

Implantable Collamer Lens vs Iris Claw Lens in Myopia Correction.

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ABSTRACT:

BACKGROUND: Myopia, an optical condition in which the eye is unable to focus on distant objects due to a non-accommodating lens, has spurred centuries of efforts toward correction and potential cure. In this study, we aim to compare the efficacy, and safety of myopia correction through the implantation of 2 types of pIOLs: the Foldable iris-fixated (Veriflex) AC pIOL and the posterior phakic ICL. Our focus is on patients presenting moderate to high myopia, divided into two distinct groups for comprehensive evaluation.

METHODS: This prospective randomized comparative study included 46 patients (80 eyes) diagnosed with myopia. The patients were randomly divided into two groups: Group A: 40 eyes from 24 patients who implant the Veriflex IOL. Group B: This group included 40 eyes from 24 patients who implant the ICL.

RESULTS: After a 3-year follow-up, in Group A, the mean pre-operative spherical error (SE) was -12.3 ± 1.5 diopters for the Veriflex, while in Group B, it was -16.9 ± 3.6 diopters for the ICL. The mean postoperative BCVA at 3 years was 0.71 ± 0.03 logMAR for Veriflex and 0.83 ± 0.13 logMAR for ICL.

CONCLUSION: Both Veriflex and ICL phakic intraocular lenses were found to be, effective, predictable and safe with a low rate of complications. They offered rapid visual rehabilitation and long-term stability for patients with myopia.

KEYWORDS: Phakic IOLs, ICL , Veriflex, myopia, refractive surgery.

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Introduction

Phakic IOLs present a valuable option for correcting high refractive errors that fall outside the scope of correction achievable through laser vision procedures^{1,2}. These lenses offer reversibility, maintain high optical quality, and may enhance visual acuity in myopic patients by leveraging retinal magnification³⁻⁵. Unlike corneal procedures, pIOLs preserve accommodation, enhance vision quality, maintain the natural prolate corneal shape, and are not limited by corneal thickness or topography.⁴⁻¹⁰

Despite these advantages, complications related to pIOLs, primarily influenced by their position and type, exist¹¹⁻¹³. It is crucial to note that complications associated with pIOLs can sometimes be more severe than those arising from keratorefractive surgeries. Common complications of Veriflex pIOLs include iritis, iris ischemic atrophy , distortion of pupil,

loss of endothelial cell, 2ry glaucoma , aqueous flare, pIOL dislocation, and cystoid macular edema (CME)¹³⁻¹⁵.

Considering these factors, this study aims to compare the outcomes and efficacy of 2 types of pIOLs: Veriflex and ICL in patients diagnosed with myopia.

Patients and Methods

This is a prospective randomized comparative study which is adhered to the principles of the Declaration of Helsinki. All patients provided written informed consent for participation in the study and for the publication of the data before being enrolled.

The study enrolled 46 patients with moderate to high myopia from Misr University Hospital , totaling 80 eyes, who completed a 3-year follow-up period. Patients underwent examinations post-pIOL implantation: 1st day, 1st week, 1st month, 6 months, 1st year, and 3rd years.

The selection of the pIOL was based solely on patient and surgeon preferences, without specific parameters dictating the choice. The patients were randomly divided into 2 groups:

- Group A (Veriflex): This group comprised 22 patients and involved the implantation of the VeriFlex IOL (AMO Santa Ana, CA) in 40 eyes.
- Group B (ICL): This group included 24 patients with 40 eyes implanted with the V4 ICL (STAAR Surgical, Monrovia, CA, USA).

Preoperatively, all cases underwent a comprehensive assessment including full history taking, ophthalmic examinations (UCVA, BCVA, manifest refraction, slit lamp examination, IOP check, fundus examination, keratometry, anterior chamber depth analysis, and pachymetry), mesopic pupillary diameter measurement in Group A (Veriflex IOLs), white to white distance measurement in Group B (ICL), and pIOL power calculation using manufacturer-provided formulas.

Exclusion criteria comprised pathological cornea (keratoconus, corneal Opacity, or dystrophy), anterior segment pathology (including cataract, pseudoexfoliation, pigment dispersion, severe iris atrophy), abnormal pupil characteristics, history or signs of iritis or uveitis, glaucoma or family history of glaucoma, AC depth less than 3.00 mm, and W/W measurement > 11.0 mm in cases of ICL.

Operative Techniques:

Group A (Veriflex):

1. Two vertical paracentesis incisions made by MVR 20G at 2 & 10 o'clock .
2. Pupil constricted using acetylcholine (Miochol) injection into the anterior chamber (AC).
3. AC filled with cohesive viscoelastic OVD through the side port.

