Original Article

Clear lens extraction for patients who are unfit for laser-assisted *in situ* keratomileusis and implantable contact lenses in central Indian population

Rajesh Subhash Joshi

Purpose: The purpose of this study is to establish the safety of clear lens extraction (CLE) for the correction of high myopia in patients unfit for implantable contact lenses (ICLs) and laser *in situ* keratomileusis in the central Indian population. **Methods:** In this retrospective observational study performed at a tertiary care centre, medical records of the patients who had undergone CLE with implantation of intraocular lens (IOL) to treat high myopia were retrieved. Details of the demographic profile, surgical procedure, complications, power, and type of IOLs implanted were recorded. **Results:** The average postoperative follow-up period was 64.1 ± 4.2 months. The average postoperative spherical power was −1.4 ± 0.6 D, which was much lower than the preoperative spectacle power -15 ± 4.4 D. There was improvement in the postoperative visual acuity (0.4 ± 0.2 logMAR) from the preoperative distant uncorrected visual acuity (0.8 ± 0.2 logMAR). No significant change in intraocular pressure (IOP) was observed. The postoperative average anterior chamber depth (ACD) (2.66 ± 0.1 mm) was significantly deeper than the preoperative ACD (2.61 ± 0.1 mm) $P = 0.00$. Barrage laser was required for lattice degeneration in one patient before CLE and in two patients during follow-up. Two patients (8.7%) required Nd:YAG capsulotomy for posterior capsular opacification. None of the patients had corneal decompensation, retinal detachment, or endophthalmitis. **Conclusion:** CLE with implantation of IOL is the safe procedure for correcting high myopia in patients who are unfit for ICL. None of the patient had eye loss in the follow-up period of 5 years. The low incidence of complications can be attributable to the closed chamber lens removal and implantation of IOL and prophylactic retinal treatment.

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Correction of a high degree of refractive error is debatable with several modalities available for correcting high myopia (myopia of >6 D) such as laser *in situ* keratomileusis (LASIK), small incision lenticule extraction, laser subepithelial keratomileusis,[1] phakic iris-claw lens,[2] photorefractive keratectomy,[3] bioptics,[4] implantable contact lenses (ICLs),[5] and clear lens extraction (CLE).[6] Keratorefractive surgeries for high myopia correction are associated with complications such as halo, glare, and loss of contrast sensitivity due to induced higher-order aberrations (HOAs). The excessive flattening of the cornea can lead to HOAs. ICLs and intraocular lenses (IOLs) can correct the high degree of refractive error without causing a change in corneal shape.[6] The advantage of ICLs is the reversible and stable correction of high myopia along with astigmatism and the preservation of accommodation. However, prerequisites for ICL implantation include a deep anterior chamber (≥3 mm) and an accurate measurement of white-to-white corneal diameter. The risk of cataract formation and glaucoma necessitating a second surgical procedure are the major concerns of the procedure.

Fukala, pioneered CLE for high myopia correction.[7-9] The main disadvantage of this procedure is retinal complications that might develop postoperatively.[10-12] With technological advancements and improved outcomes after cataract surgery, removal of the clear lens in a high myopic patient has been considered a refractive modality. The high myope with an accommodative reserve may be a good candidate for CLE. The German database places CLE second only to laser refractive procedures as the refractive surgical procedure of choice, and this trend is seen across Europe.[13,14]

Based on the results of a survey on the refractive surgical procedure trend, the United States International Society of Refractive Surgery concluded that CLE has a great future.[15]

This study investigated patient with high myopia who were unfit for LASIK and ICL surgery but desired a spectacle-free vision.

Methods

This retrospective record review study was conducted in a tertiary eye care center in central India after the institutional

Department of Ophthalmology, Government Medical College, Nagpur, Maharashtra, India

Correspondence to: Dr. Rajesh Subhash Joshi, 77, Panchatara Housing Society, Manish Nagar, Somalwada, Nagpur - 440 015, Maharashtra, India. E-mail: jrajesh5@rediffmail.com

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review board approved the study. The study followed the tenets of the Declaration of Helsinki. The records of the patients who underwent CLE during January 2014-December 2014 were retrieved, and details of the demographic profile, surgical procedure, complications, power and type of IOLs implanted, and follow-up were recorded. Patients unsuitable for ICLs and LASIK procedure for correction of myopia were operated for CLE and followed up postoperatively for 5 years were included in the study.

