Refractive lens exchange as a refractive surgery modality

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Purpose of review

Refractive lens exchange is becoming a more popular method of refractive surgery in the presbyopic patient. The limitations of keratorefractive surgery have led to a resurgence of lens exchange surgery for patients with prescriptions outside the limits of corneal refractive procedures, in addition to patients with routine refractive errors requesting a surgical procedure to achieve emmetropia and also address presbyopia. A review of the recent literature was performed to determine recent advances in this surgical procedure.

Recent findings

New multifocal and accommodative lens technology should enhance patient satisfaction. In addition, newer lens extraction techniques using microincisions and new phacoemulsification technology will enhance the safety of this procedure, ultimately allowing refractive lens exchanges to be performed through two microincisions as future lens technologies become available.

Summary

Attention to detail in regard to proper patient selection, preoperative measurements, intraoperative technique, and postoperative management has resulted in excellent outcomes and improved patient acceptance of this effective technique.

Keywords

refractive lens exchange, multifocal intraocular lens, accommodative intraocular lens, light adjustable lens, bimanual microincision phacoemulsification

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Abbreviations

IOL	intraocular lens
LAL	light adjustable lens
RLE	refractive lens exchange

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Introduction

Advances in small incision surgery have enabled cataract surgery to evolve from a procedure concerned primarily with the safe removal of the cataractous lens to a procedure refined to yield the best possible postoperative refractive result. As the outcomes of cataract surgery have improved, the use of lens surgery as a refractive modality in patients without cataracts has increased in popularity.

Removal of the crystalline lens for refractive purposes or refractive lens exchange (RLE) offers many advantages over corneal refractive surgery. Patients with high degrees of myopia, hyperopia, and astigmatism are poor candidates for excimer laser surgery. In addition, presbyopia can currently only be addressed with monovision or reading glasses. RLE with multifocal or accommodating intraocular lenses (IOLs) in combination with corneal astigmatic procedures could theoretically address all refractive errors, including presbyopia, while simultaneously eliminating the need for cataract surgery in the future.

Current attempts to enhance refractive results and improve functional vision with customized corneal ablations with the excimer laser expose another advantage of RLE. The overall spherical aberration of the human eye tends to increase with increasing age [1–4]. This is not the result of significant changes in corneal spherical aberration but rather increasing lenticular spherical aberration [5–7]. This implies that attempts to enhance visual function by addressing higher order optical aberrations with corneal refractive surgery will be sabotaged at a later date by lenticular changes. Addressing both lower order and higher order aberrations with lenticular surgery would theoretically create a more stable, ideal optical system that could not be altered by lenticular changes, since the crystalline lens would be removed and exchanged with a stable pseudophakic lens.

Intraocular lens technology

The availability of new IOL and lens extraction technology should allow RLEs to be performed with added safety and increased patient satisfaction.

Multifocal intraocular lenses

Perhaps the greatest catalyst for the resurgence of RLE has been the development of multifocal lens technology. High hyperopes, presbyopes, and patients with borderline cataracts who have presented for refractive surgery have been ideal candidates for this new technology.

Historically, multifocal IOLs have been developed and investigated for decades. Newer multifocal IOLs are currently under investigation within the United States. The 3M diffractive multifocal IOL (3M Corporation, St. Paul, Minnesota) has been acquired, redesigned, and formatted for the three-piece foldable AcrySof acrylic IOL (Alcon Laboratories, Dallas, Texas). Pharmacia (Monrovia, California) has also designed a diffractive multifocal IOL, the Ceeon 811E, which has been combined with the wavefront adjusted optics of the Technis Z9000 with the expectation of improved quality of vision [8•] in addition to multifocal optics (Fig. 1).

