

A Novel Dual-wavelength, Dual-function Laser System for Presbyopia and Glaucoma Treatments

ABSTRACT

Purpose: To update the accommodation mechanisms and propose a dual-wavelength, dual-function laser system for presbyopia and glaucoma treatments.

Study Design: laser sclera softening (LSS) for increased accommodation of presbyopic eyes.

Place and Duration of Study: New Taipei City, Taiwan, between Jan., 2023 and Feb., 2023

Methodology: Accommodation gain (AG) can be improved by: (i) thermal shrinkage of the scleral stroma and ciliary body, or (ii) softening of the scleral stroma (with temperature range of 70°C to 90°C), such that the lens front and back curvature change (or lens thickening), leading to the thickening of ciliary body and its apex, and the increase of the space of ciliary body and lens equation (SCL), and the length of the posterior vitreal zonules (PVZ) increases.

Results: A novel dual-color laser system having wavelength A and B, acting on the front-zone and back-zone of the sclera, respectively, where laser-A has a deep thermal penetration the sclera and ciliary body (CB) (0.5 to 1.0 mm); and laser-B has a shallow penetration depth in the sclera (0.3 to 0.5 mm), based on the optical property of the sclera. Laser-A (having a wavelength about 0.8 to 0.98 μm) leads to thermal shrinkage of the ciliary body such that the CLS is increased for accommodation gain which is much more effective than the prior art.

Conclusion: The increase of AG can be achieved by scleral softening and ciliary body shrinkage which increase the SCL. A proposed novel dual-color laser system acting on the front-zone and back-zone of the sclera, respectively, could provide higher AG than that of single wavelength, or prior arts using scleral ablation. However, further clinical studies are required to justify the proposed novel system with predicted advantages and efficacy based on the optical properties of sclera.

Keywords: Presbyopia; accommodation; scleral softening; glaucoma; vitreous zonules; lens; ciliary body; ciliary muscle contraction.

1. INTRODUCTION

Age related presbyopia is due to progressive weakening or atrophy of the ciliary muscles. The accommodative theory, postulated by Helmholtz, remains the most widely supported and cited [1,2]. Accommodation is the ability to focus on near objects through controlled changes in the shape and thickness of the crystalline lens and mediated by ciliary muscle (CM) contraction [3,4]. Optically, it is the lens shape change to increase the refractive power of the eye for accommodation occurs. Therefore, lens is the prime component for the loss of accommodation with age. Accommodative lens thickening and the resting CM apex thickness explained accommodative amplitude slightly better than age alone [3-7]. Croft et al [5] also demonstrated that the vitreous zonules and its posterior insertion zone have a role in accommodation and presbyopia in the human eye. During accommodation, the lens equator moves forward and inward, and this movement is reduced with age, possibly due to the age-

related loss in accommodative forward movement of the vitreous zonules posterior insertion zone [3,7].

The effectiveness of CM contraction for lens relaxation (or accommodation) may be influenced by the combined aging factors, including lens property changes (index, size, thickness and curvature), tissue elastic changes (in sclera and ciliary) and the zonular tension change [1,3]. Various options have been reported for presbyopia corrections include: bifocal or progressive spectacles, monofocal or multifocal contact lenses, scleral expansion band), scleral radial incision by knife, silicon expansion plugs, laser scleral ablation, conductive keratoplasty, diode laser thermal keratoplasty, LASIK -presbyopia and accommodative [1,2]. The surgical strategies for correction of near vision loss in presbyopia including [8]: (i) changing of the optical pathway by corneal reshaping, (ii) altering function of the accommodative mechanism of the scleral and/or ciliary tissues, and (iii) softening the lens itself. Various technologies have been reported for presbyopia corrections include [1,2,8-12]; SEB (scleral expansion band), SRI (scleral radial incision by knife), SEP (silicon expansion plugs), BIC (band implanted in ciliary body), LPR (laser presbyopia reversal using scleral ablation), CK (conductive keratoplasty), DTK (diode laser thermal keratoplasty), LASIK (presbyopia LASIK using monovision), AIOL (accommodative IOL).

