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ORIGINAL RESEARCH

Comparison of clear lens extraction and collamer lens implantation in high myopia

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Ahmed M Emarah
Mostafa A El-Helw
Hazem M Yassin

Cairo University, Cairo, Egypt

Aim: To compare the outcomes of clear lens extraction and collamer lens implantation in high myopia.

Patients and methods: Myopic patients younger than 40 years old with more than 12 diopters of myopia or who were not fit for laser-assisted *in situ* keratomileusis were included. Group 1 comprised patients undergoing clear lens extraction and Group 2 patients received the Visian implantable collamer lens. Outcome and complications were evaluated.

Results: Postoperative best corrected visual acuity was –0.61 ± 0.18 in Group 1 and 0.79 ± 0.16 in Group 2. In Group 1, 71.4% achieved a postoperative uncorrected visual acuity better than the preoperative best corrected visual acuity, while only 51.8% patients achieved this in Group 2. Intraocular pressure decreased by 12.55% in Group 1, and increased by 15.11% in Group 2. Corneal endothelial cell density decreased by 4.47% in Group 1 and decreased by 5.67% in Group 2. Posterior capsule opacification occurred in Group 1. In Group 2, lens opacification occurred in 11.11%, significant pigment dispersion in 3.7%, and pupillary block glaucoma in 3.7%.

Conclusion: Clear lens extraction presents less of a financial load up front, and less likelihood of the need for a secondary intervention in the future. Clear lens extraction is a more viable solution in developing countries with limited financial resources.

Keywords: clear lens extraction, implantable collamer lens, myopia

Introduction

The personal and socioeconomic impact of myopia is well documented.[1,2] The poor visual quality of spectacle-corrected high emmetropia with inherent optical aberrations, secondary psychologic problems, and frequent intolerance to contact lenses, justify the search for new technology in the correction of high ametropia.[3]

Surgical correction of high ametropia is a controversial issue.[4–7] Despite the widespread acceptance of laser-assisted *in situ* keratomileusis (LASIK) within the ophthalmic community, this moderately invasive technique that directly affects the clear, central, optical zone is associated with a sizeable number of potential intraoperative and postoperative complications, the incidence of which has been found to increase with higher refractive errors.[8] To this contributes the fact that the use of Excimer laser corneal ablation has some limitations concerning the amount of corneal tissue that can be removed,[9] the predictability and stability of photorefractive techniques decreases with the amount of attempted correction, and corneal ectasia might occur as a result of large ablation depths.[10] Additionally, altering the shape of the cornea in attempted high photorefractive corrections may result in poor quality of vision.[11]

Correspondence: Mostafa El-Helw
Cairo University, 52 Manyal Street,
Manyal, Cairo, 11451, Egypt
Tel +11 201 0122 8920
Fax +11 201 2747 4858
Email helw@yahoo.com

Fukala is considered the pioneer of clear lens extraction (CLE) for the correction of myopic eyes.[12] Extracting the clear lens is one procedure that has been used to treat high myopia for a long time.[13,14] The primary concern with this procedure is its association with an increased risk of retinal complications.[14,15] CLE is an invasive procedure that can result in severe visual loss. Albeit rare, the primary risk is an increased potential for retinal detachment. Other potential complications include cystoids, macular edema, and endophthalmitis. Despite these severe complications, advances in surgical techniques have led surgeons to reconsider this option and to weigh the risks against the benefits of the procedure.[16]

Phakic intraocular implants can correct high myopia and hyperopia, with the advantages of reversibility, stability of the correction, and to a great extent, preservation of accommodation.[8,17–26] An increasing number of procedures are being performed because of the expectation of a superior quality of vision obtained with phakic intraocular lens (IOL) implantation with respect to keratorefractive surgery for the correction of high ametropias.[27–30] However, induced cataract and glaucoma are at the heart of most concerns regarding these intraocular surgical procedures, especially for posterior chamber phakic IOLs.[31–39] This study was conducted with the aim of comparing CLE and the implantable collamer lens (ICL) in correction of high myopia in the patients younger than 45 years.

