Comparison between Implantable Contact Lens (ICL) versus Acry Sof Cachet Phakic Intraocular Lenses in Correction of Moderate to High Myopia

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Abstract: Purpose: to evaluate the safety, efficacy, predictability and stability of two phakic intraocular lenses (pIOLs), Visian ICL (ICL) and AcrySof Cachet for correction of moderate to high myopia. **Patients and methods***:* In this prospective study that included (42) eyes of (23) patients. (21) eyes of (11) patients received Visian ICL; (21) eyes of (12) patients received AcrySof Cachet. Uncorrected Visual Acuity (UCVA), Best Spectacle Corrected Visual Acuity (BSCVA), Endothelial cell density, Intraocular pressure (IOP) and Postoperative complications were evaluated. **Results:** All patients completed six months follow up. The mean pre-operative spherical error was -14.13 ± 3.92, and -11.68 ± 0.98 diopters (D) for ICL and AcrySof Cachet (*P*= 0.014) respectively. The mean postoperative spherical error postoperative (6months) was -0.37 ± 0.48, -0.57 ± 0.20 (D) for ICL and AcrySof Cachet (*P*= 0.001) respectively. The mean uncorrected visual acuity (UCVA) postoperative (6 months) was 0.63 ± 0.17 and 0.78 ± 0.11 (decimal) for ICL and AcrySof Cachet (*P*= 0.002) respectively. The mean preoperative endothelial cell density (ECD) was 2923.71±208.95, 2719± 188.68 cell/mm² for ICL and AcrySof Cachet (*P*= 0.002) respectively. The mean percent endothelial cell loss postoperative (6months) was -1.99%,-5.57% for ICL and AcrySof Cachet (*P*= <0.001) respectively. **Conclusion:** ICL and AcrySof Cachet are almost equal in the terms of efficacy, predictability and stability, but regarding safety ICL had much less incidence of endothelial cell loss than AcrySof Cachet.
[Khaled Nada; Mohammed Attia and Ashraf El Habbak. **Comparison between Implantable Contact Lens (ICL) versus AcrySof Cachet Phakic Intraocular Lenses in Correction of Moderate to High Myopia.** *Nat Sci* 2016;14(9):141-146]. ISSN 1545-0740 (print); ISSN 2375-7167 (online). http://www.sciencepub.net/nature. 19. doi:10.7537/marsnsj140916.19.

Key Words: Implantable contact lens (ICL), AcrySof Cachet, Phakic IOLs, Myopia

1. Introduction

Keratorefractive surgery has been used to correct a wide range of refractive errors with safety and high efficacy in the vast majority of cases. In the case that excimer laser surgery cannot be performed due to a thin corneal tissue or high myopia, the implantation of a phakic intraocular lens (pIOL) could be considered as an option of refractive surgery. [1, 2]

The surgical correction of high myopia currently includes clear lens extraction, [3] anterior and posterior chamber phakic intraocular lens (pIOL) implantation [4], and keratorefractive surgeries such as photorefractive keratectomy (PRK), laser in situ keratomileusis (LASIK). [5]

PIOLs provide better visual quality, faster visual recovery, excellent refractive accuracy and stability, improved visual acuity, preservation of accommodation, and reversibility when compared to corneal surgery. [6]

PIOLs insertion requires intraocular surgery which carries the risk of endophthalmitis, surgically induced astigmatism, corneal endothelial cell loss, chronic uveitis, pupillary block glaucoma, pigment dispersion syndrome, and cataracts. In addition, the lens power calculation and surgical implantation of pIOLs require special techniques. [7]

The Visian Implantable Collamer Lens (ICL; STAAR Surgical Co, Monrovia, California) is the only posterior pIOL that is currently approved by the United States Food and Drug Administration (FDA) for the treatment of moderate to severe myopia. [8]

The Visian ICL is a foldable pIOL made from a biocompatible material named Collamer, composed of a hydrophilic porcine collagen (0.1%) hydroxyethyl-methacrylate copolymer with an ultraviolet-absorbing chromophore. [9]

The AcrySof Cachet pIOL (Alcon, Laboratories, Inc., Fort Worth, TX) is a single piece foldable hydrophobic acrylic angle-supported pIOL implantable, in the anterior chamber (AC).[10]

Aim of The Work

To compare between implantation of The Visian Implantable Collamer Lens versus the AcrySof Cachet angle supported phakic IOL as regards: Visual performance, Endothelial cell density, Intraocular pressure (IOP), and Postoperative complications.

