# Presbyopic correction today

John S. M. Chang, MD

Department of Ophthalmology, Hong Kong Sanatorium and Hospital, Happy Valley, Hong Kong, China.

## *Correspondence and reprint requests:*

John S. M. Chang, Department of Ophthalmology, Hong Kong Sanatorium and Hospital, 8/F Li Shu Pui Block, 2 Village Road, Happy Valley, Hong Kong, China. E-mail: johnchang@hksh.com

### **Abstract**

Presbyopia is the most common refractive error in patients older than 40 years. The loss of accommodation results in difficulty with near vision. Surgical means to correct this accommodative deficiency include scleral expansion band and anterior ciliary sclerotomy, which enhances the movement of the ciliary body. Monovision in which the non-dominant eye is left with some myopia for near vision can be done by presbyopic lens exchange or LASIK. Multifocal and accommodative intraocular lenses also require crystalline lens exchange. Conductive keratoplasty reshapes the cornea by using radiofrequency energy, and corneal inlays create a hyperpositive area of the cornea by implantation of a plus lens into the cornea or create a pinhole effect to increase the depth of field by implantation of a plate with a pinhole. Presby-LASIK creates a multifocal cornea by a combination of different ablation profiles, including central steep island and decentered steep island (center for near vision) and centered steep annulus (center for distance vision). Changing the asphericity of the cornea to increase the depth of focus (global optimum) is another approach for presby-LASIK.

Key words: Accommodation, ocular, Presbyopia, Refractive errors, Surgical procedures, operative

## Introduction

Presbyopia is a progressive loss of the eye's ability to focus at near vision, which occurs with ageing. It is generally believed that the loss of elasticity of the human crystalline lens causes the lens to gradually lose its ability to change its power. There are 2 major theories regarding the mechanism of presbyopia. Helmholtz proposed that the relaxation of zonular tension is driven by the anterior and axial movement of the contracting ciliary muscle. This allows the crystalline lens to thicken and thus increase its optical power.

As the lens changes with age, the ability to increase its refractive power is lost.<sup>2</sup> In contrast, Schachar proposed that in the relaxed state of accommodation, the equatorial zonules are almost tension free.<sup>3</sup> When accommodating, the anterior radial fibers of the ciliary muscle contract, increasing tension on the equatorial zonules exclusively. The lens equator is pulled towards the sclera, resulting in peripheral lens flattening and central steepening. This leads to an increase in optical power. Schachar suggested that a decrease in the effective working distance between the ciliary body and the lens equator with age (the lens grows with age) would limit the amount of force that the ciliary muscle could exert on the lens,<sup>3</sup> resulting in presbyopia.<sup>4</sup>

Currently, the best option to correct presbyopia in patients with cataracts is cataract extraction with monofocal intraocular lenses (IOL), using monovision, accommodative, or
multifocal IOLs (MFIOL) [Table 1]. In patients without
cataracts presbyopic lens exchange can be performed.
However, the risks involved with intraocular surgery
(endophthalmitis or retinal detachment) must be considered
and explained to the patient. Anterior ciliary sclerotomy
(ACS), presby-LASIK, conductive keratoplasty (CK),
corneal implants, and scleral expansion band (SEB) may
be safer alternatives to MFIOL for younger people with presbyopia without cataract formation.

## **Monovision**

The problem of presbyopia can be solved by leaving the non-dominant eye myopic for near vision, and the dominant eye emmetropic for distance vision. This works well for patients with prepresbyopia or presbyopia who desire LASIK correction and patients with cataract with monofocal IOL implantation. The amount of myopia left is usually less than -2.00 D to avoid binocular diplopia. In a recent study of 172 patients with presbyopia and prepresbyopia receiving monovision correction by LASIK, the post-operative uncorrected visual acuity (UCVA) at near vision was J3 or better in 93% of patients. Only 7% of patients chose to forego monovision and subsequently enhance the near vision eye to distance vision. <sup>5</sup> Reily et al reported a more promising