Patients and methods

Patient selection and preparation

This was a prospective, nonrandomized interventional study carried out on 55 eyes in 31 patients seeking treatment of myopia. The research followed the tenets of the Declaration of Helsinki, and informed consent was obtained from patients, to whom all details of the procedure were explained, with emphasis on the intended outcome. The research was approved by the El-Nour Eye Hospital institutional review board.

Inclusion criteria were myopia of more than 12 diopters, myopia of less than 12 diopters if the patients were unsuitable for LASIK due to topography or pachymetry results according to guidelines suggested in literature, and age younger than 45 years (to obtain some accommodative potential). Exclusion criteria were intraocular pressure (IOP) outside the statistically normal range (more than 21 mmHg), presence of iris transillumination defects, or retinal pathology.

After appropriate counseling and signing of informed consent, the personal treatment preferences of the patients were taken into account with regard to their assignment to either group. Group 1 underwent CLE and Group 2 underwent ICL. CLE was preferred if there was a recent increase in myopia by more than 1.0 diopter, an anterior chamber depth (ACD) less than 2.8 mm, or if the patient was unable to afford ICL. ICL was undertaken in patients motivated to maintain their residual accommodation provided their refraction was stable, the anterior chamber was more than 2.8 mm deep, and adequate financial resources were available.

The preoperative evaluation included manifest and cycloplegic refraction, uncorrected (UCVA) and best-corrected visual acuity (BCVA) measured on a visual chart and expressed as Snellen's decimal, intraocular pressure (IOP) measurement by Goldmann applanation tonometry, through slit lamp biomicroscopy of the anterior segment, and dilated fundus examination using both a 90 diopters (D) lens for the posterior pole and a three-mirror lens for detailed examination of the retinal periphery.

Preoperative specular microscopy using the noncontact specular microscope (NONCON ROBO-P, Konan Medical, Torrance, CA) was done and repeated six months postoperatively. ACD, horizontal white to white diameter and corneal topography were measured using anterior segment scheimpflug imaging by Pentacam HR (OCULUS Optikgeräte GmbH, Germany). ICL diameter, power, and optic size calculation were performed by STAAR Surgical Inc. (Monrovia, CA), using a modified vertex formula based on the above diameters with targeted postoperative emmetropia and adequate lens vaulting.

Surgical technique

All CLE procedures were performed by AE and MH who are experienced anterior segment surgeons, while all ICL procedures were performed by HY who had performed numerous ICL implantations prior to commencement of the study.

Clear lens extraction

All surgeries were performed under local peribulbar anesthesia through a 3.2 mm incision placed along the steeper meridian and the creation of two side ports. Because of the soft nucleus, often only irrigation/aspiration was used. A foldable hydrophobic acrylic IOL (SENSAR Acrylic IOL with OptiEdge, Abbott Medical Optics, Inc., Abbott Park, IL) was introduced through an injector without widening the wound, into the capsular bag, with meticulous polishing of the anterior lens capsule.

Implantable collamer lens

All surgeries were performed under local peribulbar anesthesia through a 3.2 mm incision placed along the steeper meridian and the creation of a single side port. The

anterior chamber was filled with an ophthalmic viscosurgical device (OVD). Careful loading of the ICL into the cartridge was undertaken using special microforceps and with partial lubrication using a mixture of saline and OVD to eliminate electrostatic forces. The lens was then slowly injected into the anterior chamber using the STAAR injector (STAAR Surgical Inc) anterior to the iris plane, and allowed to unfold. The positioning holes on the distal and proximal footplates of the lens were checked to ensure proper orientation. The lens was rotated to be in the horizontal anterior chamber position. Each corner of the footplate was tucked beneath the iris carefully with a modified lens spatula, taking special care not to touch the optic or the crystalline lens. Once the lens was placed, the OVD was removed by irrigation/aspiration, taking care not to leave any residue. The pupil was pharmacologically constricted and a peripheral iridectomy performed at 12 o'clock using a vitrectomy probe. The wound was secured by stromal hydration.