2. Material and Methods

This study included (42) eyes of (23) adult patients. The patients were divided into two groups: Group (A) included (21) eyes of (11) patients where the posterior chamber phakic IOL (Visian Implantable Collamer Lens) ICL V4b was implanted. Group (B)

included (21) eyes of (12) patients where the anterior chamber foldable angle fixated IOL (AcrySof Cachet) was implanted. The study was performed with informed consent and following all the guidelines for experimental investigations required. In, Benha Ophthalmology Department, Benha University.

Inclusion criteria:

Best spectacle corrected visual acuity of 6/12 or better and stable refraction within ± 0.5D at least 12 months before surgery, Myopia more than -10.0 D, Myopia of less than -10.0 D when keratorefractive procedures are not suitable, Anterior chamber depth of 3.2 mm or more measured from the corneal epithelium to the anterior lens capsule using IOL Master, or 2.8 mm or more measured from the corneal endothelium to the anterior lens capsule using the pentacam, Endothelial cell density (ECD) using specular microscopy meeting the criteria proposed by the manufacturer of the Phakic IOL, age dependent, minimum from (2000- 3350 cells/mm^2), A pupil (under mesopic light conditions) smaller than 6.0 mm in diameter using the pentacam.

Exclusion criteria:

Abnormal cornea such as corneal opacity or corneal dystrophy, Abnormal pupil, fixed pupil or pupil greater than 6 mm in mesopic light conditions, Anterior segment pathology such as any form of cataract, pseudo-exfoliation, and severe iris atrophy, History and/ or any clinical signs of previous attack of uveitis, Glaucoma, Posterior segment pathology such as a previous retinal detachment surgery, diabetic retinopathy, pre-existing macular degeneration, or patient has undergone any previous intraocular surgery.

Preoperative Evaluation:

Full medical and ophthalmic history taking and full ophthalmic examination including:

- Uncorrected Visual Acuity (UCVA) using fingers counting and Snellen's visual acuity chart, Best spectacle corrected visual acuity using Snellen's visual acuity chart and cycloplegic refraction, Slit lamp examination of the anterior segment, IOP measurement using Goldmann's applanation tonometry, Gonioscopy of the anterior chamber angle using Goldmann's three mirror goniolens to exclude angle recession, angle trauma or anatomic anomalies and Fundus examination by indirect ophthalmoscopy and fundus biomicroscopy using the 90D lens.

Following investigations:

- Keratometric readings using Pentacam CSO Sirius, Pachymetry using the Pentacam CSO Sirius, Mesopic pupillary diameter using the Pentacam CSO Sirius, White to white distance using the caliber and the Zeiss IOL Master, Anterior chamber depth measurement using Zeiss IOL-Master and Pentacam CSO Sirius, Endothelial cell count measurement using a non-contact specular microscopy (Topcon SP2000), and Calculation of pIOL power using the formula provided by the manufacturer.

Operative procedure:

For eyes undergoing implantation of Visian ICL, The pupil was dilated to implant the ICL in the ciliary sulcus, and the procedure was done under general or peribulbar anesthesia. Correct loading of the ICL in the cartridge and the injector is essential for correct and easy implantation. Two 1-mm paracentesis incisions are made at 12 o'clock and 6 o'clock, The anterior chamber is filled with a dispersive (Hydroxypropyl methyl cellulose 1.4%) injected through the side port, A clear corneal tunnel incision was done by an angled keratome 3.2mm centered temporally, The cartridge is inserted bevel down, The ICL was carefully injected slowly using the MicroSTAAR injector into the anterior chamber using an advance-and-pause technique, Additional viscoelastic is injected over the ICL to deepen the chamber and direct the implant posteriorly. The paracentesis incisions are used to provide access for the ICL manipulators, the haptics were gently pushed under the iris with a blunt spatula. Removal of viscoelastic, Acetylcholine was injected into the anterior chamber to induce pupil constriction after removal of the visecoelastic. A peripheral iridectomy was performed and finally, the wounds were hydrated (Figure 1).

