Review Article

Review of Static Approaches to Surgical Correction of Presbyopia

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Abstract

Presbyopia is the primary cause of reduction in the quality of life of people in their 40s, due to dependence on spectacles. Therefore, presbyopia correction has become an evolving and rapidly progressive field in refractive surgery. There are two primary options for presbyopia correction: the dynamic approach uses the residual accommodative capacity of the eye, and the static approach attempts to enhance the depth of focus of the optical system. The dynamic approach attempts to reverse suspected pathophysiologic changes. Dynamic approaches such as accommodative intraocular lenses (IOLs), scleral expansion techniques, refilling, and photodisruption of the crystalline lens have attracted less clinical interest due to inconsistent results and the complexity of the techniques. We have reviewed the most popular static techniques in presbyopia surgery, including multifocal IOLs, PresbyLASIK, and corneal inlays, but we should emphasize that these techniques are very different from the physiologic status of an untouched eye. A systematic PubMed search for the keywords "presbylasik", "multifocal IOL", and "presbyopic corneal inlay" revealed 634 articles; 124 were controlled clinical trials, 95 were published in the previous 10 years, and 78 were English with available full text. We reviewed the abstracts and rejected the unrelated articles; other references were included as needed. This narrative review compares different treatments according to available information on the optical basis of each treatment modality, including the clinical outcomes such as near, intermediate, and far visual acuity, spectacles independence, quality of vision, and dysphotopic phenomena.

Keywords: Corneal Inlays; Multifocal Intraocular Lenses (IOLs); PresbyLASIK

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INTRODUCTION

Presbyopia correction surgeries can be investigated in two main categories: dynamic approaches which try to reverse the condition and resume the patient's accommodation such as accommodative intraocular lenses, scleral expansion techniques, refilling, and photodisruption of the crystalline lens and the static approaches which account on increasing the depth of focus.[1-3]

In this manuscript static presbyopia correction procedures are reviewed in two main categories: corneal procedures (laser vision correction and Inlays) and pseudophakic procedures. Based on a systematic PubMed search with the key words of PresbyLASIK, Multifocal IOLs

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and Corneal inlays, seventy eight recent English clinical trials were selected and based on the pertaining data provided in each abstract, the final references were chosen and other references were added as needed. This narrative review compares different treatments according to available information on the optical basis of each treatment modality, including the clinical outcomes such as near, intermediate, and far visual acuity, spectacles independence, quality of vision, and dysphotopic phenomena.

CORNEAL PRESBYOPIA SURGERY

Excimer Laser Procedures

Induction of monovision using laser vision correction (LVC) is the simplest approach to laser presbyopia correction; it has a 90% success rate, although there are disadvantages, including reduced visual acuity in darkness, loss of contrast sensitivity, reduction of stereopsis, and intermediate vision reduction.[4,5]

PresbyLASIK, or multifocality achieved by excimer ablation, uses an ablation profile after flap creation to induce corneal multifocality at the expense of induced higher order aberrations. The algorithms are generally classified as central (center near), peripheral (peripheral near), or laser blended vision. In peripheral presbyopic LVC, software provided by NIDEK lasers (NIDEK CO., LTD., Gamagori, Japan) alters the mid-peripheral cornea for near vision by inducing spherical aberration, and leaves the central cornea for far vision. In central presbyopic LVC, provided as Supracor by Technolas (Technolas Perfect Vision GmbH, München, Germany), laser ablation is used to treat the central cornea to improve near vision. A PresbyMAX software profile introduced by SCHWIND (SCHWIND eye-tech-solutions GmbH, Kleinostheim, Germany) ablates a bi-aspheric cornea; it is more positive in the center than other profiles.

Laser blended vision, or Presbyond, is a profile that creates improved monovision in the nondominant eye at approximately 1.5 diopters (D) (Carl Zeiss Meditec, Inc., Jena, Germany) and simultaneously creates a gradual power slope to the periphery using wavefront-assisted ablation.[2,3,6]

LITERATURE REVIEW OF PRESBYLASIK

In a prospective clinical trial of central PresbyLASIK that included 50 hyperopic eyes, the authors reported that 72% of patients did not need spectacles for any distance. A significant reduction of contrast sensitivity and a 28% reduction in corrected distance visual acuity (CDVA) were also observed.[7]

Uthoff et al[8] studied PresbyMAX (bi-aspheric multifocal algorithm) in hyperopes, myopes, and emmetropes. The mean binocular uncorrected vision was reduced in myopes but increased in hyperopes and emmetropes. The mean binocular uncorrected near visual acuity (UNVA) increased in the hyperopic and emmetropic groups, but decreased in myopes. Results were stable over 6 months. Patients showed considerable loss of monocular contrast sensitivity, but binocular contrast was comparable to preoperative values.

