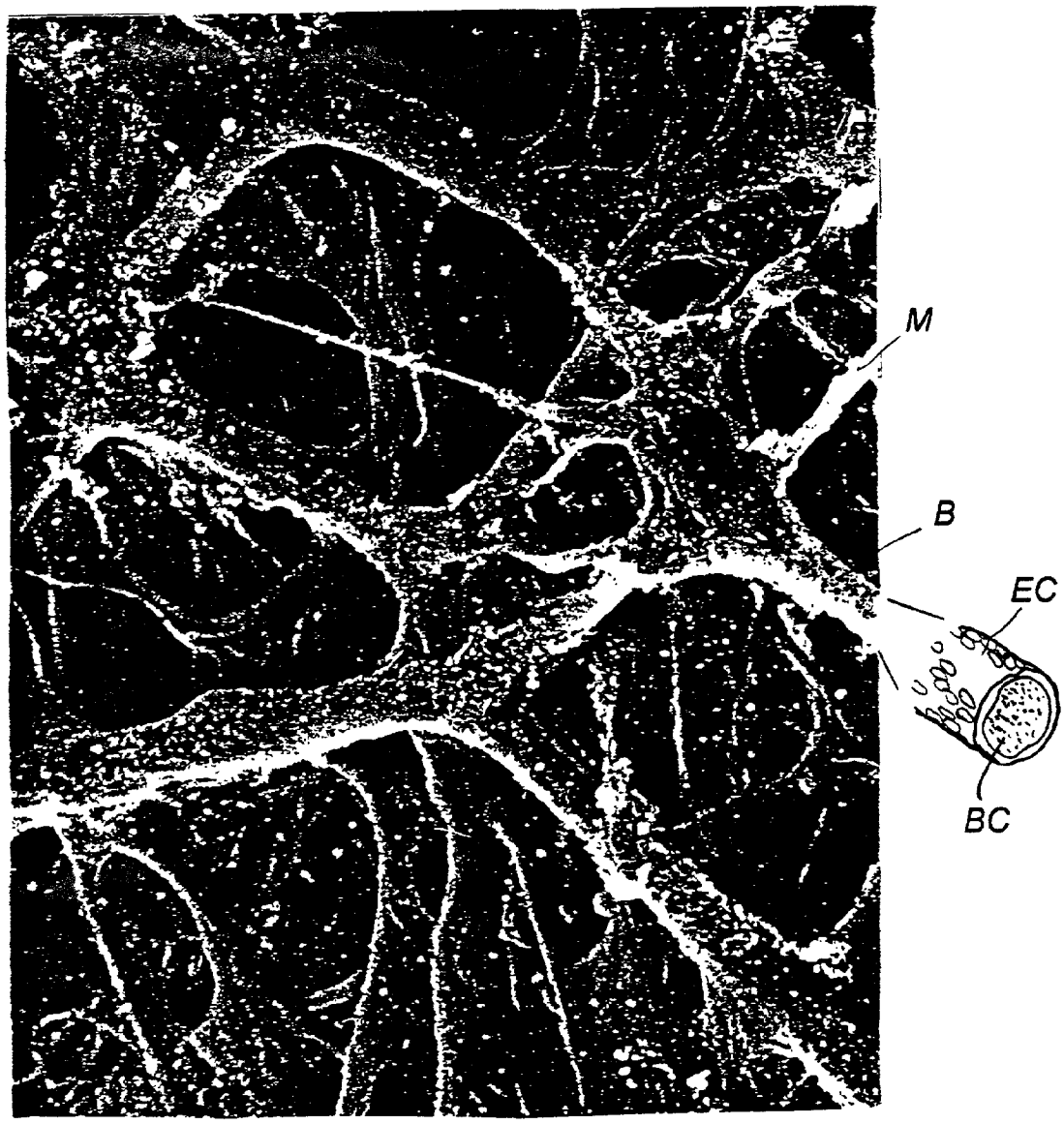


FIG. 1B

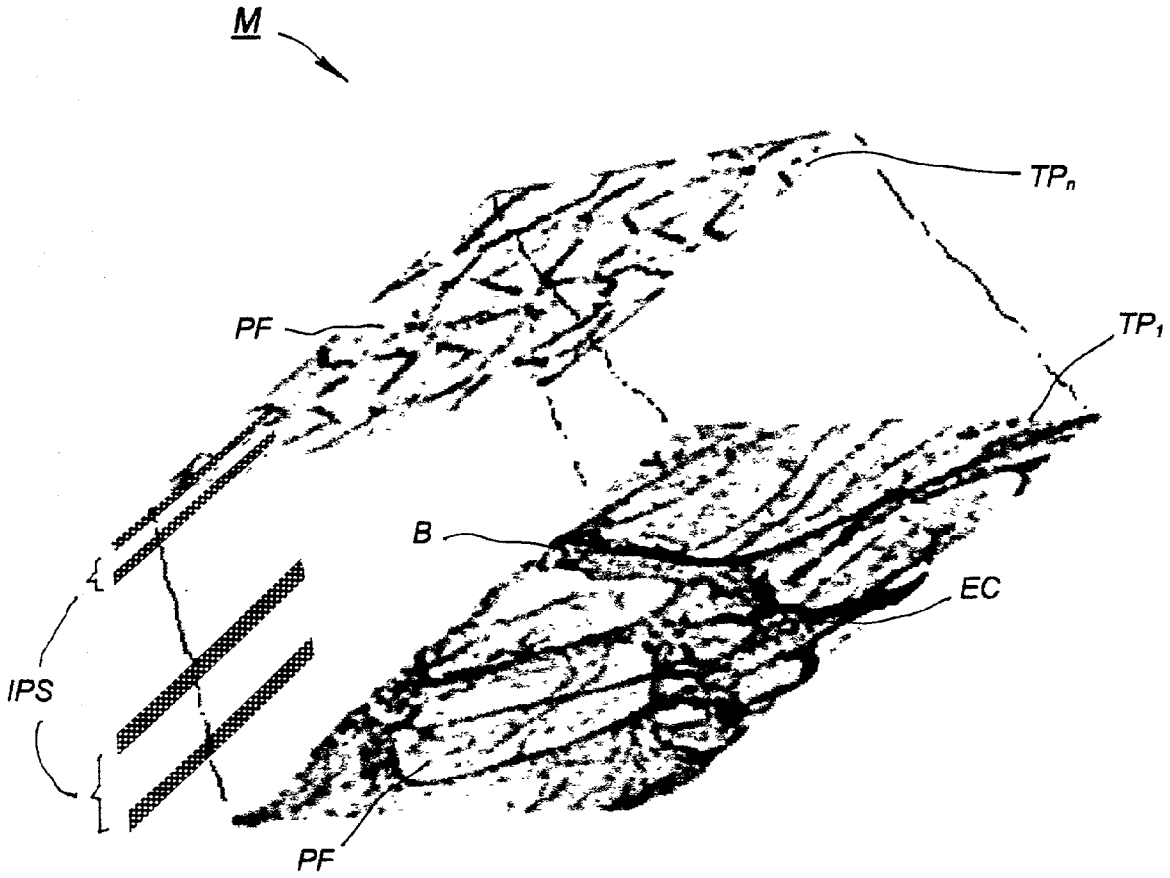


FIG. 1C

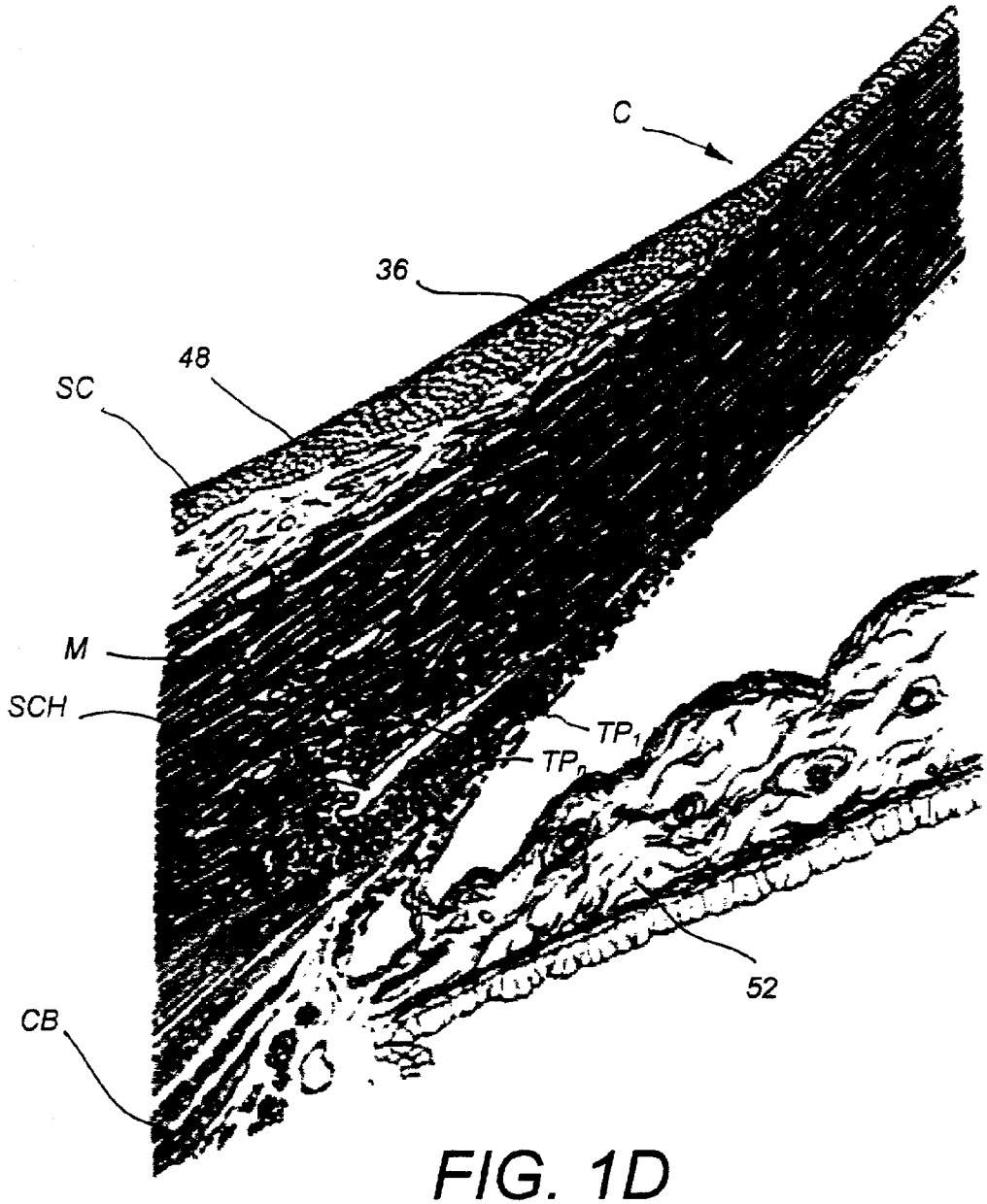


FIG. 1D

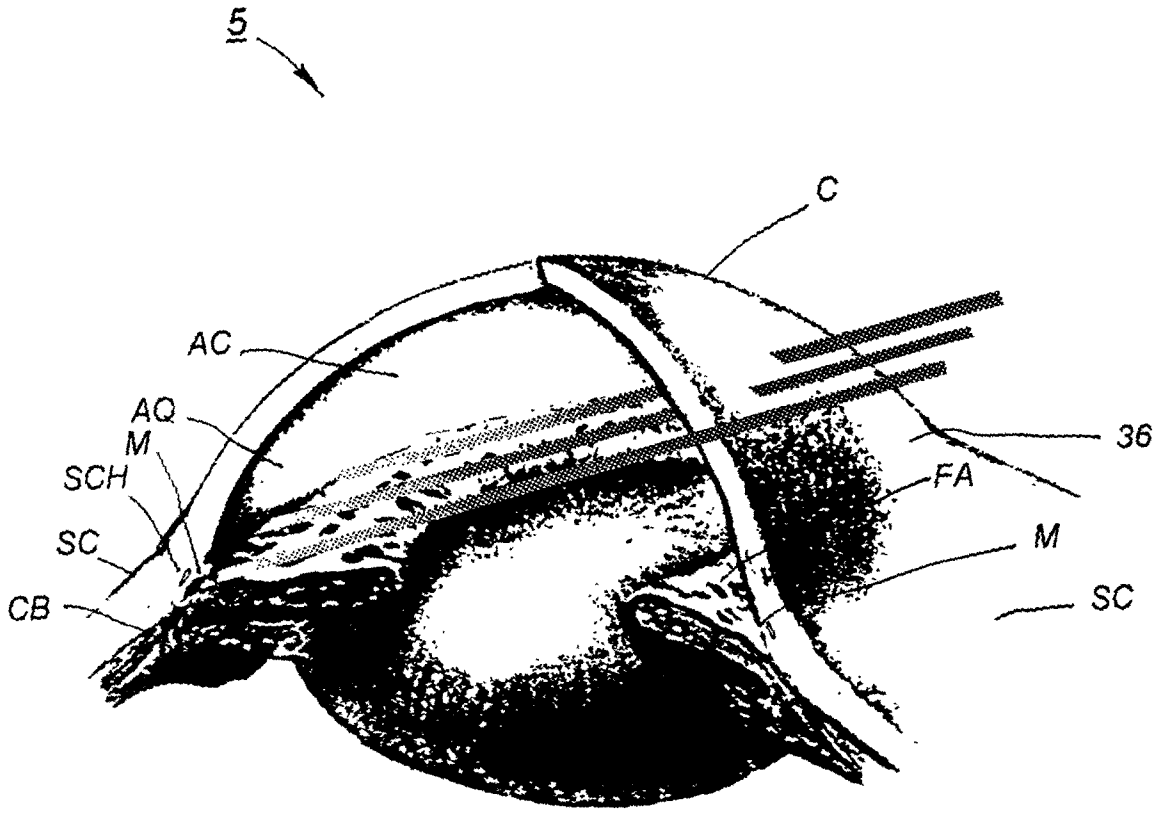


FIG. 2A
(PRIOR ART)