Table 1. Indications, contraindications, advantages, and disadvantages of presbyopic treatments.				
Method	Indications	Contraindications	Advantages	Disadvantages
Monovision	Early presbyopia	Non-tolerant to anisometropia Presbyopia >2.0 D	Clear distance and near vision Simple to perform	Loss of stereopsis/ depth of focus
Scleral expansion band	Emmetropic presbyopia	Presbyopia >1.5 D	Distance vision not affected	Long-term effect unknown Eye very red after surgery
Anterior ciliary sclerotomy	Emmetropic presbyopia	Presbyopia >1.5 D		Limited effect
Multifocal	Cataract	Small pupil (for refractive lenses)	Provides good distance,	Halo and night glare
intraocular lens	PRELEX	Decentered pupil Amblyopia	intermediate, and near vision	Reduced contrast sensitivity Diplopia (rare)
Accommodative	Cataract		Minimal or no halo and glare	Long-term effect unknown
intraocular lens			Good distance vision	Accommodative effect
			Good contrast sensitivity	≤1.25 D
Conductive	Hyperopia or	Thin cornea (<560 µm at 7 mm zone)	Less invasive to eye	May induce astigmatism
keratoplasty	emmetropic presbyopia	Corneal cylinder >0.75 D	Excellent safety profile	
Presby-LASIK	Early/low presbyopia	Presbyopia >2.0 D	Provides clear vision at all	May cause double vision
		Small pupils	distances	Long-term effect unknown
Corneal inlays	Emmetropic presbyopia		Reversible	Risk of corneal necrosis
	Post-LASIK and post-			
	cataract surgery			

result of 99% of patients with J2 or better UCVA at near vision.<sup>6</sup> Patient satisfaction after conventional monovision refractive surgery ranged from 72% to 98%. 6-10 However, depth perception is somewhat compromised and depth of focus is also diminished, that is, patients cannot see middistance and there is always a slight blurriness at all distances (which most patients become used to). Generally, for patients who are older than 40 years who do not have presbyopia yet, less than 1 D of myopia is left, and for patients who have presbyopia the non-dominant eye is left with myopia that matches their amount of presbyopia up to a maximum of -2.0 D (up to -2.5 D can be tolerated by some patients). Patients must be shown this during the initial consultation and enough residual cornea must be left to remove the residual myopia in case the patient cannot tolerate the difference.

## Scleral expansion band

The SEB works according to Schachar's accommodation theory, 11 that is, by stretching the sclera, using the scleral expansion band segments, in the plane of the crystalline lens equator. The effective working distance of the ciliary muscle is increased, which increases the amplitude of accommodation. The surgical procedure involves cutting belt loops into the sclera 3.00 mm posterior to the limbus. Two parallel 300-µm deep and 1.5-mm long radial incisions, which are separated by 4 mm, are made with a guarded square diamond blade. The parallel incisions are then connected via a tunnel using a 5-mm long lamella diamond blade. The polymethyl methacrylate scleral expansion band segment is inserted into the scleral belt loop so that the ends protrude from each side of the belt loop. This process is repeated in the 4 oblique quadrants of the eye (Figure 1). Qazi et al conducted a multicenter study to assess the effects of SEB segments on accommodative amplitude in a cohort of 29 patients with emmetropic presbyopia.<sup>4</sup> The 6-month results showed an increase in accommodative amplitude of the operated eyes by +1.7 (SD, 1.5 D) and +1.5 (SD, 1.2 D) at 70 cm and 30 cm, respectively. However, a smaller increase was also seen in control eyes (+1.2 [SD, 1.1 D] and +1.3 [SD, 1.2 D], respectively) and intercenter variation in accommodative gain was noted. As a result, further investigations into the SEB using standardized measurements and the long-term effect are required.

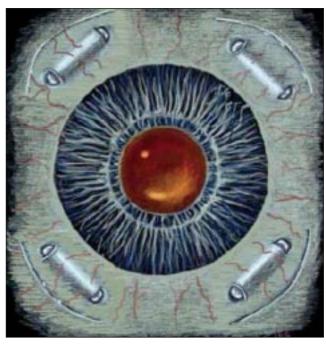


Figure 1. Schematic diagram illustrating the appearance of an eye after insertion of a scleral expansion band segment. Image reproduced courtesy of RA Schachar, MD.