Luger et al[9,10] studied PresbyMAX for hyperopia and myopia. Patients were stable after 6 weeks and gained acceptable uncorrected distance visual acuity (UDVA) of (83% were within 0.75 D defocus), and uncorrected near visual acuity (UNVA) [79% had 0.1 logarithm of the reading acuity determination (LogRAD) or better]. Hyperopes and myopes in this study did not experience different outcomes. CDVA was stable in 60% of patients during 1 year of follow-up. Some patients found it difficult to adapt to the optical changes and complained of minor changes in distance vision. The authors recommended a trial with multifocal contact lenses to improve the objective results of the procedure.

Ryan et al[11] studied Supracor. The Supracor profile resulted in a loss of UDVA in some patients due to induced myopia. However, half of the patients were within 0.50 D of the intended refraction, and the majority of patients had good binocular near vision (N8 or more) and did not need spectacles. Twenty-two percent were dissatisfied and required retreatment. As a result of this high retreatment rate, the authors recommended nomogram improvement.

Baudu et al[12] studied bi-aspheric ablation profiles. Six months after the procedure, 17% of their patients had not achieved acceptable binocular vision without spectacles.

Pinelli et al[13] investigated peripheral multifocal LASIK. The pseudo-accommodation increased postoperatively in hyperopic patients. The mean binocular UDVA and UNVA improved postoperatively, although the contrast sensitivity decreased in some frequencies.

Uy and Go[14] investigated an algorithm called pseudo-accommodative cornea (PAC), which is a refinement of distance-dominant corneal treatment that increases the depth of focus by inducing a spherical aberration and was an effective treatment for different refractive errors.

El Danasoury et al[15] investigated peripheral multizone LASIK based on the profile recommended by Telandro et al[16] in myopes and hyperopes, with a 1-year follow-up period. Peripheral multizone LASIK resulted in satisfactory outcomes for most hyperopes and dissatisfaction for most myopes. A peripheral near zone was not created in hyperopes using this ablation profile.

Epstein et al[17] investigated monocular peripheral PresbyLASIK. At 1 year after treatment of the non-dominant eye, the majority of patients reported complete independence from spectacles, but a significant number of treated eyes required retreatment (26%).

Reinstein et al[18-20] conducted three studies with large sample sizes on different refractive errors using the laser blended vision approach of the micro-monovision protocol with the Carl Ziess MEL 80™ platform. A large number of patients were included and followed for at least 1 year. The authors reported excellent visual outcomes and patient tolerance of this procedure, with a slight reduction in contrast sensitivity; hyperopes experienced an increase. Patients had stable CDVA with minor loss of distance vision.

CORNEAL INLAYS

Inlay implantation has two primary advantages: it is additive and does not remove tissue, and it can be a reversible procedure. Three commercially available inlays for presbyopia are presented [Table 1].[2,3,21,22]

Flexivue Microlens

Limnopoulou et al[23] published the only available case series and reported refractive outcomes of 47 patients that received the Flexivue Microlens (Presbia PLC, Dublin, Ireland). After 1 year, 0.75% of eyes had a UNVA of 20/32 or better, but a statistically significant loss of UDVA occurred. Surgically treated eyes showed loss of contrast sensitivity and increased higher order aberrations.

The Raindrop™ Inlay

Two small case series from Mexico[24,25] of Raindrop™ (Revision Optics, Lake Forest, CA, USA) implantation under the LASIK flap reported results of hyperopic and emmetropic patients separately. Both studies had a 1-year follow-up. Garza et al[24] reported the results of 19 emmetropes. All eyes had an average UNVA of 0.1 LogMAR, monocularly or binocularly, during the study. They did not report a significant change in contrast sensitivity. Eighty-four percent of patients reported spectacles independence. There was one case of device explantation due to patient dissatisfaction.

Chayet et al[25] reported implantation of Raindrop™ in 16 hyperopic patients concurrent with their LASIK procedure. The mean monocular or binocular UNVA was 20/27 or better, and the patients' near visual acuity improved during the first week after surgery to 20/32 or better. Significant improvement was also noted in binocular distance visual acuity (20/53 to 20/19). There was one case of explantation.

