

## Review Article

# SupraCor Lasik Treatment for Presbyopia

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### Abstract

Presbyopia, the gradual loss of accommodation that becomes clinically significant during the fifth decade of life, is a physiologic inevitability. Different technologies are being tried to achieve surgical correction of this disability; however, a number of limitations have prevented widespread acceptance of surgical presbyopia correction, such as optical and visual distortion, induced corneal ectasia, haze, anisometry with monovision, regression of effect, decline in uncorrected distance vision, and the inherent risks with invasive techniques, limiting the development of an ideal solution. The correction of the presbyopia and the restoration of accommodation are considered the final frontier of refractive surgery. The purpose of this paper is to review the current procedures available and the recent advances in presbyopia correction.

**Keywords:** SupraCor, presbyopia, treatment

### Introduction

Presbyopia is an age-related loss of accommodation that results in an inability to focus at near distances. <sup>(1)</sup> It is the most common physiological change occurring in the adult eye and is thought to cause universal near vision impairment with advancing age. <sup>(2)</sup> It is generally first reported clinically between 40 and 45 years of age, with its peak onset between ages 42 and 44 years, and generally occurs in females earlier before 40 years. It progresses gradually over a number of years. From approximately age 52 years on, the prevalence of presbyopia is considered to be essentially 100% <sup>(2)</sup>; however, its prevalence across all ages in the population is 31%. <sup>(3)</sup> The main symptoms include vision at the customary near-working distance being blurred or can be sustained only with excessive effort and some eye discomfort and also reading material must be held farther away to be seen more clearly. Presbyopia cannot be cured, but individuals can compensate

for it by wearing reading (single-vision), bifocal, or progressive eyeglasses. A convex lens is used to make up for the lost automatic focusing power of the eye. Presbyopia is not simply an inconvenience; it has significant effects on quality of life <sup>(4)</sup>. The pathophysiology of presbyopia remains poorly understood, theories propose that accommodation occurs as a result of the elastic properties of the lens and possibly the vitreous that allow the lens to round up and increase its power when zonular tension is relieved during ciliary muscle contraction <sup>(5)</sup>

Various causes have been proposed to account for the reduction in accommodative amplitude. Accommodation has two parts; one is physical and concerns the change in shape of the lens during accommodation. In presbyopia, the physical part is related to hardening or sclerosis of the crystalline lens that reduces the elasticity of the lens capsule and the plasticity of the lens core. The physiologic part of accommodation is

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the innervation and contraction of the ciliary muscles. Some hold that sclerosis of the ciliary body reduces its ability to constrict, and the lens does not sufficiently obtain the conditions required for changing its shape. If most of the cause of presbyopia is physical, that is, it is related to the inability of the crystalline lens to alter its shape to bring near objects into focus, then the lens is an indicator of age and may be considered a biological clock. <sup>(6)</sup> The passive optical methods of treating presbyopia, such as monovision, multifocality, and bifocal or progressive addition lenses provide functional distance and near vision to presbyopes, these do not restore the active change in power of the eye that occurs during accommodation in the young eye <sup>(1)</sup>

#### **Current surgical correction options of presbyopia**

Various surgical methods have been used in cataract and refractive surgery to treat presbyopia. However, none has emerged as the final solution for presbyopia.

Surgical correction by Excimer laser include monovision laser in situ keratomileusis (LASIK), photorefractive keratectomy (PRK), presbyopic LASIK (presby LASIK), surgical correction by Radio-frequency energy is by conductive keratoplasty (CK), intrastromal corneal inlay has been tried for presbyopia correction. Laser Assisted Presbyopia Reversal (LAPR) by using Infrared Erbium: YAG laser, Femto-second laser used for IntraCore and SupraCor techniques.

Presbyopic correction can be achieved through lens extraction and anterior ciliary sclerotomy is another procedure proposed for presbyopia correction.