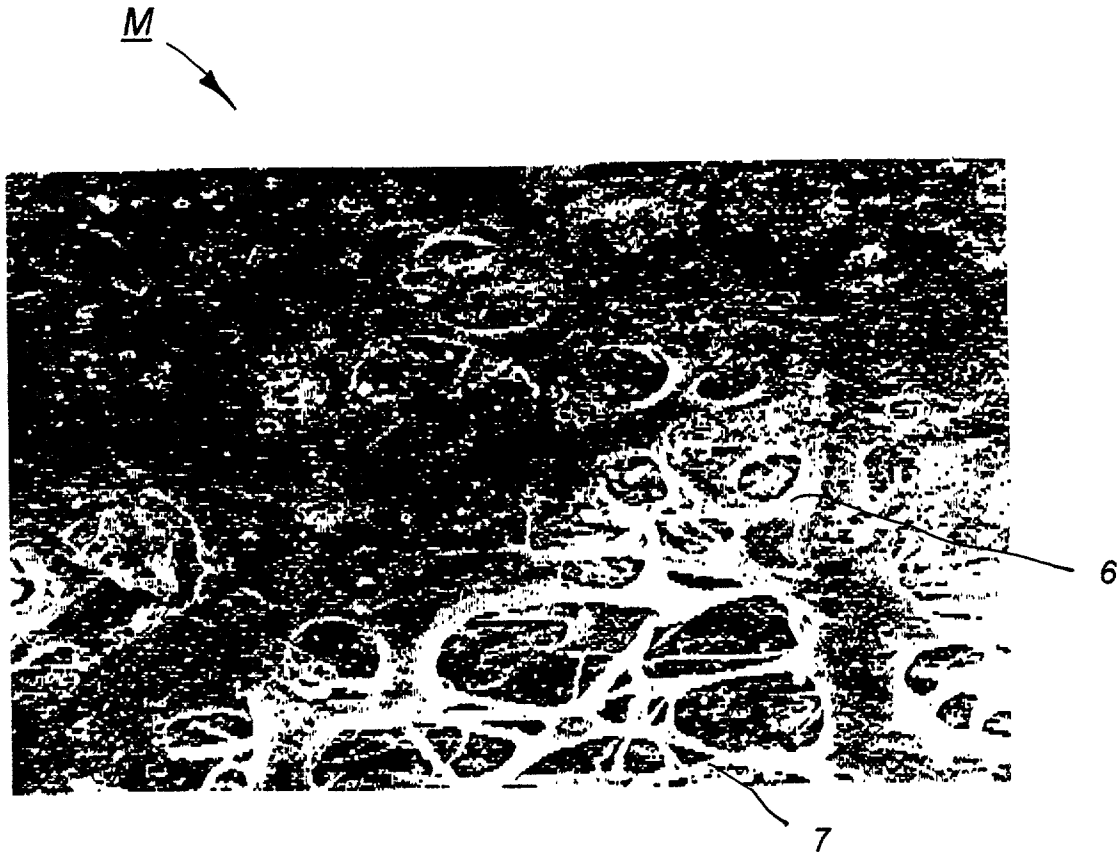


FIG. 2B
(PRIOR ART)

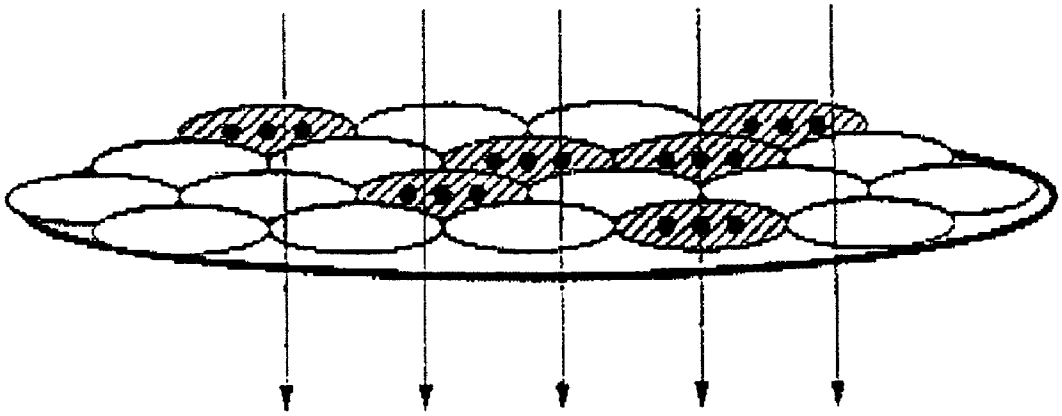


FIG. 3

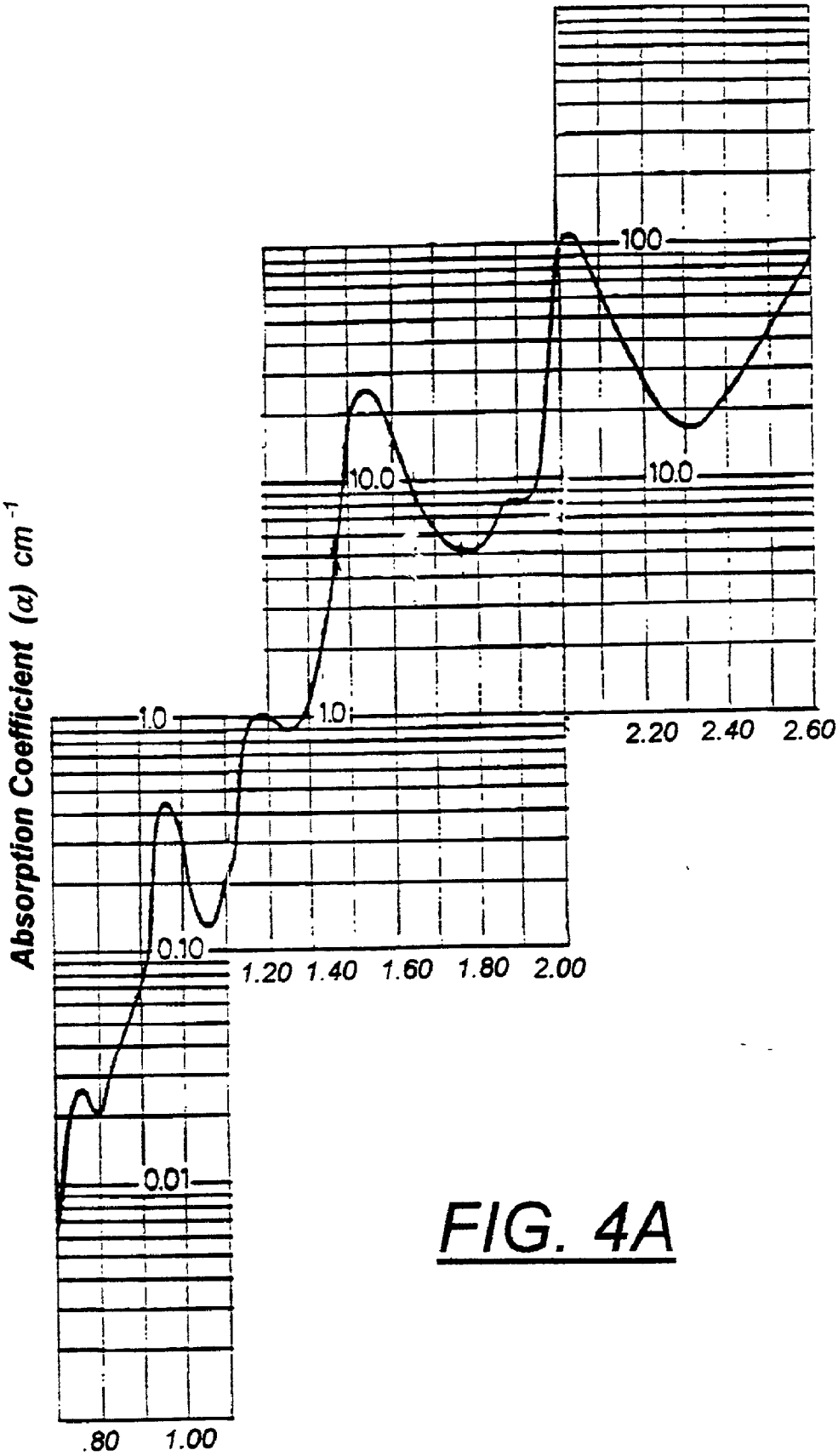

Absorption Coefficient (α) cm⁻¹
100
10.0
10.0
1.0
1.0
0.10
0.01
2.20 2.40 2.60
1.20 1.40 1.60 1.80 2.00
.80 1.00

FIG. 4A

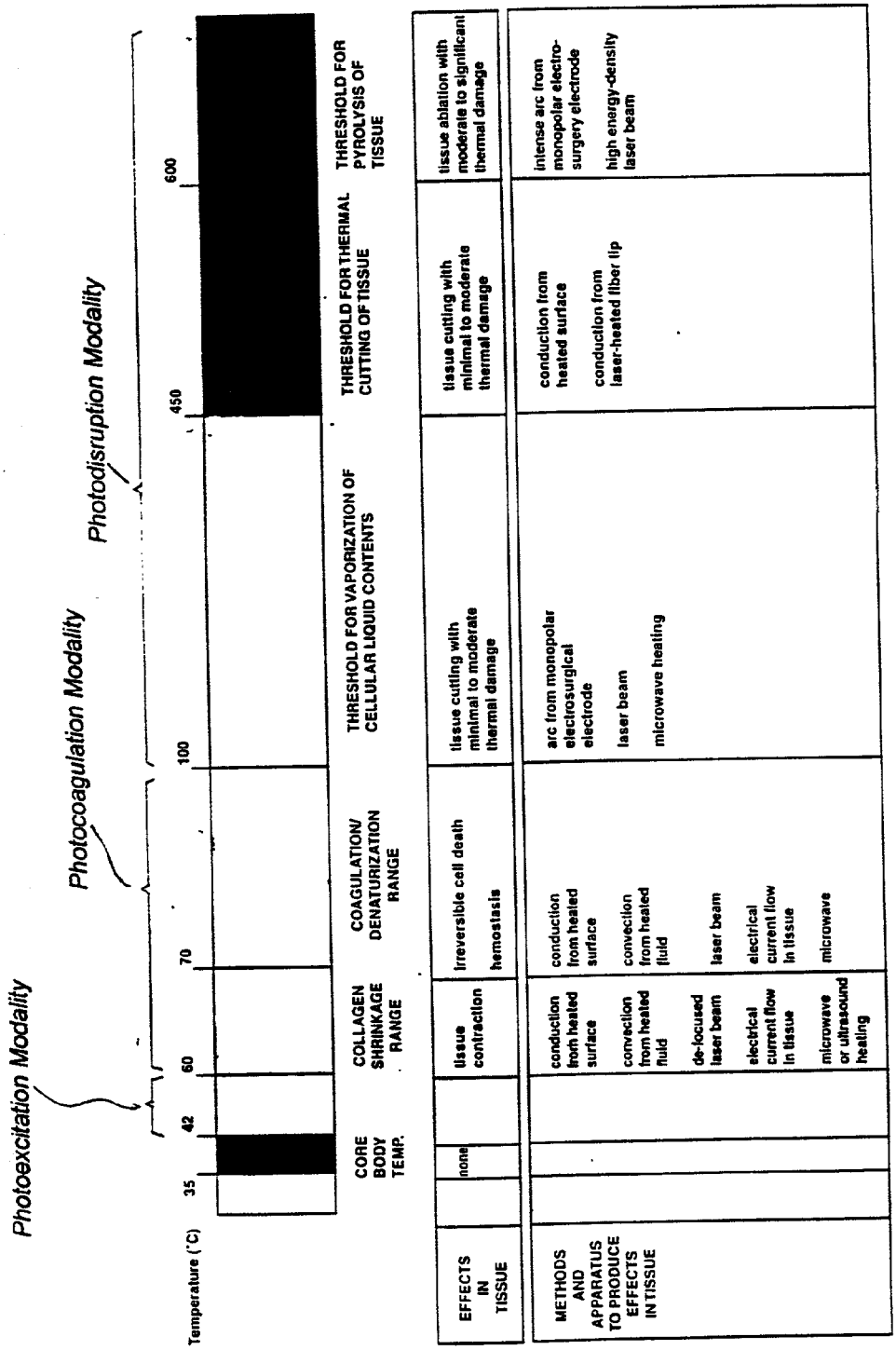

Photoexcitation Modality
Photocoagulation Modality
Photodisruption Modality
Temperature (°C)
35
42
60
70
100
450
600
CORE BODY TEMP.
COLLAGEN SHRINKAGE RANGE
COAGULATION/ DENATURIZATION RANGE
THRESHOLD FOR VAPORIZATION OF CELLULAR LIQUID CONTENTS
THRESHOLD FOR THERMAL CUTTING OF TISSUE
THRESHOLD FOR PYROLYSIS OF TISSUE
EFFECTS IN TISSUE
none
tissue contraction
irreversible cell death
hemostasis
tissue cutting with minimal to moderate thermal damage
tissue cutting with minimal to moderate thermal damage
tissue ablation with moderate to significant thermal damage
METHODS AND APPARATUS TO PRODUCE EFFECTS IN TISSUE
conduction from heated surface
convection from heated fluid
de-focused laser beam
electrical current flow in tissue
microwave or ultrasound heating
conduction from heated surface
convection from heated fluid
laser beam
electrical current flow in tissue
microwave
arc from monopolar electrosurgical electrode
laser beam
microwave heating
conduction from heated surface
conduction from laser-heated fiber tip
intense arc from monopolar electro-surgery electrode
high energy-density laser beam

