CLINICAL STUDY OF POSTERIOR CHAMBER PHAKIC IOL PLACEMENT IN MYOPIC PATIENTS
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ABSTRACT
The aim of this study was to determine the safety and efficacy of posterior chamber phakic IOL in myopic patients.

MATERIALS AND METHODS
This prospective interventional study included 50 eyes of 50 patients with myopia. Patients of age more than 18 yrs. Stable refraction, Myopia, Mild to Moderate keratoconus and absence of any ocular pathology and any history of ocular surgeries were included in this study. Prior to starting treatment certain parameters like visual acuity, AC depth, Iridocorneal Angle Aperture, Endothelial cell count, Central corneal thickness and IOP were considered. Intervention- Implantation of the phakic IOL. Main outcome Measures- Uncorrected Visual Acuity (UCVA), best spectacle corrected visual acuity (BSCVA), AS OCT AC depth-between endothelium and phakic IOL, IOP and Endothelial cell count were recorded.

RESULTS
Postoperative examinations conducted at day 1, day 3, after 1 week, 1 month and after 3 months .out of 50 patients, 4 patients had striate keratopathy, 2 patients had shallow ac during immediate post-operative period. During the postoperative follow up 10 patients had BCVA of 6/9-6/6 (20%), 14 patients had 6/9-6/12 (28%), 24 patients had 6/12-6/24(48%) and remaining 2 patients had <6/24 which was better than their preoperative uncorrected visual acuity.

CONCLUSION
Based on this prospective clinical study and on comparison with other clinical studies posterior chamber phakic IOL corrective procedures are safe and effective for treatment of myopia. It also shows that it can provide sharp and clear vision in 96% of our study population. It does not induce dry eye syndrome as in other refractive surgeries. Short term complications like endothelial damage, angle closure glaucoma, iritis, anterior capsule injury/lens changes were not encountered during our study. But still long term follow up is required to confirm long term safety of the implant.

KEYWORDS
Posterior Chamber Phakic Intraocular Lens, Phakic Refractive Lens (PRL), Refractive Surgery, Myopia.


BACKGROUND
Phakic intraocular lenses are fast becoming an important tool for the correction of ametropia.1 The main objective of refractive surgery is improving the patients quality of life by decreasing their dependence on spectacles and contact lenses. The word “phakic” means that natural crystalline lens is still there and not removed from the eye. A phakic intraocular lens (IOL) is placed over the natural lens. Phakic IOL implant functions as an internal contact lens and the view through the phakic IOL is natural and of good quality. Phakic IOLs are used to treat high myopia or hyperopia with or without astigmatism, or mild keratoconus. In the majority of cases, we are dealing with young healthy individuals with excellent quality of vision; they are seeking no less than excellent uncorrected visual acuity with at least the same quality of vision postoperatively. 2 Hence, any complication after refractive surgery has a dramatic impact on the patient’s quality of life.

Types of Phakic IOL
Anterior chamber phakic IOL
Iris fixed phakic IOL
Posterior chamber phakic IOL

Anterior Chamber Phakic IOL
It is placed in the anterior chamber of the eye between the iris and the cornea. It is made up of poly methyl methacrylate Figure (1a).

Iris Fixated Phakic IOL
It is implanted surgically into the eye and fixated to the iris to correct myopia.

Posterior Chamber Phakic IOL
It is placed in the posterior chamber behind the iris and rests against the bag of crystalline lens. It is made of collamer, the combination of collagen and HEMA polymer and inserted into the eye through a small incision; this results in rapid visual improvement Figure (1b).

MATERIALS AND METHODS
This prospective interventional study included 50 eyes of 50 patients who visited our hospital RIOGOH Chennai, between Jan 2016 to June 2016.

Inclusion Criteria
Patients with Age greater than 18 years, Myopia, Stable refraction, Mild to Moderate keratoconus were included in this study. Certain pre-operative parameters were also taken into consideration. Those were anterior chamber depth of more than 2.8 mm, Iridocorneal Angle Aperture of more than 30 degrees (Shaffer grade 3 & 4), Endothelial cell count more than 2500 cells/mm square and Central corneal thickness more than 400 μm.

Exclusion Criteria
Patients with Age less than 18 years, Unstable refraction, Ocular pathology- uveitis, cataract, glaucoma, staphyloma Figure (2), retinal detachment and history of any ocular surgeries were excluded.