Review articles for the treatment of presbyopia, including the mechanisms, principles and various surgical systems, have been published [1,2,8-16], in which Lin [15,16] proposed an invasive presbyopia treatments using a single-wavelength IR diode laser. The present article further updates the technology trend with a proposed novel strategy for improved accommodation using a dual-wavelength laser system. In addition, the action mechanism of accommodation based on the measured data [3,5,17,18] will be further explored.

2.METHOD AND THEORY OF ACCOMMODATION

2.1 The Mechanisms of Accommodation

Fig. 1 shows the eye structure consists of [cornea, sclera (13), ciliary body and its apex, the anterior vitreal zonules (AVZ), posterior vitreal zonules (PVZ), the cross vitreal zonules (CVZ), lens and iris, where the circumlental space (CLS) is the distance between the ciliary ciliary body apex and the lens equator [3,7].

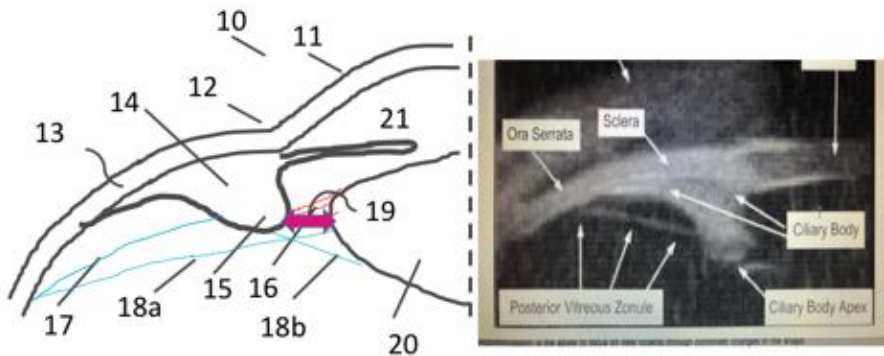


Fig. 1. Schematic of an eyestructure consists of [12,14]: cornea (11), scleral spur (12), sclera (13), ciliary body (14) and its apex (15), the anterior vitreal zonules (AVZ) (16), posterior vitreal zonules (PVZ) (17), the cross vitreal zonules (CVZ) (18a, 18b), lens (20) and iris (21), where space (CLS) (19) is the distance between the ciliary ciliary body apex (15) and the lens equator. Also shown (in right figure) is the OCT data [3,7].

Rigorous biomechanical model of the human lens and accommodation was reported with finite element modeling to show the dynamic accommodation and the changes for the key parameters were measured [3,4,7]. The CM is the core tissue for the function of accommodation process. It consists of three groups of muscle fibers: longitudinal, radial and circular [3]. Contraction of the entire CM as a whole pulls the anterior choroid forward, moving the apex of the ciliary processes towards the lens equator, and serves the primary function of releasing resting zonular tension at the lens equator to allow accommodation. During contraction of the CM, the circular portion of the CM tends to increase in thickness, whilst the radial and longitudinal portions decrease in thickness [3,7]. Furthermore, the lens undergoes several changes: its diameter decreases, its thickness increases, the anterior and posterior surfaces of the lens move anteriorly and posteriorly, respectively and the curvatures of the anterior and posterior surfaces of the lens increase.

It was reported [7,17,18] that during accommodation, the lens equator moved forward (anteriorly) with respect to the scleral spur by 0.48 mm in the young human eyes, by 0.45 mm in the middle-aged group, and by 0.11 mm in the older eyes. The CLS was significantly related to accommodative amplitude and declined significantly with age. In the young human subjects, the unaccommodated CLS was very similar to the accommodated state. Therefore, the anterior zonules (AVZ), which extend from the region of the ciliary processes to the lens equator, were observed to be taut in the unaccommodated and accommodated states. In the older eyes, the CLS in the accommodated state was 0.15 mm narrower than in the unaccommodated state. The greater the narrowing of the CLS from the unaccommodated to the accommodated state, the lower the accommodative amplitude. The CM apex thickening in young eyes was 0.34 mm, and was reduced to 0.15 mm in middle-aged eyes and to 0.08 mm in older eyes [7,18].