Preoperative evaluation

The preoperative examination included uncorrected and best-corrected visual acuity (BCVA) of the patients, cycloplegic and manifest refraction, a thorough slit-lamp examination, dilated fundus examination using a 90-D lens, peripheral retinal examination through indirect ophthalmoscopy, and intraocular pressure (IOP) measurement using an applanation tonometer (Perkins applanation hand-held tonometer, Haag Streit, UK).

During evaluation of the patient for LASIK or ICL topography (Sirius topographer, CSO, Italy), the anterior chamber depth (ACD) and corneal thickness were noted. IOL power was determined using an optical biometer (Lenstar, LS 900, Haag-Streit, USA).

Surgical procedure

Informed written consent was obtained from the participants. All the surgeries were performed by a single surgeon under topical anesthesia. Two side port incisions, one at the 12 and another at the 6 o' clock position, were created. Preservative-free 1% intracameral lignocaine (0.5 mL) was injected through the side port. A 2.2-mm clear corneal temporal incision was performed using a keratome. Continuous curvilinear capsulorhexis was performed using microcapsulorhexis forceps in the presence of viscoelastic solution. The size of the capsulorhexis was maintained approximately at 5–5.5 mm and hydrodissection was accomplished. Because of the soft nucleus, the nucleus and cortex were removed through irrigation and aspiration using a phaco machine (Oertli Swisstech Phacoemulsifier, Switzerland) at a vacuum of 350 cc and an aspiration flow rate of 35 cc/min, respectively. The polishing of the rim of the capsulorhexis was performed in a Cap Vac mode (vacuum and flow rate of 10 cc/min). The anterior chamber was filled with the viscoelastic solution, and the IOL (MA60BM, Alcon Laboratories, Fort Worth, Texas, USA) was implanted in a capsular bag. The viscoelastic solution was cleared from the anterior chamber, and the wound was closed by stromal hydration. Suturing was performed with a 10-0 nylon suture in case of wound leak. The operating surgeon noted the intraoperative difficulties and complications.

Postoperative care and follow-up

Topical steroids (1% prednisolone acetate drops) were prescribed six times a day and tapered gradually over 1 month, and antibiotic drops (0.3% moxifloxacin) were administered four times a day for 10 days.

The patients were examined on the first postoperative day, and then at 1 week, 2 weeks, 1 month, and 6 months postoperatively. Additional follow-up visits were scheduled as required. At every visit, the uncorrected and BCVA was noted, and slit-lamp examination was performed. The IOP was measured using the applanation tonometer, and a dilated fundus examination through indirect ophthalmoscopy was performed to note any degenerative lesions on the peripheral retina. The requirement of barrage laser for any treatable lesions was noted.

Statistical analysis

The data were entered in an Excel® sheet (Software version 14.1.0 [110310]/2011) (Microsoft Corporation, Redmond, WA, USA), and statistical analysis was performed using SPSS version 13.0 (SPSS Inc, Chicago, IL, USA). Snellen visual acuity measurements were converted to logMAR for statistical analysis and were described using mean ± SD or number and percentage. The repeated analysis of variance test was applied for multiple comparisons, and paired t-test was applied for comparing preoperative and postoperative parameters. $P < 0.05$ was considered statistically significant.

