



# Principles of Accommodation and Technology Update of Presbyopia Corrections using IR and UV Lasers

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## Author's contribution

*The sole author designed, analyzed, interpreted and prepared the manuscript.*

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## ABSTRACT

**Purpose:** To update and review the technology and principles of laser presbyopia reversal (LAPR) via sclera ablation and thermal shrinkage using infrared and UV lasers. Recent clinical data and new methods are also summarized.

**Study Design:** LAPR using laser sclera ablation for increased accommodation of presbyopic eyes.

**Place and Duration of Study:** New Taipei City, Taiwan, between June, 2021 and July, 2021.

**Methodology:** Accommodation gain was obtained by laser scleral ablation of an eye using Er:YAG laser (at 2.94  $\mu\text{m}$ ) using either line-pattern or dots-pattern outside the limbus in the oblique quadrants of an eye. The principles of accommodation and the key factors influencing the outcomes are discussed. The accommodation gain (AG) after the surgery is mainly due the change in anterior curvature and anterior shift of the lens. The effectiveness of ciliary body 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. Classical theories of accommodation include Helmholtz and Schachar hypothesis. The key issues and new directions to overcome the drawbacks of the existing LAPR procedure (based on scleral ablation) are proposed. Clinical outcomes from two major groups, SurgiLight and Ace Vision, with two years follow are summarized.

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**Results:** Clinical outcomes during 2000 to 2020 are summarized showing an average Accommodation gain about 2.0 D, and postoperative regression about 0.25 D (after two years).  
**Conclusion:** Laser presbyopia reversal (LAPR) via sclera ablation using infrared laser is safe and effective, but suffers drawbacks of being invasive and procedures are too slow. New directions are required for improved outcomes.

*Keywords: Presbyopia; accommodation; Er:YAG laser; scleral ablation; regression.*

## 1. INTRODUCTION

### 1.1 History of laser Vision Corrections

Methods of vision corrections include the traditional non-surgical methods of eye glasses, contact lens, bifocal lenses, varifocal lenses, orthokeratological contact lenses, and various intraocular lens (IOL). The surgical methods include: RK (radial keratomileusis), ALK (automated lamellar keratoplasty), PRK (photorefractive keratectomy), CK (conductive keratomileusis), DTK (diode laser thermal keratomileusis), LASIK (laser assisted in situ keratomileusis), LASEK (laser epithelial keratomileusis), bladeless picosecond-laser assisted LASIK, and the most recent technology called small incision lenticular extraction (SMILE), a minimally invasive and flapless procedure [1-7]. Method of presbyopia corrections include: progressive lenses, bifocal lenses, monovision-LASIK, multifocal and accommodative IOL, refractive lens exchange, scleral band expansion (SBE), and laser sclera ablation (LSA) using infrared and UV lasers [3].

LASIK has been performed by lasers in the ultraviolet (UV) wavelength of (193-213) nm. The commercial UV refractive lasers include ArF excimer laser (at 193 nm) in U.S. Pat. No. 4,773,414 of L'Esperance, et al. and non-excimer, solid-state lasers such as those proposed by Lin in 1992 (U.S. Pat. No. 5,144,630) and in 1996 (U.S. Pat. No. 5,520,679). Other than the above reshaping by laser ablation of the cornea, corneal reshaping may also be performed by thermal shrinkage using a Ho:YAG or diode laser (at about 2 microns in wavelength), disclosed by Sand in U.S. Pat. No. 5,484,432, a procedure known as Ho:YAG laser thermal keratoplasty (HLTK); or by a diode laser thermal keratoplasty (DTK); or by a procedure called conductive keratoplasty (CK) using a radio frequency (RF) wave, for example, device disclosed by Doss and Hutson in U.S. Pat. Nos. 4,326,529 and 4,381,007. These methods, however, were limited to low-diopter hyperopic corrections, and major regression was found within about one year after the procedures.

Therefore, commercial products using above methods were terminated due to the drawback of regression, although they are simple and non-invasive comparing to Lasik. Regression of effect has been known to be a limiting factor in thermal refractive procedures for decades, as reported by prior arts of : (i) J Refract Surg. 1996;12(6):705–708, and (ii) Ophthalmic Surg Lasers. 1996;27:S521–S524. These methods, however, were limited to low-diopter hyperopic corrections. Strictly speaking, these prior arts cannot be used to correct the true "presbyopia" and only performed the mono-vision for hyperopic patients, similar to the method of so-presbyopic-LASIK.