Postoperative care

Topical antibiotic (gatifloxacin 0.3% three times a day) and steroids (prednisolone 1% five times a day) were administered and gradually tapered over a period of four weeks. The ICL group also received oral acetazolamide 250 mg twice daily during the first 24 hours.

Outcome parameters

The mean follow-up period was 17.1 ± 8.56 months. During this period the patients were examined on the first postoperative day, and at one week, two weeks, one month, and quarterly thereafter until the end of follow-up. During this period the assessed outcome parameters included last visit UCVA, refraction and BCVA, IOP (with the measurement taken at six months being representative of the postoperative reading), noncontact specular microscopy at six months, Pentacam evaluation of ACD, other postoperative complications, and the need for a secondary procedure. The ICL group additionally had slit lamp examination for inflammation and lens opacities.

Statistical analysis

Data were described using the arithmetic mean ± SD or number and percentage when appropriate. Comparison of variables was done using the Mann–Whitney *U* test and Wilcoxon single-rank test for between-group comparisons and comparisons within the same group, respectively. All tests were two-tailed, and a P value < 0.05 was considered statistically significant. All statistical calculations were done using the SPSS (version 10.0; SPSS Inc., Chicago, IL) statistical program.

Results

Patient population

Group 1 involved 28 eyes in 16 patients, with 12 patients being operated bilaterally and four patients unilaterally, and a mean age of 36.04 ± 3.95. Group 2 involved 27 eyes in 15 patients, with three patients being operated unilaterally, and a mean age of 29.26 ± 6.82 (see Table 1). The age was significantly different ($P = 0.000$) between the groups, but this can be explained by the inclusion criteria. Group 1 involved eight male and eight female patients, while Group 2 involved six male and nine female patients.

Predictability

The mean preoperative spherical equivalent (SEQ) was −17.54 ± 4.99 D in the CLE group and −16.45 ± 2.64 D in the ICL group. The difference was statistically

Table 1 Summary of patient data

	CLE				ICL				Sig
	Min	Max	Mean	SD	Min	Max	Mean	SD	
Age	29	42	36.04	3.95	20	40	29.26	6.82	0.000
Pre-UCVA	0.02	0.08	0.041	0.018	0.02	0.16	0.36	0.027	0.072
Post-UCVA	0.10	0.70	0.43	0.16	0.20	0.70	0.44	0.16	0.662
Pre-BCVA	0.20	0.60	0.39	0.097	0.30	0.70	0.51	0.087	0.000
Post-BCVA	0.10	0.90	0.61	0.18	0.30	1.00	0.79	0.16	0.000
Pre-ECD	2784	3876	3258.54	295.29	2784	3332	3070	152.35	0.005
Post-ECD	2623	3781	3112.79	304.13	2634	3187	2896	151.75	0.002
Pre-SEQs	–8	–27	–17.54	4.99	–10	–22	–16.45	2.64	0.319
Post-SEQs	–2.50	1.00	–0.99	0.88	–2.00	1.25	–0.63	0.86	0.199
Pre-IOP	10	22	16.25	3.34	11	22	16.15	3.21	0.909
Post-IOP	9	25	14.21	3.75	13	24	18.59	2.74	0.000

Abbreviations: BCVA, best-corrected visual acuity; CLE, clear lens extraction; ECD, endothelial cell density; ICL, implantable collamer lens; IOP, intraocular pressure; SEQ, spherical equivalent; Max, maximum; Min, minimum; SD, standard deviation; Sig, significant; UBVA, uncorrected best visual acuity.

insignificant (P = 0.32). The mean postoperative SEQs were −0.99 ± 0.88 D in the CLE group and −0.63 ± 0.86 D in the ICL group. The difference was statistically insignificant (P = 0.199).