Investigations
Preoperative clinical assessment such as Slit Lamp Examination, Gonioscopy, Fundus Examination, White To White Measurement by Digital Callipers were done. Followed by Refraction, tension by NCT, A Scan, K Reading, IOL Power, B Scan, Specular microscopy, Pachymetry, Orb Scan, Anterior Segment OCT-To measure Postop AC depth were performed.

Figure 1a. Anterior Chamber Phakic IOL

Figure 1b. Posterior Chamber Phakic IOL

Figure 2. Posterior Staphyloma in B scan

Figure 3a. RE orb scan Showing HVID 11.89 mm, AC Depth-3.34 mm, CCT-544 μm, Irido Corneal Angle-45 deg

Figure 3b. specular image shows Endothelial count-2836.6/sqmm, Hexagonility-54%
**IOL Particulars**

Figure 4a. Shows indigenous IOL which was used in this study. The speciality of this IOL is the presence of four peripheral holes to facilitate aqueous outflow unlike other posterior chamber phakic IOLs which have a single central hole. Fig (4b) shows the peripheral holes of 500 microns.

**Surgery Technique**

It is an outpatient surgery which requires less than 30 minutes. Under local anaesthetic, a small incision is made in the cornea at 12 o’clock position. Two side port incisions made at 10 & 2 o’ clock positions. After which Cohesive Oculo Viscoelastic Device (OVD) is injected and cartridge with loaded lens is inserted with bevel down through the incision made at 12 o clock position. The tip of the injector is kept superficially and the phakic IOL is injected gently into the AC, taking care not to touch the ant capsule or the iris. Then IOL is gently positioned horizontally with blunt tip manipulator. Finally wound was closed after washing out ovd.
RESULTS
This study group comprised, 50 eyes of 50 patients with mean patient age of 30.5 years±7.5 (SD) with range (20-48 years) (Figure 5a). 64% were female and 36% were male (Figure 5b). Among the 50 patients Pre-operative BCVA of 12 patients was 6/18 - 6/12 (24%), 22 patients were in the range of 6/60-6/24 (44%) and the remaining 16 patients had <6/60 (32%) (Figure 5c). The follow up period was 6 months. The postoperative BCVA of 10 patients was 6/9-6/6 (20%), 14 patients had 6/9-6/12 (28%), 24 patients had 6/12-6/24 (48%) and remaining 2 patients (Figure 5d) had <6/24 which was better than their preoperative uncorrected visual acuity. BCVA of 6/24 or better increased from 68% preoperatively to 96% postoperatively. No eyes had vision <6/60 at any post-operative visit.

Out of 50 patients, 4 patients had striate keratopathy, 2 patients had shallow ac during immediate post operative period.

The following tables show preoperative and postoperative average values.

### Table 1. Preoperative Parameters

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Minimum</th>
<th>Maximum</th>
<th>Average</th>
<th>Standard deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>HVID</td>
<td>10.4 mm</td>
<td>12.6 mm</td>
<td>11.48±1.1mm</td>
<td>±0.67</td>
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<tr>
<td>AC depth</td>
<td>2.81 mm</td>
<td>3.45 mm</td>
<td>3.06±0.32 mm</td>
<td>±0.21</td>
</tr>
<tr>
<td>CCT</td>
<td>462 μm</td>
<td>539 μm</td>
<td>500±40 μm</td>
<td>±0.02</td>
</tr>
<tr>
<td>Axial length</td>
<td>24.16 mm</td>
<td>27.87 mm</td>
<td>26.04±1.86 mm</td>
<td>±1.04</td>
</tr>
<tr>
<td>IOL power</td>
<td>-10.00 D</td>
<td>-21.00 D</td>
<td>15.5±1.5 D</td>
<td>±1.05</td>
</tr>
<tr>
<td>Endothelial count</td>
<td>2504 cells/cu.mm</td>
<td>3214 cells/cu.mm</td>
<td>2795±355cells/cu.mm</td>
<td>±155.79</td>
</tr>
</tbody>
</table>