Corneal crosslinking (CXL), mainly for the treatment of keratoconus [8,9], combining with CK for the correction of hyperopia was also reported [10]. It was reported that timing of the CXL (epi-on) procedure after CK is critical. When CK and CXL were applied sequentially in the same session, considerable regression was observed; however, it was improved if 1-day delay of CXL after CK. However, limited stability and outcomes remained to be overcome [10].

### 1.2 Prior Arts (Patents) of Presbyopia Corrections

According to the World Health Organization (WHO), the total presbyopic patient in the world is about 1.3 billion, which has doubled in 2015. In Nepal 58.8% among age group 35 and over are presbyopic, whereas in Asia; 43.8%, in America and Africa; 58.9%, in China; 32%. Prior arts of 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, and US Pat. No. 8348932 of Hipsley are using the ablation of scleral tissue by ablating lasers, such as Er:YAG (at 2.94 um) and UV laser (at 266 nm). The major drawbacks of these prior arts include their invasive of the eye, scleral bleeding, and procedure take a long time (longer than 40 minutes per eye), and specially the post surgery regression of accommodation within a short period of from few months to 2 years. Furthermore, the average accommodation

improvement is about 2.0 D, which might not be enough after regression.

Sacks et al. [11] reported femtosecond laser for early proof of concept for high precision subsurface photodisruption in the translucent sclera for the treatment of glaucoma and/or presbyopia. The major drawbacks of this prior art includes their invasive incision of the scleral stroma and the high system cost of the femtosecond laser, in which the proof of concept has never been developed to a commercial system.

Prior art of Lin and Martin, U.S. Pat. No. 6,491,688, proposed a non-invasive method using a gonio lens guided infrared laser to heat the zonules fiber of the eye for the treatment of presbyopia. This prior art however, suffers both clinical and technological difficulties. It is very difficult to control the gonio lens angle for a laser to target at zonules while keeping the lens and iris intact. The clinical outcome and potential complications of laser thermal shrinkage of zonules have not been tested. In addition, the selected heating of zonules is limited by the transparency of cornea and humous cavity at the selected laser spectra.

The present author also proposed various methods for presbyopia corrections shown by US Publications Nos. 20060259021 and 20060224146 using various lasers and No. 20040078009 combining laser surgery and pharmacologic means. Thermal shrinkage of scleral stroma was also disclosed by US Pub No. US20200000634 using long wavelength at about 5.8 to 6.5 microns, in which means of thermal sink to avoid the overheating of the corneal surface of conjunctiva was also proposed. However, these prior arts are not patentable due to their lack of merits. By the same reasons, there are few prior US Publications having proposed various methods for presbyopia treatment, but not yet patented. Most of the prior arts of non-patented-Publications are due to their similarity to the methods patented by the present author, in US Pat. Nos. 6,258,082 and 6,263,879.

Summary of various technology for presbyopia corrections include [3,12]; 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). Table 1 summarizes the technologies for vision corrections [12].

## 2. METHODS

### 2.1 Principles of Accommodation

#### 2.1.1 The ageing effects of human eyes

Many theories have been proposed for the age-related loss of accommodation including: (a) lens-based theories; (b) geometric theories; (c) lenticular theories; and (d) multi-factor theory [13,14]. The factors, which may contribute to changes in overall refractive power, include the corneal shape and thickness, lens shape and thickness, anterior and vitreous chamber depth and globe axial length. A change in the refractive index gradient of the lens cortex has been suggested to be a substantial factor contributing to the progression of presbyopia [13] and also proposed that because of the increased thickness of the lens and the anterior shift of the zonular attachments, presbyopia is a failure of the lens to be maintained in a flattened state. Cross-sectional studies of age-related changes in resting refraction show a drift towards hyperopia from about age 30 to 65 years and then a drift towards myopia after age 65 yr attributed to growth and the forward movement of the lens [14].

It should be noted that the "lens paradox" showing "myopic-shift" with ageing (due to lens curvature changes) may be counter-balanced by all those factors which may cause a hyper-shift including the decreases of lens equivalent index and globe axial length with age. We shall also note that the increase of lens power due to radii decrease is a weaker age-dependence than that of the equivalent refractive index change, therefore the "net effects" cause a "hyper-shift" by ageing.

#### 2.1.2 The Principles of Accommodation [15-22]

The accommodative theory, postulated by Helmholtz [15] remains the most widely supported and cited despite alternative theories proposed subsequently Mathews et al. [16,17], and Schachar et al [18-20]. As shown in Figs. 1 and 2, presbyopia, as traditionally accepted Helmholtz, is due to progressive weakening or atrophy of the ciliary muscles [15]. However, Schachar believes that the ciliary muscle does

not really become weak but rather “functionally, less efficient”. This inefficiency, he proposes, can be attributed to a progressive increase in the diameter of the lens during middle-age which causes a “crowding effect”. Consequently, the ciliary muscle is left with no space to contract. Thus, with a view to give the muscle “more room” for contraction.