The refractive results were compared with the desired postoperative refraction. In the CLE group the aim was residual myopia of −1.00 D; 82% (23 patients) were within ±1.00 D of the desired refraction, and 100% were within ±2.00 D. In the ICL group the aim was emmetropia; 77% (20 patients) were within ±1.00 D of the desired refraction, and 100% were within ±2.00 D. The investigators aimed for emmetropia in the ICL group because these patients retained some residual accommodative potential, but aimed for a myopia of −1.00 in the CLE group because patients who are previously myopes are seldom happy if they become emmetropic with loss of accommodation.

Visual outcome

The mean preoperative BCVA was 0.39 ± 0.097 in the CLE group and 0.51 ± 0.87 in the ICL group. The difference was statistically significant (P = 0.000). The mean postoperative BCVA was 0.61 ± 0.18 in the CLE group and 0.79 ± 0.16 in the ICL group. The difference was statistically significant (P = 0.000). However, comparisons within each group revealed a different aspect. In the CLE group, 20 patients (71.4%) achieved a postoperative UCVA better than their preoperative BCVA, while only 14 (51.8%) patients achieved this in the ICL group. In the CLE group, 15 patients (53.5%) achieved a postoperative UCVA ≥ 0.5 versus 12 patients (44.4%) in the ICL group.

Anatomic outcome

In the CLE group, the mean IOP showed a reduction from a preoperative value of 16.25 ± 3.34 mmHg to a postoperative value of 14.21 ± 3.75 mmHg. This shift was significant (P < 0.001). On the other hand, the ICL group showed an elevation of mean IOP from a preoperative value of 16.15 ± 3.21 mmHg to a postoperative value of 18.59 ± 2.74 mmHg. This shift was again significant (P < 0.001).

Corneal endothelial cell density (ECD) showed a difference between the preoperative and postoperative values of 4.47% in the CLE group and 5.67% in the ICL group. ACD was evaluated only in the ICL group, this evaluation being performed at six months. The mean preoperative ACD of 3.18 ± 0.14 mm (range 2.99–3.42) was significantly reduced to 2.99 ± 0.17 mm (range 2.75–3.3). The P value for this variable was <0.001.

Complications

None of the cases in either series had significant corneal haze or edema, retinal detachment, endophthalmitis, or persistent inflammation during the follow-up period.

There were no notable complications in the CLE group, apart from the occurrence of posterior capsule opacification and the need for neodymium-doped yttrium aluminum garnet (Nd:YAG) capsulotomy. This occurred in four eyes (14.3%).

A number of complications were noted in the ICL group. Three forms of lens opacity were evaluated postoperatively, ie, anterior subcapsular opacity, nuclear opacity, and posterior subcapsular opacity. Evaluation was done under the slit lamp after pupillary dilation. Lens opacity was considered to be significant if it caused a loss of >two lines of BCVA. Overall lens opacity was noted in three eyes (11.11%). Only one eye had significant lens opacity, with both anterior subcapsular and nuclear opacity related to a secondary glaucoma procedure and required cataract extraction (see Table 2). Lens opacity was analyzed regarding age, gender, degree of myopia, and adequate ICL vaulting. Lens opacity was not significantly related to age and gender, but significantly related to the degree of myopia (all had myopia >18 D)

Significant pigment dispersion occurred in one eye (3.7%), with a rise of IOP (>21 mmHg). Ultrasonic biomicroscopy examination revealed ICL iris contact at the superior-temporal quadrant, requiring a second procedure in the form of lens rotation to exact horizontal meridian which achieved marked improvement.

One eye developed pupillary block glaucoma in the early postoperative period with evident pigment blocking the iridotomy, requiring glaucoma surgery and with a rapidly progressing cataract that eventually required ICL removal, cataract extraction with placement of low power monofocal posterior chamber IOL, and with a final UCVA better than the preoperative BCVA for distance work.

One eye (3.7%) had a macular dot hemorrhage with a drop of BCVA > two lines, with no fluorescein angiographic evidence of choroidal neovascular membrane, and with spontaneous clearance and improvement of visual acuity to one line less the preoperative BCVA.

