

PATENT**ASSIGNMENT**

WHEREAS, I, Michael J. Berry, resident of Texas and citizen of the United States, have invented certain new and useful improvements in “Myopia Control Device and Methods of Use” (Exhibit A) disclosed in applications for United States Letters Patent, one of said applications having been executed concurrently herewith, another of said applications filed on January 7, 2025 and assigned;

WHEREAS, VIS, Inc., a corporation organized under the laws of the state of Texas, having a place of business at 2800 North Dallas Parkway, Suite 100, Plano, Texas 75093 (hereinafter referred to as “ASSIGNEE”), is desirous of acquiring my entire right, title and interest in and to the invention and in and to the said applications and any Letters Patent that may issue thereon;

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, I do hereby sell, assign and transfer unto said ASSIGNEE, its successors, assigns and legal representatives, the full and exclusive right, title and interest in and to said invention and in and to said applications and all patents which may be granted therefor, and all divisions, reissues, substitutions, continuations, continuations-in-part and extensions thereof; and I hereby authorize and request the Commissioner of Patents to issue all patents for said invention, or patents resulting therefrom, insofar as my interest is concerned, to the said ASSIGNEE of my entire right, title and interest.

I also hereby sell and assign to said ASSIGNEE, its successors, assigns and legal representatives the full and exclusive rights, title and interest to the invention disclosed in said applications throughout the world, including the right to file applications and obtain patents, utility models, industrial models and designs for said invention in its own name throughout the world including all rights of priority, all rights to publish cautionary notices reserving ownership of said invention and all rights to register said invention in appropriate registries; and I further agree to execute any and all powers of attorney, applications, assignments, declarations, affidavits, and any other papers in connection therewith necessary to perfect such rights, title and interest in ASSIGNEE, its successors, assigns and legal representatives.

I hereby further agree that I will communicate to said ASSIGNEE, or to its successors, assigns and legal representatives, any facts known to me respecting any improvements; and, at the expense of said ASSIGNEE, to testify in any legal proceedings, sign all lawful papers, execute all divisional, continuation, continuation-in-part, reissue and substitute applications, and make all lawful oaths, and generally do everything possible to vest title in said ASSIGNEE and to aid said ASSIGNEE, its successors, assigns and legal representatives to obtain and enforce proper protection for said invention in all countries.

Date: 2/24/2025

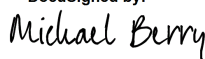
DocuSigned by:

E25DFCF44E7840C...
Michael J. Berry

Exhibit A



7 January 2025

United States Patent and Trademark Office (USPTO)
Washington, DC

Dear USPTO Representative:

Re: Provisional Patent Application

I am herein submitting a Provisional Patent Application in two files:

M Berry – Provisional Patent Application – Myopia Control.pdf (Specifications)

M Berry – Provisional Patent Application – Myopia Control - Figures.pdf

Title: Myopia Control Device and Methods of Use

Inventor: Michael James Berry, 7801 Comfort Cove, Austin, TX 78731

Details about the Application:

This invention is an ophthalmic medical device and methods for its use to provide myopia control (*i.e.*, control nearsightedness and its progression).

This provisional application meets the requirements of § 1.51(c)(1).

Please contact me if you have any questions.

Sincerely,

A handwritten signature in cursive script that reads "Michael Berry".

Michael Berry, Director
VIS, Incorporated

831-869-1384

mberry177@gmail.com

Under the Paperwork Reduction Act of 1995 no persons are required to respond to a collection of information unless it displays a valid OMB control number

PROVISIONAL APPLICATION FOR PATENT COVER SHEET – Page 1 of 2

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

Priority Mail Express® Label No. EI 65984350 US

INVENTOR(S)		
Given Name (first and middle [if any])	Family Name or Surname	Residence (City and either State or Foreign Country)
Michael James	Berry	Austin, TX

Additional inventors are being named on the _____ separately numbered sheets attached hereto.