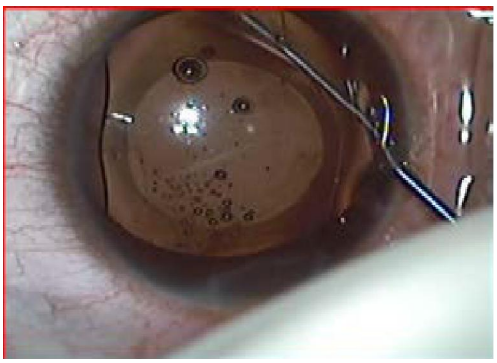

Figure 1: Manipulator used to position the footplates of ICL

For eyes undergoing implantation of AcrySof Cachet, the pupil was constricted with pilocarpine 2%, and the procedure was done under general or peribulbar anesthesia. The anterior chamber entered using a 2.60 mm microkeratome knife, the incision was usually placed in the direction of the steepest axis, Sodium Hyaluronate 1% (was then injected into the periphery of the anterior chamber mainly nasally and temporally, the AcrySof Cachet was loaded into the Monarch III IOL delivery system (Alcon Laboratories Inc., Fort worth, 46 TX) and positioned

at the midpupil in the area of maximal anterior chamber depth. Injection of the IOL was then started at the mid pupillary plan. After pausing for the leading haptics to unfold, injection was continued and as soon as the leading haptics reached the opposite angle the injector was slowly withdrawn out of the eye while continuing injection to avoid excessive compression in the distal angle. Trailing haptics were left outside the incision and then tucked one at a time into the anterior chamber, Passive removal of the viscoelastic was then carried out by injection of intraocular irrigating solution and the wound was then hydrated. Postoperative treatment included an ocular antibiotic and steroid (Figure 2).

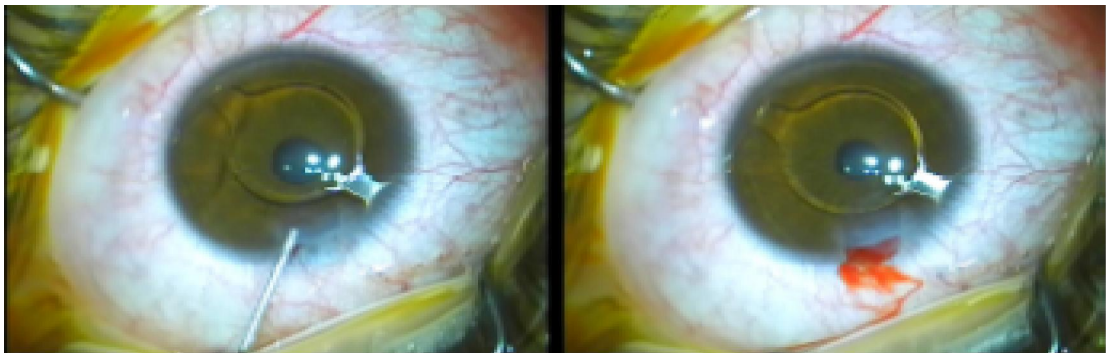

Figure 2: AcrySof Cachet after implantation.

Postoperative evaluation:

The postoperative examination was done on the first day postoperative, first week, then after one month, three months and six months.

Each visit patient was subjected to the following:

- Measurement of uncorrected visual acuity (UCVA).
- Best spectacle corrected visual acuity (BSCVA), residual refractive error and postoperative astigmatism.
- Slit lamp examination for assessment of corneal status, Inflammation, IOL position, Pupil shape, Vault evaluation: The ICL vault is the distance from the anterior capsule of the crystalline lens to the center of ICL optic from the posterior surface. It is ideally range from ½ CCT to 1 ½ CCT (from 250µm to 750µm), Lenticular changes.
- Measurement of IOP using Goldman's applanation tonometer.
- Endothelial cell counts: The specular microscope was used to assess the endothelial cell density for comparison with preoperative values from first month.

3. Results

In this study, in group A the mean age was 26.48 ± 3.63years ranged from 22 to 33 years. In group B the mean age was 28.29 ± 4.38 years ranged from 22 to 37 years.

The mean pre-operative spherical error was -14.13 ± 3.92, and -11.68 ± 0.98 diopters (D) for ICL and AcrySof Cachet (*P*= 0.014) respectively. The mean postoperative spherical error postoperative (6months) was -0.37 ± 0.48, -0.57 ± 0.20 (D) for ICL and AcrySof Cachet (*P*= <0.001) respectively. (Chart 1).