Helmholtz hypothesis and Schachar hypothesis explain how accommodation occurs in a normal person. Helmholtz says that the ciliary muscles contract which relaxes the zonules causing the lens capsule to become relax. The jelly like lens material hence bulges in the center. There is a decrease in the equatorial diameter in the process. Schachar, on the other hand, postulates that when the ciliary muscles contract the

“equatorial” zonules tighten while the non-equatorial zonules relax. This has the effect similar to holding a balloon filled with water at its two poles and pulling it outwards. The net result is a bulging in the center i.e. an increase in the anterior-posterior diameter. The degenerative changes, which have been observed in the ciliary muscle of presbyopic eyes, he postulates, may be related to disuse atrophy and not suggestive of age-related atrophy. Comments on Schachar’s theory, the concept of scleral expansion is under hot debate. Many studies have actually discounted Schachar hypothesis. Glasser and Mathews [17] demonstrated a decrease in the equatorial diameter of the crystalline lens as an effect of scleral expansion. They also found no evidence of a dynamic change in power of presbyopic patients provide by Schachar.

**Table 1. Summary of technologies for vision corrections (laser and non-laser methods) [3-8]**

<b>Method</b>	<b>Features</b>
(1) PRK, LASEK...	Corneal surface ablation with epithelium removed or preserved; suitable for low diopter corrections (<3.5 D).io
(2) LASIK	Stroma ablation by laser after a “flap” is prepared by microkeratome.
(3) LASA	Presbyopia treatment by laser scleral ablation (LASA) to increase accommodation via ciliary body contraction.
(4) LZT, LCT	Laser zonules thermal (LZT) stimulation for presbyopia; non-invasive method using gonio lens and focused laser. Laser ciliary-body thermal shrinkage (LCT) for presbyopia.
(5) SEB	Scleral expansion band implanted in scleral layer: major regression.
(6) ACS	Anterior ciliary sclerotomy by diamond knife incision; major regression which may be reduced by silicon expansion plug.
(7) CK	Conductive keratoplasty using radio frequency wave for monovision correction;
(8) LTK & DTK	Laser thermal keratoplasty (LTK) using Ho:YAG (at 2.1 um) or diode laser (1.45 to 2.1 micron) (DTK).
(9) BFCR	Bifocal corneal reshaping by excimer LASIK for pseudo-accommodation.
(10) AIOL	Accommodative IOL implanted to lens capsule; forward movement for accommodation; could be single or dual-optics IOL.
(11) Phakic IOL	IOL implanted in the anterior, posterior chamber, or lens capsular bag.
(12) MIOL	Multi-focal IOL implanted for patient with high refraction errors.
(13) ICRS	Intra corneal ring segments for low myopia and astigmatism.
(14) Advanced CL	Advanced contact lens having multi-focal or designed for the correction of high-order aberration.
(15) Super Vision	Customized LASIK combined with wave-front technology; flying-spot scanning laser with eye tracking is required for customized and irregular corneal reshaping.
(16) SMILE	Small incision lenticular extraction by femtosecond laser.
(17) LASIK-plus (extra)	LASIK combined with corneal crosslinking (CXL) for thin corneas.

*\*Major technologies (inventors): Broad beam Excimer (L'Esperance, Blum, Tsuboda); LTK (Sand); SEB (Schachar); Flying-spot LASIK (Lin); LAPR & LACA (Lin), LZT (Lin, Martinez); Eye-tracking (Lai); Solid-state UV Laser for LASIK (Lin, Lai); BFCR (Ruitz). Most of the above technologies have been patented (1988-2004) and greater details may be found in US pat. No: 4718418, 5484432, 5520679, 5144630, 6263879, 6258082, 5533997, 5354331*

In addition to the classical theories of accommodation and presbyopia that conflict with Schachar's ideas, there are additional reasons suggesting that further verification of the efficacy of scleral expansion surgery would be prudent. Mathews [16] reported that scleral expansion surgery does not restore accommodation in human presbyopia. Mathews had suggested in EyeWorld (2001) that some of the improved reading ability demonstrated with subjective push-up testing might be a result of inadequate testing procedures. It may be due to some kind of induced multifocality of the eye, either in the cornea or in the crystalline lens, as a consequence of these surgical procedures. Patients may be left with some kind of aberration, either astigmatism or higher-order aberrations of the eye, which allows them to have functional near and distance vision simultaneously. Mathews stated that it is difficult to find a physiological explanation for how a surgical procedure done on one eye should restore accommodation in the contralateral eye [16].