TITLE OF THE INVENTION (500 characters max):

Myopia Control Device and Methods of Use

Direct all correspondence to: **CORRESPONDENCE ADDRESS**

☐ The address corresponding to Customer Number:

OR

☒ Firm or Individual Name **Michael James Berry**

Address **7801 Comfort Cove**

City Austin	State Texas	Zip 78731
Country USA	Telephone 8318691384	Email mberry177@gmail.com

ENCLOSED APPLICATION PARTS (check all that apply)

☐ Application Data Sheet. See 37 CFR 1.76.	☐ CD(s), Number of CDs _____
☒ Drawing(s) Number of Sheets <u>2</u>	☒ Other (specify) <u>Cover Letter</u>
☒ Specification (e.g., description of the invention) Number of Pages <u>15</u>	

Fees Due: Filing Fee of \$300 (\$120 for small entity) (\$60 for micro entity). If the specification and drawings exceed 100 sheets of paper, an application size fee is also due, which is \$420 (\$168 for small entity) (\$84 for micro entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

METHOD OF PAYMENT OF THE FILING FEE AND APPLICATION SIZE FEE FOR THIS PROVISIONAL APPLICATION FOR PATENT

☒ Applicant asserts small entity status. See 37 CFR 1.27.	\$120.00 TOTAL FEE AMOUNT (\$)
☐ Applicant certifies micro entity status. See 37 CFR 1.29. Applicant must attach form PTO/SB/15A or B or equivalent.	
☒ A check or money order made payable to the <i>Director of the United States Patent and Trademark Office</i> is enclosed to cover the filing fee and application size fee (if applicable).	
☐ Payment by credit card. Form PTO-2038 is attached.	
☒ The Director is hereby authorized to charge the filing fee and application size fee (if applicable) or credit any overpayment to Deposit Account Number: <u>N/A</u>	

USE ONLY FOR FILING A PROVISIONAL APPLICATION FOR PATENT

A Federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with an information collection subject to the requirements of the Paperwork Reduction Act of 1995, unless the information collection has a currently valid OMB Control Number. The OMB Control Number for this information collection is 0651-0032. Public burden for this form is estimated to average 10 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the information collection. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden to the Chief Administrative Officer, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450 or email InformationCollection@uspto.gov. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. If filing this completed form by mail, send to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Under the Paperwork Reduction Act of 1995 no persons are required to respond to a collection of information unless it displays a valid OMB control number

PROVISIONAL APPLICATION FOR PATENT COVER SHEET – Page 2 of 2

The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government. (NOTE: Providing this information on a provisional cover sheet, such as this Provisional Application for Patent Cover Sheet (Form PTO/SB/16), does not satisfy the requirement of 35 U.S.C. 202(c)(6), which requires that the *specification* contain a statement specifying that the invention was made with Government support and that the Government has certain rights in the invention.)

☒ No.☐ Yes, the invention was made by an agency of the U.S. Government. The U.S. Government agency name is: _____☐ Yes, the invention was made under a contract with an agency of the U.S. Government.

The contract number is: _____

The U.S. Government agency name is: _____

In accordance with 35 U.S.C. 202(c)(6) and 37 CFR 401.14(f)(4), the specifications of any United States patent applications and any patent issuing thereon covering the invention, including the enclosed provisional application, must state the following:

“This invention was made with government support under [IDENTIFY THE CONTRACT] awarded by [IDENTIFY THE FEDERAL AGENCY]. The government has certain rights in the invention.”

WARNING:

Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available.

SIGNATURE Michael James Berry DATE 7 January 2025TYPED OR PRINTED NAME Michael James Berry REGISTRATION NO. _____
(if appropriate)TELEPHONE 8318691384 DOCKET NUMBER _____