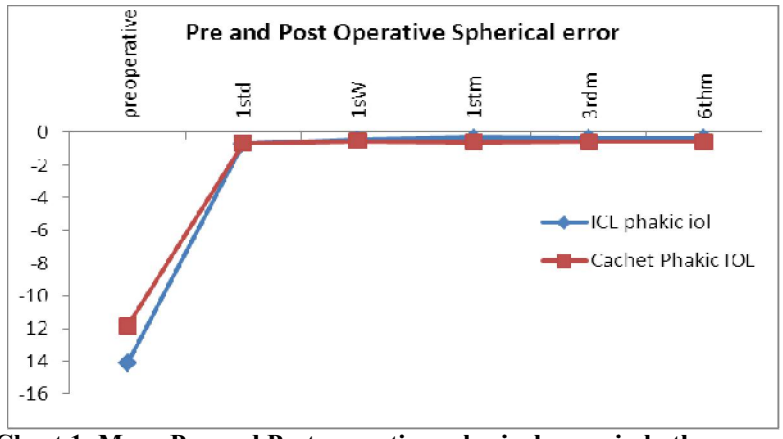

Chart 1: Mean Pre and Post-operative spherical error in both groups.

In both groups, UCVA had improved in 21 eyes (100%) within six months after surgery more than the first day postoperative. the mean UCVA was 0.63 (6/9) ± 017 in range from 0.4 (6/18)-1 (6/6) in Group A, while it was 0.78 (6/9) ± 0.11 range from 0.6 (6/9)-1 (6/6) in Group B. postoperative UCVA had statistically significant difference between both groups in follow up examinations in the first week, third month, sixth month post-operative (P < 0.05) (Chart 2).

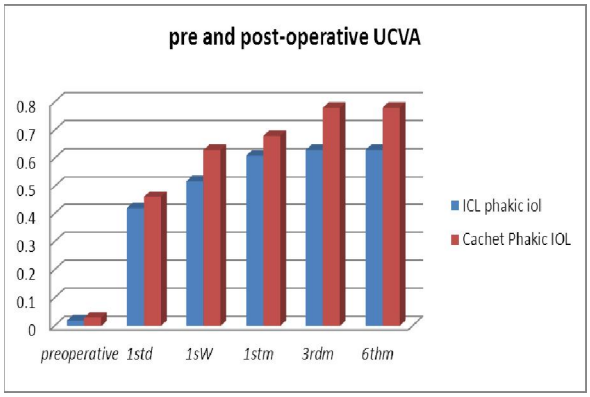

Chart 2: Mean Pre and Post-operative UCVA in both groups

In both groups, postoperatively, the best spectacle corrected visual acuity BSCVA had improved from its pre-operative value in both groups starting from the 1st week after surgery. In Group A, the mean pre-operative BSCVA was 0.62 (6\12) ±0.12 ranged from 0.5 (6\12) to 0.8 (6\9), while in Group B, it was 0.63 (6\12) ± 0.07 ranged from 0.5 (6\12) to 0.7 (6\9). The mean BSCVA was 0.70 (6/9) ± 0.15 in Group A, while it was 0.86 (6/9) ± 0.08 in Group B (Chart 3).

In Group A, the mean pre-operative cylindrical error was -1.51 ± 0.82D ranged from -0.5 D to -3.0D, while in Group B, it was -1.78 ± 0.55 D ranged from -1.0 D to -2.75D. The postoperative cylindrical error had statistically significant difference between both groups in all visits throughout the follow up period (P < 0.05).

In Group A, the mean pre-operative IOP was 15.81 ±1.47 mmHg ranged from 13 to 19 mmHg, while in Group B, it was 15.52 ±2.11 mmHg ranged from 12 to 20 mmHg. Postoperative IOP had no statistically significant difference between both groups in all visits postoperative.

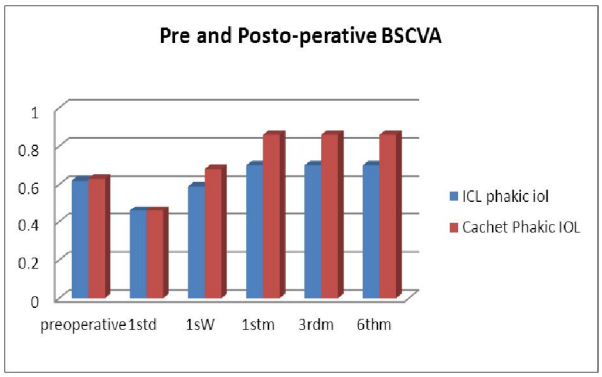

Chart 3: Mean Pre and Post-operative BSCVA in both groups.