# **Anterior ciliary sclerotomy**

ACS was developed by Thornton.<sup>12</sup> The procedure is similar to radial keratotomy in that it is an incisional technique. The surgeon makes 8 or more symmetrical partial-thickness radial incisions into the sclera over the ciliary body. These incisions allow the sclera to expand, providing more room for the eye to accommodate to close objects. However, ACS is not a popular method for treating presbyopia. Hamilton et al, in a prospective clinical trial of 9 patients, reported that ACS did not restore accommodation in eyes with presbyopia and could cause significant complications.<sup>2</sup>

### Multifocal intraocular lenses

There are 2 types of MFIOL, refractive and diffractive. The most commonly used MFIOLs are Array® (Advanced Medical Optics, Inc, Santa Ana, USA), ReZoom™ (Advanced Medical Optics, Inc), Tecnis®MF (Advanced Medical Optics, Inc) and ReSTOR® (Alcon Laboratories, Inc, Fort Worth, USA). ReZoom and Array are refractive lenses that provide distance, intermediate, and near vision with different optical zones on the lenses. TecnisMF is a diffractive lens that aims to provide clear vision at distance and near. ReSTOR combines the design of apodized diffractive and refractive technologies.

ReZoom is a distance dominant lens with 5 concentric refractive zones alternating for distance and near vision and aspheric transition zones allowing for intermediate vision. Zones 2 and 4 are near dominant and provide 3.5 D near add power at the IOL plane and 2.57 D at the spectacle plane (a near point of approximately 39 cm or 16 inches). The distribution of light with this refractive lens is dependent on pupil size, that is, the pupil needs to be greater than 3 mm or only the central zone 1 is used and patients only have distance vision. Surgeons must therefore ensure that the pupil is greater than 3 mm. However, the pupil can be enlarged during surgery or by laser pupilloplasty after surgery. The target refraction of ReZoom is plano to +0.5 D, and slight hyperopia helps reduce glare.

ReSTOR has a central 3.6-mm apodized optic region, in which 12 concentric diffractive zones on the anterior surface have a gradual reduction in diffractive step heights from the center to the periphery, resulting in an energy continuum for light to be directed at 2 primary foci — distance and near — and a lower intensity at intermediate. The add power of the IOL is approximately 4 D, which translates to 3.2 D of add at the spectacle plane (near focus at 31.25 cm or 12.30 inches). The target refraction for ReSTOR is +0.25 D.

The Tecnis ZM 900 is a foldable silicone diffractive IOL with a 6.0-mm optic. This lens also combines diffractive optic technology with an aspheric modified prolate anterior surface designed to reduce spherical aberrations. The diffraction pattern creates 2 major focal points that are 4.00 D apart. <sup>14</sup> The target refraction of the Tecnis ZM 900 is plano.

For patients who want good near vision and some intermediate vision, some surgeons are currently mixing diffractive MFIOL with refractive MFIOL, instead of bilateral implantation of the same type of MFIOL. For example Tecnis and ReSTOR (diffractive MFIOL) are strong in near and distance vision. ReZoom and Array (refractive MFIOL) are better for distance vision. Although these lenses are weaker for near vision, they provide some intermediate vision (eg, for computer use). Combining the 2 designs can achieve clearer vision at all 3 distances. Goes implanted 20 patients with Tecnis in 1 eye and ReZoom in the fellow eye. 15 The results after 1 to 2 months showed that the mean uncorrected binocular distance visual acuity was 1.06 logMAR (SD, 0.60 logMAR), mean uncorrected binocular intermediate visual acuity was 0.50 logMAR (SD, 0.90 logMAR), and mean uncorrected binocular near visual acuity was 1.10 logMAR (SD, 0.40 logMAR). One patient required LASIK to correct residual cylinder of -1.50 D, but no patients required spectacle correction.

The advantages of MFIOL are that both eyes see well at distance and near, and there is no loss of stereopsis. However, distance contrast sensitivity decreases under mesopic conditions, <sup>16</sup> and halo and glare can be problems. <sup>17</sup> Some patients may have monocular diplopia. Visual intolerance may require lens exchange.