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 contraction. To correct presbyopia, it is a fundamental necessity to understand how accommodation occurs and how it changes the optical and tissue parameters of an aged-eye. The effectiveness of ciliary body 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. We note that methods using mechanical sclera expansion techniques such as the scleral band expansion (SEB) suffer from major regression due to tissue healing, whereas the laser method showed less regression.

### 2.1.3 Formulas for Accommodation

Rigorous biomechanic model of the human lens and accommodation was reported [21-23]. Fig. 3 shows the biomechanical model of Beers and Van Der Heijde consisting of springs and a dashpot [21,22]. It also shows the eye structure consists of cornea (11), sclera (13), sclera stroma (11), ciliary body (14) zonules (15) and lens (16).

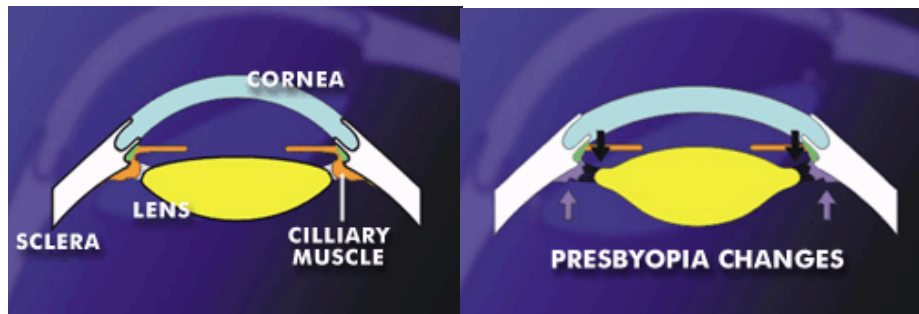


Fig. 1. Schematic depiction of a unaccommodated normal eye (left) and a prebyopic eye (right)

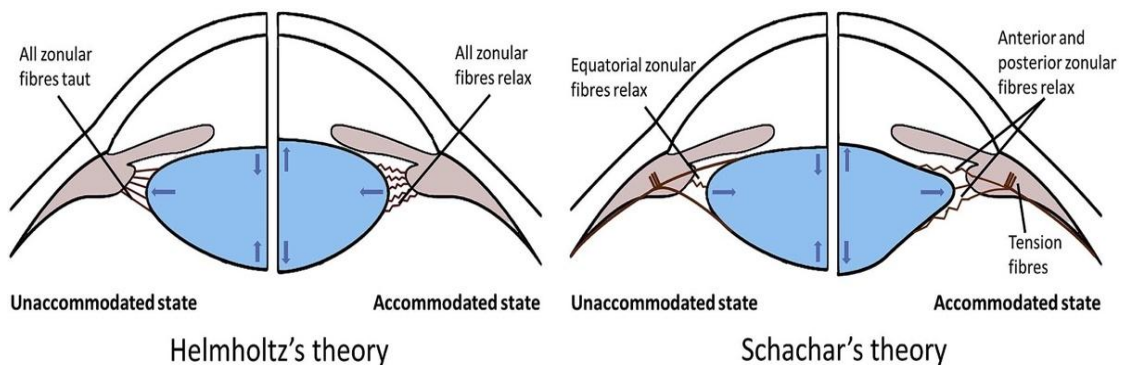


Fig. 2. Schematic depiction of the accommodative theories of Helmholtz [13] and Schachar [18; left-half are for unaccommodated-state, and right-half for accommodated-state

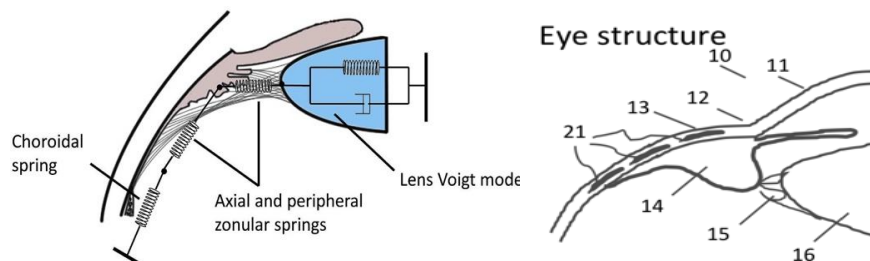
We are presenting comprehensive model based on new concepts as follows.