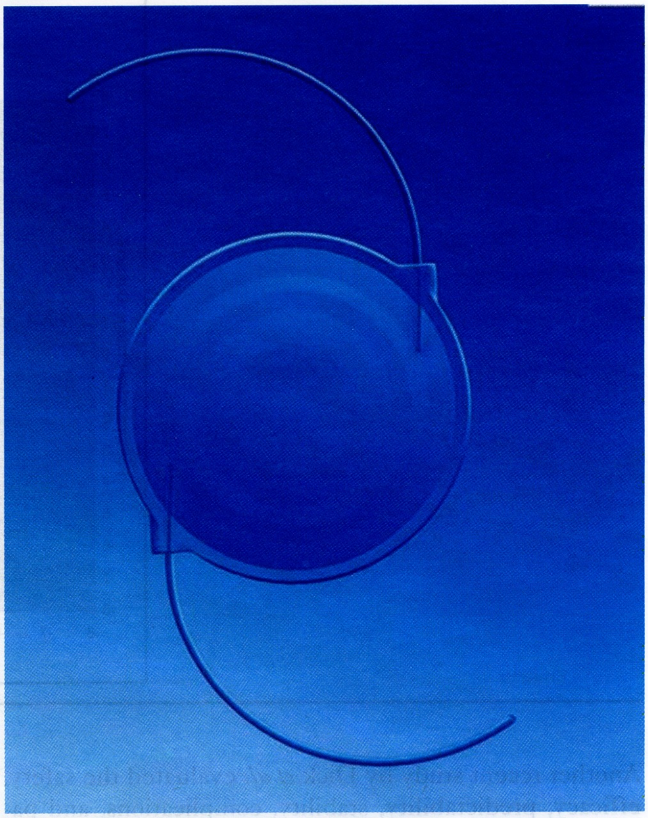
The only multifocal IOL approved for general use in the United States is currently the Array (AMO, Advanced Medical Optics, Santa Ana, California). The Array is a zonal progressive intraocular lens with five concentric zones on the anterior surface (Fig. 2). Zones 1, 3, and 5 are distance dominant zones whereas zones 2 and 4 are near dominant. The lens has an aspheric design, and each zone repeats the entire refractive sequence, corresponding to distance, intermediate, and near foci. This results in vision over a range of distances [9].

A small recent study reviewed the clinical results of bilaterally implanted Array multifocal lens implants in RLE patients [10••]. A total of 68 eyes were evaluated, comprising 32 bilateral and 4 unilateral Array implantations. One hundred percent of patients undergoing bilateral RLE achieved binocular visual acuity of 20/40 and J5 or better, measured 1 to 2 months postoperatively. More than 90% achieved uncorrected binocular visual acuity of 20/30 and J4 or better, and nearly 60% achieved uncorrected binocular visual acuity of 20/25 and J3 or better (Fig. 3). This study included patients with preoperative spherical equivalents between 7 D of myopia and 7 D of hyperopia, with most patients having preoperative spherical equivalents between plano and +2.50. Excellent lens power determinations and refractive results were achieved (Fig. 4).

Figure 1. The Tecnis ZM001 multifocal intraocular lens

(Courtesy of Pharmacia/Pfizer)

Figure 2. The AMO Array foldable silicone multifocal intraocular lens



(Courtesy of Advanced Medical Optics)

Figure 3. Clinical results of bilateral Array implantation following refractive lens exchange