FIG. 4B

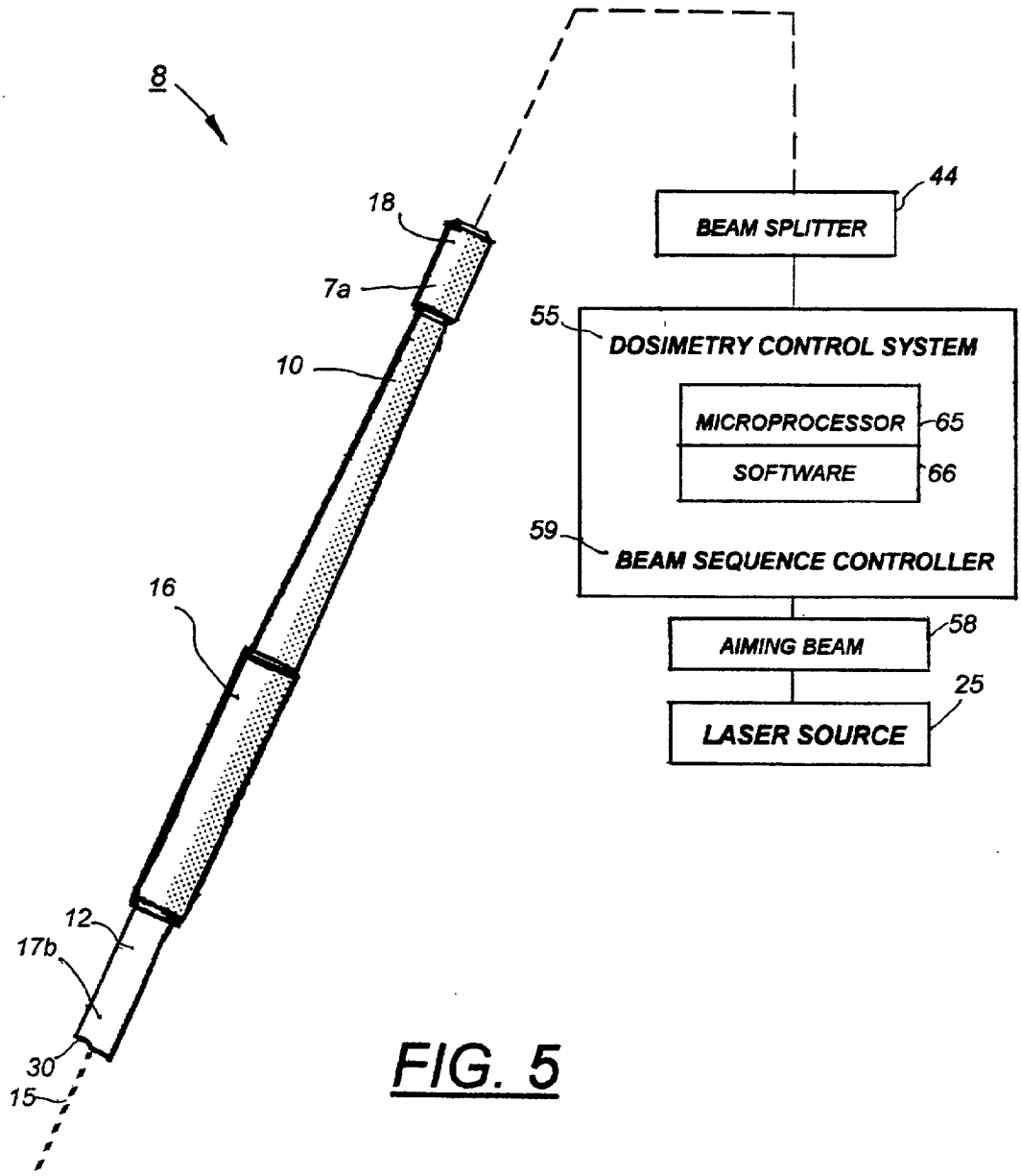

8
18
7a
10
16
12
17b
30
15
44
BEAM SPLITTER
55
DOSIMETRY CONTROL SYSTEM
MICROPROCESSOR
65
SOFTWARE
66
59
BEAM SEQUENCE CONTROLLER
58
AIMING BEAM
25
LASER SOURCE

