ISSN: 0976-3031

Available Online at http://www.recentscientific.com

International Journal of Recent Scientific Research
Vol. 7, Issue, 12, pp. 14657-14663, December, 2016

International Journal of Recent Scientific Research

Research Article

SURGICAL MANAGEMENT OF PRESBYOPIA: CURRENT AND EVOLUTION

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ARTICLE INFO

Article History:

Received 15th September, 2016
Received in revised form 25th October, 2016
Accepted 28th November, 2016
Published online 28th December, 2016

Key Words:

Presbyopia, symphony IOL, supracor , PreLex, karma, intracor

ABSTRACT

Presbyopia is age related decrease in accommodative power of eye. As the presbyopic population is growing rapidly along with increasing demands for spectacle independence new surgical solutions may offer hope to those who are seeking independence from their spectacle or contact lens corrections. The aim of this review is to focus on the advancements in surgical management of presbyopia from corneal-based surgical options with various types of corneal intrastromal inlays and laser ablation technique to advancement in lens and scleral based surgeries.

INTRODUCTION

The term "presbyopia" derives from Greek word for "old eyes" [1] and refers to the age-related loss of natural accommodation and resulting reduction of baseline near vision around the age of 40 years. In fact, the presbyopic population worldwide is predicted to rise to 1.4 billion by 2020 and to 1.8 billion by 2050.[2].

The pathophysiology of presbyopia still remains poorly understood. According to a theory proposed by Helmholtz, accommodation occurs as a result of the elastic properties of the lens and possibly the vitreous that allows the lens to expand and increase its power when zonular tension is relieved during ciliary muscle contraction.[3] As the lens changes with age, the ability to expand and increase refractive power is lost. Helmholtz's theory of sclerosis of the crystalline lens as the cause of presbyopia has been challenged in 1992 by Schachar.[4] Schachar suggests that the longitudinal muscle fibers of the ciliary muscle contract during accommodation, placing more tension on the equatorial zonules, while relaxing the anterior and posterior zonules.[4] This force distribution causes an increase in the equatorial diameter of the lens, decreasing the peripheral volume while increasing the central volume. As the central volume increases, so does the power of the lens. Under this theory, presbyopia occurs because of the increasing equatorial diameter of the aging lens. Once the lens diameter reaches a critical size, usually during the fifth decade of life, the resting tension on the zonules is significantly reduced.[5]

Presbyopia can be compensated by glasses or contact lenses, but there is an increasing interest in surgical options. While it is well established that 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. Since presbyopia is caused by progressive elasticity changes in the biological crystalline lens, presbyopic surgeries may either directly replace the lens through an intraocular approach or modify extraocular structures such as the cornea or sclera

Surgical Procedures to Treat Presbyopia

Several technologies are being explored to achieve surgical correction of presbyopia.[6-8] Despite these efforts, a number of limitations have prevented widespread acceptance of surgical correction of this disability.

Table 1 surgical procedures for presbyopia

Corneal	Lens	Scleral
Conductive keratoplasty	Accomodating iols	Anterior ciliary sclerotomies
Monovision (LASIK/PRK)	Multifocal iols	Scleral expansion implants
Presbyopic excimer laser ablation		
Supracor		
Femtosecond laser ablation (intracor)		
Corneal inlays		

The current surgical procedures for presbyopia are as in table 1.

Corneal Procedures

Conductive keratoplasty(CK)

CK is a non ablative, radiofrequency-based, collagen-shrinking procedure that has been approved by FDA 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.[9] Radiofrequency energy is delivered through a fine tip inserted into the peripheral corneal stroma in a ring pattern outside of the visual axis (Figure 1). When a series of 8 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(Figure 1).[9]

As a nonablative, nonincisional procedure that does not require creation of a flap and uses radio-frequency energy to steepen the central cornea, CK avoids LASIK-related complications.[10] CK can be performed in the office setting under topical anaesthesia. It is applied as a monovision procedure in the non-dominant eye of presbyopic individuals Advantages are non invasive nature, safety, no corneal haze, no endothelial loss. Depth perception and contrast sensitivity are preserved. But significant regression of refractive and keratometric effects of CK has been observed over extended follow-up. Esquenazi *et al* reported 26%, 36%, and 39% regression of refractive results at 4 weeks, 6 weeks, and 8 weeks, respectively, after CK treatment. [11]