### Accommodative intraocular lenses

There are several accommodative IOLs available. The most common accommodative IOLs are the 1CU® (HumanOptics AG, Erlangen, Germany), CrystaLens AT-45<sup>TM</sup>(Eyeonics, Inc, Alsio Viejo, USA), Kellan® (Lenstec Inc, St Petersburg, USA), and the Synchrony® dual-optic (Visiogen, Irvine, USA). The IOL design includes flexible haptics that allow the optic to move anteriorly during accommodative effort, thereby making the eye more myopic. The accommodative 1CU IOL has an optical diameter of 5.5 mm and an overall diameter of 9.8 mm. A study by Dogru et al showed the early results for 1CU.18 Twenty two eyes of 16 patients with cataract underwent phacoemulsification and implantation of a 1CU IOL and 20 eyes of 10 age- and sex-matched patients with cataract had the same surgery, but with a foldable acrylic IOL. The mean distance corrected near visual acuity was significantly higher in the 1CU IOL group than in the acrylic IOL group after 3 months. The peak mean amplitude of accommodation with the 1CU IOLs was observed at 3 months and was 0.5 D (SD, 0.44 D). Accommodation amplitude declined after 6 months.

The effective mechanism in which the acrylic 1CU works is via relaxation of the zonular fibers, leading to relaxation of the capsular bag, which pushes the haptics anteriorly. This changes the balance of power within the hinge area and results in a forward movement of the IOL optic.

The theoretical effective mechanism of the CrystaLens IOL is based on the concept of accommodation resulting in a rearrangement of the volume of the ciliary body — the

increase in volume of the ciliary body applies pressure on the peripheral vitreous body, which results in rising pressure within the vitreous body. This pressure pushes the optic forward along the optical axis, resulting in an IOL with more refractive power (myopia is induced) and enabling good near, intermediate, and distance vision. In the USA Food and Drug Administration (FDA) clinical trial of the CrystaLens AT-45, more than half of the patients with bilaterally implanted Crystalens AT-45 IOL achieved UCNVA of 20/25 (J1) or better through the distance correction, and 84% achieved 20/32 (J2) or better.<sup>19</sup>

One drawback of this design concept is that a low-power IOL will generate less accommodation than a high-power IOL when the lens moves forward. The amount of accommodation is also largely affected by eye parameters of axial length and keratometry.<sup>20</sup> In addition, it has recently been suggested that IOLs of this design characteristically move less than 1 mm anteriorly upon accommodative effort, as shown by ultrasound biomicroscopy.<sup>21</sup> Although simple in design, IOLs of this type are unlikely to be successful for a wide range of dioptric powers. The flexibility of the capsular bag remains an important aspect of performance for this IOL design. Since the accommodative amplitude is generally not as good as for the MFIOL, most surgeons use this IOL for distance and intermediate vision in the non-dominant eye and an MFIOL for distance and near vision in the dominant eye.

Synchrony is a single-piece dual-optic foldable silicon IOL designed with an exaggerated high-plus-power moving optic coupled to a low-power static minus lens joined by a spring haptic. When implanted in the capsular bag, the bag tension compresses the optic, reducing separation of the 2 parts. The compression of the lens system stores strained energy in the connecting haptics. Once accommodation occurs, the zonules relax, releasing tension on the capsular bag, thus allowing release of the stored energy in the spring system with anterior displacement of the anterior optic.<sup>22</sup>

In a pilot study of Synchrony, 95.8% of eyes (23 of 24 eyes) had distance-corrected near visual acuity of 20/40 (J3) or better at 6 months.<sup>23</sup> All of the 11 eyes of patients who completed follow-up achieved distance-corrected near visual acuity of 20/40 (J3) or better at the 12-month visit, with 7 eyes (63.6%) having an acuity of 20/25 (J1) or better. McLeod et al concluded that the dual-optic design appears to produce a better range of focus than a monofocal IOL.<sup>23</sup> The dual optic currently shows the most promise. However, larger trials with longer follow-up need to be done to show the full effectiveness. The advantages of these lenses are that there is minimal or no halo and glare, distance vision is as good as the monofocal IOLs, and contrast sensitivity is very good.