During accommodation, the PVZ moved forward in a sagittal plane along the curvilinear boundary of the globe (anteriorly, toward the scleral spur) by 1.01, 0.46 and 0.03 mm in the young, middle-aged, and older subjects, respectively [18]. Across the age range, the accommodative amplitude is proportional to the forward movement of the insertion zone. In the resting human eyes, the Spur-to-VZ insertion distance did not change with age. However, in the accommodated older eyes the Spur-to-VZ insertion distance tended to be longer, in comparison with the young eyes, due to the accommodative shortening of this distance in the younger eyes, but not the older eyes. Thus, neither the resting nor the accommodated Spur-to-VZ insertion distance was related to accommodative amplitude.

Accommodative CM apex thickening was related significantly to accommodative lens thickening, lens centripetal movement and lens equator forward (anterior) movement [3,5].

The more the muscle apex thickened, the more the lens thickened, and the lens equator tended to move forward (anteriorly) and internally away from the sclera toward the optical axis of the eye, so that the overall movement was antero-inwardly during accommodation.

The more the vitreous zonules insertion zone moved forward, the more the lens equator moved forward, and the more the lens thickened during accommodation. Based on above data, of Croft et al [6] proposed a model from the stepwise regression: Accommodation = $17.62 + 20.75 \times (\text{Lens thickening}) - 20.39 \times (\text{ATR apex thickness})$; where the calculation of the accommodative change is dependent upon the position of the PVZ, and the posterior restriction of the insertion zone's movement during accommodation may dampen accommodative lens thickening.

2.2 Analysis of measured accommodative gain

Lin [14,15] developed a formulas for the accommodative gain (AG and AG') due to the change of the lens anterior and posterior radius of curvature, (R, R'), given by: $AG = (m + M) dR$, and $AG' = (m' + M') dR'$, respectively. For typical value of $m=0.53$, and $M=1.35$, we

obtain $AG=1.88$ dR, that is the rate function of AG due to lens anterior curvature increase (or myopic shift) defined by $R_A=-dR/d(AG)=11/1.88=-0.53$ (mm/D), Similarly, For typical value of $m'=1.48$, and $M'=-2.67$ (D/mm), $AG'=4.15dR'$, we obtain another rate function $R_A'=dR'/d(AG')=1/4.15=-0.24$. We note that AG is more sensitive to dR' and dR , because typical value of $R'=6.0$ mm, much smaller than $R=10.2$ mm. These theoretically predicted values (for dR and dR') are very close to (within 10%) the measured data of Martinez-Enriquez et al. [19]. Fig. 4 shows the measured average rate functions (or slopes) (shown in bars and dashed curves), and theoretical curves (in solid red curves). Similar data were also reported by the modelling of Cabeza-Gil et al [6].

Cabeza-Gil [7]also reported the measured and calculated change in: (i) the anterior (R) and posterior (R') lens radius of curvature, (ii) lens thickness (TL), (iii) anterior chamber distance (ACD), (iv) anterior and posterior lens movement, and (v) lens diameter, as functions of the change in accommodation. The linear response with an increase in accommodation of 5.82 D and an increase in TL of 0.44 mm for a reduction of 0.66 mm in the CM ring diameter, or 67.54 μ m in the maximum CM thickness (CMax). Their data are comparable with that of Ruggeri et al [42] reported change of TL and CMax values of 0.20 mm and 72.0 μ m, respectively, for an accommodation stimulus of 4 D in a 22-year-old subject. Richdale et al. [17,18]also reported a change of 0.38 mm and 98.41 μ m, respectively for TL and Cmax, for a 5.85 D accommodative response in a 29-year-old subject

As shown earlier in Fig. 1 the eye structure consists of cornea, sclera, ciliary body and its apex, the anterior vitreal zonules (AVZ), posterior vitreal zonules (PVZ), the cross vitreal zonules (CVZ), lens and iris, where the circumlental space (CLS) is the distance between the ciliary body apex and the lens equator.