FIG. 5

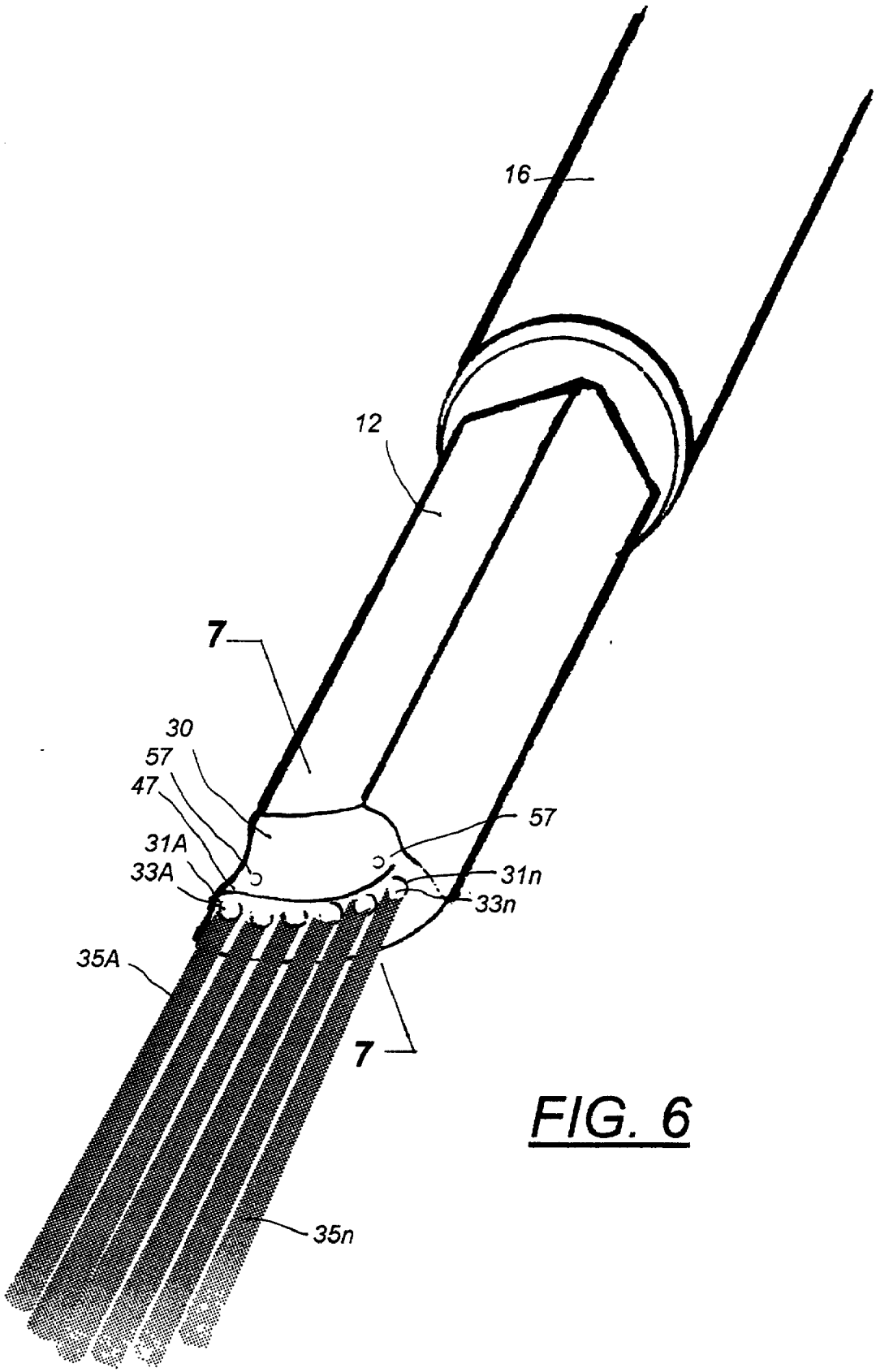


FIG. 6

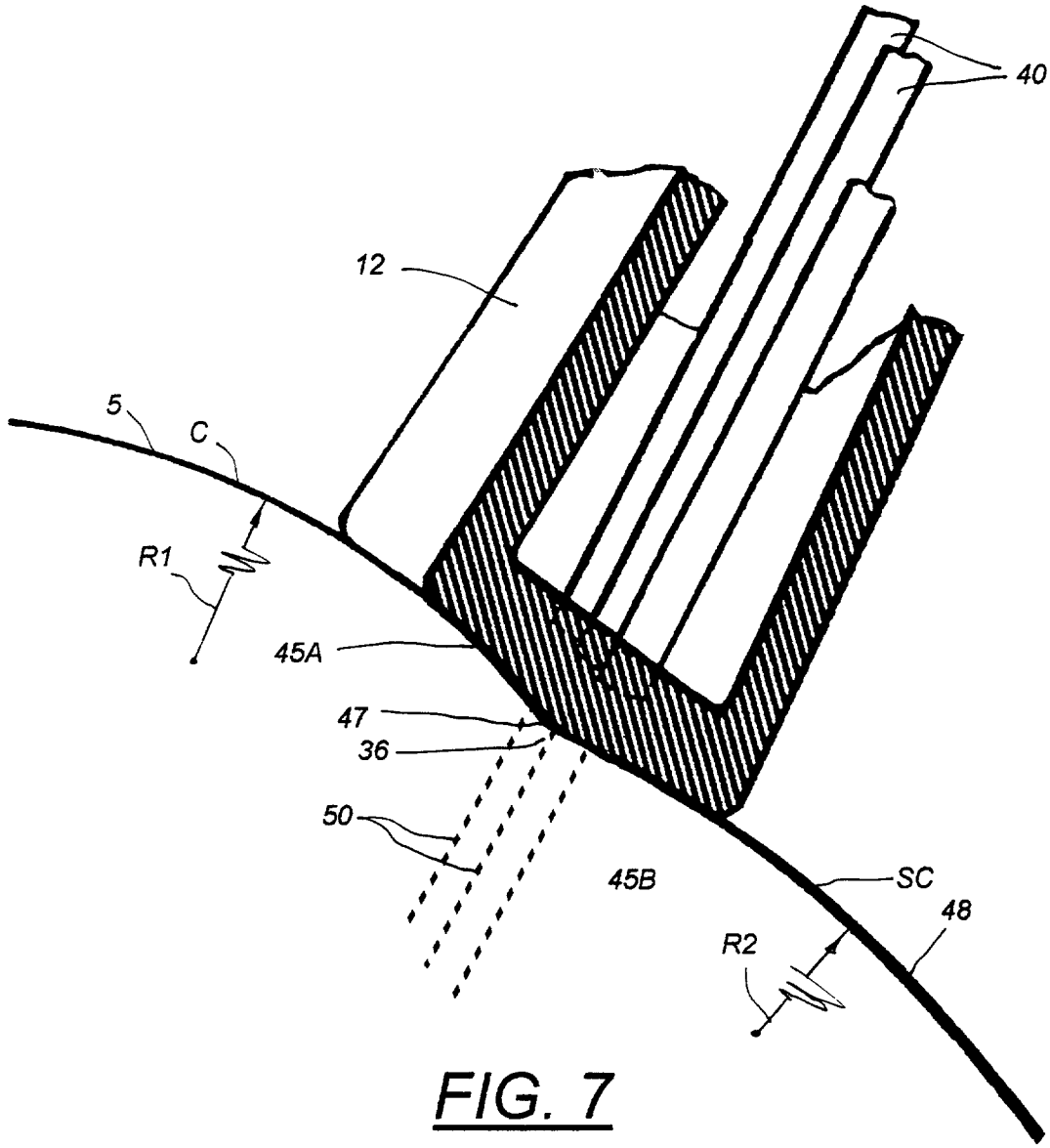


FIG. 7

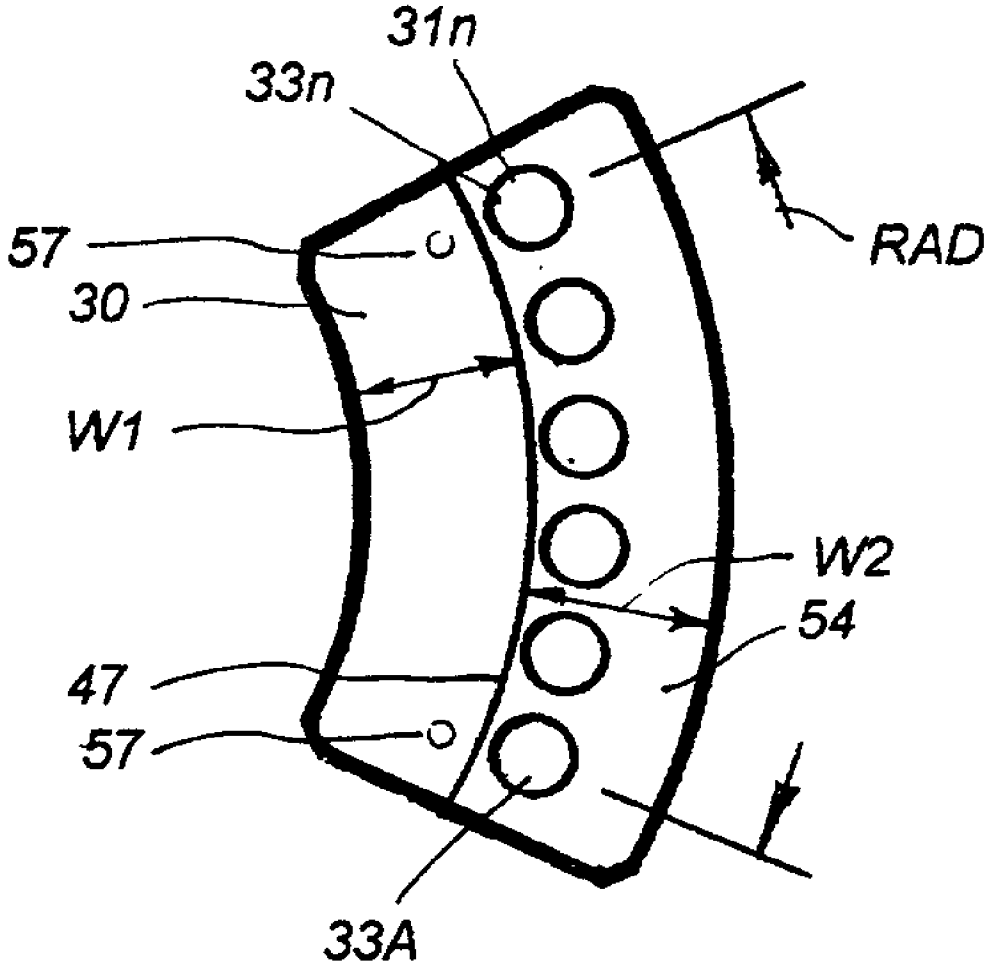


FIG. 8

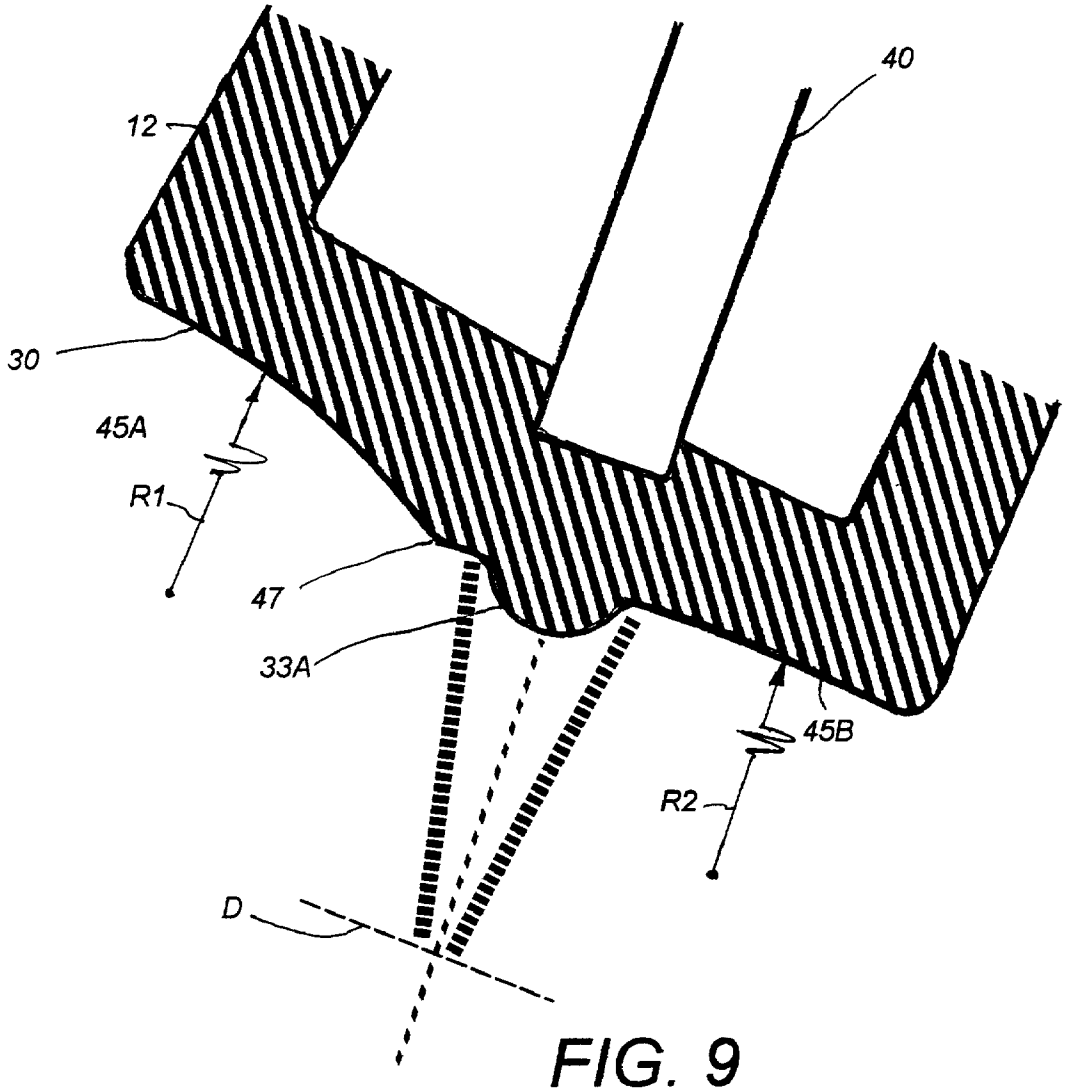


FIG. 9

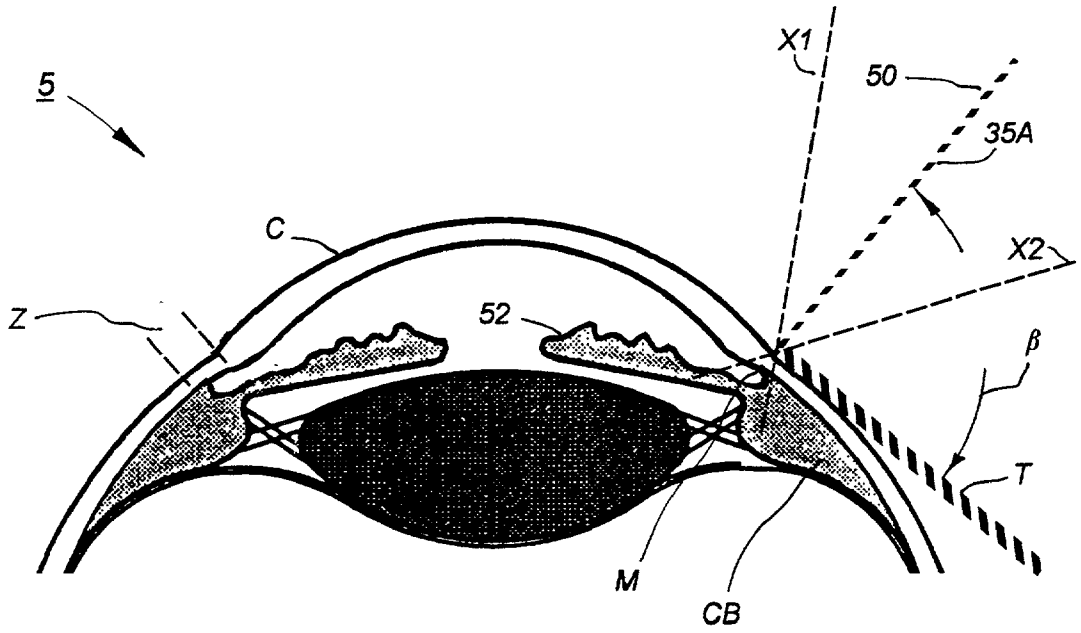


FIG. 10

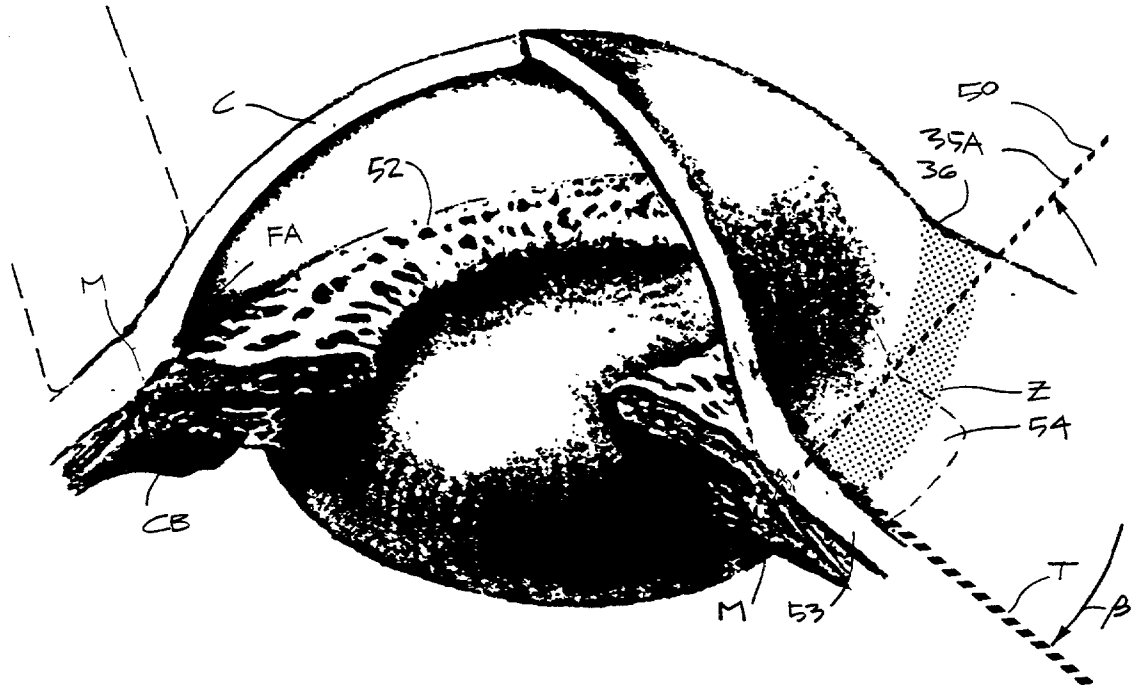


FIG. 11

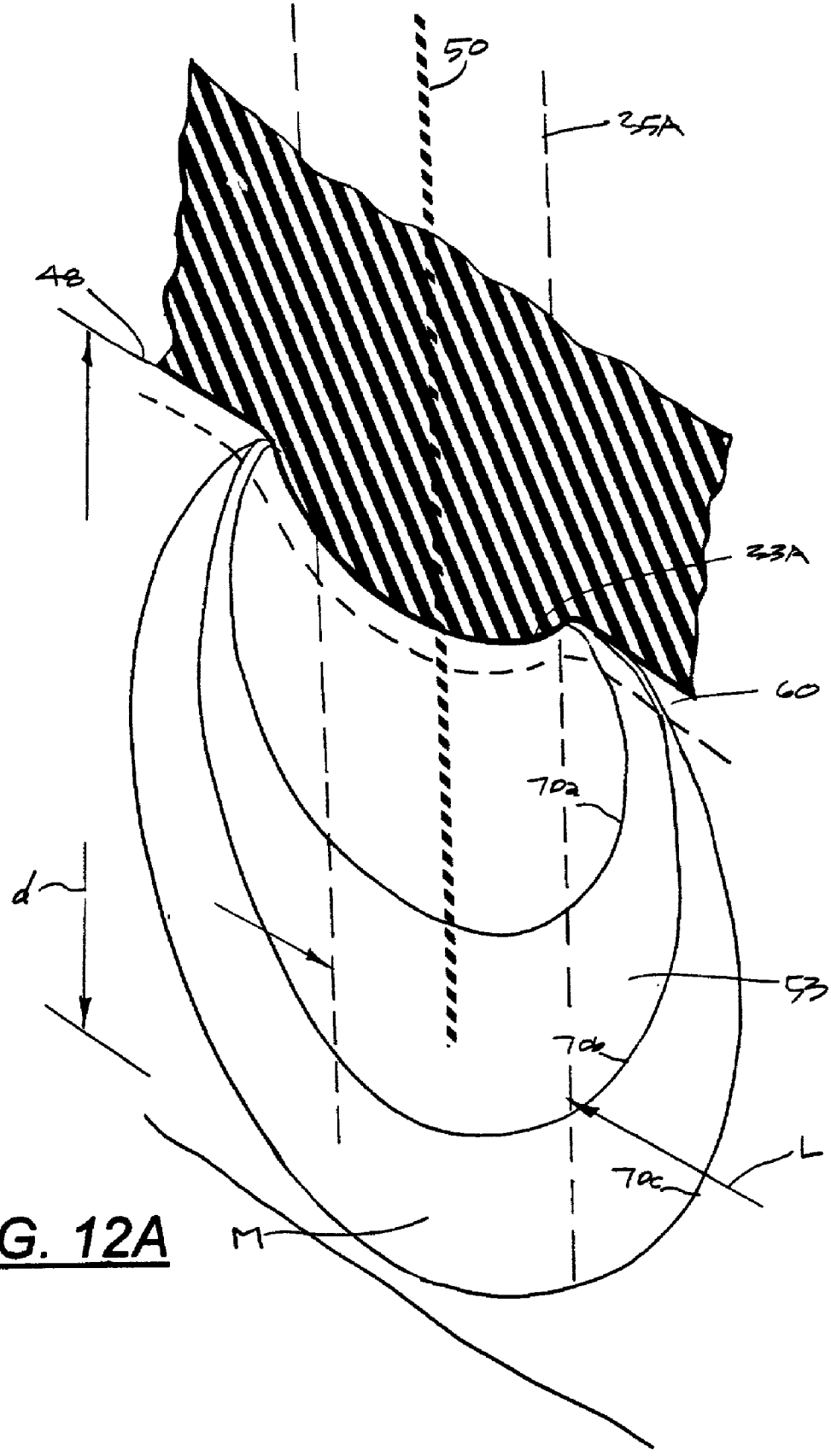


FIG. 12A

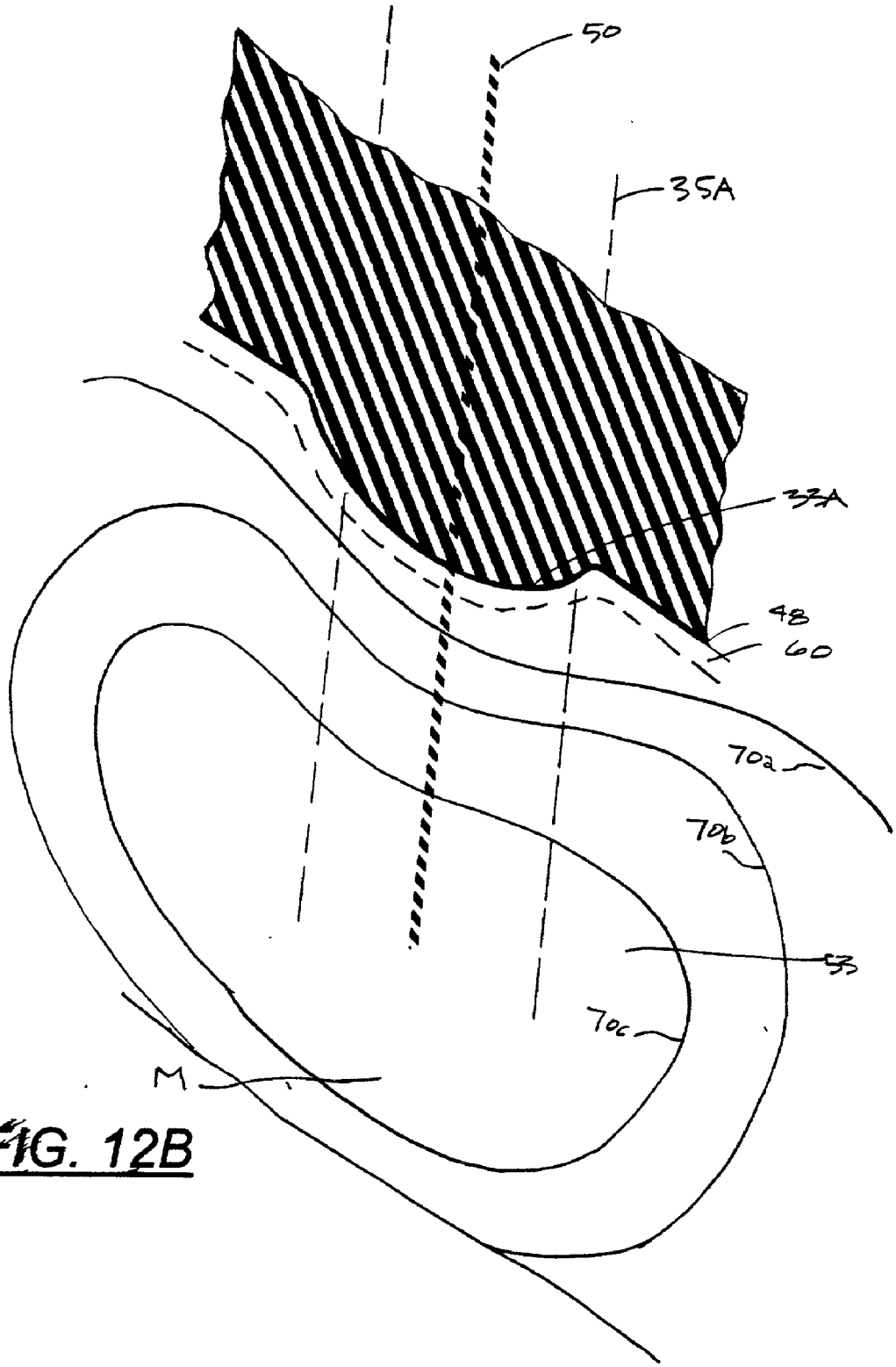


FIG. 12B

DEVICES AND TECHNIQUES FOR LIGHT-MEDIATED STIMULATION OF TRABECULAR MESHWORK IN GLAUCOMA THERAPY

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application is a Continuation of U.S. patent application Ser. No. 09/102,533 filed Jun. 22, 1998 titled "Devices and Techniques for Light-Mediated Stimulation of Trabecular Meshwork in Glaucoma Therapy."

BACKGROUND OF THE INVENTION

[0002] 1. Field of the Invention

[0003] The present invention relates to the field of medical therapeutics and more specifically relates to the field of glaucoma and ocular hypertension therapy utilizing novel instruments and techniques for opto-thermal mediation of a patient's trabecular meshwork for enhancing the mitotic rate of endothelial meshwork cells and for reduction of biostructural laxity within the meshwork, which meshwork biocharacteristics may be subject to cell-division inhibitions and/or other degradations.

[0004] 2. Description of the Related Art

[0005] Glaucomas comprise a group of debilitating eye diseases that are the leading cause of blindness in the United States and around the world. The pathophysiological mechanisms of glaucomas are not fully understood. The principal sign of the disease is elevated intraocular pressure (IOP). Such elevations of IOP ultimately can cause damage to the optic nerve head and result in impairment to, or loss of, normal visual function. It is known that elevated IOP is caused by an excess of fluid or aqueous AQ within the eye, which is continually produced by the ciliary body CB and drained through the trabecular meshwork M to leave the eye or globe **5** (see FIGS. **1A-1D**). The excess intraocular fluid generally results from blockage or impairment of the normal drainage from the anterior chamber AC via the trabecular meshwork M. The meshwork consists of about 10 to 25 layers of perforated trabecular plates ($TP_1 \ldots TP_n$) or sheets around the filtration angle FA of the anterior chamber AC, having a width of about 1,000 μm to 1,500 μm (1.0 mm. to 1.5 mm.) in a circumference ranging from 35,000 to 40,000 μm. FIGS. **1A-1B** show electron micrographs of trabecular plates TP with **FIG. 1B** including a representation of an endothelial cell layer EC of trabecular beam B with the beam core BC believed to be predominantly collagen and GAGs (glucosaminoglycans) or ground substance. **FIG. 1C** illustrates that each successively deeper plate (more anterior plate) of the meshwork M has smaller perforations PF or openings between the beams B than more exposed (posterior) trabecular plates. Further, the intraplate spacing IPS diminishes with the successively deeper plates (**FIG. 1C**). The meshwork M thus serves as a filtration mechanism wherein cellular detritus, etc. in the aqueous outflow is captured before it passes into Schlemm's canal SCH where the aqueous is transported away form the eye (**FIG. 1D**). The meshwork M lies about 750 μm to 950 μm beneath the anterior surface of the sclera SC.

[0006] A number of ophthalmic disease conditions are related to the trabecular meshwork and can be linked to distinct processes or pathological conditions within a patient's eye. Any disease of the trabecular meshwork shares the characteristic of elevating IOP. Chandler et al. described many forms of glaucoma, the principal ones being: primary open-angle glaucoma (POAG); progressive low-tension glaucoma; pigment dispersion and pigmentary glaucoma; angle-closure glaucoma; combined open-angle and angle-closure glaucoma, exfoliation and open-angle glaucoma; angle-closure glaucoma due to multiple system cysts of iris and ciliary body; angle-closure glaucoma secondary to occlusion of the central retina vein; angle-closure glaucoma secondary to bilateral transitory myopia; ghost-cell glaucoma; lens-induced glaucoma; glaucoma due to intraocular inflammation; neovascular glaucoma; glaucoma associated with extraocular venous congestion; essential atrophy of the iris with glaucoma. among others. (Chandler, et al., *Glaucoma,* 3rd Ed., Lea & Febliger, Phila. (1986)) In all of the above-listed glaucoma syndromes, elevated IOP results from an increase in resistance to aqueous humor outflows through the trabecular meshwork.