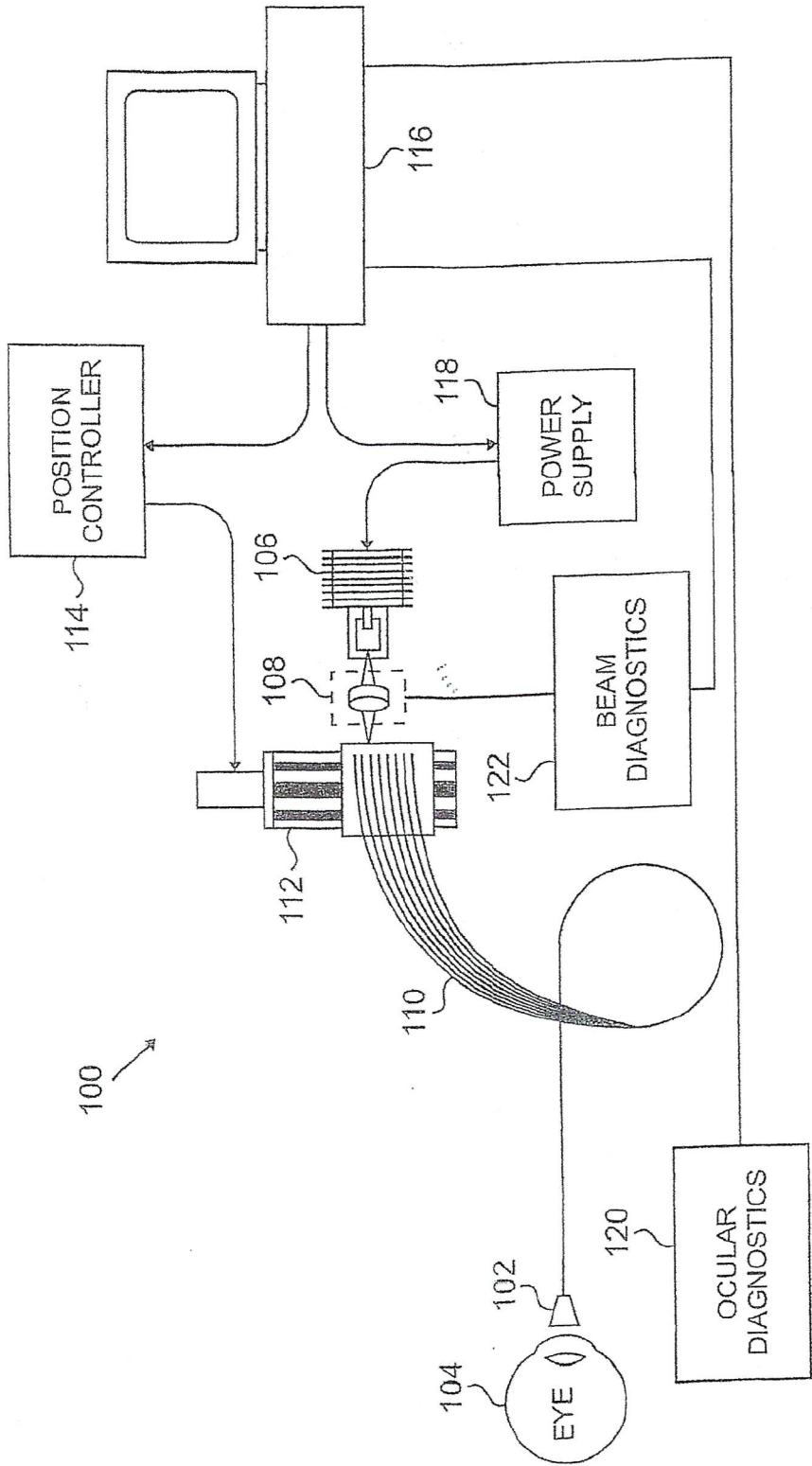


FIG. 1

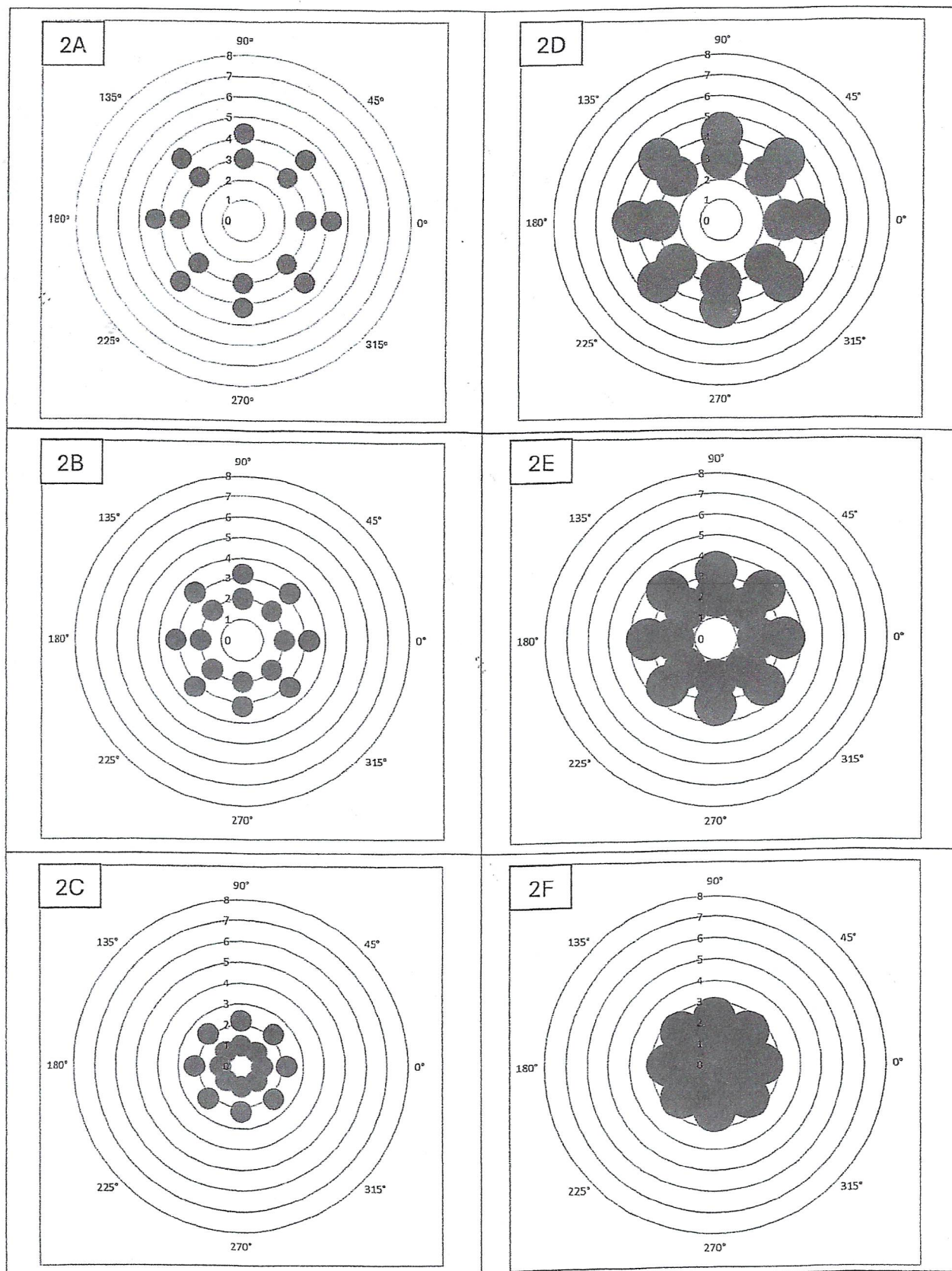


Fig. 2

VIS, Inc. - Confidential

Provisional Patent Application for United States Patent Office

TITLE: Myopia Control Device and Methods of Use

Brief Summary of the Invention

This invention is an ophthalmic medical device and methods for its use to provide myopia control (*i.e.*, control nearsightedness and its progression).

Key features include:

- An ophthalmic medical device comprising: 1) an adjustable medical laser that can deliver predetermined light energy to the cornea, 2) an optical fiber array to deliver light energy and 3) a sapphire applanation window/suction ring (SAWSR) accessory that permits accurate delivery of light energy to the cornea without causing clinically significant corneal epithelial damage.
- Methods for use of the ophthalmic medical laser device to provide required (personalized) treatment of patient eyes.

Description of the Drawings

For a more complete understanding of this disclosure and its features, reference is made to the following description, taken in conjunction with the accompanying drawings, in which:

[0001] Figure 1 illustrates an example system for corneal reshaping according to this disclosure.

[0002] Figure 2 shows example treatment patterns suitable for myopia control. Each treatment pattern is displayed on a grid of concentric diameters at 1 mm intervals. Detailed information on each example treatment pattern is presented in paragraph [00018].

VIS, Inc. - Confidential

Field of the Invention