It was proposed that accommodation may be improved by [15,19]: (i) thermal shrinkage (with temperature range of 50^oC to 70^oC) of the scleral stroma such that the space between the lens and ciliary body (CLS), or ciliary apex ring diameter (CAD) increases; or (ii)softening of the scleral stroma (with temperature range of 70^oC to 90^oC) such that the length of the posterior vitreal zonules (PVZ) increases. It was reported (US Pub. No. 2020/0000634) that in non-presbyopic eyes, the length of PVZ changes from 4.6 mm in the un-accommodative state (UAS) to 3.6 mm in the accommodative state (AS) for a net change of 1.0 mm. In comparison, PVZ mobility is substantially reduced in presbyopic eyes: the PVZ length changes from 4.6 mm in the UAS to 4.45 mm in AS. for a net change of only 0.15mm. Furthermore, the SLC is significantly smaller in presbyopic eyes compared to non-presbyopic eyes: with measured values of 0.68mm and 0.35mm (in UAS) and 0.68mm and 0.2mm in AS, respectively. They also reported [19] that the mid-stroma of the sclera can be heated to approximately 60^o C to increase scleral elasticity and shrink the mid-stroma within a range of 100 μ m to 250 μ m of shrinkage, and thereby increase the CAD about 400 μ m; and the SLC within a rage from 200 to 500 μ m. The inward mobility of the ciliary body can be enhanced post-treatment by approximately 250 μ m [12]. These data may be related to the formula [9]: $A=m(dS) + m'(dR1) + m''(dR2)$, where dS , $dR1$ and $dR2$ are associated with the increase of CLS and PVZ.

3. RESULTS AND DISCUSSION

3.1 System specification

Prior arts of US patents for presbyopia correction including such as US Pat. Nos. 5529076, 5489299, and 5722952 of Schachar using scleral band expansion. Prior arts of US Pat. Nos. 6,258,082 and 6,263,879 of the present author (JT Lin), and US Pat. No. 8348932 of Hipsley et al proposed the scleral ablation by ablating lasers, such as Er:YAG (at 2.94 μ m) and UV laser (at 266 nm). The major drawbacks of these prior arts include: invasive surgery of the eye, scleral bleeding, and complex procedure and specially the post surgery regression of

accommodation within a short period of from few months to 2 years. Furthermore, the average accommodation again is about 2.0 D, which might not be enough after regression.

To overcome the above described drawbacks of the prior arts, we have proposed a scleral softening system replacing the existing Er:YAG sclera ablation [13,15]. Another new dual-color lasersystem is proposed as follows.

Fig. 2 shows a dual-color laser system having priority wavelength A and B, acting on the front-zone and back-zone of the sclera, respectively; where laser-A is partially transparent (>60%) to the sclera, whereas laser-B is highly absorption (>80%) to by sclera. The proposed could provide higher AG than that of single wavelength, or prior arts using scleral ablation.

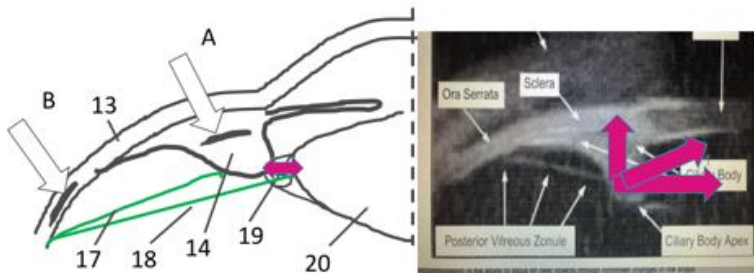


Fig. 2 A novel dual-color laser system having wavelength A and B, acting on the front-zone and back-zone of the sclera, respectively. Also shown is the antero-inward movement of the ciliary body (shown by red arrows) [3,7].