## Conductive keratoplasty

The CK system, NearVision CK® (Refractec, Inc, Irvine, USA), is the first FDA-approved refractive technology for correction of presbyopia. Radiofrequency energy is applied to the cornea in a circular pattern via a probe. The radio waves shrink small areas of collagen to create a constrictive band that increases the curvature of the cornea, bringing the near vision back into focus.

CK works by the monovision principle, whereby the non-dominant eye is made to be myopic. However, unlike LASIK monovision, CK induces an aspheric shape in the cornea, thus requiring less minus to achieve the same reading ability. Therefore, distance vision is better than with LASIK monovision. It is believed that the definable introduction of surgically induced astigmatism (SIA) and higher order spherical aberrations, and the development of a more prolate cornea contribute to the success of CK in producing a functional corneal multifocality.<sup>24</sup>

With the conventional CK technique, enough pressure is applied by the probe to indent the cornea to create a 5- to 7-mm dimple. More recently, minimal pressure or the LightTouch® technique (**Figure 2**) has been described using less pressure

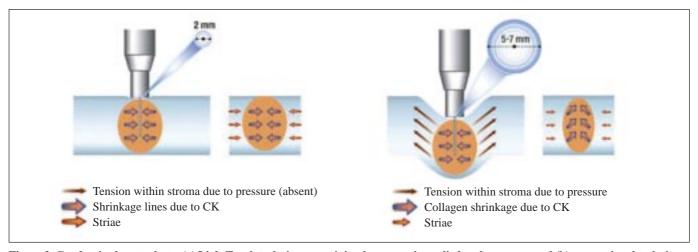


Figure 2. Conductive keratoplasty. (a) LightTouch technique — minimal pressure is applied to the cornea; and (b) conventional technique. (Images reproduced courtesy of R Milne, MD.)

Abbreviation: CK = conductive keratoplasty.

on the cornea with a 2-mm dimple, resulting in a greater effect with fewer spots. The LightTouch technique appears to provide more predictable results with faster recovery and less or no induction of cylinder.<sup>25</sup> The results also last longer than with the standard technique. A LightTouch nomogram developed by Milne suggested that 8 spots at 8 mm would provide a 0.75 D effect.<sup>26</sup> While 8 spots at 7 mm would provide a greater effect of 1.3D. Combining the 2 for 16 spots would provide approximately 1.8 D myopic shift. These estimations were made from the 12 months post-CK results. Milne described an FDA multicenter trial of the LightTouch modified CK procedure, involving 125 patients who underwent LightTouch CK on the non-dominant eye to provide +1.0 to +2.0 D change, with an eventual target refraction of -1.0 to -2.0 D.<sup>27</sup> The preliminary results at 1 month showed that 97% of patients had vision of J3 or better, with 88% achieving J1. Patients maintained 20/20 binocular distance vision.

The advantage of the LightTouch procedure is that it is very safe; corneal perforation should not occur if careful preoperative pachymetry is done. The disadvantage is that it can induce astigmatism, although this is reduced with this technique.

## **Presby-LASIK**

There are several techniques for excimer laser remodeling of the cornea to create a multifocal eye with increased depth of field. Typically, these procedures are intended to be performed bilaterally. The near vision portion of the ablation may be located in the center, the periphery, or in various transitional zones. Several types of ablations may be performed.

### **Global Optimum**

The aim of the Global Optimum technique is to create an aspheric (prolate) cornea with the central cornea more myopic than the peripheral cornea. However, this technique still uses the monovision method, whereby the non-dominant eye is left with the same residual myopia. The Q value describes the asphericity of a cornea. The lower is the Q value (more minus), the more prolate is the cornea. The dominant eye is also made more prolate but is targeted for emmetropia. A more prolate cornea increases the depth of field and therefore provides some intermediate vision. WaveLight's Global Optimum program (WaveLight AG, Erlangen, Germany) creates a target overall myopia of up to -1.5 D in the near vision eye (the Q value is available up to -1.0; an average cornea has a Q value of -0.2). Since the cornea flattens towards the periphery, when looking at distant objects the pupil gets larger and the eye becomes less myopic, thus facilitating intermediate vision. When the pupil constricts for accommodation, the steeper central cornea is more myopic and the eye can read close up (Figure 3).