4. Clear corneal tunnel incision (3.2mm) created with an angled keratome at 12 o'clock.
5. Foldable iris claw lens loaded with a specially designed spatula and inserted through the keratome incision.
6. Lens rotated horizontally and fixated into the iris.
7. Peripheral iridectomy performed to prevent pupillary block.
8. Removal of OVD from the AC and wound hydration

Group B (ICL):

1. Pupil fully dilated for ICL implantation in the ciliary sulcus.
2. ICL loaded dome up in the cartridge and inserted into the injector.
3. Two paracentesis incisions made by MVR 20G at 3 & 9 o'clock.
4. AC filled with methyl cellulose
5. Clear corneal tunnel incision (3.2mm) created with an angled keratome temporal.
6. ICL injected through the MicroSTAAR injector.
7. Haptics pushed under the iris using a blunt spatula.

Postoperative Management:

- Topical combined tobramycin/dexamethasone drops every two hours for one day, then tapered gradually over 2 weeks..
- Topical Moxifloxacin 0.5% drops every two hours in 1st day, then four times per day for 1 week.

Postoperative Evaluation:

- Initial postoperative ocular examinations on the first day, first week, then monthly up to 3 years.
- Evaluation includes BCVA, residual refractive error, IOP measurement, slit lamp examination, and retinal evaluation.

Statistical Analysis:

- Data were described using range, mean \pm SD, and median as appropriate.
- Visual acuity (VA) measurements were transformed into logMAR format for more accurate statistical analysis.
- The Mann-Whitney U-test for independent samples was used to compare the study groups (Group A and Group B).

Results:

- Group A (Veriflex): This group consisted of 22 patients, comprising 8 males (36.4%) and 14 females (63.60%). The average age was 26.30 years \pm 6.10.
- Group B (ICL): This group comprised 24 patients, with 6 males (25%) and 18 females (75.0%). The average age was 27.70 years \pm 4.10.

Table 1 illustrates the demographics and clinical characteristics of both groups. Statistical analysis showed that the two groups were similar in all demographics and clinical characteristics.

Table 1. Demographics & Clinical Characteristics of the 80 studied eyes expressed as the mean \pm SD.

	Group A (Veriflex)	Group B (ICL)	P-value
No of eyes	40	40	
Mean age (y)	26.3 \pm 6.1	27.7 \pm 4.1	0.62
Sex (% female)	7	9	0.67
Refractive error (D)	-12.3 \pm 1.5 D	-16.9 \pm 3.6 D	0.6
Axial length	27.59 \pm 1.1	27.51 \pm 1.11	0.83
Anterior chamber depth	3.53 \pm 0.36	3.34 \pm 0.30	0.08
K1(D)	43.10 \pm 2.5	43.28 \pm .4	0.78
K2(D)	44.34 \pm 2.6	44.9 \pm 1.6	0.39

The 2 groups were compared regarding spherical equivalent , BCVA , and IOP through out 36 months follow up in the 1st week , 1st month , 6th month , 1year and 3year.

Spherical equivalent (SE): Emmetropia was aimed and almost achieved in both groups post-operatively. Pre-operative spherical error was -12.34 \pm 1.6 and -16.8 \pm 3.5 diopters D for group (A)Veriflex and Group(B)ICL , respectively. Post-operative spherical error was ranging from +1.0 \pm 1.6D in the 1st month to +0.5 \pm 1.1D after 3year and -0.5 \pm 2.5D in the 1st month to -1.0 \pm 2.4D after 3year for group (A) (Veriflex) and Group(B) (ICL) , respectively.

Table 2 illustrates the comparison of pre and post-operative spherical equivalent (SE) between the two groups. P-values greater than 0.05 indicate that there is no statistically significant difference between the groups concerning pre and post-operative SE across all visits throughout the follow-up period.

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Table 2 shows pre and post-operative spherical equivalent between the two groups

SE	Group A	Group B	P value
pre-operative	-12.34 ±1.6D	-16.8 ±3.5D	0.61
1-month post-op	+1.0 ±1.5D	-0.5 ±2.6D	0.76
6-month post-op	+0.3± 1.2D	-0.6 ± 2.1D	0.74
1-year post-op	+0.5 ± 1.1D	-0.9 ± 2.1D	0.86
3-year post-op	+0.5 ± 1.2D	-1.0 ± 2.3D	0.57

Post-operatively, the BCVA had improved in both groups starting from the 1st month after surgery continuing throughout the 36 months follow up as shown in table 3. There is a statistically significance increase in **BCVA** measure in the study groups throughout the 36 months follow up with p-value <0.05. Group A, increased from (0.605±0.32) logMAR before operation, to (0.705±0.024) logMAR after 3 years follow up, versus (0.7675±0.077) logMAR to (0.825±0.133) logMAR in group B demonstrated in table (3). The BCVA were similar in both groups all over the period from pre-operative throughout 36-month post-operative illustrated in table (3). The difference between Group A (Veriflex) and Group B (ICL) in terms of pre and postoperative BCVA was statistically not significant (P=0.21).

Table (3): Comparisons of the BCVA between the two groups, in the period from pre-operative throughout 36-months follow-up.