#### **Monovision LASIK and PRK**

The age of the patient is an important factor affecting the outcomes of various corneal refractive procedures, such as LASIK and PRK <sup>(7)</sup>. Younger

patients tend to have a more aggressive healing response, which may contribute to some regression of the effect of treatment <sup>(7)</sup>. In LASIK, because of the decreased healing response, it is not clear whether age plays a significant role. Regardless of the healing process, LASIK correction can be problematic in presbyopic patients. Many presbyopic patients with myopia experience difficulties with near vision after their refractive error is corrected. Before surgery, many of these patients were able to read by taking off their eyeglasses; after surgery, they may feel frustrated by their decreased near/reading vision. Most patients choose to undergo refractive surgery to decrease their dependence on spectacles and are therefore not willing to wear reading glasses after surgery. <sup>(8)</sup> Monovision has been used as a strategy to compensate for presbyopia by optically correcting one eye for distance vision and the other eye for near vision <sup>(9)</sup>. However, this strategy induces anisometropia with a consequent reduction in binocular acuity and stereopsis. Success rates for monovision refractive laser correction range from 72% to 92.6% <sup>(10)</sup> Factors related to better results include good interocular blur suppression posttreatment of anisometropia of less than 2.50 diopters (D), successful distance correction of the dominant eye, good stereoacuity, lack of esophoric shift, and the willingness and motivation to adapt to this visual system <sup>(11)</sup>.

Although older patients may be symptomatic from presbyopia and thus more willing to accept monovision, Women selected monovision slightly more often than men did <sup>(11)</sup>. The amount of monovision – binocular summation in which two eyes are used instead of one – is greatest when the difference in dioptric power (add) of less than 1.50 D is used for the near

eye. Higher add powers cause less interocular blur stability, decreased stereoacuity, and contrast sensitivity<sup>(12)</sup>.

Since certain limitations and complications still persist in excimer laser correction, it is imperative to proceed with a complete ophthalmologic examination, including visual acuity assessment, refraction, intraocular pressure, and fundoscopic examination, as well as corneal thickness and corneal topography assessment. Thin cornea and/or abnormalities on topography, such as keratoconus, may prevent the refractive error correction. Complications such as haze and postoperative pain in PRK, as well as complications regarding the flap, diffuse lamellar keratitis, corneal ectasia and dry eye in LASIK correction may occur. LASIK and PRK for myopia and hyperopia have shown reasonable safety, efficacy, and predictability profiles in the presbyopic age group<sup>(13)</sup>.

#### **Presbyopic LASIK (multifocal laser ablation)**

The first intentional creation of a multifocal relation profile designed to correct myopic refractive error and maintain good uncorrected near vision, the strategy to create a central steeper area – resulted in a potentially safer and more consistent outcome. The use of LASIK as a more controllable technique for corneal multifocality, avoiding the plastic compensatory effect of the growing epithelium reactive to surface ablation profiles, seems to be more adequate for presbyopia correction. For the purpose of corneal multifocality, different presbyLASIK techniques have been proposed. In peripheral presbyLASIK, the central cornea is treated for distance, whereas in the periphery a negative asphericity is created to increase the depth of field<sup>(14)</sup>. The relatively important amount of cornea

tissue needed to be removed to create an intentional negative asphericity in myopic patients is the reason most of these procedures have been practiced and reported in hyperopic eyes<sup>(14)</sup>. This method also requires an efficient excimer laser-beam profile capable of compensating for the loss of energy that happens while ablating the peripheral cornea; this is one of the main difficulties in targeting specifically high negative asphericity values with this technique. In central presby LASIK, a hyperpositive area is created for the near vision at the center, whereas the periphery is left for far vision. Loss of best spectacle-corrected visual acuity (BSCVA) and decreased vision quality are the main concerns regarding presbyLASIK surgery.

#### **Conductive keratoplasty**

CK is a nonablative, radiofrequency-based, collagen-shrinking procedure that has been approved by the Food and Drug Administration for the temporary correction of mild to moderate spherical hyperopia (+0.75 D to +3.00 D) in people over the age of 40 years<sup>(15)</sup>. Radiofrequency energy is delivered through a fine tip inserted into the peripheral corneal stroma in a ring pattern outside of the visual axis. When a series of eight to 32 treatment spots are placed in up to three rings in the corneal periphery (6-, 7-, and 8-mm optical zones), striae form between the spots and create a band of tightening, resulting in a steepening of the central cornea, correction of hyperopic refractive error and improvement in near vision<sup>(15)</sup>.