For the emmetropic eye, pupil constriction provides some intermediate vision and pupil dilation provides distance vision. This works well for both myopia and hyperopia.

**Figure 4** shows the corneal topography of a post–Global Optimum treatment eye.

#### Central steep island

A central steep island for near correction can be created by hyperopic ablation with a small optical zone following the original myopic/hyperopic treatment of a larger optical zone. Bausch and Lomb modified the central steep island and developed a multifocal ablation such that around the central island is the correction for middle distance and the peripheral cornea is for distance vision (Figure 5). The Technovision Presby-One-LASIK technique (Bausch and Lomb, Inc, Rochester, USA) creates a central multifocal area. Alió et al found that 80% of patients had uncorrected distance visual acuity of 0.8 at 6 months after this technique.<sup>28</sup> Almost all patients (92%) could read J4 or better without correction, and the correction was stable over 1 year. However, these results also showed that there was a significant reduction in contrast sensitivity at spatial frequencies above 1.5 cycles/degree. Ortiz et al<sup>29</sup> also found that the Presby-One-LASIK technique provided an improvement in optical quality (Strehl ratio), and a certain degree of pseudoaccommodation.

Another technique that employs the central steep island is the Visx™ multifocal treatment design (Advanced Medical Optics, Inc), in which a pupil size—dependent central near zone, a peripheral distant zone, and the LASIK flap together produce an aspheric curve that expands the depth of focus. Jackson reported that 72% of patients undergoing this procedure achieved both 20/25 distance and J3 or better UCNVA (Bruce Jackson, presented at the 2006 Joint Meeting of the American Academy of Ophthalmology and Asia Pacific Academy of Ophthalmology; Las Vegas, USA; 11-14 November 2006) Most of the studies are of hyperopic correction and few data are available for myopic correction.

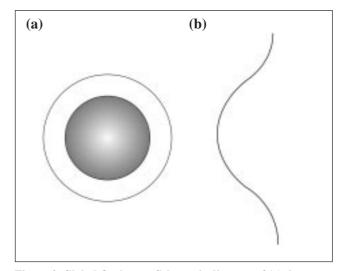


Figure 3. Global Optimum. Schematic diagram of (a) the crosssection of the cornea — the central area of the cornea is steepened and the curvature is flattened towards the periphery; and (b) the ablation profile of the cornea — extra shots are added to the periphery to make the cornea aspheric.

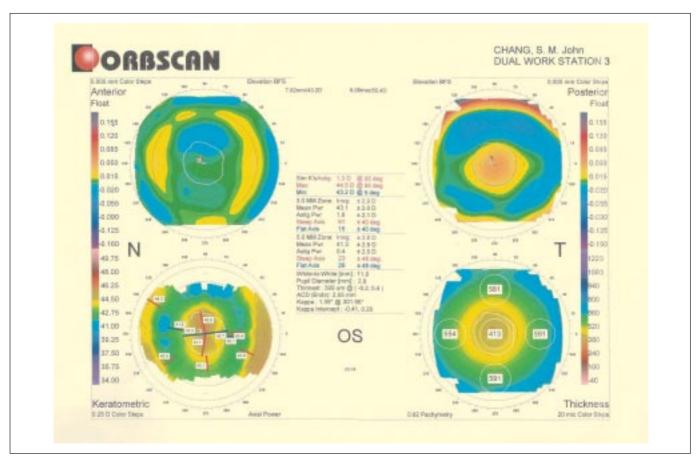


Figure 4. Corneal topography of a post–Global Optimum treatment cornea. The treatment was performed by F-CAT (WaveLight) with a target Q value of -1.0.

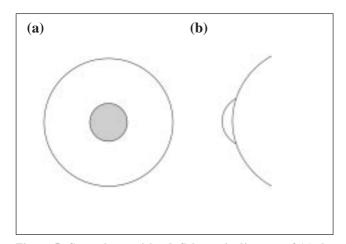


Figure 5. Central steep island. Schematic diagram of (a) the cross-section of the cornea — a small optical zone for near is created at the centre of the cornea by hyperopic ablation; and (b) the cornea showing the area for near vision — a hyperopic treatment is added to the centre of the cornea.