[0007] In terms of incidence, primary open-angle glaucoma (POAG) is the most prevalent form of the disease affecting up to 0.5% of the population between ages of 35 to 75. The incidence of glaucoma rises with age to over 6% of the population 75 years are older. One identifiable component of the POAG syndrome is the loss of endothelial cells within the meshwork which is associated with a degeneration of the normal trabecular biostructure. It is known that the human aging process itself leads to a progressive loss of trabecular endothelial cells EC which compromises normal aqueous outflows therethrough. When examined in tissue cultures, degraded endothelial tissue from POAG patients appears similar to that of "aging" individuals.

[0008] Other characteristics believed common to POAG (as well as many other glaucomas listed above) relate to a biostructural obstructive syndrome of the trabecular plates TP, for example, resulting from compression of the plates into a matt-like form that reduces intraplate spacing IPS (**FIG. 1C**). This factor reduces the capacity of the meshwork to act as a filtering mechanism and may develop after the meshwork is clogged with cellular detritus, pigments, etc. Such an obstructive syndrome, it is believed, also is characterized by increased laxity of the trabecular beams B allowing their collapse which thus reduces intraplate spacing. The most likely causes of the meshwork degradations described above may be cumulative stresses from various factors (e.g., oxidative, phagocytic, glucocorticoidal stresses). The fact that increased outflow resistance appears in the non-glaucoma "aging" population further suggests that both trabecular endothelial cellular processes and an obstructive meshwork syndrome play significant roles in decreasing aqueous outflows.

[0009] The normal IOP for humans usually ranges from about 10 to 22 mm. Hg. (1.3-2.7 kilopascals) and is maintained by a balance in the aqueous production by the ciliary body CB, inflows to the anterior chamber AC and outflows therefrom. As described above, in a normal eye, the aqueous drains from the anterior chamber through the meshwork into Schlemm's canal SCH, through which it leaves the eye. In patients in a glaucomous state, besides passing through Schlemm's canal, the aqueous may also pass through the ciliary muscle CM into the suprachoroidal space and finally leave the eye through the sclera SC (**FIG. 1D**).

[0010] For purposes of description, the intraocular pressure (IOP) in a human can be defined by a formula of the following type:

$$IOP=P_e+(F_t-F_{uv})\times R:(TM_{cep},TM_{sp},TM_{br})$$

[0011] where P_e is the episcleral venous pressure (generally regarded as being around 9 mm. Hg.); F_t is the total outflow of the aqueous humor from the anterior chamber, F_{uv} is the fraction of aqueous passing by the uveoscleral route; R is the resistance to outflow of aqueous through the trabecular meshwork into Schlemm's canal, which can be considered to be functionally related to (i) the vitality of trabecular endothelial cellular cellular and enzymatic processes (TM_{cep}), (ii) the dimensions of intraplate spacing between (TM_{ips}) relative to a norm, and (iii) the trabecular beam resiliency (T_{br}) or biostructural tension within the meshwork under the pressure of aqueous outflow therethrough. Such a formula is useful for understanding the targets of various prior art therapies, if not for use as an actual mathematical model.