Time of measurement	Group A BCVA	Group B BCVA	p-value
Pre-operative	0.65 ± 0.29	0.77 ± 0.08	0.07
1-month post-operative	0.70 ± 0.29	0.76 ± 0.11	0.39
6-month post-operative	0.70 ± 0.27	0.83 ± 0.06	0.05
12-months post-operative	0.71 ± 0.24	0.81 ± 0.18	0.14
36-months post-operative	0.71 ± 0.03	0.83 ± 0.13	0.06

Intraocular Pressure (IOP) Analysis:

1. Pre-operative IOP:

- Group A (Veriflex), the mean IOP was 14.8 ± 1.4 mmHg,(from 12.0 to 17.0 mmHg).
- Group B (ICL), the mean IOP was 16.3 ± 2.6 mmHg, (from 11 to 21 mmHg).
- There was no statistically significant distinction between the two groups (P > 0.05).

2. Post-operative IOP:

- The post-operative intraocular pressure (IOP) exhibited a statistically significant variance between the two groups only at the 1st-week post-operative visit (P < 0.05), as indicated by the Mann-Whitney test in Table 5.

Table 5: Intraocular Pressure (IOP) in Groups A and B

Time of Measurement	Group A (Veriflex) mmHg	Group B (ICL) mmHg	P-value
Pre-operative	14.80 ± 1.40	16.30 ± 2.60	0.382
1st week	16.14 ± 5.4	18.82 ± 5.1	0.006
1st month	15.12 ± 2.2	20.3 ± 6.3	0.003
6th month	16.1 ± 2.2	19.2 ± 7.2	0.399
1st year	14.2 ± 2.4	16.4 ± 2.4	0.574
3rd year	14.3 ± 2.2	16.4 ± 2.6	0.556

This analysis highlights the pre-and post-operative IOP differences between Group A (Veriflex) and Group B (ICL), with a notable significant difference in the 1st-week post-operative IOP.

During the follow up period

1. Group A (Veriflex):

- One eye (2.5%) developed elevated IOP (steroid-induced glaucoma) in the 1st week post-operative, with an IOP of 32 mmHg.
- IOP normalized within three days after replacing steroids with NSAIDs drops and using anti-glaucoma drops.

2. Group B (ICL):

- One eye (2.5%) experienced an acute rise in IOP in the 1st week postoperative, reaching 43 mmHg.
- This rise was attributed to a severe attack of iritis and anterior chamber reaction.

Discussion

Phakic intraocular lenses (pIOLs) are considered clinically acceptable when they demonstrate high efficacy, predictability, stability, and safety⁴. Our study yielded results that were consistent with these criteria, showing effectiveness, stability, predictability and VA improvement similar to other pIOL studies²⁻¹⁰. Over a follow-up period of up to three years, refractive outcomes remained stable, and BCVA improvement¹³.

The findings from the United States FDA study conducted by the ITM study group further support the positive outcomes of pIOLs, specifically the ICL pIOL, which showed efficacy, safety and good functional results with a minimal complication¹⁵.

One common concern with pIOLs is the occurrence of glare and halos¹³. Our study observed a decrease in complaints of night glare over time in both VeriFlex and ICL groups. Various authors¹³⁻¹⁹ have attributed glare and halos to factors such as pupil

characteristics, optic diameter relative to pupil size, and decentration of pIOLs. It's interesting to note the differing opinions among researchers regarding the causes of glare and halos, highlighting the complexity of these visual disturbances¹³⁻¹⁹.

Regarding cylindrical error, our results showed no significant increase postoperatively with both groups. This can be due to the small incision size needed for implantation, which minimizes induced astigmatism.

Preoperative considerations play a crucial role in optimizing outcomes and minimizing complications with pIOLs. Adequate anterior chamber depth (ACD) and pupil size are important factors to consider¹⁸⁻²⁰. We recommend ICL implantation in eyes with ACD 2.8 mm or more and consider pupil size when choosing between foldable anterior chamber PIOLs and ICL.

To avoid complications such as IOL dislocation, rotation, or pupillary block glaucoma, accurate preoperative measurements, thorough examinations, and appropriate surgical techniques are essential. Substantial lens vault maintenance is important to prevent formation of cataract, especially with ICL¹⁹⁻²⁰.

Conclusion,

pIOLs like VeriFlex and ICL demonstrate positive outcomes in terms of efficacy, predictability, stability, and safety when proper patient selection, preoperative assessments, and surgical techniques are employed.

Abbreviations

- AC: Anterior Chamber
- AC IOLs: Anterior Chamber Intraocular Lenses
- BCVA: Best Corrected Visual Acuity
- CCT: Central Corneal Thickness
- ECD: Endothelial Cell Density
- ICL: Implantable Collamer Lens
- IOP: Intraocular Pressure
- LASIK: Laser In Situ Keratomileusis
- logMAR: Logarithm of the Minimum Angle of Resolution
- No: Number
- pIOLs: Phakic Intraocular Lenses
- PC IOLs: Posterior Chamber Intraocular Lenses
- SD: Standard Deviation
- SE: Spherical Equivalent
- SPSS: Statistical Package for the Social Sciences
- W/W: White-to-White (corneal diameter measurement)

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