[0003] The present ophthalmic invention includes an ophthalmic device and methods for its use (including, but not limited to, specific treatment pattern) to provide myopia control (*i.e.*, reduction of myopia, myopic astigmatism and/or the progression of myopia and myopic astigmatism) to improve, stabilize or restore vision. The applications of the present invention include, but are not limited to, myopia control. The myopia control devices and methods of the present invention can also be used in combination with other therapies including, but not limited to, pharmacological therapies.

Background

[0004] Myopia (nearsightedness) is the most prevalent refractive error globally, with an estimated prevalence of 3 billion people in 2025 and a projected prevalence of nearly 5 billion people in 2050 [Ref. 1]. Of particular importance is the increasing prevalence of myopia progression in children, which has reached epidemic proportions [Ref. 2]. Myopia progression may advance to pathological conditions including, but not limited to, retinal detachment and myopic maculopathy. The rate of myopia progression depends upon baseline refraction, with children having hyperopia reserve (HR) progressing less rapidly [Ref. 3].

[0005] Myopia control (both myopia reduction and myopia progression reduction) can be achieved, at least in part, by current approaches such as spending time outdoors in sunlight and by use of devices including, but not limited to, specialized spectacles, specialized multifocal contact lenses, orthokeratology lenses and surgical lasers. Pharmacological approaches including, but not limited to,

VIS, Inc. - Confidential

atropine administration to the eye are also used to reduce the rate of myopia progression. These current approaches have limitations including safety, efficacy, side effects, convenience and cost. These limitations are overcome, at least in part, by the present invention.