[0012] Among several therapies targeted at various elements of the above equation, two forms of treatment are common: (i) medical or drug therapies, and (ii) trans-corneal laser irradiation of the trabecular meshwork via a goniolens (see **FIG. 2A**). In medication therapies, the objective may be to lower IOP by either of several routes: reducing the aqueous flow total (F_t in the above equation); increasing uveoscleral flow (F_{uv} in above equation); or altering resistance to outflow (R), by stimulating endothelial cellular processes (TM_{cep}) which is believed to act on outflow resistance. Drug therapies have the disadvantages of requiring a lifelong treatment; causing significant side effects; being very costly (between $1,000-$2,000/yr.); and being unavailable or unaffordable in lesser developed countries of the world where the incidence of glaucoma is highest.

[0013] In the laser therapies, ALT (argon laser trabeculoplasty) and SLT (selective laser trabeculoplasty) have been developed which both rely on a trans-corneal approach to the posterior surface of the meshwork. Introduced in the 1980's, ALT uses an argon laser operating at a wavelength (λ) of 488 nm to 514.5 nm with a long pulse duration of about 0.10 second and a power range of from 500-1000 mW to irradiate a series of about 50 spots only around the 180° of the meshwork (see **FIG. 2A**). In ALT, the ophthalmologist utilizes a goniolens to direct laser beam strikes on the exposed surface of the trabecular plates TP. The causative mechanisms of ALT have never been clearly understood. It has been proposed that each ALT beam's incidence on the meshwork causes a burn or a melt and results in the formation of scar tissue that contracts (or tensions) a portion of the meshwork around the burn (cf. TM_{br} or resiliency of beam B in above formula). According to another view, the ALT meshwork burns cause a wound healing response resulting in significant cell division and the transient repopulation of endothelial meshwork cells, at least in zones around the burns (cf. TM_{cep} above). **FIG. 2B** shows an electron micrograph of an ALT meshwork burn indicated at **6**, which may tension the meshwork at the burn periphery indicated at **7**. A principal disadvantage of ALT is that it can only be performed twice on an eye—once in the superior (or nasal) 180 degrees of the meshwork and once in the inferior (or temporal) 180 degrees. The laser melts are too significant to repeat the treatment in the same portion of the meshwork.

[0014] The more recently developed trans-corneal laser approach is SLT, which uses a short-pulse, frequency-doubled, 530 nm Nd:YAG laser with pulse duration of 3 nanoseconds and energy levels that range from 0.60 mJ to 1.20 mJ. The SLT modality is called "selective photothermolysis" by its inventor (Dr. M. Latina) wherein the proposed wavelength is absorbed by endogenous pigment within the meshwork which kills (or lyses) the pigmented cells without damaging the non-pigmented cells (see U.S. Pat. No. 5,549,596). In theory, the short pulses allow heat to dissipate from the absorbing pigmented cells before killing adjacent cells (see **FIG. 3**). The SLT inventor proposes that the causative mechanisms of increasing aqueous outflows relate to (i) an inflammatory response in the meshwork that results in activation of enzyme systems that clean up the meshwork, and (ii) a mild expansion of the meshwork plates or perforations by killing pigmented cells with a photothermal or microcavitation effect (**FIG. 3**). The following table compares the ALT and SLT parameters.

	λ	Pulse Duration	Power	Beam Size	Treatment Area
ALT	488–514.5 nm	0.1 second	500–1000 mW	50 μm	50 spots/180°
SLT	530 nm	3 nanoseconds	0.6–1.2 mJ	300–400 μm	50 spots/180°

[0015] Several disadvantages are associated with the ALT/SLT modalities. First, both systems approach the meshwork through the anterior chamber AC by means of a goniolens. For this reason, the wavelengths must be selected from a portion of the spectrum that penetrates through the cornea C and aqueous AQ without the light energy being absorbed and extinguished—a distance of about 4 mm. to 8 mm. (4000 μm to 8000 μm). This factor greatly limits the choice of possible wavelengths—each of which has a different absorption coefficient in water (see **FIG. 4A**). The requirement of using a goniolens along with a laser aiming beam also makes the ALT/SLT approach technique dependent—making the therapy available only to highly skilled surgeons.

[0016] A second disadvantage the ALT/SLT modalities relates to the lack of exact understandings of the causative mechanisms for improving outflow facility. Since ALT has effects that last for about 5 years at most—and can be repeated only once—the medical and surgical communities have not developed a consensus about sequencing medical and surgical therapies. Glaucoma is a disease state that requires lifelong management. Some physicians propose that ALT be resorted to only after drug therapies have lost their effectiveness; other physicians propose ALT as a first line of defense in order to delay a lifetime of drug therapy and the attendant side effects.

[0017] Other significant disadvantages of ALT/SLT relate to the fact that both deliver similar photothermal effects to a limited depth within the trabecular plate structure. That is, the ALT/SLT causative mechanisms—no matter what they are—probably only operate within the trabecular plates TP most exposed to the incident beam which thus absorb the beam's photonic energy. This factor suggests that only the first few plates (most posterior plates) exposed to the anterior chamber AC are affected by such energy delivery—perhaps only about 10%-20% of the larger dimensioned trabecular plates. It is postulated that the underlying (anterior) trabecular plates that have smallest dimensioned perforations PF and the least intraplate spacing IPS are degraded to the greatest degree and thus play the most significant role in increasing IOP by clogging the pathways to Schlemm's canal (see **FIG. 1D**). Yet, these most anterior meshwork regions probably remain untreated by ALT and SLT.

[0018] Further, studies have shown that ALT is not effective in all patients, and actually increases IOP in over 20% of patients. Additionally, in recent SLT patients, the following complications have been documented: uveitis in the form of iritis in virtually all treated eyes; corneal burns in up to 25% of treated eyes; and anterior synechiae or adhesions due to the significant absorption of light energy in the pigmented cells of the meshwork.

[0019] What is needed is an improved technique for effecting biostructural changes in the trabecular meshwork to facilitate aqueous outflows that provides: (i) means for stimulating endothelial cell division to cause cell repopulation and rejuvenation within the trabecular plate structure; (ii) means for inducing a slight inflammatory or wound healing response to activate enzymatic systems such as stromolysin and metalloproteases that may help clean up the meshwork; (iii) means for causing the desired biostimulative effects without photocoagulation, photodisruption or photothermolysis of endothelial layers of the meshwork as in ALT/SLT; (iv) MIS (minimally invasive surgical) means for causing the desired effects in a repeatable maintenance therapy that can continue over the lifetime of the glaucoma patient; (v) MIS means for meshwork treatment that can be evaluated in all patients before resorting to drug therapies; (vi) MIS means for treating 360° of the meshwork instead of 180° or less; (vii) means for causing the desired effects substantially equally on all trabecular plates from the most posterior to the most anterior, (viii) MIS means simultaneous treatment of a substantial arc of the meshwork with a device in a single treatment position rather than time-consuming treatment in a series of spots; (ix) MIS means for biostimulating the trabecular structure in the many forms of glaucoma (other than POAG) that are not possible with a goniolens and laser strikes through the anterior chamber, (x) MIS means for treating the meshwork without risk of any corneal burns; and (xi) MIS means for treating the trabecular structure that is not technique-dependent and capable of being performed by optometrists or other lesser-skilled health care professionals in the lesser developed countries of the world.

SUMMARY OF THE INVENTION

[0020] The laser system and handpiece of the present invention are particularly adapted for use in elevating the temperature of a patient's trabecular meshwork for purposes of stimulating cellular processes. The system is adapted for a novel transscleral approach (instead of trans-corneal) and is called opto-thermal transscleral trabeculoplasty (or OT^3). The present invention provides cooperating means to develop biostimulative opto-thermal effects in a patient's trabecular meshwork, including a working face for contacting the sclera and aligning the axes of a plurality of beams' propagation toward the meshwork, and a laser energy source having a wavelength range appropriate for penetration to the meshwork. Further, the invention includes an optional dosimetry control system for terminating or controlling energy delivery based on feedback signals from a temperature sensor array in the working face.

[0021] The working face has a 1st corneo-spherical receiving portion and a 2nd sclero-spherical receiving portion for positioning the face in contact with the globe with a footprint dimension that is large enough to stabilize the working face at a proper treatment angle. Within the working face are a plurality of light beams emitters connected with fiber optics to the laser source. The emitter axes at which the beams propagate are provided at a predetermined angle relative to the 1st and 2nd part-spherical receiving portions of the working face, for example a tangent to the sclera.

[0022] Research and modeling indicates that the preferred wavelength ranges for opto-thermal biostimulation of the trabecular plates lie in the near-infrared portion of the spectrum, preferably in ranges of about 1.30 μm to 1.40 μm or about 1.55 μm to 1.85 μm. It is believed that absorption coefficients related to the above ranges, or a subset of the such ranges, will prove best suited for such trabecular meshwork stimulation. The depth of absorption of such wavelength ranges will extend through most, if not all, of the thickness of the sclera (750 μm to 950 μm). For the proposed method of trabecular biostimulation, the targeted region is elevated in temperature to a range between about 40° C. to 55° C. for a period of time ranging from about 1 second to 120 seconds or more. More precisely, the desired range would be between about 40° C. to 50° C. for such time periods. The optimal therapeutic effects will result from a balance of appropriate light energy wavelength, power level, exposure duration, together with the thermal absorption characteristics of the heat-sink working face.

[0023] The light-mediated trabecular biostimulation techniques proposed herein differ greatly from other common laser-tissue interactions. The proposed technique develops only low energy densities in the absorbing medium as can be seen in the chart of **FIG. 4C** where various temperature levels indicate different effects on tissue. Such biostimulative effects are caused by a photoexcitation modality proposed herein which differs significantly from typical modalities of laser-tissue interactions: the photocoagulation and photodisruption modalities. In the photocoagulation modality, photons elevate tissue temperatures sufficient to coagulate, denature, shrink, desiccate or cause thermolysis of tissues such as in ALT and SLT (see **FIG. 4B**). In the photodisruption modality, photons of a light energy beam disrupt the chemical bonds of atoms or molecules making up the medium, with the end result being that the medium is vaporized as indicated in **FIG. 4B**. In the present invention, the objective is to elevate meshwork to temperatures well below those used to practice the photodisruption or photocoagulation modalities. The photoexcitation modality proposed herein uses far less energetic photons in the above-

described ranges which will cause atoms and molecules in the meshwork or aqueous AQ engulfing the meshwork to vibrate or resonate. The excitement or resonant effect will elevate the temperature within the absorbing medium (meshwork) without disrupting any intramolecular or intermolecular chemical bonds, such as would occur temperatures above about 60° C. which can cause denaturation of tissue.

[0024] The dosimetry control component of the invention can be adapted to control exposure duration, power levels and timing of energy delivery in various operational modes. A basic mode of operation can follow a pre-set program of timing and power based on treatment experience. A preferred operational mode is based on a feedback-control system that receives signals from a thermal sensor in the working end of the device. Another preferred operational mode is based on a feedback-control system and a beam sequencing controller that sequences beam delivery between or among non-adjacent emitter locations to optimize temperature elevation in the meshwork while minimizing temperature elevation in the anterior and mid-sclera.

[0025] In general, the present invention advantageously provides a system having an arrangement of a plurality of n spaced-apart beam emitters in a radius that corresponds to that of the trabecular meshwork of a patient's eye for transsclerally treating an angular portion of the meshwork with a single energy delivery.

[0026] The invention advantageously provides a device having a working face with geometry and part-spherical receiving forms for receiving portions of a patient's cornea and sclera to insure the light energy beams are directed toward the trabecular plates.

[0027] The invention advantageously provides a device having n lens elements to insure that the light energy beams penetrate and are absorbed substantially about the region of the trabecular meshwork.

[0028] The invention advantageously provides a device and method for creating a reverse thermal gradient in the sclera by lowering the temperature of the anterior surface of the scleral with a heat-sink working face to protect the scleral epithelium.

[0029] Additional features and advantages of the device and method of the present invention will be understood from the following description of the preferred embodiments, which description should be taken in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0030] **FIGS. 1A** is an electron micrograph of the trabecular meshwork of a patient's eye.

[0031] **FIG. 1B** is an enlarged electron micrograph of the trabecular meshwork of **FIG. 1A** with a schematic sectional view of a trabecular beam.

[0032] **FIG. 1C** is a sectional representation of the trabecular plate layers of meshwork of **FIG. 1A**.

[0033] FIGS. 1D-1E are sectional views of a patients' eye or globe showing the location of the trabecular meshwork.

[0034] **FIG. 2** is a view of a prior art method of laser treatment of trabecular plates.

[0035] **FIG. 2B** is an electron micrograph of a laser melt of trabecular plates in the prior art method of **FIG. 2A**.

[0036] **FIG. 3** is a schematic view of another prior art method of laser treatment of a trabecular plate.

[0037] **FIG. 4A** is a graph showing light wavelengths with absorption coefficients in water.

[0038] **FIG. 4B** is a chart indicating laser-tissue effects at various temperature levels in tissue, including the modality of photoexcitement proposed herein; the photocoagulation modality wherein tissue is caused to coagulate, denature or shrink; and the photodisruption modality wherein tissue is vaporized.

[0039] **FIG. 5** is a perspective view of the handpiece of the present invention together with a block diagram of the components and control systems of the invention.

[0040] **FIG. 6** is an enlarged perspective view of a the distal working end of the handpiece of **FIG. 5** depicting a plurality of emitter locations and light energy beams emitting therefrom.

[0041] **FIG. 7** is a sectional view of the working end of **FIG. 6** taken along line **7-7** of **FIG. 6** showing particular working end geometry.