Monovision LASIK/ PRK

It is FDA approved procedure in which the LASIK surgeon fully corrects the distance vision of one eye (usually the dominant eye), and intentionally makes the non-dominant eye mildly nearsighted. However, this strategy induces anisometropia with a consequent reduction in binocular acuity, contrast and stereopsis.[13] Success rates for monovision refractive laser correction range from 72% to 92.6%.[12-17] Factors related to better results include good interocular blur suppression, post treatment 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.[13,18-21] Although older patients may be symptomatic from presbyopia and thus more willing to accept monovision, several studies[13,19] have not shown any correlation between age and monovision success. 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.[13,17]. Goldberg's study [22] extended to 2.50 D for patients aged 65 years and older, whereas the study by Cox and Krueger had a maximum goal of 2.00 D.[23]

Presbyopic laser ablation

The first intentional creation of a multifocal relation profile designed to correct myopic refractive error and maintain good uncorrected near vision was first attempted using PRK by Moreira *et al*.[24] These authors suggested that the different strategies implemented to create a bifocal fit – in particular, the strategy to create a central steeper area – resulted in a potentially safer and more consistent outcome.

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.[25] . In central presby LASIK, a hyper positive area is created for the near vision at the center, whereas the periphery is left for far vision. One distinctive advantage is that a central hyperpositive area can be performed at the center of the cornea with minimal corneal excision associated with myopic, hyperopic profiles and also in emmetropes.

Both techniques are influenced by luminance conditions; in fact, loss of best spectacle-corrected visual acuity (BSCVA) and decreased vision quality are the main concerns regarding presbyLASIK surgery. Various studies examine the efficacy of laser refractive surgery on treating presbyopia in phakic patients. A prospective trial of central multifocal PresbyLASIK on 50 hyperopic-presbyopic eyes resulted in spectacle independence at all distances for 72% of the patients after 6 months, although nearly a third lost 1-2 lines of corrected distance visual acquity.[26] This and similar studies have suggested that multifocal laser approaches to improving uncorrected near vision in presbyopia may compromise distance vision to some degree and decrease contrast sensitivity.[27-30]

Supracor

A new aberration optimized presbyopic algorithm called SUPRACOR has been developed to treat presbyopia which offers the possibility to treat a full refractive range, including the possible suitability for post-LASIK patients, with good near, intermediate and distance vision. This represents an important advance in the search for the optimal solution to presbyopia. It was applied using a profile that steepens the center of the cornea to create hyperprolate shape resulting about 2 D near addition with controlled higher order aberrations (HOA).[31] Ninety-six percent of the patients were satisfied with this procedure at 6 months.[31]

Intracor

The utilization of femtosecond laser technology in ophthalmology introduced new techniques in the field of refractive surgery. Ruiz *et al*. performed and published for the first time the Intracor procedure using a Technolas Femtosecond Laser (Bausch and Lomb Technolas, Munich, Germany).[32] This procedures involves making concentric cylindrical rings within the stroma,(Figure 1) at 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 so avoids cutting the corneal epithelium or Bowman's membrane, hence less pain less inflammation and quick recovery.

Figure 1 application of radiofrequency energy spots at 6 to 8mm

The incisions within the stromal tissue cause localized biomechanical change, leading to slight steepening of the central cornea, not in the shape of a steep central island, but rather as a multifocal hyperprolate, corneal shape with an ideal, pupil-dependent aberration pattern. Disadvantages 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. TECHNOLAS femtosecond laser is a promising procedure for presbyopia correction. Early results of this procedure yielded a significant and stable gain of uncorrected near visual acuity (UNVA) and corneal steepening, without a significant loss of endothelial cells or corneal thinning up to 18 months postoperatively. No significant regression of visual acuity or further corneal steepening occurred during the follow-up period.[33-34]

The side effects seen to date are minimal, with a slight disturbance of visual acuity during the early postoperative hours due to the cavitation gas bubbles located in the cornea. Very recently, a case with keratectasia after intracor combined with Supracor LASIK enhancement was reported in an eye without risk factors for keratectasia.[35] This paper raised concerns on the mechanical stability of the cornea after the Intracor procedure, if combined with other corneal refractive surgery. Further studies with larger number of eyes are required to assess the safety, efficacy and long-term stability of this new procedure.