As shown by Fig. 3 for the optical properties of human sclera [21,22], such that laser-A has a thermal penetration depth into the ciliary body (CB) (about 0.5 to 1.0 mm); and laser-B has a shallow penetration depth in the sclera (about 0.3 to 0.5 mm). Laser-A (having a wavelength about 1.4 to 2.2 μm) leads to thermal shrinkage of the ciliary body such that the CLS is increased for accommodation gain which is much more effective than the prior art having a shallow penetration limited in the scleral stroma. In comparison, laser-B (having a wavelength about 800- 980 nm) leads to thermal shrinkage (and/or softening) of the sclera in the back-zone leading to the extra-space for the pulling of AVZ/PVZ during CB contraction, and the extension of PVZ-C connecting to the lens equator, such that the overall antero-inward lens movement. Accommodative CMapex thickening was related to lens thickening and centripetal movement, but also related to the lens equator forward (anterior) movement [6,8]. The more the muscle apex thickened, the more the lens thickened, and the lens equator tended to move forward (anteriorly) and internally away from the sclera toward the optical axis of the eye, so that the overall movement was antero-inwardly during accommodation. The accommodation gain in the direction as show by the "red arrows" of Fig. 3, the more the vitreous zonules insertion zone moved forward, the more the lens equator moved forward, and the more the lens thickened during accommodation.

Fig. 4 shows the proposed thermal patterns of the treated scleral areas showing the deeper (31) and shallow thermal area (32) produced by light-A and B, respectively.

Fig. 5 shows a single-laser system [15] consists of light source (10), fiber (11), a 1x4 fiber splitter (12) and hand piece (70) coupled to a end base (60) which contacts to the treated sclera surface to deliver the laser energy at a predetermined pattern. Also shown is the structure of the base (61) having 4 holes (151-154) allowing the output fibers to be inserted and positioned fit to the desired treatment patterns.

Fig.6 is an extension of Fig.5 to a dual-laser system consists of 2 output wavelength 11-A and 11-B which are coupled to 2 sets of 1x2 fiber couplers (12a and 12b) such that 4 output beams 151 to 154 are produced from the fiber ends, which are inserted to a holding base (61) contacting to the treated scleral surface.

Fig. 7 shows example of desired treatment patterns defined by 2 circles (31 and 32) having a diameter about (11 to 12 mm) and about (13 to 15 mm), respectively. The zone area (35) must be avoided to prevent eye rotating muscle. Also shown is the circle (33) defines the limbus (about 10 to 11 mm) of an eye. In this example, we have applied 3 sets of base (61) defined 4-beams in each of the semicircle, or a total of 6 sets (or $6 \times 4 = 24$ spots). We note that treatment limited to the inner circle (13) only is suitable for glaucoma diseases, whereas treatment using both circles is for presbyopia only, or dual function for presbyopia and glaucoma (when the patient also requires a reduction of high IOP).

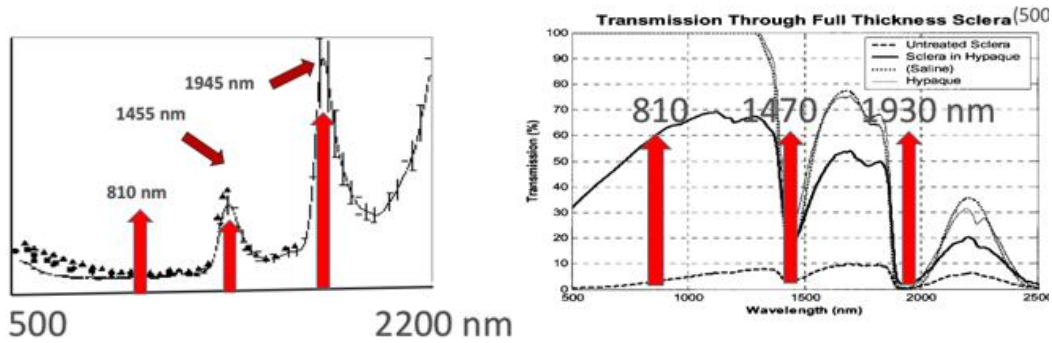


Fig. 3 The spectral dependence of absorption coefficient of human sclera [21,22]