Summary of the Invention

[0006] The invention described herein includes myopia control (both myopia reduction and myopia progression reduction) devices and methods to optically reshape the cornea of the eye in order to modify the refractive status of the eye.

Detailed Description of the Invention

Figures 1 through 2, described below, and the various embodiments used to describe the principles of the present invention in this patent document are by way of illustration only and should not be construed in any way to limit the scope of the invention. Those skilled in the art of invention will understand that the principles of the invention may be implemented in any type of suitably arranged device or system.

[0007] The device is essentially the same as that described previously [Ref. 4].

Figure 1 illustrates an example device **100** for cornea reshaping according to this disclosure. The embodiment of the device shown in Fig. 1 is for illustration only. Other embodiments of the device **100** may be used without departing from the scope of this disclosure.

[0008] In this example, device **100** includes a sapphire applanation window/suction ring (SAWSR) **102** that is mounted on the patient eye **104** during a corneal reshaping procedure. SAWSR **102** includes a sapphire applanation window

VIS, Inc. - Confidential

that is in contact with the cornea to provide epithelial protection from thermal damage during laser irradiation [Ref. 4].

[0009] In this example, device **100** includes laser **106** that produces light that is directed through optical fiber array **110** to deliver laser light through SAWSR **102** to eye **104**. Laser **106** parameters including, but not limited to, wavelength, energy and duration are characterized using beam diagnostics **108**. Laser **106** is powered by power supply **118**. Optical fiber array **110** is positioned using translation stage **112** that is operated using position controller **114**. Translation stage **112** may be operated with one or more lasers for sequential or simultaneous delivery of laser light through one or more fibers in optical fiber array **110**. Ocular characteristics are measured by ocular diagnostics **120** and that information is used by computer **116** to calculate predetermined laser parameters including, but not limited to, laser energy output and pulse duration. Computer **116** operates laser **106** with the predetermined parameters.

[00010] Laser **106** may be one or more lasers including, but not limited to, thulium fiber lasers (TFLs) or semiconductor diode lasers (SDLs). Laser **106** produces light with predetermined laser parameters including, but not limited to, wavelength, energy and duration.

[00011] Laser **106** light is delivered sequentially through one or more fibers in optical fiber array **110** or simultaneously through multiple fibers in optical fiber array **110**. In sequential operation, laser **106** light from a single laser is delivered through one or more fibers in optical fiber array **110** using translation stage **112** and position controller **114** to couple individual fibers with laser **106** light to

VIS, Inc. - Confidential

deliver each laser treatment (Tx) spot sequentially through SAWSR **102** to eye **104**. In simultaneous operation, laser **106** light from one or more lasers is delivered through two or more fibers in optical fiber array **110** using translation stage **112** and position controller **114** to couple one or more fibers with laser **106** light to deliver laser Tx spots simultaneously through SAWSR **102** to eye **104**. In simultaneous operation, laser **106** light from one or more lasers is used to produce 2 or more beams that are delivered through two or more fibers in optical fiber array **110** using translation stage **112** and position controller **114** to couple two or more fibers with laser **106** light to deliver laser Tx spots simultaneously through SAWSR **102** to eye **104**. Two or more beams of laser light may be derived from one or more lasers using one or more axicon lenses or beamsplitter and mirror arrays.

[00012] SAWSR **102** is mounted on the patient eye **104** to be treated using suction. SAWSR **102** includes, but is not limited to, a sapphire applanation window (SAW) mounted within a suction ring (SR) that is equipped with a vacuum port that is connected to a suction source. SAWSR **102** may include, but is not limited to, one or more accessories such as a reticle on the SAW and a light source on the SR, both of which aid in mounting SAWSR **102** on eye **104** accurately with respect to a predetermined position reference such as the pupil center of eye **104**.

Preferred Embodiments of the Invention

[00013] In type L1 laser embodiments of the invention, laser **106** is one or more thulium fiber lasers (TFLs) operated in continuous wave (cw) mode. In type L1A laser embodiment, laser **106** light pulse durations are produced by one or more optical shutters. For sequential delivery of laser light pulses, shutter open/off times

VIS, Inc. - Confidential

are synchronized with translation stage **112** positions to couple fibers of optical fiber array **110** with laser **106** light pulses to deliver each laser treatment spot (from one TFL) or two or more laser treatment spots (from two or more TFLs) sequentially through SAWSR **102** to eye **104**. In type L1B laser embodiment, laser **106** light pulse durations are produced by one or more optical shutters. For simultaneous delivery of laser light pulses, shutter open/off times are synchronized with translation stage **112** positions to couple one or more fibers of optical fiber array **110** with laser **106** light pulses to deliver one or more laser treatment spots simultaneously from one or more TFLs through SAWSR **102** to eye **104**.