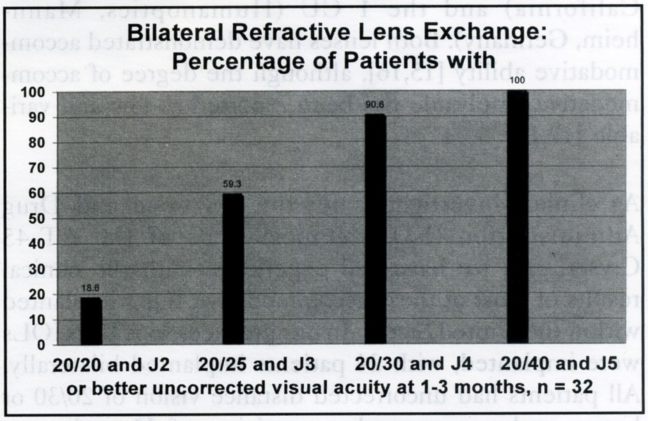
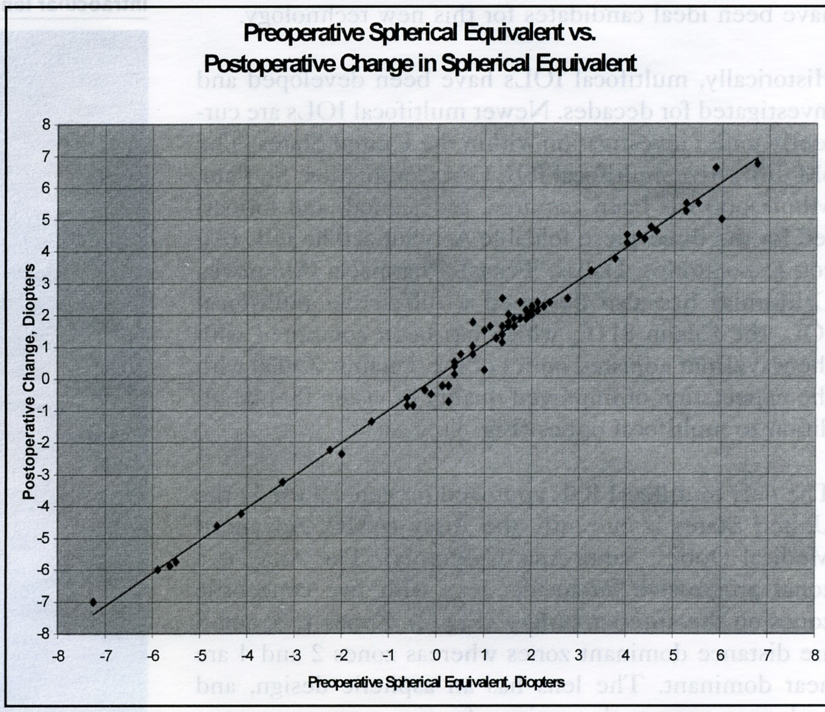


Figure 4. Scattergram demonstrating reduction of spherical equivalent in refractive lens exchange eyes



Another recent study by Dick *et al.* evaluated the safety, efficacy, predictability, stability, complications, and patient satisfaction after bilateral RLE with the Array IOL [11•]. In their study, all patients achieved uncorrected binocular visual acuity of 20/30 and J4 or better. High patient satisfaction and no intraoperative or postoperative complications in this group of 25 patients confirmed the excellent results that can be achieved with this procedure.

Accommodative intraocular lenses

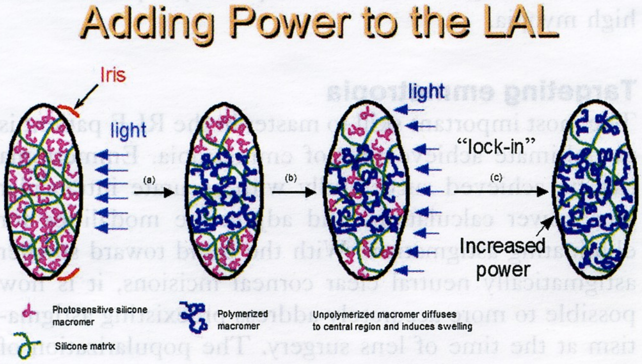
The potential for utilizing a monofocal IOL with accommodative ability may allow for RLEs without the potential photic phenomena that have been observed with some multifocal IOLs [12–14]. The two accommodative IOLs that have received the most investigation to date are the Model AT-45 CrystaLens (eyeonics, Aliso Viejo, California) and the 1 CU (Humanoptics, Mannheim, Germany). Both lenses have demonstrated accommodative ability [15,16], although the degree of accommodative amplitude has been reported as low and variable [17,18].

As clinical investigators for the US Food and Drug Administration (FDA) clinical trials of the AT-45 CrystaLens, we have had experience with the clinical results of most of these accommodative IOLs implanted within the United States. In our practice, 96 AT-45 IOLs were implanted, with 24 patients implanted bilaterally. All patients had uncorrected distance vision of 20/30 or better and uncorrected near vision of J3 or better. Eighty-three percent of patients were 20/25 or better at distance and J2 or better at near, and 71% were 20/20 or better at distance and J1 or better at near. These results confirm the potential clinical benefits of accommodative IOL technology for both cataract patients and refractive patients and place accommodative IOLs in a competitive position with multifocal IOL technology.