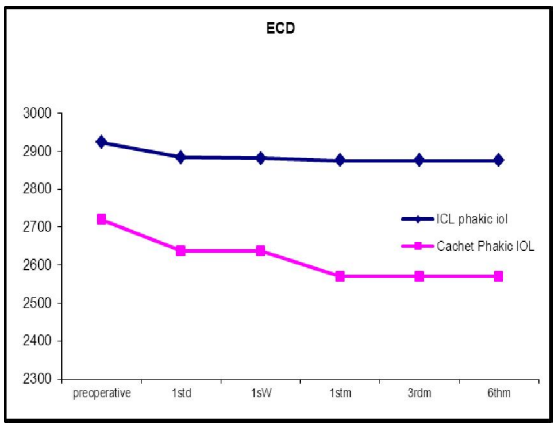

Chart 4: Endothelial Cell Density (ECD) Pre-operative and Postoperative in both groups

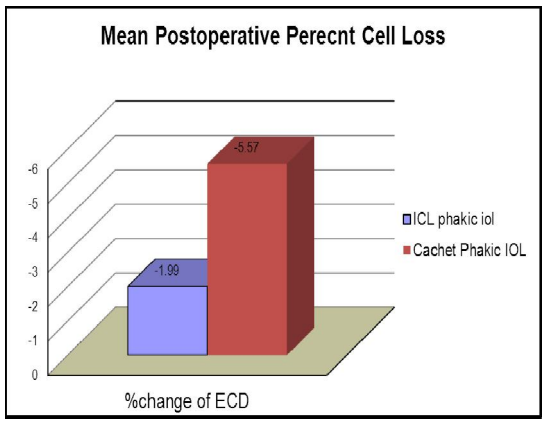

Chart 5: Mean postoperative Cell Loss in both groups after 6 months

The mean pre-operative ECD in Group A was 2923.71±208.95 cell/mm² ranged from 2621 to 3191 cell/mm². In Group B, it was 2719± 188.68 cell/mm² ranged from 2320 to 3012 cell/mm² (Chart 4).

The mean percentage endothelial cell loss in group A was -1.99 % at the end of the follow up period (6months). While in group B, it was -5.57% at the end of the follow up period (6 months). There was

statistically highly significant difference between the two groups in percentage endothelial cell loss (P <0.001), with more loss in group B (Chart 5).

No intraoperative complications were encountered in this study. In group A only one eye (4.8%) developed an asymptomatic anterior subcapsular cataract, this patient showed no change in BSCVA and no need to operation. No pupillary block, pigment dispersion syndrome, pigmentary glaucoma and retinal detachment or other vision threatening complications were seen during the follow-up. No patients needed secondary surgical intervention for reposition, replacement, removal of pIOL or cataract extraction.

4. Discussion

Regarding safety: In group A thirteen cases gained one line (61.9%), two cases gained two lines by the (9.5%). The safety index (ratio of mean postoperative BSCVA 0.7 / mean preoperative BSCVA 0, 63) was 1.12 by the end of sixth month.

The result in Group A was almost similar to Alfonso et al who reported safety index about 1.19 ± 0.27 and 1.27 ± 0.33 at 1 month and 5 years, respectively. [(11)]

In group B fourteen cases gained one line (66%) and four cases gained two lines or more (19%). The safety index (ratio of mean postoperative BSCVA 0.86 / mean preoperative BSCVA 0.63) was 1.3.

These results were almost equivalent to Kohnen et al one year's trial in which the safety index (ratio of mean postoperative BSCVA of 1.15/Mean preoperative BSCVA of 0.92) was 1.25. [(10)]

Regarding efficacy: Regarding efficacy after six months postoperatively, In group A, nineteen eyes achieved UCVA of 0.5 (90.4%) or better, two cases (9,6%) achieved 1.0 (6/6). The efficacy index (ratio of mean postoperative UCVA 0.63 / mean pre-operative BSCVA 0.62) was 1.01. Alfonso, reported the overall efficacy index was 0.89 ± 0.35 at 5 years. [(11)]