## **Decentered steep island**

With the decentered steep island, a small central steep island is created on the cornea at the inferonasal portion of the pupil centre. When the pupil constricts during near vision, it displaces inferonasally to the steep island area for near correction. When looking at far objects, the pupil enlarges and distance correction is provided by the area outside the island (**Figure 6**). However, distance vision may be affected

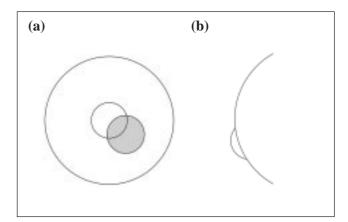


Figure 6. Decentered steep island. Schematic diagram of (a) the cross-section of the cornea — a small decentered optical zone for near vision is created at the inferionasal portion of the pupil centre; and (b) the cornea showing the area for near vision — a hyperopic treatment is added to the pupil margin of the cornea inferiornasally.

since both distance and near correction are within the pupil area.

## **Centered steep annulus**

The centered steep annulus is a multifocal cornea created by applying different amounts of correction to different parts of the cornea. The central zone is corrected for distance vision. The peripheral zone is steepened for near vision, and an intermediate zone is located between the central and peripheral zone for intermediate correction (**Figure 7**). The EC-5000 Excimer Laser (Nidek Co, Ltd, Gamagori, Japan) with its pseudo-accommodative cornea calculator software creates a peripheral myopic ring for near vision via a multistep multifocal ablation. In the retrospective study by Telandro of 83 eyes with hyperopia and 77 eyes with myopia 3 months after surgery, 72.5% of the hyperopia group and 66.7% of the myopia group were within ±0.50 D of emmetropia.<sup>30</sup> One percent of hyperopic eyes lost 2 or more lines of BCVA. All patients showed a binocular near UCVA of J3 or better. For patients with hyperopia, 35% could read J1 unaided for near vision, versus 41% of patients with myopia.

The first-generation multifocal laser procedures were empirical, basing the ablation pattern on refractive data to create transitional bifocal or a central hyperpositive multifocal area, such as for the central steep island, decentered steep island, and centered steep annulus; for example, removing -5.0 D of myopia and then adding +2.0 D hyperopia correction in the centre or periphery. The second-generation presby-LASIK procedures are based on corneal geometry and wavefront data. These techniques aim to increase the depth of field through calculated changes in asphericity by treating the peripheral cornea (eg, the Global Optimum technique). Some of these presby-LASIK surgeries can lead to loss of BCVA and diplopia, which may not be reversible.

Keratometry for post-LASIK corneas is difficult to define, and may be even harder for multifocal corneas after presby-LASIK. One may consider the clinical history to determine the K reading at distance for IOL calculation. While targeting the refraction at plano, the patient can resume the plano refraction at distance and multifocality for near and intermediate.

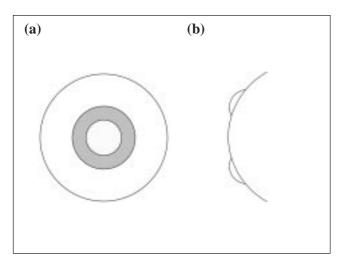


Figure 7. Centered steep annulus. Schematic diagram of (a) the cross-section of the cornea — a center emmetropic area for distance and a peripheral annulus steepened ring for near are created by applying different amounts of correction to different parts of the cornea; and (b) the cornea showing the area for near vision — a peripheral myopic ring for near vision is made via a multistep multifocal ablation.

#### **Corneal inlays**

Corneal inlays are placed inside the stromal layer of the cornea by cutting a LASIK flap or by creating a channel. Corneal inlays are designed for emmetropic eyes. These technologies, which are still in clinical trials, aim to improve near vision performance by as much as 2.5 D by creating a central myopic area or by the pinhole effect.

At least 3 corneal inlays are currently being investigated. All of them are to be implanted monocularly. The AcuFocus<sup>TM</sup> (AcuFocus, Inc, Irvine, USA) provides a pinhole effect to increase the depth of field, while the InVue<sup>TM</sup> microlens system (Biovision AG, Brüggs, Switzerland) and the Presbylens<sup>TM</sup> (ReVision Optics, Inc, Lake Forest, USA) provides a monovision system whereby one eye is made more myopic.