### Table 2. Postoperative Parameters

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Minimum</th>
<th>Maximum</th>
<th>Average</th>
<th>Standard deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>AS OCT AC depth-between endothelium and phakic IOL</td>
<td>1.96 mm</td>
<td>2.7 mm</td>
<td>2.26 ±0.37 mm</td>
<td>±0.21</td>
</tr>
<tr>
<td>Tension</td>
<td>16 mmHg</td>
<td>22 mmHg</td>
<td>19 mmHg</td>
<td>±1.94</td>
</tr>
<tr>
<td>Endothelial count</td>
<td>2514 cells/mm sq.</td>
<td>3126 cells /mm sq.</td>
<td>2820 cells /mm sq.</td>
<td>±160.66</td>
</tr>
</tbody>
</table>

Endothelial cell count was measured postoperatively using specular microscopy (Figure 6) showed minimal endothelial cell loss after surgery. The long-term effect of the ICL on the corneal endothelium requires longer follow-up.

**DISCUSSION**

Phakic IOLs are an effective treatment for the correction of myopia and have significant advantages such as reversibility, immediate correction, stability, and relative simplicity.\(^3\) Al Sabaani A, et al\(^3\) reported (92.5%) of eyes with 20/40 or better, Le Loir M et al\(^4\) (52.6%) reported lower UCVA. several studies reported an improvement in BCVA after ICL implantation with no accompanying intraoperative or postoperative complications.\(^3\) Preservation of BCVA, commonly considered the primary criterion for assessing the safety of a refractive surgical procedure, was extremely high in the study cohort presented in this article. Previously published ICL reports have also documented an improvement in BCVA after ICL implantation.\(^3\) BCVA was maintained or improved in all eyes in the series published by Senthil S et al\(^1\), Sabaani A et al\(^2\) and Le Loir M et al\(^4\) whereas only one eye lost BCVA in studies by Baradaran-Rafii A and Hashemian SJ et al\(^3\) and Zaldivar et al.\(^3,5\)

In our study, Postoperative examinations were conducted at day 1, day 3, after 1 week, 1 month and after 3 months. Comparing the proportion of eyes with 6/24 or better BCVA, only 68% had this level pre operatively, compared with 96% of eyes had this level at the postoperative visit which indicates the efficacy of phakic IOL. The mean preoperative IOP was 17.42±1.86 mm Hg (SD). The mean post-operative IOP was 18.70±1.94 mm Hg (SD). The phakic IOL used in our study had four peripheral holes (Figure 7) which facilitates the aqueous drainage. Hence we did not encounter any raise in IOP unlike other studies.\(^4,6\) during our follow up period.

The mean pre-operative AC depth was 3.06±0.21 mm (SD) and the mean post-operative AC depth was 2.26±0.21 mm (SD). Statistical analysis was done using student’s t test. The arrived P value of 0.5 indicates that the difference in the anterior chamber depth after the placement of phakic IOL is insignificant. Furthermore, as previously reported in the literature, the safety of the ICL procedure is enhanced by the low incidence of postoperative and intra operative complications.\(^3,7\) The latest generation of myopic ICLs (model V4) is presumed to completely vault the anterior crystalline lens capsule and to rest on the anterior zonular fibers. This, of course, necessitates correct selection of the overall size of the ICL, which ranges from.\(^3,8\) 11.5 to 13.5 mm. To date, the ICL size can only be estimated and is considered to be appropriate when equal to the horizontal diameter of the cornea (white-to-white distance) plus 0.5 mm. In our study, different methods (Calliper, Orbscan) were used to measure white-to-white distance. Further studies are required to determine the most accurate method of measuring the horizontal corneal diameter.\(^3,9\)
CONCLUSION
Based on this prospective clinical study and on comparison with other clinical studies posterior chamber phakic IOL corrective procedures are safe and effective for treatment of myopia. Compared to other refractive surgeries, implantation of phakic intraocular lenses (PIOLs) have more desirable results and are potentially reversible procedures due to the possibility of explanting these lenses. It also shows that it can provide sharp and clear vision in 96% of our study population. It does not induce dry eye syndrome as in other refractive surgeries. Short term complications like endothelial damage, angle closure glaucoma, iritis, anterior capsule injury/lens changes were not encountered during our study Long-term follow-up did not show a significant increase in cataract formation in implanted eyes. But still long term follow up is required to confirm long term safety of the implant. In conclusion as the follow-up in our study was relatively short, we cannot be certain of the long-term safety of this procedure. We have demonstrated excellent predictability, efficacy, and good visual results with few short-term complications.

REFERENCES