As a nonablative, nonincisional procedure that does not require creation of a flap and uses radiofrequency energy to steepen the central cornea, CK avoids LASIK-related complications<sup>(16)</sup>. CK can be performed in the office setting under

topical anesthesia and involves the use of a portable unit that is much less expensive than most other refractive surgery platforms

### **Corneal inlay**

The inlay received the Conformation of European mark (CE) for use in the European Union in 2005. This corneal inlay is designed to increase the depth of field using the principle of small-aperture optics to restore near and intermediate visual acuity without significantly affecting distance vision

<sup>(17)</sup> Femtosecond laser is used to create a superior hinged flap in the non dominant eye. The intended depth from the corneal surface is 170  $\mu\text{m}$ , and with the patient fixating on the excimer laser microscope's single light source, the corneal inlay is centered on the stromal bed, with the first Purkinje reflex in the center of the inner diameter of the inlay.

One great advantage of the corneal inlay procedure is its potential reversibility because no ablation is performed over the optical axis, as in LASIK (presbyopic or monovision). Results indicate that this technique can also be safely performed in hyperopic or myopic presbyLASIK patients as a combined refractive procedure to correct ametropia and presbyopia. The inlay, however, like other refractive procedures, causes a small loss of contrast sensitivity <sup>(17)</sup>.

### **Laser Assisted Presbyopia Reversal (LAPR)**

Infrared Erbium: YAG laser has been tried to correct presbyopia, the beam delivered through fiberoptic with a contact tip to ablate the sclera tissue in 4 surgically induced fornix based peritomies, the ablation distance about 5mm from the limbus, with the ablation of 80% of sclera, the peritomy sites closed with bipolar cautery forceps. The good features are Extraocular procedure, Surgically easy,

No adverse effects on vision. Because of No large studies of efficacy yet, Variable benefit to near vision, Regression reported in several centres and expensive laser, the use of this technique is limited <sup>(18)</sup>.

### **Anterior ciliary sclerotomy**

Anterior ciliary sclerotomy involves making radial incisions in the sclera overlying the ciliary muscle; this may allow expansion of the sclera overlying the ciliary body, increasing the space between the lens equator and ciliary body. This may place more resting tension on the equatorial zonules, allowing for increased tension to develop during ciliary muscle contraction <sup>(19)</sup>. The procedure is hypothesized to restore accommodative amplitude in presbyopic subjects. There is a good initial effect from anterior ciliary sclerotomy, with a mean increase in accommodative amplitude of 2.2 D. The effect of surgery gradually disappeared, with only 0.8 D of gain in accommodative amplitude remaining at 1 year postoperatively.

### **Intraocular lens (IOL) implantation**

As modern technology advances and expectations increase, cataract surgery is no longer purely a visual restoration procedure. The refractive component, including management of presbyopia, has become more important. At present, there is no single perfect solution for managing presbyopia <sup>(20)</sup>. There are a few ways to compensate for the loss of accommodation with an intraocular lens. The accommodative IOL uses ciliary muscle contraction to change the dioptric power of the IOL. Another option is to provide the visual system with two simultaneous images, either monocularly using multifocal IOLs or binocularly through monovision. In monovision, one eye is optimized for distance vision and the other eye for near.

Multifocal IOLs use a refractive or diffractive technology that attempts to give patients a full range of vision (near, distance, and intermediate) and to increase their independence from glasses after surgery. Excellent clinical outcomes have been reported.<sup>(21)</sup> However, patient dissatisfaction and secondary procedures, including IOL exchange, can also be significant. With the same purpose, monovision has long been used to provide near, intermediate, and distance vision and is one of the most common methods used in cataract patients to address presbyopia.<sup>(22)</sup>

#### **IntraCor femtosecond laser**

The IntraCor procedure is performed using the Technolas femtosecond laser system, which delivers a completely intrastromal customized pattern of laser pulses into the cornea to induce a local reorganization of the biomechanical forces and change in corneal shape. The basic pattern for presbyopia correction is a series of femto-disruptive cylindrical rings that are delivered within the posterior stroma, at a variable distance from Descemet's membrane, and extending anteriorly through the mid-stroma to an anterior location at a predetermined fixed distance beneath Bowman's layer. The pattern of laser delivery is entirely intrastromal, without impacting the endothelium, Descemet's membrane, Bowman's layer, or epithelium at any point throughout the procedure.<sup>(23)</sup> The net effect is a central steepening of the anterior corneal surface, not in the shape of a steep central island, but rather as a multifocal hyperprolate, corneal shape with an ideal, pupil-dependent aberration pattern.