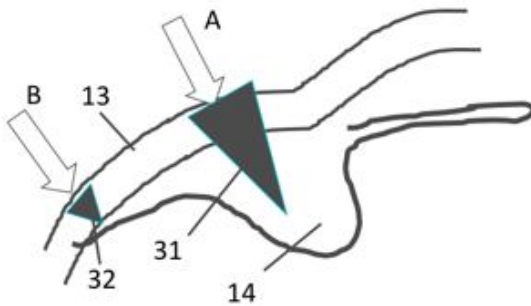


Fig. 4 The thermal patterns of the treated scleral areas showing the deeper (31) and shallow thermal area (32) produced by light-A and B, respectively.

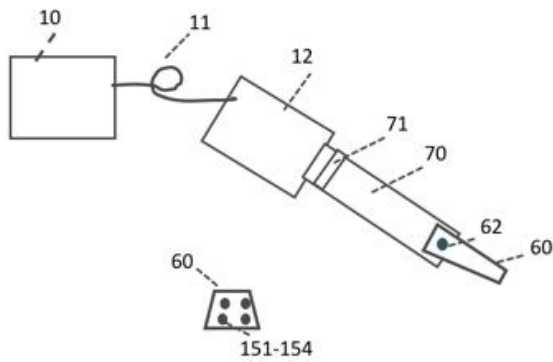


Fig. 5 A single-laser system [9] consists of light source (10), fiber (11), a 1x4 fiber splitter (12) and hand piece (70) coupled to a end base (60). Also shown is the structure of the base (61) having 4 holes (151-154).

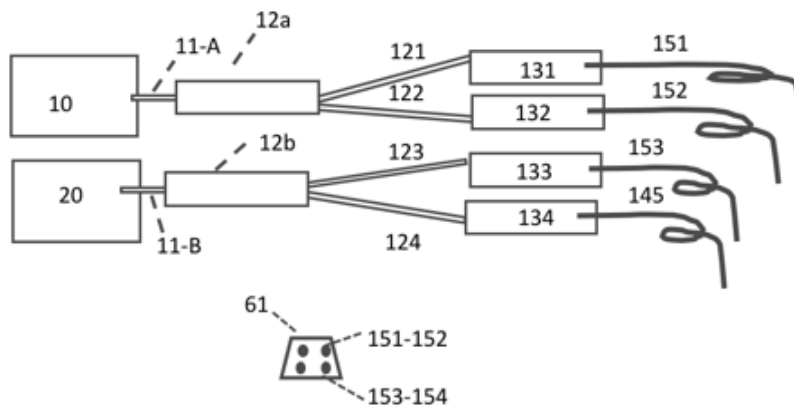


Fig. 6 A dual-laser system consists of 2 output wavelength 11-A and 11-B which are coupled to 2 sets of 1x2 fiber couplers (12a and 12b) to produce 4 output beams which are inserted to a holding base (61).

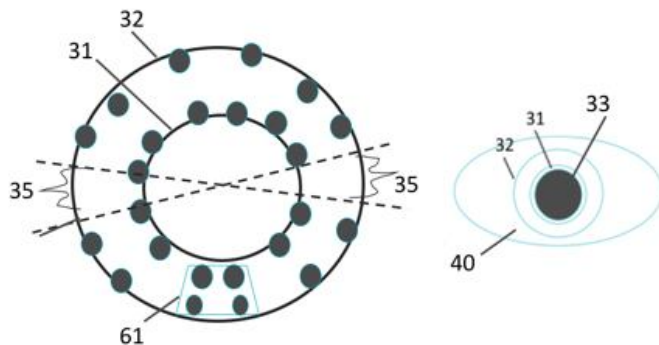


Fig. 7 Proposed treatment patterns defined by 2 circles (31 and 32) having a diameter about (11 to 12 mm) and about (13 to 15 mm), respectively.