Table 2 Incidence of postoperative lens opacity

	Clinically insignificant	Clinically significant
Anterior subcapsular	1 (3.7%)	1 (3.7%)
Nuclear opacity	0	1 (3.7%)
Posterior subcapsular	1 (3.7%)	0

Discussion

In this series we tried to compare CLE and ICL for predictability, and visual and anatomic outcome for the treatment of high myopia. Both procedures showed a high predictability, with a higher percentage of cases achieving the target refraction in the CLE group than in the ICL group, although the difference was marginal (82% versus 77%).

The mean postoperative BCVA was 0.61 ± 0.18 in the CLE group and 0.79 ± 0.16 in the ICL group. The difference was statistically significant ($P = 0.000$). We attributed this to the higher range of error in the CLE group (highest error was –27 D versus 22 D) and consequently the retinal condition was correspondingly weaker.

The first anatomic outcome to consider is the IOP. In the CLE group, the mean IOP showed a reduction from a preoperative value of 16.25 ± 3.34 mmHg to a postoperative value of 14.21 ± 3.75 mmHg. This shift was significant ($P < 0.001$). Several studies have documented a change in IOP and ACD after cataract extraction.[40–44] Increases and decreases in IOP often occur postoperatively. There are several explanations for the reduction in IOP after phacoemulsification and IOL implantation. One reason is decreased resistance to aqueous humor outflow caused by an increase in ACD, although other mechanisms are also responsible for aqueous humor outflow. Postoperative release of endogenous prostaglandin F_2 after cataract extraction is reported to enhance uveoscleral outflow. Reduced IOP may also be associated with hyposecretion of aqueous humor by increasing traction on the ciliary body via the ciliary zonular fibers due to postoperative fibrosis and contraction of the lens capsule.[40]

On the other hand, the ICL group showed an elevation of mean IOP from a preoperative value of 16.15 ± 3.21 mmHg to a postoperative value of 18.59 ± 2.74 mmHg. This shift was again significant ($P < 0.001$). Reasons for this elevated IOP include forward vaulting of the ICL and consequently of the iris, highly myopic eyes being prone to developing chronic open angle glaucoma, or presence of pigment in the trabeculum.[45] In our series, one eye (3.7%) had pigment dispersion, and one eye (3.7%) had pupillary block glaucoma in the early postoperative period, with evident pigment blocking the iridotomy, requiring glaucoma surgery with rapidly progressing cataract that eventually required ICL removal and cataract extraction with placement of a posterior chamber IOL.

The second anatomic outcome to consider is the ECD. The drop in ECD was less in the CLE than in the ICL group (4.47% versus 5.67%, respectively). The cause of endothelial cell loss after phakic IOL implantation is multifactorial. After any surgical procedure in the anterior segment, ECD decreases in proportion to the time of surgery and the type of procedure.[46] Progressive endothelial cell loss has been suggested to be the result of a chronic, smoldering uveitis associated with IOLs. Chronic subclinical inflammation has also been observed in phakic eyes with IOLs.[47] It has been suggested that while endothelial cell loss continued over the first three years of follow-up (2%–3% per year), there was a cell increase of 0.1% between three years and four years, suggesting that endothelial remodeling and stability may have occurred.[48]

Although multiple factors influence the side effect profile of phakic IOLs, the majority of complications can generally be predicted by the design and location of the phakic IOL within the anterior segment. The closer the phakic IOL comes to the corneal endothelium, angle structures, or crystalline lens, the greater the risk of endothelial cell loss, iris complications, and cataract, respectively. In addition to the inherent problems from phakic IOL designs, appropriate sizing of the phakic IOL, surgeon inexperience, and surgical trauma, as well as other patient-specific factors can contribute to intraoperative and postoperative complications. A comprehensive review and grouped analysis of phakic IOL complications and possible causes can be found elsewhere.[49]