Future lens technology

Lens technologies are under development that may contribute to increased utilization of RLE in the future. One of the most exciting technologies is the light adjustable lens (LAL) (Calhoun Vision, Pasadena, California). The LAL is designed to allow for postoperative refinements of lens power *in situ*. The current design of the LAL is a foldable three-piece IOL with a cross-linked silicone polymer matrix and a homogeneously embedded photosensitive macromer. The application of near-ultraviolet light to a portion of the lens optic results in polymerization of the photosensitive macromers and precise changes in lens power through a mechanism of macromer migration into polymerized regions and subsequent changes in lens thickness (Fig. 5). Hyperopia, myopia, and astigmatism can be fine-tuned postoperatively and Calhoun Vision is currently working on creating potentially reversible multifocal optics and higher order aberration corrections. This capability would allow for more accurate postoperative refractive results. In addition, it would enable patients to experience multifocal optics after their lens exchanges and reverse the optics back to a monofocal lens system if multifocality was unaccept-

Figure 5. Cross-sectional schematic illustration of mechanism for treating hyperopic correction



(a) Selective irradiation of central portion of lens polymerizes macromer, creating a chemical gradient between irradiated and non-irradiated regions; (b) in order to reestablish equilibrium, macromer from the peripheral lens diffuses into the central irradiated region leading to swelling of the central zone; (c) irradiation of the entire lens polymerizes the remaining macromer and "locks-in" the new lens shape. (Courtesy of Calhoun Vision)

able. The ability to correct higher order aberrations could create higher levels of functional vision that would remain stable with increasing age, since the crystalline lens, with its consistently increasing spherical aberration, would be removed and replaced with a stable pseudophakic LAL [19].

Other new lens technologies are currently being developed that will allow surgeons to perform RLEs by means of a bimanual technique through two microincisions. Medennium (Irvine, California) is developing its Smart Lens, a thermodynamic accommodating IOL. It is a hydrophobic acrylic rod that can be inserted through a 2 mm incision and expands to the dimensions of the natural crystalline lens (9.5 mm × 3.5 mm). A 1 mm version of this lens is also being developed. ThinOptX fresnel lenses (Abington, Virginia) will soon be under investigation in the United States and will also be able to be implanted through 1.5 mm incisions. In addition, injectable polymer lenses are being researched by both Pharmacia/Pfizer and Calhoun Vision [20,21•]. If viable, the Calhoun Vision injectable polymer offers the possibility of injecting an LAL through a 1 mm incision that can then be fine-tuned postoperatively to eliminate both lower order and higher order optical aberrations.

Patient selection

There is obviously a broad range of patients who would be acceptable candidates for RLE. Presbyopic hyperopic patients are excellent candidates for multifocal lens technology and perhaps the best subjects for a surgeon's initial trial of this lens technology. Relative or absolute contraindications include the presence of ocular pathologies, other than cataracts, that may degrade image formation or may be associated with less than adequate visual function postoperatively despite visual improvement following surgery. Preexisting ocular pathologies that are frequently looked upon as contraindications include age-related macular degeneration, uncontrolled diabetes or diabetic retinopathy, uncontrolled glaucoma, recurrent inflammatory eye disease, retinal detachment risk, and corneal disease or previous refractive surgery in the form of radial keratotomy, photorefractive keratectomy, or laser assisted *in situ* keratomileusis.

High myopic patients are also good candidates for RLE with multifocal lens technology, although the patient's axial length and risk for retinal detachment or other retinal complications should be considered. Many publications have documented a low rate of complications in highly myopic clear lens extractions [22–25,26•,27], but others have warned of significant long-term risks of retinal complications despite prophylactic treatment [28,29]. With this in mind, other phakic refractive modalities should be considered in patients with extremely high myopia. If RLE is performed in these patients, extensive informed consent regarding the long-term risks for retinal complications should naturally occur preoperatively.