3.2. Design specifications

Aproposed novel dual-color laser system acting on the front-zone and back-zone of the sclera, respectively, could provide higher AG than that of single wavelength, or prior arts

using scleral ablation. As shown earlier in Fig. 1 the eye structure consists of cornea, sclera, ciliary body and its apex, the anterior vitreal zonules (AVZ), posterior vitreal zonules (PVZ), the cross vitreal zonules (CVZ), lens and iris, where the circumlental space (CLS) is the distance between the ciliary body apex and the lens equator. To achieve the desired dual applications, I propose the following key parameters and treatment areas (protocols).

As shown earlier in Fig. 2, a dual-wavelength diode laser system with wavelength range about 0.8 to 0.95 μm (for laser-A) and about 1.4 to 2.2 μm (for laser-B) is proposed and depending on applications, and other parameters are discussed as follows.

(a) For presbyopia only

Laser-A requires:

laser power (P) of each spot, having spot diameter about $R=0.3$ to 0.6 mm, acting on the cornea surface is about $P=0.5$ to 1.5 W, treating period (t) is about $t=0.5$ to 2.0 seconds, or having laser dose (E) is about $E=80$ to 500 mJ; and acting area having a circle diameter (D1) of about $D1=11$ to 12 mm, Total number of spots acting around the circle-31, $N=4$ to 32 . The temperature increase in the sclera and ciliary body to about about $T=50$ to 60°C , just for enough thermal shrinkage leading the increase of CLS.

Laser-B requires:

$R=0.3$ to 0.6 mm, $P=0.5$ to 1.5 W, $t=0.2$ to 0.5 seconds; $E=40$ to 100 mJ (for each spot); and acting circle $D2=13$ to 15 mm, with $N=6$ to 32 . where higher sclera absorption leads to scleral softening and increase of CLS via higher temperature increasing to about $T=60$ to 85°C ; and the number of laser spots, $N=6$ to 32 .

(b) For dual function of presbyopia and glaucoma

Laser-A, having a dual-function of presbyopia and glaucoma, requires a higher laser power (P) of each spot, about $P=1.5$ to 3.0 W. It can be CW mode or micropulsed model of about 0.01 ms on-time and 0.1 ms off-time to reduce thermal damage. The parameters of laser-B are similar to that of case (a).

(c) For glaucoma only

Only laser-A is needed and one may use only the beam 151 and 152 and beam 153 and 154 are blocked, or no fibers are inserted to the base (61), where larger N about 24 to 36 is preferred to assure the efficacy. The technique of scanning along circle-31 may be used as shown in the system made by Iridex (www.iridex.com), which, however, is not as uniform as what is proposed in the present article. In addition, Iridex method also depends on the surgeon's control of the scanning speed.

4. CONCLUSION

The improvement of AG can be achieved by scleral softening and ciliary body shrinkage which increase the SCL. The more the muscle apex thickened, the more the lens thickened, and the lens equator tended to move forward (anteriorly) and internally away from the sclera toward the optical axis of the eye, so that the overall movement was antero-inwardly during accommodation. Thus, it is concluded that a proposed novel dual-color laser system acting on the front-zone and back-zone of the sclera, respectively, could provide higher AG than that of single wavelength, or prior arts using scleral ablation. However, further clinical studies are required to justify the proposed novel system with predicted advantages and efficacy based on the optical properties of sclera and ciliary body.

CONSENT

It is not applicable.

ETHICAL APPROVAL

It is not applicable.

COMPETING INTERESTS

The author is the CEO of New Photon Corp. and has financial interest.

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