[00014] In type L2 laser embodiments of the invention, laser **106** is a set of one or more semiconductor diode lasers (SDLs) operated in repetitively pulsed (rp) mode. For sequential delivery of laser light pulses from one or more SDLs, shutter open/off times are synchronized with translation stage **112** positions to couple individual fibers of optical fiber array **110** with laser **106** light pulses to deliver each laser Tx spot sequentially through SAWSR **102** to eye **104**.

[00015] In both L1 and L2 laser embodiments of the invention, laser **106** produces light in one or more wavelengths that correspond to cornea absorption coefficients in the range of 5 to 500 cm^{-1} . An example of these wavelengths is in the 2 μm spectral region within the 1.75 to 2.25 μm corneal absorption band. An example is a laser **106** that produces a wavelength of 1.93 μm [Ref. 4].

[00016] In both L1 and L2 laser embodiments of the invention, laser **106** produces one or more pulses of light with pulse durations in the range of 5 to 500 ms. An

VIS, Inc. - Confidential

example is a laser **106** that produces 4 sets of pulses with pulse durations of 150 ms [Ref. 4].

[00017] In both L1 and L2 laser embodiments of the invention, laser **106** produces one or more treatment (Tx) spot energies that irradiate eye **104** in the range of 5 to 500 mJ per spot. An example is a laser **106** that produces Tx spot energies of 20 to 70 mJ per spot [Ref. 4].

[00018] In optical fiber array embodiments of the invention, optical fiber array **110** includes one or more optical fibers that transmit laser light and that are arranged in treatment (Tx) patterns. Figure 2 shows example Tx patterns that are useful for myopia control. These patterns include 16 Tx spots of 0.5 mm diameter in Figs. 2A, 2B and 2C arranged symmetrically with 8 spots on 3.0/4.2 mm (Fig. 2A), 2.0/3.2 mm (Fig. 2B) and 1.0/2.2 mm (Fig. 2C) centerline diameters of the inner/outer rings. These patterns also include 16 Tx spots of 1.0 mm diameter in Figs. 2D, 2E and 2F arranged symmetrically with 8 spots on the same centerline diameters of inner/outer rings as Figs. 2A, 2B and 2C, respectively. The Tx spots can be variable in number from 1 through 16 or greater, circular or non-circular, equal or unequal in spot diameter or non-circular shape, equal or unequal in location (both distance and angular orientation) with respect to a centration reference, and equal or unequal in Tx spot energy. The Tx spots can also be configured to have predetermined distributions of laser energy within each spot. These variables are adjusted (personalized) as required for a predetermined reduction of myopia and/or myopic astigmatism in each eye. An example for hyperopia and presbyopia treatment (Tx), but not myopia Tx, is a Tx pattern of 16 spots of 0.5 mm diameter arranged

VIS, Inc. - Confidential

symmetrically with 8 spots on 6.0/7.2 mm centerline diameters of the inner/outer rings [Ref. 4]. Tx patterns of Tx spots at large centerline diameters (such as 6.0/7.2 mm) produce multifocal corneas with central steepening as demonstrated previously [Refs. 4, 5 and 6] while Tx spots at small centerline diameters (such as 3.0/4.2 mm) produce corneas with central flattening as demonstrated in animal experiments [Ref. 5] and in human eyes [Ref. 6]. The fiber optic array **110** has a distal handpiece that contains accurately positioned fibers and that is docked accurately and securely onto the SAWSR **102** using matching handpiece and SAWSR magnets [Ref. 4].

[00019] In sapphire applanation window/suction ring embodiments of this invention, SAWSR **102** includes a sapphire or non-sapphire applanation window that transmits laser light to the eye **104** and that has example dimensions of, but not limited to, 10.0 mm diameter and 0.1 mm thickness.

[00020] While the description of the invention herein shows, describes, and points out novel features as applied to various embodiments, it will be understood that various omissions, substitutions, and changes in the form and details of the device or method illustrated can be made without departing from the spirit of the disclosure. As will be recognized, certain embodiments of the inventions described herein can be embodied within a form that does not provide all of the features and benefits set forth herein, as some features can be used or practiced separately from others. All changes that come within the meaning and range of equivalency of the claims are to be embraced within their scope.