Preoperative measurements

The most important assessment for successful multifocal lens use, other then patient selection, involves precise preoperative measurements of axial length in addition to accurate lens power calculations. Applanation techniques in combination with the Holladay 2 formula can yield accurate and consistent results. The Zeiss IOLMaster is a combined biometry instrument for *noncontact* optical measurements of axial length, corneal curvature, and anterior chamber depth that yields extremely accurate and efficient measurements with minimal patient inconvenience. The axial length measurement is based on an interference-optical method termed *partial coherence interferometry*, and measurements are claimed to be compatible with acoustic immersion measurements and accurate to within 30 μm.

When determining lens power calculations, the Holladay 2 formula takes into account disparities in anterior segment and axial lengths by adding the white-to-white corneal diameter and lens thickness into the formula. Addition of these variables helps predict the exact position of the IOL in the eye and has improved refractive predictability. The SRK T formula can be used as a final check in the lens power assessment; and, for eyes with less than 22 mm in axial length, the Hoffer Q formula should be used for comparative purposes.

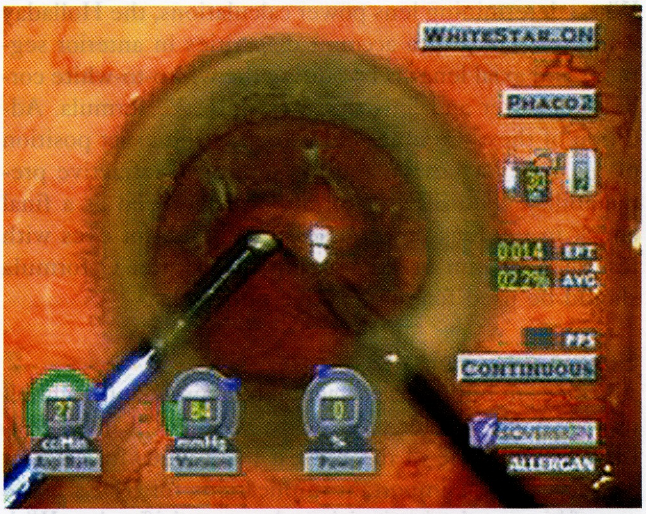
Surgical technique

Advances in both lens extraction technique and technology have allowed for safer, more efficient phacoemulsification [30]. One of the newest techniques for cataract surgery that has important implications for RLEs is the use of bimanual microincision phacoemulsification. With the development of new phacoemulsification technology and power modulations [31], we are now able to emulsify and fragment lens material without the generation of significant thermal energy. Thus, the removal of the cooling irrigation sleeve and separation of infusion and emulsification/aspiration through two separate incisions is now a viable alternative to traditional coaxial phacoemulsification (Fig. 6). Machines such as the AMO WhiteStar (Santa Ana, California), Staar Sonic (Monrovia, California), Alcon NeoSoniX (Fort Worth, Texas), and Dodick Nd:YAG Laser Photolysis systems (A.R.C. Laser Corp., Salt Lake City, Utah) offer the potential of offering relatively "cold" lens removal capabilities and the capacity for bimanual cataract surgery [32–34,35•, 36–38].

Bimanual microincision phacoemulsification offers advantages over current traditional coaxial techniques for both routine cataract extraction and RLEs. The main advantage has been an improvement in control of most of the steps involved in endocapsular surgery. Separation of irrigation from aspiration has allowed for improved followability by avoiding competing currents at the tip of the phaco needle. Perhaps the greatest advantage of the bimanual technique lies in its ability to remove subincisional cortex without difficulty. By switching infusion and aspiration handpieces between the two microincisions, 360 degrees of the capsular fornices are easily reached and cortical clean-up can be performed quickly and safely.

There is the hope that RLEs can be performed more safely using a bimanual technique. By constantly maintaining a pressurized eye with infusion from the second handpiece, intraoperative hypotony and chamber collapse can be avoided [39]. This may ultimately result in a lower incidence of surgically induced posterior vitreous

Figure 6. Bimanual phacoemulsification utilizing a bare phacoemulsification needle (right) and a 20 gauge irrigating chopper (left)



detachments and their associated morbidity, which would be of significant benefit especially in patients with high myopia.