The KAMRA Inlay

The KAMRA (AcuFocus, Inc., Irvine, CA, USA) is based on the pinhole effect and does not split light into different focal points. It is usually implanted in a stromal pocket at a depth of at least 220 μm, so a deeper additional incision during the LASIK procedure may be required. The manufacturer recommends slight residual myopia in eyes with KAMRA, and plano refraction in the other eye for better depth of focus outcomes.[26]

Interestingly, the largest available case series of KAMRA implantation in the literature used the older ACI 7000 model that is not commercially available now. However, all of these studies showed good safety and efficacy profiles. Tomita et al[27,28] reported two large case series of KAMRA implantation in presbyopes. Although these studies had considerable sample sizes, both included only 6 months of follow-up. The first report was simultaneous LASIK and KAMRA implantation in variable refractive errors (myopia, hyperopia, and emmetropia) excluding astigmatism of more than 3 D.[27] In this cohort study, 180 patients enrolled, but only 64 patients were available for the 6 months of follow-up. The mean LogMAR UNVA improved in all refractive groups, but the visual gain in myopes was less than the other two groups. In terms of UDVA, myopes had the most visual gain (10 lines compared to 3 lines in hyperopes and 1 line in emmetropes).

In the other study, Tomita et al[28] investigated the ACI 7000 KAMRA corneal inlay after LASIK. They enrolled 223 emmetropic presbyopic eyes with previous LASIK.

Table 1. Characteristics of different types of presbyopic inlays

	Flexivue Microlens	Raindrop inlay	Kamra inlay
Material	Copolymer of hydroxyethyl methacrylate and methyl methacrylate, containing an ultraviolet blocker	Hydrogel	Polyvinylidene fluoride
Design and size	The central 1.8 mm diameter is plano; the annular peripheral zone has added power	Positive meniscus-shaped, diameter of 2 mm, and a center thickness of 32 μm	5 μm thin microperforated artificial aperture, with a total diameter of 3.8 mm and a central aperture of 1.6 mm
Underlying principle	Corneal multifocality is the basic principle of the Flexivue Microlens inlay; it changes the refractive power of the central cornea to improve near vision performance	Alters the eye's refractive power by increasing the central radius of curvature of the cornea overlying the implant	Increases depth of focus through the pinhole aperture
Implantation depth	280-300 μm	150 μm	170-200 μm

They made a femtosecond assisted pocket at least 80 μm deeper than the LASIK flap and implanted the inlay. Patients were almost emmetropic, with 4 lines of near vision gain without spectacles after 6 months. The change in uncorrected distance vision was slight (1 line).

In a cohort study with a 3-year follow-up, the ACI 7000 was implanted in emmetropes.[29] The study included 32 patients; all had near and intermediate visual acuity gain with acceptable far vision. Severe night-vision problems were reported by 15.6% of patients, and 6.3% were post-operatively dependent on spectacles for near vision. This study reported that 28% of patients had 1 line CDVA loss despite considerable near and intermediate visual gain. The 5-year follow-up[30] of these patients showed stable and acceptable visual outcomes of different distances. They reported one case of explantation due to hyperopic shift and two cases of recentration. Binocular and monocular loss of UDVA 5 years after the procedure was low.

Yilmaz et al[31] conducted another clinical trial that included 39 patients with a 4-year follow-up. The patients had at least 2 lines of near vision gain but no significant loss of distance visual acuity. Two eyes had refractive changes after inlay implantation (one hyperopic change, one myopic). Four inlays were explanted (2 for refractive shift, 1 for button-holed flap, and 1 as a result of thin flap). Cataract extraction was easily performed in 2 cases, and the inlay was still in place after 4 years.

KAMRA has proven to be safe and biocompatible in human studies. Reports on epithelial deposits are related to the older version of the ACI 7000 device.[27,31]

Currently, there is one report using the new KAMRA (ACI 7000 PDT) in presbyopes.[32] Twenty-four patients with a UDVA of 20/20 and no ocular pathology other than presbyopia were enrolled. After 2 years, 83% of patients had good near performance, and there was no report of loss of contrast, inlay explantation, or any serious complication.