Corneal inlays

Corneal inlays are tiny lenses or other optical devices that are inserted into the cornea to improve reading vision. These include:

A. KAMRA (ACI 7000; AcuFocus, Irvine, CA): In April 2015, the Kamra inlay became the first corneal inlay to gain FDA approval for use in vision correction surgery performed in the United States. The AcuFocus corneal inlay is a 10.0-mm microperforated artificial aperture (3.8 mm outer diameter; 1.6 mm inner diameter) made of polyvinylidene fluoride, a material reported to have high biocompatibility in vitro.[36] A carbon pigment makes the inlay opaque (FIGURE 2) Sixteen hundred holes (25 mm diameter) arranged in a randomized pattern allow nutritional flow through the implant into the anterior stromal tissue to prevent corneal melting. When implanted in the cornea, the Kamra inlay is positioned so its central opening is directly in front of the pupil of the eye (Figure 3). This creates a "pinhole camera effect," which expands the range of clear vision to bring near objects into sharper focus while maintaining clear distance vision. The Kamra inlay typically is implanted in the non-dominant eye. This allows both eyes to see at distance, while the Kamra inlay improves near vision. Femtosecond laser is used to create a superior hinged flap in the non dominant eye. The intended depth from the corneal surface is 170 µm. The Kamra inlay implantation can be combined with LASIK improving near vision with a minimal effect on distance vision, resulting in high patient satisfaction and less dependence on reading glasses according to a recent paper by Tomita *et al*.[37]

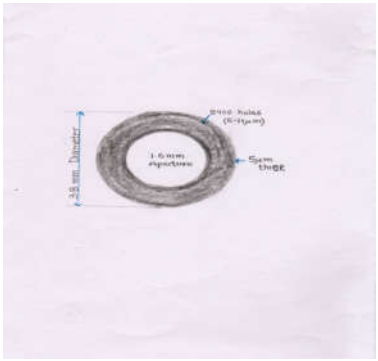

Figure 2 Acufocus corneal inlay with central aperture providing pin hole effect, 3.8mm diameter and 5um thick

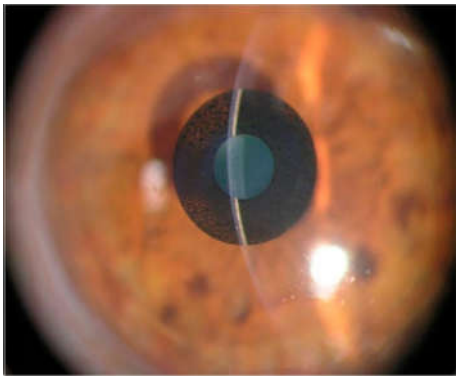

Figure 3 Kamra inlay in situ

B. PRESBYLENS (Raindrop, Revision Optics, Lake Forest, CA, USA): The Raindrop Near Vision is recently FDA approved space occupying inlay that works on the principle of creating a hyperprolate cornea. The raindrop inlay is made of hydrogel, 32 µ thick and has a diameter of 2 mm (Figure 4). In the first published paper in a peer-reviewed journal, one year FDA clinical study in USA showed average uncorrected near visual acuity improvement by 5 lines on a standard eye chart in the treated eye.[38] There was no loss in binocular distance vision. 93% of subjects achieved uncorrected near visual acuity of 20/25 or better in the treated eye. The mean uncorrected visual acuity for both eyes exceeded 20/20 at all distances with no loss in contrast.