By aging, reduction of accommodation due to ciliary muscle becomes less flexible/elastic, or lens becomes more crowded. The protocol proposed in Lin's patent is: 8-incision (outside the limbus of 0.5 to about 5.0 mm, in the oblique quadrants of an eye) to cause the increased space between the ciliary body and lens capsule in order to provide increased amounts of accommodation. The increased amount of anterior movement of the posterior vitreous zonule from the unaccommodated state to the accommodative state can be about 250 to 1000  $\mu\text{m}$ . After the procedure, the posterior vitreous zonule can move anteriorly to allow the lens capsule to move anteriorly or reshape, or both, in order to provide improved accommodation.

Fig. 3 shows the eye structure consists of cornea (11), sclera (13), sclera stroma (11), ciliary body (14) zonules (15) and lens (16). It was known that accommodation may be improved by: (i) thermal shrinkage (with temperature range of  $50^{\circ}\text{C}$  to  $70^{\circ}\text{C}$ ) of the scleral stroma such that the space between the lens and ciliary body (SLC), or ciliary apex ring diameter (CAD) increases; or (ii)softening of the scleral stroma (with temperature range of  $70^{\circ}\text{C}$  to  $90^{\circ}\text{C}$ ) 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 4.6mm in the unaccommodative 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 that the mid-

stroma of the sclera can be heated to approximately  $60^{\circ}\text{C}$  to increase scleral elasticity and shrink the mid-stroma within a range of 100  $\mu\text{m}$  to 250  $\mu\text{m}$  of shrinkage, and thereby increase the CAD about 400  $\mu\text{m}$ ; and the SLC within a rage from 200 to 500  $\mu\text{m}$ . The inward mobility of the ciliary body can be enhanced post-treatment by approximately 250  $\mu\text{m}$ . These data may be related to our formula,  $A=m(dS) + m'(dR1) + m''(dR2)$ , where  $dS$ ,  $dR1$  and  $dR2$  are associated with the increase of SLC and PVZ. McDonald et al reported an eye at age 53 administered by pilocarpine induced an accommodation of 4.25 diopter after scleral buckling. Lens thickness increase ( $dt$ ) 0.18 mm and anterior shift ( $dS$ ) 0.57 mm were measured associated with the total accommodation  $A=A1+A2$ , calculated by our theory to be  $A2=0.53\text{D}$  and  $A1=3.78\text{D}$ , where a net anterior shift  $dS=-0.57+0.18=-0.39\text{mm}$  and change rate  $m=1.36(\text{D}/\text{mm})$  are used.

As shown in Fig. 4, Lin proposed a two-component theory that the total improved accommodation is given by [24,25]  $A=m(dS) + m'(dR1) + m''(dR2)$ , where  $dS$  is the change of the anteriorly chamber depth;  $dR1$  and  $dR2$  are change of the lens anterior and posterior surface radius, after the procedure;  $m$ ,  $m'$  and  $m''$  are the changing rate of accommodated per mm (in diopter/mm). For example,  $m$  is about 1.3 to 1.5 (D/mm), depending on eye conditions; and  $m'=0.75(\text{D}/\text{mm})$ ,  $m''=2.9m'$ . For older and/or harder lens, the accommodation is mainly attributed by the lens translation (or S1 change), whereas lens shaping dominates the power change in young or soft lens. It was known that change of the rear surface of the lens is about one-third of the front surface during accommodation, our formula shows that the contribution from posterior radius (R2) is about the same as that of anterior (R1), because of  $R2(6.0\text{ mm}) < R1(10.2\text{ mm})$ , and  $m''=2.9 m'$ , for the same change of curvature, or when  $dR1= dR2$ .



**Fig. 3 The biomechanical model of Beers and Van Der Heijde consisting of springs and a dashpot [21,22]**

Lin also proposed a 4-component theory as follows [25].