AcuFocus has developed an inlay that creates a pinhole effect that is equivalent to a near correction of up to 2.5 D without a change in the refractive power of the cornea. The AcuFocus corneal inlay (Figures 8 and 9), which is positioned under a lamellar flap (approximately 160 µm thick) in the patient's non-dominant eye, is 10 µm thick, has an overall diameter of 3.8 mm, and a central aperture of 1.6 mm. The annulus between the hole and the edge of the inlay is filled with 1600 to 1800 fenestrations to admit glucose and other metabolites through the implant (earlier models have caused flap necrosis, but there have not been any reports of this with the newer 10 µm inlay). The inlay is pupilindependent since the inner diameter's hole is fixed. The inlay can enhance the depth of field by 4 to 10 times. Holladay reported positive visual results of 20/15 at both distance and near vision, with no effect on contrast sensitivity and

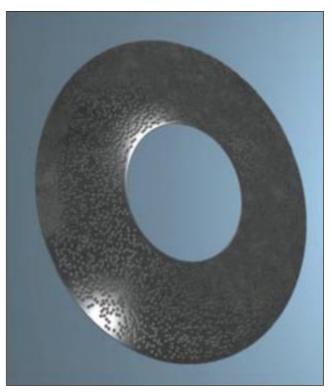


Figure 8. The AcuFocus corneal inlay.

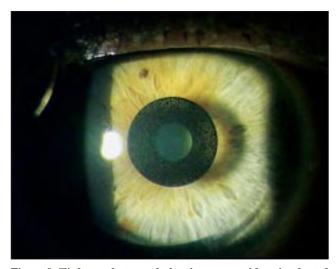


Figure 9. Slit-lamp photograph showing an eye with an implanted AcuFocus.

visual field. <sup>31</sup> With the newer 10- $\mu$ m implant, with a depth of 160  $\mu$ m, no flap necrosis has been reported. Due to the pinhole effect, the inlay causes diffraction and halo can be a problem for some patients.

The AcuFocus has currently been implanted in 200 eyes in a phase 3 trial in the USA, and the data have been submitted to the FDA for review.

The InVue system positions an intracorneal microlens in a tunnel in the center of the cornea, approximately 200 to 400  $\mu m$  deep in the patient's non-dominant eye. To create the tunnel, the surgeon uses a special microkeratome with a unique blade cartridge assembly design. The microlens is made of water-permeable biocompatible hydrogel of a higher refractive index than the cornea. The size is 20  $\mu m$  thick and 3 mm in diameter. The microlens is suitable for eyes with emmetropic presbyopia as well as eyes post–cataract surgery or post-LASIK.

Similar to the InVue system, the Presbylens provides near vision in the central 1.5 mm of the cornea. This lens is designed to change only a small central area of the cornea to increase near focusing power with little decrease in intermediate and distance vision. There is an additional draping effect of 0.5 to 1.0 mm that provides improved intermediate vision, with the remainder of the cornea available for distance vision. In the study by Chayet, 100% of patients achieved 20/40 or better distance and intermediate vision, and 94% achieved 20/40 or better near vision with a combination of the Presbylens and LASIK (A Chayet, presented at the 2006 Joint Meeting of the American Academy of Ophthalmology and Asia Pacific Academy of Ophthalmology; Las Vegas, USA; 11-14 November 2006).

The disadvantages of corneal inlays are the potential blocking of the nutrient supply to the overlying tissue, which may lead to flap/corneal necrosis. The inlays can also move from the intended position, but can easily be repositioned.

The main advantages of corneal inlays are that the technique is relatively easy to perform, the risk of infection is low and is easily treatable, and they are simple to remove with no damage to the eye.

## **Conclusions**

With significant advancements in ophthalmology, it is now possible to treat many diseases. However, presbyopia correction remains a challenging procedure. All the existing methods are either a compromise between distance and near vision or a compromise in quality of vision. The ultimate goal of presbyopic correction is to restore full-range near accommodation without affecting distance vision or quality of vision. As many procedures still require larger studies and longer follow up, it is imperative that surgeons choose procedures that are reversible and do not permanently damage the patient's eyes or vision.

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