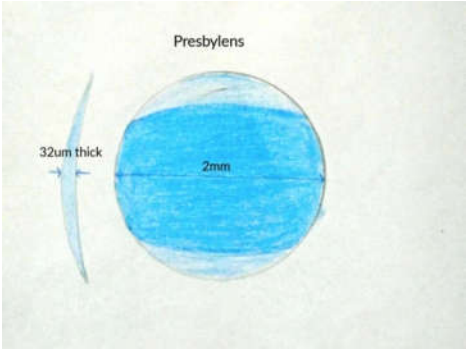

Figure 4 Rain drop corneal inlay, 2mm diameter, 32um thick

C. PRESBIA (Flexivue Microlens, Presbia, Irvine, CA, USA): Refractive annular addition lenticule that work as bifocal optical inlays separating distance and near focal points. It is made of a hydrophilic polymer, has a diameter of 3.2 mm and its edge thickness is approximately 15 µm.[39] The central 1.6 mm zone of the inlay is optically neutral. [Figure 5] The Flexivue Micro lens has a 0.5 mm hole in the centre for allowing adequate nutritional flow in the cornea. Limnopoulou *et al*. reported uncorrected near visual acuity of 20/32 or better in 75% of operated eyes, whereas mean uncorrected distance visual acuity (UDVA) decreased statistically significantly from 0.06 log MAR (20/20) preoperatively to 0.38 log MAR (20/50) postoperatively. Mean binocular UDVA was not significantly altered. Overall, higher order aberrations increased and contrast sensitivity decreased in the operated eye. No tissue alterations were found using corneal confocal microscopy.[40]

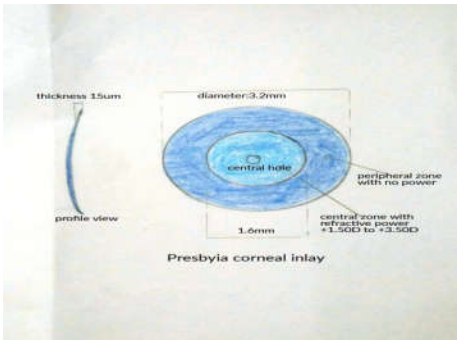

Figure 5 Presbia corneal inlay: central 1.6mm without refractive power and peripheral zone with added power +1.50D to 3.50D

A great advantage of the corneal inlays is their potential reversibility. Although the initial papers show encouraging results, further studies and longer follow up are needed for the clinical assessment of the inlays.

Lens Based Procedures

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 with the use of accommodating and multifocal IOLs. It is called *Presbyopic Lens Exchange or PreLEX.*

Current accommodative IOL approaches are based on the "focus shift" principle through an essentially hypothetical mechanism, i.e contraction of the ciliary muscle would move the optic anteriorly, thereby increasing the dioptric power of the eye.[41] Crystalens is FDA approved IOL for cataract surgery but is used off label for clear lens exchange for presbyopia .Second generation Visiogen Synchrony has two optics linked by a bridge which includes plus lens in front, minus lens in back. It has better ocular quality than single optic[42] as studied by Alio *et al*. In a recent paper by Zamora-Alejo *et al*., no significant signs of accommodation were found with a single-optic accommodative IOL.[43]

Another option is to provide the visual system with two simultaneous images, either monocularly using multifocal IOLs or binocularly. Multifocal IOLs use a refractive or diffractive technology that attempts to give patients a full range of vision and to increase their independence from glasses after surgery. Excellent clinical outcomes have been reported.[44] However, patient's dissatisfaction and secondary procedures, including IOL exchange, can also be significant. A study by Mamalis *et al*. on IOLs requiring explantation, the second most frequently explanted IOL was the multifocal hydrophobic acrylic IOL (23%). The most common reason for explantation was glare/optical aberrations (68%), followed by incorrect IOL power (21%).[45] *Symfony IOL* is the recently FDA approved first and only presbyopia-correcting extended range of vision IOL. It delivers a continuous full range of high quality vision with reduced incidence of halos and glare comparable to a multifocal IOL.[46]

Capsular bag filling*:* It is a newer method to restore accommodation with the injection of silicone polymers. Nishi *et al*, assessed the accommodation amplitudes after an intraocular lens refilling procedure by using a disk-shaped anterior foldable silicone accommodating IOL that serves as an optical device and as a mechanical device to prevent leakage of the injected silicone polymers (Figure 6). The IOL optic was 6.0 mm and the overall diameter, 9.0 mm. A central 3.0 to 4.0 mm continuous curvilinear capsulorhexis was created, after which phacoemulsification was performed in the usual manner. A new accommodating-membrane intraocular lens (IOL) for sealing the capsular opening was implanted in the capsular bag. Silicone polymers were injected beneath the IOL into the capsular bag through the delivery hole in 3 different amounts in 3 groups. Four weeks after surgery, the mean accommodation amplitudes increased in each group but the amount was different which was further dependent upon the amount of silicone polymer injected.[47]