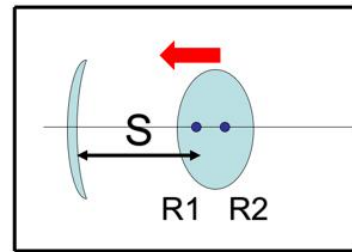
$$A = A_1 + A_2 + A_3 + A_4 \quad (1)$$

where  $A_j$  ( $j=1-4$ ) are the accommodation due to various factors of:  $A_1$  (due to lens front curvature change (dR),  $A_2$  (due to lens anterior shift, dS),  $A_3$  (due to axial length increase, dL), and  $A_4$  (due to : corneal asphericity change).  $A_1=m'$  dR, with  $m'=C_F \times 83\text{dR}$ , and  $dR=(1/R'-1/R)$ ;  $m'$  is about 0.75 D/mm;  $A_2= m$  dS, with  $m=(0.9-1.5)$  D/mm; and  $A_3= M$  dL with  $M=(2.4 - 2.8)$  D/mm.  $C_F$  is the conversion factor which translates the change of the lens power to the whole eye power, having a typical value of  $C_F=(0.7 -0.8)$ . One may also calculate the reported pseudo-accommodation caused by a myopic shift -2.6 diopter for an axial length increase 0.89 mm (with steady-state axial length of  $L=22.94$  mm). However, Uozato (Uozato, ARVO Meeting, 2003, Abstract) measured a very small axial length elongation (mean of 0.06mm) in true accommodation. Therefore, our theory proposes lens relaxation ( $A_1$ ) and anterior shift ( $A_2$ ) to be the two major components in comparing to  $A_3$  and  $A_4$ .

Lin and Mallo reported laser sclera ablation (LASA) procedures for presbyopia patients (age 42-60, mean 53.2) to cause a mean true accommodation of 1.96 diopter [26], without myopic-shift induced pseudo-accommodation. This was justified by no change of the far vision or corneal topography in treated eyes or comparing the pre-operative and post-operative kerometer (K) readings. We propose the two-component theory [27],  $A=A_1+A_2=aA + bA$ , with  $a=(0.1-0.4)$  for old eyes (age 50-60) and  $a=(0.5-0.7)$  for young eye (age 40-49) where lens capsules are less rigid. For extremely rigid eyes, lens anterior shift,  $A_2=-m\text{dS}$ , becomes the only contribution, but it is limited to about (1.0-1.5) diopters. Based on our theory, accommodation is easier to achieve (for a given amount of ciliary body contraction) under the following initial ocular parameters: smaller radius of curvature of the lens or the cornea; shallower anterior chamber depth or shorter globe axial length; less rigid lens capsule and larger spacing between the lens edge and ciliary muscle. Furthermore, any power changes due to corneal surface change or axial length elongation should be excluded from the true accommodation amplitude which may be further justified by the amount of lens anterior shift and the lens radius of curvature (or thickness) changes.

### 3. RESULTS AND DISCUSSION

Since the invention of LAPR method by Lin (US Patent, 2000), there are only two companies working on the clinical trials of LAPR in the past 21 years (2000-2021): SurgiLight and Ace Vision Group. We note that SurgiLight protocol used 8 incision lines, and Ace Vision used 36 dots-patterns in the oblique quadrants of an eye, as shown in Fig. 5. We will show in the following that the clinical outcomes are not affected by the patterns used. The key parameters are ablation depth (must be >80% of the scleral thickness) and the volume of the tissue removed by the laser, which governs extra space of SLC and PVZ, and therefore, the accommodation gain after the surgery. We note that the clinical outcomes of Ace Vision are similar to that of SurgiLight without any improvement, because the same Er:YAG laser and similar protocol are used by both groups and based on the original US patent of Lin [11,28,29].



**Fig. 4. Schematics of an accommodating eye showing the anterior shift of the lens (with decreasing distance, S), and its surface curvatures, R1 and R2 (becoming more curved)**

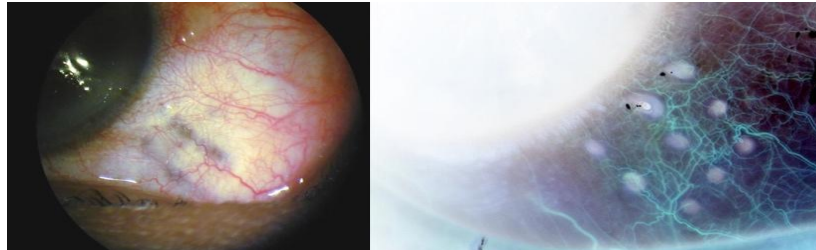
#### 3.1 Clinical Data of SurgiLight (2000-2003)

Lin and Mallo (2003) reported the first human data for laser sclera ablation (LASA) procedures for presbyopia patients (age 42-60, mean 53.2) using Er:YAG laser based on the sclera ablation method and protocol disclosed in Lin's US Pat. 6,258,082 and 6,263,879. where the laser ablated a portion of the scleral tissue outside the limbus to cause a mean true accommodation of 1.96 diopter, without myopic-shift induced pseudo-accommodation. This was justified by no change of the far vision or corneal topography in treated eyes or comparing the pre-operative and post-operative keratometer (K) readings. The recent study using collagen biomatrix to block the wound healing may offer a potential technique to

reduce the post-op regression (EyeWorld Asia-Pacific, June, 2008).