[0042] **FIG. 8** is a plan view of working end of **FIG. 6** showing other particular working end geometry.

[0043] **FIG. 9** is an enlarged sectional view of the working end of **FIG. 7** showing a lens element.

[0044] **FIG. 10** is an enlarged sectional view of a sclera and cornea and showing various transcleral angles-of-attack.

[0045] **FIG. 11** is a partial sectional view of an eye showing the footprint of the working end of **FIGS. 6, 7 & 8**.

[0046] FIGS. **12-12B** are sectional representations of a patients sclera and trabecular meshwork regions depicting a manner of utilizing the apparatus of **FIG. 5** in performing a method of the invention in elevating the temperature of the meshwork; **FIG. 12A** indicating the thermal effect of a light beams' incidence on tissue at the instant of energy absorption; **FIG. 12B** indicating the thermal effect of the light beams a number of nanoseconds later.

DETAILED DESCRIPTION OF THE INVENTION

[0047] Referring now to **FIG. 5**, the laser system **8** with handpiece **10** of the present invention is shown which is adapted for the novel technique of elevating the temperature of a patient's trabecular meshwork for biostimulation purposes. The system of the invention, for convenience, may be at times referred to as an OT^3 system ("OT-Cubed system") for the practiced technique of opto-thermal transscleral trabeculoplasty.

[0048] The present invention includes cooperating means for projection of energy beams at particular penetration angles in particular spatial locations on the anterior surface of the sclera, together with wavelength means for transscleral penetration of such energy beams to reach the patient's trabecular meshwork. The OT^3 device thus provides (i) a working end with particular geometry for propagating light beam(s) relative to the sclera's anterior surface,

(ii) a laser energy source operating within selected wavelength domains, and (iii) an optional dosimetry control system for controlling (or terminating) laser energy delivery based on a temperature feedback signals. These systems and aspects of the invention will be described in order below, and subsequently in their use in performing the technique of the invention in stimulating cellular and other processes of the trabecular meshwork.

[0049] 1. Working End Beam Propagation Geometry. As can be seen in **FIG. 5**, handpiece **10** comprises a working end portion **12** that extends along axis **15** and which is coupled to body portion **16**. The working end **12** is fabricated of any suitable transparent material, such a transparent medical grade plastic. The body is formed of any suitable material such as metal or plastic and is adapted for gripping with a human hand. Preferably, working end **12** and body **16** are of inexpensive and disposable injection-molded parts. The body **16** has proximal and distal ends, indicated at **17***a* and **17***b*, respectively, with end **17***a* having a detachable coupling **18** for connecting fiber optic cable **20** thereto for operative connection to laser energy source **25** described below.

[0050] FIGS. **6-8** show perspective, sectional and plan views of working face **30** of working end **12** with a plurality of emitter locations **31**A-**31***n* and lens elements **33**A-**33***n* from which beams **35**A-**35***n* are be emitted. The preferred embodiment shows a plurality of 6 emitter locations **31**A-**31***n*, but it should be appreciated the number of emitters may range from about 1 to 10 per any 10° to 45° of radial angle distance RAD of working face **30** (**FIG. 8**) described below (i.e., n=1 to 10). The number of emitter locations **31**A-**31***n* also will vary depending on selected beam diameter described below. **FIG. 6** shows that individual optic fibers **40** (collectively) are connected by any suitable means (e.g., cement or a clamping mechanism) at each emitter location and more particularly to each lens element **33**A-**33***n*. **FIG. 9** shows an enlarged sectional view of a lens element **33**A which is adapted as a plus-type lens to converge the beam generally at depth D which is about the depth of meshwork M (about 750 μm to 950 μm) as is known in the art. It should be appreciated that the lens element **33**A is represented as a part-hemispheric lens but that any flat field or convergent lens may be appropriate for opto-stimulation of the meshwork M and falls within the scope of the invention.

[0051] The light beams **35**A-**35***n* may be generated and emitted by the emitters from any suitable source of light, either coherent or non-coherent, and may be from a pulsed or CW laser source in the wavelength domain described below. It should be appreciated that the term "emitter" is used herein to describe the location or point at which beams **35**A-**35***n* are emitted from working end **12** and lens elements **33**A-**33***n* into the sclera, and as such, the emitter is considered to be a combination of elements including, but not limited to, the laser source **25** together with optics, fiber optics, lenses, mirrors, filters, splitters, combiners, energy attenuators, beam shapers and other arrangements operatively connected between the laser source **25** and the lens elements **33**A-**33***n*. **FIG. 5** shows beam splitter **44** that is known in the art for splitting output from one or more light sources **25** to pump the light energy into each individual optic fiber **40**.

[0052] Turning now to FIGS. **10-11**, very particular beam-angle propagation means are formed into working face **30** of working end **12** that comprises a balance between several considerations and several potential transscleral angles-of-attack to reach the trabecular meshwork M. Referring back to **FIG. 7**, the working face **30** in its treatment position is adapted to interface with globe **5** generally in surface contact with three portions of the globe: the sclera SC, the limbus **36** and the cornea C. In other words, the working face has a first corneal-spherical receiving portion **45**A and a second scleral-spherical receiving portion **45**B with annular limbus-interface portion **47** therebetween. The limbus **36** herein is defined as the particular annular transition region from 0.5 mm. to 2.0 mm. between the sclera and cornea. Further, the working face **30** extends a minimum radial angular distance RAD when measured in degrees as will be described below (see **FIG. 8**). Thus, the footprint dimensions of working face are large enough to stabilize the working face **30** against the globe, as well as for functioning as a heatsink as described below.

[0053] FIGS. **10-11** show that a particular limited range of angles-of-attack (or beam propagation) relative to anterior surface **48** that is indicated to reach meshwork M. Among the considerations for determining the most preferable angle-of-attack are (i) the reduction of incident beam reflection off the anterior surface **48** of the sclera SC; (ii) the reduction of unnecessary photon scattering in the mid-sclera **53**, and (iii) the elimination of any angle-of-attack that might align with anatomic structures that one would not want to irradiate unnecessarily. To meet these objectives, the working face **30** is formed with a geometry for angular positioning the axes **50** (collectively) of propagation of beams **35**A-**35***n* within a defined angle—for example angle β which measures the angle between an axis **50** of beam propagation and a tangent T to the sclera in an incident zone Z outside the limbus centerline **51**. In other words, axis **50** extends from the zone Z in which a light beam penetrates the anterior **48** of the sclera to hit meshwork M. As can be seen in **FIG. 10**, any beam propagation at other angles along other lines (e.g., lines X_1 or X_2) that are more oblique relative to tangent T may cause photonic energy to be absorbed in undesirable locations like ciliary body CB or iris **52** and thus damage tissue outside the meshwork M. The correct beam propagation angle β can be defined in a number of different geometric manners relative to surfaces, radii, axes etc. of globe **5**, and for that reason the ranges of radii of curvature of a normal globe are shown in **FIG. 10**. Preferably, as shown in **FIG. 8**, beam angle β is within a range of about 10° on either side of a line drawn perpendicular to tangent T in the zone Z of the sclera and limbus. Incident zone Z has in lesser diameter of about 0.0 mm. to 0.5 mm. from the centerline **51** of limbus **36** and an outer diameter to 3.0 to 5.0 mm. from the centerline **51** of the limbus **36**. Thus, the working end geometry in its "contact position" or "treatment position" against globe **5** orients beams **35**A-**35***n* to (i) allow about the least distance of travel possible through the sclera SC to the meshwork M to correspond to wavelength domains described below; (ii) allow reduction of photon scattering and heat within the mid-sclera **53** by minimizing the beams' propagation length through the sclera; and (iii) allow light beams **35**A-**35***n* delivery at close to a 90° angle relative to anterior surface **48** of sclera SC to reduce surface photon reflection.

[0054] Of particular interest to the invention, the compound curvatures **45**A and **45**B (first corneal-spherical receiving portion **45**A and second scleral-spherical receiving

portion **45**B) of working face **30** allow the ophthalmologist to gently fit the working face against the globe **5** about the corneal-scleral junction to insure the optimal beam spatial location and beam angle-of-attack. The ophthalmologist first may move the working face laterally back and forth as shown in arrow **A1** in **FIG. 10** until it fits comfortably against the eye. Thereafter, the ophthalmologist may tilt working face **30** against the curvature of the sclera and cornea as indicated by arrow **A2** as shown in **FIG. 10** to establish the correct angle β relative to globe **5**. In the previous view of the working face in **FIG. 7**, it can be seen that first part-spherical receiving form **45**A has a meridional or first cross-sectional radius **R1** of about 6.4 mm. to 7.8 mm. which represents a meridian of corneal curvature. The working face **30** has second part-spherical receiving form **45**B with a second cross-sectional radius **R2** of from about 8.0 mm. to 12.0 which represents a meridian of scleral curvature (or greater) with the forms **45**A and **45**B meeting along partial annular junction **47**. The width of first part-spherical receiving form **45**A may range from about 0.5 mm. to 4.0 mm., indicated at **W1** in **FIG. 8**. The width of second part-spherical receiving form **45**B may range from about 2.0 mm. to 5.0 mm., indicated at **W2** in **FIG. 8**.

[**0055**] **FIG. 8** shows a plan view of working face **30** indicating that it is adapted to extend a particular angular or radial angle distance RAD around globe **5** and is shown in this preferred embodiment with a radial extension RAD of about 60° out of 360°. It should be appreciated that other embodiments are possible and fall within the scope of the invention and such radial extension may range between about 10° and 180° (see **FIG. 8**). In terms of circumferential dimensions, the dimension along partial annular junction **47** of working face may range from about 2.5 mm. to 2.0 cm. The footprint **54** defining the surface area of working face **30** preferably has an area of at least 20 $mm.^2$ to meet the requirements of stabilizing the working face against globe **5** to provide the correct angle of beam propagation, and to provide sufficient heat absorption characteristics for any of the materials of working face described herein. More preferably, the footprint **54** of working face **30** has an area of at least 40 $mm.^2$ to meet above requirements. Still more preferably, the footprint **54** of working face **30** has an area of at least 60 $mm.^2$ to meet such requirements.

[**0056**] The dosimetry control system **55** will be described in detail below in Section 3. Some aspects of the dosimetry control system can be fed by a signal from sensors **57** (collectively or sensor array) in working face **30**. Therefore, referring back to **FIGS. 6 & 8**, it can be seen that sensor array **57** is provided which comprises thermisters or thermocouples carried in a spaced apart relationship close to lens elements **33**A-**33***n* in face **30**. The sensors may be in actual contact with the sclera SC or may measure the temperature of the material of face **30** that is in contact with the sclera. Each thermocouple or thermister (a temperature sensor that has resistances that vary with the temperature level) is any suitable type known in the art and may consist of paired dissimilar metals such as copper and constantan which form a T-type thermocouple.

[**0057**] Referring back to **FIG. 5, a** block diagram of the controllers of the system **8** is included and further shows a visible aiming beam (e.g., a HeNe laser) indicted at **58** operating at 630.8 nm or any other suitable visible laser wavelength. The system includes dosimetry control system indicated at **55** and optional beam sequence controller **59**, which computer controllers are adapted to operate in cooperation (as will be described below) to control the power of beams **35**A-**35***n*, as well as the timing, of laser energy delivered from laser source **25**.

[**0058**] 2. Laser Source Wavelength Selection. The preceding section described the working end geometry or positioning mechanisms of the novel OT^3 device to insure that the physician can easily and consistently locate the working face **30** in suitable "treatment positions" on or about the anterior scleral surface. This section and FIGS. **12**A-**12**B describe the means provided by the invention for controlling penetration of light beams **35**A-**35***n* beneath the anterior scleral surface **48** to provide the desired photon absorption within the trabecular meshwork M. The biostimulative effect is caused by the beam's photonic energy being absorbed and exciting (or vibrating) molecules within the meshwork, and for that reason the energy delivery effect may be called herein a photoexcitation modality to distinguish it from various high-energy laser delivery modalities described in the section above titled "Summary of the Invention".

[**0059**] Turning back to **FIG. 10**, the perspective and partial sectional view of globe **5** shows the beams **35**A-**35***n* incident within zone Z at a particular moment in time that represents a technique of the invention. **FIG. 11** also shows the approximate location of zone Z over the trabecular meshwork with the footprint **54** of working face **30** and the working end **12** in phantom view in a second treatment location. **FIG. 12A** illustrates an enlarged fill-thickness sectional view of the sclera SC and meshwork M taken along an arc-like section of **FIG. 11**. Sclera SC has a number of layers including epithelial layer **60** with the total scleral thickness ranging from about 750 μm to 950 μm.

[**0060**] The object of the invention, transscleral opto-thermal biostimulation, requires identification of a specific light wavelength domain that may be produced by laser source **25** to penetrate substantially to the depth of about 750 μm-950 μm. As background, when light energy is incident upon tissue, five effects may result: (i) the beam, or some or all of the photons thereof, may be reflected off the tissue surface; (ii) the photons thereof may be transmitted entirely through the tissue medium, (iii) the photons thereof may be absorbed along the beam's propagation in the tissue medium by absorption within a chromophore, (iv) the photons thereof may be absorbed along the beam's path of propagation by varied processes of scattering; or (v) some of beam may be scattered within the tissue beyond the region of the beams path as it propagates within the tissue medium.