The potential advantages of such a procedure are intrastromal delivery without breaking the epithelium, avoidance of pain and inflammation from the exposed ocular surface, speed

of recovery due to the absence of surface wound healing, and stability of refractive outcome by preserving the strongest, anterior corneal fibers. However, whenever a new procedure is introduced, the potential disadvantages must also be considered and studied. These may include dissatisfaction with the hyperprolate aberration pattern, diffractive effects from the paracentral laser pulse delivery, high dependability on proper centration and alignment, and progression or loss of effect over time due to changes in the biomechanical corneal forces.<sup>(23)</sup>

#### **SupraCore**

SupraCore is a LASIK based procedure which is performed on the TECHNOLAS 217P Excimer laser system. The procedure can treat a wide range of presbyopic patients, it can be applied across the whole refractive range of myopic, hyperopic and emmetropic eyes and may also be suitable for patients who have previously undergone a LASIK procedure. The procedure steepens only the central cornea leaving the remaining cornea unchanged and provides excellent distance, intermediate and near vision, whilst maintaining a high quality of vision. Currently the treatment is CE marked for use in correction of 'moderate hyperopia' but the range is expected to expand. This procedure involves creating a thin flap on the surface of the eye using an Intralase laser or manual microkeratome. The flap is lifted and the Technolas laser is used to create a customised profile on the cornea. For improved safety, the excimer laser uses the state of the art Advanced Control Eyetracking (ACE) technology. Using iris recognition technology, this dynamic tracker continuously tracks eye movements; rotation and pupil shift and simultaneously adjusts the laser beam

to ensure the laser is accurately delivered during the entire procedure. This profile has a small area in the centre of the cornea which is a little steeper and provides near vision focus as well as an increase in asphericity which improves visual quality. SupraCor provides similar vision in both eyes. Unlike monovision where one is treated for distance and the other is treated for near, this procedure treats both eyes so that both are able to focus on distance and near vision equally.

The laser system using Zyoptix Aspheric mode for myopic and the tissue saving mode (TS) for hyperopic distance correction, with the incorporated SupraCore module adding the presbyopic component to the existing profile which takes 20 seconds more for the completion of the treatment. The ablation is optimized by the corneal  $k$  - and  $Q$ -value customization available in the TS and Aspheric modes, together with full X/Y/Z and rotational eye tracking.

The treatment is bilateral (no monovision), it is multifocal treatment, the range of dioptric correction includes Spherical Equivalent: up to +4D, Astigmatism: up to +2D, Near Addition minimum of 1.5D, it the same common LASIK contraindications (keratoconus, pachymetry, diabetes...), and it involves the same pre-op evaluation of patient expectations and motivation.

While other presbyopic algorithms used by INTRACOR create undesired aberrations within the pupil region, SupraCore provides near vision addition without the induction of such aberrations<sup>(24)</sup>.

## Conclusion

Each technique used to correct presbyopia has advantages and disadvantages that leads to limitations in these surgeries, a unique and ideal

solution is still not available, and the restoration of true accommodation still a challenge. In most of the procedures, near vision is achieved at the expense of far vision and/or quality of image. Recently the use of IntraCor by femto-second laser is a closed surgery with no corneal wound, no infection or inflammation which heals rapidly with no major defect in the cornea, but has disadvantage of treating emmetropes and early hyperopes ,it cannot treat moderate hyperopia and myopia.it cause also corneal aberration that make the patient uncomfortable with low satisfaction.

SupraCor procedure had solved most of the problems with IntraCor, it can treat all refractive errors in addition to presbyopia correction, treat presbyopia of patients with old lasik surgery and there is no corneal aberration. The SupraCor procedure was found to provide a significant improvement in uncorrected near vision whilst maintaining good distance vision, with a high level of patient satisfaction.

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