Results

The mean age of the 23 patients was 28.8 ± 5.9 years (range 21–40 years) [Table 1]. The sample consisted of 19 female and 4 male patients. **CLE** was performed in the right eye for 10 patients, left eye for 11 patients, and bilaterally in 2 patients. The average postoperative follow-up period was 64.1 ± 4.2 months. The mean preoperative uncorrected distant visual acuity was 0.8 ± 0.2 logMAR, whereas the BCVA was 0.1 ± 0.1 logMAR. The average spherical spectacle power was -15 ± 4.4 D (range 9–24 D), and the cylindrical power was 1.0 ± 0.7 D (range 0–2 D). One patient had a high cylindrical power and was implanted with toric IOL. The average axial length was 28 ± 2 mm (range 26–36 mm). The mean IOL power was 6.6 ± 4.8 D (range 6–12 D). Negative power IOL was required in three patients. All patients were implanted with hydrophobic IOLs. The mean postoperative BCVA was 0.4 ± 0.2 logMAR (range 0.1–0.6 logMAR). The average postoperative spherical power was −1.4 ± 0.6 D (range 0.5–3 D) and cylindrical power was 0.4 ± 0.4 D (range 0–1 D) [Table 2]. Postoperative refractive error from −1 to −2 D was present in 78.3% (n = 18) eyes. No significant change was observed in preoperative (14 ± 2.8 mm, range 10–20 mm) and postoperative (13 ± 2.9 mm, range 9–19 mm) IOP (P = 0.52). Preoperative pachymetry (461 ± 31 µm, range 400–525 µm) did not differ from the first day (462 ± 31 µm, range 402–525 µm) and the last postoperative visit (462 ± 31 µm, range 400–525 µm) (P = 0.82). The postoperative average ACD (2.66 ± 0.1 mm, range 2.47–2.89 mm) exhibited significant

Table 1: Preoperative data of patients included in the study

Parameters	Mean±SD	Range
Age (Years)	28.8±5.9	21-40
Axial length (mm)	28±2	26-30
Spherical error in the spectacle (D)	-15±4.4	–9.0–-24.0
Astigmatism (D)	1±0.7	0–2
BCVA (LogMAR)	0.1±0.1	0-0.3

Table 2: Postoperative data of patients included in the study

Parameters	Mean±SD	Range
Follow up (Months)	64.1±4.2	60-71
Refraction (D)	-1.4±0.6	0.5-3
BCVA (LogMAR)	0.4±0.2	0.10.6

D=Diopter, BCVA=Best-corrected visual acuity

deepening than the preoperative ACD (2.61 ± 0.1, range 2.45–2.80 mm) ($P = 0.00$). One patient required barrage laser for lattice degeneration before CLE, whereas two patients required barrage laser for a hole and lattice during follow-up.

Neodymium-doped yttrium aluminum garnet (Nd:YAG) capsulotomy was needed for posterior capsular opacification (PCO) in two patients (8.7%) during the 2-year follow-up period.

None of the patients had significant corneal edema, postoperative haze, corneal decompensation, retinal detachment (RD), endophthalmitis, or persistent inflammation during the follow-up period.

Discussion

A modern development in phacoemulsification techniques for cataract surgery and the use of foldable lenses of a hydrophobic material has reduced CLE-related complications in highly myopic eyes.[9,16,17] Young high myopes with a refractive error not amenable to laser refractive surgery are candidates for either ICLs or CLE. Although both ICLs and CLE have their advantages and disadvantages, the only alternative method available for high myopia correction in patients unfit for ICLs is CLE.

The present study is a retrospective analysis of patients with high myopia who were unfit for ICLs and had undergone CLE. The mean age of the patients was 28.8 ± 5.9 years (range 21–40 years), and the female to male ratio was 19:4. Most of the studies have shown young age at the time of surgery.[6,9,18-21] and female preponderence.[18-22] Analyzing the reasons for this trend was beyond the scope of the study.

This retrospective analysis was performed to determine the visual status of and the safety of the CLE procedure in high myopes in central India. The mean postoperative BCVA at the last follow-up visit was 0.4 ± 0.2 logMAR (range 0.1–0.6 logMAR), which correlates with the study by Emarah *et al*. who reported a mean BCVA of 0.61 ± 0.18 logMAR in the CLE group.[20] Fernandez *et al*. reported a postoperative BCVA of 0.37 ± 0.17 logMAR (range 0.34–0.39 logMAR),[17] whereas Pucci *et al*. reported a postoperative BCVA of 0.61 ± 0.16 logMAR (range 0.20–0.80 logMAR).[9] A high range of refractive error correction and the presence of retinal degeneration contributed to the decreased BCVA in our study. However, most studies have shown improvement in the visual acuity after CLE.[7-9,17,18,20-24]

The postoperative spherical refractive error was between −1 and −2 D in 78.3% patients, which is the targeted refraction to compensate for the accommodation loss after CLE. Kubaloglu *et al*. reported 55.3% patients in the range of ±1.00 D.[19] A targeted spherical refractive error of −2 to −3 D was maintained in the nondominant eye in patients who had bilateral CLE ($n = 3$).