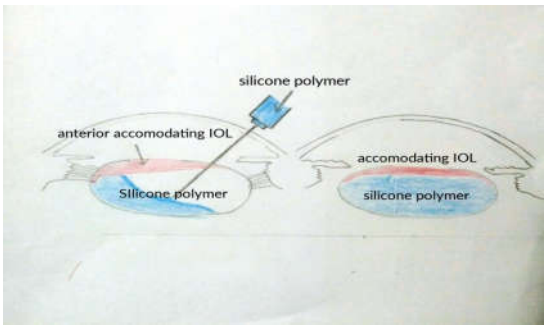

Figure 6 Anterior accommodating IOL with silicone polymers injected underneath in bag

Scleral Based Procedures

Anterior Ciliary Sclerotomy

It was first suggested by Spencer Thornton, involves making radial incisions in the sclera overlying the ciliary muscle.[4] Based on Schachar's theory, this may allow expansion of the sclera overlying the ciliary body, increasing the space between the lens equator and ciliary body.[48] Fukasaku and Marron[49] reported 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. The authors attributed the loss of effect to healing of the sclera healing. Another report by Ito *et al*. raised concerns on ocular integrity after Er: Yag laser scleral incisions.[50]

Scleral expansion segment surgery

An alternative technique for scleral expansion uses polymethyl methacrylate bands placed in tunneled partial–scleral thickness incisions overlying the ciliary body in each of the four quadrants. (Figure 7) Fukasaku and Marron suggested the placement of silicone plugs in the incisions to prevent scleral healing, yielding a mean accommodative amplitude gain of 1.5 D at 12 months.[49]

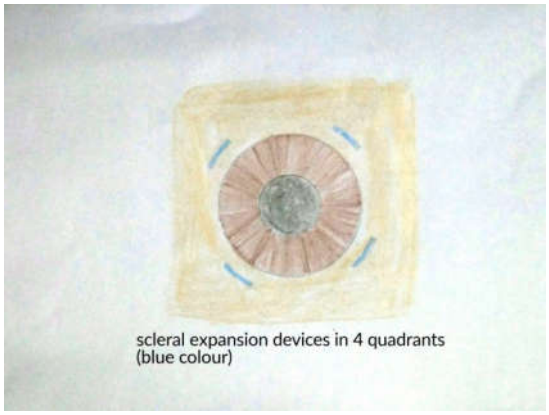

Figure 7 scleral expansion devices impanted in all 4 quadrants between 4 recti

One well-controlled study examined accommodative amplitude before and after scleral expansion segment surgery using a dynamic infrared optometer.[51] There was no evidence of improved accommodative amplitude postoperatively.

Recently, a new type of scleral expansion implant, the Presview (PSI, Refocus-Group, Dallas, Texas, USA) is being evaluated as a treatment for presbyopia, in an FDA monitored investigational device exemption clinical trial currently underway in the USA[52]

Anterior ciliary sclerotomy or any other scleral surgical technique has not been shown to be an effective treatment for the correction of presbyopia. Better controlled studies are needed for the evaluation and the possibility of utilization of this technique in the future, based on scientific evidence.

CONCLUSION

At present, the ophthalmic surgeon has several options for the correction of presbyopia in individuals who wish to decrease their dependence on reading glasses. Technological advancements in terms of surgical instruments, biomaterials, and engineering and surgical capabilities have certainly moved surgical restoration of accommodation from a theoretical concept more into real ophthalmic practice, but much work still remains. Among the procedures described in this article, monovision (LASIK or pseudophakic) and multifocal IOL insertion are the most widely used methods. The restoration of accommodation, which is considered the final frontier in refractive surgery, still remains a challenge.

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How to cite this article:

Ekta Syal., Nitasha and Karanjit.2016, Surgical Management of Presbyopia: Current and Evolution. *Int J Recent Sci Res.* 7(12), pp. 14657-14663.