Previous reports of posterior chamber phakic IOL surgery report an incidence of lens opacity from 1.5% to 25%.[23,50,51] Some of the variation may be due to the definition of cataract or opacity and the follow-up period, as well as surgical technique. In our series, lens opacity was noted in three eyes (11.11%). Only one eye had significant lens opacity, with both anterior subcapsular and nuclear opacity related to a secondary glaucoma procedure and cataract extraction. Several factors can play a role in the opacification of the crystalline lens, ie, surgical trauma, postoperative inflammation, use of topical steroids, and contact between the phakic IOL and the crystalline lens. Of these, one can postulate that phakic posterior chamber IOL implantation in eyes with early nuclear changes might promote the progression of these changes into the development of a clinically significant nuclear cataract.[52] The thickness of the crystalline lens increases as the eye ages, and this may lead to transient or permanent contact. It can be hypothesized that implantation of phakic IOLs in patients in their 40s or 50s may increase the trend to develop cataracts earlier than in nonmyopic eyes.[53]

The increasing incidence of phakic intraocular procedures warrants education regarding management and prevention of potential complications. It may be advisable to perform

preoperative biometry and axial length measurements on all patients undergoing phakic IOL implantation to be prepared for the future need of phacoemulsification.[54]

The main concern when operating on myopic eyes is retinal detachment with the attendant risk for significant visual loss. Retinal detachment secondary to cataract extraction originates from the loss and advancement of the vitreous, which is often characterized by structural modifications in myopic patients. These include massive colliquation, vitreoschisis, and fibrous organization, with consequent vitreoretinal traction. It is therefore important that the barrier provided by the capsular-zonular plane remain intact, and IOL implantation is always advisable.[55] In our series of CLE, only four eyes required Nd:YAG capsulotomy, and none of the patients developed retinal detachment. We attributed this to careful preoperative screening using three-mirror examination, avoiding doubtful cases, very careful polishing of the posterior capsule and the anterior leaf of the capsule to remove epithelial cells, our choice of IOL with an edge design believed to retard the occurrence of posterior capsule opacification, and a relatively short follow-up period of 17.1 ± 8.56 months. The incidence of this complication after CLE reported in other studies[13,15,56] is variable, ranging from 0% to 8%. It has been proposed that the causes of this variability are different patient characteristics and study designs. These and other previously reported studies have found associations between the risk of retinal detachment and one or more of several factors, including younger age, axial length, history of retinal detachment or surgery in the contralateral eye or lesions predisposing to retinal detachment, surgical technique and integrity of the posterior capsule, use of Nd:YAG capsulotomy, and longer follow-up time after surgery. Several papers have reported the incidence and characteristics of retinal detachment in patients with severe myopia corrected by phakic anterior chamber IOL implantation. An incidence of retinal detachment from 0.61% to 4.8% has been reported.[17,57–60] No cases occurred in our series.

The choice of the procedure presents a challenge to the clinician to provide adequate informed consent. This is due to two factors, ie, the greater complexity of optical issues and the greater range of options that are available now and may be available in the future. The informed consent process involves appropriately informing patients of risks, benefits, and alternatives to the proposed procedure(s). Explaining the range of visual outcomes to patients is not for the clinician in a hurry. And neither is explaining the risks. There are obvious rare but severe risks with CLE, including retinal detachment and endophthalmitis. Equally important, however, is the discussion of quality of vision, including the possible failure to achieve adequate near vision, and the compromise associated with monovision, halos, and reduced contrast sensitivity. With ICL there is the risk of developing cataract and secondary glaucoma, so clarifying patient expectations is crucial.

Another issue that also needs to be taken into account is cost. The cost of surgery in CLE and ICL is the same, apart from the lens, which is the only different consumable. The cost of the ICL is several-fold higher than that of a high-quality foldable injectable acrylic hydrophobic IOL. This is an important factor in developing countries and in some developed regions where ICL is considered to be a cosmetic procedure and therefore not funded. An additional factor to consider is the personal experience of the surgeon, because the ICL requires additional training, whereas CLE extraction is a variation of a more common procedure.

Disclosures

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