Our study did not show any effect on anatomic factors such as IOP and corneal thickness. A slight reduction was observed in the postoperative IOP (13 ± 2.9 mm, range 9–19 mm) compared with the preoperative IOP (14 ± 2.8 mm, range 10–20 mm) ($P = 0.52$). However, a significant deepening of the post-CLE anterior chamber (2.66 ± 0.1 mm, range 2.47–2.89 mm) was observed compared with the pre-CLE (2.61 ± 0.1 mm, range 2.45–2.80 mm) ($P = 0.00$). Emrah *et al*. reported a significant decrease in the IOP after CLE (pre-CLE 16.25 ± 3.34 mm and post-CLE 14.21 ± 3.75 mm).[20] Factors that play a role in IOP reduction after cataract surgery such as decreased resistance to aqueous outflow due to deepening of the anterior chamber, enhancement of the uveoscleral outflow due to the release of endogenous prostaglandin F2, and hyposecretion of the aqueous humor due to traction on the ciliary body need to be investigated.

No change was observed in the second anatomical factor, namely pachymetry (pre-CLE 461 ± 31 μm, range 400–525 μm and post-CLE 462 ± 31 μm, range 400–525 μm). Very few chances of damage to the endothelium exist due to the soft nucleus and no or minimal ultrasonic energy usage during the removal of the nucleus and cortex. El-Helw and Emarah studied supracapsular and endocapsular phacoemusification of the nucleus in high myopes and reported no significant loss of the endothelial cell count between the two groups postoperatively.[21,23] In our study, the nucleus and cortex were removed through irrigation and aspiration using the phaco machine, and no ultrasonic power was used. We could not perform the endothelial cell count and morphology study due to the nonavailability of a specular microscope at our center.

The main concern for performing CLE in young myopic eyes is RD with the risk of significant vision loss. High myopia itself is an independent risk factor for RD, accounting for 50% of the non-trauma-related RD in high myopes.[24] The incidence of RD after CLE in different studies varies from 1.5 to 8.1%.[9,12,14,25,26] **ICL** is also associated with the risk of RD.[27-30] The variability in RD incidence in various studies may be due to the different inclusion criteria for age and refractive error amount, follow-up duration, surgical techniques, and IOL type used. However, the risk of RD is more with an axial length of >30 mm, younger age at the time of surgery, peripheral degenerative changes in the retina, surgical techniques such as extracapsular cataract surgery with a large incision, history of RD,[31] surgery in the contralateral eye, posterior capsular tear, and Nd:YAG capsulotomy. In our study, none of the patients developed RD or any other retinal problems. Nd:YAG capsulotomy was required in two patients for PCO 2 years after surgery for which we used 2 mJ of energy and created an opening of approximately 3 mm. These two patients did not show any retinal problem at the last follow-up. Mixed opinions exist regarding the development of RD after Nd:YAG capsulotomy. Alio,[25] Kubaloglu, and Emrah *et al*. reported no RD after Nd:YAG capsulotomy, whereas Arne,[19,20,31] Olsen and Olsen,[30] and Javitt reported RD after Nd:YAG capsulotomy.[32] Careful preoperative examination of the peripheral retina, barrage laser for the peripheral retinal lattice and hole, and regular follow-up for the development of retinal lesions prevent RD after CLE. In our study, one patient required barrage laser for lattice degeneration before CLE, whereas two patients required barrage laser for hole and lattice during follow-up. Thorough polishing of the rim of the anterior capsule and equatorial area of the capsular bag with careful removal of the lens fibers attached to the posterior capsule may prevent PCO. The use of a hydrophobic IOL material with the square edge of the IOL reduces PCO.

Future development

Removal of the clear lens is possible through the 0.9-mm (20 G) incision. However, IOL implantation through this incision

is not possible due to the nonavailability of an injection technique. Therefore, further research is warranted in this direction.

PCO is another challenge that has been solved to some extent by hydrophobic and square-edge IOLs but remains significant problem after CLE.

Conclusion

With the development of the lens removal technique and modern IOLs, CLE for high myopia is a safe procedure and should be considered in patients unfit for ICLs. Appropriate preoperative evaluation and long-term follow-up is crucial. Postoperative risk of RD must be explained to the patient.

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Conflicts of interest

There are no conflicts of interest.

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