VIS, Inc. - Confidential

[00021] This invention can be used in combination therapy including, but not limited to, medications such as atropine, neurotransmitters such as dopamine that decrease excessive axial elongation of the eye, good environmental measures such as increased exposure to sunlight, or any other therapy that reduces excessive axial elongation of the eye during childhood and later in life.

Benefits and Advantages of the Invention

[00022] A previous laser **106** and its use to treat human eyes was unsatisfactory for myopia control since it produced highly damaged Tx spots that were prominently visible due to their dense (high) opacity, depth (greater than 200 μm) and long persistence (one month or longer post-Tx) in a Tx pattern that would be suitable for corneal flattening [Ref. 6]. Those unsatisfactory Tx spots at 3.0 mm centerline diameter were within the central region of the cornea and typically within the pupil diameter, thereby raising concern about their effect on visual acuity and the quality of vision. The laser **106** and its use to treat human eyes described herein in this invention produces undamaged Tx spots that are barely visible due to their light (low) opacity, depth (less than *ca.* 150 μm) and short persistence (typically fading significantly within a few days post-Tx) [Ref. 4]. The Tx spots of this invention are in the central region of the cornea but are out-of-focus and hence not observed by any patient whose eye(s) are treated. The Tx spots of this invention produce little or no light scattering so corneal clarity (without significant opacity and possible dysphotopsias such as glare, starburst and halo) is conserved. The Tx spots of this invention are highly suitable for myopia control.

VIS, Inc. - Confidential

[00023] The procedure for use of this invention is safe, repeatable, noninvasive and simple and rapid for both patient and physician [Ref. 4]. Patient comfort is excellent during treatment and there are typically only minor discomforts (such as, but not limited to, photophobia and foreign body sensation) for a few days post-treatment. There is little or no post-treatment recovery period or need for aftercare.

[00024] Patients of all ages with and/or at risk of myopia, myopic astigmatism and progression of these ametropias can be treated using this invention for temporary reduction of their refractive errors. Symmetrical corneal flattening and hence myopia and regular myopic astigmatism reduction is extended in duration by preselection of laser **106** parameters and Tx patterns. Irregular myopic astigmatism can also be reduced by preselection of specialized patterns. This invention offers a practical alternative to other methods of myopia control such as surgery or contact lenses.

[00025] Children and adolescents (typically in the 4- to 18-year-old age range) with, or at risk of, myopia, high myopia and myopia progression can be treated using this invention. Surgery (using excimer and/or femtosecond lasers) is not authorized by FDA and other regulatory agencies for patients less than 18 years old. The main current treatment of these children is with the use of low dose (0.01% to 0.05%) atropine in aqueous solution that is administered in eye drops daily [Ref. 3]. Atropine medication has side effects such as photophobia and reduced accommodation that affects near vision. Low dose atropine medication is only partly effective - for example, in one study for children of ages 4 to 9 without baseline myopia, children with fast myopic shift (spherical equivalent change of 0.5

VIS, Inc. - Confidential

D or less over 12 months or 1.0 D or less over 24 months) remained at 25.0% prevalence for 0.05% atropine [Ref. 7]. While this outcome was better than that for lower dose atropine (for example, children with fast myopic shift remained at 45.1% prevalence for 0.01% atropine), these outcomes are not much better than placebo with 53.9% prevalence. The invention described herein is likely to reduce fast myopic shift better than atropine and/or other modalities presently used.

[00026] An even more promising use of this invention is for prevention of myopia and myopic progression in children by producing and/or conserving hyperopia reserve (HR). If children are treated at an early age to give them, or conserve, more than 1.0 D of HR, they may experience little or no myopic shift as they age [Ref. 3]. Any myopic shift that remains can be reduced or eliminated by repeated treatments using this invention.

CLAIMS

What is claimed is:

[00027] 1. A device comprising: one or more lasers with selected laser parameters [wavelength(s), pulse duration(s) and energy output(s)] that match requirements for safe and efficacious treatment of eyes, laser beam diagnostics to monitor laser beam(s) and to provide information to adjust laser parameters, one or more inputs to optical fibers and an optical fiber array to transmit laser light to the eye, a translation stage and position controller to provide predetermined matches of laser beams to optical fibers, a sapphire applanation window/suction ring to mount on the eye to direct laser light to the eye, ocular diagnostics to provide information to predetermine laser parameters and treatment parameters required for the desired

VIS, Inc. - Confidential

treatment (such as reduction of myopia, myopic astigmatism and progression of these ametropias) and a computer-based control to operate the device with the predetermined laser parameters and treatment patterns.