In group B 100% of cases achieved 0.5 (6/12) or better, three (14.2%) cases achieved 0.9-1.0 (6/6). The efficacy index (ratio of mean postoperative UCVA 0.78 / mean pre-operative BSCVA 0.63) was 1.23. Mastropasqua et al, found that the mean UCVA was (20/40) or better in 100% of patients. BSCVA was (20/40) or better in 100% of patients. [(12)]

Regarding Predictability: In Group A, after 6 months, the deviation from the targeted refractive error was within ± 0.5D (80.9 %) of cases and within ± 1D (90.4%) of cases. Kamiya et al. study for ICL reported (79%) of the eyes were within ±0.5D of the intended correction and (93%) were within ±1.0D after 4 years. [(13)]

In group B, after 6 months, the deviation from the targeted refractive error was within ±0.5D in sixteen cases (76%) of cases and within ±1.0D in (95.2%) of cases. Yang reported after one year, the deviation from the targeted refractive error was within ±0.5D in 84% of eyes and within ±1.0D in 100% of eyes. [(14)]

Regarding refractive stability: The mean preoperative SE in group A was (-14.13 ± 3.92 D). The refractive error at one day after surgery was (-0.71 ± 0.16 D) and at six months after surgery was (-0.37 ± 0.13D).

In group B the mean preoperative SE in group A was (-11.86 ± 0.98 D). The refractive error at one day after surgery was (-0.67 ± 0.18 D) and at six months after surgery was (-0.57 ± 0.12D).

Regarding endothelial cell density and loss:

The major statistically significant finding in our study was the decrease in the endothelial cell count (ECC) in both groups: All the subjects operated upon will continue to be evaluated in an annual follow-up. However, interpretation of mean percentage change in endothelial cell density should consider the estimated 0.6% physiological related annual loss. [(15)]

The mean percentage endothelial cell loss in group A was -1.99 % at the end of the follow up period (6months). It seems that surgical trauma was the main causes of the reduction of ECC. While in group B, it was- 5.57% at the end of the follow up period (6 months). Here, it seems that surgical trauma and close proximity to the endothelial surface were the main cause of the decrease in ECC.

Regarding ICL, Alfonso, reported mean endothelial cell loss of approximately 1.5% per year and a mean cumulative endothelial cell loss of 7.7% at 5 years. [(11)] Jimenez reported a rate of postoperative endothelial cell loss of approximately 6.5% at 2 years. [(16)]

Regarding AcrySof Cachet: Mastropasqua et al were the only investigators to report the endothelial cell loss at the 1-month postoperative visit after implantation of the AcrySof angle-supported phakic IOL (-5.5%). [(12)]

Regarding intraocular pressure elevation: There is no significant increase of IOP postoperative in both groups, no pupillary block glaucoma, no acute rise of IOP due to retained visecoelastic, no malignant glaucoma, only two cases in group A reported rise of IOP due to steroid response 9.4%.

Kamiya et al. [(13)]; did not report a statistically significant IOP increase after ICL implantation.

Ramón Ruiz, reported no incidence of IOP rise or pupillary block in his series after AcrySof Cachet implantation. [(17)]

Regarding postoperative complications: One eye (4.8%) in group A reported asymptomatic anterior subcapsular cataract, it was due to low vault.

One of the most significant concerns about posterior chamber pIOL implantation is cataract formation. In the Implantable Collamer Lens FDA trial, [18] the rate of cataract formation was 2.1%. Other studies report a secondary cataract formation rate between 1.6% and 14.5%. [19] In a 5-year follow-up study by Sanders, anterior subcapsular opacities occurred in 5.9% of 526 eyes, with 1.3% progressing to clinically significant cataract. [20]

Conclusion

This study revealed that ICL and AcrySof Cachet are a good choice for treatment of refractive error in moderate to high myopic patients, in terms of efficacy, predictability, stability, reversibility, high optical quality and preservation of accommodation. In patients where laser ablative surgery isn't possible phakic IOLs are an excellent option.

Patient selection is the most important factor in the predictable outcome of phakic IOLs. Regarding refraction, anterior chamber depth, mesopic pupil size and ECD following company recommendations are substantial.

The safety concerns regarding endothelial cell loss in this study revealed that ICL had less incidence of postoperative endothelial cell loss than angle supported AcrySof Cachet with statistically significant difference, and the rate of continuous loss was much higher in AcrySof Cachet. Long-term follow up with special concern regarding ECD is mandatory especially for AcrySof Cachet cases.

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