More recent data, based on similar method, were reported by Hipsley et al. [30] and Xu et al. [31]. We note that clinical outcomes recent data

(2017-2020) are similar to those reported 20 years earlier (1999-2001) without much improvements, because they both used essentially the "same" protocols and method in the procedure, and the infrared lasers at 2.8 to 2.94  $\mu\text{m}$  are used having a similar ablation depth.



**Fig. 5. Photos of laser ablated sclera in line-pattern (left), and in dots-pattern (right)**

The clinical trials data of Lin et al (during 1999-2001) using SurgiLight, OptiVision Er:YAG laser (at 2.94  $\mu\text{m}$ , fiber-tip coupled), are summarized as follows.

<p>(1) Venezuela group (Drs. Parraso, Martiniz) total of 120 cases reported in ASCRS (April, 2001). 33 cases (eyes) from 18 patients (age: 42 - 65), follow-up: 1 - 24 months</p> <p>accommodation: pre-op: 0.36 - 0.50 D (J6 - J7) post-op: 1.61 - 2.70 D (J1 - J3) near vision: (J1-J2) (J2-J3) J3 better N= 9 15 33 (26%) (43%) (100%) regression (&lt;10%), longest follow-up 24 months,</p>
<p>(2) Argentina Group (Dr. Mallo) 65 cases reported in ASCRS (April, 2000). 41 eyes (23 patients) age: 45-62 (mean 50.5), follow up (1- 5 months),</p> <p>accommodation: pre-op: J3 - J7 (mean J5) post-op: J1 - J3 (mean J2) near vision addition: pre-op: +1.0 to +3.0 D (mean +2.5D) post-op: 0 to +1.25 D (mean +0.33D)</p>
<p>(3) Bahamas group (Dr. Rodgers) 12 US patients, both eyes (same day): pat. #1 (age 48): day-1 see J2 both eyes, day-7 see J1, both eyes. pat. #2 (age 49); US eye doctor, day-1 see J1 both eyes. post-op 6 months: J1 - J2; noting that patient's far vision also improved (+0.5 D). pat. #3 to #12: day-1 (5 hours) post-op: J1 - J2.</p> <p>(4) Brazil group (Dr. Martins), 35 cases reported at ASRS, April, 2000 (no detailed follow up data).</p>

**Chart 1. The clinical trials data**



As of April, 2003, about 300 cases (eyes) in 11 countries, for patients aged 42 to 72 received LAPR were treated (all are both eyes), reported by GEM News (April 1, 2003, in BBI), using the OptiVision of SurgiLight. More than 90% were able to read without spectacles post-operatively, with an average accommodation gain of 1.9 diopters. Even more important, at two years the average regression from this gain was only 0.25 diopters. The 10 U.S. patients were treated in New York and Las Vegas, Nevada. Their accommodation increased from an average of about 2.4 diopters pre-operatively to 4.0 diopters at four weeks post-operatively. All 10 had visual acuities of 20/30 or better following surgery. In addition, there are over 30 cases were treated in China using a UV (at 266 nm) laser (unpublished data). The laser is Er:YAG at 2.94  $\mu$ m wavelength for tissue ablation, at a repetition rate 20 Hz and energy per pulse of 20 mJ for LAPR, and using a conical contact tip contacting to the scleral surface for deeper penetration. The presbyopia project of SurgiLight was terminated in 2003, due to lack of funding supports.

### 3.2 Clinical Data of Ace Vision Group (2004-2020)

Ace Vision Group Inc (CA, USA) followed the method of Lin's US patent, and the same Er:YAG laser also performed many cases during 2004 to 2020 [23,32,33,34,31]. The outcomes reported by Xu et al [31] are summarized as follows. Binocular distance corrected intermediate visual acuity (DCIVA) had improved from  $0.33 \pm 0.12$  to  $0.12 \pm 0.12$  logMAR after 6 months and  $0.13 \pm 0.12$  logMAR after 12 months postoperatively. Binocular distance corrected near visual acuity (DCNVA) improved from  $0.41 \pm 0.10$  to  $0.24 \pm 0.12$  logMAR after 6 months and  $0.26 \pm 0.09$  log MAR after 12 months postoperatively). An average decrease of  $0.91 \pm 0.28$  D in the reading prescription at a 40 cm reading distance was observed and remained stable over 12 months. There were no significant differences in manifest refraction, uncorrected distance visual acuity (UDVA), corneal curvature, high order aberrations, pupil size compared with preoperative. They concluded that the laser sclera ablation (or anterior ciliary excision) procedure is safe and efficient for presbyopia correction without influencing distance vision or visual quality. However, its mechanism and long-term effects need further validation.