[00028] 2. The device of claim 1 that includes one or more lasers and associated power supplies that produce wavelengths of laser light that correspond to corneal absorption coefficients in the range of 5 to 500 cm^{-1} , pulse durations of 5 to 500 ms, and energy outputs to produce treatment energies per laser spot on the cornea in the range of 5 to 500 mJ per spot.

[00029] 3. The device of claim 1 that includes an optical fiber array comprising one or more optical fibers that transmit laser light to the cornea and that have sufficient transmission of the wavelength(s) of laser light to deliver sufficient treatment energies to treatment spots on the eye.

[00030] 4. The device of claim 1 that includes a translation stage for optical fibers and a position controller of the translation stage for sequential or simultaneous delivery of laser light through the optical fiber array to the eye.

[00031] 5. The device of claim 1 that includes a sapphire applanation window/suction ring that permits accurate mounting on the eye and that permits accurate delivery of laser light to the eye.

[00032] 6. The device of claim 5 that provides suction.

[00033] 7. The device of claim 1 that is configured to produce treatment patterns of laser treatment spots on the eye for safe and efficacious treatment for myopia control.

[00034] 8. The device of claim 1 that includes laser beam diagnostics [for measurements of laser wavelength(s), laser pulse duration(s), and laser output

VIS, Inc. - Confidential

energies] to provide information to predetermine laser treatment conditions for safe and efficacious treatment of the eye.

[00035] 9. The device of claim 1 that includes ocular diagnostics (such as, but not limited to, instruments to measure refraction and axial length of the eye) to provide information to predetermine laser treatment conditions for safe and efficacious treatment of the eye.

[00036] 10. The device of claim 1 that includes computer-based control of the device that uses information from both beam diagnostics and ocular diagnostics to predetermine laser treatment conditions for safe and efficacious treatment of the eye.

[00037] 11. The treatment patterns of claim 7 that are safe and efficacious for myopia control.

[00038] 12. Combination therapy by treatment of the eye using the device of claim 1 plus one or more additional therapies including, but not limited to, medications such as atropine, neurotransmitters such as dopamine that decrease excessive axial elongation of the eye, good environmental measures such as increased exposure to sunlight, or any other therapy that reduces excessive axial elongation of the eye during childhood and later in life.

VIS, Inc. - Confidential

Abstract

[00039] The present invention includes an ophthalmic device (incorporating, but not limited to, one or more lasers, an optical fiber array for delivery of laser light to a sapphire applanation window/suction ring that is mounted on the eye) and methods for use of the device (including, but not limited to, use of specific treatment patterns) to provide safe and efficacious treatment of the eye for myopia control (*i.e.*, reduction of myopia, myopic astigmatism and/or the progression of myopia and myopic astigmatism) to improve, stabilize or restore vision. The applications of the present invention include, but are not limited to, myopia control. The myopia control devices and methods of the present invention can also be used in combination with other therapies including, but not limited to, pharmacological therapies.

VIS, Inc. - Confidential

References

- 1 – Holden BA, *et al.* Global prevalence of myopia and high myopia and temporal trends from 2000 to 2050. *Ophthalmology* 2016;123:1036-1042.
- 2 – Morgan IG, *et al.* The epidemics of myopia: aetiology and prevention. *Prog Retin Eye Res* 2018;62:134-149.
- 3 – Wang J, *et al.* Normative value of hyperopia reserve and myopic shift in Chinese children and adolescents aged 3-16 years. *Br J Ophthalmol* 2024;108:1024-1029.
- 4 – Rodgers KJ, *et al.* Improved method of laser thermal keratoplasty to overcome presbyopia. In *Ophthalmic Technologies XXI*, edited by Soderberg MF, *et al.*, Proc SPIE 2011;7885:N-1 through N-8.
- 5 – Morerira H, *et al.* Holmium laser thermokeratoplasty. *Ophthalmology* 1993;100:752-761.
- 6 – Ariyasu RG, *et al.* Holmium laser thermal keratoplasty of 10 poorly sighted eyes. *J Refract Surg* 1995;11:358-3657.
- 7 – Yam JC, *et al.* Ten-year change in visual function and incidence of visual impairment in highly myopic children and adults. *JAMA* 2023;329:472-481.