Targeting emmetropia

The most important skill to master in the RLE patient is the ultimate achievement of emmetropia. Emmetropia can be achieved successfully with accurate intraocular lens power calculations and adjunctive modalities for eliminating astigmatism. With the trend toward smaller astigmatically neutral clear corneal incisions, it is now possible to more accurately address preexisting astigmatism at the time of lens surgery. The popularization of limbal relaxing incisions has added a useful means of reducing up to 3.50 D of preexisting astigmatism by placing paired 600 μm deep incisions at the limbus in the steep meridian.

Refractive surprise

On occasion, surgeons may be presented with an unexpected refractive surprise following surgery. When there is a gross error in the lens inserted, the best approach is to perform a lens exchange as soon as possible. When smaller errors are encountered or lens exchange is believed to be unsafe, various adjunctive procedures are available to address these refractive surprises.

A LASIK procedure can be performed to eliminate myopia, hyperopia, or astigmatism following surgery complicated by unexpected refractive results. Another means of reducing 0.5 to 1.0 D of hyperopia entails rotating the IOL out of the capsular bag and placing it in the ciliary sulcus to increase the functional power of the lens. Another simple intraocular approach to the postoperative refractive surprise involves the use of IOLs placed in the sulcus over the primary IOL in a piggyback fashion. Staar Surgical produces the AQ5010V foldable silicone IOL, which is useful for sulcus placement as a secondary piggyback lens. The Staar AQ5010V has an overall length of 14.0 mm and is available in powers between –4.0 to +4.0 D in whole diopter powers. In smaller eyes with larger hyperopic postoperative errors, the Staar AQ2010V is 13.5 mm in overall length and is available in powers between +5.0 to +9.0 D in whole diopter steps. This approach is especially useful when expensive refractive lasers are not available or when corneal surgery is not feasible.

Photic phenomena management

If patients are unduly bothered by photic phenomena such as halos and glare following RLEs with Array multifocal IOLs, these symptoms can be alleviated by various techniques. Weak pilocarpine at a concentration of 1/8% or weaker will constrict the pupil to a diameter that will usually lessen the severity of halos without significantly effecting near visual acuity. Similarly, brimonidine tartrate ophthalmic solution 0.2% has been shown to reduce pupil size under scotopic conditions [40] and can also be administered in an attempt to reduce halo and glare symptoms. Another approach involves the use of over-minused spectacles to push the secondary focal point behind the retina and thus lessen the effect of image blur from multiple images in front of the retina [41]. Polarized lenses have also been found to be helpful in reducing photic phenomena. Finally, most patients report that halos improve or disappear with the passage of several weeks to months.

Conclusion

Thanks to the successes of the excimer laser, refractive surgery is increasing in popularity throughout the world. Corneal refractive surgery, however, has its limitations. Patients with severe degrees of myopia and hyperopia are poor candidates for excimer laser surgery, and presbyopes must contend with reading glasses or monovision to address their near visual needs. Ironically, the current trend in refractive surgery towards improving functional vision with customized ablations to address higher order aberrations may ultimately lead to crystalline lens replacement as the best means of creating a highly efficient emmetropic optical system that will not change as a patient ages.

The rapid recovery and astigmatically neutral incisions currently being used for modern cataract surgery have allowed this procedure to be used with greater predictability for RLE in patients who are otherwise not suffering from visually significant cataracts. Successful integration of RLE into the general ophthalmologist's practice is fairly straightforward, since most surgeons are currently performing small incision cataract surgery for their cataract patients. Essentially, the same procedure is performed for a RLE, differing only in removal of a relatively clear crystalline lens and simple adjunctive techniques for reducing corneal astigmatism. Although any style of foldable IOL can be used for lens exchanges, multifocal intraocular lenses and eventually accommodative lenses offer the best option for addressing both the elimination of refractive errors and presbyopia.

Refractive lens exchange is not for every patient considering refractive surgery but does offer substantial benefits, especially in patients with high hyperopia, those with presbyopia, and patients with borderline or soon to be clinically significant cataracts who are requesting refractive surgery. Advances in both IOL and phacoemulsification technology have added to the safety and efficacy of this procedure and will contribute to its increasing utilization as a viable refractive surgery modality.

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