[**0061**] To provide photon absorption to a depth in tissue of about 750 μm-950 μm, two of the above factors are of interest to cause biostimulation of the trabecular meshwork M. Of particular interest are the photon absorption effects (iii) and (iv) listed above. Preferably, the photons of the energy beams **35**A-**35***n* will be absorbed by the H_2O content of the meshwork acting as a chromophore, and also be absorbed by photon scattering processes, thus elevating meshwork temperature. (As noted previously, photon reflection off anterior surface **48** is minimized to the extent possible, and deeper absorption is allowed, by orienting axes **50** of the beams substantially perpendicular to the anterior scleral surface which relates to beam incident effect (i) above).

[0062] Since the sclera is about 75%-80% water with little or no cellular pigmentation, **FIG. 4A** is relevant as it depicts an absorption coefficient of water as a function of wavelength (λ). As can be seen in **FIG. 4A**, the absorption coefficient of water varies by a factor of about 10,000,000 from a peak light transmission where λ=500 nm (not shown) in the visible spectrum to peak light absorption where λ=at 2.8 μm in the infrared portion of the spectrum. Tissue research and mathematical modeling of various wavelengths indicates that the preferred wavelength range for light-mediated meshwork biostimulation lies in the near-infrared, the laser source **25** preferably operating at a wavelength ranging from about 1.30 μm to 1.40 μm or from about 1.55 μm to 1.85 μm. The wavelength ranges correspond to an absorption coefficient (α) in H_2O ranging between about α=2.0 cm^{-1} to 10.0 cm^{-1}, which is similar to the sclera. Such a range of absorption coefficients would result in the photonic energy being absorbed to a depth of about 750 μm to 1100 μm—in other words the depth of the trabecular meshwork or slightly beyond. It is not important if the absorption is somewhat deeper than the meshwork, for the aqueous AQ will absorb or extinguish the energy beam. Unlike ALT and SLT wavelengths that are absorbed by a pigment (melanin) or chromophore in the meshwork, the proposed wavelengths rely on H_2O as the chromophore which is in the trabecular plates TP and the aqueous AQ which allows a substantially uniform temperature elevation in the entire region of the meshwork for biostimulation purposes.

[0063] The temperature targeted for meshwork biostimulation is in the range of about 40° C. to 55° C. for a period of time ranging from about 1 second to 120 seconds, with the temperature inversely related to the duration of exposure. More preferably, the target temperature is within a range of 40° C. to 50° C. It would be preferable to achieve an energy profile that photoexcites the region of the meshwork without over-elevating the temperature levels in the sclera overlying the meshwork. For example, it is preferable that the opto-thermal effects do not cause excessive cell death in epithelial layer **60** or in the mid-sclera region **53**. Such excessive cell death along the light beam's propagation through the sclera could induce an inflammatory response or wound healing response which would be undesirable, although not serious threat to the patient's health. Cell damage in the sclera is to be expected to some extent, but since the inventive technique is transscleral there should be few undesirable side effects. This is to be contrasted with the trans-corneal approach of SLT which causes corneal burns in significant numbers of cases resulting in at least a transient effect on corneal clarity.

[0064] The present invention provides protection means for preventing over-elevation of temperatures in the epithelial layer **60** and the midscleral region **53**, by: (i) balancing wavelength selection along with a low laser power level to penetrate the sclera; (ii) balancing exposure duration with temperature which exposure can be terminated with feedback control; and most importantly (iii) providing heat-absorption characteristics incorporated in working face **30**. In other words, a transient reverse thermal gradient in the sclera can be achieved by use of the heat-sink working face **30**. Due to the relatively low target temperatures, the heat-sink of even a plastic working face **30** around the lens elements will carry a significant amount of heat away from the anterior regions of the sclera. It should be appreciated that other heat-sink materials known in the art may be used for portions of the working face **30**, such as sapphire, quartz or heat-absorbing ceramics (other than lens elements). **FIG. 12A** depicts a sectional view of the propagation of beam **35**A through the sclera exactly at the moment of its incidence on anterior surface **48** with exemplary isotherms **70***a*-**70***c* indicating the effects of photon absorption; **FIG. 12B** depicts the same scleral location in as little as several nanoseconds after energy delivery has been terminated. In particular, **FIG. 12B** indicates that substantially all heat has been conducted away from anterior surface region **48** of the sclera to the heat-sink with exemplary isotherms **70***a*-**70***c* indicating the surface cooling effect that concentrates temperature in the region of meshwork M. Such modeling shows how a transient reverse thermal gradient (cooler at anterior surface **48** than mid-sclera **53**) can be developed to cause thermal meshwork biostimulation without raising temperatures excessively in the anterior **48** and mid-sclera **53**.

[0065] Another aspect of the OT^3 system for effective biostimulation of the meshwork M relates the preferred diameter of scanned beams **35**A-**35***n* to provide temperatures within the particular ranges described above. Either a CW (continuous wave) or fast pulsed laser is suitable to perform the biostimulation technique of the present invention utilizing a beam width ranging from about 25 μm to 1 mm. for reasons that can be explained by the mechanisms of heat transfer in tissue. In the preferred wavelengths described above, when the light beam is absorbed in tissue medium (both by chromophores and by photon scattering) the energy in the beam is imparted to the scleral absorbing medium along the path of beam propagation. The photonic energy that is absorbed by the medium heats the absorbing volume instantly, for example in a period ranging from femto-seconds to pico-seconds. Essentially, all of the energy in the light beam is deposited in the tissue within about one extinction length (which is directly related to the absorption coefficient a of the sclera). Thus, it can be calculated that a three-dimensional volume of the medium will be elevated in temperature and is dependent on (i) the beam diameter, and (ii) the extinction length of the particular wavelength (with some adjustment for photon scattering). To optimize the meshwork biostimulation, it is necessary to deposit enough energy into the absorbing volume to elevate the volume to the desired temperature range before it diffuses into surrounding tissue volumes. The process of heat diffusion, called thermal relaxation, describes such process of conduction and defines the absorbing volume's thermal relaxation time (often defined as the time over which photothermal temperature elevation is reduced by one-half). Such thermal relaxation time scales with the square of the diameter of the irradiated absorbing volume in a spherical volume, decreasing as the diameter decreases. For a cylindrical-shaped irradiated volume (see **FIG. 12A**) with diameter d and length L, such thermal relaxation time is determined by the lesser of the two dimensions. Thus, in the laser wavelengths and tissue absorption coefficients described above, it is preferable to have the heat thermal relaxation time in the anterior and mid-sclera as low as possible to diffuse and reduce temperature elevations in those regions. For these reasons, it is postulated that beam diameters in that range of about 25 μm to 1 mm. would be best suited for meshwork stimulation, with a similar spaced-apart dimension SA from about 25 μm to 1 mm. between the individual beams and lens elements **33**A-**33***n* (see **FIG. 6**).

[0066] 3. Dosimetry Control System of OT^3 Device and Methods of the Invention. The OT^3 device **8** includes a dosimetry control system indicated at **55** in **FIG. 5** that is adapted to control the power level of laser energy delivered through the emitter locations **31A-31*n*** in various operational modes. In utilizing the device of **FIG. 5** to perform the method of the invention, the ophthalmologist gently positions the working face **30** of the device against the patient's eye as shown in **FIGS. 7, 10 & 11** above following administration of a topical anesthetic. As described above, after moving the working face laterally about the surface of globe **5** and tilting the device back and forth, the physician will have a tactile feel of the correct position of the working face, at which time he may actuate the device by means of a footpedal (not shown) or any other suitable trigger mechanism to deliver laser energy under a number of different optional operational modes. The ophthalmologist repeats the biostimulative treatment in successive and slightly overlapping location in an arc around the entire 360° of the globe. The dosimetry control system **55** typically includes microprocessor **65** together with appropriate software programs **66** and may be designed to modulate the power level of the laser source **25** at any level among a continuous range of power levels as the emitters project beams **35A-35*n***. The software **66** that is part of the dosimetry control system, as the term is used herein, includes a conventional software program, a program within a programmable chip, or any other form of algorithm carried in any form of memory storage system. Within the hardware portion of dosimetry control system **55**, there may be a keyboard, disk drive or other non-volatile memory system, displays as are well known in the art for operating such a system (see **FIG. 5**).

[0067] The dosimetry control system can operate in a "basic" mode of operation, which means that the physician utilizes a pre-selected program to control to (i) the particular power level of laser source **25**; (ii) the particular exposure duration of beams **35A-35*n***. The power level may range from about 1 mJ to 100 mJ for the above-described beam diameters, with a CW source or a rapidly pulsed source with pulse length ranging from 1-1000 ms. As described above, the total duration of treatment may range from about 1 second to 120 seconds.

[0068] Another operational mode, and a preferred mode, relates to use of a feedback-controlled mode based on signals from thermal sensor(s) **57** shown in **FIGS. 6 & 8**. In a first feedback-controlled mode, surface temperature at the anterior scleral surface **48** may be monitored by sensor array **57**, such that dosimetry control system **55** may simply terminate laser energy delivery upon a detected surface temperature reaching a pre-set, for example any temperature in pre-selected from a range of about 42° C. to 55° C., each such temperature also optionally including a pre-selectable time period ranging from about 1 ms to 30 seconds. Thus, the detected temperatures at the anterior surface **48** of the sclera can be modeled (e.g., using Monte Carlo modeling as is known in the art) to predict the temperature in the region of the meshwork M for creating the biostimulation temperature parameters described above. In another feedback controlled-operational mode, the dosimetry control system **55** can be programmed to modulate power to one or more emitter locations based on feedback from the sensor array **50**.

[0069] In yet another operational mode of the invention, herein called the time-sequenced (or gated) operational mode, the dosimetry control system **55** and more specifically the beam sequence controller **59** which is adapted to sequentially deliver laser energy at any given power level between the individual emitter locations **31A-31*n***. Such "sequential" delivery can provide energy delivery to only one particular spot in the meshwork M at a time, or any spot substantially remote from an adjacent spot (either in distance or time of delivery) to allow the thermal relaxation time relative to a particular to spot to diffuse the temperature within the absorbing medium. For example, the beam sequence controller **59** may randomly, or in a pre-set sequence, select only one single emitter to emit a beam at any moment in time thus sequencing between any adjacent or non-adjacent emitters; or controller **59** may select from 2 to n non-adjacent emitters to emit beam simultaneously while sequencing between or among another single emitter or any combination of emitters **31*a*-31*n***. By this beam delivery sequencing means, and thermal modeling as is known in the art such as Monte Carlo modeling, beam sequencing patterns can be developed as a function of both the thermal relaxation time about a beam's propagation and the heat aborption characteristics of working face **30** to optimize the biostimulative temperature elevation in the trabecular meshwork.

[0070] Specific features of the invention are shown in some drawings and not in others, and this is for convenience only and any feature may be combined with another in accordance with the invention. Further variations will be apparent to one skilled in the art in light of this disclosure and are intended to fall within the scope of the appended claims.

What is claimed is:

1. A method for delivering energy to trabecular meshwork in a patient's eye, comprising:

positioning a working face of a member in contact with a patient's sclera overlying the trabecular meshwork; and

delivering at least one laser beam through the member wherein said at least one beam is transmitted transsclerally to irradiate a region of said trabecular meshwork.

2. The method of claim 1 wherein said at least one beam has a wavelength range from about of 1.30 μm to 1.85 μm.

3. The method of claim 1 further comprising the steps of:

sensing a temperature of the sclera overlying the trabecular meshwork with at least one sensor in said member to provide a signal; and

modulating or terminating the delivery of said at least one laser beam in response to said signal.

4. The method of claim 3 further comprising the step of elevating the temperature of said trabecular meshwork to a range between about 40° C. to 55° C.

5. A method for delivering energy to a patient's trabecular meshwork to treat glaucoma, comprising the steps of:

(a) placing a laser emitter in contact with a portion of the sclera of the patient's eye overlying the trabecular meshwork;

(b) delivering laser energy from the emitter at a wavelength ranging between about 1.30-1.40 μm or 1.55-1.85 μm; and

(c) modulating the power level, pulse duration and pulse intervals of the laser energy to maintain the temperature of the trabecular meshwork at less than about 60° C.

(d) wherein said laser energy delivery causes substantially uniform thermal effects in all layers of the trabecular meshwork.

6. The method of claim 5 wherein the laser emitter is carried in a contact surface of a thermally conductive material having a surface area greater that about 20 mm^2 thereby conducting heat away from surface sclera layers.

7. The method of claim 5 further comprising the steps of sensing the temperature of the sclera overlying the trabecular meshwork with at least one sensor carried within the working face to provide a signal and modulating the laser energy delivery in response to the signal.

8. A method for delivering energy to a patient's trabecular meshwork to treat glaucoma, comprising the steps of:

(a) placing a laser emitter in contact with a patient's eye wherein the axis of laser beam propagation is aligned with the trabecular meshwork;

(b) delivering laser energy from the emitter at a selected wavelength; and

(c) modulating the power level, pulse duration and pulse intervals of the laser energy to maintain the temperature of the trabecular meshwork at less than about 60° C.;

(d) wherein said laser energy delivery causes substantially uniform thermal effects in all layers of the trabecular meshwork.

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