Hipsley et al. [32] reported the long term (8,10 and 13 years) visual outcomes of laser anterior

ciliary excision (equivalent to scleral ablation of SurgiLight) [32]. They reported the six eyes of 3 patients up to 13 years and concluded that distance-corrected visual acuity, distance-corrected intermediate visual acuity, and distance-corrected near visual acuity for all patients remained at 20/20 or better up to 13 years postoperatively, having effective range of focus averaged  $1.56 \pm 0.36$  (D) for all eyes. Hipsley et al. [30] also reported 26 patients (52 eyes) outcomes for 24 months follow up. Their results are summarized as follows. Binocular UNVA improved from  $+0.20 \pm 0.16$  logMAR preoperatively, to  $+0.12 \pm 0.14$  logMAR at 24 months postoperatively. There was no statistically significant loss in DCNVA. Binocular DCNVA improved from  $+0.21 \pm 0.17$  logMAR preoperatively, to  $+0.11 \pm 0.12$  logMAR at 24 months postoperatively. Stereoacuity improved from  $74.8 \pm 30.3$  s of arc preoperatively, to  $58.8 \pm 22.9$  s of arc at 24 months postoperatively. There were no complications such as persistent hypotony, cystoid macular edema, or loss of best-corrected visual acuity (BCVA). Patients surveyed indicated reduced difficulty in areas of near vision, and were overall satisfied with the procedure.

### 4. NEW DIRECTIONS

We note that the clinical outcomes of Ace Vision are similar to that of SurgiLight without any improvement, because the same Er:YAG laser and similar protocol are used by both groups and based on the original US patent of Lin [12,28,29]. The major drawbacks of this method include: postop regression of 0.2 to 0.5 D, after two years; too much invasive (bleedings), and procedure was too slow, taking over 40 minute per eye; and the average accommodation gain (AAG) of about 2.0 diopters maybe too low if there is long term regression larger than 0.5 D. The ideal AAG would be larger than about 3.5 D, and having long term regression less than 0.5 D (for at least 5 years). In addition, procedure time should be reduced to about 10 minutes per eye, and having minimum ablation or bleeding. Based on these requirement, Lin has proposed various new methods using different lasers, and under improved protocols (US patents pending). The new directions should also explore the following key issues including:

1. Dependence of age, sclera thickness and treatment protocols;
2. Improve the fiber-scan technique for faster procedure;

3. A procedure without ablating the conjunctiva or sclera tissues (no bleeding);
4. Procedure should be possible to apply in post-LASIK patients;
5. Procedure should improve both near and far vision (or having also correction of hyperopia).
6. Average initial accommodation gain (AAG) larger than 3.5 D, such that long term regression of 0.5 D is allowed (up to at least 5 years).
7. Understanding the "exact theories" of accommodation involved in the procedure, such that efficacy can be improved accordingly.
8. Analytic formulas to predict the clinical outcomes, such as the AAG and its dependence on the eye conditions (age, lens rigidity, corneal and lens surface curvature, axial length, treated area thickness, etc).

We finally note that the general features of accommodation and presbyopia systems may be found in books edited by Garg et al. [35], Agrawal [36] and Pallikaris et al. [37],

## 5. CONCLUSION

The technology and principles of laser presbyopia reversal (LAPR) via sclera ablation using infrared and UV lasers are reviewed. Clinical outcomes during 2000 to 2020 are summarized. The principles of accommodation and the key factors influencing the outcomes are discussed, where the amount of accommodation gain (AG) after the surgery is predicted by analytic formulas based on a 2-component theory that AG is mainly due the lens anterior curvature change and its anterior shift. Finally, the key issues and new directions to overcome the drawbacks of the existing LAPR procedure (based on scleral ablation) are proposed.

## DISCLAIMER

The products used for this research are commonly and predominantly use products in our area of research and country. There is absolutely no conflict of interest between the authors and producers of the products because we do not intend to use these products as an avenue for any litigation but for the advancement of knowledge. Also, the research was not funded by the producing company rather it was funded by personal efforts of the authors.

## CONSENT

It is not applicable.

## ETHICAL APPROVAL

It is not applicable.

## COMPETING INTERESTS

Author has declared that no competing interests exist.

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