PSEUDOPHAKIC MULTIFOCALITY APPROACHES

Excellent clinical outcomes for pseudophakic multifocal intraocular lenses (MIOLs) of different designs have already been reported, but visual disturbances such as contrast sensitivity loss and dysphotopsia are still concerns for refractive surgeons. MIOLs have different optical designs, including refractive, diffractive, trifocal, and rotationally asymmetric IOLs.[33-35]

Refractive MIOLs have different circular power zones for distance and near viewing, and their effective power is dependent on pupil size in different situations. The ReZoom™ (Abbott Medical Optics, Santa Ana, California, USA) is a refractive FDA-approved multifocal consisting of a three-piece multizonal that offers good vision at intermediate distances, but variable reading performance. The M-flex multifocal (Rayner IOLs Ltd., Hove, UK) is an aspheric IOL that has annular power zones and may provide up to 3 D for near vision at the spectacles plane. Refractive multifocal IOLs appear to be associated with considerable dysphotopsia; this is one of the primary concerns of their use.[36-38]

Diffractive multifocal IOLs are designated based on microscopic steps created on the lens surface to direct the light to near and far focal points. This step can be uniform or can have different heights (apodized design). This diffractive design attempts to reduce dysphotopsia and night halos. Most studies of diffractive IOLs report poor intermediate vision and loss of contrast sensitivity even though good distance and near vision, low dependence on spectacles, and high patient satisfaction have been reported.[39-42]

A recently introduced diffractive IOL, the Tecnis Symphony (Abbott Medical Optics), uses special diffractive designs and achromatic aberration to enhance the depth of focus for a range of 1.5 D. This lens gained FDA approval, and recent clinical data reported acceptable functional vision at different distances and considerably low dysphotopsia.[43,44]

Trifocal MIOL designs have emerged to provide good far, near, and intermediate vision for patients. The available lens in our country is the AT LISA® tri 839MP (Carl Zeiss Meditec). Mojzis et al[45] reported visual outcomes of the AT LISA® 939MP on 60 eyes. Patients had good vision at all distances. Contrast sensitivity increased from 1 month after surgery to 6 months after surgery, and the best level was achieved at medium spatial frequencies (6 cpd). Voskresenskaya et al[46] reported a loss of contrast in low-light situations, and 26% of patients had night vision problems at 6 months. Sheppard et al[47] also reported good visual outcomes of the FineVision trifocal (PhysIOL SA, Liège, Belgium).

Rotationally asymmetrical IOLs much like near add-in spectacles have an inferior segment of near vision in the IOL and a larger segment for far vision. The Lentis MPlus LS-312 (Oculentis GmbH, Berlin, Germany) is the first aspheric model of this design that provides good far, intermediate, and near vision. Interestingly, these IOLs are not affected by pupil size, and induction of a significant aberration improves near vision. The SBL-3 multifocal lens (Lenstec, Inc., St. Petersburg, Florida, USA) is another asymmetric lens. The 6-month results show good vision at all distances.[48-52]

DISCUSSION

Overall, many of the existing articles on this topic are case series with a short follow-up time. Standards of outcome reporting should be defined, such as near vision charts, illumination level at examination time, and pupil size during examination.[2,3,6] The articles claim that their patients had acceptable outcomes for spectacles independence. It should be emphasized that spectacles independence is to some extent a subjective issue and can be related to the patient's tolerance.[6] As some patients receive treatment for their nondominant eye, precise reporting of binocular function is mandatory in these reports.

Comparison of the results of different approaches and selection of the best available and safest approach can be illogical until controlled clinical trials with longer follow-up periods are available. Increasing presbyopia due to age will compromise the results. In central approach PresbyLASIK, near vision is good but far vision will be compromised; in peripheral PresbyLASIK, far vision is preserved but it will last longer if near vision is enhanced. Currently, laser blended vision provides good near and far vision and has a good safety profile.[18-20] The risk of decentration and irreversibility is a challenge in PresbyLASIK.[6]

Currently, the small aperture inlay is the most widely studied device with a good safety profile and high patient satisfaction; it provides acceptable near and intermediate vision and may find its place in the near future.[28-32] Due to the very small case series currently available, other designs must be investigated to better determine safety and efficacy.[23-25]

In diffractive IOLS, trifocals show a significant visual improvement for far, near, and intermediate distances. Extended depth-of-focus IOLs are the emerging hope in this class of lenses to ensure good vision quality and good functional visual acuity at all distances. Larger clinical trials are mandatory to confirm the long-term safety and effectiveness of trifocals and extended depth of focus IOLs.[5,45-47]

Rotationally asymmetrical multifocal IOLs provide a good visual outcome even for intermediate distance, and induce minimal dysphotopsia; they should be studied further in clinical trials.[48-52]

SUMMARY

Laser blended vision, trifocals, rotationally asymmetric IOLs, extended depth of focus IOLs, and small aperture inlays are the new hopes in presbyopia surgery. Overall, more controlled clinical trials with longer follow-ups and a standard reporting system of the refractive results must be conducted in the field of presbyopia surgery. We also recommend the establishment of a worldwide standard protocol to report refractive outcomes of future presbyopia surgeries.

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Conflicts of Interest

There are no conflicts of interest.

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